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## Summary of Trends

### ## Summary of Adverse Event Reports for Implantable Cardiac Devices (ICDs)

#### Data Sources:

- \* 2-1: Analysis of Adverse Event Reports for Reveal LINQ ICDs
- \* 2-2: Analysis of Adverse Event Reports Dataset
- \* 2-3: Analysis of Adverse Event Reports Dataset

#### Common Product Problems:

- \* Over-Sensing: This is the most frequently reported problem across all datasets; occurring in 152 out of 173 events (87.86%) in 2-1 and in several events in 2-2 and 2-3.
- \* Under-Sensing: This issue is also commonly reported; appearing in 12 events (6.94%) in 2-1 and in several events in 2-2 and 2-3.
- \* No Audible Alarm: This problem is reported in 14 events in 2-2 and in 5 events in 2-3; highlighting the critical need for reliable alarms in medical devices.
- \* Communication or Transmission Problem: This issue is reported in 10 events in 2-2 and in 1 event in 2-3; indicating potential challenges in data transmission and communication with the implanted device.
- \* Defective Alarm: This problem is reported in 4 events in 2-2 and in 3 events in 2-3; emphasizing the importance of accurate and reliable alarms.

#### Malfunctions:

- \* The majority of reported events are classified as malfunctions; indicating a problem with the device itself. This highlights the importance of robust device design; manufacturing; and quality control to minimize the risk of malfunctions.

#### Root Causes:

- \* Defective speaker: This is the most likely cause for the "No Audible Alarm" problem.
- \* Software or hardware issues: These could be responsible for communication problems; under-sensing; failure to interrogate; and other malfunctions.
- \* Electrode issues: These could be responsible for biocompatibility issues and device sensing problems.
- \* Battery issues: These could be responsible for overheating and other malfunctions.

#### Trends in Adverse Event Occurrence:

- \* There is no clear trend in the occurrence of adverse events over time based on the limited data available. However; it is important to continuously monitor and analyze adverse event reports to identify potential trends and take appropriate actions to mitigate risks.

#### Patterns in Reported Device Issues:

- \* Certain device models appear to be more prone to specific problems. For example; the MX40 and Intellivue series of monitors seem to have a higher frequency of "No Audible Alarm" issues. This information can be helpful in prioritizing investigations and implementing corrective actions.

#### Frequencies of Remedial Actions Taken:

- \* The most common remedial actions taken include:
  - \* Replacing the device or component
  - \* Software updates
  - \* Troubleshooting and adjustments
  - \* No action required

## Correlations Between Reported Problems and Device Attributes:

\* There may be correlations between certain device attributes (e.g.; brand; model; age) and the types of problems reported. Further analysis with a larger dataset could reveal such correlations and help identify areas for improvement in device design or manufacturing.

## Additional Notes:

\* These analyses are based on limited datasets and may not be representative of the overall population of adverse events for these devices.

\* Further analysis with larger datasets and more detailed information about the events is needed to draw more definitive conclusions.

## Overall Conclusion:

The analyses of adverse event reports for ICDs reveal several important insights and patterns. The most common product problems are related to device alarms; followed by malfunctions like failure to alarm and under-sensing. Battery issues; software issues; and hardware issues are identified as significant root causes. There is an increasing trend in alarm-related issues and a need for improved battery management and software development practices. Device age; device model; and software version are found to be correlated with certain reported problems. These findings can be used to improve device design; manufacturing; and maintenance practices; ultimately enhancing patient safety and reducing the risk of adverse events.

## Manufacturers Summary

CRITIKON DE MEXICO S. DE R.L. DE C.V. (5)  
PHILIPS MEDICAL SYSTEMS (313)  
PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (152)  
MEDTRONIC EUROPE SARL (282)  
MEDTRONIC SINGAPORE OPERATIONS (233)  
IRHYTHM TECHNOLOGIES INC (98)  
IRHYTHM TECHNOLOGIES IN (1)  
RHYTHM TECHNOLOGIES INC (3)  
MEDTRONIC INC. (23)  
BRAEMAR MANUFACTURING LLC (66)  
MEDTRONIC MED REL MEDTRONIC PUERTO RICO (1)  
PHILIPS NORTH AMERICA LLC (1)  
BOSTON SCIENTIFIC CARDIAC DIAGNOSTIC TECHNOLOGIES INC. (4)  
GE HEALTHCARE TECHNOLOGY / GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC. (4)  
MEDTRONIC (6)  
ZOLL MANUFACTURING CORPORATION (2)  
ST. JUDE MEDICAL (1)  
ABBOTT (1)  
BOSTON SCIENTIFIC CORPORATION (1)

## Device Brands Summary

CIC PRO (5)  
INTELLIVUE MX40 802.11A/B/G (7)  
MX40 1.4 GHZ SMART HOPPING (213)  
INTELLIVUE MP50 (6)  
INTELLIVUE MULTI MEASUREMENT SERVER X2 (75)  
INTELLIVUE MX40 2.4GHZ (43)  
INTELLIVUE MP2 (4)  
INTELLIVUE MX800 PATIENT MONITOR (20)  
INTELLIVUE MX40 WLAN (17)  
INTELLIVUE MP5 (12)  
INTELLIVUE MP50 PATIENT MONITOR (2)  
TELE MX40 2.4 GHZ ECG &SP02 EXCHANGE (2)  
TELE MX40 1.4 GHZ ECG AND SP02 EX (10)  
INTELLIVUE MX700 PATIENT MONITOR (12)  
UNKNOWN PATIENT MONITORING BEDSIDE MONITOR (1)  
INTELLIVUE MP60 (5)  
MX40 PATIENT WEARABLE MONITOR (6)  
INTELLIVUE MP70 (10)  
MX40 2.4 GHZ SMART HOPPING (3)  
TELE MX40 2.4 GHZ ECG ONLY EXCHANGE (2)  
MP40 (2)  
REVEAL LINQ (515)  
TELE PWM 802.11A/B/G ECG&SP02 EX NON US (2)  
4003409 (1)  
INTELLIVUE MX600 PATIENT MONITOR (1)  
ZIO AT (101)  
PATIENT CONNECTOR (5)  
REVEAL XT (4)  
REVEAL LINQ INSERTION TOOLS (3)  
C6 MCOT PPM (62)  
INTELLIVUE MX40 802.11A/B/G (865352) (1)  
PATIENT INFORMATION CENTER IX (1)  
MEDTRONIC ILR (6)  
INTELLIVUE NMT MODULE (1)  
C6 PATCH VERIZON (1)  
REVEAL LINQ MOBILE MANAGER APP (4)  
MCOT BIOTEL HEART (1)  
LOOP RECORDER (1)  
CARDIAC EVENT MONITORING (CEM) B (1)

GE HEALTHCARE TECHNOLOGY CSCS V3 (4)  
BOSTON SCIENTIFIC BODYGUARDIAN MINI PLUS (1)  
MINI HEART MONITOR (2)  
REVEAL LINQ<sub>d</sub> (1)  
1.4 GHZ INTELLIVUE TELE TRX (2)  
UNKNOWN PATIENT MONITORING TELE (2)  
DETECTOR AND ALARM ARRHYTHMIA (7)  
REVEAL (1)  
MCOT C6 (1)  
EPATCH V2 MB (1)  
ZOLL CARDIAC MONITOR (2)  
INTELLIVUE FMS-4 (1)  
10 LEAD ECG TRUNK AAMI/IEC 2M (1)  
C6 MCOT (1)  
BODY GUARDIAN MINI PLUS WEARABLE CARDIAC MONITOR (1)

# DSI MAUDE Problems Summary

## Data Overview – Problem Summaries

Product Problems	MDR Counts	Problem Summaries
No Audible Alarm	241	<p><b>## Product Problem Summary:</b>  Device: PHILIPS MX40 1.4 GHZ SMART HOPPING DEVICE  Problem: Speaker malfunction; no sound coming from the device.  Details:  * The issue was reported by a customer and confirmed by a Philips Field Service Engineer (FSE) and a Philips Response Service Engineer (RSE).  * The device was not in use at the time of the event.  * No adverse events or patient harm were reported.  * Diagnostics testing performed at Philips Bench Repair confirmed the speaker was defective.  * The speaker was replaced by a Philips Bench Repair technician.  * The device was returned to the customer.  * The investigation is ongoing; and a follow-up report will be submitted upon completion.  Additional Notes:  * In some cases; the device was reported to be producing sound despite the speaker malfunction error message.  * The cause of the problem is believed to be a faulty speaker.  * The customer was provided with a replacement speaker to resolve the issue.  <b>## Key Points:</b>  * Speaker malfunction  * No sound  * Device not in use  * No adverse events  * Speaker replaced  * Investigation ongoing  <b>## Next Steps:</b>  * Complete the investigation and submit a follow-up report.  * Monitor for similar reports.  * Consider additional actions to prevent future occurrences.</p>
Under-Sensing	147	<p><b>## Summary of Medtronic Implantable Cardiac Monitor (ICM) Reports</b>  This document summarizes 25 reports submitted by Medtronic to the FDA regarding their Implantable Cardiac Monitor (ICM). The reports describe various issues with the ICM; including:</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* Undersensing: The ICM failed to detect heartbeats; which could lead to missed diagnoses of arrhythmias.</li> <li>* Oversensing: The ICM detected non-existent heartbeats; which could lead to unnecessary interventions.</li> <li>* False pause episodes: The ICM incorrectly detected pauses in the heartbeat; which could lead to anxiety and unnecessary interventions.</li> <li>* Electrical resets: The ICM experienced unexpected resets; which could lead to data loss and missed diagnoses.</li> <li>* Data transmission issues: The ICM failed to transmit data to the monitoring system; which could delay diagnosis and treatment.</li> <li>* End of service (EOS): The ICM reached the end of its useful life and needed to be replaced.</li> </ul> <p>In all cases; the ICM remained in use after the reported event. No patient complications were reported as a result of these events.</p> <p>## Key Findings</p> <ul style="list-style-type: none"> <li>* The most common issue reported was undersensing; which occurred in 14 of the 25 reports.</li> <li>* Oversensing was reported in 5 of the 25 reports.</li> <li>* False pause episodes were reported in 4 of the 25 reports.</li> <li>* Electrical resets were reported in 2 of the 25 reports.</li> <li>* Data transmission issues were reported in 2 of the 25 reports.</li> <li>* End of service was reported in 2 of the 25 reports.</li> </ul> <p>## Recommendations</p> <ul style="list-style-type: none"> <li>* Medtronic should investigate the root cause of the undersensing issue and implement corrective actions to prevent future occurrences.</li> <li>* Medtronic should improve the accuracy of the ICM's sensing algorithms to reduce the risk of over and undersensing.</li> <li>* Medtronic should improve the reliability of the ICM's data transmission system to ensure timely diagnosis and treatment.</li> <li>* Medtronic should provide clear guidance to clinicians on the management of ICMs that have reached end of service.</li> </ul> <p>## Conclusion</p> <p>The reports submitted by Medtronic highlight the importance of ongoing monitoring and surveillance of medical devices. By identifying and addressing issues with the ICM; Medtronic can improve the safety and effectiveness of this important device.</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
Over-Sensing	128	<p><b>## Concise Summary of Product Problem:</b>  Implantable Cardiac Monitor (ICM) experienced over-sensing and under-sensing issues; leading to inaccurate data and potentially missed events.  Specific problems reported:</p> <ul style="list-style-type: none"> <li>* P-wave over-sensing</li> <li>* T-wave over-sensing</li> <li>* Missing reports</li> <li>* Dates in remote monitoring reports resetting to implant date</li> <li>* Episodes in remote monitoring reports showing dates since implant date after interrogation</li> </ul> <p>Additional information:</p> <ul style="list-style-type: none"> <li>* Device remains in use in all reported cases.</li> <li>* No patient complications reported.</li> <li>* Medtronic is investigating the issue and submitting reports to comply with FDA regulations.</li> </ul> <p>Overall; the ICM is malfunctioning and providing inaccurate data. This could potentially lead to missed diagnoses and improper treatment for patients.</p>
No Audible Prompt/Feedback	100	<p><b>## Summary of Product Problem:</b>  The product in question is a medical device; likely a patient monitor; with a reported speaker malfunction. The speaker either produces no sound or produces very poor sound quality. This issue has been reported across various models of the device; including the MX40; MX800; and IntelliVue MP5.</p> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* Problem: Speaker malfunction; resulting in no sound or poor sound quality.</li> <li>* Affected Devices: MX40; MX800; IntelliVue MP5; and potentially other models.</li> <li>* Impact: Potential for missed alarms or other critical information.</li> <li>* Resolution: Speaker replacement in most cases.</li> <li>* Investigation Status: Ongoing for some cases.</li> </ul> <p><b>## Additional Information:</b></p> <ul style="list-style-type: none"> <li>* The cause of the speaker malfunction is not always clear; but it may be due to a defective speaker; damaged wires; or other hardware issues.</li> </ul>



## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>* In some cases; the device was not in use on a patient at the time of the event. However; there is potential for patient harm if the speaker malfunction prevents the delivery of critical information.</p> <p>* Philips is investigating the issue and has provided replacement devices in some cases.</p> <p>## Recommendations:</p> <p>* Users should be aware of the potential for speaker malfunction and report any issues to Philips immediately.</p> <p>* Philips should continue to investigate the issue and take steps to prevent future occurrences.</p> <p>## Conclusion:</p> <p>The speaker malfunction is a serious issue that could potentially impact patient safety. Philips is taking steps to address the problem; but further investigation is needed.</p>
Failure to Transmit Record	92	<p>## Concise Description of Product Problem:</p> <p>The Zio AT device reached its maximum transmission limit; preventing transmission of an arrhythmia that met medical doctor notification (MDN) criteria. The HCP was notified of the transmission limit; but the arrhythmia was not conveyed during the wear period.</p> <p>## Breakdown of the Problem:</p> <p>* Zio AT reached maximum transmission limit: This means the device stopped transmitting data after reaching a preset limit for either patient-triggered or asymptomatic transmissions.</p> <p>* Arrhythmia not conveyed to HCP: The arrhythmia data was not transmitted to the HCP during the wear period due to the transmission limit.</p> <p>* HCP notified of transmission limit: The HCP was informed that the device was approaching the transmission limit; but the specific details of the arrhythmia were not conveyed.</p> <p>## Potential Consequences:</p> <p>* Delayed diagnosis and treatment of the arrhythmia: The HCP may not be aware of the arrhythmia until the final report is prepared; potentially delaying diagnosis and treatment.</p> <p>* Increased risk of adverse events: If the arrhythmia is serious; the delay in diagnosis and treatment could increase the risk of adverse events; such as stroke or heart attack.</p> <p>## Actions Taken:</p> <p>* Investigation confirmed the transmission limit: The</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>manufacturer confirmed that the device reached its maximum transmission limit.</p> <ul style="list-style-type: none"> <li>* HCP notified of the arrhythmia: The manufacturer notified the HCP of the arrhythmia after the final report was prepared.</li> <li>* Report filed with FDA: The manufacturer filed a report with the FDA as a product problem/malfunction.</li> </ul> <p>## Additional Notes:</p> <ul style="list-style-type: none"> <li>* No adverse events; such as death or serious injury; are known to have occurred.</li> <li>* The patient experienced the arrhythmia four days after the device reached the maximum transmission limit.</li> <li>* The patient was wearing the device for 13 days of the 14-day prescribed wear period.</li> <li>* The HCP declined a replacement device.</li> <li>* The manufacturer is investigating the issue and will take appropriate action to prevent similar occurrences in the future.</li> </ul>
Communication or Transmission Problem	65	<p>## Product Problem Summary:</p> <p>The product problem described in the reports is that the implantable cardiac monitor (ICM) is not communicating with the remote monitor. This lack of telemetry can be caused by several factors; including:</p> <ul style="list-style-type: none"> <li>* Hardware malfunction: The ICM or remote monitor may have a hardware malfunction that prevents them from communicating.</li> <li>* Software issue: There may be a software issue with the ICM or remote monitor that is preventing them from communicating.</li> <li>* User error: The patient may not be using the remote monitor correctly; which could prevent it from communicating with the ICM.</li> <li>* Interference: There may be interference from other devices that is preventing the ICM and remote monitor from communicating.</li> <li>* Battery depletion: The battery in the ICM or remote monitor may be depleted; which would prevent them from communicating.</li> </ul> <p>The reports do not indicate that any patient complications have been reported as a result of this problem. However; the lack of telemetry could potentially delay the detection of a serious medical condition.</p> <p>## Additional Information:</p> <ul style="list-style-type: none"> <li>* The reports were submitted to the FDA by Medtronic; the</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>manufacturer of the ICM and remote monitor.</p> <ul style="list-style-type: none"> <li>* The reports are based on information obtained by Medtronic; which may not have been able to fully investigate or verify prior to the date the report was required by the FDA.</li> <li>* Medtronic has made reasonable efforts to obtain more complete information and has provided as much relevant information as is available to the company as of the submission date of the report.</li> <li>* This report does not constitute an admission or a conclusion by FDA; Medtronic; or its employees that the device; Medtronic; or its employee caused or contributed to the event described in the report.</li> <li>* In particular; this report does not constitute an admission by anyone that the product described in this report has any "defects" or has "malfunctioned". These words are included in the FDA 3500A form and are fixed items for selection created by the FDA to categorize the type of event solely for the purpose of regulatory reporting. Medtronic objects to the use of these words and others like them because of the lack of definition and the connotations implied by these terms.</li> <li>* This statement should be included with any information or report disclosed to the public under the Freedom of Information Act.</li> <li>* Any required fields that are unpopulated are blank because the information is currently unknown or unavailable. A good faith effort will be made to obtain the applicable information relevant to the report. If information is provided in the future; a supplemental report will be issued.</li> </ul>
Signal Artifact/Noise	39	<p><b>## Summary of Product Problems with Medtronic Implantable Cardiac Monitors (ICMs)</b></p> <p>Based on the provided reports; here's a summary of the product problems identified with Medtronic ICMs:</p> <p>Common Issues:</p> <ul style="list-style-type: none"> <li>* Noise: This is the most frequently reported issue; appearing in 14 out of 20 reports. The noise can manifest as non-cardiac signals; artifact; or interference; and can affect the accuracy of the device's readings.</li> <li>* Oversensing: This occurs when the device detects electrical activity that is not actually a heart rhythm; leading to false positive diagnoses of arrhythmias. This issue was reported in 8</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>out of 20 reports.</p> <ul style="list-style-type: none"> <li>* Undersensing: This is the opposite of over-sensing; where the device fails to detect actual heartbeats; potentially leading to missed diagnoses of arrhythmias. This issue was reported in 7 out of 20 reports.</li> <li>* False detections: This includes both false positive and false negative detections of arrhythmias; and was reported in 6 out of 20 reports.</li> <li>* Detection of non-cardiac signals: This can include muscle activity; electromagnetic interference; or other sources of electrical noise that are not related to the heart. This issue was reported in 3 out of 20 reports.</li> </ul> <p>Other Issues:</p> <ul style="list-style-type: none"> <li>* Low R-wave amplitude: This can lead to inaccurate heart rate measurements and potentially missed arrhythmias. This issue was reported in 2 out of 20 reports.</li> <li>* Remote monitoring issues: This includes problems with the device not generating reports or having different reference points for the ECG graph; making it difficult to compare readings across different reports. This issue was reported in 2 out of 20 reports.</li> <li>* Suboptimal electrode connection: This can lead to inaccurate readings and potentially missed arrhythmias. This issue was reported in 1 out of 20 reports.</li> <li>* Floating ECG: This can be caused by mechanical manipulation or movement of the implant site and can lead to inaccurate readings. This issue was reported in 1 out of 20 reports.</li> </ul> <p>Important Note:</p> <ul style="list-style-type: none"> <li>* It is important to note that these reports only represent a small sample of the total number of Medtronic ICMs implanted.</li> <li>* The frequency of these issues may not be representative of the overall population of devices.</li> <li>* Additionally; the reports do not provide information on the severity of the problems or whether they resulted in any patient harm.</li> </ul> <p>Further Investigation:</p> <ul style="list-style-type: none"> <li>* More information is needed to fully understand the scope and impact of these product problems.</li> <li>* This could include data on the frequency of these issues; the severity of the problems; and whether they resulted in any</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>patient harm.</p> <p>* Additionally; it would be helpful to understand the underlying causes of these problems and what steps Medtronic is taking to address them.</p> <p>I hope this summary is helpful. Please let me know if you have any other questions.</p>
Adverse Event Without Identified Device or Use Problem	33	<p><b>## Product Problem Summary:</b></p> <p>A patient experienced first-degree burns under both the universal and Flex ECG patches; despite switching to the Flex patch due to initial burn under the universal patch. The patient has a history of skin sensitivity and discontinued use of the device.</p> <p><b>Key Points:</b></p> <ul style="list-style-type: none"> <li>* The patient experienced first-degree burns under both the universal and Flex ECG patches.</li> <li>* The patient has a history of skin sensitivity.</li> <li>* The patient discontinued use of the device.</li> <li>* Engineering evaluation was unable to be performed as the electrodes were not returned.</li> <li>* The allegation is confirmed through the need for a prescription and is most likely a bio-incompatibility issue with the electrode adhesive.</li> <li>* The product labeling advises patients of alternate options and steps to take if skin irritation develops.</li> </ul> <p><b>Additional Information:</b></p> <ul style="list-style-type: none"> <li>* Two other reports are referenced; one involving pain experienced by a patient with an ICM and another involving bleeding after insertion of an ICM.</li> <li>* Medtronic is submitting this report to comply with FDA reporting regulations.</li> <li>* Medtronic has made reasonable efforts to obtain more complete information.</li> <li>* This report does not constitute an admission or conclusion by FDA; Medtronic; or its employees that the device caused or contributed to the event.</li> <li>* Medtronic objects to the use of the words "defects" and "malfunctioned" in the FDA 3500A form.</li> </ul> <p><b>Possible Causes:</b></p> <ul style="list-style-type: none"> <li>* Bio-incompatibility of the electrode adhesive with the patient's skin.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>* Patient's history of skin sensitivity.</p> <p>Possible Solutions:</p> <ul style="list-style-type: none"> <li>* Use of alternative electrode materials or adhesives.</li> <li>* Development of better screening methods to identify patients with skin sensitivities.</li> <li>* Improved product labeling and patient education regarding potential skin reactions.</li> </ul> <p>Next Steps:</p> <ul style="list-style-type: none"> <li>* Medtronic should continue to investigate the cause of the skin burns.</li> <li>* Medtronic should work to develop solutions to prevent future occurrences of this problem.</li> <li>* Medtronic should update the product labeling and patient education materials to reflect the potential for skin reactions.</li> </ul>
Defective Alarm	33	<p>## Summary of Product Problems:</p> <p>This document details numerous reports of malfunctioning medical devices manufactured by Philips. The reported issues include:</p> <ul style="list-style-type: none"> <li>* Alarm failures: Several reports describe instances where alarms failed to sound for critical events such as asystole; bradycardia; and desaturation. This resulted in delayed response times and potential harm to patients.</li> <li>* Speaker malfunctions: Multiple reports mention issues with the device speakers not producing sound or producing distorted sound. This could prevent caregivers from hearing important alarms and notifications.</li> <li>* Software issues: Some reports describe software problems such as alarms being turned off by default; alarms not being generated for specific conditions; and alarms being silenced by staff. These issues could lead to missed alarms and potential patient harm.</li> <li>* Hardware issues: A few reports mention hardware problems such as loose connections; faulty batteries; and defective speakers. These issues could also lead to device malfunctions and potential patient harm.</li> </ul> <p>## Common Themes:</p> <ul style="list-style-type: none"> <li>* Alarm failures: This appears to be the most prevalent issue; with numerous reports describing various scenarios where alarms failed to sound as expected.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>* User error: Several reports attribute the problem to user error; such as alarms being silenced or turned off; or improper configuration of the device.</p> <p>* Software and hardware issues: While less frequent than alarm failures; software and hardware issues also contribute to device malfunctions.</p> <p>## Potential Impact: The reported malfunctions have the potential to cause significant harm to patients; including delayed response times; missed alarms; and even death.</p> <p>## Next Steps:</p> <p>* Further investigation: Philips needs to continue investigating these reports to determine the root cause of the problems and implement corrective actions.</p> <p>* Improved communication: Philips should improve communication with customers and healthcare providers to ensure they are aware of potential issues and how to mitigate them.</p> <p>* Enhanced training: Training for healthcare staff on proper use and configuration of the devices is crucial to prevent user error.</p> <p>* Software and hardware updates: Addressing software and hardware issues through updates and improvements is essential to ensure device reliability and patient safety.</p>
Reset Problem	26	<p>## Concise Description of the Product Problem: An implantable cardiac monitor (ICM) exhibited electrical resets and undersensing. The device remains in use; and no patient complications have been reported.</p> <p>## Breakdown of the Problem:</p> <p>* Electrical resets: The ICM experienced multiple electrical resets; which may indicate a hardware or software issue.</p> <p>* Undersensing: The ICM failed to detect some heartbeats; which could lead to missed diagnoses or delayed treatment.</p> <p>* End of service: The ICM reached the end of its expected service life; which may increase the risk of malfunction.</p> <p>* Electrolysis event: The ICM experienced an electrical reset during electrolysis; which may be related to the procedure or the device itself.</p> <p>## Additional Information:</p> <p>* The device was not returned for analysis; but performance</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>data was collected and analyzed.</p> <ul style="list-style-type: none"> <li>* The cause of the problem is unknown.</li> <li>* Medtronic is submitting this report to comply with FDA reporting regulations.</li> <li>* Medtronic objects to the use of the words "defects" and "malfunctioned" in the report.</li> </ul> <p>## Conclusion:</p> <p>This product problem is concerning and requires further investigation. Medtronic should continue to monitor the device and take appropriate action to address the issue.</p>
Device Alarm System	26	<p>## Summary of Product Problem:</p> <p>The customer reported that the monitor was not capturing the patient; resulting in a patient death. The device was in use on the patient at the time of the event; and there was no adverse event reported. Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation. A final report will be submitted once the investigation is complete.</p> <p>## Key Points:</p> <ul style="list-style-type: none"> <li>* The monitor did not capture the patient's vital signs.</li> <li>* The patient died.</li> <li>* The device was in use at the time of the event.</li> <li>* There was no adverse event reported.</li> <li>* Philips is investigating the issue.</li> </ul> <p>## Additional Information:</p> <ul style="list-style-type: none"> <li>* The source notes indicated that the device alarm did not activate as intended.</li> <li>* The biomedical equipment technician stated that there was no fault with the device and that it was functioning as designed.</li> <li>* The device was repaired and returned to the customer.</li> <li>* The reported problem was not confirmed.</li> <li>* The customer indicated that the device did not alarm as intended.</li> <li>* A Philips product support engineer and Philips clinical specialist reviewed the logs; strips; and information provided.</li> <li>* The raw ECG data showed the monitor was in a learning phase during a ventricular rhythm.</li> <li>* The Star algorithm classified the beats as N instead of V; resulting in the criteria for generating a VTACH alarm not being</li> </ul>



## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>met.</p> <ul style="list-style-type: none"> <li>* There was no product malfunction; and the device remains in use.</li> <li>* Related cases are reported under MFR report numbers 1218950-2024-00243; 9610816-2024-00179; and 1218950-2024-00232.</li> <li>* The customer reported that there were no alarms for V-TACH.</li> <li>* The device was in use on the patient at the time of the event; and there was no adverse event reported.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A Philips product support engineer and Philips clinical specialist reviewed the logs; strips; and information provided.</li> <li>* The Star algorithm classified the beats as N instead of V; resulting in the criteria for generating a VTACH alarm not being met.</li> <li>* There was no product malfunction; and the device remains in use.</li> <li>* Related cases are reported under MFR report numbers 1218950-2024-00243; 1218950-2024-00233; and 9610816-2024-00179.</li> <li>* The customer reported that there were no alarms for V-TACH.</li> <li>* The device was in use on the patient at the time of the event; and there was no adverse event reported.</li> <li>* The device was returned to a Philips site for evaluation.</li> <li>* The device was tested and passed unit functional testing twice.</li> <li>* Based on the information provided; it was determined that the customer may have been experiencing network issues and not a failure of the device.</li> <li>* Additionally; since the gap was to the central station/wireless; then the device would still operate and alarm locally for any detected arrhythmia.</li> <li>* Alarms can be reviewed on the MX40 but would need to be captured at the time of the event.</li> <li>* Those alarms are text only and do not contain waveforms.</li> <li>* The customer was provided a replacement device to resolve the issue.</li> <li>* It has been concluded that no further action is required at this time.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* If additional information is received; the complaint file will be reopened.</li> <li>* The customer reported that the device failed to alarm and did not sound when a 4-second pause was noted.</li> <li>* The device was in use on the patient at the time of the event; and there was no adverse event reported.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* Diagnostic/functional testing was performed at the Philips authorized repair facility.</li> <li>* Results of functional testing indicate that the speaker did produce sound.</li> <li>* Although the speaker was confirmed to be functioning per specification during testing; it was indicated that there was no sound at the time of the event; the speaker has been replaced per current process.</li> <li>* The device was operational after repairs were completed.</li> <li>* The investigation concludes that no further action is required at this time.</li> <li>* The customer reported a speaker malfunction error with the system.</li> <li>* The device was not in use on a patient at the time of the event; and there was no adverse event reported.</li> <li>* The customer reported a speaker malfunction error with the system.</li> <li>* It is unknown if the device was in use at the time of the event; and there was no adverse event reported.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* The customer reported that the system apnea alarm was not generated; and the patient passed away.</li> <li>* A Philips technical consultant (TC) and Philips clinical specialist (CS) went onsite to collect the logs to be evaluated internally by Philips; and work with staff to preliminarily test the unit respectively.</li> <li>* The patient was being monitored via X2 on MX800 at the time</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>of the event.</p> <ul style="list-style-type: none"> <li>* The customer tested the MX800 on a simulator; and all vitals alarmed.</li> <li>* Results of functional testing could not confirm the customer's alleged malfunction.</li> <li>* The customer was concerned about the respiration and apnea functions of the unit.</li> <li>* The logs were provided by the customer to be evaluated internally by Philips.</li> <li>* Based on the information provided in the case and by Philips Clinical Specialist (CS); who evaluated the audit logs; the customer's allegation could not be confirmed.</li> <li>* The device remains at the customer site.</li> <li>* No further investigation or action is warranted at this time.</li> <li>* Diagnostic/functional testing was performed at the Philips authorized repair facility.</li> <li>* Results of the evaluation could not confirm the customer's alleged malfunction.</li> <li>* Per customer; it was indicated that there was a speaker malfunction inoperative message at the time of the event.</li> <li>* While at the bench; the speaker produced audible sound.</li> <li>* The speaker was confirmed to be functioning per specification.</li> <li>* For precaution; the speaker was replaced per current process.</li> <li>* The device was operational and returned to the customer.</li> <li>* Philips received a complaint on the MX40 1.4 GHz Smart Hopping indicating that the unit had a speaker inoperative message with no tone.</li> <li>* The device was not in use on a patient at the time of the event; and there was no adverse event reported.</li> <li>* The customer reported a speaker malfunction with the system.</li> <li>* The device was not in use on a patient at the time of the event; and there was no adverse event reported.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* The customer reported that the alarms from the Intellivue MP70 patient monitor were not recognized; and a patient was harmed.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* No additional information regarding the adverse event was provided.</li> <li>* The device was in use monitoring a patient at the time of the reported event.</li> <li>* Philips received a complaint on the Intellivue MP70 indicating that the alarms were not recognized; and the patient came to harm.</li> <li>* No additional information regarding the adverse event was provided.</li> <li>* The following functional tests were performed: <ul style="list-style-type: none"> <li>* The remote service engineer (RSE) reached out to the customer for more information; and the customer advised that this case was opened mistakenly.</li> <li>* The customer stated that the case was not due to a device defect; and the device worked properly.</li> <li>* Based on the information available and the testing conducted; the cause of the reported problem is unknown.</li> <li>* The reported problem was not confirmed.</li> <li>* Based on the information available and results of additional analysis; no further action is necessary at this time.</li> <li>* Due to the lack of available information; the exact cause for the reported issue remains unknown.</li> <li>* The customer advised that the case was not due to a device defect; and the device is working properly.</li> <li>* The investigation concludes that no further action is required at this time.</li> <li>* If additional information is received; the complaint file will be reopened.</li> <li>* H3 OTHER TEXT: Customer reported that the complaint was opened in error and there was no malfunction of the device.</li> </ul> </li> <li>* The customer reported that the invasive blood pressure (IBP) alarms reset themselves to "off" on the Intellivue MX700 patient monitor despite being enabled in the settings.</li> <li>* It is unknown if the device was in use monitoring a patient at the time of the reported issue.</li> <li>* No adverse patient event was reported.</li> <li>* Philips received a complaint on the Intellivue MX700 patient monitor indicating that the invasive blood pressure (IBP) alarms were automatically reset to off-alarm status; despite being enabled in the settings.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The following functional tests were performed: <ul style="list-style-type: none"> <li>* A field service engineer (FSE) went onsite and was unable to observe any problem.</li> <li>* The FSE retrieved the monitor logs and found no anomalies.</li> <li>* The FSE also carried out alarm testing; but everything was working correctly.</li> <li>* It was requested that the customer provide a specific example of the problem (time; patient; etc.) from the medical staff in order to better analyze it.</li> <li>* The customer will contact Philips if the problem arises again in order to recover the logs on the control unit.</li> <li>* The customer has already requested training for the staff.</li> <li>* Based on the information available and the testing conducted; the FSE was unable to replicate the reported problem.</li> <li>* The reported problem was not confirmed.</li> <li>* The device was confirmed to be operating per specifications and no failure was identified.</li> <li>* The investigation concludes that no further action is required at this time.</li> <li>* If additional information is received; the complaint file will be reopened.</li> <li>* The device remains at the customer site.</li> </ul> </li> <li>* The product support engineer (PSE) identified that there is radio frequency data acquisition (RFDA) and devicedebug log data for bed label Tele-8 in the reported incident timeframe.</li> <li>* There is audit log data for the incident timeframe and device in question.</li> <li>* The MX40 PWM logs were not collected.</li> <li>* The RFDA log shows that there are signal issues during the reported timeframe (MX40 to PIC IX); but the MX40 remained connected to the PIC IX.</li> <li>* The RFDA log shows the connection between device Tele-8 (bed label HTG1-8) and the Patient Information Center IX (PIC IX) being aborted at 06:27:24 on (B)(6) 2023; at which time the patient was discharged from the PIC IX.</li> <li>* The device debug log shows a battery change for device/bed label Tele-8/HTG1-8 at 09:58:05 on (B)(6); 2023.</li> <li>* No other activity was captured during the incident timeframe.</li> <li>* The audit log shows ongoing activity for device label/bed label</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>Tele-8/HTG1-8 throughout the timeframe of 01:30 through 06:27 on October 20; 2023.</p> <ul style="list-style-type: none"> <li>* Physiological alarms were being provided for asystole; vent fib/tachy; HR low limit violations; AFIB; pause; and irregular HR event as the patient's condition changed.</li> <li>* Technical inop alarms were provided for tele weak signal; cannot analyze ECG; and ECG leads off (R lead (right arm) events.</li> <li>* The audit log shows the patient was discharged at 06:27:24 on (B)(6); 2023.</li> <li>* The audit log shows the patient was readmitted at 08:12:34 on (B)(6); 2023.</li> <li>* No further activity for device/bed Tele-8/HTG1-8 is captured.</li> <li>* The readmit may have been to review data.</li> <li>* The audit log data ends at 08:12:34 on (B)(6); 2023.</li> <li>* The logs indicate that the Philips equipment is performing as specified.</li> <li>* It is further determined that the Philips device did not cause or contribute to the patient death.</li> <li>* The customer is using Tunstall nurse call system.</li> <li>* This secondary alarming system is alleged to not have alarmed.</li> <li>* Additional information regarding the Tunstall system has been requested.</li> <li>* A follow-up report will be submitted once the investigation is completed.</li> <li>* The logs indicate that the Philips equipment is performing as specified.</li> <li>* It is further determined that the Philips device did not cause or contribute to the patient death.</li> <li>* The customer is using Tunstall nurse call system (a non-Philips product).</li> <li>* This secondary alarming system is alleged to not have alarmed.</li> <li>* Additional information regarding the Tunstall system was requested; however; no additional information was received.</li> <li>* The Philips product support engineering (PSE) log review indicates and the customer was certain the alarms were being generated at the Patient Information Center IX (PIC IX).</li> <li>* This confirms alarming at the MX40 device as the PIC IX receives the information from the MX40.</li> <li>* The secondary alarms were not being sent to the non-Philips</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>nurse call system.</p> <ul style="list-style-type: none"> <li>* Per the PSE; the IFU states 'The paging system is a secondary alarm notification system and is not intended for primary notification of alarms; physiological data; or demographic data.'</li> <li>* Receipt by the external software device of alerts is not confirmed; and delivery to the paging device is not guaranteed.'</li> <li>* The clinical audit log review revealed the Philips devices were performing as specified and manufacturer-specific performance is to be addressed by the customer with that manufacturer.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* Reporting institution phone#: (B)(6).</li> <li>* It was reported a patient being monitored by a telemetry device passed away.</li> <li>* The customer indicated the central station was alarming; however; the secondary alarm forwarding to the nurse call was not alarming.</li> <li>* The customer requested onsite assistance gathering the device logs.</li> <li>* Device logs were retrieved and provided to the product support engineer for evaluation.</li> <li>* The Patient Information Center IX in use during this event is reported in MFR number 1218950-2023-00863.</li> <li>* Philips received a complaint on the Intellivue MX800 patient monitor indicating that the yellow alarm went off instead of red.</li> <li>* A remote service engineer (RSE) spoke with the customer and explained that the heart rate (HR) needed to be above the set limit for a ventricular tachycardia (V-TACH).</li> <li>* The patient had premature ventricular contractions (PVCs); which is why the customer got the yellow alarm.</li> <li>* The RSE advised that there had to be an HR violation as well in order to get the red alarm for V-TACH.</li> <li>* Based on the information available and the testing conducted; the device was functioning as intended; and there was no malfunction of the device.</li> <li>* The reported problem was not confirmed.</li> <li>* The device was confirmed to be operating per specifications and no failure was identified.</li> <li>* The investigation concludes that no further action is required.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The device remains at the customer site.</li> <li>* The customer reported that the Intellivue MX800 patient monitor issued a yellow alarm instead of the expected red alarm.</li> <li>* The device was in use monitoring a patient at the time of the reported issue.</li> <li>* No adverse patient or user event was reported.</li> <li>* A follow-up report will be submitted once the investigation is complete.</li> <li>* The customer reported that the Intellivue MX800 patient monitor issued a yellow alarm instead of the expected red alarm.</li> <li>* It is unknown if the device was in use at the time of the event; and there was no adverse event reported.</li> <li>* The customer provided pictures of the battery.</li> <li>* The remote support engineer (RSE) identified the battery terminals looked worn.</li> <li>* Based on the information provided and statements by the customer; the product support engineer (PSE) believes the battery was not correctly cleaned as there was still residual on the contact.</li> <li>* The customer stated that the battery showed fully charged on the charger and after scraping over the contacts with a fingernail; the battery started to function again in the telemetry monitor.</li> <li>* The customer was advised of the approved cleaning methods in the Instructions for Use (IFU).</li> <li>* The customer was also advised to replace the battery due to visible wear.</li> <li>* The customer reported the battery failed without alarming for low battery; which resulted in a loss of telemetry monitoring.</li> <li>* The battery did not work in a telemetry monitor but was showing fully charged on the charger.</li> <li>* The contact was scraped over with a fingernail; and the battery started to function again in the telemetry monitor.</li> <li>* The customer stated it appears the charger doesn't have a terminal for this contact.</li> <li>* In addition; the customer reports the terminals on the battery look clean; there are no deposits that can be seen; the battery is less than a year old; and the units are being cleaned with alcohol Sani Cloths.</li> <li>* The device was reported to be in use on a patient; but no</li> </ul>



## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>adverse event to the patient or user was reported.</p> <ul style="list-style-type: none"> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* The customer reported that there was a damaged case.</li> <li>* In addition; it was stated that the device did not alarm/alert as intended.</li> <li>* A follow-up report will be submitted once the investigation is complete.</li> <li>* The Philips authorized repair facility evaluated the device and was unable to replicate the reported problem.</li> <li>* It was confirmed the speaker produced sound.</li> <li>* After testing; it was determined that the speaker was functioning as designed.</li> <li>* If additional information is received; the complaint file will be reopened.</li> <li>* Philips received a complaint on the MX40 1.4 GHz Smart Hopping indicating that the MX40 could not provide alarming due to a broken case &amp; unable to hold batteries.</li> <li>* It is unknown if the device was in use at the time of the event; and there was no adverse event reported.</li> <li>* Philips received a complaint on the Intellivue Multi Measurement Server X2 indicating that the power supply of the monitor; on which the device was docked; failed.</li> <li>* The customer reported that the module supposedly gave no alarm.</li> <li>* The device was sent to Philips bench repair.</li> <li>* A Philips bench repair technician (BRT) evaluated the device and was unable to confirm the issue.</li> <li>* There were no functional defects found.</li> <li>* The device was confirmed to be operating per specifications and no failure was identified.</li> <li>* If additional information is received; the complaint file will be reopened.</li> <li>* The customer reported power supply of the monitor; on which the device was docked; failed.</li> <li>* The module supposedly gave no alarm.</li> <li>* It is unknown if the device was in use at the time of the event;</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>and there was no adverse event reported.</p> <ul style="list-style-type: none"> <li>* A follow-up report will be submitted once the investigation is complete.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* H3 OTHER TEXT: The customer rejected repair quote.</li> <li>* It was reported the patient desaturated into the 30s and 40s; and the device failed to generate an alarm.</li> <li>* The biomed has been unable to confirm the alarms are failing as they are unable to recreate the alarm issue.</li> <li>* An oxygen desaturation to 30% or 40% represents a change in the patient's clinical condition which can be considered life-threatening and typically requires intervention to preclude permanent impairment; therefore; this event meets criteria for a serious injury based on the information received.</li> <li>* Details of the event are incomplete; and additional information has been requested.</li> <li>* A Philips remote service engineer (RSE) the customer requested the central station and monitor logs be pulled.</li> <li>* Philips provide a quote for onsite service; however; the customer canceled the onsite service.</li> <li>* Requests were made for additional information; and no information was received.</li> <li>* The root cause is unable to be determined with the information available; however; the suspected cause is possible user error as the issue cannot be recreated.</li> <li>* Reporter phone number: (B)(6).</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* The customer reported that the Intellivue MP60 patient monitor did not generate a high-priority red alarm for a low non-invasive blood pressure (NIBP) of 44/17 mmHg on (B)(6) 2023.</li> <li>* The device was in use monitoring a patient at the time of the</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>reported issue.</p> <ul style="list-style-type: none"> <li>* No death or patient injury or harm was reported.</li> <li>* The customer reported that the Intellivue MP60 patient monitor did not generate a high-priority red alarm for a low invasive blood pressure (IBP) of 44/17 mmHg on 26-April-2023; resulting in the immediate need for adjustment in IV vasoactive medications.</li> <li>* The device was in use monitoring a patient at the time of the reported event.</li> <li>* A serious injury to the patient was reported.</li> <li>* Philips has received a complaint on the Intellivue MP60; indicating "At 16:37 on April 26; 2023; the monitor did not generate a high-priority red alarm for a low invasive blood pressure (IBP) of 44/17 mmHg."</li> <li>* The device was in clinical use during the event.</li> <li>* The customer reached out to Philips via a National Medical Products Administration report (NMPA # (B)(4)) requesting an investigation of this issue.</li> <li>* The NMPA reported that at 16:37 on April 26; 2023; the patient's blood pressure was as low as 44/17mmHg; and the average pressure was 24mmHg.</li> <li>* The monitor did not prompt a red alarm.</li> <li>* The doctor was in the ward at the time and immediately administered vasoactive drugs; and the patient's blood pressure was normal 5 minutes later without consequences.</li> <li>* No other clinical information or medical intervention was reported.</li> <li>* A good faith effort (GFE) was conducted several times; but no further information if the device was tested or logs were reviewed and information regarding the alarm settings was provided.</li> <li>* A Philips field service engineer (FSE) reached out to the customer; and confirmed that the event date was on April 26; 2023; but Philips never received any feedback on the issue at the time.</li> <li>* The customer stated that this issue was about an invasive pressure alarm; and it only happened one time.</li> <li>* The alarm was normal before and after the occurrence of the incident; and the customer added that since the incident happened on April 26; 2023; there were no valuable clues to</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>support the investigation of the problem.</p> <ul style="list-style-type: none"> <li>* Based on the information available; the cause of the reported problem remains unknown.</li> <li>* The engineer couldn't provide any analysis findings because the customer did not respond to requests for additional information.</li> <li>* It was confirmed the issue has not recurred; however; Philips is unable to confirm the final disposition of the device.</li> <li>* The investigation concludes that no further action is required.</li> <li>* H3 OTHER TEXT: Device not made available for evaluation</li> <li>* The customer reported that there is no error alarm displayed.</li> <li>* There is no reported adverse event to the patient or user.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* There was no actual failure regarding that message being present.</li> <li>* Bench repair confirmed that the "no alarm display" message is present on all devices before connecting to the communication tower.</li> <li>* After the connection is made and lead set has been inserted; the message is resolved.</li> <li>* Additional parts were replaced due to bringing the device to current rev and are not due to any failure of the device.</li> <li>* The device was operational after repairs were completed; and the device was returned to the customer.</li> <li>* The investigation concludes that no further action is required at this time.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* The customer reported that the device displays a speaker malfunction.</li> <li>* There was no reported adverse event to the patient or user.</li> <li>* The customer reported a speaker malfunction error with the system and requested assistance getting the surveillance</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>reconnected back to the primary server.</p> <ul style="list-style-type: none"> <li>* The remote service engineer (RSE) guided the biomed through the process of rebooting the station; the station was reconnected; but there is no sound.</li> <li>* Further workaround showed that the rectangular speaker is set as default (the only speaker on site); it was tested; but it did not generate a sound.</li> <li>* RSE advised the biomed to get a spare speaker as the station should not be running without sound.</li> <li>* Biomed takes full responsibility of calling us back if additional support is not needed.</li> <li>* Based on the information available and the testing conducted; the cause of the reported problem was the customer speaker.</li> <li>* The reported problem was confirmed.</li> <li>* Based on the information provided in the case; the engineer provided their analysis findings and the details of the workaround given to the customer; however; we are unable to confirm the final disposition of the device.</li> <li>* The customer takes the full responsibility of calling back if additional support is not needed.</li> <li>* The investigation concludes that no further action is required at this time.</li> <li>* If additional information is received; the complaint file will be reopened.</li> <li>* The hospital biomed did an initial evaluation of the issue; and a Philips field service engineer (FSE) performed another evaluation when on site.</li> <li>* The FSE did a visual inspection; checked configuration; changed parameters to intentionally set an alarm; and the monitor alarmed using demo mode.</li> <li>* As per the customer; only the bedside monitor was not alarming; however; the FSE confirms the device alarmed/alerted when tested and on reviewing of logs.</li> <li>* A Philips product support engineer (PSE) performed analysis of logs and configuration provided by the customer.</li> <li>* The PSE checked the times between 9:10 and 9:20 and verified a *desat alarm at 9:16:06 generated in room D24.</li> <li>* At the same time at 9:16:06; a red alarm sound played.</li> <li>* However; at 9:16:47; the alarm was acknowledged from the central station; and therefore; the alarm sound stopped at</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>9:16:47.</p> <ul style="list-style-type: none"> <li>* For the respective patient monitor; the "alarm reminder" was configured to "realarm."</li> <li>* This means that after the "reminder time" (in this case: 3 min.); the alarm tone is repeated.</li> <li>* This can be seen at 9:19:55 in the audit log.</li> <li>* Based on the information available and the testing conducted; the cause of the reported problem was the user's lack of awareness of alarm configuration.</li> <li>* The reported problem was not confirmed.</li> <li>* The engineers provided the findings to the customer to resolve the issue.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* The customer reported that the Intellivue MX800 patient monitor alarmed for a desaturation event for the patient in room D24; but the alarm cleared itself at the monitor on (B)(6) 2023 between 09:16 and 09:20.</li> <li>* The device was in use monitoring a patient at the time of the reported issue.</li> <li>* No death or patient injury or harm was reported.</li> <li>* The remote support engineer (RSE) had conversations with the customer which took place on (B)(6) 2023.</li> <li>* The customer explained that he was repairing the device due to damage to its battery case and mistakenly damaged the speaker; explaining further that the device now gives the inop message when powering the device.</li> <li>* The customer asked for part information to replace the speaker.</li> <li>* The RSE explained to the customer that the repair strategy is bench repair or full unit exchange are the only options from Philips.</li> <li>* However; the customer was provided with the replacement part no# 453564262511 and the service guide with available spare part information.</li> <li>* The customer is taking responsibility to correct/repair the device on resolving the damaged speaker.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The engineer provided their analysis findings; however; we are unable to confirm the final disposition of the device because the customer is taking responsibility to resolve the reported problem.</li> <li>* The investigation concludes that no further action is required at this time.</li> <li>* If additional information is received; the complaint file will be reopened.</li> <li>* Philips received a complaint from the customer that the MX40 1.4 GHz Smart Hopping device speaker got damaged while repairing the device for a damaged battery case/now gives speaker malfunction inop message.</li> <li>* The device was not in use.</li> <li>* Philips requested all wave strips; log files; physiological data; etc. associated with this issue in order to escalate this issue to our product support engineers for a technical investigation.</li> <li>* The customer states that there is no data available from this event.</li> <li>* Due to the lack of data; we are unable to perform a technical investigation.</li> <li>* Based on the information available; we were unable to replicate the reported problem.</li> <li>* The reported problem was not confirmed.</li> <li>* A clinical assessment was performed based on the information currently available in the complaint record.</li> <li>* It was reported the device did not generate an alarm for "pacer spikes embedded into the rhythm at random and inappropriately without capturing" for a patient with a temporary pacemaker.</li> <li>* The issue was reviewed with the clinical application specialist; who clarified the Intellivue algorithm will alarm for pacer not capturing or pacer not pacing when pacing mode is switched on.</li> <li>* Based on this information; it does not appear as if the device would have alarmed for random pacing spikes; and it cannot be determined if this affected the patient.</li> <li>* The clinical expert requested additional information; however; good faith effort confirmed that this information and data was not available.</li> <li>* The engineer provided their analysis findings; however; we are unable to confirm the final disposition of the device because</li> </ul>

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Product Problems	MDR Counts	Problem Summaries
		<p>the customer was unable to provide additional information.</p> <ul style="list-style-type: none"> <li>* The investigation concludes that no further action is required at this time.</li> <li>* If additional information is received; the complaint file will be reopened.</li> <li>* This report is based on information provided by Health Canada and a quality assurance representative from the customer's biomed team; and has been investigated by the Philips complaint handling team.</li> <li>* Philips received a complaint on the Tele MX40; 2.4 GHz; ECG only; exchange indicating that the device was not properly alarming or capturing ECG waveform spikes from the patient's pacemaker.</li> <li>* The customer stated that when examining premature ventricular contraction (PVC) alarms; they noted 6 pacer spikes embedded into the cardiac rhythm randomly.</li> <li>* The customer states that the Philips telemetry monitors did not recognize these as issues and therefore did not alarm.</li> <li>* The customer confirms that device settings were not changed and the protective covering was still on the device.</li> <li>* There was no report of a death or serious injury; nor was there a report of any adverse impact to any user or patient.</li> <li>* Philips received a complaint indicating the Patient Information Center IX (PIICIX) did not alarm on a bradycardia alarm (extreme brady limit was set on 35).</li> <li>* The device was in clinical use during the event.</li> <li>* The patient's heartbeat slowed down so much that the patient expired.</li> <li>* The PIC IX device involved in this event is reported in MFR 1218950-2023-00566.</li> <li>* The log was reviewed by the clinical application specialist (CAS).</li> <li>* The log data shows that a red asystole alarm was generated at 10H37; and the alarm was not acknowledged by a caregiver.</li> <li>* Based on this information and an audit log review by clinical application; the device alarmed per configuration.</li> <li>* It was noted a previous asystole alarm had been generated but never acknowledged by the user.</li> <li>* As the asystole condition is higher priority in the alarm chain; there was no alarm for extreme brady.</li> </ul>



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Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The asystole alarm was generated for 1 hour and 37 minutes.</li> <li>* Based on this information; the device performed per configuration and did not cause or contribute to the reported event.</li> <li>* The reported event may potentially be related to clinical workflow or alarm management; however; the cause remains unknown.</li> <li>* It was confirmed that the customer did not report any failure of a telemetry device or device malfunction.</li> <li>* The field service personnel response was that the customer had not indicated a failure or malfunction of an MX40 device; no additional information was provided.</li> <li>* The customer reported that the MX40 alarmed for a "pacer not pacing" event instead of an asystole on (B)(6) 2023 at 12:27 for the non-paced patient in room 2127/2 west when there was a 9-second pause with only P-waves noted and no QRS complexes on the ECG waveform.</li> <li>* The device was in use at the time of the event; no adverse event was reported.</li> <li>* A follow-up report will be submitted once the investigation is complete.</li> <li>* It was reported that the customer expected the product to alarm in case of an emergency.</li> <li>* Perceived result is that no alarms were not noticed at the moment of the incident.</li> <li>* The patient expired.</li> <li>* A Philips technical consultant (TC) was called on-site to do a test and verification test for the device being "used" at the moment.</li> <li>* Philips is in the process of obtaining additional information concerning this event; and the complaint is still under investigation.</li> <li>* A final report will be submitted once the investigation is complete.</li> <li>* G3 DATE RECEIVED BY MANUFACTURER WAS CORRECTED.</li> <li>* THE DATE IN THE INITIAL REPORT WAS INCORRECT.</li> <li>* Diagnostic/functional testing was performed; and the MX40 was functional.</li> <li>* The MX40 logs provided do not capture alarm events.</li> <li>* The MX40 PWM log shows a battery change at 12:55 PM on</li> </ul>

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Product Problems	MDR Counts	Problem Summaries
		<p>(B)(6) 2023.</p> <ul style="list-style-type: none"> <li>* It appears the device reconnected to the PIC IX after the battery change based on the subsequent standby invocation; which was performed at the PIC IX.</li> <li>* Based on the available information; it is likely the MX40 was powered on and connected to the PIC IX during the timeframe around 01:03 AM on (B)(6) 2023.</li> <li>* The device was put into standby mode at 02:25 AM on (B)(6) 2023.</li> <li>* Standby was invoked at the PIC IX (central).</li> <li>* Attempts were made to clarify the details of the incident; including a clear description of the incident; date and time of the event; expected alarms; and cause of death; but the customer response was asked but unknown (ASKU).</li> <li>* The customer did state that the MX40 telemetry was functional after testing.</li> <li>* Clarification around this statement was also requested to determine if the devices did not contribute to the patient death; but there was no response from the customer.</li> <li>* Based on the information available and the testing conducted; the cause of the reported problem is unknown.</li> <li>* The PIC IX device in use at the time of the event is reported in MFR report number 1218950-2023-00360.</li> <li>* The Intellivue MX400 patient monitor device used during this event is reported in MFR report number 9610816-2023-00517.</li> <li>* The customer reported on (B)(6) 2023; at approximately 01:03; the monitor failed to alarm for cardiac arrest.</li> <li>* The patient was not revived and expired.</li> <li>* The customer reported that the device failed to alarm when the patient went into cardiac arrest.</li> <li>* Philips is in the process of obtaining additional information.</li> <li>* A final report will be submitted upon completion of the investigation.</li> <li>* The Philips service team collected data associated with this issue for investigation and visited the medical facility.</li> <li>* The field service engineer (FSE) performed a full site survey and confirmed that the area; described as a canteen area; where the patient collapsed was not set up for Philips telemetry.</li> <li>* The FSE confirms that the access point in this area did not have Philips SSID on or allow access to Philips network.</li> </ul>

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Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The FSE proactively replaced the central station and upgraded the software of all MX40 devices onsite.</li> <li>* The FSE also addressed some additional wireless setup and configuration issues for the customer.</li> <li>* The wireless issues are not related to any malfunction of a Philips product and were escalated to the manufacturer of the wireless access points; Cisco; for further evaluation.</li> <li>* The complaint was escalated for technical investigation to a Philips product support engineer (PSE); and the results indicate the following: <ul style="list-style-type: none"> <li>* The PIC IX clinical audit logs and stardate logs (RFDA and devicdebug) were provided.</li> <li>* The following is what was found in the logs for the incident on (B)(6)2023 at 11:00 to 12:00: <ul style="list-style-type: none"> <li>* The logs show the following: <ol style="list-style-type: none"> <li>1. A battery change at 10:18 on (B)(6)2023 followed by connection to the network/PIC.</li> <li>2</li> </ol> </li> </ul> </li> </ul> </li> </ul>
Battery Problem	24	<p><b>## Summary of Product Events:</b>  This report details 28 events related to implantable cardiac monitors (ICMs) and remote monitors.</p> <p>ICM Events:</p> <ul style="list-style-type: none"> <li>* Oversensing: 10 events</li> <li>* Undersensing: 8 events</li> <li>* No telemetry: 7 events</li> <li>* Battery depletion: 4 events</li> <li>* Electrical reset: 1 event</li> <li>* Interference: 1 event</li> <li>* Use by date exceeded: 1 event</li> <li>* Explanted: 2 events</li> </ul> <p>Remote Monitor Events:</p> <ul style="list-style-type: none"> <li>* No telemetry: 3 events</li> <li>* Battery depletion: 1 event</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* Some events involved multiple issues; such as oversensing and undersensing.</li> <li>* Some events occurred after the ICM reached its end of service (EOS) date.</li> <li>* No patient complications were reported as a result of these events.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p><b>## Analysis:</b></p> <p>The most common issues reported were oversensing; undersensing; and no telemetry. These issues can be caused by a variety of factors; including battery depletion; lead problems; and interference from other devices. In some cases; the issues may have been related to the ICM reaching its EOS date. It is important to note that no patient complications were reported as a result of these events. However; these issues could potentially lead to serious complications if they are not addressed.</p> <p><b>## Recommendations:</b></p> <ul style="list-style-type: none"> <li>* Patients with ICMs should be monitored closely for signs of oversensing; undersensing; and no telemetry.</li> <li>* If any of these issues occur; the patient should see their doctor immediately.</li> <li>* Doctors should consider the possibility that these issues may be related to the ICM reaching its EOS date.</li> <li>* Medtronic should continue to investigate the causes of these events and take steps to prevent them from happening in the future.</li> </ul> <p><b>## Additional Information:</b></p> <ul style="list-style-type: none"> <li>* This report is based on information obtained by Medtronic from a variety of sources; including device interrogation data; patient records; and physician reports.</li> <li>* Medtronic has made reasonable efforts to obtain more complete information and has provided as much relevant information as is available to the company as of the submission date of this report.</li> <li>* This report does not constitute an admission or a conclusion by FDA; Medtronic; or its employees that the device; Medtronic; or its employee caused or contributed to the event described in the report.</li> <li>* In particular; this report does not constitute an admission by anyone that the product described in this report has any "defects" or has "malfunctioned." These words are included in the FDA 3500A form and are fixed items for selection created by the FDA to categorize the type of event solely for the purpose of regulatory reporting. Medtronic objects to the use of these words and others like them because of the lack of definition and the connotations implied by these terms.</li> </ul>

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Product Problems	MDR Counts	Problem Summaries
		<p>* This statement should be included with any information or report disclosed to the public under the Freedom of Information Act.</p> <p>* Any required fields that are unpopulated are blank because the information is currently unknown or unavailable.</p> <p>* A good faith effort will be made to obtain the applicable information relevant to the report. If information is provided in the future; a supplemental report will be issued.</p>
Migration or Expulsion of Device	21	<p><b>## Concise Description of the Product Problem:</b> An implantable cardiac monitor (ICM) migrated approximately two inches from its original implant site in the patient's body. The device remains functional; and no patient complications have been reported.</p> <p><b>## Additional Information:</b></p> <p>* This report is submitted by Medtronic to comply with FDA reporting regulations.</p> <p>* Medtronic has not been able to fully investigate or verify the information in this report.</p> <p>* Medtronic objects to the use of certain words in the FDA report; such as "defect" and "malfunctioned;" due to their lack of definition and negative connotations.</p> <p>* This statement should be included with any information disclosed to the public under the Freedom of Information Act.</p> <p>* Any missing information will be provided in a supplemental report.</p>
Overheating of Device	15	<p><b>## Summary of Product Problem:</b> The product in question is a medical device called the MCOT monitor. There have been multiple reports of the monitor overheating; melting; and/or sparking; causing damage to the device and in some cases; burns to the patient. The issue appears to be related to the charging cord; which has been reported to overheat and melt.</p> <p><b>## Key Points:</b></p> <p>* Multiple reports of overheating; melting; and/or sparking: This suggests a systemic issue with the product.</p> <p>* Damage to the device and burns to the patient: This indicates a potential safety hazard.</p> <p>* Issue appears to be related to the charging cord: This suggests a specific component failure.</p>

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Product Problems	MDR Counts	Problem Summaries
		<p>* Investigation ongoing: Philips is investigating the issue and has initiated a CAPA (Corrective and Preventive Action) for the overheating charging cords.</p> <p>## Recommendations:</p> <p>* Further investigation is needed to determine the root cause of the problem.</p> <p>* A recall of the affected charging cords may be necessary.</p> <p>* Patients should be warned about the potential hazards of the charging cord and advised to use caution when charging the device.</p> <p>## Additional Notes:</p> <p>* The reports indicate that the issue is not limited to a specific model or batch of the MCOT monitor.</p> <p>* The severity of the burns reported varies; with some patients experiencing minor burns and others experiencing more serious injuries.</p> <p>* Philips is taking the issue seriously and is working to resolve it. I hope this summary is helpful. Please let me know if you have any other questions.</p>
Unable to Obtain Readings	13	<p>## Summary of Product Problems:</p> <p>Implantable Cardiac Monitor (ICM):</p> <p>* Invalid data: The ICM contained invalid data; including invalid histograms; invalid counters; and invalid Cardiac Compass data.</p> <p>* Oversensing: The ICM exhibited oversensing; which caused episodes to terminate prematurely and prevented the device from determining the total length of the episode.</p> <p>* Undersensing: The ICM exhibited undersensing; which may have resulted in missed episodes.</p> <p>* Inaccurate AF burden: The ICM's atrial fibrillation (AF) burden was inaccurate; with the physician disagreeing with the number of AF episodes detected by the device.</p> <p>* Missing ECGs: The ICM did not record ECGs for some episodes; including pause episodes and episodes detected but not recorded.</p> <p>* Failed transmissions: The ICM experienced failed transmissions; resulting in incomplete reports and missing data.</p> <p>* Battery depletion: The ICM experienced normal battery depletion; which is expected at the end of service (EOS).</p> <p>IntelliVue Multi Measurement Server X2:</p> <p>* Failed ECG measurement: The X2 failed to measure ECG;</p>

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Product Problems	MDR Counts	Problem Summaries
		<p>resulting in a flatlining of the ECG waveform. This occurred in two separate instances; one of which resulted in the patient's death.</p> <ul style="list-style-type: none"> <li>* Software issues: The X2 was not updated with the latest firmware version; which may have contributed to the ECG measurement failures.</li> <li>* Customer negligence: The customer did not observe a service bulletin that addressed the ECG measurement failures and did not update the X2's firmware.</li> </ul> <p>MX800 Patient Monitor:</p> <ul style="list-style-type: none"> <li>* No record of patient activity: The MX800 did not record any patient activity during the final moments before the patient's expiration.</li> <li>* Configuration issue: The MX800 was not configured to send information to a database; which prevented the recording of patient activity.</li> </ul> <p>## Overall; the product problems identified in these reports are concerning and could potentially lead to serious patient harm. It is important that Medtronic investigates these issues thoroughly and takes appropriate corrective action to prevent them from happening again.</p>
Failure to Interrogate	13	<p>## Summary of Implantable Cardiac Monitor (ICM) Issues:</p> <p>1. Interrogation Issues:</p> <ul style="list-style-type: none"> <li>* The ICM could not be interrogated after implantation.</li> <li>* The ICM could not be interrogated with two programmers.</li> <li>* The ICM could not be interrogated having experienced an electrical reset.</li> <li>* The ICM was unable to be interrogated by the Patient Connector and Diagnostic Mobile Programmer Application.</li> <li>* Incorrect information was communicated to the clinic during interrogation of the ICM.</li> </ul> <p>2. Telemetry Issues:</p> <ul style="list-style-type: none"> <li>* The ICM had no telemetry with the remote monitor.</li> <li>* The ICM had no telemetry during interrogation attempts with different devices.</li> <li>* The remote monitor was unable to establish telemetry with the ICM.</li> <li>* The remote monitor had no telemetry with the ICM.</li> <li>* The remote monitor had telemetry issue with the ICM.</li> </ul>

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Product Problems	MDR Counts	Problem Summaries
		<p>* The ICM had no telemetry with the remote monitor.</p> <p>3. Battery Issues:</p> <p>* The ICM experienced early battery depletion.</p> <p>* The ICM had reached normal battery depletion.</p> <p>* The battery life of the implant was drained.</p> <p>4. Other Issues:</p> <p>* The ICM was locked.</p> <p>* The ICM was explanted.</p> <p>5. No Patient Complications Reported:</p> <p>It is important to note that no patient complications have been reported as a result of any of these events.</p> <p>6. Additional Information:</p> <p>* Medtronic is submitting these reports to comply with FDA reporting regulations.</p> <p>* Medtronic has made reasonable efforts to obtain more complete information.</p> <p>* This report does not constitute an admission or a conclusion by FDA; Medtronic; or its employees that the device; Medtronic; or its employee caused or contributed to the event described in the report.</p> <p>* Any required fields that are unpopulated are blank because the information is currently unknown or unavailable.</p> <p>* A good faith effort will be made to obtain the applicable information relevant to the report.</p> <p>* If information is provided in the future; a supplemental report will be issued.</p> <p>Overall; the reports indicate a variety of issues with the ICM; including interrogation problems; telemetry issues; battery issues; and other problems. However; it is important to note that no patient complications have been reported as a result of these events.</p>
Device Sensing Problem	12	<p>## Summary of Product Problems:</p> <p>This document details 18 reports of issues with implantable cardiac monitors (ICMs). The problems can be categorized as follows:</p> <p>Detection Issues:</p> <p>* False detection of atrial fibrillation (AF) (4 reports)</p> <p>* False detection of fascicular ventricular tachycardia (FVT) (1 report)</p>



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Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* Inaccurate AF burden (1 report)</li> <li>* Missed ventricular tachycardia (VT) (1 report)</li> <li>* Missed episodes due to suspected sensing failure (1 report)</li> <li>* Oversensing (3 reports)</li> <li>* Undersensing (3 reports)</li> <li>* Low R-wave amplitude (1 report)</li> <li>* Sensing issue during implant (1 report)</li> <li>* No signal during implant (1 report)</li> <li>* Sensing issue and no signal (1 report)</li> </ul> <p>Other Issues:</p> <ul style="list-style-type: none"> <li>* ICM repositioning unsuccessful (1 report)</li> <li>* ICM no longer sensing electrical signal (1 report)</li> <li>* ICM events ignored due to misidentification as noise (1 report)</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* The event date is not known for any of the reports.</li> <li>* The reports were submitted to comply with FDA regulations.</li> <li>* The reports do not constitute an admission of fault by Medtronic or its employees.</li> <li>* Some reports are based on information obtained from literature.</li> <li>* Some reports are based on information obtained from the remote monitoring system.</li> <li>* No patient complications have been reported as a result of these events.</li> </ul> <p>## Recommendations:</p> <ul style="list-style-type: none"> <li>* Medtronic should investigate the cause of the false AF detections.</li> <li>* Medtronic should investigate the cause of the missed VT event.</li> <li>* Medtronic should investigate the cause of the oversensing and undersensing events.</li> <li>* Medtronic should investigate the cause of the sensing issues during implant.</li> <li>* Medtronic should investigate the cause of the other issues reported.</li> <li>* Medtronic should provide additional information about the event date for each report.</li> <li>* Medtronic should provide additional information about the patient complications for each report.</li> </ul> <p>## Additional Information:</p>

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		<ul style="list-style-type: none"> <li>* This summary is based on the information provided in the document.</li> <li>* This summary is not a substitute for professional medical advice.</li> <li>* If you have any questions or concerns about your ICM; please contact your doctor.</li> </ul>
Melted	11	<p><b>## Summary of Product Problem:</b> The product in question is a medical device called the MCOT monitor. There have been multiple reports of the monitor's charging cord overheating; melting; and even catching fire. This has caused damage to the monitor itself and; in one case; resulted in a minor burn to the patient's finger.</p> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* Problem: Overheating and melting of the charging cord.</li> <li>* Affected product: MCOT monitor.</li> <li>* Reported incidents: 17.</li> <li>* Patient injuries: 1 minor burn.</li> <li>* Cause: Unknown; but likely due to an electrical fault in the charging cord.</li> <li>* Current status: Philips AM&amp;D is investigating the issue.</li> </ul> <p><b>## Additional Information:</b></p> <ul style="list-style-type: none"> <li>* The problem appears to be limited to the charging cord and not the monitor itself.</li> <li>* Philips AM&amp;D is aware of the issue and is actively investigating it.</li> <li>* A replacement charging cord is available for patients who have experienced this issue.</li> </ul> <p><b>## Recommendations:</b></p> <ul style="list-style-type: none"> <li>* Patients who are using the MCOT monitor should be aware of the potential for the charging cord to overheat and melt.</li> <li>* Patients should inspect the charging cord regularly for any signs of damage.</li> <li>* If the charging cord shows any signs of damage; it should be replaced immediately.</li> <li>* Patients should contact Philips AM&amp;D if they experience any problems with the MCOT monitor or its charging cord.</li> </ul>
Undefined Problem	11	<p><b>## Summary of Product Problems:</b></p> <p>1. Medtronic Loop Recorder:</p> <ul style="list-style-type: none"> <li>* Burn injury: A patient experienced a burn injury from a Medtronic Loop Recorder that became hot and could not be</li> </ul>

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Product Problems	MDR Counts	Problem Summaries
		<p>removed. The burn covered approximately 1.5-2% of the patient's body surface area and required medical attention.</p> <ul style="list-style-type: none"> <li>* Implantation without consent: A patient reported that a Medtronic Loop Recorder was implanted without their consent.</li> <li>* Device malfunction: A patient reported that their Medtronic Loop Recorder was not transmitting data to the cardiologist's office for over a month.</li> </ul> <p>2. GE Healthcare CARESCAPE Central Station:</p> <ul style="list-style-type: none"> <li>* Software issue: The GE Healthcare CARESCAPE Central Station software may fail to start after a power outage; causing a loss of patient monitoring. This issue has been observed in 16% of devices currently in use.</li> </ul> <p>3. Boston Scientific BodyGuardian Mini Plus:</p> <ul style="list-style-type: none"> <li>* Battery drain issue: The Boston Scientific BodyGuardian Mini Plus monitor's battery drains quickly; rendering the device unusable. This issue has been reported by multiple users.</li> <li>* Connectivity issue: The Boston Scientific BodyGuardian Mini Plus monitor may not connect to the Android phone after the battery is drained and recharged.</li> <li>* Skin irritation: A patient reported experiencing skin irritation and bleeding sores under the Boston Scientific Mini Heart Monitor patch.</li> </ul> <p>4. Reveal LINQ Insertable Cardiac Monitor:</p> <ul style="list-style-type: none"> <li>* Device dislodgement: A patient experienced a fall after the Reveal LINQ Insertable Cardiac Monitor was implanted; causing the device to partially dislodge from the chest. The device was removed without difficulty.</li> </ul> <p>## Additional Notes:</p> <ul style="list-style-type: none"> <li>* All of these product problems have been reported to the manufacturer.</li> <li>* The severity of these product problems varies; with some posing a potential risk of serious injury or death.</li> <li>* It is important to note that these are just a few examples of product problems that have been reported. There may be other product problems that have not been reported.</li> </ul> <p>## Recommendations:</p> <ul style="list-style-type: none"> <li>* If you are experiencing a problem with a medical device; it is important to report it to the manufacturer and the FDA.</li> <li>* You can find more information about reporting medical device problems on the FDA website:</li> </ul>

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		<a href="https://www.fda.gov/medical-devices/safety/how-report-medical-device-problem">https://www.fda.gov/medical-devices/safety/how-report-medical-device-problem</a> * You should also consult with your healthcare provider to discuss any concerns you have about a medical device.
Electromagnetic Interference	9	<b>## Concise Description of Product Problem:</b> The implantable cardiac monitor (ICM) is experiencing several issues; including: * False detections: The device is detecting false positive episodes (e.g.; false tachycardia; false asystole) due to oversensing noise/interference; undersensing; and artifact. * Undersensing: The device is failing to detect true R-waves; leading to missed pauses and potentially missed true tachycardia episodes. * Oversensing: The device is misinterpreting noise/interference as true R-waves; leading to false positive episodes. * Noise/interference: The device is experiencing electromagnetic interference and/or myopotential interference; which is contributing to the false detections and undersensing. * Suboptimal connection: The device may have a suboptimal electrode connection; which could be contributing to the false detections and undersensing. These issues could potentially lead to patient harm if a true arrhythmia is missed or if the device delivers inappropriate therapy.
Insufficient Information	8	<b>## Summary of Product Problems:</b> <b>Medtronic:</b> * Problem: Customer requested information from the telemetry box. * Impact: No impact to patient reported. * Action: No further action required. <b>Philips:</b> * Problem 1: Patient death associated with device use. * Impact: Patient death. * Action: Investigation ongoing. * Problem 2: Low battery notification issue and use of non-recommended batteries. * Impact: Patient death. * Action: No further action required. * Problem 3: Device explanted due to dissatisfaction.

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Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* Impact: No additional adverse effects reported.</li> <li>* Action: No further action required.</li> <li>* Problem 4: Device explanted due to unknown reason.</li> <li>* Impact: No additional information available.</li> <li>* Action: No further action required.</li> <li>* Problem 5: Device explanted due to dissatisfaction.</li> <li>* Impact: No additional adverse effects reported.</li> <li>* Action: No further action required.</li> <li>* Problem 6: Device had pin corrosion.</li> <li>* Impact: No patient impact reported.</li> <li>* Action: Device repaired.</li> </ul> <p>## Additional Notes:</p> <ul style="list-style-type: none"> <li>* The Medtronic event occurred outside the US.</li> <li>* The Philips events occurred in the US.</li> <li>* Some information is redacted due to confidentiality concerns.</li> <li>* Investigations are ongoing for some events.</li> </ul> <p>## Recommendations:</p> <ul style="list-style-type: none"> <li>* For Medtronic; continue to monitor the situation and provide the requested information to the customer.</li> <li>* For Philips; continue to investigate the patient death and provide updates to the FDA.</li> <li>* For all events; continue to collect and analyze data to identify trends and potential safety risks.</li> </ul>
Appropriate Term/Code Not Available	7	<p>## Product Problem Summary:</p> <p>Implantable Cardiac Monitor (ICM) Malfunctions:</p> <ul style="list-style-type: none"> <li>* The ICM stopped working in several instances; requiring explantation in some cases.</li> <li>* The ICM malfunctioned intermittently in other cases; sometimes working and sometimes not.</li> <li>* The cause of the malfunction was identified as a shorting/low resistance issue in the capacitor and a depleted battery.</li> </ul> <p>Patient Impact:</p> <ul style="list-style-type: none"> <li>* No patient complications were reported as a result of the ICM malfunctions.</li> <li>* One patient died in a manner unrelated to the device.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* Medtronic is investigating the issue and will submit a supplemental report if additional information becomes available.</li> <li>* Medtronic objects to the use of the terms "defects" and "malfunctioned" in the FDA report; as these terms lack</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		definition and have negative connotations. Overall; the product problem is a serious issue that could potentially harm patients. Medtronic is taking steps to investigate the issue and prevent future occurrences.
Audible Prompt/Feedback Problem	7	<p><b>## Product Problem Summary:</b>  The Philips MX40 patient wearable monitor experienced several issues; including:</p> <ul style="list-style-type: none"> <li>* Standby Mode: The monitor was placed in standby mode; resulting in a loss of monitoring for 3.5 hours. This was likely caused by human error; but the investigation is ongoing.</li> <li>* Speaker Malfunction: The monitor's speaker malfunctioned; preventing audible alarms and notifications. This issue was reported multiple times; and the cause remains under investigation.</li> <li>* Unconfirmed Patient Death: The customer reported a possible patient death associated with the monitor being in standby mode. However; the death was not confirmed by the hospital; and the root cause remains unknown.</li> <li>* Declined Repair: The customer declined to have the device repaired after it was returned unrepaired from the Philips authorized repair facility.</li> </ul> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* The investigation into the standby mode issue and speaker malfunction is ongoing.</li> <li>* The cause of the unconfirmed patient death remains unknown.</li> <li>* The customer declined to have the device repaired.</li> </ul> <p><b>## Additional Information:</b></p> <ul style="list-style-type: none"> <li>* The product problem was identified through a review of data warehouse data and customer reports.</li> <li>* The investigation is being conducted by Philips.</li> <li>* A final report will be submitted once the investigation is complete.</li> </ul>
Biocompatibility	7	<p><b>## Product Problem Summary:</b>  Skin irritation and burns associated with the use of ECG monitoring electrodes.</p> <p>Specific issues reported:</p> <ul style="list-style-type: none"> <li>* Redness; burning; and skin removal</li> <li>* Tenderness and jelly-like adhesive</li> <li>* Blisters and tears</li> <li>* Allergic reactions requiring medical attention</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>* "Burning fire" sensation</p> <p>Possible causes:</p> <ul style="list-style-type: none"> <li>* Bio-incompatibility with the electrode adhesive</li> <li>* MARSI (Medical Adhesive Related Skin Injury)</li> <li>* Skin sensitivities/allergies</li> </ul> <p>Additional notes:</p> <ul style="list-style-type: none"> <li>* The product labeling advises patients of alternative options and steps to take if skin irritation develops.</li> <li>* Engineering evaluation was often not possible due to the lack of device return.</li> <li>* The allegations were confirmed in cases where medical attention was sought or images of skin irritation were provided.</li> </ul>
Delayed Alarm	5	<p><b>## Summary of Product Problem:</b></p> <p>Product: Philips IntelliVue MX800 Patient Monitor</p> <p>Problem:</p> <ul style="list-style-type: none"> <li>* The SpO2 measurement alarms are delayed by 30 seconds.</li> <li>* The asystole alarm has an 8-second delay.</li> <li>* The telemetry alarms are incorrect; with a 4-second delay for one-star alarms.</li> </ul> <p>Potential Cause:</p> <ul style="list-style-type: none"> <li>* User error/misunderstanding of alarm settings and functionality.</li> <li>* Misinterpretation of alarm strips.</li> <li>* Software issue with alarm delays.</li> </ul> <p>Impact:</p> <ul style="list-style-type: none"> <li>* Potential for delayed response to critical patient events.</li> </ul> <p>Current Status:</p> <ul style="list-style-type: none"> <li>* Philips is investigating the issue.</li> <li>* No further action is required at this time.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* The customer reported that the SpO2 alarms were delayed by several minutes; but the RSE confirmed that the configuration was set correctly.</li> <li>* The customer reported that the SpO2 alarm did not trigger until the patient's SpO2 was at 30; but the RSE was able to simulate the alarms and they functioned correctly.</li> <li>* The customer reported that the asystole alarm was delayed by 8 seconds; but the investigation concluded that the alarm functioned correctly and the delay was due to the patient</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>transitioning from pause to asystole.</p> <ul style="list-style-type: none"> <li>* The customer reported that the telemetry alarms were incorrect; but the investigation concluded that the alarms functioned correctly and the delay was due to a software issue.</li> </ul> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>* Philips should continue to investigate the issue to determine the root cause.</li> <li>* Philips should provide additional training to customers on the use of the alarm settings and functionality.</li> <li>* Philips should update the software to address the alarm delay issue.</li> </ul> <p>## Additional Notes:</p> <ul style="list-style-type: none"> <li>* This summary is based on the information provided in the user's request.</li> <li>* The investigation is ongoing and additional information may become available.</li> <li>* It is important to note that the product problem has not been confirmed and may be due to user error.</li> </ul>
No Device Output	5	<p>The product has a problem with the speaker. The speaker is not producing any sound. This problem has been confirmed by diagnostic/functional testing. The cause of the problem is a defective speaker. The speaker has been replaced and the device is now operational. No further action is required at this time.</p>
Low Audible Alarm	4	<p>## Product Problem Summary:</p> <p>MX40 Monitor:</p> <ul style="list-style-type: none"> <li>* Speaker Malfunction: <ul style="list-style-type: none"> <li>* Two reports of very low speaker volume.</li> <li>* One report confirmed; speaker replaced.</li> <li>* One report unable to replicate; but speaker replaced as a precaution.</li> </ul> </li> <li>* Alarm Issues: <ul style="list-style-type: none"> <li>* One report of alarms not repeating after being acknowledged.</li> <li>* Investigation ongoing; no conclusion yet.</li> <li>* Another report of alarms not functioning as expected.</li> <li>* Investigation concluded; device functioning as intended.</li> <li>* Time synchronization issue identified as a potential contributing factor.</li> <li>* No further action required at this time.</li> <li>* Complaint file will be reopened if additional information is</li> </ul> </li> </ul>



## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		received.
Wireless Communication Problem	4	<p>## Product Problem Summary:</p> <ol style="list-style-type: none"> <li>Telemetry Disconnection: <ul style="list-style-type: none"> <li>* The telemetry unit (MX40) disconnected from the network; causing loss of data transmission to the Patient Information Center IX (PIC IX).</li> <li>* The disconnection was due to a customer network Wi-Fi infrastructure issue.</li> <li>* The device functioned according to specifications and no fault was found.</li> </ul> </li> <li>Missed Medical Doctor Notification (MDN): <ul style="list-style-type: none"> <li>* An arrhythmia event met MDN requirements but was not transmitted due to a gateway hardware malfunction.</li> <li>* The patient experienced a delay in pacemaker installation and a subsequent syncopal episode.</li> <li>* The device was returned and a final report generated; notifying the HCP of the arrhythmia.</li> </ul> </li> <li>Audible Alarm Issue: <ul style="list-style-type: none"> <li>* The customer reported no audible alarm on the system.</li> <li>* Philips is investigating the issue and will submit a final report upon completion.</li> </ul> </li> <li>Broken Battery Retention Tabs; Corrosion; and Improper Cleaning Damage: <ul style="list-style-type: none"> <li>* Multiple devices had broken battery retention tabs; corrosion on lead sets; and improper cleaning damage.</li> <li>* These issues contributed to intermittent ECG waveforms when alarms occurred.</li> <li>* The customer is working with Philips to replace the affected devices.</li> </ul> </li> <li>Missed Arrhythmia Transmission: <ul style="list-style-type: none"> <li>* An arrhythmia event met MDN requirements but was not transmitted.</li> <li>* The cause of the missed transmission is unknown.</li> <li>* No adverse events are reported.</li> </ul> </li> </ol> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* The patient death reported in the first section was not preventable even if the device was fully functional.</li> <li>* The second section describes an issue with a different device; the iRhythm Zio XT.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The third section describes an issue with the Philips MX40 telemetry unit.</li> <li>* The fourth section describes an issue with multiple Philips MX40 telemetry units.</li> <li>* The fifth section describes an issue with an unspecified device.</li> </ul>
Smoking	4	<p><b>## Product Problem Summary: Philips Respironics DreamStation CPAP Machine</b></p> <p>Problem: The Philips Respironics DreamStation CPAP machine has been reported to overheat; smoke; and melt; posing a potential fire hazard to users.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* Multiple reports: There have been numerous reports of the device overheating; smoking; and melting; with some instances involving the charging cord.</li> <li>* Potential causes: The most likely cause of the issue is an electrical fault within the USB-A/USB-C charging cord. Corrosion on the PCB boards and battery contact may also contribute to overheating.</li> <li>* Patient harm: While no serious injuries have been reported; one patient received a minor burn from a smoking charging cord.</li> <li>* Device status: Philips is investigating the issue and has issued a recall for affected devices.</li> </ul> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>* Stop using the affected device immediately.</li> <li>* Contact Philips for a replacement device.</li> <li>* Monitor for any signs of overheating; smoke; or melting.</li> <li>* Report any incidents to Philips and the FDA.</li> </ul>
Decreased Sensitivity	3	<p><b>## Implantable Cardiac Monitor (ICM) Issues:</b></p> <p>Problem: The ICM is experiencing diminished R-wave amplitudes; leading to false asystole and pause episodes. This could potentially result in missed heartbeats and inadequate monitoring.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* The device was not returned for analysis; but performance data was analyzed.</li> <li>* The analysis indicated diminished right ventricular sensing and undersensing.</li> <li>* The ICM remains in use; and no patient complications have been reported.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The issue may be related to the ICM being implanted past its use-by date.</li> <li>* There were also reports of failed transmissions; but these were not connected to network issues.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* Medtronic is submitting this report to comply with FDA regulations.</li> <li>* The report does not constitute an admission of fault by Medtronic or the FDA.</li> <li>* Medtronic will submit a supplemental report if additional information becomes available.</li> </ul> <p>Possible Solutions:</p> <ul style="list-style-type: none"> <li>* Reprogramming the ICM to increase sensitivity.</li> <li>* Replacing the ICM with a new device.</li> <li>* Closely monitoring the patient for any complications.</li> </ul> <p>Note: This is a summary of the product problem based on the information provided. It is important to consult with a qualified healthcare professional for further evaluation and treatment.</p>
Protective Measures Problem	3	<p>## Product Problem Summary:</p> <p>Non-Sustained VT Alarm Not Displayed:</p> <ul style="list-style-type: none"> <li>* A non-sustained VT alarm occurred on the device but was not displayed on the screen or alerted the user.</li> <li>* The alarm was acknowledged in the audit logs; but the user was not aware of it.</li> <li>* The device was operating per specifications; and no malfunction was identified.</li> <li>* No patient harm was reported.</li> </ul> <p>Speaker Malfunction:</p> <ul style="list-style-type: none"> <li>* The customer reported a speaker malfunction with the system.</li> <li>* The device was not in use on a patient at the time of the event.</li> <li>* The device is currently undergoing bench repair and evaluation.</li> </ul> <p>## Additional Information:</p> <ul style="list-style-type: none"> <li>* This record has been identified as a duplicate of another report and will be closed.</li> <li>* A final report will be submitted upon completion of the investigation into the speaker malfunction.</li> </ul>
Device Emits Odor	3	<p>The product has a known issue with the charging cord; which can cause it to overheat and emit a burning smell. In some cases;</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		the cord may also melt. The company is investigating the issue and has offered replacements to affected customers.
Inaudible or Unclear Audible Prompt/Feedback	3	The speaker on a Philips MX40 monitor was reported to be not working properly. The customer reported that the speaker volume was very low. Philips investigated the issue and found that the speaker was defective. Philips replaced the speaker and the customer was satisfied with the resolution.
Device-Device Incompatibility	3	<p><b>## Concise Description of Product Problem:</b> An implantable cardiac monitor (ICM) malfunctioned due to external noise/electromagnetic interference; causing false tachycardia and ventricular event detection issues. The device also reached end of service and potentially interfered with an implanted cardioverter defibrillator (ICD).</p> <p><b>Key Points:</b></p> <ul style="list-style-type: none"> <li>* The ICM malfunctioned due to external noise/electromagnetic interference; likely caused by an MRI.</li> <li>* The device detected false tachycardia and ignored ventricular events.</li> <li>* The ICM reached end of service and potentially interfered with an ICD.</li> <li>* No patient complications were reported.</li> </ul> <p><b>Additional Information:</b></p> <ul style="list-style-type: none"> <li>* The device was not returned for analysis; but performance data was collected and analyzed.</li> <li>* Medtronic is submitting this report to comply with FDA reporting regulations.</li> <li>* Medtronic objects to the use of the words "defects" and "malfunctioned" in the report.</li> </ul>
Use of Device Problem	3	<p><b>## Product Problem Summary:</b> Medtronic Implantable Cardiac Monitor (ICM):</p> <ul style="list-style-type: none"> <li>* Puncture of Pleural Space: During the implant procedure; the implant tool punctured the patient's pleural space; causing a massive bleed.</li> <li>* Pain and Discomfort: The patient experienced pain where the implant tool punctured and reported the ICM digging into their rib; stabbing their collarbone; and bruising their breast tissue when moving.</li> <li>* Protrusion and Sensitivity: The ICM protruded out of the skin and caused extreme sensitivity; resulting in a burning sensation.</li> <li>* Transmission Issues: The patient experienced an arrhythmia</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>that met medical doctor notification (MDN) requirements; but it was not transmitted during the wear period. Investigation revealed the gateway was not activated.</p> <ul style="list-style-type: none"> <li>* Incorrect Patient Information: The physician order contained an error; identifying the incorrect patient. Consequently; medical doctor notifications for arrhythmias were provided for the wrong patient.</li> <li>* Patient Death: The patient passed away while wearing the device. The cause of death is unknown.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* The device has not been returned for evaluation.</li> <li>* The patient's family contacted iRhythm and activated the gateway.</li> <li>* The healthcare provider was notified about the patient's arrhythmia.</li> <li>* The company contacted the healthcare provider and the patient (incorrectly identified) to notify them about the approaching transmission limit.</li> <li>* A replacement device was sent to the patient (incorrectly identified) wearing the device nearing the transmission limit.</li> </ul> <p>Note: This summary is based on the information provided in the report. Further investigation may be needed to determine the root cause of the problems and identify any potential solutions.</p>
Inappropriate or Unexpected Reset	3	<p><b>## Concise Description of the Product Problem:</b> An implantable cardiac monitor (ICM) experienced an electrical reset; but remains functional. No patient complications have been reported.</p> <p><b>## Additional Information:</b></p> <ul style="list-style-type: none"> <li>* The device was not returned for analysis; but performance data was reviewed.</li> <li>* Analysis of the device memory indicated a partial power-on reset occurred.</li> <li>* Medtronic is submitting this report to comply with FDA regulations.</li> <li>* This report does not constitute an admission of fault or malfunction.</li> </ul> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* The ICM experienced an electrical reset.</li> <li>* The ICM remains functional.</li> <li>* No patient complications have been reported.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The cause of the reset is unknown.</li> <li>* Medtronic is investigating the issue.</li> </ul> <p>## Recommendations:</p> <ul style="list-style-type: none"> <li>* Monitor the ICM for further resets.</li> <li>* Consult with a healthcare professional if you have any concerns.</li> </ul> <p>## Note:</p> <p>This summary is based on the information provided in the report. Additional information may be available from Medtronic or the FDA.</p>
Pacing Problem	3	<p>## Product Problem Summary:</p> <p>Device: Cardiac Implantable Electronic Device (CIED)</p> <p>Problem: Episodes of 3-second pauses; leading to explantation.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* The specific model of the device is unknown.</li> <li>* The device was implanted in 2011 and explanted in 2012.</li> <li>* The explantation was due to episodes of 3-second pauses detected by the device.</li> <li>* The patient was upgraded to a dual-chamber pacemaker.</li> <li>* The physician was Dr. (B)(6) at (B)(6) Medical Center in (B)(6).</li> <li>* This report reflects information received by FDA in the form of a notification per 803.22 (B)(2).</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* This event occurred outside the US.</li> <li>* Patient information is limited due to confidentiality concerns.</li> <li>* Multiple patients and multiple manufacturers were noted in the article; however; a one-to-one correlation could not be made with unique product serial/lot numbers.</li> <li>* The model listed in the report is a representative of the model family; as there is no specific model listed.</li> <li>* Without a lot number or device serial number; the manufacturing date cannot be determined.</li> <li>* Since no device ID was provided; it is unknown if this event has been previously reported.</li> </ul> <p>Source:</p> <ul style="list-style-type: none"> <li>* Impact of Intensive Follow-up of Cardiac Implantable Electronic Devices via Remote Monitoring: A Pilot Study. Heart Rhythm O2 2023; 4:90¿96. DOI: 10.1016/J.HROO.2022.11.002</li> </ul> <p>Note:</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>* This report does not constitute an admission or a conclusion by FDA; Medtronic; or its employees that the device; Medtronic; or its employee caused or contributed to the event described in the report.</p> <p>* This report does not constitute an admission by anyone that the product described in this report has any "defects" or has "malfunctioned".</p> <p>* These words are included in the FDA 3500A form and are fixed items for selection created by the FDA to categorize the type of event solely for the purpose of regulatory reporting.</p> <p>* Medtronic objects to the use of these words and others like them because of the lack of definition and the connotations implied by these terms.</p> <p>* This statement should be included with any information or report disclosed to the public under the Freedom of Information Act.</p>
Thermal Decomposition of Device	3	<p><b>## Product Problem Summary:</b></p> <p>Issue: Several reports of overheating and burning in various components of the C6 monitor and sensors.</p> <p>Specific instances:</p> <ul style="list-style-type: none"> <li>* Charger: Charred while charging; likely due to overheating.</li> <li>* Monitor: <ul style="list-style-type: none"> <li>* Physical damage on top; possibly caused by overheating.</li> <li>* Physical damage near camera; possibly caused by external heat source.</li> </ul> </li> <li>* Sensor: <ul style="list-style-type: none"> <li>* Awful smell and burn marks on patch and sensor.</li> <li>* Similar issue reported with another sensor; confirmed to be caused by excess heat due to moisture/sweat accumulation.</li> </ul> </li> </ul> <p>Overall:</p> <ul style="list-style-type: none"> <li>* The product appears to be susceptible to overheating; potentially leading to damage and safety concerns.</li> <li>* The root cause of the overheating varies across instances; but moisture and external heat sources seem to be contributing factors.</li> <li>* Further investigation is needed to determine the exact cause and implement corrective actions.</li> </ul>
Device Fell	3	<b>## Product Problem Summary:</b>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>Product: Philips MP70 and MP50 medical monitors</p> <p>Problem:</p> <ul style="list-style-type: none"> <li>* MP70: The arm broke; causing the monitor to fall and sustain physical damage.</li> <li>* MP50: The monitor fell during transport or due to a faulty mounting system; causing display and frame damage.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* Both incidents involved physical damage to the monitors.</li> <li>* One incident involved a patient being present; but no adverse event was reported.</li> <li>* Philips is investigating both incidents and will provide final reports upon completion.</li> </ul> <p>Possible Causes:</p> <ul style="list-style-type: none"> <li>* Faulty mounting system (MP70)</li> <li>* Dropped during transport (MP50)</li> <li>* Wear and tear (MP70)</li> </ul> <p>Current Status:</p> <ul style="list-style-type: none"> <li>* MP70: End of life; no repair options available.</li> <li>* MP50: Repaired and returned to normal operation.</li> </ul> <p>Next Steps:</p> <ul style="list-style-type: none"> <li>* Philips will continue investigating both incidents.</li> <li>* A final report will be submitted upon completion of the investigation.</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* The MP70 is no longer available for repair due to being end of life.</li> <li>* The MP50 was repaired and is back in use.</li> </ul>
Unintended Electrical Shock	2	<p>## Product Problem Summary:</p> <p>Dual USB Charging Plug:</p> <ul style="list-style-type: none"> <li>* Problem: The plug broke while the patient was plugging it into the wall outlet; causing an electrical shock.</li> <li>* Date: March 18; 2024</li> <li>* Severity: Minor injury (shock)</li> <li>* Action Taken: Replacement plug ordered.</li> </ul> <p>MCOT Sensor and Monitor:</p> <ul style="list-style-type: none"> <li>* Problem 1: The patient experienced electrical shocks under their armpit and towards the left side of their chest.</li> <li>* Date: February 10; 2024</li> <li>* Severity: Moderate discomfort (described as a "teaser shock")</li> <li>* Action Taken: Patient removed the device and has not</li> </ul>



## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>experienced further issues.</p> <ul style="list-style-type: none"> <li>* Problem 2: The patient experienced an electrical shock under their armpit.</li> <li>* Date: Unspecified</li> <li>* Severity: Unspecified</li> <li>* Action Taken: Device returned for investigation. Engineering evaluation could not replicate the issue and the sensor passed all testing.</li> </ul> <p>## Additional Notes:</p> <ul style="list-style-type: none"> <li>* The report mentions that the hospital staff suspected the heart monitor might have caused the issue in the first case.</li> <li>* It is unclear if the second reported shock is related to the first incident.</li> <li>* The investigation into the second reported shock did not find any issues with the sensor.</li> </ul> <p>## Recommendations:</p> <ul style="list-style-type: none"> <li>* Investigate the cause of the broken charging plug and implement corrective measures to prevent future incidents.</li> <li>* Further investigate the reported electrical shocks associated with the MCOT sensor and monitor to determine the root cause and implement appropriate solutions.</li> <li>* Consider providing additional safety information and warnings to users about potential electrical hazards associated with the device.</li> </ul>
Incorrect Inadequate or Imprecise Result or Readings	2	<p>## Summary of Product Problems:</p> <p>Problem 1:</p> <ul style="list-style-type: none"> <li>* Description: The SpO2 sensor malfunctioned; causing a delay in postpartum vital signs monitoring.</li> <li>* Cause: Defective SpO2 sensor.</li> <li>* Outcome: The sensor was replaced; and the issue was resolved.</li> <li>* Severity: Low.</li> </ul> <p>Problem 2:</p> <ul style="list-style-type: none"> <li>* Description: The SpO2 sensor malfunctioned; causing a delay in care.</li> <li>* Cause: Sensor damage and low perfusion due to low limb temperature and poor peripheral circulation.</li> <li>* Outcome: The patient died.</li> <li>* Severity: High.</li> </ul> <p>Problem 3:</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>* Description: The monitor stopped working while the patient was being monitored.</p> <p>* Cause: The monitor was put into standby mode by user interaction.</p> <p>* Outcome: The patient died.</p> <p>* Severity: High.</p> <p>## Key Differences:</p> <p>* Problem 1: This problem was caused by a defective sensor and was resolved quickly.</p> <p>* Problem 2: This problem was caused by a combination of factors; including sensor damage and low perfusion. The patient died as a result of this problem.</p> <p>* Problem 3: This problem was caused by user error. The patient died as a result of this problem.</p> <p>## Overall:</p> <p>These three product problems highlight the importance of proper device maintenance and user training. In all three cases; the patient's death could have been prevented if the device had been functioning properly or if the user had been properly trained.</p>
Material Separation	2	<p>## Product Problem Summary:</p> <p>Problem: Dual USB Power Adaptor prongs getting stuck in the wall outlet.</p> <p>Reported Cases: 4</p> <p>Injuries: None reported</p> <p>Returned Devices: 1</p> <p>Engineering Evaluation: Performed on 1 returned device; aligned with known failure mode JDSP-18928.</p> <p>Known Failure Mode: Dual USB Power Adaptor housing separation.</p> <p>Further Investigation: Ongoing by Philips AM&amp;D.</p> <p>Additional Information:</p> <p>* The problem appears to be specific to the Dual USB Power Adaptor.</p> <p>* No injuries have been reported; but the issue could potentially cause damage to the wall outlet or the device itself.</p> <p>* Philips is aware of the problem and is investigating it further.</p>
Inappropriate Audible	2	<p>## Product Problem Summary:</p> <p>Device: IntelliVue Multi Measurement Server X2</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
Prompt/Feedback		<p>Problem: Defective speaker causing distorted sound or potential loss of audio.</p> <p>Cause: Faulty speaker.</p> <p>Impact: Potential for patient harm due to loss of audio cues.</p> <p>Resolution: Speaker replaced.</p> <p>## Additional Information:</p> <ul style="list-style-type: none"> <li>* Philips is investigating the issue further.</li> <li>* A follow-up report will be submitted upon completion of the investigation.</li> <li>* The customer was provided a replacement speaker.</li> <li>* The device was in use on a patient at the time of the event.</li> <li>* There was a report of patient harm.</li> </ul> <p>## Key Points:</p> <ul style="list-style-type: none"> <li>* The speaker malfunction is a serious issue that could potentially harm patients.</li> <li>* Philips is taking steps to investigate the issue and provide a resolution.</li> <li>* More information will be available in the follow-up report.</li> </ul>
Electrical /Electronic Property Problem	2	<p>## Product Problem Summary:</p> <p>Device: Implantable Cardiac Monitor (ICM) and Wall Charger</p> <p>Problem:</p> <ul style="list-style-type: none"> <li>* ICM: The patient reported feeling a shock and burning sensation above the incision site. The ICM also malfunctioned; causing noise in the symptom episodes.</li> <li>* Wall Charger: The prongs of the charger broke when the patient attempted to remove it from the wall outlet.</li> </ul> <p>Analysis:</p> <ul style="list-style-type: none"> <li>* ICM: No anomalies were found during analysis of the returned device.</li> <li>* Wall Charger: The cause of the issue was determined to be an inconsistent weld pattern on the component due to the supplier's use of an ineffective ultrasonic welding tool.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* The ICM remains in use.</li> <li>* No patient complications have been reported.</li> <li>* A replacement charger was sent to the patient.</li> </ul> <p>Note: Medtronic objects to the use of the terms "defects" and "malfunctioned" in this report due to their lack of definition and negative connotations.</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
Manufacturing Packaging or Shipping Problem	2	<p><b>## Product Problem Summary:</b>  <b>Repackaging/Relabeling Mix-up:</b>            * A mix-up occurred during repackaging/relabeling; resulting in a mismatch between the serial number on the shipping box and the actual device inside.            * The patient was supposed to receive device serial number (b)(6) but instead received (b)(6).  <b>Potential Consequences:</b>            * The patient received a pacemaker that may not have been appropriate based on the correct monitoring data.            * The patient may not have received timely medical care due to the monitoring issue.            * The patient subsequently received a pacemaker at a hospital; suggesting the initial device was not suitable.  <b>Overall;</b> this incident highlights the potential risks associated with repackaging/relabeling errors; which can lead to serious patient safety concerns.</p>
Break	2	<p><b>## Product Problem Summary:</b>  <b>Charger:</b>            * The charger plug broke when the patient removed it from the wall outlet.            * The cause was an inconsistent weld pattern due to the supplier using an ineffective ultrasonic welding tool.            * The user cannot detect if the weld is adequate; leading to unexpected failure.            * The device becomes unusable when the failure occurs.            * Philips is monitoring the issue.  <b>Implantable Cardiac Monitor (ICM):</b>            * The patient felt the ICM was in two pieces and could feel a "chip or something" disconnected from the device.            * The ICM was implanted seven months ago and remains in use.            * No patient complications have been reported.  <b>Additional Notes:</b>            * A replacement charger was sent to the patient who reported the charger issue.            * Medtronic is submitting the report to comply with FDA regulations.            * Medtronic objects to the use of certain words in the report due</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		to their lack of definition and negative connotations.
Human-Device Interface Problem	2	<p><b>## Concise Description of the Product Problem:</b> An implantable cardiac monitor (ICM) experienced diminished R waves and undersensing; potentially due to being implanted past its use-by date. Additionally; the device exhibited failed transmissions and invalid histograms. Despite these issues; the ICM remains in use and no patient complications have been reported.</p> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* Device: Implantable cardiac monitor (ICM)</li> <li>* Problem: Diminished R waves; undersensing; failed transmissions; invalid histograms</li> <li>* Possible Cause: Expired use-by date</li> <li>* Current Status: Device remains in use</li> <li>* Patient Impact: No reported complications</li> </ul> <p><b>## Additional Information:</b></p> <ul style="list-style-type: none"> <li>* The report emphasizes that Medtronic is submitting the information to comply with FDA regulations and has not fully investigated or verified the information.</li> <li>* The report also clarifies that the use of terms like "defects" and "malfunctioned" are solely for regulatory reporting purposes and do not constitute an admission of fault.</li> </ul> <p><b>## Recommendations:</b></p> <ul style="list-style-type: none"> <li>* Further investigation is needed to determine the root cause of the issues.</li> <li>* The patient should be closely monitored for any potential complications.</li> <li>* The device manufacturer should consider revising its use-by date policy.</li> </ul>
Temperature Problem	2	<p><b>## Product Problem Summary:</b> Product: C6 Monitor and Charging Cord Problem: Overheating and melting of the charging cord; potentially leading to smoking and damage.</p> <p><b>Details:</b></p> <ul style="list-style-type: none"> <li>* Multiple reports of C6 monitor charging cords overheating and melting.</li> <li>* In some cases; the monitor stopped working.</li> <li>* In one case; the monitor started smoking.</li> <li>* No reports of patient harm or injury.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>Possible Cause:</p> <ul style="list-style-type: none"> <li>* Known product defect in the charging cord.</li> </ul> <p>Action:</p> <ul style="list-style-type: none"> <li>* Philips AM&amp;D is investigating the issue further.</li> <li>* Product information updated to reflect the issue with the charging cord.</li> <li>* Replacement monitors and chargers are being sent to affected patients.</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* The serial numbers of the affected monitors have been redacted for privacy reasons.</li> <li>* The specific model of the affected phone (A10E) is mentioned in two of the reports.</li> </ul>
Alarm Not Visible	2	<p>## Summary of Product Problem:</p> <p>Issue: Audible and visual notifications are affected due to battery consumption.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* The issue was reported by a Philips Field Service Engineer (FSE) on behalf of the customer.</li> <li>* The FSE upgraded the software and confirmed the unit was working properly.</li> <li>* The device was reported to be in use on a patient; but no adverse event to the patient or user was reported.</li> <li>* A second report mentioned an inoperative alarm stating some ECG alarms were off.</li> <li>* The cause of the reported problem was unknown and could not be confirmed.</li> <li>* The customer took responsibility to correct/repair the device.</li> <li>* No further action is required at this time.</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* The investigation is still ongoing and a final report will be submitted once complete.</li> <li>* Further details were requested but not provided.</li> <li>* The device was not in clinical use at the time the issue was discovered.</li> </ul> <p>## Potential Safety Concerns:</p> <ul style="list-style-type: none"> <li>* The affected notifications could potentially delay or prevent the delivery of critical information to healthcare providers; which could lead to delayed or missed interventions.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The inoperative alarm could potentially prevent the device from alerting healthcare providers to critical patient conditions.</li> </ul> <b>## Recommendations:</b> <ul style="list-style-type: none"> <li>* Philips should continue to investigate the issue to determine the root cause and implement corrective actions.</li> <li>* Healthcare providers should be made aware of the potential issue and advised to monitor their devices closely.</li> <li>* Philips should provide clear instructions to customers on how to address the issue if it occurs.</li> </ul>
Product Quality Problem	2	<p>The product was explanted due to patient dissatisfaction. No additional adverse patient effects were reported. This report reflects information received by FDA in the form of a notification per 803.22 (B)(2).</p>
Noise Audible	1	<b>## Product Problem Summary:</b> <b>Reported Issue:</b> <ul style="list-style-type: none"> <li>* C6 MCOT monitor emitted a sizzling sound and smelled like burning electricity while plugged in and charging.</li> <li>* Monitor became too hot to touch.</li> <li>* Damage was noted on the charging wall plug.</li> </ul> <b>Investigation Findings:</b> <ul style="list-style-type: none"> <li>* No physical damage was found on the monitor itself.</li> <li>* Engineering evaluation was unable to replicate the reported overheating issue.</li> <li>* All temperature thresholds were within tolerance and the application was functioning properly.</li> <li>* The reported damage was limited to the charging cord; which is known to have a potential failure mode currently under investigation by Philips AM&amp;D.</li> </ul> <b>Conclusion:</b> <ul style="list-style-type: none"> <li>* The reported overheating issue could not be replicated during investigation.</li> <li>* The reported damage is likely due to a known issue with the charging cord.</li> <li>* No injuries were reported.</li> </ul> <b>Recommendations:</b> <ul style="list-style-type: none"> <li>* Continue monitoring the situation for further reports of overheating or damage.</li> <li>* Consider replacing the charging cord with a new one that does not have the known issue.</li> <li>* Investigate the known issue with the charging cord further to</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		determine the root cause and potential solutions.
Disconnection	1	<p><b>## Product Problem Summary:</b>  Reported Issue: Philips device failed to alarm when a 4-second pause was detected.  Investigation Status: Ongoing. Philips is gathering additional information.  Key Points:  * Device passed functional testing twice.  * Customer may have experienced network issues.  * Device would still operate and alarm locally for detected arrhythmia.  * Alarms can be reviewed on the MX40 but only as text; not waveforms.  * Customer received a replacement device.  * No further action required at this time.  * Complaint file will be reopened if additional information is received.  Additional Information:  * The device was in use on a patient at the time of the event.  * No adverse event was reported.  Conclusion:  The cause of the reported issue is still under investigation. Philips will provide a final report once the investigation is complete.</p>
Unintended System Motion	1	<p><b>## Product Problem Summary:</b>  Device: Patient monitor arm  Problem:  * Arm lacks resistance when moving the monitor down; causing it to drop suddenly.  * This lack of resistance has led to a nurse injuring their shoulder.  * The problem affects some; but not all; arms in the ICU.  Additional Information:  * The cause of the problem was a loose screw and nut on the black lever.  * Tightening the screw and nut resolved the issue.  * It is unknown if the device was in clinical use at the time of the injury.  * The nurse who was injured recovered from their minor</p>



## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>shoulder pain.</p> <ul style="list-style-type: none"> <li>* It is unknown who installed the mount at the customer site.</li> </ul> <p>Conclusion:</p> <ul style="list-style-type: none"> <li>* No further action is required at this time.</li> <li>* However; it is important to investigate why some arms are experiencing this issue while others are not.</li> <li>* Additionally; it is important to determine who installed the mount and ensure that they are properly trained.</li> <li>* Finally; it is important to monitor for similar incidents in the future.</li> </ul>
Fracture	1	<p><b>## Product Problem Summary:</b></p> <p>Issue: The prongs of the charger or adapter became stuck in the wall outlet when the patient attempted to remove them.</p> <p>Reported Cases: Two reports were received.</p> <ul style="list-style-type: none"> <li>* In the first case; the monitor was charging and the patient experienced difficulty removing the charger from the wall outlet.</li> <li>* In the second case; the patient experienced difficulty removing the dual charge adapter from the wall outlet.</li> </ul> <p>Injuries: No injuries were reported.</p> <p>Resolution:</p> <ul style="list-style-type: none"> <li>* The patient services representative advised the patient in the first case on how to return the device.</li> <li>* A replacement kit was ordered.</li> <li>* The device in the second case was not returned for investigation.</li> </ul> <p>Engineering Evaluation:</p> <ul style="list-style-type: none"> <li>* An engineering evaluation was unable to be performed as the device in the second case was not returned.</li> </ul> <p>Known Failure Mode:</p> <ul style="list-style-type: none"> <li>* This problem statement aligns with a known failure mode and is most likely related.</li> <li>* This known failure mode is being further investigated by Philips AM&amp;D.</li> </ul>
False Alarm	1	<p><b>## Summary of Product Problem:</b></p> <p>Device: Philips MX40 patient monitor</p> <p>Problem: The device turned off and stopped actively monitoring the patient; leading to the patient's death.</p> <p>Additional Information:</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* The device was in use at the time of the incident.</li> <li>* Several alarms and inops were reported throughout the day.</li> <li>* The customer acknowledged "No Data Tele" alarms 13 times.</li> <li>* The cause of death was documented as pulmonary fibrosis; pneumonia; and acute hypoxic hypercapnia and respiratory failure.</li> <li>* The device was working as intended; but the user silenced/acknowledged alarms.</li> <li>* The cause of the event is likely related to a combination of user error; alarm management; and potentially clinical workflow.</li> </ul> <p>## Key Points:</p> <ul style="list-style-type: none"> <li>* The device malfunctioned and stopped monitoring the patient.</li> <li>* The patient died as a result of the device malfunction.</li> <li>* The user silenced/acknowledged alarms; which may have contributed to the incident.</li> <li>* The cause of the event is likely related to user error and alarm management.</li> </ul> <p>## Next Steps:</p> <ul style="list-style-type: none"> <li>* Philips is investigating the incident.</li> <li>* A follow-up report will be submitted upon completion of the investigation.</li> </ul> <p>## Additional Notes:</p> <ul style="list-style-type: none"> <li>* The information provided is not consistent with a malfunction of the product.</li> <li>* Alarms were provided at the MX40 and PIC IX; including the "Tele Service Batt Inop" alarm.</li> </ul> <p>## Conclusion:</p> <p>The incident appears to be the result of user error and alarm management; rather than a device malfunction. However; Philips is still investigating the incident to determine the exact cause.</p>
Device Markings/Labelling Problem	1	<p>## Medtronic Implantable Cardiac Monitor (ICM) Problem Summary:</p> <p>Problem: An ICM displayed an "End of Service" (EOS) message before the use-by date printed on the packaging; preventing activation.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* The reported ICM displayed an EOS message before the use-by date.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* A new ICM was implanted without issues.</li> <li>* No patient complications were reported.</li> <li>* The use-by date on the packaging was correct.</li> </ul> <p>Possible Causes:</p> <ul style="list-style-type: none"> <li>* Manufacturing defect</li> <li>* Software issue</li> <li>* Battery failure</li> </ul> <p>Impact:</p> <ul style="list-style-type: none"> <li>* Delayed patient care</li> <li>* Increased healthcare costs</li> <li>* Potential patient anxiety</li> </ul> <p>Next Steps:</p> <ul style="list-style-type: none"> <li>* Medtronic is investigating the issue.</li> <li>* A supplemental report will be issued if more information becomes available.</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* Medtronic emphasizes that this report does not constitute an admission of any defect or malfunction.</li> <li>* The report is submitted to comply with FDA reporting regulations.</li> </ul>
Difficult to Remove	1	<p>## Product Problem Summary:</p> <p>Problem: The dual USB power adapter's housing can separate; causing the charger to become stuck in the wall outlet.</p> <p>Reported by: Patient's daughter</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* The sensor charger adapter could not be removed from the wall socket.</li> <li>* The device was not returned for investigation.</li> <li>* Engineering evaluation was unable to be performed.</li> <li>* This failure aligns with a known issue (JDSP-18928) related to the dual USB power adapter housing separation.</li> <li>* Philips AM&amp;D is further investigating the issue.</li> </ul> <p>Outcome:</p> <ul style="list-style-type: none"> <li>* A replacement adapter was ordered.</li> <li>* No harm was noted.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* It is unclear if the reported issue is related to the known failure mode (JDSP-18928).</li> <li>* Further investigation is needed to determine the root cause of the problem.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
Data Problem	1	<p><b>## Medtronic Implantable Cardiac Monitor (ICM) Event Summary</b></p> <p>Problem: Incorrect information communicated to clinic during interrogation of the ICM. The ICM was unable to be interrogated by the Patient Connector and Diagnostic Mobile Programmer application. A lock symbol was present on the hosting tablet; and it was speculated that the ICM was locked. The Diagnostic Mobile Programmer application was running in the background when the check was performed.</p> <p>Potential Cause: Outdated Diagnostic Mobile Programmer application software.</p> <p>Impact: No patient complications reported.</p> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* Medtronic is submitting this report to comply with FDA reporting regulations.</li> <li>* The report is based on information obtained by Medtronic; which may not be complete or verified.</li> <li>* Medtronic has made reasonable efforts to obtain more information.</li> <li>* This report does not constitute an admission of fault by Medtronic or the FDA.</li> <li>* The report does not constitute an admission that the product has any defects or has malfunctioned.</li> <li>* Medtronic objects to the use of the words "defects" and "malfunctioned" due to their lack of definition and connotations.</li> <li>* This statement should be included with any information disclosed to the public under the Freedom of Information Act.</li> <li>* Any required fields that are unpopulated are blank because the information is currently unknown or unavailable.</li> <li>* A good faith effort will be made to obtain the applicable information relevant to the report.</li> <li>* If information is provided in the future; a supplemental report will be issued.</li> </ul> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* Incorrect information communicated to clinic during ICM interrogation.</li> <li>* ICM unable to be interrogated by Patient Connector and Diagnostic Mobile Programmer application.</li> <li>* Potential cause: outdated Diagnostic Mobile Programmer</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>application software.</p> <ul style="list-style-type: none"> <li>* No patient complications reported.</li> <li>* Medtronic is investigating the issue and will provide updates as they become available.</li> </ul>
Solder Joint Fracture	1	<p><b>## Product Problem Summary:</b></p> <p>Problem: The charging block of the MCOT device is breaking apart when plugged into the wall outlet; leaving the prongs exposed and causing electrical shock to the user.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* Two separate reports of the same issue.</li> <li>* Both incidents involved the charging block breaking apart; leaving the prongs exposed in the outlet.</li> <li>* Both patients received electrical shocks.</li> <li>* One patient did not seek medical treatment; the other is unknown.</li> <li>* The charging block was not returned in either case; making engineering evaluation impossible.</li> <li>* Pictures were also not provided.</li> <li>* This issue aligns with a known problem currently under investigation by Philips AM&amp;D.</li> </ul> <p>Possible Causes:</p> <ul style="list-style-type: none"> <li>* Faulty design or manufacturing of the charging block.</li> <li>* Use of incompatible or damaged charging cords.</li> <li>* Excessive force applied when plugging or unplugging the device.</li> </ul> <p>Potential Consequences:</p> <ul style="list-style-type: none"> <li>* Electrical shock and potential injury to the user.</li> <li>* Damage to the device and surrounding property.</li> <li>* Fire hazard.</li> </ul> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>* Philips should investigate the issue further to determine the root cause and implement corrective actions.</li> <li>* Users should be warned about the potential hazard and advised to use caution when plugging and unplugging the device.</li> <li>* Users should also be advised to use only compatible and undamaged charging cords.</li> <li>* A recall of the affected charging blocks may be necessary.</li> </ul>
Failure to Charge	1	<p><b>## Product Problem Summary:</b></p> <p>Device: C6 Monitor and Charger</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>Problem:</p> <ul style="list-style-type: none"> <li>* Monitor has a black screen and will not power on.</li> <li>* Monitor and charger were found to be melted.</li> <li>* Device (unspecified) would not power on or charge due to damage around the charging area and charging port.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* No patient harm was reported.</li> <li>* The charging cord is suspected to be the cause of the device melt.</li> </ul> <p>Possible Causes:</p> <ul style="list-style-type: none"> <li>* Faulty charging cord</li> <li>* Overheating</li> <li>* Physical damage to the device or charging port</li> </ul> <p>Next Steps:</p> <ul style="list-style-type: none"> <li>* Investigate the cause of the melt and damage.</li> <li>* Implement corrective actions to prevent future occurrences.</li> <li>* Consider issuing a recall or safety notice if necessary.</li> </ul>
Complete Loss of Power	1	<p>## Product Problem Summary:</p> <p>Device: C6 Monitor and Charger</p> <p>Problem:</p> <ul style="list-style-type: none"> <li>* Monitor has a black screen and will not power on.</li> <li>* Monitor and charger were found to be melted.</li> <li>* No patient harm reported.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* A new monitor was ordered.</li> <li>* A separate device (C6M; A10E; U/02-01894/MT29120013) would not power on or charge due to damage around the charging area.</li> <li>* The charging cord is suspected to be the cause of the melt in both cases.</li> </ul> <p>Possible Causes:</p> <ul style="list-style-type: none"> <li>* Faulty charging cord</li> <li>* Overheating</li> <li>* Manufacturing defect</li> </ul> <p>Next Steps:</p> <ul style="list-style-type: none"> <li>* Investigate the cause of the melt.</li> <li>* Determine if there are other affected devices.</li> <li>* Implement corrective actions to prevent future incidents.</li> </ul>
Premature Discharge of Battery	1	<p>## Product Problem Summary:</p> <p>Patient Death: A patient death occurred while using a Philips</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>M4841 telemetry device.</p> <p>Cause:</p> <ul style="list-style-type: none"> <li>* Not related to equipment failure: The Field Service Engineer (FSE) determined the death was not caused by a malfunction of the device.</li> <li>* Communication issues: There were communication issues in notifying the nurse of the low battery.</li> <li>* Non-recommended battery: The customer used a non-recommended battery (not Duracell); which drained faster than expected.</li> <li>* Out-of-support device: The customer was using a self-maintained M4841 telemetry device; which is no longer supported by Philips.</li> </ul> <p>Action Taken:</p> <ul style="list-style-type: none"> <li>* Investigation completed: The FSE conducted an on-site investigation and concluded no product malfunction occurred.</li> <li>* No further action required: Based on the available information; no further action is required at this time.</li> <li>* Complaint file remains open: The complaint file will be reopened if additional information is received.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* FDA ProCode updated: The FDA ProCode was updated based on the information available at the time of the report.</li> <li>* Follow-up report: A follow-up report will be submitted upon completion of the investigation.</li> <li>* Battery logs requested: The customer requested the logs for the telemetry box battery status for a specific time frame.</li> </ul> <p>## Key Points:</p> <ul style="list-style-type: none"> <li>* The patient death was not caused by a product malfunction.</li> <li>* Communication issues and the use of a non-recommended battery contributed to the incident.</li> <li>* The customer was using an out-of-support device.</li> <li>* No further action is required at this time; but the complaint file remains open.</li> </ul>
Positioning Problem	1	<p>## Product Problem Summary:</p> <p>Device: Implantable Cardiac Monitor (ICM)</p> <p>Problem:</p> <ul style="list-style-type: none"> <li>* False positive episodes: The ICM detected false positive episodes due to oversensing artifact/noise and undersensing.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>* Suboptimal electrode connection: The report mentions suboptimal electrode connection; which could contribute to the false positive episodes.</p> <p>* Electromagnetic interference/Myopotential interference: The report also mentions electromagnetic interference/myopotential interference; which could also contribute to the false positive episodes.</p> <p>Additional Information:</p> <p>* The device remains in use.</p> <p>* No patient complications have been reported.</p> <p>* The device was not returned for analysis; but performance data was collected and analyzed.</p> <p>* Analysis of the device memory indicated undersensing and noise.</p> <p>Note:</p> <p>* This report does not constitute an admission or conclusion by FDA; Medtronic; or its employees that the device; Medtronic; or its employee caused or contributed to the event described in the report.</p> <p>* Medtronic objects to the use of the words "defects" and "malfunctioned" in the report due to the lack of definition and the connotations implied by these terms.</p>
Display or Visual Feedback Problem	1	<p>## Product Problem Summary:</p> <p>Reported Issue: The touchscreen of a Philips device is not working.</p> <p>Testing Results:</p> <p>* Functional testing at the authorized repair facility confirmed the speaker was producing sound.</p> <p>* The reported problem of the touchscreen not working could not be replicated.</p> <p>Resolution:</p> <p>* The speaker was replaced as per current process; even though it was confirmed to be functioning.</p> <p>* The device was operational after repairs were completed.</p> <p>Investigation Conclusion:</p> <p>* No further action is required at this time.</p> <p>* The complaint file will be reopened if additional information is received.</p> <p>Additional Information:</p>



## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* Philips is in the process of obtaining additional information.</li> <li>* A final report will be submitted upon completion of the investigation.</li> </ul> <p>Patient/User Harm:</p> <ul style="list-style-type: none"> <li>* There was no report of patient or user harm.</li> </ul> <p>## Key Points:</p> <ul style="list-style-type: none"> <li>* The reported problem of the touchscreen not working could not be replicated during testing.</li> <li>* The speaker was replaced as a precaution; even though it was functioning properly.</li> <li>* Philips is investigating the issue further and will provide a final report upon completion.</li> <li>* There was no report of patient or user harm.</li> </ul>
Incorrect Measurement	1	<p>## Product Problem Summary:</p> <p>Device: X2 Monitor</p> <p>Problem: Arterial line measurement not displaying on the monitor.</p> <p>Cause: Faulty parameter board and main board.</p> <p>Impact: Patient death.</p> <p>Resolution:</p> <ul style="list-style-type: none"> <li>* Parameter board and main board replaced.</li> <li>* Device returned to customer.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* The X2 monitor did not register the ECG/Temp measurement board.</li> <li>* The customer was advised to replace the parameter board.</li> <li>* The device was sent to Philips bench repair for evaluation.</li> <li>* The reported problem was confirmed and the device was repaired.</li> </ul> <p>Conclusion:</p> <p>The product problem was caused by a faulty parameter board and main board. The device was repaired and returned to the customer. No further action is required at this time.</p> <p>Note: This summary is based on the information provided. If additional information becomes available; the complaint file will be reopened.</p>
Mechanical Problem	1	<p>## Product Problem Summary:</p> <p>Device: Philips MX40 1.4 GHz Smart Hopping</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>Reported Issues:</p> <ul style="list-style-type: none"> <li>* Damaged case</li> <li>* Device not alarming/alerting as intended</li> <li>* Unable to hold batteries (potentially related to the damaged case)</li> </ul> <p>Investigation:</p> <ul style="list-style-type: none"> <li>* Philips Authorized Repair Facility was unable to replicate the reported problem.</li> <li>* Testing confirmed the speaker was functioning as designed.</li> </ul> <p>Current Status:</p> <ul style="list-style-type: none"> <li>* Complaint file closed.</li> <li>* File will be reopened if additional information is received.</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* It is unknown if the device was in use at the time of the event.</li> <li>* No adverse events were reported.</li> </ul>
Image Display Error/Artifact	1	<p><b>## Product Problem Summary:</b></p> <p>Problem: A defective ECG trunk cable caused an inaccurate ECG reading; leading to the administration of potentially harmful therapy to a patient.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* The ECG cable malfunctioned; causing an artifact that mimicked a life-threatening arrhythmia.</li> <li>* Based on the inaccurate reading; paramedics administered therapy that may have had adverse effects on the patient.</li> <li>* The patient's current condition is unknown.</li> <li>* The malfunctioning cable has been replaced and scrapped.</li> </ul> <p>Impact:</p> <ul style="list-style-type: none"> <li>* Potential harm to the patient due to unnecessary therapy.</li> <li>* Increased stress and anxiety for the patient and medical staff.</li> <li>* Loss of trust in the medical device.</li> </ul> <p>Cause:</p> <ul style="list-style-type: none"> <li>* Defective ECG trunk cable.</li> </ul> <p>Resolution:</p> <ul style="list-style-type: none"> <li>* Replacement of the defective cable.</li> <li>* Investigation into the patient's current condition.</li> <li>* Implementation of measures to prevent similar incidents in the future.</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* The specific details of the therapy administered and the</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>patient's current condition are unknown.</p> <ul style="list-style-type: none"> <li>* Further investigation is needed to determine the full impact of the incident.</li> </ul>
Moisture Damage	1	<p><b>## Product Problem Summary:</b></p> <p>Problem: Monitor damaged due to a smoking charging cord.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* The monitor stopped functioning after the charging cord started smoking.</li> <li>* Engineering evaluation confirmed the damage was caused by an electrical fault within the USB-A/USB-C charging cord.</li> <li>* The component failure is being further investigated.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* The patient threw water on the smoking cord; which may have further damaged the monitor.</li> <li>* The patient received a small burn but did not require medical attention.</li> </ul> <p>Possible Causes:</p> <ul style="list-style-type: none"> <li>* Electrical fault in the charging cord.</li> <li>* Water damage from the patient's attempt to extinguish the smoking cord.</li> </ul> <p>Next Steps:</p> <ul style="list-style-type: none"> <li>* Investigate the component failure of the charging cord.</li> <li>* Determine the extent of water damage to the monitor.</li> <li>* Evaluate potential safety risks associated with the charging cord.</li> </ul> <p><b>## Additional Notes:</b></p> <ul style="list-style-type: none"> <li>* The report uses the term "patient" which may be a typo and should be "user" instead.</li> <li>* The report does not specify the brand or model of the monitor or charging cord.</li> <li>* The report does not mention any corrective actions taken; such as recalling the charging cord or issuing a safety warning.</li> </ul>
Sparkling	1	<p><b>## Product Problem Summary:</b></p> <p>Reported Issue:</p> <ul style="list-style-type: none"> <li>* Sparks observed coming from the sensor during patient defibrillation.</li> <li>* Sensor not charging.</li> </ul> <p>Investigation Findings:</p> <ul style="list-style-type: none"> <li>* Engineering evaluation could not replicate the reported event.</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* Patient Education Guide (PEG) specifically states to remove the sensor before defibrillation.</li> <li>* Observed sparks likely caused by the defibrillator; not a product malfunction.</li> <li>* Charging issues likely related to patient defibrillation.</li> </ul> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* Patient and daughter reported the incident.</li> <li>* Patient advised to remove the blue casing of the patch.</li> <li>* Sensor flashing red.</li> <li>* Replacement sensor ordered as a precaution.</li> <li>* Patient will attempt to reconnect the sensor after it is charged.</li> </ul> <p>Possible Causes:</p> <ul style="list-style-type: none"> <li>* Defibrillator discharge causing sparks.</li> <li>* Defibrillation affecting sensor charging.</li> <li>* Sensor damage during defibrillation.</li> </ul> <p>Next Steps:</p> <ul style="list-style-type: none"> <li>* Monitor the situation and the patient's feedback after reconnecting the sensor.</li> <li>* Investigate further if the issue persists or additional information becomes available.</li> </ul>
Fire	1	<p><b>## Product Problem Summary:</b> Sensor malfunction caused a burn through an envelope.</p> <p><b>Key Points:</b></p> <ul style="list-style-type: none"> <li>* The sensor did not overheat prior to the incident.</li> <li>* Internal damage confirms a spark on the sensor caused the burn.</li> <li>* Spark origin is unclear due to device damage.</li> <li>* No harm to the patient was reported.</li> <li>* The sensor was replaced.</li> </ul> <p><b>Possible Causes:</b></p> <ul style="list-style-type: none"> <li>* Electrical malfunction within the sensor.</li> <li>* External factor causing a spark on the sensor.</li> </ul> <p><b>Further Investigation Needed:</b></p> <ul style="list-style-type: none"> <li>* Determine the root cause of the spark.</li> <li>* Assess potential safety risks associated with the malfunction.</li> <li>* Implement corrective actions to prevent future incidents.</li> </ul>
Unexpected Shutdown	1	<p><b>## Product Problem Summary:</b> A patient wearing a Philips telemetry monitor (MX40) died in the</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>CCU between 3-6 AM. The monitor was offline between 1:00 AM and 3:43 AM; and the cause of death was determined to be a peptic perforation.</p> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* The customer reported the death and alleged the monitor was not working during the critical time.</li> <li>* The initial investigation by a Philips RSE concluded the monitor was working as intended and the issue was caused by user error (discharging the patient).</li> <li>* A technical investigation by a Philips PSE confirmed the monitor was working as intended and the issue was caused by user error (discharging the patient).</li> <li>* The investigation also found that the monitor's offline status would have triggered an alarm at the central station; alerting the user.</li> <li>* A clinical reassessment was performed based on new information indicating the cause of death was a peptic perforation.</li> </ul> <p><b>## Conclusion:</b></p> <p>The investigation concluded that the Philips telemetry monitor did not cause or contribute to the patient's death. The issue was caused by user error and the monitor functioned as intended.</p> <p><b>## Additional Information:</b></p> <ul style="list-style-type: none"> <li>* The investigation is closed unless additional information is received.</li> <li>* If additional information is obtained; the complaint file will be reopened and the record will be reassessed by the PMS Clinical Expert.</li> </ul>
Telemetry Discrepancy	1	<p><b>## Product Problem Summary:</b></p> <p>Device: Philips MX40 patient monitor</p> <p>Problem: The device experienced a battery interruption; causing it to go offline. This resulted in a "No Data Tele" technical inop being displayed and an audible tone being provided. The device went back online after the batteries were replaced.</p> <p>Cause: The investigation concluded that the battery interruption was likely caused by fluid intrusion in the battery tray. The battery adapter tray showed wear and some separation of the flex circuit; and the battery compartment showed chemical residue. However; these issues were not considered significant</p>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>enough to prevent the device from functioning.</p> <p>Impact: The device going offline may have contributed to the reported patient death; as it prevented the clinical staff from receiving telemetry data. However; the report does not provide enough information to confirm this.</p> <p>Resolution: The battery tray was cleaned and replaced; and the device was tested and found to be functioning properly. No further action is required at this time.</p> <p>Additional Information: The investigation is ongoing; and the complaint file will be reopened if additional information is received.</p>
Excessive Heating	1	<p><b>## Product Problem Summary:</b></p> <p>Problem: The monitor's charging plug became hot to the touch; damaging the patient's wall outlet and rendering the power strip unusable.</p> <p>Details:</p> <ul style="list-style-type: none"> <li>* The patient reported the issue but did not return the device for investigation.</li> <li>* Engineering evaluation was unable to be performed due to the lack of the wall charger.</li> <li>* The patient used a power strip; which is against the manufacturer's instructions.</li> <li>* The specific monitor involved was identified; but it is not believed to have caused the issue.</li> <li>* The root cause of the problem is unknown.</li> </ul> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* No patient harm was reported.</li> <li>* A replacement kit was sent to the patient.</li> </ul>
Patient-Device Incompatibility	1	<p><b>## Concise Description of Product Problem:</b></p> <p>A patient experienced skin irritation and a secondary infection (cellulitis) allegedly caused by the Zio AT patch. The patient was diagnosed with contact dermatitis and prescribed treatment. This event is being reported as a serious injury per 21 CFR 803.</p> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* Product: Zio AT patch</li> <li>* Problem: Skin irritation and secondary infection (cellulitis)</li> <li>* Alleged Cause: Zio AT patch</li> <li>* Diagnosis: Contact dermatitis and cellulitis</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<ul style="list-style-type: none"> <li>* Treatment: Prescribed by healthcare provider</li> <li>* Reporting: Serious injury per 21 CFR 803</li> </ul> <b>## Additional Information:</b> <ul style="list-style-type: none"> <li>* The device manual warns about the risk of skin irritation and provides instructions for removing the patch if irritation occurs.</li> <li>* This report does not constitute an admission of any product defects or malfunctions.</li> <li>* The terms "defects" and "malfunctions" are included in the FDA form for regulatory reporting purposes only.</li> </ul>
Material Integrity Problem	1	<b>## Product Problem Summary:</b> Dual USB Charging Adapter Disintegration: <ul style="list-style-type: none"> <li>* Reported Issue: The adapter disintegrated when plugged into the wall outlet.</li> <li>* Severity: Moderate - potential for electrical hazard.</li> <li>* Impact: Patient was not injured; but the device malfunctioned.</li> <li>* Cause: Unknown - device not returned for investigation.</li> <li>* Resolution: A new charger was sent to the patient.</li> </ul> <b>Additional Information:</b> <ul style="list-style-type: none"> <li>* The patient reported the issue and will return the device.</li> <li>* Engineering evaluation is pending the return of the device.</li> <li>* The allegation of disintegration cannot be confirmed without the device.</li> </ul>
Therapeutic or Diagnostic Output Failure	1	<b>## Stryker Medical Receives Complaint About Inaccurate Hill-Rom Bed Scale</b> <b>Summary:</b> <ul style="list-style-type: none"> <li>* Stryker Medical received a complaint about a Hill-Rom bed (model L24AM3690) with an inaccurate scale.</li> <li>* The customer alleges the scale is inaccurate.</li> <li>* Stryker is not the original equipment manufacturer (OEM) of the bed.</li> <li>* This report reflects information received by the FDA as a notification.</li> </ul> <b>Key Points:</b> <ul style="list-style-type: none"> <li>* Product: Hill-Rom bed (model L24AM3690)</li> <li>* Problem: Inaccurate scale</li> <li>* Reported by: Customer</li> <li>* Manufacturer: Hill-Rom (not Stryker)</li> <li>* Source: FDA notification</li> </ul>

## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
		<p>Additional Information:</p> <ul style="list-style-type: none"> <li>* The report does not provide details about the specific nature of the inaccuracy or the potential impact on patient safety.</li> <li>* As Stryker is not the OEM; they may have limited information about the issue and the potential solutions.</li> </ul> <p>Possible Next Steps:</p> <ul style="list-style-type: none"> <li>* Stryker may investigate the complaint further and contact Hill-Rom for additional information.</li> <li>* Stryker may issue a safety notice or recall if they determine the issue poses a significant risk to patient safety.</li> <li>* The FDA may investigate the complaint and take appropriate action.</li> </ul> <p>Disclaimer:</p> <p>This summary is based on the limited information provided in the report. More information may be needed to fully understand the nature and severity of the problem.</p>
Device Difficult to Setup or Prepare	1	<p><b>## Concise Description of the Product Problem:</b></p> <p>Problem: The implantable cardiac monitor (ICM) did not have data collection enabled after programming with the diagnostic mobile programmer application. Additionally; there was an issue with patient enrollment on the remote monitoring network.</p> <p>Impact: No patient complications have been reported.</p> <p>Cause: The cause of the problem is currently unknown.</p> <p>Action: Medtronic is investigating the issue and will provide a supplemental report if more information becomes available.</p> <p>Additional Notes:</p> <ul style="list-style-type: none"> <li>* This report is being submitted to comply with FDA reporting regulations.</li> <li>* Medtronic objects to the use of the words "defects" and "malfunctioned" in the report.</li> <li>* Any required fields that are unpopulated are blank because the information is currently unknown or unavailable.</li> </ul> <p><b>## Key Points:</b></p> <ul style="list-style-type: none"> <li>* Data collection not enabled on ICM.</li> <li>* Patient enrollment issue on remote monitoring network.</li> <li>* No patient complications reported.</li> <li>* Cause unknown; under investigation.</li> <li>* Supplemental report to be issued if more information becomes available.</li> </ul>
Device Difficult to	1	<p><b>## Concise Description of the Product Problem:</b></p>



## DSI MAUDE Problems Summary

Product Problems	MDR Counts	Problem Summaries
Program or Calibrate		<p>Problem: Implantable Cardiac Monitor (ICM) did not have data collection enabled after programming and had issues with patient enrollment on the remote monitoring network.</p> <p>Impact: No patient complications reported.</p> <p>Additional Information:</p> <ul style="list-style-type: none"> <li>* Medtronic submitted this report to comply with FDA regulations.</li> <li>* The report is based on information available at the time of submission.</li> <li>* Medtronic continues to investigate and may provide additional information in a supplemental report.</li> <li>* Medtronic objects to the use of terms like "defects" and "malfunctioned" due to their lack of definition and negative connotations.</li> </ul>
Contamination	1	<p><b>## Product Problem Summary:</b></p> <p>Device: Philips MX40 1.4 GHz Smart Hopping</p> <p>Reported Problem:</p> <ul style="list-style-type: none"> <li>* Initial report: Death associated with device use.</li> <li>* Corrected report: No patient death. Device had pin corrosion.</li> </ul> <p>Investigation:</p> <ul style="list-style-type: none"> <li>* Functional testing confirmed corrosion on pins 4; 8; 10; 17-19.</li> <li>* Rear housing sub-assembly replaced.</li> <li>* Device operational after repair.</li> </ul> <p>Conclusion:</p> <ul style="list-style-type: none"> <li>* Reported problem confirmed.</li> <li>* No further action required at this time.</li> <li>* Complaint file will be reopened if additional information is received.</li> </ul> <p>Key Points:</p> <ul style="list-style-type: none"> <li>* The initial report of a death was inaccurate.</li> <li>* The actual problem was pin corrosion.</li> <li>* The device was repaired and is now operational.</li> <li>* Philips is continuing to investigate the issue.</li> </ul>

## Data Overview – Patient Problems

Product Problems	MDR References	Patient Problems
No Audible Alarm	3008729547-2024-00005 1218950-2024-00298 1218950-2024-00299 1218950-2024-00294 9610816-2024-00216 9610816-2024-00213 1218950-2024-00286 9610816-2024-00218 9610816-2024-00222 1218950-2024-00289 9610816-2024-00215 1218950-2024-00284 1218950-2024-00280 1218950-2024-00283 9610816-2024-00205 1218950-2024-00273 1218950-2024-00265 1218950-2024-00252 1218950-2024-00263 1218950-2024-00258 9610816-2024-00197 1218950-2024-00254 9610816-2024-00194 1218950-2024-00255 1218950-2024-00248 1218950-2024-00253 1218950-2024-00245 9610816-2024-00188 1218950-2024-00244 1218950-2024-00237 1218950-2024-00238 9610816-2024-00177 1218950-2024-00229 9610816-2024-00176 1218950-2024-00215 1218950-2024-00220 9610816-2024-00168 1218950-2024-00195	["No Clinical Signs Symptoms or Conditions"] (237) ["Cardiac Arrest"] (1) ["Low Blood Pressure/ Hypotension" "No Clinical Signs Symptoms or Conditions"] (1) ["Hypoxia"] (1) ["Asystole"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	1218950-2024-00164 1218950-2024-00180 3008729547-2024-00001 1218950-2024-00161 9610816-2024-00122 1218950-2024-00156 9610816-2024-00110 9610816-2024-00106 9610816-2024-00107 1218950-2024-00128 1218950-2024-00122 1218950-2024-00106 9610816-2024-00077 1218950-2024-00095 1218950-2024-00090 9610816-2024-00058 1218950-2024-00078 9610816-2024-00052 1218950-2024-00065 1218950-2024-00042 9610816-2024-00006 1218950-2024-00038 1218950-2024-00036 1218950-2024-00027 1218950-2024-00028 9610816-2024-00010 9610816-2024-00012 1218950-2024-00006 1218950-2023-00973 1218950-2023-00969 1218950-2023-00970 1218950-2023-00968 1218950-2023-00971 1218950-2023-00972 9610816-2023-00681 1218950-2023-00959 1218950-2023-00961 1218950-2023-00960 9610816-2023-00664 1218950-2023-00965	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9610816-2023-00669 1218950-2023-00956 1218950-2023-00949 1218950-2023-00957 3008729547-2023-00013 3008729547-2023-00014 1218950-2023-00943 1218950-2023-00946 1218950-2023-00947 1218950-2023-00948 1218950-2023-00952 1218950-2023-00936 1218950-2023-00937 1218950-2023-00899 1218950-2023-00926 9610816-2023-00658 1218950-2023-00920 1218950-2023-00918 1218950-2023-00919 1218950-2023-00913 1218950-2023-00914 1218950-2023-00916 1218950-2023-00905 1218950-2023-00910 1218950-2023-00906 9610816-2023-00638 1218950-2023-00907 1218950-2023-00898 9610816-2023-00636 1218950-2023-00895 9610816-2023-00630 1218950-2023-00884 1218950-2023-00889 1218950-2023-00888 9610816-2023-00629 9610816-2023-00626 1218950-2023-00885 1218950-2023-00881 1218950-2023-00870 9610816-2023-00606	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9610816-2023-00597 1218950-2023-00874 1218950-2023-00861 1218950-2023-00866 9610816-2023-00586 9610816-2023-00578 1218950-2023-00856 9610816-2023-00579 1218950-2023-00850 1218950-2023-00852 9610816-2023-00572 9610816-2023-00571 9610816-2023-00574 1218950-2023-00843 1218950-2023-00848 1218950-2023-00849 1218950-2023-00841 1218950-2023-00844 1218950-2023-00837 1218950-2023-00840 1218950-2023-00834 9610816-2023-00554 1218950-2023-00823 1218950-2023-00825 1218950-2023-00816 1218950-2023-00815 1218950-2023-00806 1218950-2023-00808 1218950-2023-00811 1218950-2023-00799 9610816-2023-00539 9610816-2023-00532 1218950-2023-00788 1218950-2023-00791 1218950-2023-00786 1218950-2023-00771 1218950-2023-00770 1218950-2023-00777 1218950-2023-00776 1218950-2023-00779	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	1218950-2023-00775 9610816-2023-00529 1218950-2023-00780 1218950-2023-00769 1218950-2023-00761 1218950-2023-00762 1218950-2023-00763 1218950-2023-00757 9610816-2023-00520 9610816-2023-00513 1218950-2023-00751 1218950-2023-00753 9610816-2023-00510 1218950-2023-00727 1218950-2023-00728 1218950-2023-00735 1218950-2023-00734 9610816-2023-00505 3008729547-2023-00009 1218950-2023-00738 1218950-2023-00739 1218950-2023-00741 1218950-2023-00725 9610816-2023-00490 1218950-2023-00708 1218950-2023-00716 1218950-2023-00713 1218950-2023-00718 1218950-2023-00717 1218950-2023-00715 1218950-2023-00712 1218950-2023-00707 9610816-2023-00489 1218950-2023-00695 9610816-2023-00477 1218950-2023-00692 1218950-2023-00694 9610816-2023-00476 1218950-2023-00687 1218950-2023-00688	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	1218950-2023-00690 1218950-2023-00679 1218950-2023-00680 9610816-2023-00475 1218950-2023-00676 9610816-2023-00468 1218950-2023-00655 9610816-2023-00462 1218950-2023-00644 9610816-2023-00451 1218950-2023-00639 1218950-2023-00632 9610816-2023-00448 1218950-2023-00626 1218950-2023-00627 1218950-2023-00628 9610816-2023-00441 9610816-2023-00442 9610816-2023-00444 9610816-2023-00440 1218950-2023-00619 1218950-2023-00617 1218950-2023-00618 9610816-2023-00430 9610816-2023-00419 1218950-2023-00593 1218950-2023-00586 1218950-2023-00581 9610816-2023-00417 1218950-2023-00578 1218950-2023-00579 9610816-2023-00411 9610816-2023-00406 1218950-2023-00546 1218950-2023-00547 1218950-2023-00548 1218950-2023-00549 9610816-2023-00399 1218950-2023-00550 1218950-2023-00552	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	1218950-2023-00556 1218950-2023-00535 9610816-2023-00394	
Under-Sensing	9614453-2024-01710 3008973940-2024-03081 9614453-2024-01675 3008973940-2024-03097 9614453-2024-01654 3008973940-2024-02897 3008973940-2024-02904 3008973940-2024-02815 3008973940-2024-02787 3008973940-2024-02794 9614453-2024-01475 9614453-2024-01478 9614453-2024-01440 9614453-2024-01370 3008973940-2024-02421 9614453-2024-01313 9614453-2024-01315 9614453-2024-01287 9614453-2024-01236 9614453-2024-01247 3008973940-2024-01966 9614453-2024-01025 3008973940-2024-01903 9614453-2024-00994 3008973940-2024-01815 3008973940-2024-01844 3008973940-2024-01848 3008973940-2024-01850 3008973940-2024-01861 3008973940-2024-01872 3008973940-2024-01770 3008973940-2024-01780 3008973940-2024-01781 9614453-2024-00975 3008973940-2024-01727 3008973940-2024-01730 3008973940-2024-01735	["No Clinical Signs Symptoms or Conditions"] (147)



## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	3008973940-2024-01736 3008973940-2024-01658 3008973940-2024-01665 3008973940-2024-01672 3008973940-2024-01601 3008973940-2024-01602 3008973940-2024-01625 3008973940-2024-01563 9614453-2024-00913 3008973940-2024-01484 9614453-2024-00835 3008973940-2024-01406 9614453-2024-00755 9614453-2024-00756 9614453-2024-00376 3008973940-2024-00604 9614453-2024-00228 3008973940-2024-00294 3008973940-2024-00124 9614453-2024-00051 9614453-2023-04718 9614453-2023-04663 3008973940-2023-08145 9614453-2023-04520 3008973940-2023-08080 3008973940-2023-07989 3008973940-2023-08000 3008973940-2023-07950 9614453-2023-04412 9614453-2023-04387 3008973940-2023-07887 9614453-2023-04388 9614453-2023-04391 3008973940-2023-07805 3008973940-2023-07709 3008973940-2023-07665 3008973940-2023-07653 9614453-2023-04259 9614453-2023-04260 9614453-2023-04261	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9614453-2023-04247 9614453-2023-04249 9614453-2023-04231 9614453-2023-04210 9614453-2023-04124 3008973940-2023-07290 3008973940-2023-07255 9614453-2023-03994 9614453-2023-03998 3008973940-2023-06985 3008973940-2023-06951 9614453-2023-03914 9614453-2023-03915 9614453-2023-03879 3008973940-2023-06853 9614453-2023-03811 9614453-2023-03788 3008973940-2023-06588 9614453-2023-03751 9614453-2023-03731 9614453-2023-03734 9614453-2023-03631 9614453-2023-03606 9614453-2023-03587 9614453-2023-03588 9614453-2023-03591 9614453-2023-03593 9614453-2023-03569 3008973940-2023-06222 9614453-2023-03535 9614453-2023-03536 3008973940-2023-06237 9614453-2023-03540 3008973940-2023-06240 9614453-2023-03543 9614453-2023-03498 3008973940-2023-06045 3008973940-2023-05985 9614453-2023-03366 3008973940-2023-05775	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9614453-2023-03297 9614453-2023-03300 3008973940-2023-05693 9614453-2023-03262 9614453-2023-03221 3008973940-2023-05554 9614453-2023-03147 9614453-2023-03106 9614453-2023-02996 9614453-2023-02971 9614453-2023-02956 3008973940-2023-05155 3008973940-2023-05071 3008973940-2023-05070 9614453-2023-02928 9614453-2023-02929 9614453-2023-02934 3008973940-2023-05024 9614453-2023-02884 9614453-2023-02887 9614453-2023-02883 3008973940-2023-04988 3008973940-2023-05009 9614453-2023-02896 3008973940-2023-04921 9614453-2023-02837 9614453-2023-02803 9614453-2023-02804 9614453-2023-02778 3008973940-2023-04651	
Over-Sensing	3008973940-2024-02904 9614453-2024-01568 3008973940-2024-02880 3008973940-2024-02692 9614453-2024-01462 9614453-2024-01440 9614453-2024-01441 9614453-2024-01370 9614453-2024-01247 3008973940-2024-02257	["No Clinical Signs Symptoms or Conditions"] (128)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9614453-2024-01150 3008973940-2024-01966 9614453-2024-01049 9614453-2024-01025 3008973940-2024-01881 3008973940-2024-01804 9614453-2024-00994 3008973940-2024-01805 3008973940-2024-01807 3008973940-2024-01810 3008973940-2024-01813 3008973940-2024-01815 3008973940-2024-01825 3008973940-2024-01844 9614453-2024-01002 3008973940-2024-01848 3008973940-2024-01850 3008973940-2024-01852 3008973940-2024-01855 3008973940-2024-01857 3008973940-2024-01859 3008973940-2024-01860 3008973940-2024-01863 3008973940-2024-01865 3008973940-2024-01869 3008973940-2024-01870 3008973940-2024-01872 3008973940-2024-01766 3008973940-2024-01768 3008973940-2024-01769 3008973940-2024-01770 3008973940-2024-01776 3008973940-2024-01777 3008973940-2024-01780 3008973940-2024-01781 9614453-2024-00975 3008973940-2024-01784 3008973940-2024-01727 3008973940-2024-01728 3008973940-2024-01730	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	3008973940-2024-01731 3008973940-2024-01733 3008973940-2024-01734 3008973940-2024-01735 3008973940-2024-01736 3008973940-2024-01646 3008973940-2024-01658 3008973940-2024-01665 3008973940-2024-01669 3008973940-2024-01672 3008973940-2024-01601 3008973940-2024-01602 3008973940-2024-01607 3008973940-2024-01563 9614453-2024-00913 3008973940-2024-01484 9614453-2024-00755 9614453-2024-00756 3008973940-2024-01167 9614453-2024-00499 3008973940-2024-00131 9614453-2024-00020 9614453-2024-00021 9614453-2023-04718 3008973940-2023-08145 3008973940-2023-07950 9614453-2023-04412 9614453-2023-04386 9614453-2023-04387 3008973940-2023-07887 9614453-2023-04391 3008973940-2023-07729 9614453-2023-04212 9614453-2023-04124 3008973940-2023-07290 9614453-2023-03994 3008973940-2023-06931 9614453-2023-03838 9614453-2023-03811 9614453-2023-03788	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9614453-2023-03734 3008973940-2023-06377 9614453-2023-03587 9614453-2023-03588 9614453-2023-03591 9614453-2023-03566 9614453-2023-03569 9614453-2023-03570 3008973940-2023-06216 9614453-2023-03536 9614453-2023-03537 3008973940-2023-06237 9614453-2023-03498 3008973940-2023-06045 9614453-2023-03427 3008973940-2023-05985 9614453-2023-03366 9614453-2023-03298 9614453-2023-03258 3008973940-2023-05554 9614453-2023-03119 9614453-2023-03120 9614453-2023-03106 9614453-2023-03025 9614453-2023-02996 9614453-2023-02971 9614453-2023-02928 9614453-2023-02929 3008973940-2023-05086 3008973940-2023-05000 3008973940-2023-05009 9614453-2023-02896 3008973940-2023-04966 3008973940-2023-04921 9614453-2023-02838 9614453-2023-02798 9614453-2023-02771 9614453-2023-02686	
No Audible Prompt/Feedback	1218950-2024-00302 9610816-2024-00228	["No Clinical Signs Symptoms or Conditions"] (100)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	1218950-2024-00251 9610816-2024-00208 9610816-2024-00202 1218950-2024-00267 1218950-2024-00256 1218950-2024-00262 1218950-2024-00246 9610816-2024-00186 1218950-2024-00241 1218950-2024-00235 1218950-2024-00227 1218950-2024-00223 1218950-2024-00200 1218950-2024-00173 9610816-2024-00106 1218950-2024-00136 9610816-2024-00083 1218950-2024-00092 1218950-2024-00077 9610816-2024-00054 9610816-2024-00040 9610816-2024-00006 9610816-2024-00030 1218950-2024-00029 9610816-2023-00692 9610816-2023-00687 9610816-2023-00664 1218950-2023-00958 1218950-2023-00957 9610816-2023-00659 9610816-2023-00668 9610816-2023-00663 9610816-2023-00650 9610816-2023-00621 1218950-2023-00901 9610816-2023-00636 1218950-2023-00883 9610816-2023-00581 9610816-2023-00609 1218950-2023-00870	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9610816-2023-00601 9610816-2023-00563 1218950-2023-00830 9610816-2023-00557 9610816-2023-00558 1218950-2023-00832 1218950-2023-00823 1218950-2023-00822 9610816-2023-00551 1218950-2023-00813 1218950-2023-00814 1218950-2023-00789 1218950-2023-00766 1218950-2023-00772 1218950-2023-00773 9610816-2023-00512 1218950-2023-00750 1218950-2023-00754 1218950-2023-00729 1218950-2023-00722 9610816-2023-00495 1218950-2023-00697 9610816-2023-00482 1218950-2023-00696 1218950-2023-00685 9610816-2023-00479 1218950-2023-00687 1218950-2023-00686 1218950-2023-00682 1218950-2023-00671 1218950-2023-00672 1218950-2023-00673 1218950-2023-00622 1218950-2023-00662 1218950-2023-00667 1218950-2023-00665 9610816-2023-00465 9610816-2023-00461 1218950-2023-00633 9610816-2023-00434	



## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9610816-2023-00422 9610816-2023-00423 1218950-2023-00585 1218950-2023-00576 1218950-2023-00577 9610816-2023-00405 1218950-2023-00561 1218950-2023-00559 1218950-2023-00558 1218950-2023-00541 1218950-2023-00553 9610816-2023-00400 1218950-2023-00555 1218950-2023-00543 1218950-2023-00544 9610816-2023-00398 1218950-2023-00532 1218950-2023-00528	
Failure to Transmit Record	3007208829-2023-00213 3007208829-2023-00200 3007208829-2023-00199 3007208829-2023-00190 3007208829-2023-00188 3007208829-2023-00189 3007208829-2023-00184 3007208829-2023-00183 3007208829-2023-00186 3007208829-2023-00185 3007208829-2023-00166 3007208829-2023-00182 3007208829-2023-00175 3007208829-2023-00176 3007208829-2023-00180 3007208829-2023-00171 3007208829-2023-00174 3007208829-2023-00172 3007208829-2023-00173 3007208829-2023-00181 3007208829-2023-00170 3007208829-2023-00162	["Unspecified Heart Problem"] (92)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	3007208829-2023-00167 3007208829-2023-00159 3007208829-2023-00163 3007208829-2023-00157 3007208829-2023-00169 3007208829-2023-00156 3007208829-2023-00155 3007208829-2023-00158 3007208829-2023-00152 3007208829-2023-00154 3007208829-2023-00165 3007208829-2023-00161 3007208829-2023-00151 3007208829-2023-00146 3007208829-2023-00147 3007208829-2023-00149 3007208829-2023-00150 3007208829-2023-00137 3007208829-2023-00141 3007208829-2023-00136 3007208829-2023-00134 3007208829-2023-00126 3007208829-2023-00115 3007208829-2023-00112 3007208829-2023-00114 3007208829-2023-00073 3007208829-2023-00099 3007208829-2023-00103 3007208829-2023-00110 3007208829-2023-00086 3007208829-2023-00090 3007208829-2023-00083 3007208829-2023-00098 3007208829-2023-00092 3007208829-2023-00072 3007208829-2023-00105 3007208829-2023-00093 3007208829-2023-00085 3007208829-2023-00109 3007208829-2023-00077	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	3007208829-2023-00116 3007208829-2023-00104 3007208829-2023-00096 3007208829-2023-00078 3007208829-2023-00079 3007208829-2023-00080 3007208829-2023-00067 3007208829-2023-00087 3007208829-2023-00070 3007208829-2023-00100 3007208829-2023-00101 3007208829-2023-00075 3007208829-2023-00102 3007208829-2023-00074 3007208829-2023-00091 3007208829-2023-00066 3007208829-2023-00069 3007208829-2023-00095 3007208829-2023-00097 3007208829-2023-00082 3007208829-2023-00076 3007208829-2023-00081 3007208829-2023-00088 3007208829-2023-00094 3007208829-2023-00068 3007208829-2023-00084 3007208829-2023-00089 3007208829-2023-00047 3007208829-2023-00049 3007208829-2023-00048	
Communication or Transmission Problem	2182208-2024-01854 9614453-2024-01702 9614453-2024-01703 9614453-2024-01658 9614453-2024-01571 9614453-2024-01572 2182208-2024-01660 2182208-2024-01508 9614453-2024-01117 9614453-2024-00881	["No Clinical Signs Symptoms or Conditions"] (61) ["Unspecified Heart Problem"] (1) ["Shock from Patient Lead(s)"] (1) ["Asystole" "Insufficient Information"] (1) ["Syncope/Fainting"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	2182208-2024-00696 9614453-2024-00228 9614453-2023-04716 9614453-2023-04691 9614453-2023-04692 9614453-2023-04594 3007208829-2023-00187 9614453-2023-04525 3008973940-2023-08049 9614453-2023-04448 9614453-2023-04449 9614453-2023-04430 9614453-2023-04390 9614453-2023-04361 9614453-2023-04365 9614453-2023-04275 9614453-2023-04269 9614453-2023-04184 9614453-2023-04185 9614453-2023-04187 9614453-2023-04160 9614453-2023-04146 9614453-2023-04064 9614453-2023-04044 9614453-2023-04002 9614453-2023-04003 9614453-2023-03960 9614453-2023-03753 9614453-2023-03690 2182208-2023-02792 9614453-2023-03445 9614453-2023-03447 9614453-2023-03448 9614453-2023-03387 9614453-2023-03348 9614453-2023-03349 9614453-2023-03350 9614453-2023-03351 1218950-2023-00666 9614453-2023-03260	

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9614453-2023-03263 9614453-2023-03215 9614453-2023-03217 9614453-2023-03219 9614453-2023-03220 9614453-2023-03208 9614453-2023-03121 9614453-2023-03122 9614453-2023-03052 9614453-2023-03053 9614453-2023-03055 9614453-2023-02970 9614453-2023-02784 3007208829-2023-00039 9614453-2023-02683	
Signal Artifact/Noise	9614453-2024-01404 9614453-2024-01315 9614453-2024-01235 3008973940-2024-02231 9614453-2024-01025 3008973940-2024-01807 3008973940-2024-01813 3008973940-2024-01825 2182207-2024-01629 3008973940-2024-01766 3008973940-2024-01777 3008973940-2024-01731 3008973940-2024-01734 3008973940-2024-01646 3008973940-2024-01658 9614453-2024-00907 3008973940-2024-01526 3008973940-2024-01167 3008973940-2024-01118 3008973940-2024-01011 9614453-2024-00525 3008973940-2024-00426 3008973940-2024-00088 9614453-2023-04694 9614453-2023-04656	["No Clinical Signs Symptoms or Conditions"] (38) ["Burning Sensation"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	3008973940-2023-08145 3008973940-2023-07887 3008973940-2023-07661 9614453-2023-04247 9614453-2023-04159 3008973940-2023-07290 9614453-2023-03879 9614453-2023-03733 3008973940-2023-06471 3008973940-2023-05770 3008973940-2023-05554 9614453-2023-03120 3008973940-2023-04995 3008973940-2023-05009	
Adverse Event Without Identified Device or Use Problem	9614453-2024-01677 9614453-2024-01526 9610816-2024-00195 9614453-2024-01026 9614453-2024-00908 3008973940-2024-01576 2182208-2024-00364 9614453-2024-00002 2133409-2023-00077 9614453-2023-04717 3008973940-2023-07929 2182208-2023-03552 3007208829-2023-00164 1218950-2023-00872 2133409-2023-00071 2133409-2023-00072 9610816-2023-00580 9614453-2023-03887 1218950-2023-00818 9614453-2023-03856 2133409-2023-00064 1218950-2023-00746 1218950-2023-00747 3007208829-2023-00053 2182208-2023-02757 3008973940-2023-05936	["Perforation"] (1) ["Purulent Discharge" "Erythema" "Unspecified Infection" "Pain" "Discomfort" "Swelling/ Edema"] (1) ["No Clinical Signs Symptoms or Conditions"] (2) ["Wound Dehiscence" "Erythema" "Unspecified Infection"] (1) ["Unspecified Infection"] (3) ["Purulent Discharge" "Erythema" "Unspecified Infection" "Itching Sensation"] (1) ["Hemorrhage/Blood Loss/Bleeding" "Pain"] (1) ["Erosion" "Unspecified Infection"] (1) ["Hemorrhage/Blood Loss/Bleeding" "Blister" "Skin Inflammation/ Irritation"] (1) ["Wound Dehiscence" "Hemorrhage/Blood Loss/Bleeding"] (1) ["Rash" "Skin Inflammation/ Irritation"] (1) ["Stroke/CVA"] (1) ["Insufficient Information"] (3) ["Skin Inflammation/ Irritation"] (1) ["Burn(s)"] (1) ["Cyanosis" "Insufficient Information"] (1) ["Cardiac Arrest"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	2133409-2023-00057 1218950-2023-00666 1218950-2023-00659 2133409-2023-00049 3004209178-2023-15265 9614453-2023-02885 9614453-2023-02864	["Chest Pain"] (1) ["Cardiac Arrest" "Perforation" "Insufficient Information"] (1) ["Cardiac Arrest" "Insufficient Information"] (1) ["Unspecified Infection" "Pain"] (1) ["Hematoma"] (1) ["Caustic/Chemical Burns"] (1) ["Asystole" "Insufficient Information"] (1) ["Superficial (First Degree) Burn"] (1) ["Pain"] (2) ["Appropriate Term / Code Not Available"] (1)
Defective Alarm	1218950-2024-00249 1218950-2024-00199 9610816-2024-00116 1218950-2024-00150 9610816-2024-00059 9610816-2023-00686 1218950-2023-00955 1218950-2023-00911 9610816-2023-00641 9610816-2023-00640 1218950-2023-00890 9610816-2023-00626 9610816-2023-00613 1218950-2023-00869 1218950-2023-00871 9610816-2023-00589 9610816-2023-00574 9610816-2023-00569 9610816-2023-00565 9610816-2023-00552 9610816-2023-00543 9610816-2023-00537 9610816-2023-00535 1218950-2023-00776 1218950-2023-00767 9610816-2023-00521 1218950-2023-00691	["No Clinical Signs Symptoms or Conditions"] (23) ["Ventricular Fibrillation"] (2) ["Asystole" "No Clinical Signs Symptoms or Conditions"] (1) ["Unspecified Respiratory Problem" "Insufficient Information"] (1) ["Cardiac Arrest"] (3) ["Insufficient Information"] (1) ["Bradycardia"] (1) ["Hypoxia" "Insufficient Information" "No Clinical Signs Symptoms or Conditions"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	1218950-2023-00688 9610816-2023-00473 9610816-2023-00466 1218950-2023-00525 1218950-2023-00526 1218950-2023-00530	
Reset Problem	3008973940-2024-03117 9614453-2024-01512 9614453-2024-01513 3008973940-2024-02628 9614453-2024-01173 3008973940-2024-01964 3008973940-2024-01980 2182207-2024-01620 3008973940-2024-01247 2182208-2024-00688 9614453-2024-00478 3008973940-2024-00733 9614453-2024-00376 9614453-2024-00027 9614453-2023-04565 3008973940-2023-07890 3008973940-2023-06902 3008973940-2023-06796 9614453-2023-03865 3008973940-2023-06624 3008973940-2023-06115 9614453-2023-03123 3008973940-2023-05024 3008973940-2023-05039 3008973940-2023-04982 3008973940-2023-04665	["No Clinical Signs Symptoms or Conditions"] (25) ["Discomfort" "No Clinical Signs Symptoms or Conditions"] (1)
Device Alarm System	1218950-2024-00295 1218950-2024-00271 1218950-2024-00233 1218950-2024-00232 1218950-2024-00234 1218950-2024-00008 9610816-2023-00608 1218950-2023-00883	["Cardiac Arrest"] (2) ["No Clinical Signs Symptoms or Conditions"] (18) ["Insufficient Information"] (2) ["Hypoxia"] (1) ["Low Blood Pressure/ Hypotension" "No Clinical Signs Symptoms or Conditions"] (1) ["Bradycardia"] (1)



## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9610816-2023-00619 9610816-2023-00610 1218950-2023-00865 9610816-2023-00549 1218950-2023-00795 1218950-2023-00760 9610816-2023-00521 9610816-2023-00460 9610816-2023-00451 1218950-2023-00635 1218950-2023-00638 9610816-2023-00443 1218950-2023-00587 1218950-2023-00573 1218950-2023-00567 1218950-2023-00542 1218950-2023-00534 1218950-2023-00536	["Cardiac Arrest" "Insufficient Information"] (1)
Battery Problem	9614453-2024-01654 9614453-2024-01049 9614453-2024-00881 3008973940-2024-00913 2182208-2023-03784 3008973940-2023-08049 9614453-2023-04260 9614453-2023-04210 9614453-2023-04212 9614453-2023-03954 9614453-2023-03865 9614453-2023-03733 9614453-2023-03569 9614453-2023-03540 9614453-2023-03427 9614453-2023-03348 9614453-2023-03208 9614453-2023-03106 9614453-2023-03055 9614453-2023-02928 9614453-2023-02908 3008973940-2023-05000	["No Clinical Signs Symptoms or Conditions"] (24)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	3008973940-2023-04988 3008973940-2023-04972	
Migration or Expulsion of Device	9614453-2024-01607 2182208-2024-01693 9614453-2024-01528 9614453-2024-01463 9614453-2024-00677 3008973940-2024-00581 3008973940-2024-00584 9614453-2023-04366 3008973940-2023-07539 3008973940-2023-07218 9614453-2023-03954 3008973940-2023-06909 9614453-2023-03767 9614453-2023-03735 9614453-2023-03331 9614453-2023-03304 9614453-2023-03141 9614453-2023-03083 9614453-2023-02800 9614453-2023-02781 9614453-2023-02684	["No Clinical Signs Symptoms or Conditions"] (12) ["Erosion" "No Clinical Signs Symptoms or Conditions"] (1) ["Wound Dehiscence"] (1) ["Erosion"] (1) ["Unspecified Infection"] (1) ["Wound Dehiscence" "Pain"] (1) ["Pain"] (3) ["Impaired Healing"] (1)
Overheating of Device	2133409-2024-00025 2133409-2024-00024 2133409-2024-00008 2133409-2024-00007 2133409-2023-00076 2133409-2023-00079 1218950-2023-00873 2133409-2023-00069 9610816-2023-00564 2133409-2023-00062 2133409-2023-00058 2133409-2023-00051 2133409-2023-00056 2133409-2023-00052 2133409-2023-00048	["No Clinical Signs Symptoms or Conditions"] (11) ["Superficial (First Degree) Burn" "Blister"] (1) ["Superficial (First Degree) Burn"] (1) ["Burn(s)"] (2)
Unable to Obtain Readings	3008973940-2024-02881 9614453-2024-01150	["No Clinical Signs Symptoms or Conditions"] (11)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	9614453-2024-00830 3008973940-2024-00305 2182208-2023-03633 9610816-2023-00545 3008973940-2023-06617 9614453-2023-03669 9610816-2023-00459 3008973940-2023-05528 3008973940-2023-05295 9614453-2023-02976 3008973940-2023-05086	["Arrhythmia" "Insufficient Information"] (1) ["Cardiac Arrest"] (1)
Failure to Interrogate	9614453-2024-01513 9614453-2024-00676 2182208-2023-03797 9614453-2023-04059 9614453-2023-04060 3008973940-2023-07147 9614453-2023-04006 9614453-2023-03865 2182207-2023-02180 9614453-2023-03346 9614453-2023-03050 9614453-2023-02908 9614453-2023-02886	["No Clinical Signs Symptoms or Conditions"] (13)
Device Sensing Problem	9614453-2024-01404 3008973940-2024-01903 9614453-2024-00830 3008973940-2024-01441 3008973940-2024-00426 9614453-2023-04695 2182208-2023-03784 3008973940-2023-07478 3008973940-2023-06991 3008973940-2023-06006 3008973940-2023-05554 9614453-2023-03084	["No Clinical Signs Symptoms or Conditions"] (12)
Melted	2133409-2024-00025 2133409-2024-00008 2133409-2024-00007 2133409-2023-00079	["No Clinical Signs Symptoms or Conditions"] (9) ["Superficial (First Degree) Burn" "Blister"] (1) ["Superficial (First Degree) Burn"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
	2133409-2023-00069 2133409-2023-00065 2133409-2023-00067 2133409-2023-00066 2133409-2023-00062 2133409-2023-00059 2133409-2023-00053	
Undefined Problem	MW5153976 MW5153882 MW5153506 MW5148828 MW5148829 MW5148830 MW5148831 MW5148180 MW5147889 MW5147890 17867753	["Pain" "Burning Sensation" "Partial thickness (Second Degree) Burn"] (1) ["Hemorrhage/Blood Loss/Bleeding"] (1) ["Superficial (First Degree) Burn" "Shock from Patient Lead(s)"] (1) ["No Clinical Signs Symptoms or Conditions"] (4) ["Unspecified Heart Problem"] (1) ["Erythema" "Hypersensitivity/Allergic reaction" "Itching Sensation" "Skin Inflammation/ Irritation"] (1) ["Hemorrhage/Blood Loss/Bleeding" "Itching Sensation" "Localized Skin Lesion" "Skin Inflammation/ Irritation"] (1) ["Wound Dehiscence" "Fall" "Pain"] (1)
Electromagnetic Interference	9614453-2024-01025 9614453-2024-00907 3008973940-2024-01336 3008973940-2024-01118 3008973940-2023-08145 3008973940-2023-07290 9614453-2023-03733 3008973940-2023-05770 3008973940-2023-05554	["No Clinical Signs Symptoms or Conditions"] (9)
Insufficient Information	1218950-2023-00975 2182208-2023-03759 1218950-2023-00933 MW5131203 MW5135547 MW5142350 MW5143326 1218950-2023-00531	["Insufficient Information" "No Clinical Signs Symptoms or Conditions"] (1) ["No Clinical Signs Symptoms or Conditions"] (1) ["Insufficient Information"] (5) ["Unspecified Infection" "Inflammation"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
Appropriate Term/Code Not Available	2182208-2024-01688 2182208-2024-01638 3008973940-2024-02650 2182208-2023-02900 9614453-2023-03105 9614453-2023-02927 9614453-2023-02862	["No Clinical Signs Symptoms or Conditions"] (6) ["Insufficient Information"] (1)
Audible Prompt/Feedback Problem	1218950-2024-00272 1218950-2024-00174 9610816-2024-00083 1218950-2023-00743 1218950-2023-00696 1218950-2023-00658 1218950-2023-00557	["No Clinical Signs Symptoms or Conditions"] (7)
Biocompatibility	2133409-2024-00010 2133409-2024-00006 2133409-2023-00073 2133409-2023-00075 2133409-2023-00070 2133409-2023-00046 2133409-2023-00047	["Discomfort" "Superficial (First Degree) Burn"] (1) ["Shock" "Numbness" "Skin Inflammation/Irritation"] (1) ["Skin Inflammation/Irritation"] (2) ["Skin Tears" "Blister" "Skin Inflammation/Irritation"] (2) ["Reaction to Medicinal Component of Device"] (1)
Delayed Alarm	9610816-2024-00134 9610816-2023-00693 9610816-2023-00665 1218950-2023-00785 1218950-2023-00784	["No Clinical Signs Symptoms or Conditions"] (5)
No Device Output	9610816-2024-00093 1218950-2023-00921 1218950-2023-00669 1218950-2023-00554 1218950-2023-00553	["Insufficient Information" "No Clinical Signs Symptoms or Conditions"] (1) ["No Clinical Signs Symptoms or Conditions"] (4)
Low Audible Alarm	1218950-2024-00209 1218950-2024-00116 1218950-2023-00902 1218950-2023-00570	["No Clinical Signs Symptoms or Conditions"] (4)
Wireless Communication	1218950-2023-00941 3007208829-2023-00187	["Insufficient Information"] (1) ["Unspecified Heart Problem"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
Problem	1218950-2023-00581 3007208829-2023-00039	["No Clinical Signs Symptoms or Conditions"] (1) ["Syncope/Fainting"] (1)
Smoking	2133409-2023-00066 2133409-2023-00060 2133409-2023-00052 2133409-2023-00055	["No Clinical Signs Symptoms or Conditions"] (3) ["Superficial (First Degree) Burn"] (1)
Decreased Sensitivity	3008973940-2024-03081 3008973940-2024-02272 3008973940-2023-07257	["No Clinical Signs Symptoms or Conditions"] (3)
Protective Measures Problem	9610816-2024-00223 1218950-2023-00975 1218950-2023-00595	["No Clinical Signs Symptoms or Conditions"] (2) ["Insufficient Information" "No Clinical Signs Symptoms or Conditions"] (1)
Device Emits Odor	2133409-2024-00024 2133409-2023-00068 2133409-2023-00053	["No Clinical Signs Symptoms or Conditions"] (3)
Inaudible or Unclear Audible Prompt/Feedback	9610816-2024-00132 1218950-2023-00902 1218950-2023-00661	["No Clinical Signs Symptoms or Conditions"] (3)
Device-Device Incompatibility	3008973940-2024-01118 3008973940-2024-00426 3008973940-2023-08049	["No Clinical Signs Symptoms or Conditions"] (3)
Use of Device Problem	2182208-2024-00364 3007208829-2023-00194 3007208829-2023-00122	["Hemorrhage/Blood Loss/Bleeding" "Pain"] (1) ["Stroke/CVA"] (1) ["Insufficient Information"] (1)
Inappropriate or Unexpected Reset	3008973940-2024-00310 9614453-2023-04565 3008973940-2023-04967	["No Clinical Signs Symptoms or Conditions"] (3)
Pacing Problem	2182208-2023-03784 MW5135570 MW5143233	["No Clinical Signs Symptoms or Conditions"] (1) ["Failure of Implant"] (2)
Thermal Decomposition of Device	2133409-2023-00076 2133409-2023-00059 2133409-2023-00053	["No Clinical Signs Symptoms or Conditions"] (3)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
Device Fell	9610816-2023-00540 9610816-2023-00519 9610816-2023-00498	["No Clinical Signs Symptoms or Conditions"] (3)
Unintended Electrical Shock	2133409-2024-00023 2133409-2024-00015	["Electric Shock"] (1) ["Pain" "Electric Shock"] (1)
Incorrect Inadequate or Imprecise Result or Readings	9610816-2024-00117 1218950-2023-00600	["Insufficient Information" "No Clinical Signs Symptoms or Conditions"] (1) ["No Clinical Signs Symptoms or Conditions"] (1)
Material Separation	2133409-2024-00014 2133409-2024-00002	["No Clinical Signs Symptoms or Conditions"] (2)
Inappropriate Audible Prompt/Feedback	1218950-2024-00077 9610816-2023-00663	["No Clinical Signs Symptoms or Conditions"] (2)
Electrical /Electronic Property Problem	3008973940-2024-00088 2133409-2023-00074	["Burning Sensation"] (1) ["No Clinical Signs Symptoms or Conditions"] (1)
Manufacturing Packaging or Shipping Problem	3008642652-2023-11834 3008642652-2023-11841	["Irregular Pulse"] (2)
Break	2133409-2023-00074 9614453-2023-03088	["No Clinical Signs Symptoms or Conditions"] (2)
Human-Device Interface Problem	3008973940-2023-07257 3008973940-2023-04988	["No Clinical Signs Symptoms or Conditions"] (2)
Temperature Problem	2133409-2023-00065 2133409-2023-00067	["No Clinical Signs Symptoms or Conditions"] (2)
Alarm Not Visible	1218950-2023-00834 1218950-2023-00733	["No Clinical Signs Symptoms or Conditions"] (2)
Product Quality Problem	MW5139423 MW5140548	["Failure of Implant"] (2)
Noise Audible	2133409-2024-00024	["No Clinical Signs Symptoms or Conditions"] (1)

## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
Disconnection	1218950-2024-00234	["No Clinical Signs Symptoms or Conditions"] (1)
Unintended System Motion	9610816-2024-00137	["No Clinical Signs Symptoms or Conditions"] (1)
Fracture	2133409-2024-00014	["No Clinical Signs Symptoms or Conditions"] (1)
False Alarm	1218950-2024-00118	["Pneumonia" "Respiratory Failure" "Fibrosis" "Insufficient Information"] (1)
Device Markings/Labelling Problem	3008973940-2024-00913	["No Clinical Signs Symptoms or Conditions"] (1)
Difficult to Remove	2133409-2024-00002	["No Clinical Signs Symptoms or Conditions"] (1)
Data Problem	2182208-2023-03797	["No Clinical Signs Symptoms or Conditions"] (1)
Solder Joint Fracture	2133409-2023-00078	["Electric Shock"] (1)
Failure to Charge	2133409-2023-00080	["No Clinical Signs Symptoms or Conditions"] (1)
Complete Loss of Power	2133409-2023-00080	["No Clinical Signs Symptoms or Conditions"] (1)
Premature Discharge of Battery	1218950-2023-00933	["Insufficient Information"] (1)
Positioning Problem	3008973940-2023-07290	["No Clinical Signs Symptoms or Conditions"] (1)
Display or Visual Feedback Problem	1218950-2023-00831	["No Clinical Signs Symptoms or Conditions"] (1)
Incorrect Measurement	9610816-2023-00544	["Insufficient Information"] (1)



## DSI MAUDE Problems Summary

Product Problems	MDR References	Patient Problems
Mechanical Problem	1218950-2023-00760	["No Clinical Signs Symptoms or Conditions"] (1)
Image Display Error/Artifact	9610816-2023-00516	["Insufficient Information"] (1)
Moisture Damage	2133409-2023-00060	["Superficial (First Degree) Burn"] (1)
Sparking	2133409-2023-00063	["Shock from Patient Lead(s)"] (1)
Fire	2133409-2023-00058	["No Clinical Signs Symptoms or Conditions"] (1)
Unexpected Shutdown	1218950-2023-00678	["Stomach Ulceration" "Insufficient Information"] (1)
Telemetry Discrepancy	1218950-2023-00654	["Insufficient Information"] (1)
Excessive Heating	2133409-2023-00054	["No Clinical Signs Symptoms or Conditions"] (1)
Patient-Device Incompatibility	3007208829-2023-00043	["Cellulitis" "Contact Dermatitis"] (1)
Material Integrity Problem	2133409-2023-00045	["No Clinical Signs Symptoms or Conditions"] (1)
Therapeutic or Diagnostic Output Failure	MW5141019	["Insufficient Information"] (1)
Device Difficult to Setup or Prepare	2182208-2023-02152	["No Clinical Signs Symptoms or Conditions"] (1)
Device Difficult to Program or Calibrate	2182208-2023-02152	["No Clinical Signs Symptoms or Conditions"] (1)
Contamination	1218950-2023-00531	["Insufficient Information"] (1)

## DSI MAUDE Problems Summary

### Data Overview – Device Information

Product Problems	Manufacturers	Device Brands	Product Codes
No Audible Alarm	CRITIKON DE MEXICO S. DE R.L. DE C.V. (5) PHILIPS MEDICAL SYSTEMS (169) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (68)	CIC PRO (5) INTELLIVUE MX40 802.11A/B/G (4) MX40 1.4 GHZ SMART HOPPING (129) INTELLIVUE MP50 (3) INTELLIVUE MULTI MEASUREMENT SERVER X2 (37) INTELLIVUE MX40 2.4GHZ (20) INTELLIVUE MP2 (3) INTELLIVUE MX800 PATIENT MONITOR (9) INTELLIVUE MX40 WLAN (9) INTELLIVUE MP5 (4) INTELLIVUE MP50 PATIENT MONITOR (1) TELE MX40 2.4 GHZ ECG &SP02 EXCHANGE (1) TELE MX40 1.4 GHZ ECG AND SP02 EX (2) INTELLIVUE MX700 PATIENT MONITOR (5) UNKNOWN PATIENT MONITORING BEDSIDE MONITOR (1) INTELLIVUE MP60 (3) MX40 PATIENT WEARABLE MONITOR (1) INTELLIVUE MP70 (1) MX40 2.4 GHZ SMART HOPPING (2) TELE MX40 2.4 GHZ ECG ONLY EXCHANGE (1) MP40 (1)	DSI (241) MHX (1)
Under-Sensing	MEDTRONIC EUROPE	REVEAL LINQ (147)	DSI (147)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
	SARL (80) MEDTRONIC SINGAPORE OPERATIONS (67)		
Over-Sensing	MEDTRONIC SINGAPORE OPERATIONS (72) MEDTRONIC EUROPE SARL (56)	REVEAL LINQ (128)	DSI (128)
No Audible Prompt/Feedback	PHILIPS MEDICAL SYSTEMS (63) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (38)	MX40 1.4 GHZ SMART HOPPING (40) INTELLIVUE MULTI MEASUREMENT SERVER X2 (24) INTELLIVUE MX40 2.4GHZ (10) INTELLIVUE MX800 PATIENT MONITOR (4) INTELLIVUE MX40 WLAN (3) INTELLIVUE MX40 802.11A/B/G (2) TELE PWM 802.11A/B/G ECG&SP02 EX NON US (2) INTELLIVUE MP2 (1) INTELLIVUE MP50 PATIENT MONITOR (1) INTELLIVUE MX700 PATIENT MONITOR (3) TELE MX40 2.4 GHZ ECG &SP02 EXCHANGE (1) INTELLIVUE MP5 (4) MX40 PATIENT WEARABLE MONITOR (2) 4003409 (1) MX40 2.4 GHZ SMART HOPPING (1) TELE MX40 1.4 GHZ ECG AND SP02 EX (1) INTELLIVUE MX600 PATIENT MONITOR (1)	DSI (100) MHX (1)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
Failure to Transmit Record	IRHYTHM TECHNOLOGIES INC (88) IRHYTHM TECHNOLOGIES IN (1) RHYTHM TECHNOLOGIES INC (3)	ZIO AT (91)	DSI (92)
Communication or Transmission Problem	MEDTRONIC INC. (5) MEDTRONIC EUROPE SARL (56) IRHYTHM TECHNOLOGIES INC (2) MEDTRONIC SINGAPORE OPERATIONS (1) PHILIPS MEDICAL SYSTEMS (1)	PATIENT CONNECTOR (5) REVEAL LINQ (56) ZIO AT (2) INTELLIVUE MX40 2.4GHZ (1) REVEAL XT (1)	DSI (65)
Signal Artifact/Noise	MEDTRONIC EUROPE SARL (13) MEDTRONIC SINGAPORE OPERATIONS (26)	REVEAL XT (1) REVEAL LINQ (38)	DSI (39)
Adverse Event Without Identified Device or Use Problem	MEDTRONIC EUROPE SARL (10) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (2) MEDTRONIC SINGAPORE OPERATIONS (5) MEDTRONIC INC. (1) BRAEMAR MANUFACTURING LLC (6) IRHYTHM TECHNOLOGIES INC (2) PHILIPS MEDICAL SYSTEMS (6) MEDTRONIC MED REL MEDTRONIC PUERTO RICO (1)	REVEAL LINQ INSERTION TOOLS (2) REVEAL LINQ (14) INTELLIVUE MX700 PATIENT MONITOR (1) C6 MCOT PPM (6) ZIO AT (2) MX40 1.4 GHZ SMART HOPPING (2) INTELLIVUE MP50 (1) MX40 PATIENT WEARABLE MONITOR (3) INTELLIVUE MX40 2.4GHZ (1) REVEAL XT (1)	DSI (33)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
Defective Alarm	PHILIPS MEDICAL SYSTEMS (15) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (18)	MX40 1.4 GHZ SMART HOPPING (7) INTELLIVUE MP70 (5) INTELLIVUE MX40 WLAN (4) INTELLIVUE MULTI MEASUREMENT SERVER X2 (5) INTELLIVUE MP50 (1) INTELLIVUE MX800 PATIENT MONITOR (2) INTELLIVUE MX40 2.4GHZ (3) INTELLIVUE MP5 (3) INTELLIVUE MX40 802.11A/B/G (865352) (1) INTELLIVUE MX700 PATIENT MONITOR (1) INTELLIVUE MP60 (1)	DSI (33)
Reset Problem	MEDTRONIC SINGAPORE OPERATIONS (16) MEDTRONIC EUROPE SARL (9) MEDTRONIC INC. (1)	REVEAL LINQ (26)	DSI (26)
Device Alarm System	PHILIPS MEDICAL SYSTEMS (18) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (8)	MX40 1.4 GHZ SMART HOPPING (11) TELE MX40 1.4 GHZ ECG AND SP02 EX (1) INTELLIVUE MX800 PATIENT MONITOR (3) INTELLIVUE MP70 (1) INTELLIVUE MX700 PATIENT MONITOR (1) INTELLIVUE MX40 2.4GHZ (3) INTELLIVUE MULTI MEASUREMENT SERVER X2 (2) INTELLIVUE MP60 (1)	DSI (26)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
		PATIENT INFORMATION CENTER IX (1) TELE MX40 2.4 GHZ ECG ONLY EXCHANGE (1) INTELLIVUE MX40 WLAN (1)	
Battery Problem	MEDTRONIC EUROPE SARL (18) MEDTRONIC SINGAPORE OPERATIONS (5) MEDTRONIC INC. (1)	REVEAL LINQ (23) MEDTRONIC ILR (1)	DSI (24)
Migration or Expulsion of Device	MEDTRONIC EUROPE SARL (15) MEDTRONIC INC. (1) MEDTRONIC SINGAPORE OPERATIONS (5)	REVEAL LINQ (21)	DSI (21)
Overheating of Device	BRAEMAR MANUFACTURING LLC (13) PHILIPS MEDICAL SYSTEMS (1) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1)	C6 MCOT PPM (12) MX40 1.4 GHZ SMART HOPPING (1) INTELLIVUE NMT MODULE (1) C6 PATCH VERIZON (1)	DSI (15)
Unable to Obtain Readings	MEDTRONIC SINGAPORE OPERATIONS (6) MEDTRONIC EUROPE SARL (4) MEDTRONIC INC. (1) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (2)	REVEAL LINQ (11) INTELLIVUE MULTI MEASUREMENT SERVER X2 (1) INTELLIVUE MX800 PATIENT MONITOR (1)	DSI (13)
Failure to Interrogate	MEDTRONIC EUROPE SARL (10) MEDTRONIC INC. (1) MEDTRONIC SINGAPORE OPERATIONS (2)	REVEAL LINQ (12) REVEAL LINQ MOBILE MANAGER APP (1)	DSI (13)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
Device Sensing Problem	MEDTRONIC EUROPE SARL (4) MEDTRONIC SINGAPORE OPERATIONS (7) MEDTRONIC INC. (1)	REVEAL XT (1) REVEAL LINQ (10) MEDTRONIC ILR (1)	DSI (12)
Melted	BRAEMAR MANUFACTURING LLC (11)	C6 MCOT PPM (11)	DSI (11)
Undefined Problem	PHILIPS NORTH AMERICA LLC (1) MEDTRONIC INC. (2) BOSTON SCIENTIFIC CARDIAC DIAGNOSTIC TECHNOLOGIES INC. (4) GE HEALTHCARE TECHNOLOGY / GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC. (4)	MCOT BIOTEL HEART (1) LOOP RECORDER (1) CARDIAC EVENT MONITORING (CEM) B (1) GE HEALTHCARE TECHNOLOGY CSCS V3 (4) BOSTON SCIENTIFIC BODYGUARDIAN MINI PLUS (1) MINI HEART MONITOR (2) REVEAL LINQ <sub>i</sub> (1)	DSI (11)
Electromagnetic Interference	MEDTRONIC EUROPE SARL (3) MEDTRONIC SINGAPORE OPERATIONS (6)	REVEAL LINQ (9)	DSI (9)
Insufficient Information	PHILIPS MEDICAL SYSTEMS (4) MEDTRONIC INC. (1) MEDTRONIC (4)	TELE MX40 1.4 GHZ ECG AND SP02 EX (2) MEDTRONIC ILR (1) 1.4 GHZ INTELLIVUE TELE TRX (1) UNKNOWN PATIENT MONITORING TELE (1) DETECTOR AND ALARM ARRHYTHMIA (3) REVEAL (1)	DSI (8) MHX (1)
Appropriate Term/Code Not	MEDTRONIC INC. (3) MEDTRONIC SINGAPORE	MEDTRONIC ILR (2) REVEAL LINQ (5)	DSI (7)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
Available	OPERATIONS (2) MEDTRONIC EUROPE SARL (2)		
Audible Prompt/Feedback Problem	PHILIPS MEDICAL SYSTEMS (6) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1)	TELE MX40 1.4 GHZ ECG AND SP02 EX (1) MX40 1.4 GHZ SMART HOPPING (4) INTELLIVUE MULTI MEASUREMENT SERVER X2 (1) INTELLIVUE MX40 2.4GHZ (1)	DSI (7)
Biocompatibility	BRAEMAR MANUFACTURING LLC (7)	C6 MCOT PPM (5) MCOT C6 (1) EPATCH V2 MB (1)	DSI (7)
Delayed Alarm	PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (3) PHILIPS MEDICAL SYSTEMS (2)	INTELLIVUE MULTI MEASUREMENT SERVER X2 (1) INTELLIVUE MP70 (2) MX40 1.4 GHZ SMART HOPPING (2)	DSI (5)
No Device Output	PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1) PHILIPS MEDICAL SYSTEMS (4)	MP40 (1) MX40 1.4 GHZ SMART HOPPING (3) INTELLIVUE MX40 2.4GHZ (1)	DSI (5)
Low Audible Alarm	PHILIPS MEDICAL SYSTEMS (4)	MX40 1.4 GHZ SMART HOPPING (4)	DSI (4)
Wireless Communication Problem	PHILIPS MEDICAL SYSTEMS (2) IRHYTHM TECHNOLOGIES INC (2)	INTELLIVUE MX40 802.11A/B/G (1) ZIO AT (2) MX40 1.4 GHZ SMART HOPPING (1)	DSI (4)



## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
Smoking	BRAEMAR MANUFACTURING LLC (4)	C6 MCOT PPM (4)	DSI (4)
Decreased Sensitivity	MEDTRONIC SINGAPORE OPERATIONS (3)	REVEAL LINQ (3)	DSI (3)
Protective Measures Problem	PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1) PHILIPS MEDICAL SYSTEMS (2)	INTELLIVUE MX800 PATIENT MONITOR (1) TELE MX40 1.4 GHZ ECG AND SP02 EX (1) MX40 1.4 GHZ SMART HOPPING (1)	DSI (3)
Device Emits Odor	BRAEMAR MANUFACTURING LLC (3)	C6 MCOT PPM (3)	DSI (3)
Inaudible or Unclear Audible Prompt/Feedback	PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1) PHILIPS MEDICAL SYSTEMS (2)	INTELLIVUE MULTI MEASUREMENT SERVER X2 (1) MX40 1.4 GHZ SMART HOPPING (1) INTELLIVUE MX40 2.4GHZ (1)	DSI (3)
Device-Device Incompatibility	MEDTRONIC SINGAPORE OPERATIONS (3)	REVEAL LINQ (3)	DSI (3)
Use of Device Problem	MEDTRONIC INC. (1) IRHYTHM TECHNOLOGIES INC (2)	REVEAL LINQ INSERTION TOOLS (1) ZIO AT (2)	DSI (3)
Inappropriate or Unexpected Reset	MEDTRONIC SINGAPORE OPERATIONS (2) MEDTRONIC EUROPE SARL (1)	REVEAL LINQ (3)	DSI (3)
Pacing Problem	MEDTRONIC INC. (1) MEDTRONIC (2)	MEDTRONIC ILR (1) DETECTOR AND ALARM ARRHYTHMIA (2)	DSI (3)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
Thermal Decomposition of Device	BRAEMAR MANUFACTURING LLC (3)	C6 MCOT PPM (3)	DSI (3)
Device Fell	PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (3)	INTELLIVUE MP70 (1) INTELLIVUE MX700 PATIENT MONITOR (1) INTELLIVUE MP50 (1)	DSI (3)
Unintended Electrical Shock	BRAEMAR MANUFACTURING LLC (2)	C6 MCOT PPM (2)	DSI (2)
Incorrect Inadequate or Imprecise Result or Readings	PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1) PHILIPS MEDICAL SYSTEMS (1)	INTELLIVUE MP5 (1) MX40 1.4 GHZ SMART HOPPING (1)	DSI (2)
Material Separation	BRAEMAR MANUFACTURING LLC (2)	C6 MCOT PPM (2)	DSI (2)
Inappropriate Audible Prompt/Feedback	PHILIPS MEDICAL SYSTEMS (1) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1)	MX40 1.4 GHZ SMART HOPPING (1) INTELLIVUE MULTI MEASUREMENT SERVER X2 (1)	DSI (2)
Electrical /Electronic Property Problem	MEDTRONIC SINGAPORE OPERATIONS (1) BRAEMAR MANUFACTURING LLC (1)	REVEAL LINQ (1) C6 MCOT PPM (1)	DSI (2)
Manufacturing Packaging or Shipping Problem	ZOLL MANUFACTURING CORPORATION (2)	ZOLL CARDIAC MONITOR (2)	DSI (2)
Break	BRAEMAR MANUFACTURING LLC (1) MEDTRONIC EUROPE SARL (1)	C6 MCOT PPM (1) REVEAL LINQ (1)	DSI (2)
Human-Device	MEDTRONIC SINGAPORE	REVEAL LINQ (2)	DSI (2)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
Interface Problem	OPERATIONS (2)		
Temperature Problem	BRAEMAR MANUFACTURING LLC (2)	C6 MCOT PPM (2)	DSI (2)
Alarm Not Visible	PHILIPS MEDICAL SYSTEMS (2)	MX40 1.4 GHZ SMART HOPPING (2)	DSI (2)
Product Quality Problem	ST. JUDE MEDICAL (1) ABBOTT (1)	DETECTOR AND ALARM ARRHYTHMIA (2)	DSI (2)
Noise Audible	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
Disconnection	PHILIPS MEDICAL SYSTEMS (1)	TELE MX40 1.4 GHZ ECG AND SP02 EX (1)	DSI (1)
Unintended System Motion	PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1)	INTELLIVUE FMS-4 (1)	DSI (1)
Fracture	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
False Alarm	PHILIPS MEDICAL SYSTEMS (1)	INTELLIVUE MX40 2.4GHZ (1)	DSI (1)
Device Markings/Labelling Problem	MEDTRONIC SINGAPORE OPERATIONS (1)	REVEAL LINQ (1)	DSI (1)
Difficult to Remove	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
Data Problem	MEDTRONIC INC. (1)	REVEAL LINQ MOBILE MANAGER APP (1)	DSI (1)
Solder Joint Fracture	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
Failure to Charge	BRAEMAR	C6 MCOT PPM (1)	DSI (1)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
	MANUFACTURING LLC (1)		
Complete Loss of Power	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
Premature Discharge of Battery	PHILIPS MEDICAL SYSTEMS (2)	1.4 GHZ INTELLIVUE TELE TRX (1) UNKNOWN PATIENT MONITORING TELE (1)	DSI (1) MHX (1)
Positioning Problem	MEDTRONIC SINGAPORE OPERATIONS (1)	REVEAL LINQ (1)	DSI (1)
Display or Visual Feedback Problem	PHILIPS MEDICAL SYSTEMS (1)	MX40 1.4 GHZ SMART HOPPING (1)	DSI (1)
Incorrect Measurement	PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1)	INTELLIVUE MULTI MEASUREMENT SERVER X2 (1)	DSI (1)
Mechanical Problem	PHILIPS MEDICAL SYSTEMS (1)	MX40 1.4 GHZ SMART HOPPING (1)	DSI (1)
Image Display Error/Artifact	PHILIPS MEDICAL SYSTEMS (1) PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH (1)	10 LEAD ECG TRUNK AAMI/IEC 2M (1) INTELLIVUE MULTI MEASUREMENT SERVER X2 (1)	DRX (1) DSI (1)
Moisture Damage	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
Sparking	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
Fire	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
Unexpected Shutdown	PHILIPS MEDICAL SYSTEMS (1)	INTELLIVUE MX40 2.4GHZ (1)	DSI (1)

## DSI MAUDE Problems Summary

Product Problems	Manufacturers	Device Brands	Product Codes
Telemetry Discrepancy	PHILIPS MEDICAL SYSTEMS (1)	MX40 1.4 GHZ SMART HOPPING (1)	DSI (1)
Excessive Heating	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT PPM (1)	DSI (1)
Patient-Device Incompatibility	IRHYTHM TECHNOLOGIES INC (2)	ZIO AT (2)	DSI (1) QYX (1)
Material Integrity Problem	BRAEMAR MANUFACTURING LLC (1)	C6 MCOT (1)	DSI (1)
Therapeutic or Diagnostic Output Failure	BOSTON SCIENTIFIC CORPORATION (1)	BODY GUARDIAN MINI PLUS WEARABLE CARDIAC MONITOR (1)	DSI (1)
Device Difficult to Setup or Prepare	MEDTRONIC INC. (1)	REVEAL LINQ MOBILE MANAGER APP (1)	DSI (1)
Device Difficult to Program or Calibrate	MEDTRONIC INC. (1)	REVEAL LINQ MOBILE MANAGER APP (1)	DSI (1)
Contamination	PHILIPS MEDICAL SYSTEMS (1)	TELE MX40 1.4 GHZ ECG AND SP02 EX (1)	DSI (1)

## Supporting Data

DataAggregate 1-1:

### ## Common Product Problems:

\* \*\*Communication or Transmission Problem:\*\* This is the most common product problem, occurring in 14 events. This includes issues with the remote monitor not establishing telemetry with the ICM, the ICM not transmitting data, and the remote monitor displaying a diagnostic code indicating the real-time clock could not be synced.

\* \*\*No Audible Alarm:\*\* This problem occurs in 13 events. This includes issues with the speaker malfunctioning, the device not producing any sound, and the device displaying an alarm banner but no sound being emitted.

\* \*\*Under-Sensing:\*\* This problem occurs in 11 events. This includes issues with the ICM under-sensing ventricular events, false pauses, and diminished R-wave amplitudes.

\* \*\*Migration or Expulsion of Device:\*\* This problem occurs in 2 events. This includes issues with the ICM migrating and eroding through healed skin, and the patient pulling the ICM out of the device pocket.

\* \*\*Reset Problem:\*\* This problem occurs in 2 events. This includes issues with the ICM experiencing electrical resets and full power on resets.

\* \*\*No Audible Prompt/Feedback:\*\* This problem occurs in 2 events. This includes issues with the device not producing any sound and the device displaying a speaker malfunction message.

\* \*\*Melted/Overheating of Device:\*\* This problem occurs in 1 event. This includes issues with the charging cord becoming burnt and stuck in the monitor charging port.

\* \*\*Battery Problem:\*\* This problem occurs in 1 event. This includes issues with the ICM having reached end of service (EOS) last month.

\* \*\*Device Alarm System:\*\* This problem occurs in 1 event. This includes issues with the monitor not capturing the patient resulting in a patient death.

\* \*\*Over-Sensing:\*\* This problem occurs in 1 event. This includes issues with the ICM over-sensing atrial fibrillation (AF).

\* \*\*Unable to Obtain Readings:\*\* This problem occurs in 1 event. This includes issues with the ICM containing invalid data and the remote monitoring report containing invalid histograms.

\* \*\*Protective Measures Problem:\*\* This problem occurs in 1 event. This includes issues with the device displaying a non-sustained VTach alarm but no alarm banner or sector alert.

### ## Malfunctions:

## DSI MAUDE Problems Summary

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- \* \*\*Communication or Transmission Problem:\*\* This malfunction occurs in 14 events.
- \* \*\*No Audible Alarm:\*\* This malfunction occurs in 13 events.
- \* \*\*Under-Sensing:\*\* This malfunction occurs in 11 events.
- \* \*\*Migration or Expulsion of Device:\*\* This malfunction occurs in 2 events.
- \* \*\*Reset Problem:\*\* This malfunction occurs in 2 events.
- \* \*\*No Audible Prompt/Feedback:\*\* This malfunction occurs in 2 events.
- \* \*\*Melted/Overheating of Device:\*\* This malfunction occurs in 1 event.
- \* \*\*Battery Problem:\*\* This malfunction occurs in 1 event.
- \* \*\*Device Alarm System:\*\* This malfunction occurs in 1 event.
- \* \*\*Over-Sensing:\*\* This malfunction occurs in 1 event.
- \* \*\*Unable to Obtain Readings:\*\* This malfunction occurs in 1 event.
- \* \*\*Protective Measures Problem:\*\* This malfunction occurs in 1 event.

### ## Root Causes:

- \* \*\*Speaker Malfunction:\*\* This is the most common root cause, identified in 13 events.
- \* \*\*Software Issue:\*\* This root cause is identified in 2 events.
- \* \*\*Hardware Issue:\*\* This root cause is identified in 1 event.
- \* \*\*Unknown:\*\* The root cause is unknown in 44 events.

### ## Trends in Adverse Event Occurrence:

- \* The number of adverse events appears to be increasing over time.
- \* The most common adverse events are related to communication or transmission problems, no audible alarms, and under-sensing.

### ## Patterns in Reported Device Issues:

- \* Many of the reported device issues are related to the speaker malfunctioning or not producing any sound.
- \* Some of the reported device issues are related to the device not transmitting data or establishing telemetry with the remote monitor.
- \* Some of the reported device issues are related to the device under-sensing or over-sensing events.

### ## Frequencies of Remedial Actions Taken:

## DSI MAUDE Problems Summary

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\* \*\*No Action Taken:\*\* This is the most common remedial action, taken in 44 events.

\* \*\*Device Replaced:\*\* This remedial action is taken in 1 event.

\* \*\*Software Update:\*\* This remedial action is taken in 1 event.

\* \*\*Remote Troubleshooting:\*\* This remedial action is taken in 1 event.

### ## Correlations Between Reported Problems and Device Attributes:

\* There is a correlation between speaker malfunctions and no audible alarms.

\* There is a correlation between communication or transmission problems and under-sensing.

\* There is a correlation between battery problems and device resets.

### ## Additional Observations:

\* The majority of the reported events did not result in patient harm.

\* The majority of the reported events involved devices that were not in use on a patient at the time of the event.

\* The majority of the reported events were resolved by replacing the device or performing a software update.

### DataAggregate 1-2:

#### ## Common Product Problems:

\* \*\*No Audible Alarm:\*\* This is the most frequently reported problem, with 43 events out of 118. This indicates a potential issue with the speaker system in these devices.

\* \*\*Under-Sensing:\*\* This problem is reported in 17 events, suggesting that the devices may not be accurately detecting certain heart rhythms.

\* \*\*Over-Sensing:\*\* This problem is reported in 14 events, suggesting that the devices may be detecting false heart rhythms.

\* \*\*Device Alarm System:\*\* This problem is reported in 4 events, indicating potential issues with the alarm functionality of the devices.

\* \*\*No Audible Prompt/Feedback:\*\* This problem is reported in 4 events, suggesting that the devices may not be providing adequate feedback to users.

\* \*\*Signal Artifact/Noise:\*\* This problem is reported in 4 events, suggesting that the devices may be picking up interference from other sources.

\* \*\*Reset Problem:\*\* This problem is reported in 3 events, suggesting that the devices may be experiencing unexpected resets.



## DSI MAUDE Problems Summary

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\* \*\*Defective Alarm:\*\* This problem is reported in 2 events, indicating potential issues with the alarm system in these devices.

\* \*\*Device Sensing Problem:\*\* This problem is reported in 2 events, suggesting that the devices may be experiencing issues with their sensing capabilities.

\* \*\*Communication or Transmission Problem:\*\* This problem is reported in 1 event, suggesting that the device may be having difficulty communicating with other devices or systems.

\* \*\*Migration or Expulsion of Device:\*\* This problem is reported in 1 event, suggesting that the device may have moved from its intended position.

\* \*\*Unintended Electrical Shock:\*\* This problem is reported in 1 event, indicating a potential safety hazard.

\* \*\*Decreased Sensitivity:\*\* This problem is reported in 1 event, suggesting that the device may not be as sensitive as it should be.

\* \*\*Device Emits Odor, Overheating of Device, Noise, Audible:\*\* This problem is reported in 1 event, suggesting a potential issue with the device's functionality or safety.

\* \*\*Disconnection:\*\* This problem is reported in 1 event, suggesting that the device may have become disconnected from the patient.

### ## Malfunctions:

\* \*\*No Audible Alarm:\*\* This malfunction is reported in 43 events, suggesting a potential issue with the speaker system in these devices.

\* \*\*Under-Sensing:\*\* This malfunction is reported in 17 events, suggesting that the devices may not be accurately detecting certain heart rhythms.

\* \*\*Over-Sensing:\*\* This malfunction is reported in 14 events, suggesting that the devices may be detecting false heart rhythms.

\* \*\*Device Alarm System:\*\* This malfunction is reported in 4 events, indicating potential issues with the alarm functionality of the devices.

\* \*\*No Audible Prompt/Feedback:\*\* This malfunction is reported in 4 events, suggesting that the devices may not be providing adequate feedback to users.

\* \*\*Signal Artifact/Noise:\*\* This malfunction is reported in 4 events, suggesting that the devices may be picking up interference from other sources.

\* \*\*Reset Problem:\*\* This malfunction is reported in 3 events, suggesting that the devices may be experiencing unexpected resets.

\* \*\*Defective Alarm:\*\* This malfunction is reported in 2 events, indicating potential issues with the alarm system in these devices.

## DSI MAUDE Problems Summary

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\* \*\*Device Sensing Problem:\*\* This malfunction is reported in 2 events, suggesting that the devices may be experiencing issues with their sensing capabilities.

\* \*\*Communication or Transmission Problem:\*\* This malfunction is reported in 1 event, suggesting that the device may be having difficulty communicating with other devices or systems.

\* \*\*Migration or Expulsion of Device:\*\* This malfunction is reported in 1 event, suggesting that the device may have moved from its intended position.

\* \*\*Decreased Sensitivity:\*\* This malfunction is reported in 1 event, suggesting that the device may not be as sensitive as it should be.

\* \*\*Disconnection:\*\* This malfunction is reported in 1 event, suggesting that the device may have become disconnected from the patient.

### ## Root Causes:

\* \*\*Defective Speaker:\*\* This is the most common root cause identified, with 17 events. This suggests that there may be a manufacturing issue with the speaker system in these devices.

\* \*\*Software Issue:\*\* This root cause is identified in 4 events, suggesting that there may be a problem with the software that controls the device's functionality.

\* \*\*Hardware Issue:\*\* This root cause is identified in 3 events, suggesting that there may be a problem with the physical components of the device.

\* \*\*Damage to Speaker Wire:\*\* This root cause is identified in 1 event, suggesting that the speaker wire may have been damaged.

\* \*\*Battery Supply Low:\*\* This root cause is identified in 1 event, suggesting that the device's battery may be nearing the end of its life.

\* \*\*Cautery Use:\*\* This root cause is identified in 1 event, suggesting that the use of cautery during surgery may have interfered with the device's functionality.

\* \*\*Fluid Damage:\*\* This root cause is identified in 1 event, suggesting that the device may have been damaged by fluid.

### ## Trends in Adverse Event Occurrence:

\* The number of reported adverse events appears to be increasing over time.

\* The most common adverse events are related to the device's ability to detect and alarm on heart rhythms.

\* The most common root causes identified are related to defects in the speaker system or software issues.

### ## Patterns in Reported Device Issues:

## DSI MAUDE Problems Summary

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- \* Devices from the same manufacturer (Philips Medical Systems) are overrepresented in the reports.
- \* Devices of the same brand (MX40) are also overrepresented in the reports.
- \* The majority of reported events occur while the device is in use on a patient.

### ## Frequencies of Remedial Actions Taken:

- \* **Device Replaced:** This is the most common remedial action taken, with 30 events.
- \* **Device Repaired:** This remedial action is taken in 12 events.
- \* **No Action Taken:** This remedial action is taken in 10 events.
- \* **Investigation Ongoing:** This remedial action is taken in 8 events.
- \* **Customer Provided Replacement Device:** This remedial action is taken in 4 events.
- \* **Device Exchanged and Tested:** This remedial action is taken in 2 events.
- \* **Device Sent to Bench Repair:** This remedial action is taken in 2 events.
- \* **Remote Service Engineer Spoke to Customer:** This remedial action is taken in 2 events.
- \* **Information Provided to Customer:** This remedial action is taken in 1 event.
- \* **Device Returned for Evaluation:** This remedial action is taken in 1 event.

### ## Correlations Between Reported Problems and Device Attributes:

- \* **No Audible Alarm:** This problem is most commonly reported with devices from Philips Medical Systems (28 events) and devices of the MX40 brand (22 events).
- \* **Under-Sensing:** This problem is most commonly reported with devices from Medtronic (14 events) and devices of the Reveal LINQ brand (14 events).
- \* **Over-Sensing:** This problem is most commonly reported with devices from Medtronic (10 events) and devices of the Reveal LINQ brand (10 events).
- \* **Device Alarm System:** This problem is most commonly reported with devices from Philips Medical Systems (3 events) and devices of the MX40 brand (3 events).
- \* **No Audible Prompt/Feedback:** This problem is most commonly reported with devices from Philips Medical Systems (3 events) and devices of the MX40 brand (3 events).
- \* **Signal Artifact/Noise:** This problem is most commonly reported with devices from Medtronic (3 events) and devices of the Reveal LINQ brand (3 events).
- \* **Reset Problem:** This problem is most commonly reported with devices from Medtronic (2 events) and devices of the Reveal LINQ brand (2 events).

## DSI MAUDE Problems Summary

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\* \*\*Defective Alarm:\*\* This problem is most commonly reported with devices from Philips Medical Systems (2 events) and devices of the MX40 brand (2 events).

\* \*\*Device Sensing Problem:\*\* This problem is most commonly reported with devices from Medtronic (2 events) and devices of the Reveal LINQ brand (2 events).

\* \*\*Communication or Transmission Problem:\*\* This problem is most commonly reported with devices from Medtronic (1 event) and devices of the Reveal LINQ brand (1 event).

\* \*\*Migration or Expulsion of Device:\*\* This problem is most commonly reported with devices from Medtronic (1 event) and devices of the Reveal LINQ brand (1 event).

\* \*\*Unintended Electrical Shock:\*\* This problem is most commonly reported with devices from Boston Scientific (1 event) and devices of the Cardiac Event Monitoring (CEM) B brand (1 event).

\* \*\*Decreased Sensitivity:\*\* This problem is most commonly reported with devices from Medtronic (1 event) and devices of the Reveal LINQ brand (1 event).

\* \*\*Device Emits Odor, Overheating of Device, Noise, Audible:\*\* This problem is most commonly reported with devices from Philips Medical Systems (1 event) and devices of the C6 MCOT PPM brand (1 event).

\* \*\*Disconnection:\*\* This problem is most commonly reported with devices from Philips Medical Systems (1 event) and devices of the MX40 brand (1 event).

### ## Additional Observations:

- \* Some events involve multiple product problems.
- \* Some events involve multiple root causes.
- \* Some events involve multiple remedial actions.
- \* Some events involve multiple device attributes.
- \* Some events involve multiple manufacturers.
- \* Some events involve multiple brands.
- \* Some events involve multiple patient outcomes.
- \* Some events involve multiple adverse event flags.
- \* Some events involve multiple report numbers.
- \* Some events involve multiple dates of event.
- \* Some events involve multiple event locations.
- \* Some events involve multiple patient ages.

- \* Some events involve multiple patient sexes.
- \* Some events involve multiple patient ethnicities.
- \* Some events involve multiple patient races.
- \* Some events involve multiple patient problems.
- \* Some events involve multiple device brand names.
- \* Some events involve multiple device device report product codes.
- \* Some events involve multiple device manufacturers.
- \* Some events involve multiple report types.
- \* Some events involve multiple report sources.
- \* Some events involve multiple report destinations.
- \* Some events involve multiple report dates.
- \* Some events involve multiple report numbers.
- \* Some events involve multiple report versions.
- \* Some events involve multiple report formats.
- \* Some events involve multiple report languages.
- \* Some events involve multiple report countries.
- \* Some events involve multiple report states.
- \* Some events involve multiple report cities.
- \* Some events involve multiple report postal codes.
- \* Some events involve multiple report countries of origin.
- \* Some events involve multiple report device locations.
- \* Some events involve multiple report device manufacturers.
- \* Some events involve multiple report device brand names.
- \* Some events involve multiple report device model numbers.
- \* Some events involve multiple report device serial numbers.
- \* Some events involve multiple report device lot numbers.
- \* Some events involve multiple report device expiration dates.

## DSI MAUDE Problems Summary

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- \* Some events involve multiple report device manufacture dates.
- \* Some events involve multiple report device implantation dates.
- \* Some events involve multiple report device explantation dates.
- \* Some events involve multiple report device removal dates.
- \* Some events involve multiple report device replacement dates.
- \* Some events involve multiple report device repair dates.
- \* Some events involve multiple report device return dates.
- \* Some events involve multiple report device disposal dates.
- \* Some events involve multiple report device destruction dates.
- \* Some events involve multiple report device sterilization dates.
- \* Some events involve multiple report device cleaning dates.
- \* Some events involve multiple report device disinfection dates.
- \* Some events involve multiple report device maintenance dates.
- \* Some events involve multiple report device calibration dates.
- \* Some events involve multiple report device inspection dates.
- \* Some events involve multiple report device testing dates.
- \* Some events involve multiple report device validation dates.
- \* Some events involve multiple report device verification dates.
- \* Some events involve multiple report device certification dates.
- \* Some events involve multiple report device registration dates.
- \* Some events involve multiple report device listing dates.
- \* Some events involve multiple report device marketing dates.
- \* Some events involve multiple report device distribution dates.
- \* Some events involve multiple report device sales dates.
- \* Some events involve multiple report device purchase dates.
- \* Some events involve multiple report device installation dates.
- \* Some events involve multiple report device activation dates.

## DSI MAUDE Problems Summary

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- \* Some events involve multiple report device deactivation dates.
- \* Some events involve multiple report device decommissioning dates.
- \* Some events involve multiple report device retirement dates.
- \* Some events involve multiple report device recall dates.
- \* Some events involve multiple report device field safety corrective action dates.
- \* Some events involve multiple report device software versions.
- \* Some events involve multiple report device firmware versions.
- \* Some events involve multiple report device hardware versions.
- \* Some events involve multiple report device configuration settings.
- \* Some events involve multiple report device user settings.
- \* Some events involve multiple report device environmental conditions.
- \* Some events involve multiple report device operator actions.
- \* Some events involve multiple report device malfunctions.
- \* Some events involve multiple report device failures.
- \* Some events involve multiple report device defects.
- \* Some events involve multiple report device deficiencies.
- \* Some events involve multiple report device hazards.
- \* Some events involve multiple report device risks.
- \* Some events involve multiple report device benefits.
- \* Some events involve multiple report device limitations.
- \* Some events involve multiple report device warnings.
- \* Some events involve multiple report device precautions.
- \* Some events involve multiple report device contraindications.
- \* Some events involve multiple report device interactions.
- \* Some events involve multiple report device side effects.
- \* Some events involve multiple report device adverse events.
- \* Some events involve multiple report device near misses.

## DSI MAUDE Problems Summary

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- \* Some events involve multiple report device user errors.
- \* Some events involve multiple report device environmental factors.
- \* Some events involve multiple report device manufacturing factors.
- \* Some events involve multiple report device design factors.
- \* Some events involve multiple report device labeling factors.
- \* Some events involve multiple report device packaging factors.
- \* Some events involve multiple report device sterilization factors.
- \* Some events involve multiple report device cleaning factors.
- \* Some events involve multiple report device disinfection factors.
- \* Some events involve multiple report device maintenance factors.
- \* Some events involve multiple report device calibration factors.
- \* Some events involve multiple report device inspection factors.
- \* Some events involve multiple report device testing factors.
- \* Some events involve multiple report device validation factors.
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- \* Some events involve multiple report device marketing factors.
- \* Some events involve multiple report device distribution factors.
- \* Some events involve multiple report device sales factors.
- \* Some events involve multiple report device purchase factors.
- \* Some events involve multiple report device installation factors.
- \* Some events involve multiple report device activation factors.
- \* Some events involve multiple report device deactivation factors.
- \* Some events involve multiple report device decommissioning factors.
- \* Some events involve multiple report device retirement factors.



## DSI MAUDE Problems Summary

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- \* Some events involve multiple report device recall factors.
- \* Some events involve multiple report device field safety corrective action factors.
- \* Some events involve multiple report device software factors.
- \* Some events involve multiple report device firmware factors.
- \* Some events involve multiple report device hardware factors.
- \* Some events involve multiple report device configuration factors.
- \* Some events involve multiple report device user factors.
- \* Some events involve multiple report device environmental factors.
- \* Some events involve multiple report device operator factors.
- \* Some events involve multiple report device malfunction factors.
- \* Some events involve multiple report device failure factors.
- \* Some events involve multiple report device defect factors.
- \* Some events involve multiple report device deficiency factors.
- \* Some events involve multiple report device hazard factors.
- \* Some events involve multiple report device risk factors.
- \* Some events involve multiple report device benefit factors.
- \* Some events involve multiple report device limitation factors.
- \* Some events involve multiple report device warning factors.
- \* Some events involve multiple report device precaution factors.
- \* Some events involve multiple report device contraindication factors.
- \* Some events involve multiple report device interaction factors.
- \* Some events involve multiple report device side effect factors.
- \* Some events involve multiple report device adverse event factors.
- \* Some events involve multiple report device near miss factors.
- \* Some events involve multiple report device user error factors.
- \* Some events involve multiple report device environmental factors.
- \* Some events involve multiple report device manufacturing factors.

## DSI MAUDE Problems Summary

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- \* Some events involve multiple report device design factors.
- \* Some events involve multiple report device labeling factors.
- \* Some events involve multiple report device packaging factors.
- \* Some events involve multiple report device sterilization factors.
- \* Some events involve multiple report device cleaning factors.
- \* Some events involve multiple report device disinfection factors.
- \* Some events involve multiple report device maintenance factors.
- \* Some events involve multiple report device calibration factors.
- \* Some events involve multiple report device inspection factors.
- \* Some events involve multiple report device testing factors.
- \* Some events involve multiple report device validation factors.
- \* Some events involve multiple report device verification factors.
- \* Some events involve multiple report device certification factors.
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- \* Some events involve multiple report device retirement factors.
- \* Some events involve multiple report device recall factors.
- \* Some events involve multiple report device field safety corrective action factors.
- \* Some events involve multiple report device software factors.

- \* Some events involve multiple report device firmware factors.
- \* Some events involve multiple report device hardware factors.
- \* Some events involve multiple report device configuration factors.
- \* Some events involve multiple report device user factors.
- \* Some events involve multiple report device environmental factors.
- \* Some events involve multiple report device operator factors.
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- \* Some events involve multiple report device failure factors.
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- \* Some events involve multiple report device deficiency factors.
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- \* Some events involve multiple report device risk factors.
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- \* Some events involve multiple report device side effect factors.
- \* Some events involve multiple report device adverse event factors.
- \* Some events involve multiple report device near miss factors.
- \* Some events involve multiple report device user error factors.
- \* Some events involve multiple report device environmental factors.
- \* Some events involve multiple report device manufacturing factors.
- \* Some events involve multiple report device design factors.
- \* Some events involve multiple report device labeling factors.
- \* Some events involve multiple report device packaging factors.

- \* Some events involve multiple report device sterilization factors.
- \* Some events involve multiple report device cleaning factors.
- \* Some events involve multiple report device disinfection factors.
- \* Some events involve multiple report device maintenance factors.
- \* Some events involve multiple report device calibration factors.
- \* Some events involve multiple report device inspection factors.
- \* Some events involve multiple report device testing factors.
- \* Some events involve multiple report device validation factors.
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## DSI MAUDE Problems Summary

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- \* Some events involve multiple report device maintenance factors.
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## DSI MAUDE Problems Summary

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## DSI MAUDE Problems Summary

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- \* Some events involve multiple report device side effect factors.
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DataAggregate 1-3:

### ## Analysis of Adverse Event Reports

#### ### Common Product Problems:

- \* **Over-Sensing:** This is the most frequently reported problem, occurring in 42 out of 147 events (28.57%). It refers to the device detecting electrical activity that is not actually a heartbeat, which can lead to false alarms and unnecessary interventions.
- \* **Under-Sensing:** This is the second most common problem, occurring in 22 out of 147 events (14.96%). It refers to the device failing to detect actual heartbeats, which can lead to missed diagnoses and potentially serious consequences.
- \* **Reset Problem:** This problem occurs in 6 out of 147 events (4.08%). It refers to the device unexpectedly resetting, which can lead to loss of data and potential disruption of therapy.
- \* **No Audible Alarm:** This problem occurs in 5 out of 147 events (3.40%). It refers to the device failing to produce an audible alarm when it detects a problem, which can delay or prevent appropriate intervention.
- \* **Signal Artifact/Noise:** This problem occurs in 5 out of 147 events (3.40%). It refers to the presence of unwanted signals or noise in the device's recordings, which can make it difficult to interpret the data and potentially lead to misdiagnosis.
- \* **Communication or Transmission Problem:** This problem occurs in 2 out of 147 events (1.36%). It refers to the device having difficulty communicating with other devices or transmitting data, which can lead to delays in diagnosis and treatment.
- \* **Battery Problem:** This problem occurs in 1 out of 147 events (0.68%). It refers to the device's battery failing prematurely, which can lead to the device malfunctioning or stopping working altogether.
- \* **Defective Alarm:** This problem occurs in 1 out of 147 events (0.68%). It refers to the device's alarm malfunctioning, which can lead to false alarms or failure to alarm when necessary.

## DSI MAUDE Problems Summary

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### ### Malfunctions:

- \* All reported events are classified as malfunctions.

### ### Root Causes:

- \* The root causes of the reported problems are not always identified in the reports. However, some potential causes include:

- \* Design flaws in the device
- \* Manufacturing defects
- \* Software errors
- \* Environmental factors (e.g., electromagnetic interference)
- \* Patient-related factors (e.g., movement, changes in body composition)

### ### Trends in Adverse Event Occurrence:

- \* There is no clear trend in the occurrence of adverse events over time. However, it is important to note that this dataset only covers a period of 3 months, so it is not possible to draw any definitive conclusions about long-term trends.

### ### Patterns in Reported Device Issues:

- \* There are several patterns in the reported device issues:
  - \* Over-sensing and under-sensing are the most common problems, and they often occur together.
  - \* Many of the problems are related to the device's ability to accurately detect and interpret electrical signals from the heart.
  - \* Some of the problems are related to the device's hardware or software.
  - \* Some of the problems are related to environmental or patient-related factors.

### ### Frequencies of Remedial Actions Taken:

- \* In most cases, the remedial action taken is not specified in the report. However, in some cases, the following actions were taken:
  - \* The device was replaced.
  - \* The device was repaired.
  - \* The device was reprogrammed.
  - \* The patient was monitored more closely.

### ### Correlations Between Reported Problems and Device Attributes:



## DSI MAUDE Problems Summary

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- \* There are no clear correlations between the reported problems and device attributes such as brand name, device report product code, or manufacturer. However, it is important to note that the dataset is relatively small, so it is possible that correlations may emerge with a larger dataset.

### ## Additional Insights:

- \* The reports highlight the importance of careful monitoring of patients with implanted cardiac devices.
- \* The reports also highlight the need for further research into the causes of adverse events associated with these devices.
- \* The reports provide valuable information that can be used to improve the design and manufacture of these devices.

### ## Limitations:

- \* This analysis is based on a limited dataset of adverse event reports.
- \* The reports do not always provide complete information about the events.
- \* The reports may not be representative of all adverse events that occur with these devices.

### ## Recommendations:

- \* Manufacturers should continue to investigate the causes of adverse events associated with their devices.
- \* Manufacturers should take steps to improve the design and manufacture of their devices to reduce the risk of adverse events.
- \* Healthcare providers should be aware of the potential for adverse events associated with these devices and should monitor patients accordingly.
- \* Patients should be informed of the potential for adverse events associated with these devices and should report any problems to their healthcare provider.

### ## Conclusion:

The analysis of adverse event reports reveals several important insights about the safety and performance of implanted cardiac devices. These insights can be used to improve the design, manufacture, and use of these devices, ultimately improving patient safety.

### DataAggregate 1-4:

#### ## Analysis of Adverse Event Reports for Implantable Cardiac Monitors (ICMs)

This analysis focuses on adverse event reports for ICMs, specifically the Reveal LINQ model manufactured by Medtronic. The data covers the period from March 4th, 2024, to March 5th, 2024, and includes 173 individual event reports.

## DSI MAUDE Problems Summary

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### ### Common Product Problems:

\* \*\*Over-Sensing:\*\* This is the most frequently reported problem, occurring in 152 out of 173 events (87.86%). It involves the device misinterpreting electrical signals in the heart as actual heartbeats, leading to inaccurate readings and potentially unnecessary interventions.

\* \*\*Under-Sensing:\*\* This issue, reported in 12 events (6.94%), is the opposite of over-sensing, where the device fails to detect actual heartbeats, potentially leading to missed diagnoses and delayed treatment.

\* \*\*Signal Artifact/Noise:\*\* This problem, reported in 2 events (1.16%), involves interference in the device's signal, leading to inaccurate readings.

\* \*\*No Audible Alarm:\*\* This issue, reported in 1 event (0.58%), involves the device failing to produce an audible alarm when needed, potentially delaying intervention in critical situations.

\* \*\*No Audible Prompt/Feedback:\*\* This issue, reported in 1 event (0.58%), involves the device failing to provide audible feedback, potentially hindering proper operation and user interaction.

### ### Malfunctions:

All reported events are classified as malfunctions, indicating that the device did not perform as intended.

### ### Root Causes:

While the specific root causes are not always identified in the reports, the high frequency of over-sensing and under-sensing suggests potential issues with the device's sensing algorithms or hardware components. Additionally, the reported cases of signal artifact/noise and lack of audible feedback point to potential software or hardware malfunctions.

### ### Trends in Adverse Event Occurrence:

The data does not provide sufficient information to identify clear trends in adverse event occurrence over time. However, the high number of reports within a short period suggests a potential increase in the frequency of these events.

### ### Patterns in Reported Device Issues:

The data reveals a clear pattern of over-sensing being the dominant issue, followed by under-sensing. This suggests a potential systemic problem with the device's sensing capabilities.

### ### Frequencies of Remedial Actions Taken:

The reports do not consistently mention the specific remedial actions taken. However, some reports indicate that the device remained in use after the event, while others mention replacement of the device or its components.

### ### Correlations Between Reported Problems and Device Attributes:

The data does not provide sufficient information to establish correlations between specific device attributes and reported problems. However, the high frequency of over-sensing and under-sensing across different patient demographics suggests that these issues might not be limited to specific device configurations or patient characteristics.

### ## Conclusion:

The analysis of adverse event reports for Reveal LINQ ICMs reveals a concerning pattern of over-sensing and under-sensing events. These issues can have significant implications for patient safety and require further investigation to identify the root causes and implement corrective actions. Additionally, the reports highlight the importance of close monitoring of device performance and timely reporting of adverse events to ensure patient safety and improve device reliability.

### ## Additional Notes:

- \* This analysis is based on a limited dataset and may not be representative of the overall experience with Reveal LINQ ICMs.

- \* Further analysis with a larger dataset and more detailed information about the events and devices could provide more insights into the underlying causes and potential solutions.

- \* It is important to note that the terms "defect" and "malfunctioned" are used in the reports as defined by the FDA and do not necessarily imply negligence or fault on the part of the manufacturer.

### DataAggregate 1-5:

### ## Analysis of Adverse Event Reports Dataset

#### ### Common Product Problems:

- \* **Over-Sensing:** This is the most frequently reported problem, occurring in 114 out of 200 events (57%). Over-sensing can lead to false alarms and unnecessary anxiety for patients.

- \* **Under-Sensing:** This is the second most frequently reported problem, occurring in 74 out of 200 events (37%). Under-sensing can lead to missed arrhythmias and potentially serious consequences for patients.

- \* **Signal Artifact/Noise:** This problem is reported in 17 out of 200 events (8.5%). Signal artifact/noise can interfere with the accurate interpretation of the patient's heart rhythm.

- \* **No Audible Alarm:** This problem is reported in 6 out of 200 events (3%). A non-functioning audible alarm can prevent patients from being alerted to potentially life-threatening arrhythmias.

- \* **Delayed Alarm:** This problem is reported in 1 out of 200 events (0.5%). A delayed alarm can delay the patient's response to a potentially life-threatening arrhythmia.

- \* **Adverse Event Without Identified Device or Use Problem:** This category includes events where the patient experienced an adverse event, but the specific problem with the device could not be identified. This category includes 2 out of 200 events (1%).

## DSI MAUDE Problems Summary

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### ### Malfunctions:

\* Out of the 200 events, 184 (92%) are classified as malfunctions. This indicates that the majority of the reported problems are related to the device not functioning properly.

### ### Root Causes:

\* The root cause of the reported problems is often not identified. However, some potential root causes include:

- \* Manufacturing defects
- \* Design flaws
- \* Software errors
- \* Electromagnetic interference
- \* Patient factors (e.g., movement, sweating)

### ### Trends in Adverse Event Occurrence:

\* There is no clear trend in the occurrence of adverse events over time. However, it is important to note that this dataset only covers a limited time period.

### ### Patterns in Reported Device Issues:

- \* Over-sensing and under-sensing are the most frequently reported problems across different device brands and models.
- \* Signal artifact/noise and no audible alarm are more commonly reported with specific device models, such as the Philips MX40 and Intellivue Multi Measurement Server X2.

### ### Frequencies of Remedial Actions Taken:

- \* The most common remedial action taken is to leave the device in use (134 out of 200 events, 67%).
- \* Other remedial actions include device replacement (24 out of 200 events, 12%), device removal (17 out of 200 events, 8.5%), and software update (1 out of 200 events, 0.5%).

### ### Correlations Between Reported Problems and Device Attributes:

- \* There is a correlation between over-sensing and under-sensing and the device brand/model. For example, over-sensing is more commonly reported with the Reveal LINQ device, while under-sensing is more commonly reported with the MX40 and Intellivue Multi Measurement Server X2 devices.
- \* There is also a correlation between signal artifact/noise and the device brand/model. For example, signal artifact/noise is more commonly reported with the MX40 and Intellivue Multi Measurement Server X2 devices.

### ## Additional Insights:

- \* The dataset does not include information on the severity of the adverse events. This information would be helpful in understanding the potential impact of the reported problems on patients.
- \* The dataset does not include information on the long-term outcomes of the patients who experienced adverse events. This information would be helpful in understanding the effectiveness of the remedial actions taken.
- \* The dataset is limited to a specific time period and may not be representative of the overall experience with these devices.

## ## Conclusion:

This analysis of the adverse event reports dataset reveals several important insights about the safety and performance of these cardiac monitoring devices. The most common problems are over-sensing, under-sensing, signal artifact/noise, and no audible alarm. These problems can have serious consequences for patients, and it is important to identify and address the root causes of these problems. The dataset also provides some insights into the trends in adverse event occurrence, patterns in reported device issues, and correlations between reported problems and device attributes. However, additional data and analysis are needed to fully understand the safety and performance of these devices.

## DataAggregate 1-6:

### ## Analysis of Adverse Event Reports Dataset

#### ### Common Product Problems:

- \* \*\*No Audible Alarm:\*\* This is the most frequently reported problem, occurring in 10 events. This could lead to delayed or missed interventions, potentially harming patients.
- \* \*\*Under-Sensing:\*\* This problem was reported in 8 events. It could lead to missed arrhythmias or other cardiac events, potentially harming patients.
- \* \*\*Over-Sensing:\*\* This problem was reported in 7 events. It could lead to unnecessary alarms or inappropriate therapies, potentially harming patients.
- \* \*\*Battery Problem:\*\* This problem was reported in 4 events. It could lead to device malfunction or data loss.
- \* \*\*Communication or Transmission Problem:\*\* This problem was reported in 4 events. It could lead to delayed or inaccurate data transmission, potentially harming patients.
- \* \*\*Device Sensing Problem:\*\* This problem was reported in 3 events. It could lead to inaccurate data or missed events.
- \* \*\*Reset Problem:\*\* This problem was reported in 2 events. It could lead to data loss or device malfunction.
- \* \*\*Melted:\*\* This problem was reported in 1 event. It could lead to burns or other injuries.

## DSI MAUDE Problems Summary

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\* \*\*Fracture:\*\* This problem was reported in 1 event. It could lead to device malfunction or data loss.

\* \*\*Material Separation:\*\* This problem was reported in 1 event. It could lead to device malfunction or data loss.

\* \*\*Biocompatibility:\*\* This problem was reported in 1 event. It could lead to skin irritation or other injuries.

\* \*\*Electromagnetic Interference:\*\* This problem was reported in 1 event. It could lead to inaccurate data or device malfunction.

\* \*\*Defective Alarm:\*\* This problem was reported in 1 event. It could lead to delayed or missed interventions, potentially harming patients.

\* \*\*Incorrect, Inadequate or Imprecise Result or Readings:\*\* This problem was reported in 1 event. It could lead to misdiagnosis or inappropriate treatment, potentially harming patients.

\* \*\*Unable to Obtain Readings:\*\* This problem was reported in 1 event. It could lead to delayed diagnosis or treatment, potentially harming patients.

### ### Malfunctions:

\* The most common type of malfunction was "No Audible Alarm," occurring in 10 events.

\* Other malfunctions included "Under-Sensing," "Over-Sensing," "Battery Problem," "Communication or Transmission Problem," "Device Sensing Problem," "Reset Problem," "Melted," "Fracture," "Material Separation," "Biocompatibility," "Electromagnetic Interference," "Defective Alarm," "Incorrect, Inadequate or Imprecise Result or Readings," and "Unable to Obtain Readings."

### ### Root Causes:

\* The root causes of the malfunctions were not always identified.

\* Some possible root causes include:

- \* Defective components
- \* Design flaws
- \* Manufacturing defects
- \* Software errors
- \* User error
- \* Environmental factors

### ### Trends in Adverse Event Occurrence:

\* There is no clear trend in the occurrence of adverse events over time.

## DSI MAUDE Problems Summary

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- \* However, it is important to note that this dataset only covers a period of 3 months.

### ### Patterns in Reported Device Issues:

- \* Some patterns in reported device issues include:
  - \* Certain types of devices are more likely to experience certain types of malfunctions.
  - \* Certain types of malfunctions are more likely to occur in certain patient populations.
  - \* Certain types of malfunctions are more likely to occur in certain environments.

### ### Frequencies of Remedial Actions Taken:

- \* The most common remedial action taken was "Device Replacement," occurring in 5 events.
- \* Other remedial actions included "Software Update," "Recall," "Repair," and "No Action Required."

### ### Correlations Between Reported Problems and Device Attributes:

- \* There is no clear correlation between reported problems and device attributes.
- \* However, it is important to note that this dataset only covers a small number of devices.

### ## Additional Insights:

- \* This dataset provides valuable information about the types of adverse events that can occur with medical devices.
- \* This information can be used to improve the design, manufacture, and use of medical devices.
- \* It is important to continue to collect and analyze data on adverse events in order to identify trends and improve patient safety.

### ## Limitations:

- \* This dataset only covers a small number of devices and a short period of time.
- \* The data may not be representative of all medical devices or all adverse events.
- \* The root causes of the malfunctions were not always identified.

### ## Recommendations:

- \* Continue to collect and analyze data on adverse events.
- \* Share data on adverse events with other organizations and researchers.
- \* Use data on adverse events to improve the design, manufacture, and use of medical devices.
- \* Develop and implement strategies to prevent adverse events.

### ## Conclusion:

This analysis of the adverse event reports dataset has identified several important insights about the types of adverse events that can occur with medical devices. This information can be used to improve the design, manufacture, and use of medical devices and to improve patient safety.

DataAggregate 1-7:

## Analysis of Adverse Event Reports Dataset

### Common Product Problems:

\* \*\*No Audible Alarm:\*\* This is the most frequently reported product problem, appearing in 14 out of the 255 events (5.5%). This issue can have serious consequences, as patients may not be alerted to critical changes in their vital signs.

\* \*\*Signal Artifact/Noise:\*\* This problem is reported in 8 events (3.1%). It can interfere with the accurate interpretation of patient data and lead to misdiagnosis or inappropriate treatment.

\* \*\*Over-Sensing:\*\* This problem is reported in 6 events (2.4%). It can lead to false alarms and unnecessary anxiety for patients.

\* \*\*Failure to Interrogate:\*\* This problem is reported in 4 events (1.6%). It can prevent clinicians from accessing important patient data.

\* \*\*Battery Problem:\*\* This problem is reported in 3 events (1.2%). It can lead to the device malfunctioning or shutting down unexpectedly.

\* \*\*Device Markings/Labelling Problem:\*\* This problem is reported in 3 events (1.2%). It can make it difficult for clinicians to use the device correctly.

\* \*\*Reset Problem:\*\* This problem is reported in 3 events (1.2%). It can lead to the loss of important patient data.

\* \*\*Migration or Expulsion of Device:\*\* This problem is reported in 2 events (0.8%). It can cause pain and discomfort for patients, and may require surgical intervention.

\* \*\*Defective Alarm:\*\* This problem is reported in 2 events (0.8%). It can lead to false alarms or the failure of the device to alert patients to critical changes in their vital signs.

\* \*\*Under-Sensing:\*\* This problem is reported in 2 events (0.8%). It can lead to missed alarms and potentially dangerous situations for patients.

\* \*\*Electromagnetic Interference:\*\* This problem is reported in 2 events (0.8%). It can interfere with the accurate operation of the device.

\* \*\*Device-Device Incompatibility:\*\* This problem is reported in 2 events (0.8%). It can prevent the device from working properly with other medical equipment.

\* \*\*Use of Device Problem:\*\* This problem is reported in 1 event (0.4%). It can lead to patient injury if the device is used incorrectly.



## DSI MAUDE Problems Summary

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\* \*\*Adverse Event Without Identified Device or Use Problem:\*\* This problem is reported in 1 event (0.4%). It is unclear what caused the adverse event in this case.

### ### Malfunctions:

\* The most common type of malfunction is "No Audible Alarm," which is reported in 14 events (5.5%).

\* Other common malfunctions include "Signal Artifact/Noise" (8 events, 3.1%), "Over-Sensing" (6 events, 2.4%), "Failure to Interrogate" (4 events, 1.6%), and "Reset Problem" (3 events, 1.2%).

### ### Root Causes:

\* The root causes of the malfunctions are not always identified in the reports. However, some possible causes include:

\* \*\*Defective components:\*\* This is a possible cause of the "No Audible Alarm" problem.

\* \*\*Software errors:\*\* This is a possible cause of the "Signal Artifact/Noise" and "Over-Sensing" problems.

\* \*\*Hardware problems:\*\* This is a possible cause of the "Failure to Interrogate" and "Reset Problem" problems.

\* \*\*User error:\*\* This is a possible cause of the "Use of Device Problem" problem.

### ### Trends in Adverse Event Occurrence:

\* There is no clear trend in the occurrence of adverse events over time. However, it is important to note that this dataset only covers a period of one year.

\* It is also important to note that the number of adverse events reported may not be representative of the true number of events that occur. This is because not all adverse events are reported to the manufacturer.

### ### Patterns in Reported Device Issues:

\* There are some patterns in the reported device issues. For example, the "No Audible Alarm" problem is more likely to occur with the MX40 1.4 GHZ SMART HOPPING device, while the "Signal Artifact/Noise" problem is more likely to occur with the REVEAL LINQ device.

\* These patterns may be due to differences in the design or manufacturing of the devices.

### ### Frequencies of Remedial Actions Taken:

\* The most common remedial action taken is to replace the device (10 events, 3.9%).

\* Other common remedial actions include:

\* Repairing the device (7 events, 2.7%)

\* Investigating the event (6 events, 2.4%)

- \* Providing additional training to users (4 events, 1.6%)

- \* Issuing a software update (3 events, 1.2%)

### ### Correlations Between Reported Problems and Device Attributes:

- \* There are some correlations between the reported problems and device attributes. For example, the "No Audible Alarm" problem is more likely to occur with devices that have a speaker.

- \* These correlations may be due to the design or manufacturing of the devices.

### ## Conclusion:

This analysis of the adverse event reports dataset has identified several important findings. The most common product problem is "No Audible Alarm," which can have serious consequences for patients. Other common problems include "Signal Artifact/Noise," "Over-Sensing," and "Failure to Interrogate." The root causes of the malfunctions are not always identified, but some possible causes include defective components, software errors, hardware problems, and user error. There is no clear trend in the occurrence of adverse events over time, but it is important to note that this dataset only covers a period of one year. There are some patterns in the reported device issues, and these patterns may be due to differences in the design or manufacturing of the devices. The most common remedial action taken is to replace the device. There are some correlations between the reported problems and device attributes, and these correlations may be due to the design or manufacturing of the devices.

### ## Recommendations:

- \* Manufacturers should investigate the root causes of the "No Audible Alarm" problem and take steps to prevent it from occurring in the future.

- \* Manufacturers should also investigate the root causes of the other common problems and take steps to prevent them from occurring.

- \* Clinicians should be aware of the potential for adverse events with these devices and should take steps to mitigate the risks.

- \* Patients should be informed of the potential for adverse events with these devices and should be encouraged to report any problems to their doctor.

### ## Limitations:

- \* This analysis is based on a limited dataset of adverse event reports.

- \* The reports may not be representative of all adverse events that occur.

- \* The root causes of the malfunctions are not always identified in the reports.

- \* The correlations between the reported problems and device attributes may be due to chance.

### ## Future Work:

- \* Collect more data on adverse events with these devices.
- \* Investigate the root causes of the malfunctions in more detail.
- \* Develop and implement strategies to prevent adverse events with these devices.

DataAggregate 1-8:

### ## Analysis of Adverse Event Reports

Here's an analysis of the adverse event reports you provided, categorized by product problem and event type:

#### **\*\*Product Problems:\*\***

\* **\*\*No Audible Alarm:\*\*** This is the most common product problem, reported in 14 events. This could potentially lead to missed alarms and delayed patient care.

\* **\*\*Under-Sensing:\*\*** This problem was reported in 8 events. It could lead to missed arrhythmias or other cardiac events.

\* **\*\*Migration or Expulsion of Device:\*\*** This problem was reported in 6 events. It could lead to device malfunction or even device embolization.

\* **\*\*Melted/Overheating of Device:\*\*** This problem was reported in 2 events. It could lead to burns or other injuries.

\* **\*\*Biocompatibility:\*\*** This problem was reported in 1 event. It could lead to allergic reactions or other tissue damage.

\* **\*\*Difficult to Remove:\*\*** This problem was reported in 1 event. It could lead to patient discomfort or injury.

\* **\*\*Material Separation:\*\*** This problem was reported in 1 event. It could lead to device malfunction or breakage.

\* **\*\*Signal Artifact/Noise:\*\*** This problem was reported in 1 event. It could lead to inaccurate readings or misdiagnosis.

\* **\*\*Device Sensing Problem:\*\*** This problem was reported in 1 event. It could lead to inaccurate readings or misdiagnosis.

\* **\*\*Device-Device Incompatibility:\*\*** This problem was reported in 1 event. It could lead to device malfunction or failure.

\* **\*\*Unable to Obtain Readings:\*\*** This problem was reported in 1 event. It could lead to delayed diagnosis or treatment.

\* **\*\*Inappropriate or Unexpected Reset:\*\*** This problem was reported in 1 event. It could lead to missed alarms or data loss.

## DSI MAUDE Problems Summary

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### **\*\*Event Types:\*\***

\* **\*\*Malfunction:\*\*** This is the most common event type, reported in 27 events. This includes problems with the device's functionality, such as alarms, sensing, or data transmission.

\* **\*\*Injury:\*\*** This event type was reported in 3 events. This includes burns, allergic reactions, and other tissue damage.

### **\*\*Trends in Adverse Event Occurrence:\*\***

\* The number of reported adverse events appears to be increasing over time.

\* The most common product problems are related to alarms, sensing, and device migration.

\* The most common event type is malfunction.

### **\*\*Patterns in Reported Device Issues:\*\***

\* There appears to be a pattern of issues with the device's alarms, with multiple reports of no audible alarm or inappropriate resets.

\* There are also several reports of under-sensing, which could potentially lead to missed arrhythmias or other cardiac events.

\* Device migration is another concerning issue, as it could lead to device malfunction or even device embolization.

### **\*\*Frequencies of Remedial Actions Taken:\*\***

\* In most cases, the remedial action taken was to replace the device or repair it.

\* In some cases, the device was removed and the patient received a different type of device.

\* In a few cases, no remedial action was taken.

### **\*\*Correlations Between Reported Problems and Device Attributes:\*\***

\* It is difficult to identify any clear correlations between reported problems and device attributes based on the available data.

\* However, it is worth noting that the majority of reported problems occurred with the REVEAL LINQ device.

### **\*\*Additional Insights:\*\***

\* The reports highlight the importance of proper device selection and implantation.

\* They also underscore the need for ongoing monitoring of patients with implanted devices.

\* It is important to note that these reports represent only a small sample of the total number of adverse events that may occur with these devices.

## DSI MAUDE Problems Summary

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### **\*\*Limitations:\*\***

- \* This analysis is based on a limited number of adverse event reports.
- \* The reports may not be representative of all adverse events that occur with these devices.
- \* The data may be incomplete or inaccurate.

### **\*\*Recommendations:\*\***

- \* Manufacturers should continue to investigate and address the reported problems with their devices.
- \* Clinicians should be aware of the potential risks associated with these devices and monitor patients accordingly.
- \* Patients should be informed of the potential risks and benefits of these devices before they are implanted.

### **\*\*Further Analysis:\*\***

- \* Additional analysis could be conducted to identify any trends or patterns in the data.
- \* This could help to identify the root causes of the problems and develop strategies to prevent them from occurring in the future.

I hope this analysis is helpful. Please let me know if you have any questions.

DataAggregate 1-9:

### **## Analysis of Adverse Event Reports Dataset**

#### **### Common Product Problems:**

- \* **\*\*No Audible Alarm:\*\*** This is the most frequently reported product problem, accounting for a significant portion of the events. This issue can have serious consequences for patient safety, as it may prevent timely intervention in critical situations.
- \* **\*\*Signal Artifact/Noise:\*\*** This problem can interfere with the accurate interpretation of patient data and potentially lead to misdiagnosis or inappropriate treatment.
- \* **\*\*Over-Sensing:\*\*** This problem can lead to unnecessary pacing or shocks, which can be uncomfortable and even dangerous for patients.
- \* **\*\*Under-Sensing:\*\*** This problem can prevent the device from delivering necessary pacing or shocks, which can be life-threatening in some cases.
- \* **\*\*Communication or Transmission Problem:\*\*** This problem can prevent the device from communicating with external devices or transmitting data, which can hinder patient care and monitoring.

\* \*\*Device Sensing Problem:\*\* This problem can lead to inaccurate readings or misinterpretation of patient data.

\* \*\*Pacing Problem:\*\* This problem can lead to ineffective pacing or even harm the patient.

\* \*\*Battery Problem:\*\* This problem can lead to the device malfunctioning or stopping working altogether.

\* \*\*Reset Problem:\*\* This problem can lead to the device resetting unexpectedly, which can disrupt patient care.

\* \*\*Electrical /Electronic Property Problem:\*\* This problem can lead to the device malfunctioning or behaving erratically.

### ### Malfunctions:

The majority of the reported events are classified as malfunctions. This indicates that the devices are not functioning as intended, which can have serious implications for patient safety.

### ### Root Causes:

The root causes of the reported problems are not always clear. However, some potential causes include:

\* \*\*Defective components:\*\* This is a common cause of device malfunctions.

\* \*\*Software errors:\*\* Software errors can lead to a variety of problems, including inaccurate readings, communication problems, and device malfunctions.

\* \*\*Design flaws:\*\* Design flaws can make devices more susceptible to malfunctions or other problems.

\* \*\*User error:\*\* User error can also contribute to device malfunctions or other problems.

### ### Trends in Adverse Event Occurrence:

It is difficult to identify clear trends in adverse event occurrence based on the available data. However, it is worth noting that the number of reported events appears to be relatively consistent over time.

### ### Patterns in Reported Device Issues:

There are some patterns in the reported device issues. For example, certain types of devices, such as implantable cardiac monitors, appear to be more prone to certain types of problems, such as sensing issues and communication problems. Additionally, certain brands of devices appear to be more prone to certain types of problems than others.

### ### Frequencies of Remedial Actions Taken:

The most common remedial actions taken in response to adverse events include:

\* \*\*Device replacement:\*\* This is the most common remedial action, as it is often the most effective way to resolve the problem.

## DSI MAUDE Problems Summary

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- \* \*\*Software update:\*\* This can be an effective way to resolve software errors.
- \* \*\*Repair:\*\* This can be an effective way to resolve problems caused by defective components.
- \* \*\*No action taken:\*\* In some cases, no action is taken if the problem is not considered to be serious or if it is not possible to identify the root cause of the problem.

### ### Correlations Between Reported Problems and Device Attributes:

There are some correlations between the reported problems and device attributes. For example, certain types of devices, such as implantable cardiac monitors, appear to be more prone to certain types of problems, such as sensing issues and communication problems. Additionally, certain brands of devices appear to be more prone to certain types of problems than others.

### ## Additional Insights:

- \* The data suggests that there is a need for improved device design and manufacturing to reduce the number of malfunctions.
- \* There is also a need for improved software development and testing to reduce the number of software errors.
- \* User training and education can help to reduce the number of problems caused by user error.
- \* It is important to continue to monitor adverse event reports to identify trends and patterns that can help to improve device safety.

### ## Limitations:

- \* The data is limited to the events that have been reported to the manufacturer. It is possible that there are other events that have not been reported.
- \* The data does not include information about the severity of the adverse events.
- \* The data does not include information about the long-term outcomes of the adverse events.

### ## Conclusion:

The analysis of the adverse event reports dataset reveals a number of important insights about the safety of medical devices. The data suggests that there is a need for improved device design, manufacturing, software development, and user training to reduce the number of adverse events. It is also important to continue to monitor adverse event reports to identify trends and patterns that can help to improve device safety.

DataAggregate 1-10:

### ## Analysis of Adverse Event Reports Dataset

### ### Common Product Problems:

## DSI MAUDE Problems Summary

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\* \*\*No Audible Alarm:\*\* This is the most frequently reported problem, occurring in 144 events. This could lead to missed critical events and delayed patient care.

\* \*\*Failure to Transmit Record:\*\* This problem was reported in 12 events. This could lead to delayed diagnosis and treatment.

\* \*\*No Audible Prompt/Feedback:\*\* This problem was reported in 10 events. This could lead to confusion and frustration for users.

\* \*\*Melted/Overheating of Device:\*\* This problem was reported in 4 events. This could lead to burns or other injuries.

\* \*\*Solder Joint Fracture:\*\* This problem was reported in 1 event. This could lead to device failure.

### ### Malfunctions:

\* \*\*No Audible Alarm:\*\* This malfunction was reported in 144 events.

\* \*\*Failure to Transmit Record:\*\* This malfunction was reported in 12 events.

\* \*\*No Audible Prompt/Feedback:\*\* This malfunction was reported in 10 events.

\* \*\*Melted/Overheating of Device:\*\* This malfunction was reported in 4 events.

\* \*\*Solder Joint Fracture:\*\* This malfunction was reported in 1 event.

\* \*\*Under-Sensing:\*\* This malfunction was reported in 1 event.

\* \*\*Over-Sensing:\*\* This malfunction was reported in 1 event.

\* \*\*Signal Artifact/Noise:\*\* This malfunction was reported in 1 event.

\* \*\*Electromagnetic Interference:\*\* This malfunction was reported in 1 event.

\* \*\*Reset Problem:\*\* This malfunction was reported in 1 event.

\* \*\*Communication or Transmission Problem:\*\* This malfunction was reported in 1 event.

\* \*\*Delayed Alarm:\*\* This malfunction was reported in 1 event.

### ### Root Causes:

\* \*\*Defective Speaker:\*\* This was the most common root cause, identified in 104 events.

\* \*\*Software Issue:\*\* This was identified as the root cause in 12 events.

\* \*\*Hardware Issue:\*\* This was identified as the root cause in 4 events.

\* \*\*User Error:\*\* This was identified as the root cause in 1 event.

\* \*\*Unknown:\*\* The root cause was unknown in 22 events.

### ### Trends in Adverse Event Occurrence:



## DSI MAUDE Problems Summary

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- \* The number of reported adverse events has been increasing over the past year.

- \* The most common type of adverse event is a malfunction.

- \* The most common root cause of adverse events is a defective speaker.

### ### Patterns in Reported Device Issues:

- \* Devices with speakers are more likely to experience malfunctions.

- \* Devices that transmit data are more likely to experience communication problems.

- \* Devices that are used for long periods of time are more likely to experience overheating problems.

### ### Frequencies of Remedial Actions Taken:

- \* **Device Replaced:** This was the most common remedial action, taken in 104 events.

- \* **Software Update:** This was the remedial action taken in 12 events.

- \* **Hardware Repair:** This was the remedial action taken in 4 events.

- \* **No Action Taken:** This was the remedial action taken in 22 events.

### ### Correlations Between Reported Problems and Device Attributes:

- \* Devices with speakers are more likely to experience malfunctions.

- \* Devices that transmit data are more likely to experience communication problems.

- \* Devices that are used for long periods of time are more likely to experience overheating problems.

### ## Additional Insights:

- \* The data suggests that there is a need for improved quality control for devices with speakers.

- \* There is also a need for improved software and hardware design to prevent communication problems and overheating.

- \* It is important to investigate the root cause of adverse events to prevent them from happening again.

- \* It is also important to take appropriate remedial actions to address adverse events.

### ## Limitations:

- \* This analysis is based on a limited dataset.

- \* The data may not be representative of all adverse events that occur.

- \* The root cause of some adverse events may not be known.

### ## Recommendations:

- \* Manufacturers should improve quality control for devices with speakers.

## DSI MAUDE Problems Summary

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- \* Manufacturers should improve software and hardware design to prevent communication problems and overheating.

- \* Healthcare providers should investigate the root cause of adverse events to prevent them from happening again.

- \* Healthcare providers should take appropriate remedial actions to address adverse events.

### ## Conclusion:

This analysis has identified several important trends and patterns in adverse event reports. This information can be used to improve the safety and reliability of medical devices.

### DataAggregate 1-11:

#### ## Common Product Problems:

- \* **Failure to Transmit Record:** This is the most common product problem, with 14 events reported. This issue occurs when the device fails to transmit the recorded data to the healthcare provider, potentially delaying diagnosis and treatment.

- \* **Communication or Transmission Problem:** This problem, reported in 10 events, involves issues with the device's ability to communicate with the remote monitor or other devices. This can lead to data loss or delays in receiving important information.

- \* **Under-Sensing:** This problem, reported in 7 events, occurs when the device fails to detect certain heart rhythms, potentially leading to missed diagnoses and delayed treatment.

- \* **No Audible Alarm:** This problem, reported in 6 events, involves the device failing to sound an alarm when it detects a critical event, potentially putting the patient at risk.

- \* **Battery Problem:** This problem, reported in 2 events, involves issues with the device's battery, such as premature depletion or malfunction.

- \* **Device-Device Incompatibility:** This problem, reported in 1 event, occurs when the device is incompatible with another device, potentially leading to data loss or errors.

- \* **Defective Alarm:** This problem, reported in 1 event, involves the device sounding a false alarm, potentially causing unnecessary anxiety or intervention.

- \* **Use of Device Problem:** This problem, reported in 1 event, involves the patient or caregiver using the device incorrectly, potentially leading to inaccurate data or harm.

#### ## Malfunctions:

All reported events are classified as malfunctions, indicating that the device did not perform as intended.

#### ## Root Causes:

## DSI MAUDE Problems Summary

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The root causes of the reported problems are not always identified. However, some potential causes include:

\* \*\*Software bugs:\*\* This is a likely cause for problems such as failure to transmit records, communication issues, and under-sensing.

\* \*\*Hardware defects:\*\* This is a likely cause for problems such as no audible alarm, battery problems, and device-device incompatibility.

\* \*\*User error:\*\* This is a likely cause for the use of device problem.

\* \*\*Algorithm sensitivity issues:\*\* This is a potential cause for failure to transmit records, as the device's algorithm may not be sensitive enough to detect certain arrhythmias.

### ## Trends in Adverse Event Occurrence:

The data does not show any clear trends in the occurrence of adverse events. However, it is important to note that this is a relatively small dataset, and more data is needed to draw any definitive conclusions.

### ## Patterns in Reported Device Issues:

The data shows that certain device issues are more likely to occur together. For example, failure to transmit records and communication problems are often reported together. This suggests that these issues may be related to the same underlying cause, such as a software bug.

### ## Frequencies of Remedial Actions Taken:

The most common remedial action taken was to replace the device (10 events). Other actions taken included repairing the device (4 events), reprogramming the device (1 event), and providing additional training to the user (1 event).

### ## Correlations Between Reported Problems and Device Attributes:

The data does not show any clear correlations between reported problems and device attributes such as brand, model, or manufacturing date. However, it is important to note that this is a relatively small dataset, and more data is needed to draw any definitive conclusions.

### ## Conclusion:

The data analysis reveals several important insights about the adverse events associated with these cardiac monitoring devices. The most common problems are related to data transmission, communication, and sensing. These issues can potentially delay diagnosis and treatment, putting patients at risk. The root causes of these problems are not always identified, but software bugs and hardware defects are likely contributors. More data is needed to identify trends in adverse event occurrence and to determine the correlations between reported problems and device attributes.

DataAggregate 1-12:

## ## Analysis of Adverse Event Reports Dataset

### ### Common Product Problems:

- \* \*\*No Audible Alarm:\*\* This is the most frequently reported problem, appearing in 12 events. This could potentially lead to delayed or missed interventions in critical situations.
- \* \*\*Over-Sensing:\*\* This issue is reported in 8 events and can lead to unnecessary pacing or therapies for the patient.
- \* \*\*Under-Sensing:\*\* This problem is reported in 7 events and can lead to missed arrhythmias or other critical events.
- \* \*\*Failure to Transmit Record:\*\* This issue is reported in 7 events and can delay diagnosis and treatment.
- \* \*\*Communication or Transmission Problem:\*\* This issue is reported in 4 events and can prevent effective communication between the device and the healthcare team.
- \* \*\*No Audible Prompt/Feedback:\*\* This issue is reported in 3 events and can lead to confusion or uncertainty about the device's status.
- \* \*\*Reset Problem:\*\* This issue is reported in 1 event and can potentially lead to data loss or device malfunction.
- \* \*\*Migration or Expulsion of Device:\*\* This issue is reported in 1 event and can lead to serious complications for the patient.
- \* \*\*Device Alarm System:\*\* This issue is reported in 1 event and can potentially lead to missed or delayed interventions.
- \* \*\*Signal Artifact/Noise:\*\* This issue is reported in 1 event and can lead to misinterpretation of the patient's data.

### ### Malfunctions:

- \* \*\*No Audible Alarm:\*\* This malfunction is reported in 12 events.
- \* \*\*Over-Sensing:\*\* This malfunction is reported in 8 events.
- \* \*\*Under-Sensing:\*\* This malfunction is reported in 7 events.
- \* \*\*Failure to Transmit Record:\*\* This malfunction is reported in 7 events.
- \* \*\*Communication or Transmission Problem:\*\* This malfunction is reported in 4 events.
- \* \*\*No Audible Prompt/Feedback:\*\* This malfunction is reported in 3 events.
- \* \*\*Reset Problem:\*\* This malfunction is reported in 1 event.
- \* \*\*Device Alarm System:\*\* This malfunction is reported in 1 event.

## DSI MAUDE Problems Summary

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\* \*\*Signal Artifact/Noise:\*\* This malfunction is reported in 1 event.

### ### Root Causes:

\* \*\*Defective Speaker:\*\* This is the most frequently identified root cause, appearing in 5 events.

\* \*\*Algorithm Sensitivity Issue:\*\* This is identified as the root cause in 7 events related to failure to transmit records.

\* \*\*Software Issue:\*\* This is identified as the root cause in 1 event related to failure to transmit records.

\* \*\*Device Opened and Modified:\*\* This is identified as the root cause in 1 event related to no audible alarm.

\* \*\*Unknown:\*\* The root cause is unknown in many cases.

### ### Trends in Adverse Event Occurrence:

\* The number of reported adverse events appears to be increasing over time.

\* The most common types of adverse events are related to alarms, sensing, and data transmission.

\* The most common root causes are related to device defects and software issues.

### ### Patterns in Reported Device Issues:

\* Devices with audible alarms seem to be particularly prone to malfunction.

\* Devices that rely on algorithms for data interpretation can be susceptible to false positives or negatives.

\* Data transmission issues can be caused by a variety of factors, including software problems and network connectivity issues.

### ### Frequencies of Remedial Actions Taken:

\* \*\*Replacement of Device Component:\*\* This is the most common remedial action, taken in 6 events.

\* \*\*Reprogramming of Device:\*\* This is the second most common remedial action, taken in 2 events.

\* \*\*No Further Action Required:\*\* This is the third most common remedial action, taken in 1 event.

\* \*\*Device Returned to Manufacturer:\*\* This is done in 1 event for further evaluation.

\* \*\*Software Update:\*\* This is done in 1 event to address the root cause.

### ### Correlations Between Reported Problems and Device Attributes:

\* \*\*Brand:\*\* Some brands appear to be more prone to certain types of problems than others. For example, Philips devices seem to be more prone to problems with audible alarms.

## DSI MAUDE Problems Summary

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\* \*\*Model:\*\* Some models may be more prone to certain types of problems than others.

\* \*\*Age of Device:\*\* Older devices may be more likely to experience malfunctions.

### ## Additional Insights:

\* The dataset does not include information on the total number of devices in use, making it difficult to calculate the rate of adverse events.

\* The dataset does not include information on the severity of the adverse events.

\* The dataset does not include information on the long-term outcomes of the adverse events.

### ## Recommendations:

\* Manufacturers should investigate the root causes of the most common adverse events and take steps to mitigate them.

\* Healthcare providers should be aware of the potential for adverse events with these devices and should monitor patients closely for any signs or symptoms of malfunction.

\* Patients should be educated about the potential for adverse events and should be encouraged to report any problems they experience to their healthcare provider.

### ## Limitations:

\* This analysis is based on a limited dataset and may not be representative of all adverse events that occur with these devices.

\* The analysis does not include information on the severity of the adverse events or the long-term outcomes.

\* The analysis does not identify all possible root causes of the adverse events.

### ## Conclusion:

Adverse events associated with medical devices can have serious consequences for patients. It is important to identify the root causes of these events and take steps to mitigate them. Healthcare providers and patients should be aware of the potential for adverse events and should report any problems they experience to the manufacturer and the FDA.

DataAggregate 1-13:

### ## Common Product Problems:

\* \*\*Device Alarm System:\*\* This is the most frequently reported product problem, with 12 events mentioning it. This includes issues such as alarms not working, alarms being too quiet, and alarms not being recognized.

## DSI MAUDE Problems Summary

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\* \*\*No Audible Alarm:\*\* This problem is reported in 11 events. This can be a serious issue, as it can prevent patients from receiving timely medical attention.

\* \*\*No Audible Prompt/Feedback:\*\* This problem is reported in 8 events. This can be a nuisance, as it can make it difficult for patients to use the device properly.

\* \*\*Under-Sensing:\*\* This problem is reported in 7 events. This can be a serious issue, as it can lead to the device not detecting a patient's heart rhythm correctly.

\* \*\*Defective Alarm:\*\* This problem is reported in 6 events. This can be a serious issue, as it can lead to the device giving false alarms.

\* \*\*Battery Problem:\*\* This problem is reported in 5 events. This can be a nuisance, as it can cause the device to stop working unexpectedly.

\* \*\*Communication or Transmission Problem:\*\* This problem is reported in 4 events. This can be a serious issue, as it can prevent the device from communicating with other medical devices.

\* \*\*Migration or Expulsion of Device:\*\* This problem is reported in 1 event. This can be a serious issue, as it can lead to the device needing to be surgically removed.

\* \*\*Over-Sensing:\*\* This problem is reported in 1 event. This can be a serious issue, as it can lead to the device detecting a patient's heart rhythm incorrectly.

\* \*\*Signal Artifact/Noise:\*\* This problem is reported in 2 events. This can be a nuisance, as it can make it difficult to interpret the device's readings.

\* \*\*Manufacturing, Packaging or Shipping Problem:\*\* This problem is reported in 2 events. This can be a serious issue, as it can lead to patients receiving the wrong device or a device that is not properly packaged.

### ## Malfunctions:

\* \*\*Device Alarm System:\*\* This is the most frequently reported malfunction, with 12 events mentioning it. This includes issues such as alarms not working, alarms being too quiet, and alarms not being recognized.

\* \*\*No Audible Alarm:\*\* This malfunction is reported in 11 events. This can be a serious issue, as it can prevent patients from receiving timely medical attention.

\* \*\*No Audible Prompt/Feedback:\*\* This malfunction is reported in 8 events. This can be a nuisance, as it can make it difficult for patients to use the device properly.

\* \*\*Under-Sensing:\*\* This malfunction is reported in 7 events. This can be a serious issue, as it can lead to the device not detecting a patient's heart rhythm correctly.

\* \*\*Defective Alarm:\*\* This malfunction is reported in 6 events. This can be a serious issue, as it can lead to the device giving false alarms.

## DSI MAUDE Problems Summary

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\* \*\*Battery Problem:\*\* This malfunction is reported in 5 events. This can be a nuisance, as it can cause the device to stop working unexpectedly.

\* \*\*Communication or Transmission Problem:\*\* This malfunction is reported in 4 events. This can be a serious issue, as it can prevent the device from communicating with other medical devices.

\* \*\*Migration or Expulsion of Device:\*\* This malfunction is reported in 1 event. This can be a serious issue, as it can lead to the device needing to be surgically removed.

\* \*\*Over-Sensing:\*\* This malfunction is reported in 1 event. This can be a serious issue, as it can lead to the device detecting a patient's heart rhythm incorrectly.

\* \*\*Signal Artifact/Noise:\*\* This malfunction is reported in 2 events. This can be a nuisance, as it can make it difficult to interpret the device's readings.

\* \*\*Manufacturing, Packaging or Shipping Problem:\*\* This malfunction is reported in 2 events. This can be a serious issue, as it can lead to patients receiving the wrong device or a device that is not properly packaged.

### ## Root Causes:

\* \*\*Defective Speaker:\*\* This is the most frequently reported root cause, with 10 events mentioning it. This can be caused by a manufacturing defect or by wear and tear.

\* \*\*Software Issue:\*\* This root cause is reported in 4 events. This can be caused by a bug in the device's software.

\* \*\*Hardware Issue:\*\* This root cause is reported in 3 events. This can be caused by a defect in the device's hardware.

\* \*\*User Error:\*\* This root cause is reported in 3 events. This can be caused by the user not using the device correctly.

\* \*\*Unknown:\*\* This root cause is reported in 10 events. This means that the cause of the problem has not been identified.

### ## Trends in Adverse Event Occurrence:

\* There is a trend of increasing adverse events related to the Device Alarm System. This could be due to a number of factors, such as the increasing complexity of medical devices and the increasing reliance on alarms to alert clinicians to potential problems.

\* There is also a trend of increasing adverse events related to No Audible Alarm. This could be due to the increasing use of wireless medical devices, which are more likely to have problems with their speakers.

\* There is a trend of decreasing adverse events related to Under-Sensing. This could be due to improvements in the algorithms used by medical devices to detect heart rhythms.



## DSI MAUDE Problems Summary

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### ## Patterns in Reported Device Issues:

- \* There is a pattern of device issues related to the speaker. This could be due to a design flaw in the speaker or to the use of low-quality speakers.
- \* There is also a pattern of device issues related to the software. This could be due to the complexity of the software or to the use of outdated software.
- \* There is also a pattern of device issues related to the battery. This could be due to the use of low-quality batteries or to the batteries not being properly maintained.

### ## Frequencies of Remedial Actions Taken:

- \* **Device Replacement:** This is the most frequently reported remedial action, with 14 events mentioning it. This is typically done when the device is found to be defective.
- \* **Software Update:** This remedial action is reported in 4 events. This is typically done when the device is found to have a software issue.
- \* **Hardware Repair:** This remedial action is reported in 3 events. This is typically done when the device is found to have a hardware issue.
- \* **User Training:** This remedial action is reported in 3 events. This is typically done when the device is found to be due to user error.
- \* **No Action Taken:** This remedial action is reported in 10 events. This is typically done when the cause of the problem is unknown or when the problem is not considered to be serious.

### ## Correlations Between Reported Problems and Device Attributes:

- \* There is a correlation between the Device Alarm System problem and the MX40 device. This could be due to a design flaw in the MX40 device or to the use of low-quality speakers in the MX40 device.
- \* There is also a correlation between the No Audible Alarm problem and the MX40 device. This could be due to the increasing use of wireless medical devices, which are more likely to have problems with their speakers.
- \* There is also a correlation between the Under-Sensing problem and the REVEAL LINQ device. This could be due to the complexity of the REVEAL LINQ device or to the use of outdated software in the REVEAL LINQ device.

### ## Additional Insights:

- \* The majority of adverse events are reported by healthcare professionals. This suggests that healthcare professionals are more likely to notice and report adverse events than patients.
- \* The majority of adverse events are reported in the United States. This could be due to the fact that the United States has a large population and a well-developed healthcare system.

\* The majority of adverse events are reported for devices that are used in hospitals. This could be due to the fact that hospitals use a wide variety of medical devices and that patients in hospitals are more likely to be monitored closely.

## ## Conclusion:

The data in this report can be used to identify trends in adverse event occurrence, patterns in reported device issues, and correlations between reported problems and device attributes. This information can be used to improve the safety of medical devices and to prevent future adverse events.

## DataAggregate 1-14:

### ## Adverse Event Report Analysis

This report analyzes adverse event reports associated with medical devices.

### ### Common Product Problems:

\* \*\*No Audible Alarm:\*\* This is the most frequently reported problem, occurring in 12 events. This could potentially lead to delayed or missed treatment for patients.

\* \*\*Communication or Transmission Problem:\*\* This problem is reported in 10 events. This could lead to patients not receiving necessary data or alerts from their devices.

\* \*\*Failure to Transmit Record:\*\* This problem is reported in 8 events. This could lead to delays in diagnosis and treatment.

\* \*\*Device Sensing Problem:\*\* This problem is reported in 2 events. This could lead to inaccurate readings or missed events.

\* \*\*Overheating of Device:\*\* This problem is reported in 1 event. This could lead to burns or other injuries.

\* \*\*Biocompatibility:\*\* This problem is reported in 3 events. This could lead to skin irritation or other allergic reactions.

\* \*\*Break, Electrical /Electronic Property Problem:\*\* This problem is reported in 1 event. This could lead to device malfunction or failure.

### ### Malfunctions:

\* \*\*No Audible Alarm:\*\* This malfunction is reported in 12 events.

\* \*\*Communication or Transmission Problem:\*\* This malfunction is reported in 10 events.

\* \*\*Failure to Transmit Record:\*\* This malfunction is reported in 8 events.

\* \*\*Device Sensing Problem:\*\* This malfunction is reported in 2 events.

\* \*\*Overheating of Device:\*\* This malfunction is reported in 1 event.

## DSI MAUDE Problems Summary

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### ### Injuries:

- \* \*\*Burn(s):\*\* This injury is reported in 2 events.
- \* \*\*Skin Inflammation/ Irritation:\*\* This injury is reported in 4 events.
- \* \*\*Skin Tears, Blister:\*\* This injury is reported in 1 event.

### ### Deaths:

- \* \*\*Death:\*\* This outcome is reported in 1 event.

### ### Trends in Adverse Event Occurrence:

- \* The number of reported adverse events appears to be increasing.
- \* The most common product problems are related to alarms, communication, and data transmission.
- \* The most common injuries are burns and skin irritation.

### ### Patterns in Reported Device Issues:

- \* Devices from Philips and Medtronic are over-represented in the reports.
- \* The MX40 device from Philips is associated with several reports of overheating and alarms.
- \* The Reveal LINQ device from Medtronic is associated with several reports of communication and data transmission problems.

### ### Frequencies of Remedial Actions Taken:

- \* No remedial action was taken in 17 events.
- \* A replacement device was provided in 5 events.
- \* The device was repaired in 4 events.
- \* The device was explanted in 1 event.

### ### Correlations Between Reported Problems and Device Attributes:

- \* The overheating problem appears to be specific to the MX40 device from Philips.
- \* The communication and data transmission problems appear to be more common with devices from Medtronic.
- \* The skin irritation problems appear to be more common with devices that have adhesive electrodes.

### ## Conclusion:

This analysis reveals several important findings about adverse events associated with medical devices. The most common problems are related to alarms, communication, and data transmission. These problems can lead to delayed or missed treatment, inaccurate readings, and other serious

consequences. It is important to continue to monitor these events and to take steps to improve the safety and reliability of medical devices.

### ## Additional Notes:

- \* This analysis is based on a limited number of adverse event reports.
- \* The data may not be representative of all adverse events that occur with medical devices.
- \* Further investigation is needed to determine the root causes of these problems and to develop effective solutions.

### ## Recommendations:

- \* Manufacturers should investigate the root causes of the reported problems and take steps to correct them.
- \* Healthcare providers should be aware of the potential risks associated with these devices and should monitor patients closely for any adverse events.
- \* Patients should be informed of the potential risks associated with these devices and should report any adverse events to their healthcare provider.

### DataAggregate 1-15:

### ## Analysis of Adverse Event Reports Dataset

#### ### Common Product Problems:

- \* **No Audible Alarm:** This is the most frequently reported product problem, appearing in 14 events. This could potentially lead to delayed or missed alerts for critical patient conditions.
- \* **Communication or Transmission Problem:** This issue, reported in 8 events, could result in delayed data transmission or loss of communication with the implanted device, potentially impacting patient care.
- \* **Under-Sensing:** This problem, reported in 7 events, could lead to missed or inaccurate readings of the patient's heart rhythm, potentially delaying or preventing appropriate treatment.
- \* **Failure to Interrogate:** This issue, reported in 5 events, could prevent access to important data from the implanted device, hindering diagnosis and treatment decisions.
- \* **Defective Alarm:** This problem, reported in 4 events, could lead to false alarms or missed alarms, potentially causing unnecessary anxiety or delaying appropriate interventions.
- \* **Device Emits Odor:** This issue, reported in 1 event, could indicate a potential malfunction or safety hazard.
- \* **Melted:** This issue, reported in 1 event, could indicate a potential fire hazard.

## DSI MAUDE Problems Summary

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\* \*\*Biocompatibility:\*\* This issue, reported in 1 event, could lead to allergic reactions or other adverse reactions in the patient.

\* \*\*Overheating of Device:\*\* This issue, reported in 1 event, could lead to burns or other injuries to the patient.

\* \*\*Device Sensing Problem:\*\* This issue, reported in 1 event, could lead to inaccurate readings or missed events, potentially impacting patient care.

### ### Malfunctions:

The majority of reported events (27 out of 34) are classified as malfunctions, indicating a problem with the device itself. This highlights the importance of robust device design, manufacturing, and quality control to minimize the risk of malfunctions.

### ### Root Causes:

While the root cause is not always identified in the reports, some potential causes can be inferred from the reported problems. These include:

\* \*\*Defective speaker:\*\* This is the most likely cause for the "No Audible Alarm" problem.

\* \*\*Software or hardware issues:\*\* These could be responsible for communication problems, under-sensing, failure to interrogate, and other malfunctions.

\* \*\*Electrode issues:\*\* These could be responsible for biocompatibility issues and device sensing problems.

\* \*\*Battery issues:\*\* These could be responsible for overheating and other malfunctions.

### ### Trends in Adverse Event Occurrence:

There is no clear trend in the occurrence of adverse events over time based on the limited data available. However, it is important to continuously monitor and analyze adverse event reports to identify potential trends and take appropriate actions to mitigate risks.

### ### Patterns in Reported Device Issues:

Certain device models appear to be more prone to specific problems. For example, the MX40 and Intellivue series of monitors seem to have a higher frequency of "No Audible Alarm" issues. This information can be helpful in prioritizing investigations and implementing corrective actions.

### ### Frequencies of Remedial Actions Taken:

The most common remedial actions taken include:

\* \*\*Replacing the device or component:\*\* This is the most common action for malfunctions caused by hardware defects.

\* \*\*Software updates:\*\* These can address software-related issues.

\* \*\*Troubleshooting and adjustments:\*\* These can resolve issues related to configuration or user error.

\* \*\*No action required:\*\* This is typically the case when the issue is not confirmed or the device is no longer in use.

### ### Correlations Between Reported Problems and Device Attributes:

There may be correlations between certain device attributes (e.g., brand, model, age) and the types of problems reported. Further analysis with a larger dataset could reveal such correlations and help identify areas for improvement in device design or manufacturing.

### ## Conclusion:

This analysis provides valuable insights into the types of adverse events reported for the specific device models. By identifying common product problems, potential root causes, and trends in occurrence, manufacturers and healthcare providers can take proactive steps to improve device safety and patient care.

It is important to note that this analysis is based on a limited dataset and may not be representative of the overall population of adverse events for these devices. Further analysis with a larger dataset and more detailed information about the events is needed to draw more definitive conclusions.

### DataAggregate 1-16:

#### ## Analysis of Adverse Event Reports

##### ### Common Product Problems:

\* \*\*Migration or Expulsion of Device:\*\* This issue was reported in Event 556, where the ICM partially migrated through the chest wall, leading to wound dehiscence and pain. This highlights the potential for serious complications associated with device migration.

\* \*\*Battery Problem:\*\* Event 579 reported premature battery depletion in an ICM, leading to failure to interrogate the device. This emphasizes the importance of battery life and the potential consequences of its depletion.

\* \*\*No Audible Prompt/Feedback:\*\* This problem was reported in multiple events, including 557, 561, 563, 566, 567, 568, and 573. The absence of audible alarms or prompts can lead to missed critical events and potentially compromise patient safety.

\* \*\*Under-Sensing:\*\* Events 553, 554, 570, and 571 reported under-sensing issues with the ICM, leading to missed or inaccurate detection of cardiac events. This highlights the potential for under-sensing to impact patient care negatively.

\* \*\*Reset Problem:\*\* Events 555 and 578 reported electrical resets in the ICM, potentially affecting data integrity and requiring additional interrogation attempts. This emphasizes the potential impact of resets on device functionality.

## DSI MAUDE Problems Summary

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\* \*\*Melted:\*\* Events 560 and 564 reported melting issues with the C6 monitor and charger cord, posing a potential fire hazard. This highlights the importance of addressing overheating and potential fire risks associated with medical devices.

\* \*\*Temperature Problem:\*\* Similar to the "Melted" issue, Events 560 and 564 also reported temperature problems with the C6 monitor and charger cord, further emphasizing the need to address overheating risks.

\* \*\*Communication or Transmission Problem:\*\* Event 549 reported communication issues with the ICM, leading to loss of telemetry and inability to establish connection. This highlights the importance of reliable communication for effective patient monitoring.

\* \*\*Display or Visual Feedback Problem:\*\* Event 552 reported a display issue with the MX40, affecting the user's ability to access information. This emphasizes the importance of clear and functional displays for proper device operation.

\* \*\*Defective Alarm:\*\* Event 565 reported a defective alarm on the MP70, potentially leading to missed critical events. This highlights the importance of reliable alarm functionality for patient safety.

### ### Malfunctions:

The majority of reported events (548, 549, 551, 552, 553, 554, 555, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 573, 574, 575, 577, 578, 579, and 580) were classified as malfunctions. These malfunctions involved various issues, including:

\* \*\*No Audible Prompt/Feedback:\*\* This was the most frequently reported malfunction, affecting various devices like MX40, MP5, MP70, and Multi Measurement Server X2.

\* \*\*Under-Sensing:\*\* This issue was reported for the ICM, potentially leading to missed or inaccurate detection of cardiac events.

\* \*\*Reset Problem:\*\* Electrical resets were reported for the ICM, potentially affecting data integrity and requiring additional interrogation attempts.

\* \*\*Melted:\*\* Melting issues were reported for the C6 monitor and charger cord, posing a potential fire hazard.

\* \*\*Temperature Problem:\*\* Overheating issues were reported for the C6 monitor and charger cord, emphasizing the need to address overheating risks.

\* \*\*Communication or Transmission Problem:\*\* Communication issues with the ICM led to loss of telemetry and inability to establish connection.

\* \*\*Display or Visual Feedback Problem:\*\* Display issues with the MX40 affected the user's ability to access information.

\* \*\*Defective Alarm:\*\* A defective alarm on the MP70 potentially led to missed critical events.

### ### Root Causes:

## DSI MAUDE Problems Summary

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While the reports provide details of the observed issues, the root causes for many of the malfunctions remain under investigation. Further analysis and investigation are needed to determine the underlying causes of these problems and implement corrective actions.

### ### Trends in Adverse Event Occurrence:

\* \*\*No Audible Prompt/Feedback:\*\* This issue appears to be a recurring problem across various devices, suggesting a potential systemic issue requiring further investigation.

\* \*\*Under-Sensing:\*\* Under-sensing issues with the ICM were reported multiple times, highlighting the need for improvement in accurate detection of cardiac events.

\* \*\*Battery Problem:\*\* Premature battery depletion in the ICM emphasizes the importance of reliable battery performance and addressing potential causes of early depletion.

\* \*\*Melted/Temperature Problem:\*\* The reported melting and overheating issues with the C6 monitor and charger cord warrant further investigation to address potential fire hazards.

### ### Patterns in Reported Device Issues:

\* \*\*Specific Device Models:\*\* Certain device models, such as the ICM, MX40, and C6 monitor, appear to be associated with a higher frequency of reported issues. This suggests the need for focused investigation and potential improvement efforts for these specific models.

\* \*\*Device Type:\*\* Issues were reported across various device types, including ICMs, patient monitors, and telemetry devices. This highlights the need for comprehensive analysis and improvement efforts across different device categories.

### ### Frequencies of Remedial Actions Taken:

\* \*\*Investigation Ongoing:\*\* Many reports indicate that investigations are ongoing to determine the root causes of the reported issues. This emphasizes the importance of thorough investigation and timely resolution of identified problems.

\* \*\*Device Replaced:\*\* In some cases, the reported devices were replaced with new ones. This highlights the importance of addressing device malfunctions promptly and ensuring patient safety.

\* \*\*No Further Action:\*\* For some reports, no further action was deemed necessary after initial investigation. This suggests that the reported issues were either resolved or deemed not to pose significant risks.

### ### Correlations Between Reported Problems and Device Attributes:

\* \*\*Device Age:\*\* The age of the device could potentially be a factor in some malfunctions, such as battery depletion or overheating issues. Further analysis is needed to investigate potential correlations between device age and reported problems.

\* \*\*Software Version:\*\* In some cases, software updates or firmware issues might contribute to malfunctions. Investigating the software versions associated with reported problems could provide



valuable insights.

\* \*\*Environmental Factors:\*\* Environmental factors, such as temperature or humidity, could potentially play a role in certain malfunctions. Analyzing the environmental conditions during reported events could help identify potential contributing factors.

## ## Conclusion:

The analysis of adverse event reports reveals several important insights:

\* \*\*Recurring issues:\*\* Certain problems, such as "No Audible Prompt/Feedback" and "Under-Sensing," appear to be recurring issues across various devices, requiring focused attention and improvement efforts.

\* \*\*Device-specific issues:\*\* Some device models seem to be associated with a higher frequency of reported problems, suggesting the need for specific investigation and potential improvement efforts for those models.

\* \*\*Importance of investigation:\*\* Thorough investigation is crucial to determine the root causes of reported issues and implement effective corrective actions.

\* \*\*Addressing patient safety:\*\* Timely resolution of identified problems and ensuring patient safety are paramount concerns.

Further analysis and investigation are needed to fully understand the underlying causes of the reported issues, identify potential trends, and implement effective corrective actions to improve device safety and reliability.

## DataAggregate 1-17:

### ## Adverse Event Report Analysis

This report analyzes adverse event reports associated with medical devices. The analysis focuses on identifying common product problems, malfunctions, root causes, trends in adverse event occurrence, patterns in reported device issues, frequencies of remedial actions taken, correlations between reported problems and device attributes, and insights into device safety and effectiveness.

### #### Common Product Problems

The most frequently reported product problems include:

\* \*\*No Audible Alarm:\*\* This issue was reported in 14 events, indicating a potential safety concern as patients or healthcare professionals might not be alerted to critical situations.

\* \*\*Under-Sensing:\*\* This problem was reported in 8 events, potentially leading to missed diagnoses or delayed treatment.

\* \*\*Over-Sensing:\*\* This issue was reported in 6 events, potentially leading to unnecessary interventions or anxiety for patients.

\* \*\*Defective Alarm:\*\* This problem was reported in 5 events, raising concerns about the reliability of alarm systems in notifying about critical situations.

\* \*\*Device Fell:\*\* This issue was reported in 1 event, highlighting the importance of secure device placement to prevent potential injuries.

### ### Malfunction Types

The majority of reported events (28) were classified as malfunctions, indicating a device failure or performance issue. Other event types included death (1), injury (1), and communication or transmission problem (1).

### ### Root Causes

The root causes of reported problems varied, including:

\* \*\*Defective Speaker:\*\* This was identified as the cause in 10 events, highlighting the importance of reliable audio output for alarms and notifications.

\* \*\*Software Issue:\*\* This was identified as the cause in 2 events, emphasizing the need for robust software development and testing.

\* \*\*Hardware Failure:\*\* This was identified as the cause in 1 event, underlining the importance of device durability and reliability.

\* \*\*User Error:\*\* This was identified as a contributing factor in some events, highlighting the need for clear instructions and training for device users.

### ### Trends in Adverse Event Occurrence

While the dataset covers a limited timeframe, some trends can be observed:

\* \*\*Increased reports of "No Audible Alarm" issues:\*\* This suggests a potential area for improvement in device design and manufacturing.

\* \*\*Under-Sensing and Over-Sensing issues:\*\* These problems require further investigation to determine underlying causes and potential solutions.

\* \*\*Fewer reports of "Device Fell" incidents:\*\* This could indicate improved device design or user awareness.

### ### Patterns in Reported Device Issues

Certain patterns emerge from the reported device issues:

\* \*\*Alarms and notifications:\*\* Many problems relate to alarm functionality, highlighting the critical role of reliable alarms in patient safety.

\* \*\*Sensor accuracy:\*\* Issues with under-sensing and over-sensing suggest the need for improved sensor technology and algorithms.

# DSI MAUDE Problems Summary

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\* \*\*Software and hardware reliability:\*\* Device malfunctions due to software or hardware issues emphasize the importance of robust design and testing.

## ### Frequencies of Remedial Actions Taken

The most common remedial actions included:

\* \*\*Device replacement:\*\* This was performed in 12 events, indicating a need for improved device reliability.

\* \*\*Software update:\*\* This was performed in 2 events, highlighting the importance of ongoing software maintenance and updates.

\* \*\*Investigation:\*\* This was initiated in 22 events, demonstrating a commitment to understanding the root causes of problems and implementing corrective actions.

## ### Correlations Between Reported Problems and Device Attributes

Some correlations can be observed between reported problems and device attributes:

\* \*\*Speaker malfunctions:\*\* These issues were more frequent in specific device models, suggesting potential design or manufacturing flaws.

\* \*\*Sensor issues:\*\* These problems were reported across different device models, indicating a broader challenge in sensor technology.

\* \*\*Software problems:\*\* These issues were reported in devices from various manufacturers, highlighting the importance of robust software development practices.

## ### Insights into Device Safety and Effectiveness

The analysis provides valuable insights into device safety and effectiveness:

\* \*\*Areas for improvement:\*\* The report identifies specific areas where device design, manufacturing, and software development can be enhanced to improve reliability and safety.

\* \*\*Importance of investigations:\*\* Thorough investigations into the root causes of adverse events are crucial for preventing future occurrences and improving device safety.

\* \*\*Need for ongoing monitoring:\*\* Continuous monitoring of adverse event reports is essential for identifying emerging trends and implementing necessary corrective actions.

## ### Limitations

It is important to note that this analysis is based on a limited dataset and may not represent the full picture of adverse events associated with medical devices. Further analysis with larger datasets and longer timeframes is needed to draw more definitive conclusions.

## ## Conclusion

This analysis provides valuable insights into the types of adverse events, product problems, and root causes associated with medical devices. By identifying common issues and trends, this report can inform efforts to improve device design, manufacturing, and software development, ultimately enhancing patient safety and device effectiveness.

DataAggregate 1-18:

## Analysis of Adverse Event Reports

### Common Product Problems:

\* \*\*No Audible Alarm:\*\* This is the most frequently reported problem, with 17 instances across various devices. This could potentially lead to delayed or missed interventions in critical situations.

\* \*\*Over-Sensing:\*\* This issue was reported for REVEAL LINQ devices, potentially leading to unnecessary alarms and anxiety for patients.

\* \*\*Under-Sensing:\*\* Also reported for REVEAL LINQ, this could result in missed detection of critical events.

\* \*\*Failure to Transmit Record:\*\* This problem was observed with ZIO AT devices, potentially delaying diagnosis and treatment.

\* \*\*Communication or Transmission Problem:\*\* Reported for REVEAL LINQ, this could hinder data transmission and remote monitoring.

\* \*\*Migration or Expulsion of Device:\*\* This occurred with REVEAL LINQ, potentially requiring additional surgery.

\* \*\*Signal Artifact/Noise:\*\* This issue was reported for REVEAL LINQ, potentially affecting data accuracy and interpretation.

\* \*\*Device Fell:\*\* This occurred with MX700 Patient Monitor, potentially causing damage or disruption of monitoring.

\* \*\*Melted/Overheating of Device:\*\* This was reported for C6 MCOT PPM, posing a potential burn hazard.

\* \*\*Defective Alarm:\*\* This issue was observed with MX40 devices, potentially leading to false alarms or missed alerts.

\* \*\*No Audible Prompt/Feedback:\*\* This problem was reported for several MX40 and Intellivue devices, potentially hindering user interaction and awareness.

\* \*\*Unable to Obtain Readings:\*\* This occurred with REVEAL LINQ, potentially affecting data collection and monitoring.

\* \*\*Device Alarm System:\*\* This issue was reported for MX40, potentially leading to malfunctioning alarms.

## DSI MAUDE Problems Summary

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\* \*\*Mechanical Problem:\*\* Also reported for MX40, this could contribute to device malfunction.

\* \*\*Use of Device Problem:\*\* This was observed with ZIO AT, potentially related to incorrect patient identification or device registration.

### ### Malfunctions:

The majority of reported events (54 out of 64) were classified as malfunctions, indicating a problem with the device's functionality.

### ### Root Causes:

\* \*\*Defective Speaker:\*\* This was the most common root cause identified for "No Audible Alarm" issues, requiring speaker replacement.

\* \*\*Software Issue:\*\* This was identified as a potential cause for "Failure to Transmit Record" and "Communication or Transmission Problem" with ZIO AT devices.

\* \*\*Hardware Malfunction:\*\* This could be a contributing factor to various issues like "Over-Sensing," "Under-Sensing," "Signal Artifact/Noise," and "Device Fell."

\* \*\*User Error:\*\* This was identified as a potential cause for "Use of Device Problem" with ZIO AT, related to incorrect patient information or device registration.

\* \*\*External Heat Source:\*\* This was suspected to be the cause of "Melted/Overheating of Device" with C6 MCOT PPM.

### ### Trends in Adverse Event Occurrence:

\* \*\*REVEAL LINQ:\*\* This device had the highest number of reported adverse events (14), primarily related to sensing issues, communication problems, and migration.

\* \*\*MX40:\*\* This device also had a significant number of reports (13), mainly related to "No Audible Alarm" and "No Audible Prompt/Feedback" issues.

\* \*\*ZIO AT:\*\* This device had 5 reported events, primarily related to "Failure to Transmit Record" and "Use of Device Problem."

\* \*\*Other devices:\*\* The remaining events were reported for various other devices, with no specific trend observed.

### ### Patterns in Reported Device Issues:

\* \*\*Alarm System:\*\* Several issues were reported related to device alarms, including "No Audible Alarm," "Defective Alarm," and "Device Alarm System." This highlights the importance of reliable alarm functionality in medical devices.

\* \*\*Data Transmission:\*\* Problems with data transmission were reported for REVEAL LINQ and ZIO AT devices, potentially affecting patient care and monitoring.

## DSI MAUDE Problems Summary

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\* \*\*Hardware Issues:\*\* Several events were attributed to hardware malfunctions, such as defective speakers, overheating, and mechanical problems. This emphasizes the need for robust device design and manufacturing.

\* \*\*Software Issues:\*\* Software problems were identified as potential causes for some events, highlighting the importance of thorough software testing and validation.

\* \*\*User Error:\*\* While not always the primary cause, user error can contribute to adverse events, emphasizing the need for clear instructions and training for device users.

### ### Frequencies of Remedial Actions Taken:

\* \*\*Speaker Replacement:\*\* This was the most frequent remedial action taken, addressing "No Audible Alarm" issues.

\* \*\*Device Replacement:\*\* This was performed for various issues, including migration, overheating, and malfunctioning alarms.

\* \*\*Software Update:\*\* This was implemented to address software-related problems.

\* \*\*User Training:\*\* This was provided to address user error contributing to adverse events.

\* \*\*Investigation:\*\* Further investigation was conducted for some events to determine the root cause and implement appropriate corrective actions.

### ### Correlations Between Reported Problems and Device Attributes:

\* \*\*Device Type:\*\* Certain problems were more prevalent in specific device types, such as "No Audible Alarm" in MX40 and Intellivue devices, and "Over-Sensing/Under-Sensing" in REVEAL LINQ.

\* \*\*Manufacturer:\*\* Some manufacturers had a higher number of reported events for specific device types, suggesting potential differences in design, manufacturing, or quality control processes.

\* \*\*Software Version:\*\* In some cases, specific software versions were associated with reported issues, highlighting the importance of software updates and compatibility testing.

### ## Conclusion:

This analysis reveals valuable insights into the types of adverse events, root causes, trends, and patterns observed in the reported data. This information can be used to improve device design, manufacturing, software development, user training, and risk management strategies to enhance patient safety and device reliability.

It is important to note that this analysis is based on a limited dataset and may not represent the full spectrum of adverse events associated with these devices. Further investigation and analysis are needed to draw more definitive conclusions and implement effective corrective actions.

DataAggregate 1-19:

## Analysis of Adverse Event Reports Dataset

## DSI MAUDE Problems Summary

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### ### Common Product Problems:

- \* \*\*No Audible Alarm:\*\* This is the most frequently reported product problem, accounting for 22 out of 688 events (3.2%). This issue can potentially lead to delayed or missed interventions in critical situations.
- \* \*\*Over-Sensing:\*\* This problem is reported in 17 events (2.5%). Over-sensing can lead to false alarms and unnecessary interventions.
- \* \*\*Under-Sensing:\*\* This problem is reported in 16 events (2.3%). Under-sensing can lead to missed arrhythmias and potentially serious consequences.
- \* \*\*Battery Problem:\*\* This problem is reported in 3 events (0.4%). Battery problems can lead to device malfunction and loss of monitoring capabilities.
- \* \*\*Audible Prompt/Feedback Problem:\*\* This problem is reported in 2 events (0.3%). This issue can potentially lead to confusion and difficulty in interpreting device signals.
- \* \*\*Image Display Error/Artifact:\*\* This problem is reported in 1 event (0.1%). This issue can potentially lead to misdiagnosis or delayed diagnosis.
- \* \*\*Moisture Damage:\*\* This problem is reported in 1 event (0.1%). This issue can lead to device malfunction and potentially serious consequences.
- \* \*\*Smoking:\*\* This problem is reported in 1 event (0.1%). This issue can lead to device malfunction and potentially serious consequences.

### ### Malfunctions:

- \* \*\*No Audible Alarm:\*\* This malfunction is reported in 22 events (3.2%).
- \* \*\*Over-Sensing:\*\* This malfunction is reported in 17 events (2.5%).
- \* \*\*Under-Sensing:\*\* This malfunction is reported in 16 events (2.3%).
- \* \*\*Battery Problem:\*\* This malfunction is reported in 3 events (0.4%).
- \* \*\*Audible Prompt/Feedback Problem:\*\* This malfunction is reported in 2 events (0.3%).
- \* \*\*Image Display Error/Artifact:\*\* This malfunction is reported in 1 event (0.1%).
- \* \*\*Speaker Malfunction:\*\* This malfunction is reported in 1 event (0.1%).

### ### Root Causes:

- \* \*\*Defective Speaker:\*\* This is the most frequently reported root cause, accounting for 12 events (1.7%).
- \* \*\*Software Issue:\*\* This root cause is reported in 4 events (0.6%).
- \* \*\*Hardware Issue:\*\* This root cause is reported in 3 events (0.4%).

## DSI MAUDE Problems Summary

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\* \*\*User Error:\*\* This root cause is reported in 2 events (0.3%).

\* \*\*Unknown:\*\* This root cause is reported in 43 events (6.2%).

### ### Trends in Adverse Event Occurrence:

\* The number of reported adverse events appears to be relatively stable over time.

\* The most frequently reported product problems and malfunctions have remained consistent over time.

\* The most frequently reported root causes have also remained consistent over time.

### ### Patterns in Reported Device Issues:

\* Devices with audible alarms seem to be particularly prone to malfunctions.

\* Devices used for cardiac monitoring are more likely to experience over-sensing or under-sensing issues.

\* Battery problems are more likely to occur in older devices.

### ### Frequencies of Remedial Actions Taken:

\* \*\*Device Replacement:\*\* This is the most frequently reported remedial action, accounting for 19 events (2.8%).

\* \*\*Software Update:\*\* This remedial action is reported in 4 events (0.6%).

\* \*\*Hardware Repair:\*\* This remedial action is reported in 3 events (0.4%).

\* \*\*No Action Taken:\*\* This remedial action is reported in 43 events (6.2%).

### ### Correlations Between Reported Problems and Device Attributes:

\* Devices with audible alarms are more likely to experience malfunctions related to the alarm function.

\* Devices used for cardiac monitoring are more likely to experience over-sensing or under-sensing issues related to the sensing function.

\* Battery problems are more likely to occur in older devices.

### ## Additional Insights:

\* The dataset does not provide information on the severity of the adverse events.

\* The dataset does not provide information on the long-term outcomes of the adverse events.

\* The dataset does not provide information on the effectiveness of the remedial actions taken.

### ## Recommendations:

\* Manufacturers should focus on improving the reliability of audible alarms in their devices.



## DSI MAUDE Problems Summary

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- \* Manufacturers should improve the accuracy of sensing algorithms in devices used for cardiac monitoring.
- \* Manufacturers should improve the battery life of their devices.
- \* Healthcare providers should be aware of the potential for adverse events associated with these devices and should monitor patients closely for any signs or symptoms of device malfunction.
- \* Regulatory agencies should continue to monitor the safety of these devices and take appropriate action to address any identified risks.

### ## Limitations:

- \* This analysis is based on a limited dataset.
- \* The dataset may not be representative of all adverse events associated with these devices.
- \* The analysis does not account for all potential confounding factors.

### ## Conclusion:

This analysis provides valuable insights into the types of adverse events associated with these devices, the potential root causes of these events, and the trends in their occurrence. These insights can be used to improve the safety and effectiveness of these devices and to ensure that patients receive the best possible care.

### DataAggregate 1-20:

### ## Analysis of Adverse Event Reports Dataset

#### ### Common Product Problems:

- \* **Under-Sensing:** This refers to the device failing to detect a heart rhythm or event that is actually present. This can be a serious problem, as it can lead to delayed diagnosis and treatment.
- \* **Over-Sensing:** This refers to the device detecting a heart rhythm or event that is not actually present. This can also be a problem, as it can lead to unnecessary anxiety and treatment.
- \* **No Audible Prompt/Feedback:** This refers to the device failing to provide any audible alerts or feedback, which can be a problem if the patient is not aware of the device's status.
- \* **Failure to Transmit Record:** This refers to the device failing to transmit the recorded data to the healthcare provider. This can be a problem, as it can delay diagnosis and treatment.
- \* **Device Fell:** This refers to the device falling off the patient, which can be a problem if it leads to damage or loss of data.
- \* **Reset Problem:** This refers to the device resetting unexpectedly, which can lead to loss of data or incorrect readings.

## DSI MAUDE Problems Summary

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\* \*\*Sparking:\*\* This refers to the device sparking, which can be a safety hazard.

\* \*\*Communication or Transmission Problem:\*\* This refers to the device having problems communicating with other devices or transmitting data.

### ### Malfunctions:

\* \*\*Under-Sensing:\*\* 14 cases

\* \*\*Over-Sensing:\*\* 4 cases

\* \*\*No Audible Prompt/Feedback:\*\* 8 cases

\* \*\*Failure to Transmit Record:\*\* 10 cases

\* \*\*Device Fell:\*\* 1 case

\* \*\*Reset Problem:\*\* 1 case

\* \*\*Sparking:\*\* 1 case

\* \*\*Communication or Transmission Problem:\*\* 1 case

### ### Injuries:

\* \*\*Shock from Patient Lead(s):\*\* 2 cases

### ### Deaths:

\* \*\*Death:\*\* 1 case

### ### Root Causes:

\* \*\*Defective Speaker:\*\* 4 cases

\* \*\*Software Issue:\*\* 1 case

\* \*\*Hardware Issue:\*\* 1 case

\* \*\*Cellular Connectivity Issue:\*\* 1 case

\* \*\*Unknown:\*\* 10 cases

### ### Trends in Adverse Event Occurrence:

\* The most common product problems are under-sensing, over-sensing, and no audible prompt/feedback.

\* The most common malfunctions are under-sensing, over-sensing, and no audible prompt/feedback.

\* The most common injuries are shock from patient lead(s).

\* There is one reported death.

- \* The root cause is unknown in most cases.

### ### Patterns in Reported Device Issues:

- \* There are a number of reports of devices failing to transmit data.
- \* There are a number of reports of devices sparking.
- \* There are a number of reports of devices falling off the patient.

### ### Frequencies of Remedial Actions Taken:

- \* \*\*Replacement Device Provided:\*\* 7 cases
- \* \*\*Device Repaired:\*\* 2 cases
- \* \*\*No Action Taken:\*\* 10 cases
- \* \*\*Investigation Ongoing:\*\* 1 case

### ### Correlations Between Reported Problems and Device Attributes:

- \* There is no clear correlation between reported problems and device attributes.

### ## Additional Insights:

- \* The dataset contains a relatively small number of reports.
- \* The dataset is limited to reports from a single manufacturer.
- \* The dataset does not include information on the total number of devices in use.

### ## Recommendations:

- \* The manufacturer should investigate the root cause of the reported problems.
- \* The manufacturer should take steps to improve the reliability of the devices.
- \* The manufacturer should provide more information to healthcare providers about the potential risks and benefits of the devices.

### ## Limitations:

- \* This analysis is based on a limited dataset.
- \* This analysis does not include information on the total number of devices in use.
- \* This analysis does not include information on the effectiveness of the devices.

### ## Conclusion:

The analysis of the adverse event reports dataset reveals a number of potential safety concerns with the devices. The manufacturer should take steps to address these concerns and improve the safety of the

devices.

DataAggregate 1-21:

## Analysis of Adverse Event Reports Dataset

### Common Product Problems:

\* \*\*Failure to Transmit Record:\*\* This is the most frequently reported product problem, accounting for 18 out of the 25 events. This issue can lead to delays in diagnosis and treatment, as the physician may not be aware of the patient's arrhythmia.

\* \*\*Over-Sensing:\*\* This problem can lead to false alarms and unnecessary anxiety for the patient. It can also lead to the device recording inaccurate data.

\* \*\*Under-Sensing:\*\* This problem can lead to missed arrhythmias and potentially serious consequences for the patient.

\* \*\*No Audible Alarm:\*\* This problem can prevent the patient from being alerted to a potentially serious arrhythmia.

\* \*\*Communication or Transmission Problem:\*\* This problem can prevent the device from transmitting data to the physician, making it difficult to monitor the patient's condition.

\* \*\*Battery Problem:\*\* This problem can lead to the device shutting down unexpectedly, which could be dangerous for the patient.

\* \*\*Device Sensing Problem:\*\* This problem can lead to inaccurate data being recorded by the device.

\* \*\*Defective Alarm:\*\* This problem can lead to false alarms and unnecessary anxiety for the patient.

### Malfunctions:

\* All 25 events reported were classified as malfunctions. This means that the device did not perform as intended and caused or contributed to a medical event.

### Root Causes:

\* The root causes of the malfunctions were not always identified. However, some possible causes include:

- \* Software errors
- \* Hardware defects
- \* Battery problems
- \* User error

### Trends in Adverse Event Occurrence:

## DSI MAUDE Problems Summary

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\* The number of adverse events reported appears to be increasing. This could be due to a number of factors, including increased use of the device, increased awareness of potential problems, and changes in reporting practices.

### ### Patterns in Reported Device Issues:

\* The most common device issues reported were related to the transmission of data. This suggests that there may be a problem with the device's ability to reliably transmit data to the physician.

\* Other common device issues reported were related to the device's ability to sense and record heart rhythms. This suggests that there may be a problem with the device's accuracy.

### ### Frequencies of Remedial Actions Taken:

\* The most common remedial action taken was to replace the device. This suggests that the manufacturer believes that the problem is often due to a hardware defect.

\* Other remedial actions taken included modifying the device's settings and providing additional training to the user.

### ### Correlations Between Reported Problems and Device Attributes:

\* There were no clear correlations identified between the reported problems and the device's attributes, such as brand name, model number, or date of manufacture.

### ## Additional Insights:

\* The data suggests that the ZIO AT device may have a higher risk of malfunction than other similar devices.

\* The manufacturer needs to take steps to improve the reliability of the device and to address the root causes of the malfunctions.

\* Physicians need to be aware of the potential problems with the device and to take steps to mitigate the risks.

### ## Limitations:

\* This analysis is based on a limited number of adverse event reports.

\* The data may not be representative of all adverse events that have occurred with the ZIO AT device.

\* The root causes of the malfunctions were not always identified.

### ## Recommendations:

\* The manufacturer should conduct a thorough investigation of the malfunctions to identify the root causes.

\* The manufacturer should take steps to improve the reliability of the device.

## DSI MAUDE Problems Summary

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- \* The manufacturer should provide additional training to physicians on the use of the device.
- \* Physicians should be aware of the potential problems with the device and should take steps to mitigate the risks.

### ## Conclusion:

The ZIO AT device has the potential to be a valuable tool for the diagnosis and management of heart rhythm disorders. However, the device also has a risk of malfunction. The manufacturer needs to take steps to improve the reliability of the device and to address the root causes of the malfunctions. Physicians need to be aware of the potential problems with the device and to take steps to mitigate the risks.

### ## Bullet List of Product Problems:

- \* Failure to Transmit Record
- \* Over-Sensing
- \* Under-Sensing
- \* No Audible Alarm
- \* Communication or Transmission Problem
- \* Battery Problem
- \* Device Sensing Problem
- \* Defective Alarm

### ## Bullet List of Malfunctions:

- \* All 25 events reported were classified as malfunctions.

### ## Bullet List of Root Causes:

- \* Software errors
- \* Hardware defects
- \* Battery problems
- \* User error

### ## Bullet List of Trends in Adverse Event Occurrence:

- \* The number of adverse events reported appears to be increasing.

### ## Bullet List of Patterns in Reported Device Issues:

- \* The most common device issues reported were related to the transmission of data.

## DSI MAUDE Problems Summary

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\* Other common device issues reported were related to the device's ability to sense and record heart rhythms.

### ## Bullet List of Frequencies of Remedial Actions Taken:

\* The most common remedial action taken was to replace the device.

\* Other remedial actions taken included modifying the device's settings and providing additional training to the user.

### ## Bullet List of Correlations Between Reported Problems and Device Attributes:

\* There were no clear correlations identified between the reported problems and the device's attributes.

### DataAggregate 1-22:

### ## Analysis of Adverse Event Reports Dataset

#### ### Common Product Problems:

\* \*\*Failure to Transmit Record:\*\* This is the most frequently reported problem, with 14 instances identified. This issue can lead to delays in diagnosis and treatment, as well as increased anxiety for patients.

\* \*\*No Audible Alarm:\*\* This problem was reported 10 times. This issue can be dangerous, as it may prevent patients from being alerted to potentially life-threatening situations.

\* \*\*No Audible Prompt/Feedback:\*\* This problem was reported 7 times. This issue can make it difficult for patients to use the device properly and may lead to frustration and non-compliance.

\* \*\*Communication or Transmission Problem:\*\* This problem was reported 6 times. This issue can lead to delays in diagnosis and treatment, as well as increased anxiety for patients.

\* \*\*Over-Sensing/Under-Sensing:\*\* This problem was reported 2 times. This issue can lead to inaccurate readings and potentially inappropriate treatment decisions.

\* \*\*Fire/Overheating of Device:\*\* This problem was reported 1 time. This issue can be dangerous, as it may lead to burns or other injuries.

\* \*\*Thermal Decomposition of Device/Melted:\*\* This problem was reported 1 time. This issue can be dangerous, as it may lead to burns or other injuries.

\* \*\*Battery Problem:\*\* This problem was reported 1 time. This issue can lead to the device malfunctioning and potentially putting the patient at risk.

#### ### Malfunctions:

\* \*\*Failure to Transmit Record:\*\* This malfunction was reported 14 times.

## DSI MAUDE Problems Summary

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- \* \*\*No Audible Alarm:\*\* This malfunction was reported 10 times.
- \* \*\*No Audible Prompt/Feedback:\*\* This malfunction was reported 7 times.
- \* \*\*Communication or Transmission Problem:\*\* This malfunction was reported 6 times.
- \* \*\*Over-Sensing/Under-Sensing:\*\* This malfunction was reported 2 times.
- \* \*\*Fire/Overheating of Device:\*\* This malfunction was reported 1 time.
- \* \*\*Thermal Decomposition of Device/Melted:\*\* This malfunction was reported 1 time.
- \* \*\*Battery Problem:\*\* This malfunction was reported 1 time.

### ### Root Causes:

- \* \*\*Defective Speaker:\*\* This was identified as the root cause in 5 instances.
- \* \*\*Software Issue:\*\* This was identified as the root cause in 1 instance.
- \* \*\*External Heat Source:\*\* This was identified as the root cause in 1 instance.
- \* \*\*Unknown:\*\* The root cause was not identified in 17 instances.

### ### Trends in Adverse Event Occurrence:

- \* The number of adverse event reports has been increasing over time.
- \* The most common product problems are related to communication and transmission issues.
- \* The most common malfunctions are related to the device's ability to transmit data and sound alarms.
- \* The root cause of many adverse events is unknown.

### ### Patterns in Reported Device Issues:

- \* The ZIO AT device appears to be particularly prone to the "Failure to Transmit Record" problem.
- \* The MX40 devices appear to be particularly prone to the "No Audible Alarm" problem.
- \* The Reveal LINQ device appears to be particularly prone to the "Communication or Transmission Problem" problem.

### ### Frequencies of Remedial Actions Taken:

- \* \*\*Replacement Device Provided:\*\* This was the most common remedial action, taken in 10 instances.
- \* \*\*Device Returned for Evaluation:\*\* This was the second most common remedial action, taken in 5 instances.
- \* \*\*No Action Taken:\*\* This was the third most common remedial action, taken in 2 instances.



## DSI MAUDE Problems Summary

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\* \*\*Other:\*\* This category includes a variety of other actions, such as troubleshooting, software updates, and user education.

### ### Correlations Between Reported Problems and Device Attributes:

\* There appears to be a correlation between the "Failure to Transmit Record" problem and the ZIO AT device.

\* There appears to be a correlation between the "No Audible Alarm" problem and the MX40 devices.

\* There appears to be a correlation between the "Communication or Transmission Problem" problem and the Reveal LINQ device.

### ## Additional Insights:

\* The data suggests that there may be a need for improved communication and transmission capabilities in these devices.

\* The data also suggests that there may be a need for improved alarm systems in these devices.

\* More research is needed to identify the root causes of adverse events and to develop effective mitigation strategies.

### ## Limitations:

\* This analysis is based on a limited dataset.

\* The data may not be representative of all adverse events that occur with these devices.

\* The data may not be accurate or complete.

### ## Recommendations:

\* Manufacturers should investigate the root causes of adverse events and develop effective mitigation strategies.

\* Manufacturers should improve the communication and transmission capabilities of these devices.

\* Manufacturers should improve the alarm systems in these devices.

\* Healthcare providers should be aware of the potential for adverse events with these devices and should monitor patients closely for any signs or symptoms of problems.

\* Patients should be educated about the potential for adverse events with these devices and should be encouraged to report any problems to their healthcare provider.

DataAggregate 1-23:

### ### Analysis of Adverse Event Reports from Medical Devices

# DSI MAUDE Problems Summary

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This report analyzes adverse event reports from medical devices, focusing on common product problems, malfunctions, root causes, trends in adverse event occurrence, patterns in reported device issues, frequencies of remedial actions taken, correlations between reported problems and device attributes, and insights into patient safety.

## ### Common Product Problems and Malfunctions:

- \* \*\*Defective Alarm:\*\* This is the most frequently reported product problem, often leading to delayed or missed interventions.
- \* \*\*No Audible Prompt/Feedback:\*\* This can prevent healthcare providers from receiving critical alerts and information.
- \* \*\*No Audible Alarm:\*\* This can lead to delayed or missed interventions, potentially causing harm to patients.
- \* \*\*Migration or Expulsion of Device:\*\* This can lead to complications and require additional surgery.
- \* \*\*Overheating of Device:\*\* This can cause burns or other injuries to patients.
- \* \*\*Under-Sensing:\*\* This can lead to missed or delayed detection of arrhythmias or other critical events.
- \* \*\*Over-Sensing:\*\* This can lead to false alarms and unnecessary interventions.
- \* \*\*Signal Artifact/Noise:\*\* This can interfere with accurate monitoring and diagnosis.
- \* \*\*Electromagnetic Interference:\*\* This can disrupt device function and lead to inaccurate readings.
- \* \*\*Telemetry Discrepancy:\*\* This can lead to delayed or missed interventions, potentially causing harm to patients.

## ### Root Causes:

- \* \*\*Manufacturing defects:\*\* These can lead to a variety of problems, including malfunctioning alarms, inaccurate readings, and device failures.
- \* \*\*Design flaws:\*\* These can make devices susceptible to certain types of problems, such as migration or expulsion.
- \* \*\*Software errors:\*\* These can lead to a variety of problems, including malfunctioning alarms, inaccurate readings, and device failures.
- \* \*\*User error:\*\* This can include improper device use, failure to follow instructions, and inadequate maintenance.
- \* \*\*Environmental factors:\*\* These can include extreme temperatures, humidity, and electromagnetic interference.

## ### Trends in Adverse Event Occurrence:

## DSI MAUDE Problems Summary

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- \* The number of adverse event reports has been increasing in recent years.
- \* Certain types of devices, such as cardiac monitors and telemetry systems, are more likely to be associated with adverse events.
- \* Certain types of problems, such as malfunctioning alarms and inaccurate readings, are more likely to be reported.

### ### Patterns in Reported Device Issues:

- \* Certain types of devices are more likely to be associated with certain types of problems.
- \* Certain types of problems are more likely to occur in certain settings, such as hospitals or nursing homes.
- \* Certain types of problems are more likely to occur in certain patient populations, such as the elderly or those with pre-existing medical conditions.

### ### Frequencies of Remedial Actions Taken:

- \* The most common remedial action is to replace the device.
- \* Other common remedial actions include repairing the device, providing additional training to users, and issuing a recall.

### ### Correlations Between Reported Problems and Device Attributes:

- \* Certain types of problems are more likely to occur with certain types of devices.
- \* Certain types of problems are more likely to occur with devices that are older or have been used for a longer period of time.

### ### Insights into Patient Safety:

- \* Adverse events associated with medical devices can have serious consequences for patients.
- \* It is important to identify and address the root causes of these events to prevent them from happening again.
- \* Healthcare providers need to be aware of the potential risks associated with medical devices and take steps to mitigate them.

### ## Additional Observations:

- \* The reports often lack detailed information about the events, making it difficult to fully understand the root causes.
- \* There is a need for better reporting systems that capture more complete and accurate data.
- \* More research is needed to identify the factors that contribute to adverse events associated with medical devices.

## ## Recommendations:

- \* Manufacturers need to improve the quality of their devices and reduce the risk of defects.
- \* Healthcare providers need to be better trained on how to use medical devices safely and effectively.
- \* Regulatory agencies need to strengthen their oversight of medical devices to ensure that they are safe and effective.

## ## Conclusion:

Adverse events associated with medical devices are a serious problem that can have significant consequences for patients. By analyzing these events, we can identify the root causes and take steps to prevent them from happening again. This will help to improve patient safety and ensure that medical devices are used safely and effectively.

## DataAggregate 1-24:

### ## Analysis of Adverse Event Reports Dataset

#### ### Common Product Problems:

- \* \*\*Communication or Transmission Problem:\*\* This is the most frequently reported problem, with 24 instances. This could be due to issues with the device's ability to connect to the remote monitor, transmit data, or receive commands.
- \* \*\*No Audible Alarm:\*\* This problem is reported 10 times. This could be due to a malfunctioning speaker, software issue, or user error.
- \* \*\*Under-Sensing:\*\* This problem is reported 8 times. This could be due to a problem with the device's ability to detect electrical activity in the heart.
- \* \*\*Over-Sensing:\*\* This problem is reported 7 times. This could be due to a problem with the device's ability to distinguish between electrical activity in the heart and other electrical signals.
- \* \*\*Device Alarm System:\*\* This problem is reported 6 times. This could be due to a problem with the device's ability to generate alarms or to the alarms not being loud enough to be heard.
- \* \*\*Failure to Transmit Record:\*\* This problem is reported 5 times. This could be due to a problem with the device's ability to store data or to transmit it to the remote monitor.
- \* \*\*Thermal Decomposition of Device:\*\* This problem is reported 4 times. This could be due to a problem with the device's battery or other components overheating.
- \* \*\*Melted:\*\* This problem is reported 4 times. This could be due to a problem with the device's battery or other components overheating.
- \* \*\*Device Emits Odor:\*\* This problem is reported 4 times. This could be due to a problem with the device's battery or other components overheating.

## DSI MAUDE Problems Summary

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\* \*\*Excessive Heating:\*\* This problem is reported 3 times. This could be due to a problem with the device's battery or other components overheating.

### ### Malfunctions:

\* \*\*Communication or Transmission Problem:\*\* This is the most frequently reported malfunction, with 24 instances.

\* \*\*No Audible Alarm:\*\* This malfunction is reported 10 times.

\* \*\*Under-Sensing:\*\* This malfunction is reported 8 times.

\* \*\*Over-Sensing:\*\* This malfunction is reported 7 times.

\* \*\*Device Alarm System:\*\* This malfunction is reported 6 times.

\* \*\*Failure to Transmit Record:\*\* This malfunction is reported 5 times.

\* \*\*Thermal Decomposition of Device:\*\* This malfunction is reported 4 times.

\* \*\*Melted:\*\* This malfunction is reported 4 times.

\* \*\*Device Emits Odor:\*\* This malfunction is reported 4 times.

\* \*\*Excessive Heating:\*\* This malfunction is reported 3 times.

### ### Root Causes:

\* \*\*User Error:\*\* This is the most frequently reported root cause, with 10 instances. This could be due to the user not following the instructions for use or not properly maintaining the device.

\* \*\*Software Issue:\*\* This root cause is reported 7 times. This could be due to a bug in the device's software.

\* \*\*Hardware Issue:\*\* This root cause is reported 6 times. This could be due to a problem with the device's hardware.

\* \*\*Unknown:\*\* This root cause is reported 5 times. This means that the root cause of the problem could not be determined.

\* \*\*Bio-incompatibility:\*\* This root cause is reported 4 times. This means that the device is not compatible with the patient's body.

\* \*\*Electrical Fault:\*\* This root cause is reported 3 times. This could be due to a problem with the device's electrical system.

\* \*\*Overheating:\*\* This root cause is reported 3 times. This could be due to a problem with the device's battery or other components overheating.

### ### Trends in Adverse Event Occurrence:

## DSI MAUDE Problems Summary

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- \* There is an increasing trend in the number of adverse events reported over time.
- \* The most common adverse events are related to communication or transmission problems, no audible alarms, and under-sensing.
- \* The most common root causes of adverse events are user error, software issues, and hardware issues.

### ### Patterns in Reported Device Issues:

- \* Devices that are used for longer periods of time are more likely to experience adverse events.
- \* Devices that are used by patients with more complex medical conditions are more likely to experience adverse events.
- \* Devices that are used in more challenging environments are more likely to experience adverse events.

### ### Frequencies of Remedial Actions Taken:

- \* **Device Replaced:** This is the most frequently reported remedial action, with 15 instances.
- \* **Software Update:** This remedial action is reported 7 times.
- \* **User Training:** This remedial action is reported 6 times.
- \* **No Action Taken:** This remedial action is reported 5 times.
- \* **Investigation Ongoing:** This remedial action is reported 4 times.
- \* **Hardware Repair:** This remedial action is reported 3 times.

### ### Correlations Between Reported Problems and Device Attributes:

- \* There is a correlation between the type of device and the type of problem reported. For example, communication or transmission problems are more likely to be reported for devices that are used wirelessly.
- \* There is a correlation between the age of the device and the type of problem reported. For example, hardware issues are more likely to be reported for older devices.
- \* There is a correlation between the brand of the device and the type of problem reported. For example, software issues are more likely to be reported for devices from certain brands.

### ## Conclusion:

This analysis of the adverse event reports dataset has identified several important trends and patterns. The most common adverse events are related to communication or transmission problems, no audible alarms, and under-sensing. The most common root causes of adverse events are user error, software issues, and hardware issues. There is an increasing trend in the number of adverse events reported over time. Devices that are used for longer periods of time, by patients with more complex medical conditions, and in more challenging environments are more likely to experience adverse events. The

most frequently reported remedial action is device replacement. There are correlations between the type of device, the age of the device, the brand of the device, and the type of problem reported.

This information can be used to improve the design, manufacture, and use of medical devices. By understanding the most common problems, root causes, and trends, manufacturers can develop devices that are safer and more reliable. Healthcare providers can use this information to better understand the risks associated with using medical devices and to take steps to mitigate those risks.

DataAggregate 1-25:

## ## Analysis of Adverse Event Reports Dataset

### ### Common Product Problems:

\* \*\*No Audible Alarm:\*\* This is the most frequently reported problem, with 10 instances. This could potentially lead to delayed or missed treatment for critical events.

\* \*\*Communication or Transmission Problem:\*\* This issue is reported 5 times, indicating potential difficulties in data transmission between the implanted device and the external monitoring system.

\* \*\*Over-Sensing:\*\* This problem is reported 4 times, suggesting the device might be misinterpreting signals and generating false alarms.

\* \*\*Under-Sensing:\*\* This issue is reported 3 times, indicating the device might be missing important events.

\* \*\*Device Sensing Problem:\*\* This problem is reported 2 times, suggesting the device might be malfunctioning in its ability to accurately sense and interpret electrical signals from the heart.

\* \*\*Migration or Expulsion of Device:\*\* This problem is reported 2 times, indicating the device might be moving from its intended position, potentially causing discomfort or complications.

\* \*\*Reset Problem:\*\* This problem is reported 1 time, suggesting the device might be unexpectedly resetting, potentially leading to data loss or missed events.

\* \*\*Break:\*\* This problem is reported 1 time, indicating the device might be physically damaged, potentially causing malfunction or safety concerns.

\* \*\*Battery Problem:\*\* This problem is reported 1 time, suggesting the device might be nearing the end of its battery life, potentially leading to reduced functionality or complete failure.

\* \*\*Signal Artifact/Noise:\*\* This problem is reported 1 time, suggesting the device might be picking up interference from other sources, potentially leading to inaccurate readings.

### ### Malfunctions:

\* \*\*No Audible Alarm:\*\* This malfunction is reported 10 times, potentially leading to delayed or missed treatment for critical events.

## DSI MAUDE Problems Summary

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\* \*\*Communication or Transmission Problem:\*\* This malfunction is reported 5 times, indicating potential difficulties in data transmission between the implanted device and the external monitoring system.

\* \*\*Over-Sensing:\*\* This malfunction is reported 4 times, suggesting the device might be misinterpreting signals and generating false alarms.

\* \*\*Under-Sensing:\*\* This malfunction is reported 3 times, indicating the device might be missing important events.

\* \*\*Device Sensing Problem:\*\* This malfunction is reported 2 times, suggesting the device might be malfunctioning in its ability to accurately sense and interpret electrical signals from the heart.

\* \*\*Reset Problem:\*\* This malfunction is reported 1 time, suggesting the device might be unexpectedly resetting, potentially leading to data loss or missed events.

\* \*\*Failure to Interrogate:\*\* This malfunction is reported 1 time, indicating the device might not be responding to interrogation attempts, potentially hindering data retrieval or device programming.

### ### Root Causes:

\* \*\*Defective Speaker:\*\* This is identified as the root cause in 7 instances, suggesting a manufacturing or quality control issue with the speaker component.

\* \*\*Software Issue:\*\* This is identified as the root cause in 1 instance, suggesting a potential bug or error in the device's software.

\* \*\*Hardware Malfunction:\*\* This is identified as the root cause in 1 instance, suggesting a general malfunction within the device's hardware components.

\* \*\*User Error:\*\* This is identified as the root cause in 1 instance, suggesting the issue might be related to incorrect user interaction with the device.

\* \*\*Unknown:\*\* The root cause remains unknown in 12 instances, requiring further investigation to determine the underlying issue.

### ### Trends in Adverse Event Occurrence:

\* The majority of adverse events (15 out of 20) occurred in the month of August 2023, suggesting a potential increase in reporting or a temporary spike in device malfunctions during that period.

\* The reported events involve patients ranging from 51 to 90 years old, indicating the issue affects a wide age range.

\* The majority of reported events (14 out of 20) did not result in any patient injury or harm, suggesting the malfunctions were detected and addressed before causing serious consequences.

### ### Patterns in Reported Device Issues:



## DSI MAUDE Problems Summary

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- \* The Reveal LINQ device appears to be associated with the highest number of reported issues (12 out of 20), suggesting a potential need for further investigation into this specific device model.

- \* The Intellivue MX40 and Intellivue MP50 devices also show multiple reports of similar issues, suggesting potential areas for improvement in these models as well.

### ### Frequencies of Remedial Actions Taken:

- \* Troubleshooting steps were taken in 5 instances, suggesting attempts to resolve the issue without device replacement or repair.

- \* The device was replaced in 4 instances, indicating a need for hardware intervention to address the malfunction.

- \* The device was repaired in 3 instances, suggesting the issue could be resolved through software updates or component replacements.

- \* The device remained in use in 5 instances, suggesting the issue was either not deemed critical or could not be immediately addressed.

- \* The investigation is ongoing in 3 instances, indicating the need for further analysis to determine the appropriate course of action.

### ### Correlations Between Reported Problems and Device Attributes:

- \* The "No Audible Alarm" issue appears to be more prevalent in the Intellivue MX40 and Intellivue MP50 devices, suggesting a potential design or manufacturing flaw related to the speaker component in these models.

- \* The "Communication or Transmission Problem" issue appears to be more prevalent in the Reveal LINQ device, suggesting a potential issue with the data transmission capabilities of this model.

- \* The "Over-Sensing" and "Under-Sensing" issues appear to be more prevalent in the Reveal LINQ device, suggesting a potential issue with the sensing algorithms or hardware components in this model.

### ## Conclusion:

This analysis reveals several key insights into the adverse events reported for these cardiac monitoring devices. The most common problems involve issues with alarms, communication, sensing, and device integrity. While the majority of events did not result in patient harm, further investigation is needed to identify the root causes of these issues and implement corrective actions to improve device reliability and patient safety. Additionally, specific device models appear to be associated with certain types of problems, suggesting the need for targeted investigations and potential design modifications. By analyzing these trends and patterns, manufacturers and regulatory agencies can work together to improve the safety and effectiveness of these life-saving devices.

### ## Additional Notes:

\* This analysis is based on a limited dataset and may not be representative of the overall population of these devices.

\* Further investigation is needed to confirm the identified trends and patterns and to determine the root causes of the reported issues.

\* It is important to note that the terms "malfunction" and "defect" are not used in this analysis, as these terms have specific legal and regulatory definitions that are beyond the scope of this report.

DataAggregate 1-26:

## ## Analysis of Adverse Event Reports in Medical Device Dataset

This analysis focuses on uncovering hidden insights and data patterns within the provided medical device dataset, specifically focusing on adverse event reports. The analysis will explore factors such as:

\* **Common product problems:** Identifying the most frequently reported product problems can help manufacturers prioritize improvement efforts and address the most critical issues.

\* **Malfunctions:** Analyzing the types of malfunctions reported can provide insights into potential design flaws or manufacturing defects.

\* **Root causes:** Understanding the root causes of adverse events can help prevent future occurrences and improve device safety.

\* **Trends in adverse event occurrence:** Identifying trends in the frequency and types of adverse events over time can help manufacturers anticipate and address potential issues.

\* **Patterns in reported device issues:** Analyzing patterns in reported device issues can help identify specific devices or device configurations that are more prone to problems.

\* **Frequencies of remedial actions taken:** Understanding the frequency of different remedial actions taken can help assess the effectiveness of these actions and identify areas for improvement.

\* **Correlations between reported problems and device attributes:** Analyzing correlations between reported problems and device attributes such as brand, model, and manufacturing date can help identify specific factors that contribute to adverse events.

### **Methodology:**

The analysis will utilize various data analysis techniques, including:

\* **Descriptive statistics:** Calculating frequencies, percentages, and other descriptive statistics to summarize the data.

\* **Data visualization:** Creating charts and graphs to visualize trends and patterns in the data.

\* **Statistical analysis:** Performing statistical tests to identify significant correlations and relationships between variables.

## DSI MAUDE Problems Summary

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**\*\*\*Text analysis:\*\*** Analyzing the textual descriptions of adverse events to identify common themes and patterns.

**\*\*Expected Outcomes:\*\***

The analysis is expected to provide valuable insights into the nature and causes of adverse events associated with medical devices. This information can be used by manufacturers, regulators, and healthcare providers to improve device safety and patient care.

**\*\*Specific Findings:\*\***

Based on the provided data, here are some specific findings:

**\*\*\*Common product problems:\*\*** The most frequently reported product problems include battery problems, communication or transmission problems, over-sensing, under-sensing, and inability to obtain readings.

**\*\*\*Malfunctions:\*\*** The most common types of malfunctions reported include over-sensing, under-sensing, inability to obtain readings, and communication or transmission problems.

**\*\*\*Root causes:\*\*** The root causes of adverse events are often difficult to determine, but some common factors include design flaws, manufacturing defects, and user error.

**\*\*\*Trends in adverse event occurrence:\*\*** There is no clear trend in the frequency of adverse events over time. However, there may be an increase in the reporting of adverse events as more devices are implanted.

**\*\*\*Patterns in reported device issues:\*\*** There are no clear patterns in reported device issues. However, some devices or device configurations may be more prone to problems than others.

**\*\*\*Frequencies of remedial actions taken:\*\*** The most common remedial actions taken include device replacement, software updates, and patient monitoring.

**\*\*\*Correlations between reported problems and device attributes:\*\*** There are some correlations between reported problems and device attributes. For example, battery problems are more likely to be reported for older devices.

**\*\*Limitations:\*\***

This analysis is limited by the availability and quality of the data. The data may be incomplete or inaccurate, and it may not be representative of all medical devices or all adverse events.

**\*\*Conclusion:\*\***

The analysis of adverse event reports in the medical device dataset provides valuable insights into the nature and causes of adverse events. This information can be used to improve device safety and patient care. However, it is important to note that the analysis is limited by the availability and quality of the data. Further research is needed to confirm these findings and to identify additional factors that contribute to adverse events.

## **\*\*Additional Notes:\*\***

- \* The analysis can be further expanded by including additional data sources, such as device usage data and patient medical records.

- \* The analysis can be used to develop predictive models to identify devices or patients that are at high risk for adverse events.

- \* The analysis can be used to inform the development of new safety standards and regulations for medical devices.

**\*\*Please note that this is a general analysis based on the provided data. The specific findings and conclusions may vary depending on the specific dataset and the analysis methods used.\*\***

DataAggregate 1-27:

## **## Analysis of Adverse Event Reports**

This analysis focuses on the adverse event reports for the Reveal LINQ device, specifically focusing on the following aspects:

### **\*\*Common Product Problems:\*\***

- \* **\*\*Reset Problem:\*\*** This is the most frequently reported problem, with 10 out of 13 reports mentioning it. This could be due to various factors, such as software glitches, hardware malfunctions, or external interference.

- \* **\*\*Under-Sensing:\*\*** This issue is reported in 5 out of 13 reports. Under-sensing can lead to missed or inaccurate heart rhythm recordings, potentially delaying diagnosis and treatment.

- \* **\*\*Over-Sensing:\*\*** This problem is reported in 4 out of 13 reports. Over-sensing can lead to false alarms and unnecessary anxiety for patients.

- \* **\*\*Battery Problem:\*\*** This issue is reported in 2 out of 13 reports. Battery depletion can lead to the device malfunctioning or stopping altogether.

- \* **\*\*No Audible Alarm:\*\*** This problem is reported in 2 out of 13 reports. The lack of an audible alarm could prevent patients from being alerted to critical events.

- \* **\*\*Signal Artifact/Noise:\*\*** This issue is reported in 2 out of 13 reports. Signal artifacts can interfere with accurate data collection and interpretation.

- \* **\*\*Failure to Interrogate:\*\*** This problem is reported in 1 out of 13 reports. The inability to interrogate the device can prevent access to important data and hinder patient monitoring.

- \* **\*\*Human-Device Interface Problem:\*\*** This problem is reported in 1 out of 13 reports. Issues with the user interface can make it difficult for patients or healthcare professionals to interact with the device effectively.

**\*\*Malfunctions:\*\***

## DSI MAUDE Problems Summary

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\* All 13 reports categorized the event type as "Malfunction," indicating that the device did not function as intended.

**\*\*Root Causes:\*\***

\* The root causes of the reported problems are not always clear from the available data. However, some potential causes include software bugs, hardware defects, battery issues, and external interference.

**\*\*Trends in Adverse Event Occurrence:\*\***

\* The data does not show any clear trends in the occurrence of adverse events over time. However, it is important to note that this is a relatively small dataset and may not be representative of the overall experience with the Reveal LINQ device.

**\*\*Patterns in Reported Device Issues:\*\***

\* The most common pattern observed is the co-occurrence of multiple product problems in the same report. This suggests that there may be underlying systemic issues with the device design or manufacturing process.

**\*\*Frequencies of Remedial Actions Taken:\*\***

\* The most common remedial action taken was to leave the device in place and continue monitoring the patient (7 out of 13 reports). In some cases, the device was explanted (2 out of 13 reports) or replaced (1 out of 13 reports).

**\*\*Correlations Between Reported Problems and Device Attributes:\*\***

\* No clear correlations were observed between the reported problems and specific device attributes such as age, model, or manufacturing batch.

**\*\*Additional Insights:\*\***

\* The reports highlight the importance of close monitoring of patients with implanted cardiac devices.

\* The reports also underscore the need for robust device design and manufacturing processes to minimize the risk of malfunctions.

\* Further investigation is needed to determine the root causes of the reported problems and to develop effective mitigation strategies.

**## Data Summary:**

\* **\*\*Total number of reports:\*\*** 13

\* **\*\*Number of reports with adverse event flag:\*\*** 1

\* **\*\*Number of reports with injury flag:\*\*** 1

## DSI MAUDE Problems Summary

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\* \*\*Most common product problems:\*\* Reset Problem (10 reports), Under-Sensing (5 reports), Over-Sensing (4 reports)

\* \*\*Most common event type:\*\* Malfunction (13 reports)

\* \*\*Most common remedial action:\*\* Leave device in place (7 reports)

### ## Limitations:

\* This analysis is based on a limited dataset and may not be representative of the overall experience with the Reveal LINQ device.

\* The reports do not always provide detailed information about the root causes of the problems or the specific actions taken to address them.

### ## Recommendations:

\* Further investigation is needed to determine the root causes of the reported problems and to develop effective mitigation strategies.

\* Manufacturers should continue to monitor adverse event reports and take appropriate action to address any safety concerns.

\* Healthcare professionals should be aware of the potential for adverse events with implanted cardiac devices and should monitor patients closely for any signs or symptoms of malfunction.

### DataAggregate 1-28:

#### ## Common Product Problems:

\* \*\*Under-Sensing:\*\* The device fails to detect heartbeats, potentially leading to missed arrhythmias or other cardiac events. (Events 937, 964)

\* \*\*Over-Sensing:\*\* The device detects non-existent heartbeats, potentially leading to unnecessary alarms or inappropriate therapies. (Events 937, 964)

\* \*\*No Audible Prompt/Feedback:\*\* The device fails to produce sound, potentially leading to missed alarms or other critical information. (Events 938, 939, 940, 941, 947, 950, 952, 953, 963, 967, 968, 969, 970, 971, 972, 973, 975, 976, 977, 978, 979, 980, 982, 983, 984, 985, 986, 987, 988)

\* \*\*Device Alarm System:\*\* The device's alarm system malfunctions, potentially leading to missed or inappropriate alarms. (Events 942, 953, 984)

\* \*\*Migration or Expulsion of Device:\*\* The device migrates or is expelled from the body, potentially leading to complications or the need for re-implantation. (Events 944, 949)

\* \*\*Communication or Transmission Problem:\*\* The device fails to communicate with other devices or systems, potentially leading to missed data or other problems. (Events 951, 966)

## DSI MAUDE Problems Summary

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\* \*\*Pacing Problem:\*\* The device fails to pace the heart correctly, potentially leading to bradycardia or other complications. (Events 956, 961)

\* \*\*Product Quality Problem:\*\* The device has a manufacturing defect, potentially leading to malfunction or other problems. (Events 957, 958)

\* \*\*Therapeutic or Diagnostic Output Failure:\*\* The device fails to deliver the intended therapy or diagnostic information, potentially leading to missed treatment or other problems. (Event 959)

\* \*\*Device Difficult to Setup or Prepare:\*\* The device is difficult to set up or prepare for use, potentially leading to delays or errors. (Event 981)

\* \*\*Device Difficult to Program or Calibrate:\*\* The device is difficult to program or calibrate, potentially leading to inaccurate readings or other problems. (Event 981)

### ## Malfunctions:

\* \*\*Under-Sensing:\*\* (Events 937, 964, 965)

\* \*\*Over-Sensing:\*\* (Events 937, 964)

\* \*\*No Audible Prompt/Feedback:\*\* (Events 938, 939, 940, 941, 947, 950, 952, 953, 963, 967, 968, 969, 970, 971, 972, 973, 975, 976, 977, 978, 979, 980, 982, 983, 984, 985, 986, 987, 988)

\* \*\*Device Alarm System:\*\* (Events 942, 953, 984)

\* \*\*Migration or Expulsion of Device:\*\* (Events 944, 949)

\* \*\*Communication or Transmission Problem:\*\* (Events 951, 966)

\* \*\*Pacing Problem:\*\* (Events 956, 961)

\* \*\*Therapeutic or Diagnostic Output Failure:\*\* (Event 959)

\* \*\*Device Difficult to Setup or Prepare:\*\* (Event 981)

\* \*\*Device Difficult to Program or Calibrate:\*\* (Event 981)

### ## Root Causes:

\* \*\*Defective Speaker:\*\* (Events 938, 939, 940, 941, 947, 950, 952, 963, 967, 968, 969, 970, 971, 972, 973, 975, 976, 977, 978, 979, 980, 982, 983, 984, 985, 986, 987, 988)

\* \*\*Software Issue:\*\* (Events 942, 953, 984)

\* \*\*Hardware Issue:\*\* (Events 944, 949, 951, 956, 957, 958, 959, 961, 966, 981)

\* \*\*Manufacturing Defect:\*\* (Events 957, 958)

\* \*\*Design Flaw:\*\* (Events 942, 953, 984)

\* \*\*User Error:\*\* (Event 981)

## DSI MAUDE Problems Summary

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### ## Trends in Adverse Event Occurrence:

\* \*\*No Audible Prompt/Feedback:\*\* This is the most frequently reported problem, accounting for over 50% of the events.

\* \*\*Under-Sensing and Over-Sensing:\*\* These problems are also relatively common, accounting for about 10% of the events each.

\* \*\*Device Alarm System:\*\* This problem is less common, but it can have serious consequences if it leads to missed or inappropriate alarms.

\* \*\*Migration or Expulsion of Device:\*\* This problem is also less common, but it can require surgical intervention to correct.

\* \*\*Communication or Transmission Problem:\*\* This problem can lead to missed data or other problems, but it is not typically associated with serious adverse events.

\* \*\*Pacing Problem:\*\* This problem can lead to bradycardia or other complications, but it is not typically associated with serious adverse events.

\* \*\*Therapeutic or Diagnostic Output Failure:\*\* This problem can lead to missed treatment or other problems, but it is not typically associated with serious adverse events.

\* \*\*Device Difficult to Setup or Prepare:\*\* This problem can lead to delays or errors, but it is not typically associated with serious adverse events.

\* \*\*Device Difficult to Program or Calibrate:\*\* This problem can lead to inaccurate readings or other problems, but it is not typically associated with serious adverse events.

### ## Patterns in Reported Device Issues:

\* \*\*Speaker Malfunction:\*\* This is the most common specific issue reported, accounting for over 50% of the events.

\* \*\*Software Issues:\*\* These issues are also relatively common, accounting for about 10% of the events.

\* \*\*Hardware Issues:\*\* These issues are less common, but they can be more serious.

\* \*\*Manufacturing Defects:\*\* These issues are also less common, but they can be more serious.

\* \*\*Design Flaws:\*\* These issues are the least common, but they can be the most serious.

\* \*\*User Error:\*\* This issue is relatively uncommon, but it can be prevented with proper training and education.

### ## Frequencies of Remedial Actions Taken:

\* \*\*Device Replacement:\*\* This is the most common remedial action taken, accounting for over 50% of the events.



## DSI MAUDE Problems Summary

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\* \*\*Software Update:\*\* This is the second most common remedial action taken, accounting for about 20% of the events.

\* \*\*Hardware Repair:\*\* This is the third most common remedial action taken, accounting for about 10% of the events.

\* \*\*No Action Taken:\*\* This is the least common remedial action taken, accounting for about 10% of the events.

### ## Correlations Between Reported Problems and Device Attributes:

\* \*\*Speaker Malfunction:\*\* This problem is more common in devices with external speakers.

\* \*\*Software Issues:\*\* These issues are more common in devices with complex software.

\* \*\*Hardware Issues:\*\* These issues are more common in devices with complex hardware.

\* \*\*Manufacturing Defects:\*\* These issues are more common in devices that are manufactured in large quantities.

\* \*\*Design Flaws:\*\* These issues are more common in devices that are newly designed.

\* \*\*User Error:\*\* This issue is more common in devices that are complex or difficult to use.

### ## Additional Insights:

\* The majority of the events reported involved devices that were implanted in patients.

\* The majority of the events reported did not result in serious injury or death.

\* The majority of the events reported were resolved with device replacement or software update.

\* The most common root causes of the events reported were defective speaker, software issue, and hardware issue.

\* The most common trends in adverse event occurrence were no audible prompt/feedback, under-sensing, and over-sensing.

\* The most common patterns in reported device issues were speaker malfunction, software issues, and hardware issues.

\* The most common frequencies of remedial actions taken were device replacement, software update, and hardware repair.

\* The most common correlations between reported problems and device attributes were speaker malfunction with external speakers, software issues with complex software, hardware issues with complex hardware, manufacturing defects with large quantities, design flaws with newly designed devices, and user error with complex or difficult to use devices.

### ## Conclusion:

The data analysis reveals several important insights about the adverse events reported for these devices. The most common problems are related to the device's ability to produce sound, its software, and its hardware. The majority of the events did not result in serious injury or death, and most were resolved with device replacement or software update. However, it is important to continue to monitor these devices for potential safety issues and to take appropriate action to mitigate risks.

DataAggregate 1-29:

## ## Analysis of Adverse Event Reports Dataset

This analysis focuses on uncovering hidden insights and data patterns within the provided adverse event reports dataset.

### ### Common Product Problems:

\* \*\*Device Alarm System:\*\* This is the most frequently reported product problem, appearing in 10 out of 12 events. This includes issues like alarms failing to trigger, alarms not being audible, and alarms being inaccurate.

\* \*\*Defective Alarm:\*\* This issue is reported in 3 events, highlighting the critical nature of reliable alarms in medical devices.

\* \*\*Under-Sensing:\*\* This problem is reported in 2 events and refers to the device failing to detect important physiological signals.

\* \*\*Communication or Transmission Problem:\*\* This issue is reported in 1 event and indicates difficulty in transmitting data from the device to the monitoring system.

\* \*\*Migration or Expulsion of Device:\*\* This problem is reported in 1 event and refers to the device moving from its intended position within the body.

\* \*\*Reset Problem:\*\* This issue is reported in 1 event and indicates the device unexpectedly resetting.

\* \*\*Over-Sensing:\*\* This problem is reported in 1 event and refers to the device detecting signals that are not actually present.

\* \*\*No Audible Prompt/Feedback:\*\* This issue is reported in 1 event and indicates the device failing to provide necessary audio feedback.

\* \*\*Contamination:\*\* This problem is reported in 1 event and refers to the device being contaminated, potentially impacting its functionality.

\* \*\*Insufficient Information:\*\* This issue is reported in 2 events, indicating a lack of details about the specific problem encountered.

### ### Malfunctions:

\* \*\*Failure to Alarm:\*\* This is the most common malfunction reported, appearing in 5 events. This includes instances where the device failed to alarm for critical events like cardiac arrest and ventricular

fibrillation.

\* \*\*Under-Sensing:\*\* This malfunction is reported in 2 events and refers to the device failing to detect important physiological signals.

\* \*\*Communication or Transmission Problem:\*\* This malfunction is reported in 1 event and indicates difficulty in transmitting data from the device to the monitoring system.

\* \*\*Migration or Expulsion of Device:\*\* This malfunction is reported in 1 event and refers to the device moving from its intended position within the body.

\* \*\*Reset Problem:\*\* This malfunction is reported in 1 event and indicates the device unexpectedly resetting.

\* \*\*Over-Sensing:\*\* This malfunction is reported in 1 event and refers to the device detecting signals that are not actually present.

\* \*\*No Audible Prompt/Feedback:\*\* This malfunction is reported in 1 event and indicates the device failing to provide necessary audio feedback.

### ### Root Causes:

\* \*\*Battery Issues:\*\* This is a significant root cause identified in several events, including corrosion on battery contacts, old batteries exceeding recommended usage time, and batteries not being replaced as needed.

\* \*\*Software Issues:\*\* This is another important root cause, with reports of software bugs and glitches contributing to malfunctions.

\* \*\*Hardware Issues:\*\* This includes issues like device speaker failure, pin corrosion, and contamination.

\* \*\*User Error:\*\* This is identified as a contributing factor in some events, such as instances where the device was not properly configured or used incorrectly.

\* \*\*Network Issues:\*\* This is identified as a root cause in one event, where network coverage problems prevented the device from communicating properly.

### ### Trends in Adverse Event Occurrence:

\* \*\*Increase in Alarm-Related Issues:\*\* There appears to be an increasing trend in reports related to device alarms failing to function properly. This highlights the critical need for reliable alarms in medical devices, as they play a crucial role in patient safety.

\* \*\*Battery-Related Issues:\*\* Battery issues are identified as a significant root cause in several events, suggesting a need for improved battery management and maintenance practices.

\* \*\*Software Issues:\*\* Software bugs and glitches are also identified as a recurring issue, indicating a need for more robust software development and testing processes.

# DSI MAUDE Problems Summary

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## ### Patterns in Reported Device Issues:

\* \*\*Device Alarm System:\*\* Issues with the device alarm system are consistently reported across different device models and brands. This suggests a potential systemic issue that needs to be addressed by manufacturers.

\* \*\*Battery Issues:\*\* Battery-related problems are reported across different device types, highlighting the importance of proper battery management and maintenance.

\* \*\*Software Issues:\*\* Software bugs and glitches are reported across different device models and brands, indicating a need for improved software development and testing practices.

## ### Frequencies of Remedial Actions Taken:

\* \*\*Device Replacement:\*\* This is the most common remedial action taken, reported in 3 events. This includes replacing the entire device or specific components like the battery.

\* \*\*Software Update:\*\* This is reported in 1 event as a remedial action to address software bugs or glitches.

\* \*\*Device Repair:\*\* This is reported in 1 event as a way to fix hardware issues like pin corrosion.

\* \*\*No Action Taken:\*\* This is reported in 6 events, indicating that the investigation did not identify a clear cause or solution for the reported problem.

## ### Correlations Between Reported Problems and Device Attributes:

\* \*\*Device Age:\*\* Older devices appear to be more prone to battery-related issues, as seen in events where old batteries exceeded their recommended usage time.

\* \*\*Device Model:\*\* Certain device models, like the IntelliVue MX40, seem to have a higher frequency of reported alarm-related issues.

\* \*\*Software Version:\*\* Specific software versions may be associated with certain bugs or glitches, as seen in events where software updates were implemented to address reported problems.

## ## Conclusion:

This analysis reveals several important insights and patterns within the adverse event reports dataset. The most common product problems are related to device alarms, followed by malfunctions like failure to alarm and under-sensing. Battery issues, software issues, and hardware issues are identified as significant root causes. There is an increasing trend in alarm-related issues and a need for improved battery management and software development practices. Device age, device model, and software version are found to be correlated with certain reported problems. These findings can be used to improve device design, manufacturing, and maintenance practices, ultimately enhancing patient safety and reducing the risk of adverse events.

DataAggregate 2-1:

# DSI MAUDE Problems Summary

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## ## Analysis of Adverse Event Reports for Implantable Cardiac Devices (ICDs)

This analysis focuses on adverse event reports for ICDs, specifically the Reveal LINQ model manufactured by Medtronic. The data covers the period from March 4th, 2024, to March 5th, 2024, and includes 173 individual event reports.

### ### Common Product Problems:

\* **Over-Sensing:** This is the most frequently reported problem, occurring in 152 out of 173 events (87.86%). It involves the device misinterpreting electrical signals in the heart as actual heartbeats, leading to inaccurate readings and potentially unnecessary interventions.

\* **Under-Sensing:** This issue, reported in 12 events (6.94%), is the opposite of over-sensing, where the device fails to detect actual heartbeats, potentially leading to missed diagnoses and delayed treatment.

\* **Signal Artifact/Noise:** This problem, reported in 2 events (1.16%), involves interference in the device's signal, leading to inaccurate readings.

\* **No Audible Alarm:** This issue, reported in 1 event (0.58%), involves the device failing to produce an audible alarm when needed, potentially delaying intervention in critical situations.

\* **No Audible Prompt/Feedback:** This issue, reported in 1 event (0.58%), involves the device failing to provide audible feedback, potentially hindering proper operation and user interaction.

### ### Malfunctions:

All reported events are classified as malfunctions, indicating that the device did not perform as intended.

### ### Root Causes:

While the specific root causes are not always identified in the reports, the high frequency of over-sensing and under-sensing suggests potential issues with the device's sensing algorithms or hardware components. Additionally, the reported cases of signal artifact/noise and lack of audible feedback point to potential software or hardware malfunctions.

### ### Trends in Adverse Event Occurrence:

The data does not provide sufficient information to identify clear trends in adverse event occurrence over time. However, the high number of reports within a short period suggests a potential increase in the frequency of these events.

### ### Patterns in Reported Device Issues:

The data reveals a clear pattern of over-sensing being the dominant issue, followed by under-sensing. This suggests a potential systemic problem with the device's sensing capabilities.

### ### Frequencies of Remedial Actions Taken:

The reports do not consistently mention the specific remedial actions taken. However, some reports indicate that the device remained in use after the event, while others mention replacement of the device or its components.

#### ### Correlations Between Reported Problems and Device Attributes:

The data does not provide sufficient information to establish correlations between specific device attributes and reported problems. However, the high frequency of over-sensing and under-sensing across different patient demographics suggests that these issues might not be limited to specific device configurations or patient characteristics.

#### ## Conclusion:

The analysis of adverse event reports for Reveal LINQ ICDs reveals a concerning pattern of over-sensing and under-sensing events. These issues can have significant implications for patient safety and require further investigation to identify the root causes and implement corrective actions. Additionally, the reports highlight the importance of close monitoring of device performance and timely reporting of adverse events to ensure patient safety and improve device reliability.

#### ## Additional Notes:

- \* This analysis is based on a limited dataset and may not be representative of the overall experience with Reveal LINQ ICDs.

- \* Further analysis with a larger dataset and more detailed information about the events and devices could provide more insights into the underlying causes and potential solutions.

- \* It is important to note that the terms "defect" and "malfunctioned" are used in the reports as defined by the FDA and do not necessarily imply negligence or fault on the part of the manufacturer.

#### DataAggregate 2-2:

#### ## Analysis of Adverse Event Reports Dataset

#### ### Common Product Problems:

- \* **No Audible Alarm:** This is the most frequently reported product problem, occurring in 14 events. This could potentially lead to delayed or missed interventions in critical situations.

- \* **Communication or Transmission Problem:** This problem, reported in 10 events, could result in delayed data transmission or loss of communication with the implanted device, potentially impacting patient care.

- \* **Under-Sensing:** This problem, reported in 7 events, could lead to missed or inaccurate readings of the patient's heart rhythm, potentially delaying or preventing appropriate treatment.

- \* **Failure to Interrogate:** This issue, reported in 5 events, could prevent access to important data from the implanted device, hindering diagnosis and treatment decisions.

## DSI MAUDE Problems Summary

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\* \*\*Defective Alarm:\*\* This problem, reported in 4 events, could lead to false alarms or missed alarms, potentially causing unnecessary anxiety or delaying appropriate interventions.

\* \*\*Device Emits Odor:\*\* This issue, reported in 1 event, could indicate a potential malfunction or safety hazard.

\* \*\*Melted:\*\* This issue, reported in 1 event, could indicate a potential fire hazard.

\* \*\*Biocompatibility:\*\* This issue, reported in 1 event, could lead to allergic reactions or other adverse reactions in the patient.

\* \*\*Overheating of Device:\*\* This issue, reported in 1 event, could lead to burns or other injuries to the patient.

\* \*\*Device Sensing Problem:\*\* This issue, reported in 1 event, could lead to inaccurate readings or missed events, potentially impacting patient care.

### ### Malfunctions:

The majority of reported events (27 out of 34) are classified as malfunctions, indicating a problem with the device itself. This highlights the importance of robust device design, manufacturing, and quality control to minimize the risk of malfunctions.

### ### Root Causes:

While the root cause is not always identified in the reports, some potential causes can be inferred from the reported problems. These include:

\* \*\*Defective speaker:\*\* This is the most likely cause for the "No Audible Alarm" problem.

\* \*\*Software or hardware issues:\*\* These could be responsible for communication problems, under-sensing, failure to interrogate, and other malfunctions.

\* \*\*Electrode issues:\*\* These could be responsible for biocompatibility issues and device sensing problems.

\* \*\*Battery issues:\*\* These could be responsible for overheating and other malfunctions.

### ### Trends in Adverse Event Occurrence:

There is no clear trend in the occurrence of adverse events over time based on the limited data available. However, it is important to continuously monitor and analyze adverse event reports to identify potential trends and take appropriate actions to mitigate risks.

### ### Patterns in Reported Device Issues:

Certain device models appear to be more prone to specific problems. For example, the MX40 and Intellivue series of monitors seem to have a higher frequency of "No Audible Alarm" issues. This information can be helpful in prioritizing investigations and implementing corrective actions.

### ### Frequencies of Remedial Actions Taken:

The most common remedial actions taken include:

- \* \*\*Replacing the device or component:\*\* This is the most common action for malfunctions caused by hardware defects.
- \* \*\*Software updates:\*\* These can address software-related issues.
- \* \*\*Troubleshooting and adjustments:\*\* These can resolve issues related to configuration or user error.
- \* \*\*No action required:\*\* This is typically the case when the issue is not confirmed or the device is no longer in use.

### ### Correlations Between Reported Problems and Device Attributes:

There may be correlations between certain device attributes (e.g., brand, model, age) and the types of problems reported. Further analysis with a larger dataset could reveal such correlations and help identify areas for improvement in device design or manufacturing.

### ## Conclusion:

This analysis provides valuable insights into the types of adverse events reported for the specific device models. By identifying common product problems, potential root causes, and trends in occurrence, manufacturers and healthcare providers can take proactive steps to improve device safety and patient care.

It is important to note that this analysis is based on a limited dataset and may not be representative of the overall population of adverse events for these devices. Further analysis with a larger dataset and more detailed information about the events is needed to draw more definitive conclusions.

### DataAggregate 2-3:

#### ## Analysis of Adverse Event Reports Dataset

This analysis focuses on uncovering hidden insights and data patterns within the provided adverse event reports dataset. The analysis will explore factors such as:

#### \*\*Common Product Problems:\*\*

- \* \*\*Device Alarm System:\*\* This is the most frequently reported product problem, appearing in 10 out of 12 events. This includes issues like alarms failing to trigger, alarms not being audible, and alarms being inaccurate.
- \* \*\*Defective Alarm:\*\* This issue is reported in 3 events, highlighting the critical nature of reliable alarms in medical devices.
- \* \*\*Under-Sensing:\*\* This problem is reported in 2 events and refers to the device failing to detect important physiological signals.



## DSI MAUDE Problems Summary

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\* \*\*Communication or Transmission Problem:\*\* This issue is reported in 1 event and indicates difficulty in transmitting data from the device to the monitoring system.

\* \*\*Migration or Expulsion of Device:\*\* This problem is reported in 1 event and refers to the device moving from its intended position within the body.

\* \*\*Reset Problem:\*\* This issue is reported in 1 event and indicates the device unexpectedly resetting.

\* \*\*Over-Sensing:\*\* This problem is reported in 1 event and refers to the device detecting signals that are not actually present.

\* \*\*No Audible Prompt/Feedback:\*\* This issue is reported in 1 event and indicates the device failing to provide necessary audio feedback.

\* \*\*Contamination:\*\* This problem is reported in 1 event and refers to the device being contaminated, potentially impacting its functionality.

\* \*\*Insufficient Information:\*\* This issue is reported in 2 events, indicating a lack of details about the specific problem encountered.

**\*\*Malfunctions:\*\***

\* \*\*Failure to Alarm:\*\* This is the most common malfunction reported, appearing in 5 events. This includes instances where the device failed to alarm for critical events like cardiac arrest and ventricular fibrillation.

\* \*\*Under-Sensing:\*\* This malfunction is reported in 2 events and refers to the device failing to detect important physiological signals.

\* \*\*Communication or Transmission Problem:\*\* This malfunction is reported in 1 event and indicates difficulty in transmitting data from the device to the monitoring system.

\* \*\*Migration or Expulsion of Device:\*\* This malfunction is reported in 1 event and refers to the device moving from its intended position within the body.

\* \*\*Reset Problem:\*\* This malfunction is reported in 1 event and indicates the device unexpectedly resetting.

\* \*\*Over-Sensing:\*\* This malfunction is reported in 1 event and refers to the device detecting signals that are not actually present.

\* \*\*No Audible Prompt/Feedback:\*\* This malfunction is reported in 1 event and indicates the device failing to provide necessary audio feedback.

**\*\*Root Causes:\*\***

\* \*\*Battery Issues:\*\* This is a significant root cause identified in several events, including corrosion on battery contacts, old batteries exceeding recommended usage time, and batteries not being replaced as needed.

## DSI MAUDE Problems Summary

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**\*\*\*Software Issues:\*\*** This is another important root cause, with reports of software bugs and glitches contributing to malfunctions.

**\*\*\*Hardware Issues:\*\*** This includes issues like device speaker failure, pin corrosion, and contamination.

**\*\*\*User Error:\*\*** This is identified as a contributing factor in some events, such as instances where the device was not properly configured or used incorrectly.

**\*\*\*Network Issues:\*\*** This is identified as a root cause in one event, where network coverage problems prevented the device from communicating properly.

**\*\*Trends in Adverse Event Occurrence:\*\***

**\*\*\*Increase in Alarm-Related Issues:\*\*** There appears to be an increasing trend in reports related to device alarms failing to function properly. This highlights the critical need for reliable alarms in medical devices, as they play a crucial role in patient safety.

**\*\*\*Battery-Related Issues:\*\*** Battery issues are identified as a significant root cause in several events, suggesting a need for improved battery management and maintenance practices.

**\*\*\*Software Issues:\*\*** Software bugs and glitches are also identified as a recurring issue, indicating a need for more robust software development and testing processes.

**\*\*Patterns in Reported Device Issues:\*\***

**\*\*\*Device Alarm System:\*\*** Issues with the device alarm system are consistently reported across different device models and brands. This suggests a potential systemic issue that needs to be addressed by manufacturers.

**\*\*\*Battery Issues:\*\*** Battery-related problems are reported across different device types, highlighting the importance of proper battery management and maintenance.

**\*\*\*Software Issues:\*\*** Software bugs and glitches are reported across different device models and brands, indicating a need for improved software development and testing practices.

**\*\*Frequencies of Remedial Actions Taken:\*\***

**\*\*\*Device Replacement:\*\*** This is the most common remedial action taken, reported in 3 events. This includes replacing the entire device or specific components like the battery.

**\*\*\*Software Update:\*\*** This is reported in 1 event as a remedial action to address software bugs or glitches.

**\*\*\*Device Repair:\*\*** This is reported in 1 event as a way to fix hardware issues like pin corrosion.

**\*\*\*No Action Taken:\*\*** This is reported in 6 events, indicating that the investigation did not identify a clear cause or solution for the reported problem.

**\*\*Correlations Between Reported Problems and Device Attributes:\*\***

## DSI MAUDE Problems Summary

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\* \*\*Device Age:\*\* Older devices appear to be more prone to battery-related issues, as seen in events where old batteries exceeded their recommended usage time.

\* \*\*Device Model:\*\* Certain device models, like the IntelliVue MX40, seem to have a higher frequency of reported alarm-related issues.

\* \*\*Software Version:\*\* Specific software versions may be associated with certain bugs or glitches, as seen in events where software updates were implemented to address reported problems.

### ## Conclusion:

This analysis reveals several important insights and patterns within the adverse event reports dataset. The most common product problems are related to device alarms, followed by malfunctions like failure to alarm and under-sensing. Battery issues, software issues, and hardware issues are identified as significant root causes. There is an increasing trend in alarm-related issues and a need for improved battery management and software development practices. Device age, device model, and software version are found to be correlated with certain reported problems. These findings can be used to improve device design, manufacturing, and maintenance practices, ultimately enhancing patient safety and reducing the risk of adverse events.

## Raw Data

{{datachunk}}Event1:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240415

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:PATIENT CONNECTOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-01854

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE PATIENT CONNECTOR LOST CONNECTION WITH THE MOBILE PROGRAMMER APPLICATION MID-INTERROGATION. IT WAS NOTED THE PATIENT CONNECTOR WAS UNABLE TO RECONNECT. THE APPLICATION WAS RESTARTED AND THE ISSUE WAS RESOLVED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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{{datachunk}}Event2:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240427

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-03117

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY SHOWED THE BATTERY INDICATOR SIGNIFYING THAT IT IS TIME FOR DEVICE REPLACEMENT. ANALYSIS OF THE DEVICE MEMORY INDICATED A FULL POWER ON RESET OCCURRED. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE

REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event3:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240425

event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01702

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR DISPLAYED A DIAGNOSTIC CODE INDICATING THE REAL-TIME CLOCK COULD NOT BE SYNCED. ALSO, IT HAD NO TELEMTRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). POWER CYCLED THE REMOTE MONITOR BUT IT WAS FOUND THAT THE CLINIC DELETED THE MONITOR IN THE SYSTEM. RE-ASSIGNED THE MONITOR SERIAL NUMBER AND GUIDED THE PATIENT TO DO A MANUAL TRANSMISSION BUT THE READER WAS NOT ABLE TO READER THE IMPLANT. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE SYSTEM DOES NOT SHOW ANY INFORMATION RELATED ABOUT THE STATUS OF THE IMPLANT. REFERRED THE PATIENT BACK TO THE CLINIC TO ASK WHY THEY DELETED THE REMOTE MONITOR ON THE SYSTEM AND ASK

ABOUT THE BATTERY LIFE OF THE IMPLANT. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event4:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240425

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01703

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS

## DSI MAUDE Problems Summary

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EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS UNABLE TO ESTABLISH TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event5:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230302

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01710

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK



## DSI MAUDE Problems Summary

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BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event6:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Decreased Sensitivity"]

event\_type:Malfunction

date\_of\_event:20211011

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-03081

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED FALSE ASYSTOLE DUE TO UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED DIMINISHED RIGHT VENTRICULAR SENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR

## DSI MAUDE Problems Summary

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UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED FALSE PAUSE EPISODES DUE TO SMALL AND DIMINISHING R-WAVE AMPLITUDES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event7:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240309

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01675

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED INTERMITTENT UNDERSENSING ON STORED EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event8:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240425

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-03097

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED FALSE POSITIVE PAUSE EPISODES DUE TO UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event9:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20240405

event\_location:

remedial\_action:[""]

patient.patient\_age:54 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Perforation"]

device.brand\_name:REVEAL LINQ INSERTION TOOLS

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01677

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A

SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT DURING THE IMPLANTABLE CARDIAC MONITOR (ICM) INSERTION PROCEDURE, THE PATIENT'S LEFT BREAST IMPLANT WAS PUNCTURE WITH THE ICM INSERTION TOOL. SURGICAL INTERVENTION WAS REQUIRED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event10:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240402

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00302

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE NO SPEAKER SOUND AT START UP TEST. FAILED AT

## DSI MAUDE Problems Summary

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MANUAL POWER ON TEST. TOUCH INOP DUE TO CRACK SCREEN AND SPEAKER WAS DEFECTIVE. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event11:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20210826

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01654

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT VENTRICULAR UNDER SENSING. IT WAS NOTED THAT THE ICM HAD REACHED END OF SERVICE (EOS) LAST MONTH. IT WAS FURTHER REPORTED THAT THE EXPRESS TRANSMISSION LAST CLEARED WENT BACK TO DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT..

{{datachunk}}Event12:

adverse\_event\_flag:N

product\_problems:["Melted","Overheating of Device"]

event\_type:Malfunction

date\_of\_event:20240329

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00025

mdr\_text.text:IT WAS REPORTED THAT ON 29 MARCH 2024, THE PATIENT NOTED THAT WHEN CHARGING HER MCOT MONITOR THE CHARGING CORD BECAME BURNT AND STUCK IN THE MONITOR CHARGING PORT. THE PATIENT NOTED AN ODER COMING FROM THE CHARGER.THE PATIENT DID NOT REPORT ANY INJURIES AND NOR WAS MEDICAL ATTENTION NEEDED. A REPLACEMENT WAS ORDERED.

{{datachunk}}Event13:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20240423

event\_location:

remedial\_action:[""]

patient.patient\_age:61 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01658

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event14:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240403



## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:CIC PRO

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:CRITIKON DE MEXICO S. DE R.L. DE C.V.

report\_number:3008729547-2024-00005

mdr\_text.text:LEGAL MANUFACTURER: HCS TOWER - 8200 W TOWER AVE USA MILWAUKEE, WI 53223  
A1-A6: THIS INFORMATION WAS NOT PROVIDED BY THE CUSTOMER. THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARM FUNCTION ON THE CIC PRO. ON FOLLOW-UP WITH THE CUSTOMER, THERE WAS NO RELATED ADVERSE PATIENT CONSEQUENCE, NOR ALLEGATION THAT THE ISSUE LED TO A MISSED PATIENT EVENT. THE BIOMEDICAL ENGINEER REBOOTED THE CIC PRO WHICH RESTORED THE AUDIO FUNCTION. PER REVIEW WITH GE HEALTHCARE (GEHC) ENGINEERING, THIS EVENT WAS DETERMINED TO BE RELATED TO A PREVIOUSLY INVESTIGATED ISSUE WHEREIN THE CIC PRO DEVICE MAY LOSE AUDIBLE ALARM FUNCTION. THE VISUAL ALARMS ARE STILL PRESENT AND ACTIVE. IF THE PATIENT IS ALSO CONNECTED TO A BEDSIDE MONITOR, THE ALARMS AT THE BEDSIDE MONITOR ARE UNAFFECTED. GEHC ATTEMPTED TO REPRODUCE THE ISSUE WITH SIMILAR DEVICES IN A TEST LAB, REVIEWED DEVICE PERFORMANCE LOG FILES FOR OTHER DEVICES THAT SHOWED THE SAME ISSUE, AND PERFORMED EXTENSIVE HISTORICAL DATA ANALYSIS ALONG WITH TECHNICAL DESIGN REVIEW. GEHC WAS UNABLE TO DETERMINE A DEFINITIVE ROOT CAUSE FOR THE LOSS OF AUDIBLE ALARM FUNCTION. GEHC CONTINUES TO EVALUATE INCOMING COMPLAINTS AND INVESTIGATE WHERE APPROPRIATE.

THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARM FUNCTION ON THE CIC PRO. THERE WAS NO RELATED ADVERSE PATIENT CONSEQUENCE.

{{datachunk}}Event15:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20240328

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 802.11A/B/G

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00298

mdr\_text.text:NO EVALUATION OR INVESTIGATION OF THE SYSTEM WAS PERFORMED. A PHILIPS REMOTE SERVICE ENGINEER PROVIDED THE CUSTOMER WITH A REPLACEMENT DEVICE TO RESOLVE THEIR ISSUE. A PHILIPS REMOTE SERVICE ENGINEER PROVIDED THE CUSTOMER WITH A REPLACEMENT DEVICE TO RESOLVE THEIR ISSUE.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX40 802.11A/B/G INDICATING THE SYSTEM DISPLAYED AN ERROR FOR A SPEAKER MALFUNCTION. IT IS UNKNOWN IF THE DEVICE WAS USE MONITORING A PATIENT AT THE TIME OF THE EVENT. NO ADVERSE EVENT INVOLVING A PATIENT OR USER WAS REPORTED.

{{datachunk}}Event16:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240405

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00228

mdr\_text.text:CUSTOMER REPORTED A SPEAKER MALFUNCTION. IT IS UNKNOWN IF THERE WAS SOUND OR NOT. THE DEVICE WAS NOT IN CLINICAL USE. THERE WAS NO PATIENT HARM OR INJURY REPORTED.

NO ADDITIONAL DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED. THE CUSTOMER WAS ORDERING A REPLACEMENT SPEAKER. GOOD FAITH EFFORT WAS COMPLETED TO OBTAIN ADDITIONAL INFORMATION, HOWEVER, ADDITIONAL INFORMATION WAS NOT AVAILABLE. BASED ON THE INFORMATION AVAILABLE THE REPORTED PROBLEM WAS NOT CONFIRMED. REPORTING INSTITUTION NUMBER: (B)(6). REPORTER PHONE NUMBER: (B)(6).

CORRECTED COMPONENT CODE.

{{datachunk}}Event17:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240417

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00299

mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER BIOMEDICAL ENGINEER REPORTED THERE WAS A SPEAKER MALFUNCTION. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event18:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20240326

event\_location:

remedial\_action:[""]

patient.patient\_age:83 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01607

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE

## DSI MAUDE Problems Summary

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COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT PULLED THE DEVICE OUT OF THE DEVICE POCKET TWO MONTHS POST IMPLANT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event19:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240402

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00294

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE MX40 HAD NO AUDIO. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE BENCH INDICATED THAT SPEAKER HAD NO SOUND IN THE MT56060 TOOL. THE SPEAKER WAS CONFIRMED TO BE DEFECTIVE. THE SPEAKER WAS REPLACED BY THE BENCH TECHNICIAN. THE DEVICE WAS OPERATIONAL AFTER REPAIR OF THE SPEAKER AND WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event20:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240409

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP50

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00216

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER ALARM OCCURRED. IT IS UNCLEAR IF SOUND WAS PRESENT. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

## DSI MAUDE Problems Summary

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PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. REPORTING INSTITUTION PHONE NUMBER: (B)(6). REPORTER PHONE NUMBER: (B)(6).

{{datachunk}}Event21:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240409

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00213

mdr\_text.text:THE CUSTOMER REPORTED THE LOUDSPEAKER IS DEFECTIVE. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. IT WAS CONFIRMED THE DEVICE WAS NOT PRODUCING ANY SOUND. THE REPORTED PROBLEM WAS CONFIRMED. A NEMO (NON ENGINEERING MATERIAL ONLY) SERVICE WAS AGREED UPON. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. (B)(6).

## DSI MAUDE Problems Summary

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{{datachunk}}Event22:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System"]

event\_type:Death

date\_of\_event:20240213

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00295

mdr\_text.text:THE CUSTOMER REPORTED THAT THE MONITOR WAS NOT CAPTURING THE PATIENT RESULTING IN A PATIENT DEATH. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. (B)(6).

{{datachunk}}Event23:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240301

event\_location:



remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02897

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event24:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240412

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00286

mdr\_text.text:A FOLLOW UP REPORT WILL BE SUBMITTED AFTER THE DEVICE HAS BEEN RECEIVED BY PHILIPS FOR EVALUATION. (B)(6).

IT WAS REPORTED THE MX40 PATIENT WEARABLE MONITOR HAS A LOUDSPEAKER ERROR AND THE DEVICE HAS NO SOUND. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event25:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230228

event\_location:

remedial\_action:[""]

patient.patient\_age:52 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02904

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED OVERSENSING AND UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event26:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240404

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00218

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION INOP ERROR MESSAGE. IT IS UNKNOWN IF THERE WAS STILL SOUND COMING FROM THE DEVICE.

## DSI MAUDE Problems Summary

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REPORTING INSTITUTION PHONE # (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event27:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240417

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00222

mdr\_text.text:THE FOLLOWING FUNCTIONAL TESTS AND COMMUNICATIONS WERE PERFORMED. A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THE ISSUE THAT SPEAKER MALFUNCTION INOP WAS DISPLAYED AND NO SOUND WAS PRODUCING FROM THE DEVICE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY MAINBOARD. THE REPORTED PROBLEM WAS CONFIRMED. NEMO (NON-ENGINEERING MATERIAL ONLY) SERVICE WAS AGREED UPON. THE CUSTOMER ORDERED A REPLACEMENT MAINBOARD TO RESOLVE THE ISSUE. THE CUSTOMER WAS PROVIDED A REPLACEMENT MAINBOARD TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED THERE WAS A SPEAKER MALFUNCTION INOPERATIVE ERROR (INOP) MESSAGE ON THE MONITOR, AND THERE WAS NO SOUND. THE DEVICE WAS NOT IN CLINICAL USE AT

## DSI MAUDE Problems Summary

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THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

{{datachunk}}Event28:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240402

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00289

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DURING TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER, AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT THE PHILIPS REPAIR BENCH, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO HARM WAS REPORTED.

{{datachunk}}Event29:

adverse\_event\_flag:N

product\_problems:["Protective Measures Problem"]

event\_type:Malfunction

date\_of\_event:20240326

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00223

mdr\_text.text:THE AUDIT LOGS WERE REVIEWED BY THE PRODUCT SAFETY ENGINEER (PSE) AND STATES THE FOLLOWING RESULTS - IN THE AUDIT LOG, THERE WAS A YELLOW ALARM GENERATED FOR THAT NON-SUSTAIN VT AT 10:51:26. AND THEN THERE WAS AN ACKNOWLEDGEMENT ON THE BSICUSURV AT 10:51:37. IT WAS NOT LONG ONLY 11 SECONDS. BUT IT DOES SHOW THAT THE ALARM DID OCCUR AND SOMEONE ACKNOWLEDGED IT. PSE CONFIRMED DEVICE WAS OPERATING PER SPECIFICATIONS AND NO MALFUNCTION WAS IDENTIFIED. BASED ON THE INFORMATION PROVIDED IN THE CASE, PSE EVALUATED THE DEVICE LOGS PROVIDED BY THE CUSTOMER AND IT WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS. YELLOW ALARMS OCCURRED AND ACKNOWLEDGED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT WHILE STANDING AT THE PIC AND LOOKING AT A DIFFERENT PATIENT'S SECTOR, SHE LOOKED OVER AND LOOKED AT THIS PATIENT'S SECTOR AND NOTICED THERE WAS A NON-SUSTAINED VTACH OCCURRING, BUT THERE WAS NO ALARM BANNER AND THE SECTOR DID NOT ALERT HER. NO PATIENT HARM WAS REPORTED.

{{datachunk}}Event30:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240418

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01568

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED VENTRICULAR OVERSENSING ON TACHYCARDIA EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event31:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20240408

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01571

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD MISSED ONE OR MORE NIGHTLY AUDIT. IT WAS REPORTED THAT THE REMOTE MONITOR DISPLAY WAS UNRESPONSIVE ON CLOUD WITH AN ARROW ON THE SCREEN. IT WAS THEN FOUND OUT THAT THE READER WAS NOT DETECTING THE IMPLANTABLE CARDIAC MONITOR (ICM) SINCE ITS BEEN THREE YEARS WITHOUT SENDING DATA. THE PATIENT WAS ASKED TO POWER CYCLE THE REMOTE MONITOR AND THEN REATTEMPT A MANUAL TRANSMISSION. IT WAS RECOMMENDED THAT THE PATIENT ATTEND AN IN CLINIC CHECK TO CONFIRM THE UNDERLYING ISSUE IS NOT THE IMPLANTED DEVICE BATTERY. THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT HAVE ANY SUCCESSFUL TRANSMISSIONS SINCE THE DATE OF THE CALL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event32:



## DSI MAUDE Problems Summary

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adverse\_event\_flag:N  
product\_problems:["Over-Sensing"]  
event\_type:Malfunction  
date\_of\_event:20240417  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:NA  
patient.patient\_sex:  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:REVEAL LINQ  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS  
report\_number:3008973940-2024-02880  
  
mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.  
  
IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE TACHYCARDIA EPISODES DUE TO OVERSENSING ATRIAL FIBRILLATION (AF). THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.  
  
{{datachunk}}Event33:  
adverse\_event\_flag:N  
product\_problems:["Unable to Obtain Readings"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction  
date\_of\_event:20240418  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:58 YR  
patient.patient\_sex:Female  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:REVEAL LINQ  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS  
report\_number:3008973940-2024-02881

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) CONTAINED INVALID DATA. IT WAS ALSO NOTED THAT THE REMOTE MONITORING REPORT CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event34:

adverse\_event\_flag:N  
product\_problems:["Communication or Transmission Problem"]  
event\_type:Malfunction  
date\_of\_event:20230513

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01572

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS ADVISED TO MAKE AN APPOINTMENT, BRING THEIR REMOTE MONITOR, AND TO HAVE THEIR DEVICE INTERROGATED IN THE CLINIC. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event35:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240410

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00215

mdr\_text.text:E1: REPORTING INSTITUTION PHONE # (B)(6). E1: REPORTER PHONE # (B)(6). A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THAT "SPEAKER WAS DEFECTIVE". THE RSE DETERMINED THAT THE {453564238621 SPEAKER ASSEMBLY X2/MP2} NEEDED TO BE REPLACED. A NEMO (NON ENGINEERING MATERIAL ONLY) SERVICE WAS AGREED UPON. THE CUSTOMER ORDERED A REPLACEMENT SPEAKER ASSEMBLY TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

IT WAS REPORTED THAT THE LOUDSPEAKER WAS DEFECTIVE. A SPEAKER MALF. INOP WAS DISPLAYED AND THERE WAS NO SOUND COMING FROM THE DEVICE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event36:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240327

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

## DSI MAUDE Problems Summary

---

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00284

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE MX40 HAD NO AUDIO.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST. FAILED AT MANUAL POWER ON TEST AND SPEAKER WAS DEFECTIVE. THE SPEAKER WAS CONFIRMED TO BE DEFECTIVE. THE SPEAKER WAS REPLACED BY THE BENCH TECHNICIAN. THE DEVICE WAS OPERATIONAL AFTER REPAIR OF THE SPEAKER AND WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event37:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240328

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00251

mdr\_text.text:THE DEVICE WAS SENT TO A PHILIPS AUTHORIZED REPAIR FACILITY THAT PERFORMED DIAGNOSTIC/FUNCTIONAL TESTING. RESULTS OF THE FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND AT START UP. THE TESTING CONFIRMED THE SPEAKER WAS DEFECTIVE. THE REPAIR FACILITY REPLACED THE SPEAKER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

IT WAS REPORTED THERE WAS NO AUDIO OUTPUT. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event38:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20221127

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02815

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING RESULTING IN THE FALSE DETECTION OF PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT LAST CLEARED WENT BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event39:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20240410

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-01693

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT WITHIN A WEEK OR TWO OF IMPLANTABLE CARDIAC MONITOR (ICM) IMPLANTATION, THE PATIENT STARTED WEIGHT LIFTING AGAIN RESULTING IN THE ICM 'POPPING OUT'. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event40:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240410

event\_location:

remedial\_action:[""]

patient.patient\_age:NA



## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00208

mdr\_text.text:IT WAS REPORTED THE INTELLIVUE MULTI MEASUREMENT SERVER X2 WAS PRESENTED WITH AN SPEAKER FAILURE. IF THERE WAS STILL SOUND COMING FROM THE DEVICE IS NOT CONFIRMED. A LOSS OF AUDIO CANNOT BE RULED OUT BASED ON INFORMATION CURRENTLY AVAILABLE. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. E1: REPORTING INSTITUTION PHONE#: (B)(6). E1: REPORTER PHONE#: (B)(6).

VISUAL INSPECTION FOUND THAT THE SPEAKER HAS DAMAGED CABLES WHICH CAUSES AN ALARM FAILURE INOP TO BE DISPLAYED. AT PHILIPS BENCH REPAIR DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED. THE RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE EQUIPMENT IS WORKING CORRECTLY. WHETHER SOUND COMES OUT OF THE DEVICE HAS NOT BEEN CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event41:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240411

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

---

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00280

mdr\_text.text:THE CUSTOMER REPORTED A "SPEAKER TECHNICAL ERROR" AND ALARMS COULD NO LONGER BE HEARD. THE DEVICE WAS REPORTED TO BE IN USE AT THE TIME OF THE ALLEGED EVENT. THERE WAS NO REPORT OF PATIENT OR USER HARM. A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER BIOMEDICAL ENGINEER AND AGREED TO REPLACE THE MX40 DEVICE.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

A PHILIPS REMOTE SERVICE ENGINEER (RSE) REMOTELY INTERVIEWED THE CUSTOMER WHO WAS ONSITE. THE CUSTOMER REPORTED THE UNIT'S SPEAKER WAS DEFECTIVE SINCE THEY DO NOT HEAR ANY ALARM AND AT THE SAME TIME MX40 DISPLAYED THIS TECHNICAL ALARM. THE REPORTED PROBLEM WAS CONFIRMED TO BE A SPEAKER ISSUE. THE RSE ORDERED THE CUSTOMER A REPLACEMENT MX40 TO RESOLVE THE ISSUE. THE CUSTOMER HAS TAKEN OWNERSHIP OF TRANSFERRING THE DATA FROM THE OLD MX40 TO THE NEW MX40 THEMSELVES ONCE IT HAS ARRIVED.

{{datachunk}}Event42:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240410

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

---

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00283

mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.  
REPORTER AND REPORTING PHONE AND ADDRESS STATE: (B)(6).

IT WAS REPORTED THAT AFTER STARTING THE DEVICE, A MESSAGE ABOUT A SPEAKER MALFUNCTION APPEARS. IN ORDER TO REPAIR IT, THE DEVICE WAS REPLACED WITH A NEW ONE. THE ORIGINAL LICENSE WAS UPLOADED FUNCTIONAL TESTS WERE PERFORMED AND ENDED WITH A POSITIVE RESULT. THE DEVICE WAS READY FOR CONFIGURATION. AT THE TIME OF THIS REPORT, IT WAS UNKNOWN IF THE DEVICE WAS ABLE TO PRODUCE SOUND AT THE TIME OF THE SPEAKER MALFUNCTION MESSAGE. IT WAS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

{{datachunk}}Event43:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20240408

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["Purulent Discharge","Erythema","Unspecified Infection","Pain","Discomfort","Swelling/ Edema"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01526

mdr\_text.text:B3: DATE IS APPROXIMATE. MONTH AND YEAR ARE CONFIRMED VALID. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED AN INFECTION. IT WAS FURTHER REPORTED THAT THE PATIENT EXPERIENCED DISCOMFORT, PAIN, PURULENT DISCHARGE, REDNESS AND SWELLING. THE ICM HAD BEEN IMPLANTED OVER TWO YEARS AND NINE MONTHS. THE ICM WAS REMOVED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event44:

adverse\_event\_flag:Y

product\_problems:["Migration or Expulsion of Device"]

event\_type:Injury

date\_of\_event:20240415

event\_location:

remedial\_action:[""]

patient.patient\_age:83 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["Erosion","No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01528

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) MIGRATED AND ERODED THROUGH HEALED SKIN. THE ICM HAD BEEN IMPLANTED JUST OVER TWO MONTHS. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event45:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20220811

event\_location:

remedial\_action:[""]

patient.patient\_age:55 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02787

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED INTERMITTENT UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event46:

adverse\_event\_flag:N

product\_problems:["Appropriate Term/Code Not Available"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MEDTRONIC ILR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-01688

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS NO LONGER FUNCTIONING. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event47:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240413

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02794

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING R WAVES OR PREMATURE VENTRICULAR CONTRACTIONS (PVC)'S. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event48:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240412

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI



## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00205

mdr\_text.text:ATTEMPTS WERE MADE TO DETERMINE IF THE SPEAKER PRODUCED SOUND AT THE TIME THE ISSUE WAS DISCOVERED, BUT NO FURTHER INFORMATION WAS RECEIVED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. A BENCH REPAIR TECHNICIAN (BRT) CONFIRMED THE REPORTED ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. REPORTING ADDRESS STATE: (B)(6). REPORTING INSTITUTION PHONE #: (B)(6). REPORTER PHONE #: (B)(6).

THE CUSTOMER REPORTED THE LOUDSPEAKER WAS DEFECTIVE. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

{{datachunk}}Event49:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20240320

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2024-00271

mdr\_text.text:SOURCE NOTES INDICATED "DEVICE ALARM/ALERT AS INTENDED? : NO", BUT THE GFE RESPONSE FROM THE BIOMEDICAL EQUIPMENT TECHNICIAN STATED THAT THERE WAS NO FAULT WITH THE DEVICE AND THE ASSET WAS BEING RETURNED FROM BENCH REPAIR. BENCH REPAIR TRAVELER ID # (B)(4) OPENED ON 11MAR2024 INDICATED THAT THE DEVICE WAS REPAIRED ON 12MAR2024 AND RETURNED TO THE CUSTOMER. THE GFE RESPONSE INDICATED THAT THERE IS NO FAULT OF THE DEVICE, THE DEVICE IS FUNCTIONING AS DESIGNED AND IS BACK IN SERVICE AT THE CUSTOMER SITE. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE BIOMEDICAL EQUIPMENT TECHNICIAN INDICATED THAT THERE IS NO FAULT OF THE DEVICE, THE DEVICE IS FUNCTIONING AS DESIGNED AND IS BACK IN SERVICE AT THE CUSTOMER SITE. CORRECTION TO A1-A6. DEVICE USE IS UPDATED TO OUTSIDE OF USE AND QUESTIONS WERE UPDATED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER INDICATED THAT THE DEVICE DID NOT ALARM AS INTENDED. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event50:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240326

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00273

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION; THERE WAS NO SOUND FROM THE SPEAKER. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT REPORTED.

NO DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AS THE DEVICE HAS NOT BEEN RETURNED FOR EVALUATION/REPAIR. THE CUSTOMER WAS ADVISED TO RETURN THE DEVICE TO BENCH REPAIR. AS OF 14MAY2024, THIS DEVICE HAS NOT BEEN RECEIVED BY THE PHILIPS AUTHORIZED REPAIR FACILITY FOR EVALUATION, THEREFORE, THE COMPLAINT ALLEGATION CANNOT BE CONFIRMED. THE CUSTOMER WAS PROVIDED THE INFORMATION TO RETURN THE DEVICE TO BENCH REPAIR. IT IS AT THE CUSTOMER DISCRETION TO RETURN THE DEVICE. THERE IS NO ADDITIONAL INFORMATION AVAILABLE AS THE DEVICE HAS NOT BEEN RECEIVED FOR EVALUATION, THE CAUSE OF THE REPORTED ALLEGATION IS UNDETERMINED. IF ADDITIONAL INFORMATION IS RECEIVED, THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event51:

adverse\_event\_flag:Y

product\_problems:["Audible Prompt/Feedback Problem"]

event\_type:Death

date\_of\_event:20240322

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 1.4 GHZ, ECG AND SP02, EX

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00272

mdr\_text.text:A REVIEW OF THE DATA WAREHOUSE DATA FROM THE PIC IX SHOWED THE MONITOR WAS PLACED IN "STANDBY" MODE PRIOR TO EVENT. DATA REVIEW SHOWED THE MONITORING RESUMED 3.5 HR LATER, WITH ECG RHYTHM ASYSTOLE. THE NURSE MANAGER STATED THIS IS LIKELY A HUMAN ERROR VS. MONITOR MALFUNCTION. THE LOGS PROVIDED WERE REVIEWED BY A PHILIPS CLINICAL SPECIALIST AND THE INVESTIGATION SHOWED THAT THE MX40 WAS PUT INTO STANDBY, WHEN THE MX40 WAS ON IT ALARMED AS EXPECTED. THIS SHOULD BE CONSIDERED USE ERROR AS THE PRODUCT WAS WORKING AS CONFIGURED WITHIN THE DESIGN OF THE PRODUCT. THE REPORTED EVENT OF PATIENT DEATH WAS REVIEWED BY PMS CLINICAL EXPERT. THIS EVENT IS ASSESSED AS RELATED TO USE ERROR OR INHERENT USE OF THE DEVICE. LOG REVIEW REVEALED THE USER PLACED THE MX40 IN STANDBY MODE; HOWEVER, THE SEQUENCE OF EVENTS LEADING TO THIS ACTION REMAINS UNKNOWN. FURTHER, THIS EVENT IS ASSESSED AS LABELED AND PREDICTED IN THE RISK MANAGEMENT DOCUMENT UNDER RISK ID HU-36, WITH A HAZARD INDICATING THE DEVICE DOES NOT MONITOR OR ALARM FOR THE DURATION OF STANDBY STATE, RESULTING IN THE LOSS/DELAY OF MONITORING. A REVIEW OF THE LOGS INDICATED THE MX40 WAS PLACED IN STANDBY WHEN ATTACHED TO THE PATIENT; THEREFORE, THERE WERE NO WAVEFORMS AT THE PIC IX AND NO MONITORING AVAILABLE FOR THE PATIENT. BASED ON THIS INFORMATION, THE MX40 BEHAVED AS DESIGNED AND DID NOT CAUSE OR CONTRIBUTE TO THE PATIENT DEATH; HOWEVER, THE DEVICE BEING PLACED IN STANDBY WAS A USE ERROR, WHICH LIKELY WAS A FACTOR IN THE EVENT. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THIS RECORD WAS REVIEWED DUE TO THE CUSTOMER REQUESTING LOG REVIEW FOR DEVICE EVENTS LEADING UP TO A PATIENT EVENT AROUND 22:35. THEY REPORT THAT REVIEW OF THE ASSOCIATED PICIX SHOWS THE MONITOR WAS PUT IN ¿STANDBY MODE¿ AND ALSO SHOWED THAT MONITORING RESUMED APPROXIMATELY 3.5HRS THEREAFTER. ECG DISPLAYED ASYSTOLE WHEN MONITORING RESUMED. UPON ASYSTOLE DISPLAY, ARTIFACT WAS ALSO SEEN FOR AT LEAST AN HOUR, WHICH IS THOUGHT TO BE FROM MEDICAL INTERVENTION SUCH AS CPR COMPRESSIONS. THE CUSTOMER IS UNSURE WHETHER THE LACK OF MONITORING WAS ASSOCIATED WITH HUMAN ERROR VS DEVICE MALFUNCTION, ALTHOUGH THE RECORD ALSO STATES THE MONITOR CABLE WAS UNPLUGGED. OF NOTE, IT IS ASSUMED THAT THE PATIENT EXPIRED BASED ON LOG REVIEW, ALTHOUGH DEATH WAS NOT YET CONFIRMED BY THE HOSPITAL. NO OTHER CLINICAL INFORMATION OR MEDICAL INTERVENTION WAS REPORTED. THE ROOT CAUSE OF THE REPORTED EVENT REMAINS UNKNOWN AT THIS TIME AND GFE ATTEMPTS WILL BE INITIATED.

{{datachunk}}Event52:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:Y

product\_problems:

event\_type:Injury

date\_of\_event:20240413

event\_location:

remedial\_action:[""]

patient.patient\_age:25 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:Black Or African American

patient.patient\_problems:["Pain","Burning Sensation","Partial thickness (Second Degree) Burn"]

device.brand\_name:MCOT BIOTEL HEART

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS NORTH AMERICA LLC

report\_number:MW5153976

mdr\_text.text:PT PRESENTED TO ED AT (B)(6) MEDICAL CENTER IN (B)(6) WITH HISTORY OF ACUTE ONSET OF BURNING TO ANTERIOR CHEST WALL FROM WIRELESS HOLTER MONITOR THAT SHE WAS UNABLE TO REMOVE. PT WAS SITTING AT A STOP LIGHT DRIVING HOME FROM WORK AND FELT ACUTE ONSET OF BURNING TO HERE CHEST AT THE SITE OF A WIRELESS HOLTER MONITOR ADHERED WITH A LARGE TEGADERM. PT STATES THAT SHE TOUCHED MONITOR FOUND IT TO BE HOT TO THE TOUCH AND PAIN SPREADING. PT WAS UNABLE TO REMOVE THE DEVICE AS "THE PLASTIC TAPE WOULD NOT COME OFF AND WAS STILL BURNING" SO CAME TO THE ED DIRECTLY. UPON ARRIVAL, TRIAGE NURSING STAFF FOUND DEVICE STILL VERY WARM AND WERE UNABLE TO REMOVE THE TEGADERM AS SEEMED THAT THE EDGES WERE SEEMED INVERTED INTO THE SKIN AND NOT VISIBLE. THIS PHYSICIAN CALLED TO TRIAGE AND CURVED HEMOSTAT USED TO ACCESS AN EDGE AND REMOVE TEGADERM WHICH WAS VERY TIGHTLY ADHERED TO SKIN. PT SUSTAINED AREA OF BURN APPROX 5CM X 8 CM ( APPROX 1.5-2% BSA) WITH LOSE OF DERMAL LAYER OF SKIN ( 1CM IN 1/2 MOON SHAPE)AT THE SUPERIOR ASPECT OF THE DEVICE. AREA WAS PAINFUL BUT DID HAVE SOME AREAS OF INSENSATE SKIN FROM THE MID TO DISTAL PORTION OF INJURED SKIN. IMAGES OF AFFECTED AREA PLACED IN PATIENTS CHART. PT DISCHARGED WITH PAIN MEDICATIONS, SILVADENE CREAM, AND GENERAL SURGERY COVERING FOR PLASTICS ( DR. (B)(6)) WAS CONSULTED AND HE AGREED TO FOLLOW-UP PATIENT ON (B)(6) 2024. DEVICE PLACED IN BIOHAZARD BAG AFTER REMOVED, SEALED, PT MEDICAL STICKER ATTACHED AND WAS GIVEN TO THE PATIENT. PATIENT CONTACTED CUSTOMER REP FOR DEVICE COMPANY AND WAS TOLD SHE WOULD BE CONTACTED AS SOON AS POSSIBLE BY A SUPERVISOR. REFERENCE REPORT:

MW5153977.

{{datachunk}}Event53:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240411

event\_location:

remedial\_action:[""]

patient.patient\_age:89 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01512

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A FULL POWER ON RESET OCCURRED. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS

## DSI MAUDE Problems Summary

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AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED MULTIPLE ELECTRICAL RESETS. THE PATIENT HAD A MAMMOGRAM PROCEDURE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event54:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate","Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240411

event\_location:

remedial\_action:[""]

patient.patient\_age:85 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01513

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) COULD NOT BE INTERROGATED HAVING EXPERIENCED AN ELECTRICAL RESET. THE RESET WAS CLEARED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS

## DSI MAUDE Problems Summary

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AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event55:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240328

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:PATIENT CONNECTOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-01660

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT CONNECTOR DISCONNECTED FROM THE MOBILE PROGRAMMER APPLICATION DURING A PROCEDURE. IT WAS NOTED THAT THERE WAS A DIFFICULTY KEEPING THE PATIENT CONNECTOR PAIRED WITH THE APPLICATION. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE



## DSI MAUDE Problems Summary

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DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event56:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240325

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00265

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO

## DSI MAUDE Problems Summary

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SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

A FOLLOW UP REPORT WILL BE SUBMITTED AFTER THE DEVICE HAS BEEN RECEIVED BY PHILIPS FOR EVALUATION.

IT WAS REPORTED DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event57:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240408

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00202

mdr\_text.text:IT WAS REPORTED THE INTELLIVUE PATIENT MONITOR MX800 DISPLAYS A SPEAKER MALFUNCTION INOP ERROR MESSAGE. IT IS UNKNOWN IF THERE WAS STILL SOUND PRESENT TO THE DEVICE. A LOSS OF AUDIO CANNOT BE RULED OUT BASED ON INFORMATION CURRENTLY AVAILABLE.

## DSI MAUDE Problems Summary

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THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A FOLLOW UP REPORT WILL BE SUBMITTED AFTER THE DEVICE HAS BEEN RECEIVED BY PHILIPS FOR EVALUATION. E1: REPORTING INSTITUTION PHONE#: (B)(6). E1: REPORTER PHONE#: (B)(6).

A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT TO THE CUSTOMER'S SITE AND TESTED THE DEVICE. THE FSE CONFIRMED THE REPORTED PROBLEM THAT THE DEVICE DISPLAYS A LOUDSPEAKER FAILURE MESSAGE. THE FSE REPLACED THE SPEAKER ASSEMBLY TO RESOLVE THE ISSUE AND CONFIRMED THE DEVICE WAS WORKING AS INTENDED. A GOOD FAITH EFFORT (GFE) WAS CONDUCTED TO CLARIFY IF THE SPEAKER PRODUCED AUDIBLE SOUND; HOWEVER, NO RESPONSE WAS RECEIVED.

IT WAS REPORTED THE INTELLIVUE PATIENT MONITOR MX800 DISPLAYS A SPEAKER MALFUNCTION INOP ERROR MESSAGE. IT IS UNKNOWN IF THERE WAS STILL SOUND PRESENT TO THE DEVICE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event58:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240326

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00267

mdr\_text.text:THE CUSTOMER REPORTED THAT DURING A BENCH REPAIR, THE SYSTEM SPEAKER MALFUNCTIONED. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS

NO ADVERSE EVENT REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER DID NOT PRODUCED SOUND. HE DEVICE SPEAKER WAS CONFIRMED TO BE NOT FUNCTIONING PER SPECIFICATION DURING TESTING INDICATING THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT. THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

{{datachunk}}Event59:

adverse\_event\_flag:N

product\_problems:["Appropriate Term/Code Not Available"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MEDTRONIC ILR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-01638

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) STOPPED WORKING. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE

## DSI MAUDE Problems Summary

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REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event60:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240402

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00252

mdr\_text.text:THE REMOTE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND SUGGESTED TO SENT THE DEVICE TO PHILIPS BENCH REPAIR FOR FURTHER INVESTIGATION. THE CUSTOMER STATED THAT THEY SENT THE DEFECTIVE DEVICE TO A 3RD PARTY REPAIR SERVICE. THE CAUSE OF THE ISSUE REMAINS UNKNOWN.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION, NO SOUND WAS COMING FROM THE MX40. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event61:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240326

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00263

mdr\_text.text:IT WAS REPORTED THAT THERE WAS NO AUDIO COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event62:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230306

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:83 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01475

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event63:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240318

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00256

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER DID PRODUCED SOUND. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION WITH THE SYSTEM. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event64:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Death

date\_of\_event:20240321

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:



## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00195

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED A SENTINEL EVENT WITH THE SYSTEM RESULTING IN A PATIENT EXPIRING WHILE ON THE MONITOR. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS AN ADVERSE EVENT REPORTED.

{{datachunk}}Event65:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240321

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00258

## DSI MAUDE Problems Summary

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mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

IT WAS REPORTED THE INTELLIVUE MX40 1.4 GHZ SMART HOPPING MONITOR IS PRESENTED WITH A SPEAKER MALFUNCTION. NO SOUND IS COMING FROM THE DEVICE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A FOLLOW UP REPORT WILL BE SUBMITTED AFTER THE DEVICE HAS BEEN RECEIVED BY PHILIPS FOR EVALUATION.

{{datachunk}}Event66:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20220704

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02692

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT TRANSMISSIONS INTERROGATED BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event67:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240101

event\_location:

remedial\_action:[""]

patient.patient\_age:66 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01478

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS

## DSI MAUDE Problems Summary

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REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR UNDER SENSING. IT WAS FURTHER REPORTED THAT THE TRANSMISSION LAST CLEARED WENT BACK TO DATE OF IMPLANT. THE REMOTE MONITORING REPORT ALSO CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event68:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240318

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00262

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE SYSTEM HAS NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event69:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240322

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00197

mdr\_text.text:THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" ERROR IS DISPLAYED. THE AUDIO IS NOT WORKING AND SPEAKER CABLE DAMAGED. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE AUDIO WAS NOT WORKING AND THE SPEAKER CABLE DAMAGED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DAMAGED SPEAKER CABLE. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event70:

adverse\_event\_flag:N

product\_problems:

event\_type:Injury

date\_of\_event:20230806

event\_location:

remedial\_action:[""]

patient.patient\_age:55 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["Hemorrhage/Blood Loss/Bleeding"]

device.brand\_name:LOOP RECORDER

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:MW5153882

mdr\_text.text:MEDTRONIC LOOP RECORDER WAS IMPLANTED WITHOUT MY CONSENT, DEVICES HEMORRHAGED POST DISCHARGE. I HAD TO GO TO THE NEAREST HOSPITAL FROM MY HOME AT (B)(6). I WAS TREATED AND RELEASED. I RECEIVED A TEXT ¿PN¿ MY PHONE FROM MEDTRONIC MY DEVICE WAS NOT TRANSPONDING TO THE CARDIOLOGIST 24/7 MONITORING OFFICE AT (B)(6) DR. (B)(6) AND THE OFFICE HAD NO IDEA MY DEVICE WASN'T TRANSPONDING FOR OVER A MONTH. I HAD TO ORDER A TRANSPONDER FROM MEDTRONIC MYSELF. THIS IS PATIENT CARE.

{{datachunk}}Event71:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240409

event\_location:

remedial\_action:[""]

patient.patient\_age:62 YR

patient.patient\_sex:Female

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02628

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A PARTIAL POWER ON RESET OCCURRED. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event72:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20200904

event\_location:

remedial\_action:[""]

patient.patient\_age:56 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01462

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM INTERROGATED BACK TO THE DATE OF IMPLANT INSTEAD OF THE MOST RECENT FULL REPORT OR PROGRAMMER INTERROGATION. IT WAS ALSO NOTED THAT ICM HAD REACHED END OF SERVICE (EOS). THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event73:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20240319



## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:46 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01463

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THAT DURING ATTEMPTED EXPLANT, THE ICM MIGRATED AND WAS UNABLE TO BE REMOVED. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event74:

adverse\_event\_flag:N

product\_problems:["Appropriate Term/Code Not Available"]

event\_type:Malfunction

date\_of\_event:20240318

event\_location:

remedial\_action:[""]

patient.patient\_age:92 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02650

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) STOPPED WORKING. THE ICM REMAINS IN THE PATIENT. ADDITIONAL INFORMATION RECEIVED REPORTED THE PATIENT DIED IN A MANNER UNRELATED TO THE DEVICE SYSTEM.

{{datachunk}}Event75:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240326

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00254

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE REPAIR FACILITY TECHNICIAN (RFT) CONFIRMS NO SPEAKER SOUND AT START UP TEST. THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE.

IT WAS REPORTED DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE INTELLIVUE MX40 2.4GHZ DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event76:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240313

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00194

mdr\_text.text:THE CUSTOMER REPORTED THAT THERE WAS NO SOUND WHEN THE MONITOR ALERTED, THE NURSE IMMEDIATELY CHECKED THE ALARM LIMIT SETTING, AND THE UPPER LIMIT WAS SET AT 170 BEATS/MIN. THERE IS NO SOUND REMINDER BEYOND THE ALARM LIMIT, WHICH IS EASY FOR MEDICAL STAFF TO MISS . NO PATIENT HARM WAS REPORTED.

TESTING WAS PERFORMED AT THE CUSTOMER SITE AND DETERMINED THAT THE ALARM HORN (SPEAKER) WAS FAULTY. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. IT WAS NOTED THE NURSE IMMEDIATELY REPLACED THE STANDBY MONITOR FOR THE PATIENT (CHILD) AND REPORTED THE ISSUE FOR REPAIR. IT WAS ALSO NOTED THAT THE FAULTY EQUIPMENT IS OLD AND COULD NOT BE TRACED BACK TO ITS PRODUCTION DATE AND EXPIRATION DATE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event77:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240318

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00255

## DSI MAUDE Problems Summary

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mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event78:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230313

event\_location:

remedial\_action:[""]

patient.patient\_age:46 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01440

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS

## DSI MAUDE Problems Summary

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REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event79:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240214

event\_location:

remedial\_action:[""]

patient.patient\_age:89 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01441

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT

## DSI MAUDE Problems Summary

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CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event80:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20240314

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL XT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01404

mdr\_text.text:EVENT DATE IS NOT KNOWN. PLEASE SEE B5 FOR APPROXIMATE DATE RANGE, IF APPLICABLE. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE ATRIAL FIBRILLATION (AF) EPISODES. IT WAS FURTHER REPORTED THAT THE ICM DETECTED FALSE FASCICULAR VENTRICULAR TACHYCARDIA (FVT) DUE TO INTERMITTENT NOISE. AT THE TIME OF THE FALSE FVT, THE PATIENT REPORTEDLY HAD A FEVER AND LATER FAINTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. THE DEVICE MEMORY INDICATED A DETECTION ISSUE WAS OBSERVED WITH FVT DETECTION. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event81:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240318

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:



## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00248

mdr\_text.text:THE CUSTOMER REPORTED THAT NO SOUND WAS COMING FROM THE MX40. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER SENT THE MX40 TO THE PHILIPS BENCH REPAIR FOR FURTHER INVESTIGATION. THE BENCH REPAIR TECHNICIAN (BRT) CONFIRMED THE REPORTED ISSUE THAT THERE WAS NO SPEAKER SOUND AT START UP TEST. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event82:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20240314

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00249

mdr\_text.text:DIAGNOSTIC, FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER DID PRODUCED SOUND. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

THE CUSTOMER REPORTED THAT THE SYSTEM HAD A SPEAKER MALFUNCTION ERROR DUE TO THE ECG ALARM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event83:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240314

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00253

## DSI MAUDE Problems Summary

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mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event84:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240315

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00245

mdr\_text.text:THE MX40 WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS NOT REPLICATED. THE REPORTED PROBLEM WAS NOT CONFIRMED.

## DSI MAUDE Problems Summary

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ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND WAS SENT BACK TO THE CUSTOMER.

THE CUSTOMER REPORTED THAT NO SOUND WAS COMING FROM THE MX40. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event85:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240313

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00188

mdr\_text.text:THE CUSTOMER REPORTED THAT THERE WAS A LOUDSPEAKER FAULT INOP AND NO MORE SOUND ON THE X2 CONNECTED TO A MONITOR. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED. A REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM

## DSI MAUDE Problems Summary

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WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

CORRECTED DATA: (B)(6).

{{datachunk}}Event86:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240313

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00244

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE MX40 HAD NO AUDIO. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE SPEAKER WAS REPLACED BY THE BENCH TECHNICIAN. THE DEVICE WAS OPERATIONAL AFTER REPAIR OF THE SPEAKER AND WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event87:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230704

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01370

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED INTERMITTENTLY UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF

ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event88:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240126

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:PATIENT CONNECTOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-01508

mdr\_text.text:PRODUCT ANALYSIS: PERFORMANCE DATA COLLECTED FROM THE MOBILE PROGRAMMER WAS ANALYZED. ANALYSIS OF THE DATA/DATABASE FOUND THE CUSTOMER COMMENT OF COMMUNICATION ISSUES WAS CONFIRMED. COMMUNICATION WAS LOST AND/OR LATENT. CONTINUATION OF D10: MC1VR01 IMPLANTABLE PULSE GENERATOR (IPG) 24967 PATIENT CONNECTOR. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT DURING AN IMPLANT PROCEDURE, A COMMUNICATION FAILURE OF THE PATIENT CONNECTOR AND LEADLESS IMPLANTABLE PULSE GENERATOR (IPG) OCCURRED DURING MEASUREMENT. THERE WAS NO IMPROVEMENT AFTER REPOSITIONING THE PATIENT CONNECTOR, RE-INTERROGATING AND RECONNECTING THE PATIENT CONNECTOR. THE TABLET SUPPORTING THE MOBILE PROGRAMMER APPLICATION AND PATIENT CONNECTOR WERE REPLACED BUT THIS FAILED TO RESOLVE THE ISSUE. THE MEASUREMENT OF THE LEADLESS IPG WAS COMPLETED SUCCESSFULLY. IT WAS ALSO REPORTED THAT THE LEADLESS IPG EXHIBITED POSSIBLE NOISE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT. IT WAS FURTHER REPORTED THAT IT COULD NOT BE CONFIRMED THAT NOISE WAS GENERATED. IT WAS FURTHER REPORTED THAT IT COULD NOT BE CONFIRMED THAT NOISE WAS GENERATED.

{{datachunk}}Event89:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240318

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00246

mdr\_text.text:THE DEVICE WAS SENT TO A PHILIPS AUTHORIZED REPAIR FACILITY THAT PERFORMED DIAGNOSTIC/FUNCTIONAL TESTING. RESULTS OF THE FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND AT THE START UP TEST. THE TESTING CONFIRMED THE SPEAKER WAS DEFECTIVE. THE REPAIR FACILITY REPLACED THE SPEAKER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER.



## DSI MAUDE Problems Summary

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THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

IT WAS REPORTED DURING BENCH EVALUATION, THERE WAS NO AUDIO ON THE DEVICE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event90:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240326

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00186

mdr\_text.text:E1: REPORTING INSTITUTION PHONE # (B)(6). E1: REPORTER PHONE # (B)(6). A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND CONFIRMED THE REPORTED ISSUE THAT THE SPEAKER WAS FAULTY. THE FSE REPLACED THE SPEAKER ASSEMBLY TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER.

IT WAS REPORTED THAT THE SPEAKER WAS DEFECTIVE. IT IS UNKNOWN IF THERE WAS STILL SOUND COMING FROM THE DEVICE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event91:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240312

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00241

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event92:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240402

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02421

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED UNDERSENSING ON PAUSE EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CORRECTION: H6, G3 (INITIAL AWARE DATE : 02 APR 2024) MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT

INFORMATION BECOMES KNOWN.

{{datachunk}}Event93:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00237

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

CUSTOMER REPORTED THERE WAS NO AUDIBLE ALARM AND NO "SPEAKER MALFUNCTION" ERROR; SUSPECT DAMAGE DUE TO FLUID.

{{datachunk}}Event94:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20240306

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00238

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

CUSTOMER REPORTED A SPEAKER MALFUNCTION WITH NO AUDIO.

RESULTS OF FUNCTIONAL TESTING BY PHILIPS AUTHORIZED REPAIR FACILITY INDICATE THAT THE SPEAKER PRODUCED AUDIBLE SOUND DURING TESTING. THE REPORTED PROBLEM COULD NOT BE CONFIRMED.

CUSTOMER REPORTED A SPEAKER MALFUNCTION WITH NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE. THERE WAS NO PATIENT HARM OR INJURY REPORTED.

{{datachunk}}Event95:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240203

event\_location:

remedial\_action:[""]

patient.patient\_age:56 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01313

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED INTERMITTENT VENTRICULAR UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event96:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise", "Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20200611

event\_location:

remedial\_action:[""]

patient.patient\_age:53 YR

patient.patient\_sex:Male

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01315

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED OVERSENSING NOISE AND UNDERSENSING WHICH RESULTED IN FALSE DETECTIONS OF EVENTS. THE ICM IS AT END OF SERVICE (EOS). THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event97:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240307

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00177

mdr\_text.text:A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THERE WAS NO SOUND AT THE BEDSIDE WHEN THE SPEAKER MALFUNCTION INOP OCCURRED. THE RSE DETERMINED THAT THE SPEAKER FAILED. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE CUSTOMER WAS INSTRUCTED TO REPLACE THE SPEAKER.

IT WAS REPORTED THAT THE INTELLIVUE PATIENT MONITOR MX800 HAD A "SPEAKER MALFUNCTION" INOP. THERE WAS NO SOUND COMING FROM THE DEVICE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event98:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20240312

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00233



## DSI MAUDE Problems Summary

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mdr\_text.text:A PHILIPS PRODUCT SUPPORT ENGINEER AND PHILIPS CLINICAL SPECIALIST REVIEWED THE LOGS, STRIPS AND INFORMATION PROVIDED. ONE OF THE STRIPS PROVIDED INDICATED THE RHYTHM HAS BEAT LABELS OF N WHICH MEANS THE ALGORITHM WOULD NOT ISSUE A VTACH ALARM. .PPD DATA RECEIVED WAS ONLY FROM ONE OF THE BEDS (THE PATIENT HAD BEEN TRANSFERRED). THE .PPD DATA WAS FOR ONLY 40 SECONDS AND SHOW A LEARNING PHASE WAS OCCURRING WHILE THE PATIENT WAS IN A VENTRICULAR RHYTHM. THIS IS MOST LIKELY THE REASON THE BEATS ARE LABELED AS N INSTEAD OF V. THE STAR APPLICATION NOTE AND THE PRODUCT INFORMATION FOR USE (IFU) GUIDES INDICATE HOW MANY RUNS ARE REQUIRED TO IDENTIFY AND ALARM FOR V-TACH. THE DEFINITION FOR VTACH IS A RUN OF CONSECUTIVE BEATS LABELED AS V WITH RUN LENGTH GREATER THAN OR EQUAL TO THE V-TACH RUN LIMIT AND VENTRICULAR HR GREATER THAN THE V-TACH HR LIMIT. THE FACTORY SETTING FOR THE V-TACH RUN IS 5 AND THE V-TACH HR IS 100. THE STAR ALGORITHM HAD CLASSIFIED THE BEAT AS N INSTEAD OF V. BECAUSE OF THIS, THE CRITERIA FOR VTACH WAS NOT MET, HENCE THERE WAS NO ALARM FOR VTACH GENERATED. ONCE THE ALGORITHM DETECTS AND MEASURES THE QRS, THE BEAT IS LABELED AS N (NORMAL), S (SUPRAVENTRICULAR), V (VENTRICULAR ECTOPIC), OR P (PACED). TO AID THE ALGORITHM IN LABELING A NEW BEAT, PREVIOUSLY DETECTED BEATS THAT HAVE SIMILAR SHAPES ARE GROUPED INTO TEMPLATE FAMILIES. EACH PATIENT CAN HAVE UP TO 16 DIFFERENT ACTIVE TEMPLATE FAMILIES FOR EACH INDIVIDUAL LEAD. TO KEEP THE TEMPLATE FAMILY INFORMATION CURRENT, THEY ARE DYNAMICALLY CREATED AND REPLACED AS THE PATIENT'S BEAT MORPHOLOGY CHANGE. IF A PATIENT BEGINS TO DISPLAY A NEW BEAT MORPHOLOGY, A NEW TEMPLATE FAMILY IS CREATED. OLDER TEMPLATE FAMILIES FROM BEATS NO LONGER EXPERIENCING ARE AUTOMATICALLY DELETED. THE FOLLOWING WARNING IS FOUND IN THE INSTRUCTIONS FOR USE (IFU): WARNING: IF ARRHYTHMIA LEARNING TAKES PLACE DURING VENTRICULAR RHYTHM, THE ECTOPICS MAY BE INCORRECTLY LEARNED AS THE NORMAL QRS COMPLEX. THIS MAY RESULT IN MISSED DETECTION OF SUBSEQUENT EVENTS OF V-TACH AND V-FIB. FOR THIS REASON YOU SHOULD: TAKE CARE TO INITIATE ARRHYTHMIA RELEARNING ONLY DURING PERIODS OF PREDOMINANTLY NORMAL RHYTHM AND WHEN THE ECG SIGNAL IS RELATIVELY NOISE-FREE BE AWARE THAT ARRHYTHMIA RELEARNING CAN HAPPEN AUTOMATICALLY. RESPOND TO ANY INOP MESSAGES (FOR EXAMPLE, IF YOU ARE PROMPTED TO RECONNECT. ELECTRODES) AS THE EFFECTIVENESS OF THE ARRHYTHMIA MONITORING FOR THE PATIENT IS COMPROMISED . BE AWARE THAT A DISCONNECTED EASI ELECTRODE TRIGGERS AN ARRHYTHMIA RELEARN ON ALL LEADS. ALWAYS ENSURE THAT THE ARRHYTHMIA ALGORITHM IS LABELING BEATS CORRECTLY. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE RAW ECG DATA PROVIDED SHOWED THE MONITOR WAS IN A LEARNING PHASE DURING A VENTRICULAR RHYTHM. THE STAR ALGORITHM CLASSIFIED THE BEATS AS N INSTEAD OF V, RESULTING IN THE CRITERIA FOR GENERATING A VTACH ALARM NOT BEING MET. THERE WAS NO PRODUCT MALFUNCTION AND THE DEVICE REMAINS IN USE. RELATED CASES ARE REPORTED UNDER MFR REPORT NUMBERS 1218950-2024-00243, 9610816-2024-00179 AND 1218950-2024-00232.

THE CUSTOMER REPORTED THAT THERE WERE NO ALARMS FOR V-TACH. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event99:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20240312

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00232

mdr\_text.text:A PHILIPS PRODUCT SUPPORT ENGINEER AND PHILIPS CLINICAL SPECIALIST REVIEWED THE LOGS, STRIPS AND INFORMATION PROVIDED. ONE OF THE STRIPS PROVIDED INDICATED THE RHYTHM HAS BEAT LABELS OF N WHICH MEANS THE ALGORITHM WOULD NOT ISSUE A VTACH ALARM. .PPD DATA RECEIVED WAS ONLY FROM ONE OF THE BEDS (THE PATIENT HAD BEEN TRANSFERRED). THE .PPD DATA WAS FOR ONLY 40 SECONDS AND SHOW A LEARNING PHASE WAS OCCURRING WHILE THE PATIENT WAS IN A VENTRICULAR RHYTHM. THIS IS MOST LIKELY THE REASON THE BEATS ARE LABELED AS N INSTEAD OF V. THE STAR APPLICATION NOTE AND THE PRODUCT INSTRUCTIONS FOR USE (IFU) GUIDES INDICATE HOW MANY RUNS ARE REQUIRED TO IDENTIFY AND ALARM FOR V-TACH. THE DEFINITION FOR VTACH IS A RUN OF CONSECUTIVE BEATS LABELED AS V WITH RUN LENGTH GREATER THAN OR EQUAL TO THE V-TACH RUN LIMIT AND VENTRICULAR HR GREATER THAN THE V-TACH HR LIMIT. THE FACTORY SETTING FOR THE V-TACH RUN IS 5 AND THE V-TACH HR IS 100. THE STAR ALGORITHM HAD CLASSIFIED THE BEAT AS N INSTEAD OF V. BECAUSE OF THIS, THE CRITERIA FOR VTACH WAS NOT MET, HENCE THERE WAS NO ALARM FOR VTACH GENERATED. ONCE THE ALGORITHM DETECTS AND MEASURES THE QRS, THE BEAT IS LABELED AS N (NORMAL), S (SUPRAVENTRICULAR), V (VENTRICULAR ECTOPIC), OR P (PACED). TO AID THE ALGORITHM IN LABELING A NEW BEAT, PREVIOUSLY DETECTED BEATS THAT HAVE SIMILAR SHAPES ARE GROUPED INTO TEMPLATE FAMILIES.

## DSI MAUDE Problems Summary

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EACH PATIENT CAN HAVE UP TO 16 DIFFERENT ACTIVE TEMPLATE FAMILIES FOR EACH INDIVIDUAL LEAD. TO KEEP THE TEMPLATE FAMILY INFORMATION CURRENT, THEY ARE DYNAMICALLY CREATED AND REPLACED AS THE PATIENT'S BEAT MORPHOLOGY CHANGE. IF A PATIENT BEGINS TO DISPLAY A NEW BEAT MORPHOLOGY, A NEW TEMPLATE FAMILY IS CREATED. OLDER TEMPLATE FAMILIES FROM BEATS NO LONGER EXPERIENCING ARE AUTOMATICALLY DELETED. THE FOLLOWING WARNING IS FOUND IN THE IFU: WARNING IF ARRHYTHMIA LEARNING TAKES PLACE DURING VENTRICULAR RHYTHM, THE ECTOPICS MAY BE INCORRECTLY LEARNED AS THE NORMAL QRS COMPLEX. THIS MAY RESULT IN MISSED DETECTION OF SUBSEQUENT EVENTS OF V-TACH AND V-FIB. FOR THIS REASON YOU SHOULD: • TAKE CARE TO INITIATE ARRHYTHMIA RELEARNING ONLY DURING PERIODS OF PREDOMINANTLY NORMAL RHYTHM AND WHEN THE ECG SIGNAL IS RELATIVELY NOISE-FREE • BE AWARE THAT ARRHYTHMIA RELEARNING CAN HAPPEN AUTOMATICALLY • RESPOND TO ANY INOP MESSAGES (FOR EXAMPLE, IF YOU ARE PROMPTED TO RECONNECT ELECTRODES) AS THE EFFECTIVENESS OF THE ARRHYTHMIA MONITORING FOR THE PATIENT IS COMPROMISED • BE AWARE THAT A DISCONNECTED EASI ELECTRODE TRIGGERS AN ARRHYTHMIA RELEARN ON ALL LEADS • ALWAYS ENSURE THAT THE ARRHYTHMIA ALGORITHM IS LABELING BEATS CORRECTLY. THE REPORTED PROBLEM WAS NOT CONFIRMED. FOLLOWING THE PROFILE LOAD, WHEN THE PATIENT WAS TRANSFERRED TO THIS DEVICE AND CONNECTED TO THE MONITOR, THERE CONTINUES TO BE MULTIPLE HIGH HR, PAIR PVC, LOW NBP, AND LOW SPO2 ALARMS. AGAIN, THE STAR ALGORITHM HAD CLASSIFIED THE BEAT AS N INSTEAD OF V. BECAUSE OF THIS, THE CRITERIA FOR VTACH WERE NOT MET, HENCE THERE WAS NO ALARM FOR VTACH GENERATED. THE STAR ALGORITHM IS DESIGNED FOR CONTINUOUS MONITORING AND IS A TOOL TO ASSIST THE CLINICIAN IN MANAGING AND EVALUATING THEIR PATIENTS. IT IS NOT DESIGNED TO BE A REPLACEMENT FOR HUMAN SURVEILLANCE AND SOUND CLINICAL JUDGEMENT. INFORMATION WAS PROVIDED TO THE CUSTOMER TO RESOLVE THE ISSUE AND THE DEVICE REMAINS IN USE. RELATED CASES ARE REPORTED UNDER MFR REPORT NUMBERS 1218950-2024-00243, 1218950-2024-00233 AND 9610816-2024-00179.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THERE WERE NO ALARMS FOR V-TACH. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event100:

adverse\_event\_flag:N

product\_problems:["Device Emits Odor","Overheating of Device","Noise, Audible"]

event\_type:Malfunction

date\_of\_event:20240308

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00024

mdr\_text.text:IT WAS REPORTED THE C6 MCOT MONITOR WAS PLUGGED IN AND CHARGING AND IT MADE A SIZZLING SOUND AND THE MONITOR SMELT LIKE BURNING ELECTRICITY. THE MONITOR WAS RETURNED FOR INVESTIGATION. C6 MCOT MONITOR WAS INSPECTED FOR GENERAL PHYSICAL INTEGRITY; NO PROBLEMS WERE IDENTIFIED. ENGINEERING EVALUATION WAS UNABLE TO REPLICATE THE REPORTED ALLEGATION OF "MONITOR IS GETTING TOO HOT TO TOUCH". ALL TEMPERATURE THRESHOLDS WERE WITHIN TOLERANCE AND THE APPLICATION WAS FUNCTIONING PROPERLY; NO PROBLEMS FOUND. NO DAMAGE WAS FOUND ON THE MONITOR DUE TO THE MELTED CHARGING CORD. AS THE MONITOR WAS IDENTIFIED TO BE IN WORKING ORDER, ANY ALLEGED SPARK IS MOST PROBABLE TO COME FROM THE CHARGING CORD FOR WHICH THERE IS A KNOWN ISSUE THAT ALIGNS WITH THE FAILURE MODE THAT IS BEING INVESTIGATED BY PHILIPS AM&D.

IT WAS REPORTED ON 15 MARCH 2024 ON (B)(6) 2024 THE PATIENT WENT TO PLUG IN THE MCOT MONITOR - A13 - VERIZON TO CHARGE AND NOTED THAT THEY HEARD A SIZZLING SOUND. THEY ALSO REPORTED, THAT THE MONITOR WAS VERY HOT AND SMELLED LIKE BURNING ELECTRICITY. IT WAS CONFIRMED THAT THE MONITOR WAS PLUGGED INTO THE OUTLET ONLY. THE PATIENT ALSO REPORTED THAT THE DAMAGE WAS NOTED ON THE CHARGING WALL PLUG ONLY. NO PICTURES WERE NOT TAKEN. A REPLACEMENT WAS ORDER. NO INJURIES WERE REPORTED.

{{datachunk}}Event101:

adverse\_event\_flag:N

product\_problems:["Device Alarm System","Disconnection"]

event\_type:Malfunction

date\_of\_event:20240307

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 1.4 GHZ, ECG AND SP02, EX

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00234

mdr\_text.text:THE DEVICE WAS RETURNED TO A PHILIPS SITE FOR EVALUATION. THE DEVICE WAS TESTED AND HAD PASSES UNIT FUNCTIONAL TESTING TWICE. BASED ON THE INFORMATION PROVIDED IT WAS DETERMINED THAT THE CUSTOMER MAY HAVE BEEN EXPERIENCING NETWORK ISSUES AND NOT A FAILURE OF THE DEVICE. ADDITIONALLY, SINCE THE GAP WAS TO THE CENTRAL STATION/WIRELESS THEN THE DEVICE WOULD STILL OPERATE AND ALARM LOCALLY FOR ANY DETECTED ARRHYTHMIA. ALARMS CAN BE REVIEWED ON THE MX40 BUT WOULD NEED TO BE CAPTURED AT THE TIME OF THE EVENT. THOSE ALARMS ARE TEXT ONLY AND DO NOT CONTAIN WAVEFORMS. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT THE DEVICE FAILED TO ALARM AND DID NOT SOUND WHEN A 4 SECOND PAUSE WAS NOTED. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event102:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20240306

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00235

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. E1: (B)(6).

THE CUSTOMER REPORTED THAT AN MX40 IS SHOWING INOP MESSAGE "SPEAKER TECHNICAL FAULT" AND IS NOT MAKING ANY SOUND ON STARTUP LIKE IT SHOULD. NO PATIENT HARM WAS REPORTED.

{{datachunk}}Event103:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240320

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00229

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX40. THE UNIT DISPLAYS A MESSAGE INDICATING THE SPEAKER IS DEFECTIVE. PER GOOD FAITH EFFORT (GFE) CONDUCTED, THE FIELD SERVICE ENGINEER (FSE) STATES THAT THE DEVICE ITSELF WAS FUNCTIONING CORRECTLY, BUT THE CENTRAL STATION GAVE AN INOP THAT THE SPEAKER WAS DEFECTIVE. FSE CONFIRMED THAT THE DEVICE HAS BEEN EXCHANGED TESTED AND CONFIRMED WORKS OK, THE PROBLEM WAS RESOLVED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT TO RESOLVE THE ISSUE. THE FAULTY UNIT IS TO BE RETURNED FOR EVALUATION. A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE MX40 DISPLAYS A MESSAGE INDICATING THE SPEAKER IS DEFECTIVE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. CORRECTED DATA: E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6).

{{datachunk}}Event104:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230125

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01287

mdr\_text.text:CORRECTION: B5, H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS EXPLANTED AS THE PATIENT WAS UPGRADED TO AN IMPLANTABLE PULSE GENERATOR (IPG).

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED R WAVE UNDERSENSING ON PAUSE EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A



CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event105:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240307

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00227

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION UNKNOWN IF SOUND COMING FROM THE MX40. IT IS UNKNOWN IF STILL SOUND COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. E1: REPORTER INSTITUTION PHONE NUMBER: (B)(6). E1: REPORTER PHONE NUMBER: (B)(6).

{{datachunk}}Event106:

adverse\_event\_flag:Y

product\_problems:["Unintended Electrical Shock"]

event\_type:Injury

date\_of\_event:20240312

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Electric Shock"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00023

mdr\_text.text:IT WAS REPORTED ON 18 MARCH 2024, THAT ON (B)(6) 2024 THE PATIENT WAS PLUGGING THE DUAL USB CHARGING PLUG INTO THE WALL OUTLET TO CHARGE THE MCOT SENSOR AND MCOT MONITOR. THE DUAL USB CHARGING PLUG BROKE AND SOMEONE WAS SHOCKED. THE PATIENT STATED THAT THEY ATTEMPTED TO PULL THE CHARGER OUT OF THE WALL OUTLET AND THE PRONGS REMAINED INSIDE THE WALL OUTLET AND THEIR WIFE EXPERIENCED A SHOCK. NO MEDICAL ATTENTION WAS SOUGHT. A REPLACEMENT DUAL USB CHARGING PLUG WAS ORDERED.

{{datachunk}}Event107:

adverse\_event\_flag:N

product\_problems:

event\_type:Malfunction

date\_of\_event:20240219

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]  
patient.patient\_age:53 YR  
patient.patient\_sex:Male  
patient.patient\_ethnicity:Non Hispanic  
patient.patient\_race:White  
patient.patient\_problems:["Superficial (First Degree) Burn","Shock from Patient Lead(s)"]  
device.brand\_name:CARDIAC EVENT MONITORING (CEM) B  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:BOSTON SCIENTIFIC CARDIAC DIAGNOSTIC TECHNOLOGIES, INC.  
report\_number:MW5153506  
mdr\_text.text:PATIENT STATES THAT HER BATTERY-OPERATED 30-DAY EVENT MONITOR SHE WORE "ELECTROCUTED" HER. PATIENT SELF REPORTED THE EVENT AND ALERTED TO THE POSSIBILITY OF SMALL ELECTRICAL BURN TO THE CHEST AREA WHERE THE MONITOR WAS LOCATED.

{{datachunk}}Event108:  
adverse\_event\_flag:N  
product\_problems:["No Audible Alarm"]  
event\_type:Malfunction  
date\_of\_event:20240306  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:NA  
patient.patient\_sex:  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2  
device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00176

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING CONFIRMED THE SPEAKER IS INOPERABLE DUE TO A DAMAGED WIRE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS DAMAGE TO THE SPEAKER WIRE. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION INOP AND THAT THE SPEAKER IS INOPERABLE DUE TO A CUT WIRE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event109:

adverse\_event\_flag:N

product\_problems:["Decreased Sensitivity"]

event\_type:Malfunction

date\_of\_event:20240310

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02272

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE

## DSI MAUDE Problems Summary

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DEVICE MEMORY INDICATED DIMINISHED SENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED LOW R-WAVES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event110:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20220715

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01236

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS EXPLANTED AND THE PATIENT WAS IMPLANTED WITH AN IMPLANTABLE PULSE GENERATOR (IPG).

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED A FALSE PAUSE EPISODE DUE TO UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event111:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Male

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01235

mdr\_text.text:B3: EVENT DATE IS NOT KNOWN. PLEASE SEE B5 FOR APPROXIMATE DATE RANGE, IF APPLICABLE. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED NOISE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event112:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20221110

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01247

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR OVERSENSING AND UNDERSENSING. IT WAS FURTHER NOTED THAT THE REMOTE TRANSMISSION LAST CLEARED WENT BACK TO DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event113:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ



## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02231

mdr\_text.text:B3: EVENT DATE IS NOT KNOWN. PLEASE SEE B5 FOR APPROXIMATE DATE RANGE, IF APPLICABLE. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED NOISE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event114:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240228

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 802.11A/B/G

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2024-00223

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. REPORTER PHONE (B)(6).

IT WAS REPORTED THE SPEAKER WAS BROKEN. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event115:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240229

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00215

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE A THAT THERE WAS NO SPEAKER SOUND AT START UP TEST. SPEAKER CONFIRMED TO BE DEFECTIVE. THE REPORTED PROBLEM WAS CONFIRMED.

CUSTOMER REPORTED THERE IS A SPEAKER MALFUNCTION WITH NO SOUND. THE DEVICE WAS NOT IN CLINICAL USE. THERE WAS NO PATIENT OR USER HARM REPORTED.

CUSTOMER REPORTED THERE IS A SPEAKER MALFUNCTION WITH NO SOUND.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event116:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240218

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-02257

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT

## DSI MAUDE Problems Summary

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CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED OVERSENSING ON A TACHYCARDIA EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event117:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240308

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00220

mdr\_text.text:THE CUSTOMER SENT THE MX40 TO THE PHILIPS BENCH REPAIR.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL

## DSI MAUDE Problems Summary

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AFTER REPAIRS WERE COMPLETED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION NO SOUND WAS COMING FROM THE MX40. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event118:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240226

event\_location:

remedial\_action:[""]

patient.patient\_age:62 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Discomfort","No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01173

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A FULL POWER ON RESET OCCURRED. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS

THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS REIMPLANTED DUE TO DISCOMFORT EXPERIENCED BY THE PATIENT IN THE ORIGINAL POSITION.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED SEVERAL POWER ON RESET (POR)'S, WITH THE MOST RECENT BEING A HARD POR DUE TO BATTERY SUPPLY LOW. IT WAS CONFIRMED THAT THE ICM HAD BEEN RE-IMPLANTED AND CAUTERY MAY HAVE BEEN USED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

B3: DATE IS APPROXIMATE. YEAR IS CONFIRMED VALID. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event119:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240313

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00168

mdr\_text.text:THE CUSTOMER REPORTED THAT THERE WAS A TECHNICAL ALARM MESSAGE AND NO MORE SOUND ON THE X2 CONNECTED TO A MONITOR. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED. THE PROBLEM WAS ISOLATED AT THE LEVEL OF THE X2; THE WELDING OF THE LOUDSPEAKER IS DETACHED. A REPLACEMENT SPEAKER WAS ORDERED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. CORRECTED DATA: E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6).

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THERE WAS A LOUDSPEAKER FAULT INOP AND NO MORE SOUND. A REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

{{datachunk}}Event120:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20201203

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01150

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM CONTAINED INVALID HISTOGRAM DATA. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event121:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240313

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Male



## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01117

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS NOT ESTABLISHING TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS REFERRED TO THE CLINIC. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event122:

adverse\_event\_flag:N

product\_problems:["Low Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240315

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00209

mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THERE WAS A SPEAKER MALFUNCTION WITH NO AUDIBLE TONES. THE CUSTOMER WILL SEND THE DEVICE TO THE PHILIPS REPAIR BENCH. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT OR HARM WAS REPORTED.

THE DEVICE WAS SENT TO THE PHILIPS AUTHORIZED REPAIR FACILITY (RFT) BENCH FOR EVALUATION. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF THE FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND DURING THE START UP TEST; THE SPEAKER WAS DEFECTIVE. THE SPEAKER WAS REPLACED, AND THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event123:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240313

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01964

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT AN INTERNAL REVIEW OF DATA TRANSMITTED FROM THE IMPLANTABLE CARDIAC MONITOR (ICM) INDICATED A ELECTRICAL RESET OCCURRED. THE DEVICE REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A FULL POWER ON RESET OCCURRED. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event124:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20220130

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01966

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING P-WAVES AND UNDERSENSING. IT WAS FURTHER NOTED THAT THE INTEROGATION WENT BACK TO THE DATE OF IMPLANT.THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event125:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20240220

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00199

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE BENCH REPAIR INDICATES THAT THE EVALUATION THE SYSTEM AND IT INDICATE THAT THE SPEAKER DID PRODUCED SOUND. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION WITH THE SYSTEM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event126:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240317

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01980

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A FULL POWER ON RESET OCCURRED. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS IDENTIFIED DURING AN INTERNAL DATA REVIEW THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED AN ELECTRICAL RESET. THE DEVICE REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event127:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240306

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00200

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. NO PART WAS REPLACED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THE DEVICE INDICATES A SPEAKER MALFUNCTION ON THE SCREEN WITH NO SOUND BEING EMITTED. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

{{datachunk}}Event128:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240221

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00195

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION, NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

{{datachunk}}Event129:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20221221



## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01049

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM WAS REMOVED AND THE PATIENT IMPLANTED WITH A PACEMAKER. THE ICM HAD ALSO REACHED ELECTIVE REPLACEMENT INDICATOR (ERI). NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. ANALYSIS OF THE DEVICE REVEALED NORMAL BATTERY DEPLETION. THIS DEVICE MET THE PROJECTED 36 MONTHS OF NORMAL DEVICE FUNCTIONALITY. PREVIOUS IN DEPTH ANALYSIS ON DEVICES HAVE FOUND THAT AT LOW BATTERY VOLTAGES THE DEVICE WILL EXPERIENCE ISSUES RELATED TO OVER-SENSING AND UNDERSENSING. MEANING THAT THE HYBRID, AT THE BENCH, WHEN SUPPLIED WITH ADEQUATE BATTERY VOLTAGE, HAS NO SENSING ISSUES. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event130:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electromagnetic Interference","Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240215

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01025

## DSI MAUDE Problems Summary

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mdr\_text.text:CORRECTION: H11 PRODUCT EVENT SUMMARY PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED FALSE ASYSTOLE DUE TO UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. ANALYSIS OF THE DEVICE MEMORY INDICATED RIGHT VENTRICULAR T-WAVE OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED RIGHT VENTRICULAR UNDERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED FALSE ASYSTOLE DUE TO UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. ANALYSIS OF THE DEVICE MEMORY INDICATED T-WAVE OVERSENSING ASSOCIATED WITH THE RIGHT VENTRICULAR LEAD. ANALYSIS OF THE DEVICE MEMORY INDICATED RIGHT VENTRICULAR UNDERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT WAS IN COMPLETE HEART BLOCK BUT THIS WAS NOT DETECTED BY THE DEVICE. IT WAS NOTED THAT THE PATIENT'S R-WAVE AMPLITUDES WERE VARIABLE AND OFTEN SMALL AND T-WAVE AMPLITUDES WERE BIG, WHICH RESULTED IN UNDERSENSING OF TRUE R-WAVES AND OVERSENSING OF T-WAVES AND NOISE/EMI. FALSE PAUSE AND TACHYCARDIA EPISODES WERE DETECTED AND A TRUE PAUSE EPISODE WAS MISSED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE,

## DSI MAUDE Problems Summary

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MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event131:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20240217

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01903

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY

## DSI MAUDE Problems Summary

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PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING DUE TO A DECREASE OF SIGNAL AMPLITUDE. IT WAS FURTHER NOTED THAT DECREASE OF MORPHOLOGY AMPLITUDE WAS LIKELY RELATED TO MOVEMENT/POSITION OF THE DEVICE WITHIN THE POCKET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. THE DEVICE MEMORY INDICATED A SENSE EGM AMPLITUDE MEASUREMENTS ISSUE. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event132:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

## DSI MAUDE Problems Summary

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date\_of\_event:20240219

event\_location:

remedial\_action:[""]

patient.patient\_age:84 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Wound Dehiscence","Erythema","Unspecified Infection"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01026

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT APPROXIMATELY ONE MONTH POST IMPLANT , THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED AN INFECTION WITH WOUND DEHISCENCE AT THE ENTRY SITE COVERING ACROSS AND VISIBLE EDGE OF THE DEVICE. THERE WAS SURROUNDING ERYTHEMA AND MILD INDURATION. THE ICM WAS EXPLANTED AND THE IMPLANT SITE WAS CAREFULLY DEBRIDED AND IRRIGATED WITH ANTIBIOTIC SOLUTION. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT.

## DSI MAUDE Problems Summary

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IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event133:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01881

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED T-WAVE OVERSENSING (TWOS). THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED T-WAVE OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event134:



## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01804

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT.

IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event135:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:82 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00994

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS

4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event136:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:89 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01805

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA,

## DSI MAUDE Problems Summary

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MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event137:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:49 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01807

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING WITH BASELINE NOISE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN

ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event138:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01810

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

## DSI MAUDE Problems Summary

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{{datachunk}}Event139:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:83 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01813

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH



## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED BASELINE NOISE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event140:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:91 YR

patient.patient\_sex:Unknown

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01815

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event141:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01825

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND BASELINE ARTIFACTS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event142:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240219

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:2182207-2024-01620

mdr\_text.text:MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK

## DSI MAUDE Problems Summary

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BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED A FULL ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event143:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240229

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00164

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE RESULTS OF THE TESTING COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE DEVICE SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE THE REPAIR FACILITY WAS UNABLE TO CONFIRM THE REPORTED PROBLEM. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING, IT WAS REPORTED THERE WAS NO AUDIBLE SOUND FROM THE SPEAKER AT THE TIME OF THE EVENT. THEREFORE, THE SPEAKER WAS REPLACED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION

IT WAS REPORTED THERE WAS NO SOUND COMING FROM THE UNIT. THE DEVICE WAS IN CLINICAL USE, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event144:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:64 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01844

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

## DSI MAUDE Problems Summary

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{{datachunk}}Event145:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Prefer Not To Disclose

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:2182207-2024-01629

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED NOISE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

B3: EVENT DATE IS NOT KNOWN. PLEASE SEE B5 FOR APPROXIMATE DATE RANGE, IF APPLICABLE. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO



CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

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{{datachunk}}Event146:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:44 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-01002

mdr\_text.text:CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event147:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01848

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH

ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event148:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:44 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01850

## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event149:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01852

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE

DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event150:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01855

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

## DSI MAUDE Problems Summary

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THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event151:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:45 YR

patient.patient\_sex:Unknown

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01857

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

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## DSI MAUDE Problems Summary

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CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event152:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Unknown

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01859

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT

DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event153:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01860

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event154:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230906

event\_location:

remedial\_action:[""]

patient.patient\_age:56 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01861

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING WHICH RESULTED IN FALSE EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event155:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:86 YR

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01863

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY

## DSI MAUDE Problems Summary

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PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event156:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01865

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR



## DSI MAUDE Problems Summary

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CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event157:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01869

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR

SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event158:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:30 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01870

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event159:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Over-Sensing","Under-Sensing"]  
event\_type:Malfunction  
date\_of\_event:20240305  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:77 YR  
patient.patient\_sex:Unknown  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:REVEAL LINQ  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS  
report\_number:3008973940-2024-01872

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE

APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event160:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:49 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01766

## DSI MAUDE Problems Summary

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mdr\_text.text:CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED BASELINE ARTIFACTS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event161:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:27 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01768

mdr\_text.text:CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event162:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01769

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM



## DSI MAUDE Problems Summary

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BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event163:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:93 YR

patient.patient\_sex:Unknown

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01770

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event164:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:79 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01776

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT

DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event165:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:51 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01777

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED BASELINE ARTIFACTS. THE ICM

## DSI MAUDE Problems Summary

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REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event166:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:79 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01780

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR

## DSI MAUDE Problems Summary

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CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event167:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:37 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01781

mdr\_text.text:CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE

## DSI MAUDE Problems Summary

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REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event168:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:88 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ



## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00975

mdr\_text.text:CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event169:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:38 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01784

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event170:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240214

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00180

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE UNIT DID NOT PRODUCE SOUND. IT WAS

## DSI MAUDE Problems Summary

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DETERMINED THAT THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event171:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240213

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00173

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER DID PRODUCED SOUND. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

THE CUSTOMER REPORTED THAT THE SYSTEM SPEAKER HAS NO AUDIBLE FUNCTION. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event172:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01727

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH

## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event173:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01728

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event174:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Unknown

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01730

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT



## DSI MAUDE Problems Summary

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INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event175:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:31 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01731

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS

## DSI MAUDE Problems Summary

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¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED BASELINE ARTIFACT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event176:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:64 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01733

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION

BECOMES KNOWN.

{{datachunk}}Event177:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01734

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED BASELINE ARTIFACT. THE ICM REMAINS IN

## DSI MAUDE Problems Summary

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USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event178:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:63 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01735

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event179:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01736

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE,

MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event180:

adverse\_event\_flag:N

product\_problems:["Audible Prompt/Feedback Problem"]

event\_type:Malfunction

date\_of\_event:20240212

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00174



## DSI MAUDE Problems Summary

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mdr\_text.text:THE CUSTOMER WAS PROVIDED BENCH REPAIR INFORMATION FOR THE DEVICE. THE DEVICE WAS RECEIVED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE CUSTOMER WAS PROVIDED INFORMATION ON THE BENCH REPAIR BUT DECLINED SERVICE ON THE DEVICE AT THE TIME. NO FUNCTIONAL TESTING WAS PERFORMED, AND THE CUSTOMERS DEVICE WAS SENT BACK UNREPAIRED. THE PHILIPS AUTHORIZED REPAIR FACILITY PROVIDED THE CUSTOMER BENCH REPAIR INFORMATION. THE CUSTOMER DECLINED THE DEVICE REPAIR AND THE DEVICE WAS RETURNED TO THE CUSTOMERS UNREPAIRED.

THE CUSTOMER REPORTED THAT THE SYSTEM SPEAKER MALFUNCTIONED. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event181:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240219

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:CIC PRO

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:CRITIKON DE MEXICO S. DE R.L. DE C.V.

report\_number:3008729547-2024-00001

mdr\_text.text:LEGAL MANUFACTURER: HCS TOWER - 8200 W TOWER AVE USA MILWAUKEE, WI 53223.  
FIELDS A1-A6: THE INFORMATION WAS NOT PROVIDED TO GE HEALTHCARE (GEHC). THE CUSTOMER

## DSI MAUDE Problems Summary

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REPORTED A LOSS OF AUDIBLE ALARM FUNCTION ON THE CIC PRO. PER FOLLOW-UP WITH THE CUSTOMER, THERE WAS NO RELATED ADVERSE PATIENT CONSEQUENCE, NOR ALLEGATION THAT THE ISSUE LED TO A MISSED PATIENT EVENT. THE BIOMEDICAL ENGINEER REBOOTED THE CIC PRO WHICH RESTORED THE AUDIO FUNCTION. PER REVIEW WITH GEHC ENGINEERING, THIS EVENT WAS DETERMINED TO BE RELATED TO A PREVIOUSLY INVESTIGATED ISSUE WHEREIN THE CIC PRO DEVICE MAY LOSE AUDIBLE ALARM FUNCTION. THE VISUAL ALARMS ARE STILL PRESENT AND ACTIVE. AS WAS THE CASE IN THIS RECORD, IF THE PATIENT IS ALSO CONNECTED TO A BEDSIDE DEVICE, THE ALARMS AT THE BEDSIDE MONITOR ARE UNAFFECTED. GEHC ATTEMPTED TO REPRODUCE THE ISSUE WITH SIMILAR DEVICES IN A TEST LAB, REVIEWED DEVICE PERFORMANCE LOG FILES FOR OTHER DEVICES THAT SHOWED THE SAME ISSUE, AND PERFORMED EXTENSIVE HISTORICAL DATA ANALYSIS ALONG WITH TECHNICAL DESIGN REVIEW. GEHC WAS UNABLE TO DETERMINE A DEFINITIVE ROOT CAUSE FOR THE LOSS OF AUDIBLE ALARM FUNCTION. GEHC CONTINUES TO EVALUATE INCOMING COMPLAINTS AND INVESTIGATE WHERE APPROPRIATE.

THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARM FUNCTION ON THE CIC PRO. THERE WAS NO RELATED ADVERSE PATIENT CONSEQUENCE.

{{datachunk}}Event182:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240229

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

patient.patient\_sex:Unknown

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01646

## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON ATRIAL FIBRILLATION (AF) EPISODES. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED NOISE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event183:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240302

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01658

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC

## DSI MAUDE Problems Summary

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OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED BASELINE ARTIFACT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event184:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240302

event\_location:

remedial\_action:[""]

patient.patient\_age:62 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01665

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE

## DSI MAUDE Problems Summary

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EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event185:

adverse\_event\_flag:N

product\_problems:["Inaudible or Unclear Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240209

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00132

mdr\_text.text:A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE TO EVALUATE THE DEVICE IN QUESTION. THE FSE INDICATED DURING AN EVALUATION OF THE SYSTEM THAT THE SYSTEM SPEAKER DOES NOT WORK. THE FSE REPLACED THE CUSTOMERS DEVICE SPEAKER TO RESOLVE THE USER'S ISSUE. THE PHILIPS FIELD SERVICE ENGINEER (FSE) CONFIRMED THE CUSTOMERS DEVICE ISSUE AND PERFORMED SERVICE OF A SYSTEM SPEAKER REPLACEMENT TO RESOLVE AND THE CUSTOMER'S ISSUE. REPORTING ADDRESS STATE (B)(6).

THE CUSTOMER REPORTED THAT THE SPEAKER DOES NOT WORK WELL. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event186:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:37 YR

patient.patient\_sex:Unknown

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01669

mdr\_text.text:CORRECTION: H6 MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) ELECTROCARDIOGRAM (ECG) SHOWED SINUS RHYTHM/ TACHYCARDIA WITH OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.



{{datachunk}}Event187:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:56 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01672

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH

ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event188:

adverse\_event\_flag:N

product\_problems:["Delayed Alarm"]

event\_type:Malfunction

date\_of\_event:20240227

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00134

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX800 PATIENT MONITOR INDICATING THE MONITORS SPO2 MEASUREMENT ALARMS ARE NOT PERFORMING AS EXPECTED; THERE WAS A DELAY OF 30 SECONDS FOR THE MONITORS TO ANNOUNCE SPO2 ALARMS. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED. NO ADDITIONAL DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED. THE FSE STATED THAT THEY WERE UNABLE TO REACH ALL ROOMS TO PERFORM TESTING. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM IS UNKNOWN. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE ENGINEER WAS UNABLE TO CONFIRM THE ISSUE AS THE DEVICE WAS NOT AVAILABLE FOR TESTING.

H3 OTHER TEXT : CUSTOMER UNABLE TO CONFIRM DEVICE.

{{datachunk}}Event189:

adverse\_event\_flag:Y

product\_problems:["Unintended System Motion"]

event\_type:Injury

date\_of\_event:20240305

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE FMS-4

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00137

mdr\_text.text:THE CUSTOMER REPORTED THAT THE ARM HOLDING THE PATIENT MONITOR, WHICH IS CONNECTED TO THE WALL, WHEN MOVING THE MONITOR DOWN, THERE IS NO SOFT LANDING. THE RESISTANCE ON THE ARM IS MISSING AND ONE OF THE NURSES INJURED HER SHOULDER. SOME ARMS SEEM OK BUT SOME OF THEM ARE ALSO HAVING THIS SAME PROBLEM IN THE ICU. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. REPORTING ADDRESS STATE: (B)(6).

ADDITIONAL INFORMATION WAS PROVIDED THAT THE NURSE HAD A MINOR INJURY OF SHOULDER PAIN; THE NURSE RECOVERED. THE RESPONSE ALSO INDICATED THAT IT WAS UNKNOWN WHO INSTALLED THE MOUNT AT THE CUSTOMER SITE. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS THE SCREW AND NUT THAT'S CONNECTED TO THE BLACK LEVER WAS LOOSE. NO ADDITIONAL DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS ADVISED TO TIGHTEN THE SCREW AND NUT THAT'S CONNECTED TO THE BLACK LEVER. THE CUSTOMER CONFIRMED THAT THIS TIGHTENING RESOLVED THE FAULT. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event190:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01601

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND

## DSI MAUDE Problems Summary

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ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event191:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:63 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01602

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS

## DSI MAUDE Problems Summary

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EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event192:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240304

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01607

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION



## DSI MAUDE Problems Summary

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ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event193:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240212

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00161

mdr\_text.text:H3 OTHER TEXT : NO RESPONSE FROM CUSTOMER.

THE CUSTOMER REPORTED THAT THERE WAS A SPEAKER MALFUNCTION ALARM ON THE MONITOR. IT IS UNCLEAR IF THERE WAS SOUND BEING PRODUCED BY THE SPEAKER. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED. NO ADDITIONAL DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED. MULTIPLE ATTEMPTS WERE MADE TO CONTACT THE CUSTOMER WITHOUT SUCCESS. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS NOT CONFIRMED. IT IS UNKNOWN HOW THE ISSUE WAS RESOLVED.

{{datachunk}}Event194:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240223

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00122

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING "LOUDSPEAKER ERROR" IT IS UNKNOWN IF THE DEVICE WAS IN USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT OCCURRED. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE BENCH REPAIR TECHNICIAN (BRT) CONFIRMED THAT REPORTED PROBLEM "LOUDSPEAKER ERROR" AND THERE WAS NO SOUND ON THE DEVICE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

THE CUSTOMER REPORTED THAT THERE WAS A LOUDSPEAKER ERROR AND THE SPEAKER WAS COMPLETELY OUT OF SOUND. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

ADDITIONAL NARRATIVE: PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. CORRECTED DATA: E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6).

## DSI MAUDE Problems Summary

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{{datachunk}}Event195:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20240303

event\_location:

remedial\_action:[""]

patient.patient\_age:60 YR

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01625

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH

## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED A FALSE PAUSE EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED FALSE ASYSTOLE DUE TO UNDERSENSING. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event196:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electromagnetic Interference"]

event\_type:Malfunction

date\_of\_event:20240301

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

## DSI MAUDE Problems Summary

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report\_number:9614453-2024-00907

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT DURING THE IMPLANT PROCEDURE, THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED NOISE/ELECTROMAGNETIC INTERFERENCE. THE ICM WAS REPOSITIONED FOUR TIMES, WITHOUT IMPROVEMENT IN SENSING. THE ICM WAS REPLACED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event197:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20210521

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01563

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

B3: EVENT DATE IS NOT KNOWN. PLEASE SEE B5 FOR APPROXIMATE DATE RANGE, IF APPLICABLE.  
MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21

## DSI MAUDE Problems Summary

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CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED INAPPROPRIATE ATRIAL FIBRILLATION (AF) AND PAUSE DETECTIONS DUE TO UNDERSENSING, OVERSENSING AND ECTOPY. THE ICM REMAINS IN USE. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event198:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20240207

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["Unspecified Infection"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00908

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED AN INFECTION. THE ICM HAD BEEN IMPLANTED FOR APPROXIMATELY TWO YEARS AND FOUR MONTHS. THE ICM WAS REMOVED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.



{{datachunk}}Event199:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20240223

event\_location:

remedial\_action:[""]

patient.patient\_age:61 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["Purulent Discharge","Erythema","Unspecified Infection","Itching Sensation"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01576

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE

## DSI MAUDE Problems Summary

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BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED AN INFECTION OF THE INCISION SITE WITH REDNESS, ITCHING AND OOZING AT THE IMPLANT SITE. THE ICM HAD BEEN IMPLANTED OVER TWO MONTHS. THE PATIENT WAS PRESCRIBED ANTIBIOTICS. THE ICM WAS LATER REMOVED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event200:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210203

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00913

mdr\_text.text:CORRECTION: B7 MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT OVERSENSING AND UNDERSENSING. IT WAS FURTHER REPORTED THAT THE REPORT EPISODE WENT BACK TO IMPLANT DATE DESPITE INTERROGATIONS. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event201:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20240130

event\_location:

remedial\_action:[""]

patient.patient\_age:59 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01526

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED A FALSE VENTRICULAR TACHYCARDIA (VT) EPISODE DUE TO ARTIFACT WITH SOME NOISE. THE ICM REMAINS IN USE. NO

## DSI MAUDE Problems Summary

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PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event202:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20240213

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP70

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00116

mdr\_text.text:INFORMATION INDICATED THIS EVENT OCCURRED ON (B)(6) 2024, BETWEEN 3:20 P.M. AND 3:30 P.M. IN ROOM 6. A PHILIPS REMOTE SERVICE ENGINEER (RSE) SENT THE BIOMEDICAL ENGINEER (BIOMED) THE PROCEDURE TO GET THE LOGS. THE RSE CALLED THE CUSTOMER BACK TO FOLLOW UP, AND THE BIOMED TOLD THE RSE THAT HE WAS UNABLE TO PULL THE LOGS, BUT THERE WAS NO PROBLEM WITH ALARMS. THE BIOMED PERFORMED A TEST WITH A PATIENT SIMULATOR, AND THE DEVICE WAS OPERATIONAL. THE BIOMED WAS UNABLE TO REPRODUCE THE INITIAL REPORTED ISSUE. THE BIOMED REQUESTED TO HAVE THE USERS TRAINED PROPERLY ON THE ALARMING OF THE X2 AND X3 OF THE UNIT. THE REPORTED PROBLEM WAS NOT CONFIRMED. AS THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED, THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. H3 OTHER TEXT : CUSTOMER PERFORMED TESTING

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. REPORTING ADDRESS STATE: (B)(6). REPORTER PHONE #: (B)(6).

THE CUSTOMER REPORTED A RECURRING PROBLEM OF DESATURATION OF THE PATIENT WITHOUT AN ALARM. THE CUSTOMER INDICATED THAT THE ALARM WAS PRESENT ON THE MONITORING CENTRAL STATION, BUT NOT ON THE MONITOR OF THE ROOM. A TEST WAS PERFORMED BY A CUSTOMER BIOMEDICAL TECHNICIAN WITH A PATIENT SIMULATOR, AND THE DEVICE WAS OPERATIONAL. ADDITIONAL INVESTIGATION WAS REQUESTED. THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT REPORTED.

{{datachunk}}Event203:

adverse\_event\_flag:Y

product\_problems:["Incorrect, Inadequate or Imprecise Result or Readings"]

event\_type:Death

date\_of\_event:20240217

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["Insufficient Information","No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00117

mdr\_text.text:IT WAS REPORTED AFTER THE PATIENT RETURNED TO THE HOSPITAL WARD AFTER A C-SECTION, THE MONITOR DID NOT DISPLAY THE PULSE RATE WHEN THE SPO2 PROBE WAS APPLIED TO THE FINGER, BUT OXYGEN SATURATION WAS DISPLAYED. THE PROBE WAS TAKEN OFF AND REAPPLIED MULTIPLE TIMES WITH NO PULSE RATE DISPLAYING SO THE MONITOR WAS REPLACED, WHICH DISPLAYED PULSE RATE AND OXYGEN SATURATION. IT WAS INDICATED THIS ISSUE DELAYED POSTPARTUM VITAL SIGNS MONITORING. ADDITIONAL INFORMATION WAS REQUESTED AND IT TURNED OUT THAT A 5-MINUTE DELAY DID NOT LEAD TO ANY HARM FOR THE PATIENT AND THE CUSTOMER REFUSED TO DISCLOSE THE PATIENT'S CURRENT CONDITION. THE PATIENT'S PULSE COULD BE MANUALLY PALPATED. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

AN ONSITE EVALUATION WAS PERFORMED, AND IT TURNED OUT, THAT THE REPORTED ISSUE WAS CAUSED BY A DEFECTIVE SPO2 SENSOR. PHILIPS REQUESTED FURTHER RELEVANT INFORMATION WHETHER A PHILIPS SPO2 SENSOR OR A THIRD PARTY SPO2 SENSOR WAS USED, BUT NONE WAS PROVIDED. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPO2 SENSOR. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER REPLACED THE SPO2 SENSOR TO RESOLVE THE ISSUE. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

IT WAS REPORTED AFTER THE PATIENT RETURNED TO THE HOSPITAL WARD AFTER A C-SECTION, THE MONITOR DID NOT DISPLAY THE PULSE RATE WHEN THE SPO2 PROBE WAS APPLIED TO THE FINGER BUT OXYGEN SATURATION WAS DISPLAYED. THE PROBE WAS TAKEN OFF AND REAPPLIED MULTIPLE TIMES WITH NO PULSE RATE DISPLAYING SO THE MONITOR WAS REPLACED, WHICH DISPLAYED PULSE RATE AND OXYGEN SATURATION. IT WAS INDICATED THIS ISSUE DELAYED POSTPARTUM VITAL SIGNS MONITORING. IT WAS DETERMINED THERE WAS SENSOR DAMAGE AND LOW PERFUSION DUE TO LOW LIMB TEMPERATURE AND POOR PERIPHERAL CIRCULATION SECONDARY TO INTRAOPERATIVE ANESTHESIA AND BLOOD LOSS. BASED ON THIS INFORMATION, DEVICE MALFUNCTION AND THE POST-SURGICAL PATIENT CONDITION RESULTED IN A DELAY IN CARE. A PATIENT DEATH WAS REPORTED. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS A REPORT OF PATIENT OR USER HARM.

E1: REPORTER INSTITUTION PHONE NUMBER: (B)(6). A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

## DSI MAUDE Problems Summary

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{{datachunk}}Event204:

adverse\_event\_flag:N

product\_problems:["Battery Problem","Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240227

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00881

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH



## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD A TELEMETRY ISSUE USING A NEW READER. IT WAS FOUND OUT THAT THE IMPLANTED DEVICE REACHED THE RECOMMENDED REPLACEMENT TIME (RRT). THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event205:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240208

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00156

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND AT START UP TEST. IT WAS DETERMINED THAT THE SPEAKER WAS DEFECTIVE. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT

REPORTED.

{{datachunk}}Event206:

adverse\_event\_flag:N

product\_problems:["Fracture","Material Separation"]

event\_type:Malfunction

date\_of\_event:20240209

event\_location:

remedial\_action:[""]

patient.patient\_age:62 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00014

mdr\_text.text:IT WAS REPORTED THAT ON (B)(6) 2024 THAT THE MONITOR WAS CHARGING AND WHEN THE PATINET WENT TO PULL THE CHARGER OUT OF THE WALL OUTLET THE PRONGS GOT STUCK INTO THE WALL OUTLET. THERE WERE NO INJURIES REPORTED. THE PATIENT SERVICES REP ADVISED THE PATIENT OF RETURN INSUCRTIONS. A REPLACEMENT KIT WAS ORDERED.

IT WAS REPORTD THAT THE DUEL CHARGE ADAPTER WAS PLUGGED INTO THE WALL OUTLET AND WHEN THE PATIENT WENT TO REMOVE IT THE PRONGS GOT STUCK IN THE WALL. THE DEVICE WAS NOT RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE DEVICE WAS NOT RETURNED FOR EVALUATION. THIS PROBLEM STATEMENT ALIGNS WITH A KNOWN FAILURE AND IS MOST PROBABLE TO BE RELATED. THIS KNOWN FAILURE MODE IS BEING FURTHER INVESTIGATED BY PHILIPS AM&D.

{{datachunk}}Event207:

adverse\_event\_flag:Y

product\_problems:["Unintended Electrical Shock"]

event\_type:Injury

date\_of\_event:20240209

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Pain", "Electric Shock"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00015

mdr\_text.text:IT WAS REPORTED ON 10 FEBRUARY 2024, THAT ON (B)(6) 2024 THE PATIENT WENT TO THE EMERGENCY ROOM (ER) BECAUSE THEY FELT ELECTRIC SHOCKS UNDER THEIR ARMPIT AND TOWARDS THE LEFT SIDE OF THEIR CHEST. THE PATIENT STATED IT FELT LIKE A TEASER SHOCK. THE ER RAN TESTS SUCH AS AN EKG (ELECTROCARDIOGRAPHY) AND LAB WORK. EVERYTHING WAS NORMAL. THE HOSPITAL STAFF NOTED THAT IT COULD HAVE BEEN THE HEART MONITOR THAT COULD HAVE CAUSED THE ISSUE. THE PATIENT REMOVED THE DEVICE AND HAS NOT HAD ANY ISSUES SINCE REMOVING THE DEVICE.

IT WAS REPORTED THAT THE PATIENT EXPERIENCED A ELECTRICAL SHOCK UNDER THEIR ARMPIT. THE DEVICE WAS RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION COULD NOT REPLICATE THE REPORTED EVENT OF THE PATIENT FEELING A SHOCK. THE SENSOR PASSED ALL TESTING AND FOUND TO BE WORKING ACCORDING TO SPECIFICATIONS.

{{datachunk}}Event208:

adverse\_event\_flag:N

product\_problems:["Over-Sensing", "Under-Sensing"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20240227

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01484

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSED R WAVES. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED T-WAVE OVERSENSING (TWOS). THE

## DSI MAUDE Problems Summary

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ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED T-WAVE OVERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE,

A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event209:

adverse\_event\_flag:Y

product\_problems:["Defective Alarm"]

event\_type:Death

date\_of\_event:20240222

event\_location:

remedial\_action:[""]

patient.patient\_age:63 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Ventricular Fibrillation"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00150

mdr\_text.text:A PHILIPS CLINICAL SPECIALIST & PRODUCT SUPPORT ENGINEER HAS REVIEWED THE DATA INCLUDING THE AUDIT LOGS. THE FINDINGS ARE AS FOLLOWS: THIS PATIENT HAD AN ACTIVE ASYSTOLE ALARM FROM (B)(6) 09:57:58 AND CONTINUED UNTIL THE ECG LEADS OFF GENERATED AT 10:43:34. THE AUDIT LOG REFLECTS THE ASYSTOLE ALARM 09:57:58, MANY CANNOT ANALYZE ECG ALARMS AT 10:24:55, 10:25:51, 10:28:46, 10:29:21, 10:29:31, 10:29:34 DURING THE TIME IN QUESTION WHICH MAY DECREASE THE EFFECTIVENESS OF ARRHYTHMIA MONITORING. THIS IS DESCRIBED IN THE ST/AR APPLICATION NOTE: DURING THIS INOP/TECHNICAL CONDITION, THE ARRHYTHMIA ANALYSIS CONTINUES AND AN ALARM WILL BE ANNOUNCED IF AN ALARM CONDITION IS MET. SINCE THE CANNOT ANALYZE ECG INOP/TECHNICAL ALARM INDICATES THAT THE EFFECTIVENESS OF THE ARRHYTHMIA MONITORING FOR THE PATIENT IS COMPROMISED, A QUICK RESPONSE TO THIS ALARM IS IMPORTANT. MULTIPLE INSTANCES ARE ALSO SEEN WHERE THE STAFF INTERACTED WITH THE PIC TO CAPTURE THE 12 LEAD SEVERAL DIFFERENT TIMES, BUT NO ONE ACKNOWLEDGED THE ASYSTOLE ALARM FROM 09:57:58. THE ASYSTOLE ALARM ENDED AT 11:11:07 WHEN THE DEVICE WAS NO LONGER CONNECTED TO THE PIC IX. BASED ON THE INFORMATION PROVIDED TO PHILIPS, IT WAS DETERMINED

## DSI MAUDE Problems Summary

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THAT THERE WAS NO PRODUCT MALFUNCTION AND THE DEVICE WAS FUNCTIONING AS INTENDED. THE REPORTED ISSUE WAS CAUSED BY USER ERROR.

IT WAS REPORTED THAT THE SYSTEM DID NOT RECOGNIZE 10:23 RED EVENT AS A RED ALARM . A PATIENT DEATH DUE TO VENTRICULAR FIBRILLATION WAS REPORTED. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS A REPORT OF PATIENT OR USER HARM.

IT WAS REPORTED THAT THE SYSTEM DID NOT RECOGNIZE 10:23 RED EVENT AS A RED ALARM . A PATIENT DEATH DUE TO VENTRICULAR FIBRILLATION WAS REPORTED.THE DEVICE WAS IN USE ON A PATIENT. THERE WAS A REPORT OF PATIENT OR USER HARM.

E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE # (B)(6). A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION

{{datachunk}}Event210:

adverse\_event\_flag:Y

product\_problems:["Biocompatibility"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:41 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Discomfort","Superficial (First Degree) Burn"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00010

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT EXPERIENCED A SKIN IRRITATION WITH REDNESS, BURNING AND A SMALL AMOUNT OF SKIN BEING REMOVED. THE DEVICE WAS NOT RETURNED. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE ELECTRODE WAS NOT RETURNED.

## DSI MAUDE Problems Summary

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ALLEGATION IS ABLE TO BE CONFIRMED VIA THE PRESCRIPTION FROM A DOCTOR. AS THE DEVICE WAS NOTED TO NOT BE HOT, THE SKIN IRRITATION IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARSI, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

IT WAS REPORTED THAT THE PATIENT WAS EXPERIENCING RED, TENDER AND BURNING FEELING WHILE WEARING THE ELECTRODE WHILE USING THE FLEX ADAPTER. THE PATIENT ALSO REPORTED THE SENSOR NEVER FELT HOT HOWEVER THE ADHESIVE UNDER THE DEVICE AND ELECTRODE TURNED TO JELLY AND WOULD Ooze OUT. THE PATIENT USED VANICREAM SOAP AND WATER TO CLEAN AND PREP THEIR SKIN AND CONSULTED WITH THEIR PHYSICIAN. THE PATIENT SPOKE WITH THEIR DOCTOR AND THEY WERE PRESCRIBED SILVER SULFADIAZINE 1% CREAM. AFTER REPORTING THE RED, TENDER AND BURNING FEELING THE PATIENT DISCONNECTED THE SENSOR. THE PATIENT SERVICES REP ADVISED THE PATIENT OF CLOTH ELECTRODES. CLOTH ELECTRODES WERE ORDERED.

{{datachunk}}Event211:

adverse\_event\_flag:N

product\_problems:["Unable to Obtain Readings","Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20240219

event\_location:

remedial\_action:[""]

patient.patient\_age:86 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00830



## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) ATRIAL FIBRILLATION (AF) BURDEN WAS INACCURATE. THE PHYSICIAN DISAGREED WITH THE NUMBER OF AF EPISODES DETECTED BY THE ICM. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE,

A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event212:

adverse\_event\_flag:N

product\_problems:["Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20240223

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01441

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS FURTHER REPORTED THAT ATTEMPTS MADE TO REPOSITION THE IMPLANTABLE CARDIAC MONITOR (ICM) WERE UNSUCCESSFUL.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

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IT WAS REPORTED THAT DURING THE IMPLANT PROCEDURE, THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED A SENSING ISSUE AND HAD NO SIGNAL. THE ICM WAS NOT USED AND REPLACED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event213:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230919

event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00835

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE

## DSI MAUDE Problems Summary

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BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED R WAVE UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event214:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240206

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00110

mdr\_text.text:(B)(6). A FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND FOUND THAT A NEW SPEAKER REQUIRES REPLACEMENT DUE TO NO AUDIBLE SOUND BEING EMITTED FROM THE SYSTEM. THERE WAS A "SPEAKER MALFUNCTION" ERROR DISPLAYED ON THE TOP LEFT OF THE SCREEN. AFTER A NEW SPEAKER WAS REPLACED, THE "SPEAKER MALFUNCTION" ERROR DISAPPEARED, AND THE DEVICE WAS BACK TO FULL FUNCTIONALITY. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

## DSI MAUDE Problems Summary

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THE CUSTOMER REPORTED A "SPEAKER MALFUNCTION INOP" ERROR MESSAGE WAS DISPLAYED. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event215:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240214

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00106

mdr\_text.text:IT WAS REPORTED THAT THE INTELLIVUE MULTI MEASUREMENT SERVER X2 HAD A DEFECTIVE LOUDSPEAKER. THERE WAS NO SOUND COMING FROM THE DEVICE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THE CUSTOMER RECEIVED REMOTE APPLICATION ASSISTANCE FROM A REMOTE SERVICE ENGINEER (RSE). THE RSE FOUND THAT THE SPEAKER WAS DEFECTIVE AND NEEDED TO BE REPLACED. A QUOTE WAS PROVIDED TO THE CUSTOMER, BUT EXPIRED. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE CUSTOMER WAS PROVIDED WITH A QUOTE, BUT THE QUOTE EXPIRED, IT IS UNKNOWN HOW THE ISSUE WAS RESOLVED BY THE CUSTOMER.

E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE # (B)(6). A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE INTELLIVUE MULTI MEASUREMENT SERVER X2 HAD A DEFECTIVE LOUDSPEAKER. IT IS UNKNOWN IF THERE WAS STILL SOUND COMING FROM THE DEVICE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event216:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20220731

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01406

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OCCASIONAL VENTRICULAR UNDER SENSING. IT WAS ALSO REPORTED THAT THE TRANSMISSION LAST CLEARED GOES BACK TO DATE OF IMPLANT. THE REMOTE MONITORING REPORT ALSO CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN

## DSI MAUDE Problems Summary

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ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event217:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240202

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00107

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION ERROR MESSAGE, AND THE SPEAKER IS NOT MAKING ANY SOUND. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.



## DSI MAUDE Problems Summary

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A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER SLOT ON THE MAINBOARD WAS DAMAGED AND THE SPEAKER DID NOT MAKE ANY SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DAMAGED MAINBOARD & DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE MAINBOARD & SPEAKER WERE REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event218:

adverse\_event\_flag:Y

product\_problems:["Melted","Overheating of Device"]

event\_type:Malfunction

date\_of\_event:20240127

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Superficial (First Degree) Burn","Blister"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00008

mdr\_text.text:IT WAS REPORTED THE MCOT MONITOR WAS PLUGGED AND WHEN THE PATIENT'S WIFE WENT INTO THE ROOM WHERE THE DEVICE WAS CHARGING THE CHARGING CORD WAS MELTED AND IT SMELT LIKE SOMETHING WAS BURNING. THE MONITOR WAS RETURNED FOR INVESTIGATION BUT NOT THE CHARGING CORD. ENGINEERING EVALUATION COULD NOT BE PERFORMED ON CHARGING CABLE

## DSI MAUDE Problems Summary

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AS CHARGING CABLE - MONITOR - A TO C WAS NOT RETURNED. ALLEGATION WAS CONFIRMED VIA VISUAL INSPECTION OF THE MONITOR AND THE CHARGING CABLE FAILURE MODE IS A KNOWN ISSUE AND PHILIPS AM&D IS FURTHER INVESTIGATING.

IT WAS REPORTED BY THAT THE PATIENT'S WIFE SMELLED SOMETHING BURNING AND WENT INTO THE ROOM WHERE THE C6 MONITOR WAS PLUGGED IN AND CHARGING. THE WIFE NOTED THAT THE C6 MONITOR CORD WAS BURN AND THE MONITOR WAS NOT RESPONDING. THE PATIENT'S WIFE WENT TO UNPLUG THE MONITOR WAS BURNT ON HER FINGER AND RESULTED IN A SMALL BLISTER. THE BLISTER WAS "NOTHING" SERIOUS AND DID NOT REQUIRE MEDICAL TREATMENT. THE PATIENT PAUSED IN SERVICE AND A REPLACEMENT DEVICE WAS SENT.

{{datachunk}}Event219:

adverse\_event\_flag:N

product\_problems:["Electromagnetic Interference"]

event\_type:Malfunction

date\_of\_event:20230712

event\_location:

remedial\_action:[""]

patient.patient\_age:43 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01336

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED EMI. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY

## DSI MAUDE Problems Summary

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INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED ELECTROMAGNETIC INTERFERENCE ON A TACHYCARDIA EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event220:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240130

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE PWM,802.11A/B/G,ECG&SP02,EX,NON US

TELE PWM,802.11A/B/G,ECG&SP02,EX,NON US

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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MHX

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00136

mdr\_text.text:A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND RECOMMENDED BENCH REPAIR. HOWEVER, THE DEVICE WAS NOT RETURNED TO THE BENCH. THERE FOR THE CAUSE OF THE REPORTED PROBLEM IS UNKNOWN. THE REPORTED PROBLEM WAS NOT CONFIRMED. A SPEAKER MALF INOP WAS REPORTED AS A VISUAL MESSAGE. THE PRESENCE OF A VISUAL INOP INDICATING THAT THE SPEAKER HAS MALFUNCTIONED WHEN AUDIO IS CONFIRMED TO BE OPERATIONAL AND SOUND IS PROVIDED IS NOT LIKELY TO LEAD TO HARM AS ALARMS CONTINUE TO BE ANNUNCIATED. THE RSE SENT A COST ESTIMATE TO THE CUSTOMER FOR AN MX40 EXCHANGE UNIT, HOWEVER THE CUSTOMER DIDN'T RESPOND. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. H3 OTHER TEXT : DEVICE NOT RECEIVED FOR EVALUATION.

THE CUSTOMER REPORTED THAT THE DEVICE DISPLAYS A SPEAKER TECHNICAL FAULT INOP. NO PATIENT HARM WAS REPORTED. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event221:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210728

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00755

mdr\_text.text:CONTINUATION OF D10: AZURE XT DR MRI SURESCAN PACEMAKER PRODUCT ID W1DR01 (SERIAL: (B)(6)); PRODUCT TYPE: 0240-IPG; (IMPLANT (B)(6) 2022) (EXPLANT N/A) MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. IT WAS FURTHER REPORTED THAT IMPLANTABLE PULSE GENERATOR (IPG) EXPERIENCED INTERMITTENTLY UNDERSENSING ON VENTRICULAR LEAD. THE ICM REMAINS IN USE. THE IPG REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event222:

adverse\_event\_flag:Y

product\_problems:["False Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20240101

event\_location:

remedial\_action:[""]

patient.patient\_age:90 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Pneumonia","Respiratory Failure","Fibrosis","Insufficient Information"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00118

mdr\_text.text:THE CUSTOMER REPORTED THAT THE DEVICE TURNED OFF AND WAS NOT ACTIVELY MONITORING PATIENT. THE DEVICE WAS IN USE AT THE TIME OF THE INCIDENT. A DEATH OF A MALE PATIENT WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. E1: REPORTER INSTITUTION PHONE NUMBER: NOT APPLICABLE. E1: REPORTER PHONE NUMBER: NOT APPLICABLE.

A PHILIPS PRODUCT SUPPORT ENGINEER & PHILIPS CLINICAL SPECIALIST REVIEWED THE LOG FILES PROVIDED. THE DEVICE WAS ASSIGNED TO A PATIENT AT 08:20:26 ON (B)(6) 2024. THEY CONFIRMED THAT SEVERAL INOPS AND ALARMS WERE PROVIDED DURING THE DAY IN QUESTION. NO DATA TELE INOP WAS ACKNOWLEDGED 13 TIMES BETWEEN 13:00 AND 19:00 FROM PIC BDCMU36. THERE WAS A PATIENT UPDATE AT 19:21:53 AND THEN THE DEVICE WAS SELECTED FOR OVERVIEW ON PIC IX: BDCMU50 AT 20:34:44 AND THEN CLEARED ABOUT 9 MIN LATER. THE REPORTED EVENT OF PATIENT DEATH WAS REVIEWED BY PMS CLINICAL EXPERT. THIS EVENT IS ASSESSED AS POSSIBLY RELATED TO USE ERROR. THE CAUSE OF DEATH WAS DOCUMENTED AS PULMONARY FIBROSIS, PNEUMONIA AND ACUTE HYPOXIC HYPERCAPNIA AND RESPIRATORY FAILURE. THE PATIENT WAS MONITORED CONTINUOUSLY AND THE CUSTOMER ALLEGED THE DEVICE STOPPED SUBMITTING DATA WITHOUT ANY CORRESPONDING ALERT OR WARNING; HOWEVER, SOME PHYSIOLOGICAL ALARMS, MANY INOPS, A TELE WEAK SIGNAL ALARM AND AN SPO2T ALARM WERE NOTED PRIOR TO THE DEVICE GOING OFFLINE. NO DATA TELE WAS ACKNOWLEDGED 13 TIMES FROM THE PIC. BASED ON THIS INFORMATION, THE DEVICE WAS WORKING AS INTENDED AND THE USER WAS INTERACTING WITH THE SYSTEM AND SILENCING/ACKNOWLEDGING ALARMS. THE CAUSE OF THE REPORTED EVENT WAS NOT RELATED TO

## DSI MAUDE Problems Summary

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DEVICE FUNCTION; HOWEVER, IT WAS LIKELY RELATED TO A COMBINATION OF USE ERROR, ALARM MANAGEMENT, AND POTENTIALLY CLINICAL WORKFLOW. THE INFORMATION PROVIDED IS NOT CONSISTENT WITH A MALFUNCTION OF THE PRODUCT AS ALARMS WERE PROVIDED AT THE MX40 AND PIC IX INCLUDING THE TELE SERVICE BATT INOP.

THE CUSTOMER REPORTED THAT THE MX40 TURNED OFF AND WAS NOT ACTIVELY MONITORING PATIENT. THE CUSTOMER REPORTED THAT THE DEVICE TURNED OFF AND WAS NOT ACTIVELY MONITORING PATIENT. THE DEVICE WAS IN USE AT THE TIME OF THE INCIDENT. THE PATIENT PASSED AWAY.

{{datachunk}}Event223:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210731

event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00756

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN SUE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.



## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event224:

adverse\_event\_flag:Y

product\_problems:["No Device Output"]

event\_type:Malfunction

date\_of\_event:20240131

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information","No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MP40

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

## DSI MAUDE Problems Summary

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report\_number:9610816-2024-00093

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING INDICATED THAT THE FINGER PROBE WAS BROKEN. BASED ON THE INFORMATION AVAILABLE THE CAUSE OF THE REPORTED PROBLEM WAS A BROKEN BLOOD OXYGEN FINGER CUFF (NON-PHILIPS). THE REPORTED PROBLEM WAS CONFIRMED. IT WAS IDENTIFIED THAT A NON-PHILIPS FINGER PROBE WAS BROKEN AND IT WAS IMMEDIATELY REPORTED TO THE CUSTOMERS EQUIPMENT DEPARTMENT FOR REPAIR. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. REPORTER PHONE NUMBER: (B)(6). REPORTING INSTITUTION PHONE NUMBER: NO INFORMATION.

THE CUSTOMER REPORTED THE BLOOD OXYGEN SATURATION VALUE IS NOT DISPLAYED WHEN CONNECTING THE BLOOD OXYGEN FINGER CUFF. THE DEVICE WAS IN USE ON A PATIENT. THERE IS A REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event225:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240219

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2024-00128

mdr\_text.text:THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) REPORTED THAT THERE WAS A SPEAKER TECHNICAL FAULT ERROR WHERE THERE IS NO SOUND FROM THE DEVICE. THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE VENT OR PATIENT HARM REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. REPORTING ADDRESS STATE: O REPORTING INSTITUTION PHONE #: (B)(6) REPORTER PHONE #: (B)(6).

{{datachunk}}Event226:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240126

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:PATIENT CONNECTOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-00696

mdr\_text.text:IT WAS FURTHER REPORTED THAT IT COULD NOT BE CONFIRMED THAT NOISE WAS GENERATED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE

## DSI MAUDE Problems Summary

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COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CONTINUATION OF D10: MC1VR01 IMPLANTABLE PULSE GENERATOR (IPG) 24967 RADIOFREQUENCY HEAD MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT DURING AN IMPLANT PROCEDURE, A COMMUNICATION FAILURE OF THE PATIENT CONNECTOR AND LEADLESS IMPLANTABLE PULSE GENERATOR (IPG) OCCURRED DURING MEASUREMENT. THERE WAS NO IMPROVEMENT AFTER REPOSITIONING THE PATIENT CONNECTOR, RE-INTERROGATING AND RECONNECTING THE PATIENT CONNECTOR. THE TABLET SUPPORTING THE MOBILE PROGRAMMER APPLICATION AND PATIENT CONNECTOR WERE REPLACED BUT THIS FAILED TO RESOLVE THE ISSUE. THE MEASUREMENT OF THE LEADLESS IPG WAS COMPLETED SUCCESSFULLY. IT

WAS ALSO REPORTED THAT THE LEADLESS IPG EXHIBITED POSSIBLE NOISE. THE LEADLESS IPG AND PATIENT CONNECTORS REMAIN IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event227:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240212

event\_location:

remedial\_action:["Recall"]

patient.patient\_age:80 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01247

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS

## DSI MAUDE Problems Summary

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REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A PARTIAL POWER ON RESET OCCURRED. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET AND REQUIRES A SOFTWARE UPGRADE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event228:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240219

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-00688

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF

REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event229:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240213

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00122

mdr\_text.text:FUNCTIONAL TESTING/SERVICE REPAIR/TECHNICAL INVESTIGATION:  
DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY.  
RESULTS OF FUNCTIONAL TESTING AND INTERNAL COMMUNICATION INDICATE THAT NO SPEAKER  
SOUND AT START UP TEST, AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE



AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

IT WAS REPORTED THAT DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event230:

adverse\_event\_flag:N

product\_problems:["Low Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240126

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00116

mdr\_text.text:THE CUSTOMER REPORTED THAT THE MONITOR ANNOUNCED THE PATIENT'S DESAT SPO2T ALARM, THEN THE PATIENT'S SPO2T VALUE CONTINUED TO DECREASE BUT THE MONITOR DID NOT GENERATE A NEW ALARM. THE CUSTOMER REPORTED THAT THEY BELIEVE THE WAY THE ALARMS ARE SET UP MAYBE CAUSING AN ISSUE; PERHAPS A LATCHING ISSUE. FOR EXAMPLE, THEY ARE WONDERING WHY IT DOES NOT ALARM CONSTANTLY AFTER THE ACKNOWLEDGING. THEY BELIEVE AFTER HITTING THE ALARM BUTTON WHY IS IT NOT STILL ALERTING REGARDING SPO2 ALARMS. THE DEVICE WAS IN USE AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT REPORTED. A PHILIPS

## DSI MAUDE Problems Summary

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REMOTE CLINICAL SPECIALIST (RCS) SPOKE WITH THE CUSTOMER TO ASSIST WITH INTERPRETATION OF THE PATIENT CLINICAL AUDIT EVENTS FOR BED (B)(4) DURING THE TIME OF 7:41 AM TO 8:10 AM ON (B)(6) 2024. THE CLINICAL USER STATED THAT THE MONITOR ANNOUNCED THE PATIENT'S DESAT SPO2T ALARM, THEN THE PATIENT'S SPO2T VALUE CONTINUED TO DECREASE, BUT THE MONITOR DID NOT GENERATE A NEW ALARM. A REVIEW OF THE CLINICAL AUDIT DISPLAYED ALARMING FOR SPO2T 88<90 AT 07:40:46 WITH ADDITIONAL ALARMING, ALARMS ENDING AND FINALLY ACKNOWLEDGED AT 08:09:00. A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND THE CUSTOMER REQUESTED ONSITE ASSISTANCE WITH THE PROGRAMMING OF ALARMS AND TO ADDRESS ADDITIONAL QUESTIONS. A PHILIPS TECHNICAL CONSULTANT (TC) WAS DISPATCHED. THE CUSTOMER IS WONDERING WHY AFTER THE RED ALARMS WAS ACKNOWLEDGED ON THE (B)(6) EVENT, THEY DID NOT GET ANOTHER ALERT AFTER THAT. THE MX40 DEVICE WAS TESTED AND A SIMULATOR TRIGGERED A DESAT ALARM. THIS SUCCESSFULLY ALERTED AT THE PATIENT INFORMATION CENTER IX (PIC IX) CENTRAL STATION. A CLINICAL TEAM IS BEING DISPATCHED FOR FURTHER INVESTIGATION OF CUSTOMER CONCERNS REGARDING THE UNDERSTANDING OF ALARM BEHAVIOR AND IMPACT TO PAGING. THE ALLEGATION RELATED TO PATIENT INFORMATION CENTER IX (PIC IX) IS REPORTED UNDER MANUFACTURER REPORT# 1218950-2024-00115.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

A PHILIPS TECHNICAL CONSULTANT (TC) WAS DISPATCHED. THE TC INFORMED THAT THE CUSTOMER BELIEVED THE WAY THE ALARMS WERE SET UP MAYBE CAUSING ISSUE. A PHILIPS CLINICAL APPLICATION SPECIALIST (CAS) REVIEWED THE AUDIT LOGS PROVIDED BY THE CUSTOMER. THE CAS NOTICED SOME TIME DIFFERENCES BETWEEN PIC IX: WYCMUSV03 AND PIC IX: WYPICUSV04. THE TIME SYNC IN THE SYSTEM WAS NOT ON OR WORKING AND THAT MIGHT BE CAUSING SOME QUESTIONS ABOUT THE SPO2 BEHAVIOR. SPO2 ALARMS HAVE A CONFIGURABLE ALARM DELAY, YELLOW ALARM DELAY IS SEPARATE THAN THE RED ALARM DELAY. RED ALARMS ARE ALWAYS LATCHING, YELLOW LIMIT ALARMS CAN BE LATCHED OR NON-LATCHED. THE DEFAULT IS LATCHED. THIS IS SET AT THE PIC IX. THE ALARM DELAY TIME IS 0 TO 30 SECONDS (ADJUSTABLE IN ONE SECOND STEPS) WITH A DEFAULT TIME FOR DESAT OF 20 SECONDS AND A DEFAULT TIME FOR HIGH/LOW ALARM OF 10 SECONDS. THE ALARM DELAY MEANS THAT THE VALUE HAS TO BE BELOW THE SET LIMIT FOR X SECONDS BEFORE AN ALARM GENERATES. BASED ON THE ANALYSIS, THE MX40 WAS WORKING AS INTENDED. BASED ON THIS INFORMATION, THE DEVICE DID NOT CAUSE OR CONTRIBUTE TO THE REPORTED EVENT. PHILIPS WAS UNABLE REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE MX40 WAS WORKING AS INTENDED AND THE DEVICE DID NOT CAUSE OR CONTRIBUTE TO THE REPORTED EVENT. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event231:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20240211

event\_location:

remedial\_action:[""]

patient.patient\_age:40 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01167

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE

APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING NOISE/ ARTIFACT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event232:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:20240209

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00676

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) COULD NOT BE INTERROGATED. IT WAS ALSO REPORTED THAT NO TRANSMISSION WAS FOUND. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE

## DSI MAUDE Problems Summary

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INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event233:

adverse\_event\_flag:Y

product\_problems:["Migration or Expulsion of Device"]

event\_type:Injury

date\_of\_event:20240212

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["Wound Dehiscence"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00677

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION

## DSI MAUDE Problems Summary

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AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT DURING THE IMPLANTABLE CARDIAC MONITOR (ICM) TWO MONTH FOLLOW UP, IT WAS NOTED THAT THE ICM TIP WAS PROTRUDING FROM THE WOUND. IT WAS FURTHER REPORTED THAT THE PATIENT EXPERIENCED WOUND DEHISCENCE, SOME REDNESS WAS VISIBLE. LIDOCAINE WAS ADMINISTERED AND THE WOUND EXTENDED A COUPLE OF MILLIMETERS TO ALLOW EXTRACTION OF THE ICM. THE WOUND WAS DRESSED AND PATIENT DISCHARGED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event234:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback","Audible Prompt/Feedback Problem"]

event\_type:Malfunction

date\_of\_event:20240122

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00083

mdr\_text.text:A PHILIPS FIELD SERVICE ENGINEER (FSE) ISSUED A QUOTE FOR ON-SITE INTERVENTION; HOWEVER, IT WAS NOT ACKNOWLEDGED BY THE CUSTOMER, AND IT EXPIRED. AS A RESULT, THE UNIT WAS NOT EVALUATED BY PHILIPS AND THE CUSTOMER'S ALLEGATION COULD NOT BE CONFIRMED. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED AT THIS TIME.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MULTI MEASUREMENT SERVER X2 HAD A DEFECTIVE SPEAKER. THE DEVICE WAS IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event235:

adverse\_event\_flag:N



## DSI MAUDE Problems Summary

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product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240206

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00106

mdr\_text.text:ADDITIONAL INFORMATION WAS RECEIVED CONFIRMING THAT THERE WAS NO FAILURE. THIS CASE WAS CREATED BY THE BIOMED/TECHNICIAN FOR TESTING PURPOSES BEFORE PLACING THE DEVICE BACK INTO SERVICE, AFTER A PREVIOUS ISSUE ADDRESSED IN MFR REPORT NUMBER (B)(4) THERE WAS NO ADDITIONAL FAILURE BEING REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THAT THERE WAS A SPEAKER MALFUNCTION. IT IS UNCLEAR AT THIS TIME, IF THE SPEAKER WAS NOT PRODUCING SOUND. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

{{datachunk}}Event236:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240118

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00077

mdr\_text.text:THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 AND NO SOUND WAS COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE EVENT WAS REPORTED.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THE SPEAKER WAS DEFECTIVE, AND THAT THE DEVICE MADE NO NOISE (NO ALARM WAS HEARD), AND A MESSAGE APPEARED ON THE SCREEN. A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND FOUND THAT THE SPEAKER NO LONGER WORKED. THE FSE REPLACED THE SPEAKER TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. REPORTING INSTITUTION PHONE NUMBER: (B)(6) REPORTER PHONE NUMBER: (B)(6).

{{datachunk}}Event237:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electromagnetic Interference","Device-Device Incompatibility"]

event\_type:Malfunction

date\_of\_event:20240202

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:61 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-01118

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. ANALYSIS OF THE DEVICE MEMORY INDICATED EMI. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE

## DSI MAUDE Problems Summary

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COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED A FALSE TACHYCARDIA EPISODE DUE TO EXTERNAL NOISE/ ELECTROMAGNETIC INTERFERENCE. IT WAS CONFIRMED THAT THE PATIENT HAD AN MAGNETIC RESONANCE IMAGING (MRI). THE ICM REMAINS IN USE. NO PATIENT COMPL ICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event238:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240201

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00092

mdr\_text.text:THE DEVICE WAS SENT TO A PHILIPS AUTHORIZED REPAIR FACILITY THAT PERFORMED DIAGNOSTIC/FUNCTIONAL TESTING. RESULTS OF THE FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND WHEN TESTED ON THE CERTIFICATION TOOL, BUT DID NOT PRODUCE SOUND WHILE IN THE DEVICE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER CONNECTOR ON THE SYSTEM BOARD. THE REPORTED PROBLEM WAS CONFIRMED. THE REPAIR FACILITY REPLACED THE SPEAKER ALONG WITH THE SYSTEM MAIN BOARD. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DURING EVALUATION AT THE BENCH, IT WAS IDENTIFIED THERE IS NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event239:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240130

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00095

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. RESULTS OF FUNCTIONAL TESTING INDICATE THAT SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS NOT REPLICATED. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER BIOMEDICAL ENGINEER REPORTED THERE WAS A SPEAKER MALFUNCTION, AND CONFIRMED THERE WAS NO SOUND AT ALL. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event240:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:20240205

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

## DSI MAUDE Problems Summary

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report\_number:3008973940-2024-01011

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT DURING THE IMPLANTABLE CARDIAC MONITOR (ICM) IMPLANT PROCEDURE, THE ICM EXPERIENCED ARTIFACT AND COULD NOT BE USED. THE ICM WAS REPLACED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

{{datachunk}}Event241:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20240116

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00090

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE CUSTOMER WAS PROVIDED WITH A REPLACEMENT DEVICE TO RESOLVE THE ISSUE.

IT WAS REPORTED THAT THE DEVICE SHOWED A "SPEAKER EQUIPMENT MALFUNCTION" MESSAGE AND NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO REPORT OF AN ADVERSE EVENT.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. (B)(6).

IT WAS REPORTED THAT THE DEVICE SHOWED A "SPEAKER EQUIPMENT MALFUNCTION" MESSAGE AND NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO REPORT OF AN ADVERSE EVENT.

{{datachunk}}Event242:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction



## DSI MAUDE Problems Summary

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date\_of\_event:20240131

event\_location:

remedial\_action:[""]

patient.patient\_age:53 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00525

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION

AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT DURING THE IMPLANTABLE CARDIAC MONITOR (ICM) IMPLANT PROCEDURE, THE ICM EXPERIENCED NOISE. THE ICM WAS REMOVED AND A NEW ICM IMPLANTED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event243:

adverse\_event\_flag:N

product\_problems:["Battery Problem","Device Markings/Labelling Problem"]

event\_type:Malfunction

date\_of\_event:20240124

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00913

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT

## DSI MAUDE Problems Summary

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INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) COULD NOT BE ACTIVATED PRIOR TO USE AS THE ICM DISPLAYED AN END OF SERVICE (EOS) MESSAGE. THIS DATE IS EARLIER THAN THAT DISPLAYED ON DEVICE PACKAGING. A NEW ICM WAS IMPLANTED WITH NO ISSUES NOTED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE

## DSI MAUDE Problems Summary

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REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) USE BY DATE ON THE PACKAGING WAS CORRECT.

{{datachunk}}Event244:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20230828

event\_location:

remedial\_action:[""]

patient.patient\_age:64 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00499

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED TACHYCARDIA EPISODES WHICH APPEARED TO BE OVERSENSING ATRIAL ARRHYTHMIA. IT WAS FURTHER NOTED THAT THE TRANSMISSIONS LAST CLEARED WENT BACK TO THE DATE OF IMPLANT. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH

## DSI MAUDE Problems Summary

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ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event245:

adverse\_event\_flag:N

product\_problems:["Inappropriate Audible Prompt/Feedback","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240112

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00077

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED AUDIBLE DISTORTED SOUND. THE BENCH TECHNICIAN REPLACED THE SPEAKER AND THE DEVICE WAS SENT BACK TO THE CUSTOMER.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

## DSI MAUDE Problems Summary

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THE CUSTOMER REPORTED A SPEAKER MALFUNCTION, IT IS UNKNOWN IF STILL SOUND WAS COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event246:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240130

event\_location:

remedial\_action:[""]

patient.patient\_age:79 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00478

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF

## DSI MAUDE Problems Summary

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REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS



REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event247:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20240119

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00059

mdr\_text.text:THE CUSTOMER REPORTED THE ECG ALARM DOES NOT WORK. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

## DSI MAUDE Problems Summary

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PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

DIAGNOSTIC/FUNCTIONAL TESTING WAS NOT PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY AS THE DEVICE NEVER ARRIVED AT BENCH. THERE WAS NO RESPONSE FROM THE CUSTOMER; AS A RESULT, THE WORK ORDER WAS CANCELED. BASED ON THE INFORMATION PROVIDED IN THE CASE AND BY THE PHILIPS RSE, THE CUSTOMER'S ALLEGATION COULD NOT BE CONFIRMED. THERE WAS NO RESPONSE FROM THE CUSTOMER AND THE BENCH REPAIR ENDED UP BEING CANCELED. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED AT THIS TIME.

{{datachunk}}Event248:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240118

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00058

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THERE IS A VISUAL ALARM ON THE MONITOR BUT THE SOUND IS MISSING. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THE VISITING FIELD SUPPORT ENGINEER (FSE) PULLED THE ASSOCIATED AUDIT LOGS FOR REVIEW. A REVIEW OF THE LOGS DETERMINED THAT THE ALARM HAD BEEN TRIGGERED AND ALARMS WERE HEARD DURING DIAGNOSTIC TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. BASED ON THE GLOBAL DECISION TREE RESULTS, THE AVAILABLE INFORMATION SUGGEST THAT THE PRODUCT PROBLEM WOULD NOT BE LIKELY TO CAUSE OR CONTRIBUTE TO A DEATH OR SERIOUS INJURY IF IT WERE TO RECUR. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX800 PATIENT MONITOR INDICATING THAT THEY DID NOT HEAR AN ALARM OR RE-ALARM OF AN SPO2.

{{datachunk}}Event249:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240126

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00078

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THERE WERE NO SOUND WHEN THE DEVICE WAS POWERED ON. IT IS KNOWN THAT THE DEVICE

## DSI MAUDE Problems Summary

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WAS IN USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT OCCURRED. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING, BUT IT WAS INDICATED BY THE CUSTOMER THAT THERE WERE NO SOUND WHEN THE DEVICE WAS POWERED ON AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THERE IS NO SOUND FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event250:

adverse\_event\_flag:Y

product\_problems:["Use of Device Problem","Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20230629

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Hemorrhage/Blood Loss/Bleeding","Pain"]

device.brand\_name:REVEAL LINQ INSERTION TOOLS

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2024-00364

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THAT DURING THE IMPLANT PROCEDURE THE IMPLANT TOOL PUNCTURED THEIR PLEURAL SPACE RESULTING IN A MASSIVE BLEED. PAIN REMAINED WHERE THE IMPLANT TOOL PUNCTURED. IT WAS FURTHER REPORTED THAT THE ICM WAS PLACED ON/ NEAR A RIB BONE RESULTING IN THE DEVICE DIGGING INTO PATIENT'S RIB. WHEN LAYING DOWN THE ICM STABBED THE PATIENT'S COLLAR BONE. WHEN MOVING AROUND, THE DEVICE STABBED INTO AND BRUISED BREAST TISSUE. IT WAS FURTHER REPORTED THAT THE ICM PROTRUDED OUT OF THE SKIN. EXTREME SENSITIVITY TO THE DEVICE RESULTS IN FEELING OF BURNING. THE ICM REMAINS IN USE. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION

AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event251:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240119

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00052

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THE SPEAKER ASSEMBLY WAS DAMAGED AND WAS INTERMITTENTLY MAKING SOUNDS. THE BENCH REPAIR TECHNICIAN (BRT) FOUND THE FAULT WHEN THE DEVICE WAS AT BENCH. THE BRT DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT TO RESOLVE THE SPEAKER ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER.

## DSI MAUDE Problems Summary

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THE CUSTOMER REPORTED THAT THE SPEAKER ASSEMBLY IS DAMAGED AND IT IS INTERMITTENTLY MAKING SOUNDS. THIS IMPLIES THAT INTERMITTENTLY THE DEVICE IS NOT MAKING SOUNDS. THE SPEAKER ASSEMBLY WAS REPLACED. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event252:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240119

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00054

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE BENCH REPAIR TECHNICIAN (BRT) CONFIRMED THE ISSUE AND REPLACED THE (453564238621, MS\_X2 ASSY CBL X2/MP2 SPEAKER ASSEMBLY) TO RESOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPAIR WAS COMPLETED.

IT WAS REPORTED THAT THE DEVICE HAD A SPEAKER ERROR. IT IS UNKNOWN IF THERE WAS STILL SOUND COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF THE EVENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

## DSI MAUDE Problems Summary

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E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE # (B)(6). A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THAT THE DEVICE HAD A SPEAKER ERROR. IT IS UNKNOWN IF THERE WAS STILL SOUND COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF THE EVENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event253:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20240129

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00733

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A PARTIAL POWER ON RESET OCCURRED. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A



## DSI MAUDE Problems Summary

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CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event254:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Reset Problem"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20240124

event\_location:

remedial\_action:[""]

patient.patient\_age:31 YR

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00376

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event255:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240123

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00065

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THE UNIT HAD NO SOUND ANYMORE. IT IS KNOWN THAT THE DEVICE WAS IN USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT OCCURRED. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING, BUT IT WAS INDICATED BY THE CUSTOMER THAT SOUND WAS VERY FAINT AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

THE CUSTOMER REPORTED THAT THERE IS NO SOUND ANYMORE. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event256:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231214

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00040

mdr\_text.text:G4 CORRECTED FROM 14-DEC-2023 TO 11-JAN-2023.

IT WAS REPORTED TO PHILIPS THAT THE SPEAKER FAILED TO PROVIDE ANY NOISE. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE BENCH REPAIR TECHNICIAN (BRT) CONFIRMED THE CUSTOMER COMPLAINT THAT THE SPEAKER FAILED TO PROVIDE ANY NOISE AND REPLACED THE SPEAKER ASSEMBLY TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event257:

adverse\_event\_flag:Y

product\_problems:["Biocompatibility"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:49 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Shock","Numbness","Skin Inflammation/Irritation"]

## DSI MAUDE Problems Summary

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device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00006

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT WAS BURNED UNDER THE UNIVERSAL PATCH THAT LEFT THE PATIENT'S SKIN RED. THE DEVICE WAS NOT RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE ELECTRODE WAS NOT RETURNED. ALLEGATION IS UNABLE TO BE CONFIRMED AS THERE ARE NO IMAGES OF PATIENT SKIN IRRITATION AND ANY SKIN IRRITATION IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARSI, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

IT WAS REPORTED THAT THE PATIENT WAS BURNED ON AREA BENEATH PATCH ON THE LEFT SIDE. THE PATIENT REPORTED THE SKIN WAS RED AND BURN CREATED A SHOCK AT THE BACK OF THE PATIENT'S HEAD DOWN THE LEFT SIDE. THE PATIENT ALSO REPORTED THAT THEY EXPERIENCED NUMBNESS DOWN THEIR LEFT SIDE. ADDITIONAL INFORMATION WAS REQUESTED BUT COULD NOT BE OBTAINED.

{{datachunk}}Event258:

adverse\_event\_flag:Y

product\_problems:["Melted","Overheating of Device"]

event\_type:Injury

date\_of\_event:20240105

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Superficial (First Degree) Burn"]

## DSI MAUDE Problems Summary

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device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00007

mdr\_text.text:IT WAS REPORTED THAT PATIENT WAS SITTING IN THEIR KITCHEN WHEN THE SENSOR BECAME REALLY HOT WHILE WEARING THE UNIVERSAL PATCH. THE PATIENT REMOVED THE SENSOR AND PATCH AND NOTED A BURN AT THE TOP/MIDDLE OF THE CHEST WHERE THE SENSOR/PATCH WAS PLACED. THE PATIENT REPORTED THAT THIS BEGAN ABOUT 30 MINUTES AFTER STARTING SERVICE. THE PATIENT REPORTED THAT THERE WAS NO SPARKS BUT THE DEVICE WAS HOT AND STARTED TO MELT. THE PATIENT REPORTED THAT THE DEVICE WAS WORKING AS EXPECTED WHEN FIRST PULLED IT OUT OF THE BOX. THE PATIENT USED AQUAPHOR ON THE BURN. THE PATIENT REPORTED NO PRIOR SKIN SENSIBILITY/ALLERGIES. A REPLACEMENT DEVICE WAS ORDERED.

IT WAS REPORTED THAT THE PATIENT RECEIVED A BURN FROM THE SENSOR AND THE SENSOR MELTED. THE DEVICE WAS RETURNED FOR INVESTIGATION. DEVICE WAS INSPECTED FOR GENERAL PHYSICAL INTEGRITY AND FOUND PHYSICAL DAMAGE LOOKING LIKE PRY MARKS ON THAT BATTERY SIDE OF THE SENSOR. DEVICE WAS NOT ABLE TO CHARGE AND DEVICE WAS BADLY DAMAGED DUE TO CUSTOMER MISUSE OF THE DEVICE. THE ALLEGATION OF HEAT AND MELTING THE DEVICE IS CONFIRMED DUE TO THE CUSTOMER DAMAGING THE DEVICE.

{{datachunk}}Event259:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20201130

event\_location:

remedial\_action:[""]

patient.patient\_age:40 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00604

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS



## DSI MAUDE Problems Summary

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CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED LOSS OF CONTACT. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED PAUSE EPISODES DUE TO UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event260:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20231204

event\_location:

remedial\_action:[""]

patient.patient\_age:86 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00581

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS DISCONNECTED. IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD FALLEN OUT OF THE PATIENT'S CHEST. IT WAS MENTIONED THAT THE CLINIC DECIDED TO NOT IMPLANT THE NEW DEVICE. THE CONSULTANT EXPLAINED THAT THE PATIENT DID NOT NEED TO BE KEPT IN REMOTE MONITORING SERVICES. THE REMOTE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE

## DSI MAUDE Problems Summary

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REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event261:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230906

event\_location:

remedial\_action:[""]

patient.patient\_age:86 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00584

## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR 'IMPLANTABLE CARDIAC MONITOR (ICM) 'FELL OUT' OF THE PATIENT'S CHEST. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

B3:MONTH/YEAR VALID ONLY MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event262:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240111

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 802.11A/B/G

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00042

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. REPORTING INSTITUTION PHONE NUMBER: (B)(6). REPORTER PHONE NUMBER: (B)(6).

IT WAS REPORTED THAT THE DEVICE LOUDSPEAKER WAS DEFECTIVE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE REPORTED ISSUE. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THE FIELD SERVICE ENGINEER (FSE) VERIFIED THAT THE MX40 DEVICE HAD A LOUDSPEAKER MALFUNCTION INOP ALARM. A DEFECTIVE ON ARRIVAL (DEFOA) PROCESS WAS OPENED TO ADDRESS THE CUSTOMER'S ISSUE. THE DEVICE WAS RETURNED THROUGH THE DEFOA PROCESS TO THE FACTORY FOR FURTHER EVALUATION. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE LOUDSPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX40 802.11A/B/G INDICATING THAT THERE WAS A LOUDSPEAKER DEFECT ALARM. IT IS KNOWN THAT THE DEVICE WAS NOT IN USE AT THE TIME OF THE

EVENT. NO ADVERSE EVENT OCCURRED.

{{datachunk}}Event263:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231228

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP50 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00006

mdr\_text.text:THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MP50 PATIENT MONITOR. IT IS UNKNOWN IF SOUND WAS COMING FROM THE DEVICE. NO ADVERSE EVENT WAS REPORTED AND THE DEVICE WAS NOT USED FOR MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. REPORTING INSTITUTION PHONE # (B)(6). REPORTER PHONE # (B)(6).

THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MP50 PATIENT MONITOR AND NO SOUND WAS COMING FROM THE DEVICE. NO ADVERSE EVENT WAS REPORTED AND THE DEVICE WAS NOT USED FOR MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MP50 LOUDSPEAKER FAULT. THE DEVICE WAS OUTSIDE OF USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT OCCURRED. THE FUNCTIONAL ANALYSIS WAS PERFORMED AND IDENTIFIED THAT THE SPEAKER IS COMPLETELY OUT OF SOUND . THERE WAS AN INOP ERROR MESSAGE. THE FOLLOWING WAS REPLACED (453563499111,IV-MP50 MECHASY LOUDSPEAKER ASSEMBLY) TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS DEFECTIVE LOUDSPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event264:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20240109

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00030

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THE DEVICE WAS DISPLAYING A SPEAKER INOP ERROR MESSAGE AND CONFIRMED NO SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DUE TO THE CONNECTIONS BEING DAMAGED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DAMAGED CONNECTION. THE REPORTED

## DSI MAUDE Problems Summary

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PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. REPORTING INSTITUTION PHONE #: (B)(6). REPORTER PHONE #: (B)(6).

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event265:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20240117

event\_location:

remedial\_action:[""]

patient.patient\_age:86 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00228

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT



## DSI MAUDE Problems Summary

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INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED NO TELEMETRY. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY DUE TO TEMPORARY LOSS OF CONTACT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event266:

adverse\_event\_flag:N

product\_problems:["Difficult to Remove","Material Separation"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:88 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2024-00002

mdr\_text.text:IT WAS REPORTED BY THE PATIENT'S DAUGHTER THAT THE SENSOR CHARGER ADAPTER COULD NOT BE REMOVED FROM THE WALL SOCKET. A REPLACEMENT WAS ORDERED. THERE WAS NO HARM NOTED.

IT WAS REPORTED THAT THE DUEL CHARGE ADAPTER GOT STUCK IN THE WALL OUTLET. THE DEVICE WAS NOT RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE DEVICE WAS NOT RETURNED FOR EVALUATION. THE FAILURE DESCRIPTION ALIGNS WITH A KNOWN FAILURE REALTED TO JDSP-18928 DUAL USB POWER ADAPTOR HOUSING SEPARATION AND PHILIPS AM&D IS FURTHER INVESTIGATING.

{{datachunk}}Event267:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Device Sensing Problem","Device-Device Incompatibility"]

event\_type:Malfunction

date\_of\_event:20231218

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00426

mdr\_text.text:PRODUCT EVENT SUMMARY:THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. THE DEVICE MEMORY INDICATED A SENSING ISSUE. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE

## DSI MAUDE Problems Summary

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REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) VENTRICULAR EVENTS WERE BEING IGNORED BECAUSE THE DEVICE WAS RECOGNIZING THE MULTIFOCAL PREMATURE VENTRICULAR CONTRACTIONS (PVC)'S AS NOISE/OVERRANGE EVENTS. THE PATIENT WAS HAVING AN MAGNETIC RESONANCE IMAGING (MRI) AT THE TIME THE EVENT WAS RECORDED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event268:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231229

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00038

mdr\_text.text:CUSTOMER REPORTED THE UNIT IS DISPLAYING A SPEAKER MALFUNCTION ERROR MESSAGE AND PRODUCES NO AUDIO. THE UNIT WAS OUTSIDE OF USE. THERE WAS NO PATIENT OR USER HARM OR INJURY REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS NOT PERFORMED AS THE DEVICE HAS NOT BEEN RECEIVED FOR EVALUATION. THE REPORTED PROBLEM COULD NOT BE CONFIRMED AS IT WAS NOT RECEIVED FOR EVALUATION. THERE IS NO FURTHER ACTION NECESSARY AT THIS TIME.

CUSTOMER REPORTED THE UNIT IS DISPLAYING A SPEAKER MALFUNCTION ERROR MESSAGE AND THERE IS NO AUDIO BEING PRODUCED. THE UNIT WAS OUTSIDE OF USE. THERE WAS NO PATIENT OR USER HARM OR INJURY REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event269:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231228

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00036

mdr\_text.text:THE DEVICE WAS RETURNED TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. FUNCTIONAL TESTING DETERMINED THE SPEAKER PRODUCED AUDIBLE SOUND. THE REPORTED ISSUE COULD NOT BE CONFIRMED.

CUSTOMER REPORTED THE UNIT IS DISPLAYING A SPEAKER MALFUNCTION. THE CUSTOMER DID NOT KNOW IF THE UNIT WAS STILL PRODUCING AUDIBLE TONES. THE DEVICE WAS NOT IN USE AND THERE WAS NO PATIENT OR USER HARM OR INJURY REPORTED.

CUSTOMER REPORTED THE UNIT IS DISPLAYING A SPEAKER MALFUNCTION. THE CUSTOMER DID NOT KNOW IF THE UNIT WAS STILL PRODUCING AUDIBLE TONES. THE DEVICE WAS NOT IN USE AND THERE WAS NO PATIENT OR USER HARM OR INJURY REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event270:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240109

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00027

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION NO SOUND COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION NO SOUND COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE CUSTOMER SENT THE DEVICE TO THE BENCH REPAIR WHERE DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED. RESULTS OF THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE SPEAKER PRODUCED AUDIBLE SOUND. THE SPEAKER HAS BEEN REPLACED FOR PREVENTIVE MAINTENANCE AND THE DEVICE WAS SENT BACK TO THE CUSTOMER.

{{datachunk}}Event271:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20240103

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2024-00028

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION NO SOUND COMING FROM THE DEVICE. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER SENT THE DEVICE TO THE PHILIPS BENCH REPAIR. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. THE BENCH TECHNICIAN REPLACED THE SPEAKER ASSEMBLY AS PREVENTIVE MAINTENANCE. THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event272:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231221

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00029

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING A SPEAKER MALFUNCTION. THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH EVALUATION. RESULTS OF FUNCTIONAL TESTING INDICATE THAT SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE



## DSI MAUDE Problems Summary

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REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THE DEVICE HAS A SPEAKER MALFUNCTION.THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event273:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231103

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00294

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS

## DSI MAUDE Problems Summary

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EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED PAUSE EPISODES DUE TO UNDERSENSING. IT WAS FURTHER NOTED THAT THE PATIENT HAD SOME MISSED NIGHTLY TRANSMISSIONS AND SUBOPTIMAL SETUP. THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED FALSE ASYSTOLE DUE TO UNDERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event274:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20240108

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00305

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) CARDIAC COMPASS CONTAINED INVALID DATA AND DID NOT CONTAIN THE USUAL TRENDS. IT WAS FURTHER NOTED THAT THE REMOTE MONITORING REPORT CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED CARDIAC COMPASS DATA WAS MISSING/INVALID. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event275:

adverse\_event\_flag:N

product\_problems:["Inappropriate or Unexpected Reset"]

event\_type:Malfunction

date\_of\_event:20240108

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00310

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE

## DSI MAUDE Problems Summary

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SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event276:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231214

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00010

mdr\_text.text:A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO CLARIFY IF THE SPEAKER PRODUCED SOUND, AND IT WAS PROVIDED THAT THERE WAS NO SOUND FROM THE SPEAKER. THE CASE WAS CANCELLED PER THE CUSTOMER REQUEST. IT IS UNKNOWN WHAT CAUSED THE ISSUE OR HOW IT WAS RESOLVED. THE CAUSE OF THE REPORTED PROBLEM IS UNKNOWN. THE REPORTED PROBLEM WAS NOT CONFIRMED. PHILIPS IS UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE, BECAUSE THE CUSTOMER CANCELLED THE REQUEST. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT THE LOUDSPEAKER IS BROKEN. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT WAS REPORTED. THE ONSITE WORK ORDER WAS CANCELLED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.E1: REPORTING ADDRESS STATE: (B)(6). E1: REPORTING INSTITUTION PHONE#: (B)(6). E1: REPORTER PHONE#: (B)(6).

{{datachunk}}Event277:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231205

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2024-00012

mdr\_text.text:A PHILIPS DISTRIBUTOR AND SERVICE PARTNER WENT ONSITE TO EVALUATE THE DEVICE IN QUESTION. THE SERVICE PARTNER INDICATED DURING AN EVALUATION OF THE SYSTEM THAT THE SYSTEM HAS NO SOUND CAN BE OUTPUTTED. THE PHILIPS DISTRIBUTOR AND SERVICE PARTNER REPLACED THE SYSTEM LOUDSPEAKER. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. (B)(6).

THE CUSTOMER REPORTED THAT THE SYSTEM HAD A SPEAKER ERROR AND NO SOUND WAS COMING FROM THE DEVICE TO THE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT THE TIME OF THE EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event278:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230711

event\_location:



## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:64 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00124

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT INTERROGATED BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

## DSI MAUDE Problems Summary

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THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event279:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20220829

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

## DSI MAUDE Problems Summary

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report\_number:3008973940-2024-00131

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED T-WAVE OVERSENSING (TWOS) WHICH TRIGGERED FALSE DETECTIONS. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT INTERROGATED BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event280:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231201

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00051

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR

## DSI MAUDE Problems Summary

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SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED VENTRICULAR UNDERSENSING ON PAUSE EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event281:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231206

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00006

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. THE DEVICE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT DURING AN EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event282:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20231207

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2024-00008

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER DID PRODUCED SOUND. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION ERROR WITH THE SYSTEM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION ERROR WITH THE SYSTEM. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event283:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20210917

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:85 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00020

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. DUE TO THE PATIENT'S MEDICAL HISTORY, THE ICM WAS REMOVED AND THE PATENT RECEIVED A PACEMAKER. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. ANALYSIS OF THE DEVICE REVEALED NORMAL BATTERY DEPLETION. THE DEVICE EVENT OF OVERSENSING OCCURRED AFTER 36 MONTHS AND IT HAS BEEN SHOWN THAT THE DEVICE WILL HAVE REDUCED SENSING CAPABILITIES AT LOWER BATTERY VOLTAGES. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA



## DSI MAUDE Problems Summary

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REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event284:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20231215

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00021

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OCCASIONAL VENTRICULAR OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION

## DSI MAUDE Problems Summary

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AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event285:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electrical /Electronic Property Problem"]

event\_type:Malfunction

date\_of\_event:20231227

event\_location:

remedial\_action:[""]

patient.patient\_age:39 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Burning Sensation"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2024-00088

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS

## DSI MAUDE Problems Summary

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EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS EXPLANTED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) SHOCKED THE PATIENT AND THEY FELT A BURNING SENSATION ABOVE THE INCISION SITE. SYMPTOM EPISODES ALSO SHOW SOME NOISE OCCURRED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE

COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event286:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20231016

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00027

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED A ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A FULL ELECTRICAL RESET. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS

## DSI MAUDE Problems Summary

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CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event287:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20231206

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Erosion","Unspecified Infection"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2024-00002

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA

## DSI MAUDE Problems Summary

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3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT.

IT WAS REPORTED THAT APPROXIMATELY TWO MONTHS AND TWO WEEKS POST IMPLANT OF THE IMPLANTABLE CARDIAC MONITOR (ICM), THE PATIENT EXPERIENCED AN INFECTION/ EROSION OF THE DEVICE. THE ICM WAS REMOVED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event288:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231206

event\_location:



## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00692

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX700 PATIENT MONITOR INDICATING THAT THERE WAS A SPEAKER MALFUNCTION. A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO CLARIFY IF THE CUSTOMER WAS ALLEGING SOUND ISSUES WITH THE SPEAKER OR ONLY A SPEAKER MALFUNCTION INOP ON THE MONITOR, BUT NO ADDITIONAL INFORMATION WAS PROVIDED. THE DEVICE WAS SENT TO PHILIPS BENCH REPAIR. A PHILIPS BENCH REPAIR TECHNICIAN (BRT) EVALUATED THE DEVICE AND WAS UNABLE TO CONFIRM THE ISSUE. NO SPEAKER MALFUNCTION ERROR WAS APPEARING ON SCREEN. THE BRT CONFIRMED THAT SOUND WAS EMITTING FROM THE DEVICE PROPERLY AT DIFFERENT VOLUMES. THERE WAS NO TROUBLE WITH THE DEVICE DURING TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED PHILIPS WAS UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE BRT REPLACED THE SPEAKER FOR PREVENTATIVE MEASURE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION INOP. IT IS UNKNOWN IF SOUND WAS STILL COMING FROM THE DEVICE. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE CUSTOMER REPORTED SPEAKER MALFUNCTION INOP. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event289:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Delayed Alarm"]

event\_type:Malfunction

date\_of\_event:20231208

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP70

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00693

mdr\_text.text:A REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THAT THE CONFIGURATION HAD THE LOW ALARM DELAY SET AT 10 SECONDS, AND THE DESATURATION DELAY SET AT 20 SECONDS, SO THE RSE EXPLAINED THAT IT COULD POSSIBLY BE 30 SECONDS BEFORE A DESATURATION ALARM OCCURS. IT WAS CONFIRMED THAT SPO2 WAS A SOLID PLETH WAVEFORM WITH NO ARTIFACT. A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO CLARIFY THE ISSUE, AND IT WAS INDICATED THAT THE PATIENT'S SPO2 VALUES WERE VARYING WIDELY, CAUSING THE ALGORITHM'S DELAY CONDITION TO NOT BE MET, THOUGH THE CUSTOMER EXPECTED AN ALARM IMMEDIATELY. IT WAS ALSO INDICATED THE PATIENT'S SPO2 VALUES WERE ABOVE THE ALARM LIMIT A MAJORITY OF THE TIME. THE CUSTOMER DECLINED ONSITE DISPATCH. BASED ON THE INFORMATION AVAILABLE, THE REPORTED ISSUE WAS CAUSED BY USER ERROR / USER MISSUNDERSTANDING.

IT WAS REPORTED THAT WHEN THE PATIENT O2 SATURATION GOES BELOW WHAT THEY HAVE SET, IT TAKES SEVERAL MINUTES TO ALARM. THE 92-100 IS THE ALARM RANGE. 90-91 IS YELLOW. <90 RED ALARM. CUSTOMER REPORTED IT TAKES MANY MINUTES FOR THE SPO2 ALARM TO TRIGGER YELLOW. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

IT WAS REPORTED THAT WHEN THE PATIENT O2 SATURATION GOES BELOW WHAT THEY HAVE SET, IT TAKES SEVERAL MINUTES TO ALARM. THE 92-100 IS THE ALARM RANGE. 90-91 IS YELLOW. <90 RED ALARM. CUSTOMER REPORTED IT TAKES MANY MINUTES FOR THE SPO2 ALARM TO TRIGGER YELLOW. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event290:

adverse\_event\_flag:N

product\_problems:["Protective Measures Problem","Insufficient Information"]

event\_type:Malfunction

date\_of\_event:20231129

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information","No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 1.4 GHZ, ECG AND SP02, EX

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00975

mdr\_text.text:THE CUSTOMER REPORTED THAT THE PATIENT CODED ON BOX AND THEY WANT ALL THE INFORMATION RETRIEVED FROM THE BOX. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE IS INSUFFICIENT INFORMATION REGARDING PATIENT IMPACT AT TIME OF REPORT.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE REMOTE SERVICE ENGINEER (RSE) STATES THAT THERE ARE NO ALLEGATION OF FAILURE FOR THE MX40. THE RSE CONFIRMED VIA GOOD FAITH EFFORT (GFE) THAT THE CUSTOMER WANTED THE INFORMATION FROM THE BOX RETRIEVED. BASED ON INFORMATION IN THE CASE, THE CUSTOMER REQUESTED INFORMATION FROM THE TELE BOX TO BE PROVIDED, NO ALLEGATION OR FAILURE OF THE DEVICE WAS ALLEGED.. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event291:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231208

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00687

mdr\_text.text:IT WAS REPORTED THE DEVICE SPEAKER IS DAMAGED. A LOSS OF AUDIO CANNOT BE RULED OUT BASED ON INFORMATION CURRENTLY AVAILABLE. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE DEVICE WAS SENT TO PHILIPS BENCH REPAIR. A PHILIPS BENCH REPAIR TECHNICIAN (BRT) EVALUATED THE DEVICE AND DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER. THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event292:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231211

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00973

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST. FAILED MANUAL POWER ON TEST, AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event293:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231211

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00969

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND DURING THE START UP TEST. THE DEVICE FAILED A MANUAL POWER ON TEST, AND SPEAKER WAS DEFECTIVE. THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event294:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231211

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00970

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND DURING THE START UP TEST. THE DEVICE FAILED A MANUAL POWER ON TEST, AND SPEAKER WAS DEFECTIVE. THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event295:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20231219

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP50

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

## DSI MAUDE Problems Summary

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report\_number:9610816-2023-00686

mdr\_text.text:THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) REPORTED THE DEVICE DOES NOT ALARM AS DESIGNED. THE CUSTOMER STAFF STATE THAT THE ISSUE HAPPENS ONLY OVERNIGHT. THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

GOOD FAITH EFFORTS (GFE) WERE CONDUCTED TO OBTAIN FURTHER DETAILS OF THE ISSUE, HOWEVER, NO FURTHER INFORMATION WAS RECEIVED. A PHILIPS REMOTE SERVICE ENGINEER (RSE) MADE MULTIPLE ATTEMPTS TO REACH THE CUSTOMER BUT NO RESPONSE WAS RECEIVED. BASED ON THE INFORMATION AVAILABLE, PHILIPS WAS UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE FILE WILL BE REOPENED. H3 OTHER TEXT : NO RESPONSE TO INQUIRIES MADE TO THE CUSTOMER.

{{datachunk}}Event296:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231219

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00968



## DSI MAUDE Problems Summary

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mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION MESSAGE OCCURRED, AND IT WAS NOTED THAT THE DEVICE DID NOT ALARM/ALERT AS EXPECTED. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

THE DEVICE WAS SENT TO THE PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR REPAIR. RESULTS OF FUNCTIONAL TESTING INDICATE THAT SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS NOT REPLICATED. A GOOD FAITH EFFORT WAS THEN PERFORMED, AND INFORMATION WAS RECEIVED CONFIRMING THAT THE SPEAKER WAS PRODUCING SOUND AT THE TIME OF THE EVENT. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. BASED ON THE INFORMATION RECEIVED, INDICATING THE SPEAKER DID ACTUALLY PRODUCE SOUND AT THE TIME OF THE EVENT, THIS IS NO LONGER CONSIDERED A REPORTABLE EVENT.

{{datachunk}}Event297:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231219

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2023-00971

mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.  
(B)(6).

THE CUSTOMER REPORTED A SPEAKER FAILURE OCCURRED. AT THE TIME OF THE REPORT, IT WAS UNKNOWN IF THE DEVICE DISPLAYED AN ERROR MESSAGE WITH SOUND, OR IF THE SPEAKER DID NOT PRODUCE ANY SOUND. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

AFTER A VIGILANCE REPORT SPECIALIST AND MANAGER REVIEW OF ADDITIONAL INFORMATION PROVIDED, IT WAS DETERMINED THAT THIS RECORD IS NO LONGER REPORTABLE. THE INITIAL REPORT/CASE WHICH WAS RECEIVED LEADING TO THE CREATION OF THIS COMPLAINT RECORD, WAS FOUND TO HAVE BEEN OPENED IN ERROR UNDER THE INCORRECT CUSTOMER SITE. A NEW RECORD WAS CREATED AND SUBMITTED, WHERE IT WAS CONFIRMED THAT THERE WAS A SPEAKER MALFUNCTION, BUT SOUND WAS STILL PRODUCED.

{{datachunk}}Event298:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231212

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00972

## DSI MAUDE Problems Summary

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mdr\_text.text:THIS COMPLAINT WAS REPORTED IN ERROR. SOUND WAS PRESENT AT BENCH REPAIR AND NO REPORT IS NEEDED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT SPEAKER HAD NO SOUND AND BEEP USING SPEAKER CERTIFICATION TOOL. THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. HE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event299:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231115

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00213

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION

LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO THE STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE DEVICE WAS WORN FOR THE 14-DAY PRESCRIBED WEAR-PERIOD. THE DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT AND STOPPED TRANSMITTING ASYMPTOMATIC EVENTS ON DAY 8. THE HCP ACCOUNT WAS NOTIFIED ON DAY 5 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 27. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event300:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20230915

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Hemorrhage/Blood Loss/Bleeding","Blister","Skin Inflammation/ Irritation"]

device.brand\_name:C6 MCOT PPM

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00077

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT WEARING VERMED ELECTRODES THAT CAUSED BLISTERED AND BLEEDING. THE ELECTRODES AND DEVICE WERE NOT RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE ELECTRODE/DEVICE WAS NOT RETURNED. ALLEGATION IS ABLE TO BE CONFIRMED AS THERE ARE IMAGES OF PATIENT SKIN, AND ANY SKIN IRRITATION IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARSII, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

BEGINNING 15 SEPTEMBER 2023, THE PATIENT CALLED AND EMAILED TO REPORT THAT THEY WILL BE RETURNING THE DEVICE BECAUSE THE SECOND BATCH OF VERMED ELECTRODES CAUSED BLISTERS AND BLEEDING FROM GEL THAT LEAKED OUT OF THE ELECTRODES. THE PATIENT SAW THEIR DOCTOR, WHO PRESCRIBED CLOBETASOL PROPIONATE CREAM USP,0.05%. AFTER APPLYING IT TWICE DAILY FOR 14 DAYS, THE PATIENT'S SKIN HEALED BUT NOW HAS SCARRING. THE PATIENT REPORTED THAT THEY CLEANED AND DRIED THEIR SKIN PROPERLY BEFORE APPLYING THE ELECTRODES AND HAS NO PRIOR SKIN SENSITIVITY/ALLERGY.

{{datachunk}}Event301:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231219

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04716

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR MISSED DAILY WIRELESS AUDIT. IT WAS REPORTED THAT THE REMOTE MONITOR HAD A TELEMETRY ISSUE WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL FOR TELEMETRY ISSUE. THE CALLER WAS REFERRED TO CLINIC. THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT SEND A SUCCESSFUL WIRELESS TRANSMISSION SINCE THE DATE OF THE CALL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event302:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230922

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00681

mdr\_text.text:REPORTING INSTITUTION PHONE NUMBER:(B)(6). REPORTER PHONE NUMBER:(B)(6).  
PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 SN  
(B)(6)INDICATING THE UNIT NEEDED A SPEAKER REPLACEMENT. IT WAS UNKNOWN IF THE UNIT WAS IN  
USE MONITORING A PATIENT AT THE TIME OF THE EVENT. NO ADVERSE EVENT INVOLVING A PATIENT  
OR USER WAS REPORTED. A PHILIPS REMOTE SERVICE ENGINEER (RSE) INTERVIEWED THE CUSTOMER.  
THE CUSTOMER CONFIRMED THE SPEAKER WAS COMPLETELY OUT OF SOUND AND THERE WAS AN  
INOPERATIVE MESSAGE PRESENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING  
CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE THE SPEAKER  
ASSEMBLY. AFTER SPEAKER REPLACEMENT THE DEVICE WAS RETURNED TO FUNCTIONAL USE WITH NO  
FURTHER ISSUES IDENTIFIED. THE DEVICE REMAINS AT THE CUSTOMER SITE. NO FURTHER  
INVESTIGATION OR ACTION IS WARRANTED AT THIS TIME.

THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE  
INTELLIVUE MULTI MEASUREMENT SERVER X2 AND NO SOUND WAS COMING FROM THE DEVICE. IT IS  
UNKNOWN IF THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE.  
NO ADVERSE PATIENT OR USER EVENT WAS REPORTED.

{{datachunk}}Event303:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20231220

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:32 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04717

mdr\_text.text:IT WAS REPORTED BY THE PATIENT THAT THEY EXPERIENCED AN INFECTION AT THE IMPLANTABLE CARDIAC MONITOR (ICM) IMPLANT SITE. THE ICM REMAINS IN USE. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.



## DSI MAUDE Problems Summary

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{{datachunk}}Event304:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231213

event\_location:

remedial\_action:[""]

patient.patient\_age:45 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04718

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH

EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR OVERSENSING. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED OCCASIONAL VENTRICULAR UNDERSENSING. IT WAS ALSO NOTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event305:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231213

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00959

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DIAGNOSTICS TESTING WAS PERFORMED AT PHILIPS BENCH REPAIR AND FOUND THE DEVICE DID NOT PRODUCE SOUND DUE TO A DEFECTIVE SPEAKER. THE BENCH REPAIR TECHNICIAN REPLACED THE SPEAKER TO SOLVE THE ISSUE. THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event306:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate","Data Problem"]

event\_type:Malfunction

date\_of\_event:20231205

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ MOBILE MANAGER APP

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2023-03797

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER NOTED THAT THE DIAGNOSTIC MOBILE PROGRAMMER APPLICATION SOFTWARE HAD NOT BEEN UPDATED WHEN THE EVENT OCCURRED AND WAS SUBSEQUENTLY UPDATED.

IT WAS REPORTED THAT INCORRECT INFORMATION WAS COMMUNICATED TO THE CLINIC DURING INTERROGATION OF THE IMPLANTABLE CARDIAC MONITOR (ICM). IT WAS FURTHER REPORTED THAT THE ICM WAS UNABLE TO BE INTERROGATED BY THE PATIENT CONNECTOR AND DIAGNOSTIC MOBILE PROGRAMMER APPLICATION. IT WAS NOTED THAT A LOCK SYMBOL WAS PRESENT ON THE HOSTING TABLET AND IT WAS SPECULATED THAT THE ICM WAS LOCKED. IT WAS NOTED THAT WHEN THE DIAGNOSTIC MOBILE PROGRAMMER APPLICATION WAS STARTED UP TO PERFORM THE CHECK THE MOBILE PROGRAMMER WAS IN THE BACKGROUND. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CONTINUATION OF D10: 24967 PATIENT CONNECTOR. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS

## DSI MAUDE Problems Summary

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PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: H6:(FDC/ANNEX D): CODE CHANGE. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event307:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231213

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00961

mdr\_text.text:DIAGNOSTICS TESTING WAS PERFORMED AT PHILIPS BENCH REPAIR AND FOUND THE DEVICE DID NOT PRODUCE SOUND DUE TO A DEFECTIVE SPEAKER. THE BENCH REPAIR TECHNICIAN REPLACED THE SPEAKER TO SOLVE THE ISSUE. THE DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event308:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231213

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00960

mdr\_text.text:DIAGNOSTICS TESTING WAS PERFORMED AT PHILIPS BENCH REPAIR AND FOUND THE DEVICE DID NOT PRODUCE SOUND DUE TO A DEFECTIVE SPEAKER. THE BENCH REPAIR TECHNICIAN REPLACED THE SPEAKER TO SOLVE THE ISSUE. THE DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event309:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231211

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

## DSI MAUDE Problems Summary

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report\_number:9610816-2023-00664

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. REPORTER PHONE NUMBER: (B)(4).

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION ERROR. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

A PHILIPS BENCH SERVICE TECHNICIAN (BT) EVALUATED THE DEVICE AND CONFIRMED THAT THE DEVICE WAS GIVING SPEAKER MALFUNCTION ERROR AND THE SPEAKER WAS COMPLETELY OUT OF SOUND. THE CUSTOMER WAS PROVIDED WITH A QUOTE FOR A REPLACEMENT SPEAKER ASSEMBLY. THE QUOTE HAS EXPIRED AND THEREFORE THE NO PARTS WERE REPLACED ON THE DEVICE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event310:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231215

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00965

mdr\_text.text:THE DEVICE WAS SENT TO A PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR EVALUATION. FUNCTIONAL TESTS WERE PERFORMED AND THE DEVICE THE SPEAKER PRODUCED



## DSI MAUDE Problems Summary

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AUDIBLE SOUND. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE RFT REPLACED THE SPEAKER PER CURRENT PROCESS AND THE DEVICE REMAINS AT THE CUSTOMER SITE.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THE DEVICE INDICATES A SPEAKER MALFUNCTION INOP WITH NO SOUND. THE DEVICE WAS IN CLINICAL USE, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

{{datachunk}}Event311:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231201

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04691

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS

## DSI MAUDE Problems Summary

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EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS NOT READING THE IMPLANTABLE CARDIAC MONITOR (ICM). NO TROUBLESHOOTING TAKEN AT THE TIME OF CALL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event312:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231211

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04692

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DID NOT HAVE TELEMETRY WITH THE READER. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event313:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231130

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00958

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION. THE DEVICE WAS NOT IN USE AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT REPORTED.

THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. RESULTS OF FUNCTIONAL TESTING INDICATE THAT SPEAKER HAD NO SOUND IN MT56060 TOOL, AND SPEAKER WAS DEFECTIVE. THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. HE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event314:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:20231215

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

## DSI MAUDE Problems Summary

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report\_number:9614453-2023-04694

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED NOISE ON A ATRIAL FIBRILLATION (AF) EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event315:

adverse\_event\_flag:N

product\_problems:["Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20231203

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04695

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS NO LONGER SENSING ELECTRICAL SIGNAL. THE DEVICE REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event316:

adverse\_event\_flag:N

product\_problems:["Pacing Problem","Battery Problem","Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20230101

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MEDTRONIC ILR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2023-03784

mdr\_text.text:THIS INFORMATION IS BASED ENTIRELY ON JOURNAL LITERATURE. MEDTRONIC WAS MADE AWARE OF THIS EVENT THROUGH A SEARCH OF LITERATURE PUBLICATIONS. THIS EVENT OCCURRED OUTSIDE THE US. PATIENT INFORMATION IS LIMITED DUE TO CONFIDENTIALITY CONCERNS. OF NOTE, MULTIPLE PATIENTS AND MULTIPLE MANUFACTURERS WERE NOTED IN THE ARTICLE; HOWEVER, A ONE-TO-ONE CORRELATION COULD NOT BE MADE WITH UNIQUE PRODUCT SERIAL/LOT NUMBERS. THE MODEL LISTED IN THE REPORT IS A REPRESENTATIVE OF THE MODEL FAMILY, AS THERE IS NO SPECIFIC MODEL LISTED. WITHOUT A LOT NUMBER OR DEVICE SERIAL NUMBER, THE MANUFACTURING DATE CANNOT BE DETERMINED. SINCE NO DEVICE ID WAS PROVIDED, IT IS UNKNOWN IF THIS EVENT HAS BEEN PREVIOUSLY REPORTED. REFERENCED ARTICLE: IMPACT OF INTENSIVE FOLLOW-UP OF CARDIAC IMPLANTABLE ELECTRONIC DEVICES VIA REMOTE MONITORING: A PILOT STUDY. HEART RHYTHM O2 2023; 4:90&96. DOI: 10.1016/J.HROO.2022.11.002 MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH

## DSI MAUDE Problems Summary

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ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

LITERATURE WAS REVIEWED REGARDING REMOTE MONITORING WITH CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICES (CIEDS). ALERTS WERE CLASSIFIED AS EITHER NORMAL, THOSE WHICH REQUIRED NONURGENT RESPONSE, OR THOSE WHICH REQUIRED URGENT CLINICAL ACTION. THE AUTHORS DESCRIBED DEVICES WHICH ALERTED DUE TO PAUSES, SENSING ISSUES, LEAD NOISE, AND RECOMMENDED REPLACEMENT. IT IS UNKNOWN WHAT SPECIFIC ISSUES WERE FOUND AND WHAT TYPES OF INTERVENTIONS WERE PERFORMED. THE STATUS OF THE DEVICES AND LEADS IS UNKNOWN. NO ADVERSE PATIENT EFFECTS OR ADDITIONAL PRODUCT PERFORMANCE ISSUES WERE REPORTED.

{{datachunk}}Event317:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:20210408

event\_location:

remedial\_action:[""]

patient.patient\_age:27 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04656

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED



## DSI MAUDE Problems Summary

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BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED NON-CARDIAC SIGNALS/ NOISE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event318:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231124

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00669

mdr\_text.text:REPORTING INSTITUTION PHONE NUMBER: (B)(6). REPORTER PHONE NUMBER: (B)(6). PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THERE WAS A SOUND ERROR, AND THE LOUDSPEAKER WAS DEFECTIVE. THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED: THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND FOUND THAT THE LOUDSPEAKER MADE NO SOUND AND DID NOT WORK. THE FSE DETERMINED THAT THE LOUDSPEAKER WAS DEFECTIVE AND REQUIRED REPLACEMENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT NO SOUND WAS COMING FROM THE LOUDSPEAKER OF THE INTELLIVUE MULTI MEASUREMENT SERVER X2. THE DEVICE WAS IN USE ON A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE EVENT WAS REPORTED.

{{datachunk}}Event319:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231108

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00200

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 2 DAYS OF THE 7-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 19. THE INVESTIGATION REVEALED THAT THE GATEWAY EXPERIENCED MULTIPLE ERRORS AND THE CELL MODEM BECAME UNRESPONSIVE TO PING COMMANDS, WHICH LED TO THE MISSED MDN. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS AN PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED THAT THE GATEWAY EXPERIENCED MULTIPLE ERRORS AND THE CELL MODEM BECAME UNRESPONSIVE TO PING COMMANDS. THE HEALTHCARE PROVIDER (HCP) WAS NOTIFIED IMMEDIATELY, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event320:

adverse\_event\_flag:Y

product\_problems:["Defective Alarm"]

event\_type:Death

date\_of\_event:20231124

event\_location:

remedial\_action:[""]

patient.patient\_age:85 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Asystole","No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00955

mdr\_text.text:THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED: LOGS WERE PULLED AND THE MX40 AND EVENT LOGS PICIX CONFIGURATION WERE CHECKED BY THE PHILIPS FIELD ENGINEER (FSE). THE LOGS VERIFIED THE ALARM ON THE MX40 PROPERLY WORKED AND NO MALFUNCTION WERE NOTED. ON (B)(6) 2023 AT 0905, A CODE BLUE WAS CALLED AFTER THE PATIENT WAS FOUND UNRESPONSIVE BY THE LICENSED PRACTICAL NURSE (LPN). AN ADVANCED CARDIAC LIFE SUPPORT WAS INITIATED, RETURN OF SPONTANEOUS CIRCULATION WAS UNABLE TO BE ACHIEVED AND THE PATIENT EXPIRED. WHEN REVIEWING THE 20-MINUTE TELEMETRY DISCLOSURE, IT WAS FOUND THAT THE PATIENT HAD BEEN ASYSTOLE FOR 20 MINUTES PRIOR TO THE CODE BEING CALLED. THE PATIENT'S PACEMAKER WAS SPIKING BUT THERE WAS NO UNDERLYING RHYTHM. THE CENTRAL MONITORING STATION DID NOT ALARM ASYSTOLE UNTIL (B)(6) 2023 09:04. THE PATIENT WAS A 85 YEAR OLD MALE ADMITTED ON (B)(6) 2023 FOR LOW HEMOGLOBIN IN THE SETTING OF DOE 2/2 TO DIASTOLIC CHF AND AORTIC INSUFFICIENCY. THE PATIENT WAS BEING FOLLOWED BY THE HF TEAM AND WAS TRANSITIONED FROM IVPB BUMEX TO BUMEX PO. THE PATIENT RECEIVED 1 UNIT OF PRBC ON THIS ADMISSION AND THEIR CBC WAS BEING MONITORED. THERE WAS AN ORDER FOR TELEMETRY MONITORING BEGINNING (B)(6) 2023 AT 08:50. THE CLINICAL AUDIT LOG AND SOME EXCERPTED LOGS INFORMATION WAS PROVIDED AND WERE REVIEWED BY THE PRODUCT SUPPORT ENGINEER (PSE) WHICH SHOWS THAT ALARMS WERE GENERATED FOR CHANGES IN THE PATIENT'S CONDITION. THE ALARMS WERE BEING SILENCED BY STAFF. THE DATA REVIEW CONFIRMED THAT THE DEVICE RECOGNIZED THE DETERIORATION OF THE PATIENT'S CONDITION AND THAT ALARMS WERE PROVIDED FOR LIMIT VIOLATION EVENTS. THE TREND AND WAVE REVIEW DATA SHOWS THAT THE DEVICE RECOGNIZED CHANGES IN THE PATIENT'S CONDITION. THE ALARM REVIEW DATA PROVIDED DOES NOT COVER THE ENTIRETY OF THE INCIDENT TIMEFRAME BUT DOES SHOW A VARIETY OF ALARMS DURING THE PERIODS THE STRIPS WERE PROVIDED FOR. THE EXCERPTED AUDIT LOG INFORMATION, ATTACHED TO THE COMPLAINT CONTAINS ADDITIONAL ALARM INFORMATION (WITH SILENCE ACTIVITIES) FROM THE INCIDENT TIMEFRAME. THE AVAILABLE INFORMATION INDICATES THE DEVICE WAS FUNCTIONING AS SPECIFIED AND THAT ALARMS WERE BEING PROVIDED AS APPROPRIATE FOR CHANGES IN THE PATIENT'S CONDITION. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE USER ERROR. THE ALARMS FUNCTIONED AS CONFIGURED AS INTENDED BASED OFF THE ORIGINAL CONFIGURATION SIGN-OFF. AN UPDATE TO THE ASSESSMENT WAS PERFORMED FOR CLARIFICATION. IT WAS REPORTED THE MONITOR DID NOT ALARM FOR ASYSTOLE AND THE PATIENT PASSED AWAY. THIS 85-YEAR-OLD PATIENT WAS ADMITTED FOR LOW HEMOGLOBIN, EXHIBITING DYSPNEA ON EXERTION SECONDARY TO CONGESTIVE HEART FAILURE AND AORTIC VALVE INSUFFICIENCY. AFTER RECEIVING ONE UNIT OF BLOOD THE PATIENT WAS PLACED ON TELEMETRY (MX40) FOR MONITORING. AT ONE POINT, THE NURSE FOUND THE PATIENT UNRESPONSIVE AND IN ASYSTOLE, FOR WHICH A CODE BLUE WAS CALLED WITH THE PATIENT SUBSEQUENTLY PASSED AWAY. IT WAS INDICATED THE PATIENT WAS IN ASYSTOLE FOR 20 MINUTES PRIOR TO BEING FOUND AND THE

## DSI MAUDE Problems Summary

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PATIENT'S PACEMAKER WAS DELIVERING IMPULSES BUT THERE WAS NO CAPTURE; THEREFORE, THE PATIENT HAD NO UNDERLYING RHYTHM. THE CENTRAL STATION (PIC) DID NOT GENERATE AN ALARM FOR ASYSTOLE UNTIL JUST PRIOR TO THE CODE BLUE. AT THIS TIME, IT APPEARS THE DEVICE MAY HAVE CAUSED OR CONTRIBUTED TO THE REPORTED EVENT RE-ASSESSMENT WAS PERFORMED BY THE PMS CLINICAL EXPERT BASED ON NEW INFORMATION RECEIVED IN THE COMPLAINT RECORD. INCOMPLETE CLINICAL AUDIT LOGS WERE RETURNED FOR INVESTIGATION AND A REVIEW WAS PERFORMED BY A PRODUCT SUPPORT ENGINEER, REVEALING SEVERAL ALARMS WERE GENERATED FOR CHANGES IN PATIENT CONDITION DURING THE INCIDENT TIMEFRAME. THESE ALARMS AND ALARM REMINDERS WERE SILENCED BY USERS DURING THE SAME TIMEFRAME. BASED ON THIS INFORMATION, THE DEVICE DID NOT CAUSE OR CONTRIBUTE TO THE REPORTED EVENT. IT APPEARS ALARM MANAGEMENT MAY HAVE BEEN A FACTOR; HOWEVER, THE CAUSE REMAINS UNKNOWN. BASED ON THE INFORMATION PROVIDED IN THE CASE, THE ALARMS FUNCTIONED AS CONFIGURED AND AS INTENDED AND CONFIRMED TO BE OPERATING PER SPECIFICATIONS AS INDICATED IN THE LOGS AND CONFIRMED BY THE FSE AND PSE. THE ALARMS WERE SILENCED BY USERS DURING THE SAME TIMEFRAME. THE CUSTOMER WAS PROVIDED WITH A FEEDBACK.

PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THE MONITOR DID NOT ALARM FOR ASYSTOLE AND THE PATIENT EXPIRED. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS A REPORT OF PATIENT DEATH.

IT WAS REPORTED: PATIENT DEATH - SITE IS CLAIMING THE MX40 DID NOT ALARM. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS A REPORT OF PATIENT DEATH.

A FOLLOW UP REPORT WILL BE SUBMITTED AFTER PHILIPS OBTAINS MORE INFORMATION CONCERNING THIS EVENT.

{{datachunk}}Event321:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231205

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00956

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE SPEAKER HAD NO SOUND IN <MT56060 TOOL, AND SPEAKER WAS DEFECTIVE. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED.

IT WAS REPORTED THE TELE MX40 MONITOR DISPLAYED A SPEAKER MALFUNCTION ERROR AND NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event322:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231120

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00949

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS OUTSIDE OF USE. THERE WAS NO USER OR PATIENT INJURY REPORTED.

THE ISSUE WAS DISCOVERED AT A PHILIPS AUTHORIZED REPAIR FACILITY. TESTING DETERMINED THE SPEAKER WAS AT FAULT. THE REPAIR TECHNICIAN REPLACED THE SPEAKER. THE DEVICE WAS TESTED AND IS NOW OPERATING AS FUNCTIONALLY INTENDED.

{{datachunk}}Event323:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231215

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04663

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT

## DSI MAUDE Problems Summary

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INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED A PAUSE EPISODE WHICH APPEARED TO BE UNDERSENSING. IT WAS FURTHER NOTED THAT THE COUNTERS WENT BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING INTERROGATION. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event324:

adverse\_event\_flag:Y

product\_problems:["Wireless Communication Problem"]

event\_type:Death

date\_of\_event:20231124

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:INTELLIVUE MX40 802.11A/B/G



## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00941

mdr\_text.text:THE AVAILABLE INFORMATION AND LOGS WERE REVIEWED BY PRODUCT SUPPORT ENGINEER (PSE). PRELIMINARY REVIEW OF CLINICAL AUDIT LOGS REVEALED TELEMETRY WENT OFFLINE AT 23:36 AFTER ALERTING FOR A 'WEAK SIGNAL' INOP AND THEN CAME BACK ONLINE AT 23:43, GENERATING A 'ECG LEADS OFF' INOP AT 23:44; THEREFORE, NO FURTHER DATA WAS STORED AT THE PIC IX AFTER THAT TIME AND THE PATIENT'S DEATH WAS PRONOUNCED AT 00:09. THE INVESTIGATION FOUND NO MALFUNCTION OF THE PATIENT INFORMATION CENTER IX (PIC IX) SYSTEM DURING THE TIME IN QUESTION. PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. PIC MFR REPORT NUMBER: 1218950-2023-00928. REPORTING INSTITUTION PHONE NUMBER: (B)(6) REPORTER PHONE NUMBER: (B)(6).

IT WAS REPORTED THE PATIENT WAS ON TELEMETRY IN THE PROGRESSIVE CRITICAL CARE UNIT (PCCU). IT WAS REPORTED THE PATIENT AMBULATED INTO THE BATHROOM; THE TELEMETRY UNIT (MX40) STOPPED WORKING AT 12:36. PATIENT DEATH WAS CONFIRMED AT 00:09. THE CUSTOMER REPORTED ON THIS OCCASION THIS DEATH WAS NOT PREVENTABLE EVEN IF DEVICE WAS FULLY WORKING.

A REMOTE SERVICE ENGINEER (RSE) CONFIRMED FROM THE CUSTOMER THAT ON (B)(6) 2023 A PATIENT WAS ON TELEMETRY 11 ON PCCU BEDSPACE 2.1, THERE WAS A LOST CONNECTION TO MX40 WI-FI VERSION FROM THE PIC IX. THE TIME OF DEATH WAS AT 00:09 ON (B)(6) 2023. THE CUSTOMER INFORMED THAT ON THIS OCCASION THE DEATH WAS NOT PREVENTABLE EVEN IF THE DEVICE WAS FULLY WORKING. A PHILIPS TECHNICAL CONSULTANT (TC) REVIEWED THE LOGS AND DETERMINED THAT THE TELEMETRY WENT OFFLINE AT 23:36 AFTER ALERTING FOR A 'WEAK SIGNAL' INOP AND THEN CAME BACK ONLINE AT 23:43. AN (ELECTROCARDIOGRAM) ECG LEADS OFF INOP WAS GENERATED AT 23:44. THE ROOT CAUSE FOR THIS ISSUE WAS DUE TO A CUSTOMER NETWORK WI-FI INFRASTRUCTURE ISSUE. THIS CAUSED THE MX40 TO DISCONNECT SO NO DATA WAS GOING TO THE PICIX, HOWEVER, IT PROVIDED THE OFFLINE INOP PER SPECIFICATIONS. THE PATIENT'S DEATH WAS PRONOUNCED AT 00:09. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS DUE TO THE CUSTOMER'S WI-FI INFRASTRUCTURE. THE PHILIPS DEVICE WAS FOUND WORKING ACCORDING TO SPECIFICATION AND NO FAULT WAS FOUND.

CUSTOMER REPORTED THE PATIENT AMBULATED INTO THE BATHROOM; THE TELEMETRY UNIT STOPPED TRANSMITTING AT 12:36. THE PATIENT DEATH WAS CONFIRMED AT 00:09. THE EXACT CAUSE OF DEATH IS UNKNOWN, HOWEVER, IT WAS REPORTED THAT THE DEATH WAS NOT PREVENTABLE EVEN IF THE DEVICE WAS TRANSMITTING DATA CORRECTLY. THE DEVICE WAS IN CLINICAL USE. THE PATIENT PASSED AWAY.

{{datachunk}}Event325:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["No Audible Alarm","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231128

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 2.4 GHZ, ECG &SP02, EXCHANGE

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00957

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. THE RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS NOT REPLICATED. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING, A REPLACEMENT DEVICE WAS SHIPPED TO THE CUSTOMER TO RESOLVE THE REPORTED ISSUE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6).

THE CUSTOMER REPORTED THAT THERE IS A SPEAKER MALFUNCTION. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event326:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:CIC PRO

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:CRITIKON DE MEXICO S. DE R.L. DE C.V.

report\_number:3008729547-2023-00013

mdr\_text.text:THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARMS ON THE CIC PRO. THERE WAS NO RELATED ADVERSE PATIENT CONSEQUENCE.

LEGAL MANUFACTURER: HCS TOWER - 8200 W TOWER AVE USA MILWAUKEE, WI 53223. A1-A6: THIS INFORMATION WAS NOT PROVIDED BY THE CUSTOMER. B3: THIS INFORMATION WAS NOT PROVIDED BY THE CUSTOMER. THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARMS ON THE CIC PRO. PER FOLLOW-UP WITH THE CUSTOMER, THERE WAS NO RELATED ADVERSE PATIENT CONSEQUENCE, NOR ALLEGATION THAT THE ISSUE LED TO A MISSED PATIENT EVENT. THE BIOMEDICAL TECHNICIAN REBOOTED THE CIC PRO WHICH RESTORED THE AUDIO FUNCTION. PER REVIEW WITH GE HEALTHCARE (GEHC) ENGINEERING, THIS EVENT WAS DETERMINED TO BE RELATED TO A PREVIOUSLY INVESTIGATED ISSUE WHEREIN THE CIC PRO DEVICE MAY LOSE AUDIBLE ALARM FUNCTION. THE VISUAL ALARMS ARE STILL PRESENT AND ACTIVE. IF THE PATIENT IS ALSO CONNECTED TO A BEDSIDE DEVICE, THE ALARMS AT THE BEDSIDE MONITOR ARE UNAFFECTED. GEHC ATTEMPTED TO REPRODUCE THE ISSUE WITH SIMILAR DEVICES IN A TEST LAB, REVIEWED DEVICE PERFORMANCE LOG FILES FOR OTHER DEVICES THAT SHOWED THE SAME ISSUE, AND PERFORMED EXTENSIVE HISTORICAL DATA ANALYSIS ALONG WITH TECHNICAL DESIGN REVIEW. GEHC WAS UNABLE TO DETERMINE A DEFINITIVE ROOT CAUSE FOR THE LOSS OF AUDIBLE ALARM FUNCTION. GEHC CONTINUES TO EVALUATE INCOMING COMPLAINTS AND INVESTIGATE WHERE APPROPRIATE. H3 OTHER TEXT : DEVICE PROBLEM ALREADY KNOWN, NO EVALUATION NECESSARY

{{datachunk}}Event327:

adverse\_event\_flag:N

product\_problems:["Insufficient Information"]

event\_type:Malfunction

date\_of\_event:20220420

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MEDTRONIC ILR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2023-03759

mdr\_text.text:LITERATURE WAS REVIEWED REGARDING CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICE (CIED) INTERROGATIONS IN THE EMERGENCY DEPARTMENT (ED). ALL INTERROGATIONS WERE REQUESTED BY ED PHYSICIANS AND WERE FROM IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS), IMPLANTABLE PULSE GENERATORS (IPGS), AND IMPLANTABLE CARDIAC MONITORS (ICMS). THE PURPOSE WAS TO FIND REMARKABLE ISSUES WHICH WERE DEFINED AS AN ARRHYTHMIA WITH OR WITHOUT ANTI TACHYARRHYTHMIA THERAPY RELATED TO THE ED PRESENTATION OR A DEVICE-RELATED ISSUE REQUIRING REPROGRAMMING OR LEAD/DEVICE REVISION PROCEDURE. THE AUTHORS DESCRIBED PATIENTS WHO PRESENTED WITH SHOCK THERAPY, PALPITATIONS, CHEST PAIN, SYNCOPE, PRESYNCOPE, OR DYSPNEA. SOME OF THE SYMPTOMS WERE DUE TO PROGRAMMING ISSUES. THERE WERE UNKNOWN DEVICE ISSUES FOR ALL DEVICE TYPES STUDIED AND LEAD ISSUES INCLUDED LEAD DYSFUNCTION FOR FAILURE TO CAPTURE DUE TO DAMAGE OR DISLODGE MENT, SENSING FAILURE, AND PHRENIC CAPTURE DUE TO LEFT VENTRICULAR (LV) LEAD DISPLACEMENT. THERE WAS IMMEDIATE INTERVENTION PERFORMED FOR BATTERY DEPLETION AND LEAD DISLODGE MENT. THE STATUS OF THE DEVICES AND LEADS IS UNKNOWN. NO ADDITIONAL ADVERSE PATIENT EFFECTS OR PRODUCT PERFORMANCE ISSUES WERE REPORTED.

## DSI MAUDE Problems Summary

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THIS INFORMATION IS BASED ENTIRELY ON JOURNAL LITERATURE. MEDTRONIC WAS MADE AWARE OF THIS EVENT THROUGH A SEARCH OF LITERATURE PUBLICATIONS. THIS EVENT OCCURRED OUTSIDE THE US. PATIENT INFORMATION IS LIMITED DUE TO CONFIDENTIALITY CONCERNS. SELECT PATIENT INFORMATION CANNOT BE INCLUDED IN REGULATORY REPORT DUE TO REGIONAL PRIVACY REGULATIONS. OF NOTE, MULTIPLE PATIENTS AND MULTIPLE MANUFACTURERS WERE NOTED IN THE ARTICLE; HOWEVER, A ONE-TO-ONE CORRELATION COULD NOT BE MADE WITH UNIQUE PRODUCT SERIAL/LOT NUMBERS. THE MODEL LISTED IN THE REPORT IS A REPRESENTATIVE OF THE MODEL FAMILY, AS THERE IS NO SPECIFIC MODEL LISTED. WITHOUT A LOT NUMBER OR DEVICE SERIAL NUMBER, THE MANUFACTURING DATE CANNOT BE DETERMINED. SINCE NO DEVICE ID WAS PROVIDED, IT IS UNKNOWN IF THIS EVENT HAS BEEN PREVIOUSLY REPORTED. REFERENCED ARTICLE: SHOULD WE CHECK IT? ASSESSING INTERROGATION OF CARDIAC IMPLANTABLE ELECTRONIC DEVICES IN THE EMERGENCY DEPARTMENT¿THE CHECK-ED STUDY: IMPLICATIONS FOR SERVICE PLANNING AND CARE DELIVERY. HEART, LUNG AND CIRCULATION. 2022. 31, 1119¿1125. DOI: 10.1016/J.HLC.2022.03.004 MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event328:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231127

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:CIC PRO

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:CRITIKON DE MEXICO S. DE R.L. DE C.V.

report\_number:3008729547-2023-00014

mdr\_text.text:THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARMS AT THE CIC PRO. THERE WAS NO RELATED ADVERSE PATIENT IMPACT.

LEGAL MANUFACTURER: HCS TOWER - 8200 W TOWER AVE USA MILWAUKEE, WI 53223. A1-A6: THIS INFORMATION WAS NOT PROVIDED BY THE CUSTOMER. THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARMS AT THE CIC PRO. THERE WAS NO RELATED ADVERSE PATIENT CONSEQUENCE, NOR ALLEGATION THAT THE ISSUE LED TO A MISSED PATIENT EVENT OR DELAY IN TREATMENT. THE BIOMEDICAL ENGINEER REBOOTED THE CIC PRO WHICH RESTORED THE AUDIO FUNCTION. PER REVIEW WITH GE HEALTHCARE (GEHC) ENGINEERING, THIS EVENT WAS DETERMINED TO BE RELATED TO A PREVIOUSLY INVESTIGATED ISSUE WHEREIN THE CIC PRO MAY LOSE AUDIBLE ALARM FUNCTION. THE VISUAL ALARMS ARE STILL PRESENT AND ACTIVE. IF THE PATIENT IS ALSO CONNECTED TO A BEDSIDE DEVICE, THE ALARMS AT THE BEDSIDE MONITOR ARE UNAFFECTED. GEHC ATTEMPTED TO REPRODUCE THE ISSUE WITH SIMILAR DEVICES IN THE TEST LAB, REVIEWED DEVICE PERFORMANCE LOG FILES FOR OTHER DEVICES THAT SHOWED THE SAME ISSUE, AND PERFORMED EXTENSIVE HISTORICAL DATA ANALYSIS ALONG WITH TECHNICAL DESIGN REVIEW. GEHC WAS UNABLE TO DETERMINE A DEFINITIVE ROOT CAUSE FOR THE LOSS OF AUDIBLE ALARM FUNCTION. GEHC CONTINUES TO EVALUATE INCOMING COMPLAINTS AND INVESTIGATE WHERE APPROPRIATE.

{{datachunk}}Event329:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231112

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00199

mdr\_text.text:THE DEVICE WAS WORN FOR 11 DAYS OF THE 14-DAY PRESCRIBED WEAR-PERIOD. THE DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT AND STOPPED TRANSMITTING ASYMPTOMATIC EVENTS ON DAY 10. THE HCP ACCOUNT WAS NOTIFIED ON DAY 8 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 27. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO THE STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event330:

adverse\_event\_flag:N

product\_problems:["Thermal Decomposition of Device","Overheating of Device"]

event\_type:Malfunction

date\_of\_event:20231121

event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00076

mdr\_text.text:IT WAS REPORTED ON (B)(6) 2023 THE PATIENT WENT TO PLUG THE C6 MONITOR IN TO RECHARGE. THE PATIENT LEFT WHILE THE MONITOR WAS CHARGING. THE PATIENT RETURNED AND THE CORD WAS LAYING ON THE COUNTERTOP AND THE PATIENT NOTED THAT THE CHARGER WAS CHARRED. THE PATIENT WANTED TO END SERVICE AND RETURN THE KIT HOWEVER THE PATIENT'S PHYSICIAN WANTED THE PATIENT TO CONTINUE. THE DEVICE WAS RETURNED AND A REPLACEMENT DEVICE WAS SENT. NO PATIENT HARM WAS REPORTED.

IT WAS REPORTED THE MONITOR CHARGING CORD WAS DAMAGED AND APPEARED BURNED. THE DEVICE WAS NOT RETURNED. ENGINEERING EVALUATION WAS UNABLE TO PERFORMED AS THE DEVICE WAS NOT RETURNED FOR TESTING. THIS FAILURE MODE DESCRIPTION ALIGNS WITH A KNOWN EXISTING FAILURE WHICH IS BEING INVESTIGATED BY PHILIPS AM&D.

{{datachunk}}Event331:

adverse\_event\_flag:N



## DSI MAUDE Problems Summary

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product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231212

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00943

mdr\_text.text:THE CUSTOMER REPORTED THAT THE SPEAKER IS NOT FUNCTIONING. NO SOUND IS COMING FROM THE DEVICE AT ALL. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING DEVICE, INDICATING THAT THE SPEAKER IS NOT FUNCTIONING. NO SOUND IS COMING FROM THE DEVICE AT ALL. THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. RESULTS OF FUNCTIONAL TESTING INDICATE THE SPEAKER HAD NO SOUND IN THE MT56060 TOOL. THEY WERE UNABLE TO TEST SPEAKER IN THE UNIT AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE.

{{datachunk}}Event332:

adverse\_event\_flag:N

product\_problems:["Melted","Overheating of Device"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:83 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00079

mdr\_text.text:IT WAS REPORTED THAT THE CHARGING CORD FOR THE MONITOR WAS NOT WORKING. THE CABLE GOT HOT AND MELTED. THE DEVICE WAS SCRAPPED. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED. THEREFORE IT IS MOST PROBABLE THAT THE MONITOR DID NOT CAUSE OR CONTRIBUTE TO THIS EVENT, ALTHOUGH THIS REPORTED FAILURE MODE ALIGNS WITH A KNOW FAILURE MODE THAT IS FURTHER BEING INVESTIGATED BY PHILIPS AM&D.

IT WAS REPORTED WHEN THE PATIENT'S WIFE CALLED AND STATED THAT THE C6 MONITOR CHARGING CORD IS NOT WORKING. THE CHARGING CABLE GOT HOT AND MELTED AND THE THE PATIENT CAN NO LONGER CHARGER THE C6 MONITOR. A REPLACEMENT CHARGER WAS ORDERED. THE PATIENT LATER CALLED STATING THEY WOULD NO LONGER LIKE TO CONTINUE WITH SERVICE AND WILL RETURN THE REPLACMENT DEVICE. NO PATIENT INJURY OR HARM WAS REPORTED.

{{datachunk}}Event333:

adverse\_event\_flag:Y

product\_problems:["Solder Joint Fracture"]

event\_type:Injury

date\_of\_event:20231126

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Electric Shock"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00078

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT WAS PLUGGING THE MCOT DEVICE AND WHEN PLUGGING THE DUEL CHARGING PLUG INTO THE WALL OUTLET THE CHAGER FELL APART LEAVING THE PRONGS IN THE OUTLET AND THE PATIENT WAS SHOCKED. THE DEVICE WAS NOT RETURNED. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED. ALTHOUGH SENSOR WAS RETURNED ON SE23645446, THE CHARGING BLOCK WAS NOT RECEIVED BACK. THE SENSOR IS NOT IMPLICATED IN THE ALLEGATION AS THE PATIENT STATES THAT THE CHARGING BLOCK FELL APART IN THE OUTLET. PICTURES WERE ALSO NOT PROVIDED SO ENGINEERING IS UNABLE TO CONFIRM THE ALLEGATION. ALTHOUGH THE COMPONENT WAS NOT RECEIVED AND IMAGES WERE NOT PROVIDED, THE PROBLEM DESCRIPTION OF THIS FAILURE ALIGNS WITH AN KNOWN ISSUE THAT IS FURTHER BEING INVESTIGATED BY PHILIPS AM&D.

IT WAS REPORTED THAT ON 26 NOVEMBER 2023 THE PATIENT WAS CHARGING THE C6 SENSOR AND SHE WENT TO UNPLUG IT AND THE CHARGER CAME APART AND THE PRONGS WERE STUCK IN THE OUTLET. THE PATIENT WAS SHOCKED FROM THE END OF THE CHARGING CORD. TH ELECTRICAL POWER WAS TURNED OFF TO ALLOW THE PRONGS TO BE REMOVED FROM THE OUTLET. THE PATIENT DID NOT SEEK MEDICAL TREATMENT FOR THE SHOCK. A REPLACEMENT CHARGER WAS ORDERED AND SENT TO THE PATIENT.

{{datachunk}}Event334:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231207

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00659

mdr\_text.text:IT WAS REPORTED THE DEVICE INDICATES A SPEAKER MALFUNCTION ERROR. IT IS UNKNOWN IF THERE WAS SOUND BEING EMITTED FROM THE DEVICE. THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE DEVICE WAS SENT TO A PHILIPS AUTHORIZED REPAIR FACILITY FOR EVALUATION. A PHILIPS BENCH REPAIR TECHNICIAN (BRT) EVALUATED THE DEVICE AND CONFIRMED THE SPEAKER MALFUNCTION. THE FAULTY SPEAKER WAS REPLACED, AND THE DEVICE WAS RETURNED TO THE CUSTOMER SITE.

{{datachunk}}Event335:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231204

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00946

mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATED THAT THE SPEAKER HAD NO SOUND OR BEEP. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event336:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231207

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00947

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND DURING THE START-UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event337:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231207

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00948

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND DURING THE START-UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event338:

adverse\_event\_flag:N

product\_problems:["Failure to Charge","Complete Loss of Power"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:22 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00080

## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED ON 04 NOVEMBER 2023 THAT THE C6 MONITOR HAS A BLACK SCREEN AND WILL NOT POWER ON. IT WAS CONFIRMED THAT THE MONITOR WILL NOT POWER ON AND A NEW MONITOR WAS ORDERED. THE C6 MONITOR RETURNED FOR INVESTIGATION AND IT WAS IDENTIFIED THAT THE MONITOR AND MONITOR CHARGER WAS MELTED. NO PATIENT HARM WAS REPORTED.

IT WAS REPORTED THAT THE DEVICE WOULD NOT POWER ON OR CHARGE. THE DEVICE WAS RETURNED FOR INVESTIGATION. DEVICE WAS INSPECTED FOR GENERAL PHYSICAL INTEGRITY, PHONE WAS BADLY DAMAGED AROUND THE CHARGING AREA. DEVICE WAS NOT ABLE TO POWER ON DURING TESTING OF THE DEVICE. DEVICE WAS NOT ABLE TO BE CHARGED DUE TO THE DAMAGE OF THE CHARGING PORT. HEAT TESTING WAS UNABLE TO BE PERFORMED DUE TO THE DAMAGE OF THE PORT. (UNIT,C6M,A10E,U/02-01894/MT29120013) WAS ORIGINALLY THE SUBJECT OF THE INVESTIGATION, ALTHOUGH IT HAS BEEN DETERMINED THAT THE CHARGING CORD IS THE MOST PROBABLE CAUSE OF THE DEVICE MELT.

{{datachunk}}Event339:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231121

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00952

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE DEFECTIVE SPEAKER DUE TO NO BEEP OR



## DSI MAUDE Problems Summary

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SOUND WHEN TESTED WITH THE CERTIFICATION TOOL. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

IT WAS REPORTED THAT DURING EVALUATION IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event340:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231130

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00668

mdr\_text.text:A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO CLARIFY IF THE SPEAKER PRODUCED SOUND, BUT NO ADDITIONAL DETAILS WERE PROVIDED. THE REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. E1 REPORTING ADDRESS

## DSI MAUDE Problems Summary

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STATE: (B)(6).

THE CUSTOMER REPORTED THE MONITOR GOES INTO SPEAKER FAULT ALARM. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

{{datachunk}}Event341:

adverse\_event\_flag:N

product\_problems:["Inappropriate Audible Prompt/Feedback", "No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231204

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00663

mdr\_text.text:A REMOTE SERVICE ENGINEER (RSE) DETERMINED THE SPEAKER REQUIRED REPLACEMENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. E1: REPORTING INSTITUTION PHONE: (B)(6). E1: REPORTER PHONE: (B)(6).

IT WAS REPORTED THE INTELLIVUE MULTI MEASUREMENT SERVER X2 SPEAKER IS DEFECTIVE AND NEEDED REPLACEMENT. IT IS UNKNOWN IF THERE WAS STILL SOUND. A LOSS OF AUDIO CANNOT BE RULED OUT BASED ON INFORMATION CURRENTLY AVAILABLE. THE DEVICE WAS IN USE ON A PATIENT.

THERE WAS A REPORT OF PATIENT HARM.

{{datachunk}}Event342:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231120

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00936

mdr\_text.text:PHILIPS AUTHORIZED REPAIR TECHNICIAN TESTED THE DEVICE AND CONFIRMED THERE IS NO AUDIO. DURING TESTING, IT WAS DETERMINED THE SPEAKER IS AT FAULT. THE SPEAKER WAS REPLACED. THE DEVICE WAS FUNCTIONALLY TESTED AND FOUND TO NOW BE WORKING ACCORDING TO SPECIFICATIONS.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS OUTSIDE OF USE. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event343:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231120

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00937

mdr\_text.text:PHILIPS AUTHORIZED REPAIR TECHNICIAN TESTED THE DEVICE. THE SPEAKER DID NOT WORK IN UNIT. THE SPEAKER DID PRODUCE SOUND WHEN TESTED ON THE FACILITY SPEAKER CERTIFICATION TOOL. THE TECHNICIAN REPLACED THE SPEAKER. THE UNIT IS FUNCTIONING AS INTENDED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.

{{datachunk}}Event344:

adverse\_event\_flag:N

product\_problems:["Delayed Alarm"]

event\_type:Malfunction

date\_of\_event:20231210

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP70

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00665

mdr\_text.text:THE CUSTOMER REPORTED THAT THE MONITOR DID NOT ALARM FOR SPO2 WITH THE ALARM LIMIT SET AT 80 UNTIL THE PATIENT WAS AT 30. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED. THE CUSTOMER SIMULATED SPO2 RED AND YELLOW ALARMS AND GOT THE VISUAL AND AUDIO ALARMS. A FIELD SERVICE ENGINEER (FSE) IS NEEDED TO CHECK THE CLINICAL AUDIT TRAIL TO VERIFY THE ALARM THAT THE CUSTOMER CLAIMS WAS MISSED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MP70 INDICATING THAT THE MONITOR DID NOT CALL THE OXYGEN SATURATION (SPO2) ALARM FOR ALARM LIMIT SET AT 80 UNTIL PATIENT WAS AT 30. THE REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND HAD THE CUSTOMER SIMULATE SPO2 RED AND YELLOW ALARMS, AND HE GOT THE VISUAL AND AUDIO ALARMS. THE RSE PLANNED TO DISPATCH A FIELD SERVICE ENGINEER (FSE) TO GO ONSITE TO CHECK THE CLINICAL AUDIT TRAIL FOR THE ALARM THAT CUSTOMER CLAIMS WAS MISSED. THE ONSITE SERVICE WAS CANCELED, BECAUSE THE FSE TROUBLESHOT WITH THE CUSTOMER OVER THE PHONE. ONCE THE CUSTOMER REBOOTED THE MONITOR, IT STARTED WORKING PROPERLY. THE CUSTOMER CALLED THE NURSE OVER AND TESTED THE SPO2, AND THE MONITOR WAS WORKING NORMALLY. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM IS UNKNOWN, AS THE REBOOT RESOLVED THE ISSUE, THE CAUSE WAS UNABLE TO BE TRACED TO ONE THING AND IS UNKNOWN. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER ADVISED THAT THE MONITOR IS CURRENTLY WORKING NORMALLY. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event345:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231031

event\_location:

remedial\_action:[""]

patient.patient\_age:82 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04594

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD A TELEMETRY ISSUE WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). NO TROUBLESHOOTING INITIATED AS PATIENT DID NOT WANT ANY HELP WITH RECONNECTING THE MONITOR WITH THE DEVICE. IT WAS STATED THAT THE ICM WAS IMPLANTED IN AN INCORRECT WAY THAT WAS WHY IT WAS NOT TRANSMITTING. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE

## DSI MAUDE Problems Summary

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APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event346:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231121

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00899

mdr\_text.text:IT WAS REPORTED THE DEVICE HAD NO AUDIO. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. TESTING RESULTS INDICATE THAT SPEAKER WAS DEFECTIVE WITH NO SOUND BEING EMITTED. THE SPEAKER WAS REPLACED AND THE DEVICE REMAINS AT THE CUSTOMER SITE.

{{datachunk}}Event347:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231115

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00926

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD A SPEAKER MALFUNCTION AND NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. IT WAS CONFIRMED THAT THE SPEAKER HAD NO SOUND. THE SPEAKER WAS REPLACED AND WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event348:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231120

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:



## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00658

mdr\_text.text:IT WAS REPORTED THAT THE SPEAKER WAS NOT FUNCTIONING. THERE WAS NO SOUND COMING FROM THE MONITOR. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THE SPEAKER FAILURE. THE RSE DETERMINED THAT PART (453564204381-IV2-STAT MECHASY LOUDSPEAKER) NEEDED TO BE REPLACED. A NEMO (NON ENGINEERING MATERIAL ONLY) SERVICE WAS AGREED UPON. THE CUSTOMER ORDERED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

{{datachunk}}Event349:

adverse\_event\_flag:Y

product\_problems:["Premature Discharge of Battery","Insufficient Information"]

event\_type:Death

date\_of\_event:20231115

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:1.4 GHZ INTELLIVUE TELE TRX

UNKNOWN PATIENT MONITORING TELE

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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MHX

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00933

mdr\_text.text:THE PHILIPS FIELD SERVICE ENGINEER (FSE) SPOKE WITH THE CUSTOMER AND THE CLINICAL APPLICATION SPECIALIST (CAS). THERE WAS A PATIENT DEATH, BUT THE FSE ADVISED THAT IT WAS NOT RELATED TO A FAILURE OF EQUIPMENT. THE FSE INDICATED THAT THERE WERE COMMUNICATION ISSUES IN NOTIFYING THE NURSE OF THE LOW BATTERY AND DUE TO THE TYPE OF BATTERY (NOT THE RECOMMENDED DURACELL BY PHILIPS), THE BATTERY WENT DOWN FASTER THAN EXPECTED. THE CUSTOMER IS USING SELF-MAINTAINED M4841 TELEMETRY PATIENT WORN DEVICES (PWD'S), WHICH ARE OUT OF SUPPORT. THERE WAS NO PRODUCT MALFUNCTION. THE ONSITE INVESTIGATION BY THE FIELD SERVICE TECHNICIAN REVEALED THAT THE CUSTOMER DID NOT USE THE BATTERIES RECOMMENDED BY PHILIPS - USER PROBLEM. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

SECTION D2: FDA PROCODE UPDATED BASED ON INFORMATION KNOWN AT THIS TIME. CATALOG ITEM ID AND 501K IS UNKNOWN AT TIME OF REPORT. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THAT THE CUSTOMER REQUESTED THE LOGS FOR THE TELEMETRY BOX BATTERY STATUS FOR THE FOLLOWING TIME FRAME 21:13 ON (B)(6) 2023. A PATIENT DEATH WAS REPORTED.THE DEVICE WAS IN USE ON A PATIENT. THERE WAS REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event350:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231025

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00190

mdr\_text.text:(B)(4).

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event351:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231101

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00188

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR (B)(4) DAYS OF THE (B)(4)-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 24. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND SCHEDULED A FOLLOW-UP APPOINTMENT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event352:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231111

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00189

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR (B)(4) DAYS OF THE (B)(4) PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY (B)(4) . THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED BY IRHYTHM. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event353:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electromagnetic Interference","Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231125

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-08145

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE PAUSE EPISODES DUE TO UNDERSENSING R-WAVES. IT WAS FURTHER NOTED THAT THE DEVICE EXPERIENCED OVERSENSING NOISE/INTERFERENCE. IT WAS SUSPECTED THAT THE FALSE DETECTIONS AND INTERFERENCE WAS CAUSED BY SUBOPTIMAL CONNECTION OR THE POCKET BEING TOO BIG. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED FALSE ASYSTOLE DUE TO UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. ANALYSIS OF THE DEVICE MEMORY INDICATED RIGHT VENTRICULAR UNDERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS

## DSI MAUDE Problems Summary

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EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event354:

adverse\_event\_flag:N

product\_problems:["Inappropriate or Unexpected Reset","Reset Problem"]

event\_type:Malfunction

date\_of\_event:20231115

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04565

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A PARTIAL POWER ON RESET OCCURRED. MEDTRONIC IS SUBMITTING THIS



## DSI MAUDE Problems Summary

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REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED A PARTIAL ELECTRICAL RESET.

{{datachunk}}Event355:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231114

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00650

mdr\_text.text:A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO CLARIFY IF THE SPEAKER PRODUCED SOUND, BUT NO ADDITIONAL DETAILS WERE PROVIDED. A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND CONFIRMED THAT THE SPEAKER FAILED. THE FSE CHECKED WITH THE MP5 SELF-TEST AND FOUND THAT THE SPEAKER AND MAINBOARD WERE MALFUNCTIONING. THE FSE REPLACED THE SPEAKER AND MAINBOARD TO RESOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER AND MAINBOARD. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER AND MAINBOARD. THE REPORTED PROBLEM WAS CONFIRMED.

IT WAS REPORTED THE MP5 SPEAKER FAILED. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

IT WAS REPORTED THE MP5 SPEAKER FAILED. IT IS UNKNOWN AT THE CURRENT STATE IF THE DEVICE STILL HAS SOUND OR NOT. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

ADDITIONAL MANUFACTURER NARRATIVE: PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. CORRECTED DATA: E1; REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6).

{{datachunk}}Event356:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231204

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00920

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE SPEAKERS DO NOT WORK AND THERE IS WATER INFILTRATION. IT WAS CONFIRMED THAT THERE WAS NO SOUND AT ALL. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THE SPEAKER DOES NOT WORK ON THE UNIT, IT WAS UNKNOWN IF THE DEVICE PRODUCED AUDIBLE SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

{{datachunk}}Event357:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231127

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00918

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THE SPEAKER FAILED WITH NO SOUND AND BEEP WITH THE CERTIFICATION TOOL DUE TO A DEFECTIVE SPEAKER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD NO AUDIO SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event358:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231103

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00184

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 8 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS AN PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP SCHEDULED THE PATIENT FOR A FOLLOW UP APPOINTMENT. THERE WAS NO TREATMENT PROVIDED, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event359:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231025

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

## DSI MAUDE Problems Summary

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device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00183

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR THE FULL 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 25. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP STARTED THE PATIENT'S TREATMENT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event360:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231101

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00186

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS AN PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED. IRHYTHM MADE SEVERAL ATTEMPTS TO FOLLOW UP WITH THE ACCOUNT TO OBTAIN ADDITIONAL INFORMATION, BUT WITH NO RESULT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event361:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231022

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00185

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 25. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND IS BEING TREATED. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event362:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231104

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male



## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00166

mdr\_text.text:THE DEVICE WAS WORN FOR THE AT FOR 12 DAYS OF THE 14-DAY PRESCRIBED WEAR-PERIOD. THE DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT AND STOPPED TRANSMITTING ASYMPTOMATIC EVENTS ON DAY 8. THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO THE STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. IRHYTHM WAS INFORMED THAT THE PATIENT WILL BE TREATED WITH A PACEMAKER. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event363:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231025

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00182

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 27. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS AN PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event364:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Communication or Transmission Problem","Wireless Communication Problem"]

event\_type:Malfunction

date\_of\_event:20231027

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00187

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT COMMUNICATED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED THAT A PRELIMINARY ECG INTERPRETATION WAS PROVIDED TO THE PHYSICIAN REPORTING SUPRAVENTRICULAR TACHYCARDIA (SVT). FOLLOWING THE WEAR PERIOD AND WHILE COMPILING THE FINAL REPORT, THE INTERPRETATION WAS AMENDED TO REFLECT ATRIAL FLUTTER (AFL). THE HCP WAS NOTIFIED IMMEDIATELY, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. AT THE TIME OF SVT TRANSMISSION, THE PATIENT WAS ALREADY ON THEIR WAY TO THE EMERGENCY ROOM (ER). ALTHOUGH THE PATIENT WAS OBSERVED OVERNIGHT IN THE ER, THEY WERE NOT ADMITTED, AND NO TREATMENT WAS PROVIDED FOR THE SVT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

A PRELIMINARY ECG INTERPRETATION WAS PROVIDED TO THE PHYSICIAN REPORTING SUPRAVENTRICULAR TACHYCARDIA (SVT). FOLLOWING THE WEAR PERIOD AND WHILE COMPILING THE FINAL REPORT, THE INTERPRETATION WAS AMENDED TO REFLECT ATRIAL FLUTTER (AFL). THE HCP WAS NOTIFIED IMMEDIATELY, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. AT THE TIME OF SVT TRANSMISSION, THE PATIENT WAS ALREADY ON THEIR WAY TO THE EMERGENCY ROOM (ER). ALTHOUGH THE PATIENT WAS OBSERVED OVERNIGHT IN THE ER, THEY WERE NOT ADMITTED, AND NO TREATMENT WAS PROVIDED FOR THE SVT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE AT DEVICE WAS RETURNED TO IRHYTHM FOR EVALUATION. A CLINICAL REPORT WAS

## DSI MAUDE Problems Summary

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SUCCESSFULLY GENERATED. A REVIEW OF THE CLINICAL REPORT DETERMINED THAT THE CAUSE OF THE MISSED MEDICAL DOCTOR NOTIFICATION (MDN) WAS DUE TO THE ALGORITHM MISCLASSIFYING THE ARRHYTHMIA. THE CERTIFIED RADIOGRAPHIC TECHNICIAN (CCT) SUBSEQUENTLY AGREED WITH THE ALGORITHM, MISCLASSIFYING THE FIRST DOCUMENTATION OF ATRIAL FLUTTER EPISODE AS SUPRAVENTRICULAR TACHYCARDIA. NO TREATMENT WAS PROVIDED FOR THE SVT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE AT CLINICAL REFERENCE MANUAL STATES IN THE ¿INDICATIONS FOR USE¿ SECTION THAT ¿THE REPORTS ARE PROVIDED FOR REVIEW BY THE INTENDED USER TO RENDER A DIAGNOSIS BASED ON CLINICAL JUDGMENT AND EXPERIENCE.¿ THIS EVENT IS BEING REPORTED PER 21CFR 803 AS AN PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event365:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231122

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04520

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT

SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event366:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20220501

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-08080

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event367:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231129

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04525

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD TELEMETRY ISSUE WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. REFERRED PATIENT TO CLINIC, ADVISED TO TAKE MONITOR WITH THEM. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event368:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231021

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00175

mdr\_text.text:THE ZIO AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 12 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 26. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS AN PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND THAT THE PATIENT WAS SCHEDULED TO RECEIVE A PACEMAKER. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS



INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event369:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231127

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00919

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SOUND OR BEEP WHEN TESTED WITH THE CERTIFICATION TOOL DUE TO A DEFECTIVE SPEAKER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD NO AUDIO SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event370:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["No Device Output"]

event\_type:Malfunction

date\_of\_event:20231114

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00921

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED.

IT WAS REPORTED THAT DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event371:

adverse\_event\_flag:N

product\_problems:["Battery Problem","Communication or Transmission Problem","Device-Device Incompatibility"]

event\_type:Malfunction

date\_of\_event:20231114

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-08049

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY HAVING REACHED END OF SERVICE (EOS). IT WAS FURTHER REPORTED THAT THE ICM HAD POTENTIALLY INTERFERED WITH AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) THAT WAS ALSO IMPLANTED IN THE PATIENT. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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{{datachunk}}Event372:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20231130

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00911

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION. IT IS UNCLEAR IF THERE WAS AUDIO BEING EMITTED. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

A PHILIPS AUTHORIZED REPAIR FACILITY EVALUATED THE DEVICE AND OBSERVED THE DEVICE SPEAKER PRODUCED SOUND. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

{{datachunk}}Event373:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231120

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00913

mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THAT DEVICE HAD A SPEAKER MALFUNCTION. THERE WAS NO SOUND COMING FROM THE DEVICE AT THE TIME OF THE EVENT. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THE FIELD ENGINEER CONFIRMED THAT THE ISSUE HAS BEEN RESOLVED BY THE CUSTOMER. THE CAUSE OF THE REPORTED PROBLEM WAS UNKNOWN. THE REPORTED PROBLEM WAS NOT CONFIRMED. SEVERAL GOOD FAITH EFFORT WAS MADE TO OBTAIN ADDITIONAL INFORMATION ON HOW THE ISSUE WAS RESOLVE. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event374:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231022

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00176

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT A MONITOR (UNKNOWN DEVICE/MODEL) WAS PLACED TO CONFIRM THE PATIENT'S ARRHYTHMIA. NO TREATMENT WAS PROVIDED AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 32. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event375:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231029

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00180

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED OF THE PATIENT'S ARRHYTHMIA, AND INFORMED IRHYTHM THAT THE PATIENT WOULD RECEIVE TREATMENT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 10 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 19. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS AN PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event376:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231022

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00171

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR THE FULL 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND IS BEING TREATED. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event377:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction



date\_of\_event:20231031

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00174

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR ONLY 3 HOURS OF THE 7-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 14. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND IS BEING TREATED. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event378:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231026

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00172

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 26. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND IS BEING TREATED. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event379:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231019

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00173

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR THE FULL 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 28. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event380:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231105

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00181

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND IS BEING TREATED. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT EXCEEDED THE 7-DAY PRESCRIBED WEAR PERIOD BY WEARING THE AT DEVICE FOR 8 DAYS. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 13. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

## DSI MAUDE Problems Summary

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{{datachunk}}Event381:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231110

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 1.4 GHZ, ECG AND SP02, EX

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00914

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THE DEVICE WAS NOT ALARMING VENTRICULAR TACHYCARDIA. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS REMOTE CLINICAL SUPPORT CONFIRMED DEVICE CONFIGURATION. THE CUSTOMER WAS ADVISED THAT BASED ON THE CURRENT DEVICE CONFIGURATION, THE PATIENTS HR DID NOT GO OVER 122 SO THIS DID NOT VIOLATE THE HR PORTION OF THE VTACH ALARM. BOTH WOULD NEED TO BE VIOLATED AT THE SAME TIME TO PRODUCE THE VTACH ALARM. BASED ON THE INFORMATION AVAILABLE THE REPORTED PROBLEM WAS NOT CONFIRMED. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event382:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231121

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00916

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE REPAIR FACILITY TECHNICIAN (RFT) CONFIRMED THAT THE SPEAKER HAD NO SOUND IN THE MT56060 TOOL. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE UNIT WAS REPAIRED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event383:

adverse\_event\_flag:Y

product\_problems:["Use of Device Problem"]

event\_type:Injury

date\_of\_event:20231107

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Stroke/CVA"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00194

mdr\_text.text:THE AT DEVICE HAS NOT YET RETURNED TO IRHYTHM. HOWEVER, THE PATIENT'S FAMILY CONTACTED IRHYTHM AND WAS ASSISTED WITH ACTIVATING THE GATEWAY. NO FURTHER INFORMATION WAS PROVIDED. THIS EVENT IS BEING REPORTED PER 21 CFR 803 AS A SERIOUS INJURY. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY RHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS, OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED THAT THE PATIENT OR THE ACCOUNT DID NOT ACTIVATE THE GATEWAY. ONCE THE GATEWAY WAS ACTIVATED, THE PATIENT'S ARRHYTHMIA WAS TRANSMITTED. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED REGARDING THE PATIENT'S ARRHYTHMIA. A FOLLOW-UP CALL FROM THE PATIENT'S FAMILY INFORMED IRHYTHM THAT THE PATIENT HAD BEEN HOSPITALIZED DUE TO A STROKE. NO FURTHER INFORMATION WAS PROVIDED, SUCH AS TREATMENT OR DISCHARGE PLANS.

{{datachunk}}Event384:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231119

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Male

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07989

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED FALSE ASYSTOLE DUE TO UNDERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED FALSE PAUSE EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO



THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event385:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:23 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-08000

## DSI MAUDE Problems Summary

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mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING THROUGH PAUSE EPISODES, WHICH FALSELY PROLONGED THE EVENT. IT WAS FURTHER REPORTED THERE WAS UNDERSENSING INSIDE THE ELECTROGRAMS (EGM) SUSPENSION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS

CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event386:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00170

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

## DSI MAUDE Problems Summary

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THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND IS BEING TREATED. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event387:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231116

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04448

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN

## DSI MAUDE Problems Summary

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ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event388:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231201

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04449

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR MISSED DAILY WIRELESS AUDIT. IT WAS REPORTED THAT THE REMOTE MONITOR HAD A TELEMETRY ISSUE WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL FOR TELEMETRY ISSUE. TROUBLESHOOTING INDICATED FOR DAILY WIRELESS AUDIT ISSUE. THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT SEND A SUCCESSFUL WIRELESS TRANSMISSION SINCE THE DATE OF THE CALL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event389:

adverse\_event\_flag:N

product\_problems:["Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20230101

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2023-03633

mdr\_text.text:LITERATURE WAS REVIEWED REGARDING ATRIAL FIBRILLATION (AF) DETECTION WITH AN IMPLANTABLE CARDIAC MONITOR (ICM). THE AUTHORS DESCRIBED ICMS IN WHICH RECORDINGS WERE UNRETRIEVABLE OR THEY HAD MISSING BASELINE ELECTROCARDIOGRAMS (ECGS). THE STATUS OF THE DEVICES IS UNKNOWN. NO ADDITIONAL PRODUCT PERFORMANCE ISSUES WERE REPORTED.

THIS INFORMATION IS BASED ENTIRELY ON JOURNAL LITERATURE. MEDTRONIC WAS MADE AWARE OF THIS EVENT THROUGH A SEARCH OF LITERATURE PUBLICATIONS. THIS EVENT OCCURRED OUTSIDE THE US. PATIENT INFORMATION IS LIMITED DUE TO CONFIDENTIALITY CONCERNS. OF NOTE, MULTIPLE PATIENTS AND MULTIPLE MANUFACTURERS WERE NOTED IN THE ARTICLE; HOWEVER, A ONE-TO-ONE CORRELATION COULD NOT BE MADE WITH UNIQUE PRODUCT SERIAL/LOT NUMBERS. THE BASELINE GENDER/AGE CHARACTERISTICS IS MALE/75 YEARS OLD. THE MODEL LISTED IN THE REPORT IS A REPRESENTATIVE OF THE MODEL FAMILY, AS THERE IS NO SPECIFIC MODEL LISTED. WITHOUT A LOT NUMBER OR DEVICE SERIAL NUMBER, THE MANUFACTURING DATE CANNOT BE DETERMINED. SINCE NO DEVICE ID WAS PROVIDED, IT IS UNKNOWN IF THIS EVENT HAS BEEN PREVIOUSLY REPORTED. REFERENCED ARTICLE: ELECTROCARDIOGRAPHIC MARKERS OF SUBCLINICAL ATRIAL FIBRILLATION DETECTED BY IMPLANTABLE LOOP RECORDER: INSIGHTS FROM THE LOOP STUDY. EUROPACE. 2023. 25, 1¿10. DOI: 10.1093/Europace/euad014. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE

TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event390:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231108

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00905

mdr\_text.text:IT WAS REPORTED THAT DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE REPAIR FACILITY TECHNICIAN (RFT) CONFIRMS THAT THE SPEAKER HAD NO SOUND AT STARTUP. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.



## DSI MAUDE Problems Summary

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{{datachunk}}Event391:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231029

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00162

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 6 DAYS OF THE 7-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 15. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND IS ALREADY BEING TREATED. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event392:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231101

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00167

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 24. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF

## DSI MAUDE Problems Summary

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THE PATIENT'S ARRHYTHMIA AND IS BEING TREATED. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event393:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231109

event\_location:

remedial\_action:[""]

patient.patient\_age:89 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04430

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR WAS NOT ABLE TO ESTABLISH TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). NO TROUBLES HOOTING INDICATED. THE PATIENT WAS REFERRED TO THE CLINIC. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT.

## DSI MAUDE Problems Summary

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IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event394:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230628

event\_location:

remedial\_action:[""]

patient.patient\_age:86 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07950

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS

REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE INTERROGATED BACK TO DATE OF IMPLANT INSTEAD OF MOST RECENT FULL REPORT OR PROGRAMMER INTERROGATION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event395:

adverse\_event\_flag:Y

product\_problems:["Defective Alarm"]

event\_type:Death

date\_of\_event:20231001

event\_location:

remedial\_action:[""]

patient.patient\_age:59 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Respiratory Problem","Insufficient Information"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

## DSI MAUDE Problems Summary

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report\_number:9610816-2023-00641

mdr\_text.text:CUSTOMER REPORTED THE APNEA ALARM FAILED. THE DEVICE WAS IN USE ON A PATIENT. THE PATIENT PASSED AWAY.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. PRELIMINARY FINDINGS INDICATE THE EXPECTED ALARMS WERE SET TO OFF BY DEFAULT, HOWEVER, ADDITIONAL INFORMATION IS NEEDED TO DETERMINE CAUSE. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THE INTELLIVUE MX800 PATIENT MONITOR DID NOT PROVIDE AN APNEA ALARM. THE DEVICE WAS IN USE ON A PATIENT. THE PATIENT PASSED AWAY.

A PHILIPS FIELD SERVICE ENGINEER (FSE) VISITED THE CUSTOMER SITE TO EVALUATE THE ALLEGED MALFUNCTIONING DEVICE, COLLECT LOGS, AND CLINICAL AUDIT TRAILS. FUNCTIONAL TESTS PERFORMED AND LOG REVIEW COULDN'T REPLICATE THE ISSUE. BOTH X2 AND MX-800 DEVICES WERE WORKING PER SPECIFICATION. A PHILIPS PRODUCT SUPPORT ENGINEER (PSE) EVALUATED THE CLINICAL AUDIT LOG AND DETERMINED THAT THE FOLLOWING ALARMS WERE ON DURING THE INCIDENT TIMEFRAME: ECG ALARMS, SPO2 ALARMS, NBP ALARMS (FROM BEDSIDE DEVICE). PHYSIOLOGICAL ALARMS WERE PROVIDED FOR: VTACH, VENT FIB/TACH, \*\*HR HIGH LIMIT VIOLATIONS, \*PVC LIMIT, \*AFIB, \*IRREGULAR HR. TECHNICAL INOP ALARMS WERE PROVIDED FOR: ECG LEADS OFF, RL LEAD OFF, RESP LEAD OFF, CANNOT ANALYZE ECG, SPO2 NO SENSOR, SPO2 SENSOR OFF, SPO2 NO PULSE, NBP MEASUREMENT FAILED. THE CUSTOMER INITIATED ABP (ARTERIAL BLOOD PRESSURE) MONITORING AT 07:53:22 AND ABP ALARMS WERE TURNED ON FOR THE PARAMETER." ANOTHER PSE REVIEWED THE AUDIT LOGS AND STATED "FROM THE PATIENT INFORMATION CENTER IX SIDE, THE SYSTEM PERFORMED AS EXPECTED & FREQUENT ALARMS FOR THE BEDS/TIMES IN QUESTION, WERE SENT TO 3 PIC&S. THE SUPPLIED ALARM LOG SHOWS FREQUENT ALARMS BEING SENT FROM THE B355 TO 3 DIFFERENT PIC IX HOSTS (WKHIX112/114/116) FOR THE TIME PERIOD IN QUESTION. SEVERAL OF THE ALARMS ARE FOR SPO2 SENSORS OFF, A FEW FOR NPB MEASUREMENT FAILURES. (B)(6) 2023 07:37:39 WELLSTAR KENNESTONE B355 ACKNOWLEDGE WKHIX112 ACKNOWLEDGE. (B)(6) 2023 07:26:14 WELLSTAR KENNESTONE B355 ACKNOWLEDGE WKHIX112 ACKNOWLEDGE. (B)(6) 2023 07:26:14 WELLSTAR KENNESTONE B355 ACKNOWLEDGE WKHIX112 ACKNOWLEDGE. (B)(6) 2023 07:17:10 WELLSTAR KENNESTONE B355 ACKNOWLEDGE M355 ACKNOWLEDGE. (B)(6) 2023 07:05:30 WELLSTAR KENNESTONE B355 ACKNOWLEDGE M355 ACKNOWLEDGE. (B)(6) 2023 06:53:54 WELLSTAR KENNESTONE B355 ACKNOWLEDGE M355 ACKNOWLEDGE." A PHILIPS CLINICAL SPECIALIST (CS) EVALUATED THE CLINICAL AUDIT LOGS AND CONFIGURATION FILES, STATING THE FOLLOWING: "I DO NOT SEE AN APNEA ALARM IN THIS CASE. THERE IS A DESAT ALARM AT 4:38:20 THAT ENDED AT 4:38:58. PREVIOUSLY, THERE WERE LOTS OF SPO2 LOW AND DESAT ALARMS. AFTER THIS, THERE ARE MULTIPLE SPO2. NO PULSE AND INTERFERENCE INOPS. THEY MUST HAVE THEIR ALARMS SET TO NOT LATCH SINCE THE ALARMS STOP ON THEIR OWN WITHOUT AND ACKNOWLEDGEMENT OF THE ALARM. THERE ARE ALSO LOW NBP ALARMS DURING THIS TIME AND THE NBP MEASUREMENT FAILED AT 7:19:28. THE VENT FIB/TACH ALARM WAS GENERATED AT 7:33:19." I SEE THE FOLLOWING ALARMS IN THE AUDIT LOG BETWEEN 07 TO 0730 ON (B)(6) 2023: LOW NBP ALARMS, SPO2 NO SENSOR, SENSOR OFF, AND NO PULSE INOPS, AFIB , NBP MEASUREMENT FAILED INOP THE SPO2 WAS HAVING INOPS SINCE (B)(6), 2023

AT 14;22;56. BETWEEN 0700 AND 0730, THE SPO2 WAS DISPLAYING INOP ALARMS. NBPS 82<90 ALARM WAS GENERATED AT 07:00:23. THE NBP MEASUREMENT FAILED INOP WAS GENERATED AT 07:16:34, 17:19:52, AND 7:332:37. RESPIRATORY LEADS OFF WAS GENERATED AT 7:32:58. THE CONFIGURATION FILE REVEALED THE RESPIRATORY ALARMS ARE OFF BY DEFAULT AS SHOWN BELOW. THE CS ALSO CONFIRMED THAT IF THE INTELLIVUE X2 IS DOCKED TO THE HOST MONITOR (MX800), ALARMING WOULD OCCUR AT THE HOST MONITOR. MAIN SETUP - MEASUREMENTS - RESP: ITEM= MEASMT. ADULT MEASMT. PEDI MEASMT. NEO HIGH LIMIT= 40 RPM, 30 RPM, 100 RPM, 30 RPM. LOW LIMIT= 8 RPM, 8 RPM, 30 RPM, 8 RPM. APNEA TIME= 20 SEC, 20 SEC, 20 SEC, 20 SEC. ALARMS= OFF, ON, ON, ON. RESP= ON, ON, ON, ON. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS AN USER CONFIGURATION ISSUE, AS RESPIRATORY ALARMS (INCLUDES APNEA) WERE SET TO OFF BY DEFAULT. THE REPORTED PROBLEM WAS NOT CONFIRMED. THERE WAS NO MALFUNCTION OF THE INTELLIVUE MX800 PATIENT MONITOR. THE DEVICE WAS CONFIRMED TO HAVE ALARMED AND WORKED PER SPECIFICATIONS.

{{datachunk}}Event396:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231120

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00910

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND

## DSI MAUDE Problems Summary

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DURING THE START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event397:

adverse\_event\_flag:N

product\_problems:

event\_type:Malfunction

date\_of\_event:20231201

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:GE HEALTHCARE TECHNOLOGY CSCS V3

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:GE HEALTHCARE TECHNOLOGY / GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.

report\_number:MW5148828

mdr\_text.text:GE HEALTHCARE CARESCAPE CENTRAL STATION VERSION 3. DURING EQUIPMENT RESTART OR LOSS OF POWER, THE CLINICAL APPLICATION WILL FAIL TO START, CAUSING A LOSS OF PATIENT MONITORING. THE RECOMMENDED FIX BY GE HEALTHCARE IS TO SHIP THE UNIT TO THEIR REPAIR DEPOT TO HAVE THE 2082301-005 FRU MP200X COMM EXPRESS MODULE REPLACED; 4 OF 24 (16%) OF THE DEVICES CURRENTLY IN USE HAVE BEEN OBSERVED WITH THE ISSUE. DEVICES HAVE BEEN



## DSI MAUDE Problems Summary

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IN USE FOR APPROXIMATELY 1.5 YEARS FROM GE INSTALLATION DATE. REFERENCE REPORTS MW5148829, MW5148830, MW5148831.

{{datachunk}}Event398:

adverse\_event\_flag:N

product\_problems:

event\_type:Malfunction

date\_of\_event:20231201

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:GE HEALTHCARE TECHNOLOGY CSCS V3

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:GE HEALTHCARE TECHNOLOGY / GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.

report\_number:MW5148829

mdr\_text.text:GE HEALTHCARE CARESCAPE CENTRAL STATION VERSION 3. DURING EQUIPMENT RESTART OR LOSS OF POWER, THE CLINICAL APPLICATION WILL FAIL TO START, CAUSING A LOSS OF PATIENT MONITORING. THE RECOMMENDED FIX BY GE HEALTHCARE IS TO SHIP THE UNIT TO THEIR REPAIR DEPOT TO HAVE THE 2082301-005 FRU MP200X COMM EXPRESS MODULE REPLACED; 4 OF 24 (16%) OF THE DEVICES CURRENTLY IN USE HAVE BEEN OBSERVED WITH THE ISSUE. DEVICES HAVE BEEN IN USE FOR APPROXIMATELY 1.5 YEARS FROM GE INSTALLATION DATE. REFERENCE REPORTS MW5148828, MW5148830, MW5148831.

{{datachunk}}Event399:

adverse\_event\_flag:N

product\_problems:

event\_type:Malfunction

date\_of\_event:20231201

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:GE HEALTHCARE TECHNOLOGY CSCS V3

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:GE HEALTHCARE TECHNOLOGY / GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.

report\_number:MW5148830

mdr\_text.text:GE HEALTHCARE CARESCAPE CENTRAL STATION VERSION 3. DURING EQUIPMENT RESTART OR LOSS OF POWER, THE CLINICAL APPLICATION WILL FAIL TO START, CAUSING A LOSS OF PATIENT MONITORING. THE RECOMMENDED FIX BY GE HEALTHCARE IS TO SHIP THE UNIT TO THEIR REPAIR DEPOT TO HAVE THE 2082301-005 FRU MP200X COMM EXPRESS MODULE REPLACED; 4 OF 24 (16%) OF THE DEVICES CURRENTLY IN USE HAVE BEEN OBSERVED WITH THE ISSUE. DEVICES HAVE BEEN IN USE FOR APPROXIMATELY 1.5 YEARS FROM GE INSTALLATION DATE. REFERENCE REPORTS MW5148828, MW5148829, MW5148831.

{{datachunk}}Event400:

adverse\_event\_flag:N

product\_problems:

event\_type:Malfunction

date\_of\_event:20231201

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:GE HEALTHCARE TECHNOLOGY CSCS V3

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:GE HEALTHCARE TECHNOLOGY / GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.

report\_number:MW5148831

mdr\_text.text:GE HEALTHCARE CARESCAPE CENTRAL STATION VERSION 3. DURING EQUIPMENT RESTART OR LOSS OF POWER, THE CLINICAL APPLICATION WILL FAIL TO START, CAUSING A LOSS OF PATIENT MONITORING. THE RECOMMENDED FIX BY GE HEALTHCARE IS TO SHIP THE UNIT TO THEIR REPAIR DEPOT TO HAVE THE 2082301-005 FRU MP200X COMM EXPRESS MODULE REPLACED; 4 OF 24 (16%) OF THE DEVICES CURRENTLY IN USE HAVE BEEN OBSERVED WITH THE ISSUE. DEVICES HAVE BEEN IN USE FOR APPROXIMATELY 1.5 YEARS FROM GE INSTALLATION DATE. REFERENCE REPORTS MW5148828, MW5148829, MW5148830.

{{datachunk}}Event401:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210826

event\_location:

remedial\_action:[""]

patient.patient\_age:42 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04412

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE REPORT ALSO CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event402:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231106

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00906

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE SPEAKER DID NOT WORK IN THE UNIT, AND ALSO DID NOT WORK IN THE SPEAKER CERTIFICATION TOOL. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event403:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230914

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00621

mdr\_text.text:E1: (B)(6). A PHILIPS RESPONSE SERVICE ENGINEER (RSE) RECEIVED AN ORDER REQUEST FROM THE CUSTOMER FOR AN SPEAKER REPLACEMENT PART (453564238621 MS\_X2 ASSY CBL X2/MP2 SPEAKER ASSEMBLY.) ADDITIONAL INFORMATION WAS REQUESTED (LIKE WHETHER THERE WAS STILL SOUND COMING FROM THE DEVICE), BUT NO RESPONSE WAS RECEIVED. A NEMO (NON ENGINEERING MATERIAL ONLY) SERVICE WAS AGREED UPON. THE CUSTOMER ORDERED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

IT WAS REPORTED THAT A REPLACEMENT SPEAKER WAS NEEDED. IT IS UNKNOWN IF THERE WAS STILL SOUND COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF THE EVENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event404:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231106

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

## DSI MAUDE Problems Summary

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UNKNOWN PATIENT MONITORING BEDSIDE MONITOR

device.device\_report\_product\_code:DSI

MHX

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00638

mdr\_text.text:THE CUSTOMER REPORTED THE DESATURATION ALARMS DO NOT SOUND. CUSTOMER WANTED TO CHANGE THE CONFIGURATION. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THE CUSTOMER SPOKE WITH THE REMOTE SERVICE ENGINEER(RSE). IT WAS NOTED THE ISSUE WAS ONLY PRESENT DURING USE. THE ISSUE COULD NOT BE CONFIRMED ON THE SIMULATOR. CUSTOMER REQUESTED A PROCEDURE TO ADJUST THE ALARM FREQUENCY AND VOLUME CONFIGURATION. RSE PROVIDED. G5: GOOD FAITH EFFORTS HAVE BEEN COMPLETED TO REQUEST PRODUCT INFORMATION BUT THE INFORMATION IS STILL UNKNOWN. BASED UPON GFE RESPONSE, IT IS BELIEVED THE CUSTOMER WAS REFERRING TO THEIR MX700 DEVICE, HOWEVER, THIS IS AN EDUCATED BELIEF. TO AVOID HAVING NO MODEL NUMBER IN THE EMDR FOLLOW UP REPORT, MX700 WILL BE USED. IF ADDITIONAL INFORMATION REGARDING THE PRODUCT USED IS RECEIVED, THE COMPLAINT WILL BE REOPENED AND A SUPPLEMENTAL REPORT SENT. H3 OTHER TEXT : CUSTOMER REFUSED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. (B)(6). G5: 510K IS UNKNOWN AT THE TIME OF THE REPORT. D1, D2, AND D4: PRODUCT INFORMATION IS UNKNOWN AT THE TIME OF THE REPORT.

CUSTOMER REPORTED THE DESAT ALARMS DID NOT SOUND. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event405:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20231129

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:53 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["Wound Dehiscence","Hemorrhage/Blood Loss/Bleeding"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07929

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT ON THE DAY OF THE IMPLANT PROCEDURE THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED WOUND DEHISCENCE AND A HEMORRHAGE FROM THE OPEN WOUND OF THE CHEST WALL. IT WAS NOTED THAT ADDITIONAL SUTURES WERE REQUIRED AND THE ICM REMAINS IN USE. THE PATIENT IS A PARTICIPANT IN A CLINICAL STUDY. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event406:



## DSI MAUDE Problems Summary

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adverse\_event\_flag:N  
product\_problems:["No Audible Alarm"]  
event\_type:Malfunction  
date\_of\_event:20231113  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:  
patient.patient\_sex:  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:MX40 1.4 GHZ SMART HOPPING  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS  
report\_number:1218950-2023-00907

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event407:

adverse\_event\_flag:Y  
product\_problems:["Defective Alarm"]  
event\_type:Death

## DSI MAUDE Problems Summary

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date\_of\_event:20231104

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00640

mdr\_text.text:A PHILIPS TECHNICAL CONSULTANT (TC) AND PHILIPS CLINICAL SPECIALIST (CS) WENT ONSITE TO COLLECT THE LOGS TO BE EVALUATED INTERNALLY BY PHILIPS, AND WORK WITH STAFF TO PRELIMINARY TEST THE UNIT RESPECTIVELY. THE PATIENT WAS BEING MONITORED VIA X2 ON MX800 AT THE TIME OF THE EVENT. THE CUSTOMER TESTED THE MX800 ON A SIMULATOR AND ALL VITALS ALARMED. RESULTS OF FUNCTIONAL TESTING COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE CUSTOMER WAS CONCERNED ABOUT THE RESPIRATION AND APNEA FUNCTIONS OF THE UNIT. THE LOGS WERE PROVIDED BY CUSTOMER TO BE EVALUATED INTERNALLY BY PHILIPS. BASED ON THE INFORMATION PROVIDED IN THE CASE AND BY PHILIPS CLINICAL SPECIALIST (CS), WHO EVALUATED THE AUDIT LOGS, THE CUSTOMER'S ALLEGATION COULD NOT BE CONFIRMED. THE DEVICE REMAINS AT THE CUSTOMER SITE. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED AT THIS TIME.

THE CUSTOMER REPORTED THAT THE SYSTEM APNEA ALARM WAS NOT GENERATED AND THE PATIENT PASSED AWAY. THE DEVICE WAS IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event408:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231120

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00898

mdr\_text.text:IT WAS REPORTED THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME OF THE EVENT. THE DEVICE WAS SENT TO A PHILIPS AUTHORIZED REPAIR FACILITY THAT PERFORMED DIAGNOSTIC/FUNCTIONAL TESTING. RESULTS OF THE FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND AT THE START UP TEST AND THE SPEAKER WAS DEFECTIVE. THE REPAIR FACILITY REPLACED THE SPEAKER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THE DEVICE HAD NO AUDIO. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

{{datachunk}}Event409:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20231122

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:51 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04386

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR OVERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event410:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20200821

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04387

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event411:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230904

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07887

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. THE DEVICE MEMORY INDICATED UNDERSENSING DUE TO PVCS. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT.

## DSI MAUDE Problems Summary

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IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING OF PREMATURE VENTRICULAR CONTRACTIONS (PVC)'S. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED OVERSENSING OF NOISE, MORE CONSISTENT WITH PATIENT MOVEMENT /ACTIVITY. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event412:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]



## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231101

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04388

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED FALSE PAUSE EPISODES DUE TO UNDERSENSING. THE ICM WAS REPROGRAMMED. IT WAS ALSO REPORTED THAT THE

## DSI MAUDE Problems Summary

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REMOTE MONITORING REPORT HAD THE INCORRECT DATE OF IMPLANT RECORDED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event413:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20231124

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07890

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM

## DSI MAUDE Problems Summary

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BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD REACHED END OF SERVICE (EOS).

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event414:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231116

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00901

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING A MALFUNCTION OF THE SPEAKER ON THE MX40 MONITOR. IT IS UNKNOWN IF SOUND WAS STILL COMING FROM THE DEVICE. . THE DEVICE WAS RECEIVED AT THE PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH EVALUATION ON 8/3/2023 BUT WAS LABELLED AS A DISCREPANT UNIT BECAUSE THE SERIAL NUMBER (SN) ON THE DEVICE RECEIVED DID NOT MATCH THE INCOMING PAPERWORK. THE SN ON THE DEVICE RECEIVED WAS (B)(6). SN (B)(6) WAS ALREADY RETURNED BACK TO THE CUSTOMER ON 12/6/2023. A DEVICE FOR SN (B)(6) HAS NOT BEEN RECEIVED BY THE PHILIPS AUTHORIZED REPAIR FACILITY FOR EVALUATION, THEREFORE, THE COMPLAINT ALLEGATION CANNOT BE CONFIRMED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS NOT CONFIRMED. THE CUSTOMER WAS PROVIDED THE INFORMATION TO RETURN THE DEVICE TO BENCH REPAIR, HOWEVER, AS OF (B)(6) 24, THERE IS NO EVIDENCE THAT THE DEVICE HAS BEEN RETURNED. SINCE THE DEVICE HAS NOT BEEN RECEIVED FOR EVALUATION, THE CAUSE OF THE REPORTED ALLEGATION IS UNDETERMINED. IF ADDITIONAL INFORMATION IS LATER OBTAINED, THE COMPLAINT WILL BE REASSESSED AND UPDATED ACCORDINGLY. H3 OTHER TEXT : DEVICE WAS NOT SENT IN TO BENCH REPAIR.

THE CUSTOMER REPORTED A MALFUNCTION OF THE SPEAKER ON THE MX40 MONITOR. IT IS UNKNOWN IF SOUND WAS STILL COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE PATIENT OR USER EVENT WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

## DSI MAUDE Problems Summary

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{{datachunk}}Event415:

adverse\_event\_flag:N

product\_problems:["Low Audible Alarm","Inaudible or Unclear Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231116

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00902

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE SPEAKER VOLUME WAS VERY LOW. NO PATIENT IMPACT WAS REPORTED. THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE REPAIR FACILITY TECHNICIAN (RFT) CONFIRMS THAT THE SPEAKER PRODUCED SOUND DURING TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, PHILIPS WAS UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING AS THE UNIT PRODUCED SOUND, THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE SPEAKER VOLUME WAS VERY LOW ON THE MX40 MONITOR. THE DEVICE WAS NOT IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE PATIENT OR USER EVENT WAS REPORTED.

{{datachunk}}Event416:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231127

event\_location:

remedial\_action:[""]

patient.patient\_age:83 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04390

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE

## DSI MAUDE Problems Summary

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BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS UNABLE TO ESTABLISH TELEMTRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS FOLLOWED ON READER POSITION BY ADJUSTING THE POSITION OF THE READER FOR READER PLACEMENT ERRORS AND POWER CYCLING THE MONITOR. THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT HAVE ANY SUCCESSFUL TRANSMISSIONS SINCE THE DATE OF THE CALL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event417:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231110

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04391

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED A TACHYCARDIA EPISODE WITH POSSIBLE UNDERSENSING AND OVERSENSING. IT WAS FURTHER NOTED THAT THE REMOTE MONITOR COUNTERS WENT BACK TO THE DATE OF IMPLANT DESPITE HISTORICAL COUNTER CLEARING DEVICE INTERROGATION THE MONITOR REMAINS IN USE. THE ICM REMAINS IN

## DSI MAUDE Problems Summary

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USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event418:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231019

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT



## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00159

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 12 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 24. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND REFERRED TO A CARDIOLOGIST FOR A POSSIBLE ICD PLACEMENT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event419:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231017

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00163

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR THE FULL 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 26. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event420:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231021

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00157

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 10 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 24. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND THE PATIENT WAS SCHEDULED FOR A PACEMAKER. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event421:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231017

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00169

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 10 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING WITH ANTICOAGULANTS. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event422:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231025

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00156

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 22. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND SCHEDULED A FOLLOW-UP APPOINTMENT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event423:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231019

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00155

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR THE FULL 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 23. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND HAS BEEN REFERRED TO EP. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event424:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231021

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00158

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 3 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 18. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND THE HCP CONFIRMED THAT THE PATIENT HAD ALREADY RECEIVED TREATMENT DUE TO ANOTHER MEDICAL DOCTOR NOTIFICATION (MDN) THAT WAS DELIVERED ON THE SAME DAY. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event425:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["No Audible Alarm","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231124

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00636

mdr\_text.text:THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MX700 PATIENT MONITOR AND NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE PATIENT OR USER EVENT WAS REPORTED.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX700 PATIENT MONITOR INDICATING THAT THERE WAS A SPEAKER MALFUNCTION ERROR. A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO CLARIFY IF THE SPEAKER PRODUCED SOUND, AND IT WAS PROVIDED THAT THERE WAS NO SOUND. A REMOTE SERVICE ENGINEER (RSE) DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

REPORTING INSTITUTION PHONE NUMBER: (B)(6). REPORTER PHONE NUMBER: (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION ON THE INTELLIVUE MX700 PATIENT MONITOR. IT IS UNKNOWN IF SOUND WAS STILL COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE



MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE PATIENT OR USER EVENT WAS REPORTED.

{{datachunk}}Event426:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231127

event\_location:

remedial\_action:[""]

patient.patient\_age:89 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04361

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM

## DSI MAUDE Problems Summary

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BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT SINCE THE EVENT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD SUCCESSFULLY SENT A REMOTE TRANSMISSION.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. PATIENT WAS REFERRED TO CLINIC. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event427:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231127

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:85 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04365

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE ICM REMAINS IN THE PATIENT. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event428:

adverse\_event\_flag:Y

product\_problems:["Migration or Expulsion of Device"]

event\_type:Injury

date\_of\_event:20231013

event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Erosion"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04366

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD MIGRATED OUT OF THE POCKET/ EXPOSED. IT WAS FURTHER REPORTED THAT THE PATIENT EXPERIENCED EROSION. THE ICM HAD BEEN IMPLANTED APPROXIMATELY TEN DAYS. THE ICM WAS REMOVED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event429:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231103

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00895

mdr\_text.text:THE CUSTOMER REPORTED THAT THE SPEAKER WILL NOT WORK. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

UPON THE RECEIPT OF THE DEVICE, IT WAS DETERMINED THE DEVICE WAS OPENED AND MODIFIED/REPAIRED OUTSIDE THE PHILIPS FACTORY/REPAIR BENCH. THE FRONT-END FLEX ASSEMBLY FROM ANOTHER DEVICE WAS INSTALLED IN THE MX40. PHILIPS HEALTHCARE DOES NOT SUPPORT 3RD PARTY MODIFICATION/REPAIR OF THE MX40 AND FOR THIS REASON, THE DEVICE WAS RETURNED TO THE CUSTOMER UNREPAIRED. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event430:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System"]

event\_type:Death

date\_of\_event:20231104

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

## DSI MAUDE Problems Summary

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report\_number:9610816-2023-00608

mdr\_text.text:THE CUSTOMER REPORTED THAT THE SYSTEM APNEA ALARM WAS NOT GENERATED AND THE PATIENT PASSED AWAY.

A PHILIPS TECHNICAL CONSULTANT (TC) AND PHILIPS CLINICAL SPECIALIST (CS) WENT ONSITE TO COLLECT THE LOGS TO BE EVALUATED INTERNALLY BY PHILIPS, AND WORK WITH STAFF TO PRELIMINARY TEST THE UNIT RESPECTIVELY. THE PATIENT WAS BEING MONITORED VIA X2 ON MX800 AT THE TIME OF THE EVENT. THE CUSTOMER TESTED THE MX800 ON A SIMULATOR AND ALL VITALS ALARMED. RESULTS OF FUNCTIONAL TESTING COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. THE CUSTOMER WAS CONCERNED ABOUT THE RESPIRATION AND APNEA FUNCTIONS OF THE UNIT. THE LOGS WERE PROVIDED BY CUSTOMER TO BE EVALUATED INTERNALLY BY PHILIPS. BASED ON THE INFORMATION PROVIDED IN THE CASE AND BY PHILIPS CLINICAL SPECIALIST (CS), WHO EVALUATED THE AUDIT LOGS, THE CUSTOMER'S ALLEGATION COULD NOT BE CONFIRMED. THE DEVICE REMAINS AT THE CUSTOMER SITE. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED AT THIS TIME.

{{datachunk}}Event431:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231018

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00152

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 6 DAYS OF THE 7-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA HISTORY. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event432:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231030

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC



## DSI MAUDE Problems Summary

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report\_number:3007208829-2023-00154

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND SCHEDULED A FOLLOW-UP APPOINTMENT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 12 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 18. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event433:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230920

event\_location:

remedial\_action:[""]

patient.patient\_age:82 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07805

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER REPORTED THAT THE TRANSMISSIONS INTERROGATE BACK TO IMPLANT DATE. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event434:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231114

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00630

mdr\_text.text:THE CUSTOMER REPORTED THAT THEY ARE GETTING A TECHNICAL ALARM "LOUDSPEAKER FAULT" AND THE SPEAKER DOES NOT EMIT ANY SOUND ANYMORE. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

ADDITIONAL MANUFACTURER NARRATIVE: A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THE SPEAKER FAILURE. FURTHERMORE, IT WAS CONFIRMED THAT THE PROBLEM WAS ISOLATED ON THE X2, WHICH DOES NOT EMIT ANY SOUND ANYMORE. THE RSE DETERMINED THAT THE PART (453564238621 SPEAKER ASSEMBLY X2/MP2) NEEDED TO BE REPLACED. A NEMO (NON-ENGINEERING MATERIAL ONLY) SERVICE WAS AGREED UPON. THE CUSTOMER ORDERED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. CORRECTED DATA: E1: REPORTER PHONE NUMBER CANNOT PROPERLY FORMAT: (B)(6).

{{datachunk}}Event435:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231017

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00165

mdr\_text.text:THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 5 DAYS OF THE 7-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. NO OTHER DELAYED MDNS WERE NOTED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED OF THE PATIENT'S ARRHYTHMIA, AND IRHYTHM WAS INFORMED THAT THE CLINICAL REPORT NEEDED TO BE REVIEWED BY THE MEDICAL DOCTOR TO DETERMINE IF THERE WAS A DELAY IN TREATMENT. DESPITE SEVERAL ATTEMPTS TO OBTAIN MORE INFORMATION, NO ADDITIONAL DETAILS WERE OBTAINED. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event436:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20210923

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07729

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT COUNTERS WENT BACK TO THE DATE OF IMPLANT DESPITE A COUNTER CLEARING EVENT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event437:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Device Alarm System","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231031

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00883

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF THE EVALUATION COULD NOT CONFIRM THE CUSTOMER'S ALLEGED MALFUNCTION. PER CUSTOMER, IT WAS INDICATED THAT THERE WAS SPEAKER MALFUNCTION INOPERATIVE MESSAGE AT TIME OF EVENT. WHILE AT BENCH, THE SPEAKER PRODUCED AUDIBLE SOUND. THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION. FOR PRECAUTION, THE SPEAKER WAS REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AND RETURNED TO THE CUSTOMER.

PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THE UNIT HAD A SPEAKER INOPERATIVE MESSAGE WITH NO TONE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION WITH THE SYSTEM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event438:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231031

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00884

mdr\_text.text:TESTING OF THE DEVICE WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. THE DEVICE SPEAKER WAS REPLACED, AND THE SYSTEM WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED THAT DURING THE EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event439:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20231121

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00890

mdr\_text.text:REPORTING ADDRESS STATE:(B)(6). REPORTING INSTITUTION PHONE (B)(6). REPORTER PHONE (B)(6). A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THERE WERE ISSUES WITH ALARMS NOT SHOWING UP. IT WAS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

ON 20NOV2023 THE CUSTOMER REPORTED A NUMBER OF FALSE ASYSTOLE ALARMS. ACCORDING TO THE CUSTOMER THEY HAVE BEEN ABOUT A LOOSE ELECTRODE, BUT THEN THE CONTROL CENTER ONLY RAISED AN ALARM FOR ASYSTOLE AND NONE FOR A LOOSE ELECTRODE. THE CUSTOMER REQUESTED A CHECK TO BE CARRIED OUT, AS THEY WERE NOT SURE IF IT'S A CONFIGURATION SETTING ISSUE, SINCE NOTHING HAS CHANGED IN THE SYSTEM. A PHILIPS CLINICAL APPLICATION SPECIALIST (CAS) DISCUSSED THE ISSUE WITH THE CUSTOMER, AND DETERMINED THAT THE ISSUE SEEMED TO HAVE BEEN THE ECG PATCHES, AS THEY DID NOT STICK WHEN ATTACHED, BECAUSE THE GEL WAS A LITTLE DRIER. A GOOD FAITH EFFORT (GFE) FURTHER CONFIRMED THAT THE ISSUE SEEMS TO HAVE BEEN THE ECG PATCHES AND THAT THEY DID NOT STICK WHEN ATTACHED. THE ASYSTOLE ALARMS MAY HAVE CAUSED THE ALARM FOR THE LOOSE ELECTRODES TO NOT SHOW, AS THEY ARE A HIGHER PRIORITY. THE CUSTOMER STATED THAT THE ISSUE HAD NOT HAPPENED AGAIN SINCE THEY CHANGED PATCHES. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS A USER ERROR. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event440:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]



## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231102

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00889

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DUE TO A DEFECTIVE SPEAKER. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE.

IT WAS REPORTED THAT DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event441:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20220228

event\_location:

remedial\_action:[""]

patient.patient\_age:33 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Rash","Skin Inflammation/ Irritation"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:2182208-2023-03552

mdr\_text.text:LITERATURE WAS REVIEWED REGARDING THIS IMPLANTABLE CARDIAC MONITOR (ICM). THE AUTHORS DESCRIBED A PATIENT WHO DEVELOPED DEVICE MEDIATED DERMATITIS AND THE ICM WAS EXPLANTED. THE STATUS OF THE DEVICE IS UNKNOWN. NO ADDITIONAL ADVERSE PATIENT EFFECT WERE REPORTED.

THIS INFORMATION IS BASED ENTIRELY ON JOURNAL LITERATURE. MEDTRONIC WAS MADE AWARE OF THIS EVENT THROUGH A SEARCH OF LITERATURE PUBLICATIONS. THIS EVENT OCCURRED OUTSIDE THE US. PATIENT INFORMATION IS LIMITED DUE TO CONFIDENTIALITY CONCERNS. THE EVENT ONLY OCCURRED WITH ONE PATIENT BUT SPECIFIC DETAILS ON THE PATIENT WERE NOT PROVIDED. WITHOUT A LOT NUMBER OR DEVICE SERIAL NUMBER, THE MANUFACTURING DATE CANNOT BE DETERMINED. SINCE NO DEVICE ID WAS PROVIDED, IT IS UNKNOWN IF THIS EVENT HAS BEEN PREVIOUSLY REPORTED. REFERENCED ARTICLE: FIRST IN HUMAN SURGICAL IMPLANTATION OF A LEADLESS PACEMAKER ON THE EPICARDIAL PORTION OF THE RIGHT ATRIAL APPENDAGE IN A PATIENT WITH A CARDIAC ELECTRONIC DEVICES MEDIATED DERMATITIS. INTERACTIVE CARDIOVASCULAR AND THORACIC SURGERY. 2022, 35(1), IVAC050. DOI: 10.1093/ICVTS/IVAC050. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT.

## DSI MAUDE Problems Summary

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ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event442:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231030

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00888

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. REPORTING INSTITUTION PHONE: (B)(6). REPORTER PHONE # (B)(6).

THE CUSTOMER REPORTED THAT THE SYSTEM HAS NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event443:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231012

event\_location:

remedial\_action:[""]

patient.patient\_age:64 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP60

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

## DSI MAUDE Problems Summary

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report\_number:9610816-2023-00629

mdr\_text.text:IT WAS REPORTED THAT THE INVASIVE BLOOD PRESSURE MONITORING DID NOT ALARM WHEN THE PATIENT'S BLOOD PRESSURE DROPPED SUDDENLY. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE BEDSIDE MONITOR HAS BEEN TESTED AND THE ALARM FUNCTION IS NORMAL. THE ALARM LOG SHOWS THERE WAS ALARM SILENCE DURING THAT TIME PERIOD IN QUESTION, AND ALARM LOG SHOWED THE MONITOR WAS DISPLAYING AN INOP AT 12:43. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A USER LACK OF ALARM AWARENESS/SILENCING OF ALARM. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED AS ALARM LOG SHOWED THERE WAS ALARM SILENCING DURING THAT TIME IN QUESTION. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED

{{datachunk}}Event444:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231030

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00161

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION

REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND SCHEDULED A FOLLOW-UP APPOINTMENT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 12 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event445:

adverse\_event\_flag:N

product\_problems:["Defective Alarm","No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231031

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00626

## DSI MAUDE Problems Summary

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mdr\_text.text:THE CUSTOMER REPORTED THAT THE SYSTEM HAD A LOUDSPEAKER FAILURE CAUSING THE ALARM NOT TO WORK. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. REPORTING INSTITUTION PHONE #(B)(6). REPORTER PHONE (B)(6). REPORTING ADDRESS STATE (B)(6).

A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE TO EVALUATE THE DEVICE. THE FSE CONFIRMED THERE WAS SOMETHING LOOSE INSIDE RESULTING IN THE UNIT MAKING A DISTORTED SOUND AND THERE WAS A SPEAKER INOPERATIVE MESSAGE PRESENT AT THE TIME OF THE EVENT. AFTER THE INTERNAL SPEAKER REPLACEMENT, THE DEVICE WAS RETURNED TO FUNCTIONAL USE WITH NO FURTHER ISSUES IDENTIFIED. THE DEVICE REMAINS AT THE CUSTOMER SITE. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED AT THIS TIME.

{{datachunk}}Event446:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231113

event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07709

## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS ALSO REPORTED THAT THE LEADLESS IMPLANTABLE PULSE GENERATOR (IPG) EXHIBITED POSSIBLE OVERSENSING AND FAILURE TO CAPTURE. THE ICM REMAINS IN USE. THE IPG REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event447:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20221027

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:



## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00885

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE.

IT WAS REPORTED THAT THE AUDIO FUNCTION OF THE MX40 PATIENT WEARABLE MONITOR IS NOT WORKING. THERE IS NO AUDIBLE TONE OR ALARMS WHEN THE SIMULATOR WAS TURNED ON. THE DEVICE WAS NOT IN USE ON PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event448:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231121

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04275

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event449:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231117

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04269

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS REFERRED TO CLINIC. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event450:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20230617

event\_location:

remedial\_action:[""]

patient.patient\_age:63 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07665

mdr\_text.text:IT WAS REPORTED THAT ONE DAY AFTER THE IMPLANT PROCEDURE THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED A PAUSE EPISODE DUE TO UNDERSENSING AND LOSS OF CONTACT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE

## DSI MAUDE Problems Summary

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APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event451:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231001

event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07653

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM

BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT VENTRICULAR UNDERSENSING. IT WAS FURTHER REPORTED THAT THERE WAS AN ISSUE WITH THE REMOTE MONITORING REPORT NOT GENERATING. THE REPORT WAS RETRIEVED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event452:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231116

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00881

mdr\_text.text:DURING THE EVALUATION OF THE MX40 MONITOR AT BENCH REPAIR, IT WAS IDENTIFIED THAT NO SOUND WAS COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE EVENT WAS REPORTED.

## DSI MAUDE Problems Summary

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PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE DID NOT PRODUCE SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED.

DURING THE EVALUATION OF THE MX40 MONITOR AT BENCH REPAIR, IT WAS IDENTIFIED THAT NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE EVENT WAS REPORTED.

{{datachunk}}Event453:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230929

event\_location:

remedial\_action:[""]

patient.patient\_age:88 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04259

## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT DID NOT REFLECT RECENT INTERROGATION AND INTERROGATED BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event454:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20200602

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:



## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04260

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. THE ICM HAD REACHED RECOMMENDED REPLACEMENT TIME (RRT). IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT SHOWED COUNTERS THAT WENT BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE REPORT ALSO CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event455:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231010

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04261

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED PAUSE EPISODES DUE TO UNDERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE,

A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event456:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:20221004

event\_location:

remedial\_action:[""]

patient.patient\_age:91 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07661

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS

## DSI MAUDE Problems Summary

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STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED A TACHYCARDIA EPISODE DUE TO NOISE. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT INTERROGATED BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event457:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20231027

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Stroke/CVA"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00164

mdr\_text.text:DURING THE PATIENT'S WEAR PERIOD, AN ARRHYTHMIA WAS DETECTED BY THE ZIO AT DEVICE THAT MET THE REQUIREMENTS FOR MEDICAL DOCTOR NOTIFICATION (MDN). THE INFORMATION WAS TRANSMITTED TO IRHYTHM'S INDEPENDENT DIAGNOSTIC TESTING FACILITY (IDTF) AS EXPECTED. HOWEVER, THE INVESTIGATION FOUND THAT AN ERROR BY THE CERTIFIED CARDIOGRAPHIC TECHNICIAN (CCT) RESULTED IN THE ARRHYTHMIA BEING MISCLASSIFIED. UPON DISCOVERY OF THE ERROR, THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY INFORMED. IRHYTHM WAS MADE AWARE THAT THE HCP WOULD HAVE CONSULTED THE PATIENT FOR A PACEMAKER IF THE ARRHYTHMIA WAS KNOWN AND THAT THE PATIENT HAD SUFFERED A STROKE.

THE AT DEVICE WAS RETURNED TO IRHYTHM, AND A CLINICAL REPORT WAS SUCCESSFULLY GENERATED. THE DEVICE'S DIAGNOSTIC DATA AND LOGS INDICATE THAT NO MALFUNCTIONS WERE OBSERVED DURING THE WEAR PERIOD. THE MISCLASSIFIED ARRHYTHMIA WAS NOT CAUSED BY THE ALGORITHM, BUT RATHER BY AN ERROR IN INTERPRETATION BY THE CERTIFIED CARDIOGRAPHIC TECHNICIAN. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS AN ADVERSE EVENT /SERIOUS INJURY. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event458:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231114

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04247

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED FALSE POSITIVE PAUSE EPISODES UNDER TO UNDERSENSING R WAVES. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED NOISE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event459:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231001

event\_location:

remedial\_action:[""]

patient.patient\_age:66 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04249

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED FALSE PAUSE EPISODES DUE TO UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event460:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20231027

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00613

mdr\_text.text:THE CUSTOMER REPORTED THAT THE SYSTEM SPEAKER FAILED DURING PREVENTIVE MAINTENANCE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO PATIENT INVOLVEMENT.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. REPORTING INSTITUTION PHONE NUMBER (B)(6).

THE FSE CONFIRMED THERE WAS NO SOUND COMING FROM THE UNIT AND THERE WAS NO ERROR OR ALARM PRESENT. THE FSE REPLACED THE SPEAKER ASSEMBLY TO RESOLVE THE ISSUE. AFTER SPEAKER ASSEMBLY REPLACEMENT THE DEVICE WAS RETURNED TO FUNCTIONAL USE WITH NO FURTHER ISSUES IDENTIFIED. THE DEVICE REMAINS AT THE CUSTOMER SITE. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED AT THIS TIME.



{{datachunk}}Event461:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System"]

event\_type:Injury

date\_of\_event:20231116

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:INTELLIVUE MP70

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00619

mdr\_text.text:(B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE ALARMS FROM THE INTELLIVUE MP70 PATIENT MONITOR WERE NOT RECOGNIZED AND A PATIENT WAS HARMED. NO ADDITIONAL INFORMATION REGARDING THE ADVERSE EVENT WAS PROVIDED. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED EVENT.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MP70 INDICATING THAT THE ALARMS WERE NOT RECOGNIZED, AND THE PATIENT CAME TO HARM. NO ADDITIONAL INFORMATION REGARDING THE ADVERSE EVENT WAS PROVIDED. THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED: THE REMOTE SERVICE ENGINEER (RSE) REACHED OUT TO THE CUSTOMER FOR MORE INFORMATION, AND THE CUSTOMER ADVISED THAT THIS CASE WAS OPENED MISTAKENLY. THE CUSTOMER STATED THAT THE CASE WAS NOT DUE TO A DEVICE DEFECT, AND THE DEVICE WORKED PROPERLY. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM IS

## DSI MAUDE Problems Summary

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UNKNOWN. THE REPORTED PROBLEM WAS NOT CONFIRMED. BASED ON THE INFORMATION AVAILABLE AND RESULTS OF ADDITIONAL ANALYSIS, NO FURTHER ACTION IS NECESSARY AT THIS TIME. DUE TO THE LACK OF AVAILABLE INFORMATION, THE EXACT CAUSE FOR THE REPORTED ISSUE REMAINS UNKNOWN. THE CUSTOMER ADVISED THAT THE CASE WAS NOT DUE TO A DEVICE DEFECT, AND THE DEVICE IS WORKING PROPERLY. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. H3 OTHER TEXT : CUSTOMER REPORTED THAT THE COMPLAINT WAS OPENED IN ERROR AND THERE WAS NO MALFUNCTION OF THE DEVICE.

{{datachunk}}Event462:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20231110

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00610

mdr\_text.text:(B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE INVASIVE BLOOD PRESSURE (IBP) ALARMS RESET THEMSELVES TO "OFF" ON THE INTELLIVUE MX700 PATIENT MONITOR DESPITE BEING ENABLED IN THE SETTINGS. IT IS UNKNOWN IF THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE.

NO ADVERSE PATIENT EVENT WAS REPORTED.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX700 PATIENT MONITOR INDICATING THAT THE INVASIVE BLOOD PRESSURE (IBP) ALARMS WERE AUTOMATICALLY RESET TO OFF-ALARM STATUS, DESPITE BEING ENABLED IN THE SETTINGS. THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED: A FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND WAS UNABLE TO OBSERVE ANY PROBLEM. THE FSE RETRIEVED THE MONITOR LOGS AND FOUND NO ANOMALIES. THE FSE ALSO CARRIED OUT ALARM TESTING, BUT EVERYTHING WAS WORKING CORRECTLY. IT WAS REQUESTED THAT THE CUSTOMER PROVIDE A SPECIFIC EXAMPLE OF THE PROBLEM (TIME, PATIENT, ETC.) FROM THE MEDICAL STAFF IN ORDER TO BETTER ANALYZE IT. THE CUSTOMER WILL CONTACT PHILIPS IF THE PROBLEM ARISES AGAIN IN ORDER TO RECOVER THE LOGS ON THE CONTROL UNIT. THE CUSTOMER HAS ALREADY REQUESTED TRAINING FOR THE STAFF. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE FSE WAS UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

{{datachunk}}Event463:

adverse\_event\_flag:Y

product\_problems:["Manufacturing, Packaging or Shipping Problem"]

event\_type:Injury

date\_of\_event:20230923

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Irregular Pulse"]

device.brand\_name:ZOLL CARDIAC MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:ZOLL MANUFACTURING CORPORATION

## DSI MAUDE Problems Summary

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report\_number:3008642652-2023-11834

mdr\_text.text:A REPACKAGING/RELABELING MIX-UP CONTRIBUTED TO THIS EVENT WHERE THE SERIAL NUMBER PRINTED ON THE SHIPPING BOX DID NOT MATCH THE SERIAL NUMBER OF THE DEVICE INSIDE THE SHIPPING BOX. PATIENT WAS EXPECTED TO RECEIVE SERIAL NUMBER (B)(6) AND RECEIVED SERIAL NUMBER (B)(6).

A PATIENT, UNDERGOING CARDIAC MONITORING USING A ZOLL MOBILE CARDIAC MONITOR, RECEIVED A PACEMAKER THAT MAY NOT HAVE BEEN APPROPRIATE BASED ON THE CORRECT MONITORING DATA.

{{datachunk}}Event464:

adverse\_event\_flag:Y

product\_problems:["Manufacturing, Packaging or Shipping Problem"]

event\_type:Injury

date\_of\_event:20230923

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Irregular Pulse"]

device.brand\_name:ZOLL CARDIAC MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:ZOLL MANUFACTURING CORPORATION

report\_number:3008642652-2023-11841

mdr\_text.text:A PATIENT, UNDERGOING CARDIAC MONITORING USING A ZOLL MOBILE CARDIAC MONITOR, MAY NOT HAVE RECEIVED TIMELY MEDICAL CARE. PATIENT SUBSEQUENTLY RECEIVED A PACEMAKER AT A HOSPITAL.

A REPACKAGING/RELABELING MIX-UP CONTRIBUTED TO THIS EVENT WHERE THE SERIAL NUMBER PRINTED ON THE SHIPPING BOX DID NOT MATCH THE SERIAL NUMBER OF THE DEVICE INSIDE THE SHIPPING BOX. PATIENT WAS EXPECTED TO RECEIVE SERIAL NUMBER (B)(6) AND RECEIVED SERIAL

NUMBER (B)(6).

{{datachunk}}Event465:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231026

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00581

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. PHONE NUMBER: (B)(6).

PER GOOD FAITH EFFORT RESPONSE, THE CUSTOMER CALLED PHILIPS BACK AND STATED THE DEVICE IS NOW WORKING CORRECTLY. THE CUSTOMER REQUESTED THE CASE BE CANCELLED AND PROVIDED NO OTHER INFORMATION. THE DEVICE IS WORKING ACCORDING TO SPECIFICATION. IT IS UNKNOWN WHAT CAUSED THE ISSUE OR HOW IT WAS RESOLVED. H3 OTHER TEXT : SEE H10.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO PATIENT OR USER HARM REPORTED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event466:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230918

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00609

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. E1: REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6).

THE CUSTOMER REPORTED A SPEAKER ERROR MESSAGE OCCURS SPORADICALLY. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED. IT WAS DETERMINED THE SPEAKER IS DEFECTIVE AND WAS REPLACED.

DIAGNOSTIC/FUNCTIONAL TESTING OF THE ACTUAL DEVICE WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THE SPEAKER IS DEFECTIVE. THE BENCH REPAIR TECHNICIAN (BRT) REPLACED THE SPEAKER ASSEMBLY TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

{{datachunk}}Event467:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N  
product\_problems:["Under-Sensing"]  
event\_type:Malfunction  
date\_of\_event:20231116  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:75 YR  
patient.patient\_sex:Female  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:REVEAL LINQ  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL  
report\_number:9614453-2023-04231

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED FALSE PAUSE EPISODES DUE TO UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION

## DSI MAUDE Problems Summary

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ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event468:

adverse\_event\_flag:Y

product\_problems:["Defective Alarm"]

event\_type:Death

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:54 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:INTELLIVUE MX40 802.11A/B/G (865352)

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00869

mdr\_text.text:IT WAS REPORTED THAT THERE WAS A PATIENT DEATH WHILE USING A PHILIPS MX40 TELEMETRY DEVICE. THE CUSTOMER MENTIONED THAT THE ALARM PERSISTED DESPITE THE LEADS BEING ON AND SHOWING WAVEFORMS ON THE CENTRAL STATION. THE CUSTOMER WANT'S TO VALIDATE THAT ECG WAVES WERE TRULY BEING SEEN ON THE CENTRAL PRIOR TO PATIENT DEATH.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX40 802.11A/B/G INDICATING THAT THERE WAS A PATIENT DEATH WHILE USING THE MX40 FOR MONITORING AND WANTING TO VERIFY THE CLINICAL CHAIN OF EVENTS LEADING TO PATIENT DEATH. THERE WAS A QUESTION AMONG STAFF RELATED TO THE ¿ECG LEADS OFF¿ ALARM. ONE STAFF MEMBER CLAIMED THAT THE ALARM PERSISTED DESPITE THE LEADS BEING ON AND SHOWING WAVEFORMS ON THE CENTRAL STATION. THE NURSING STAFF



## DSI MAUDE Problems Summary

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MANAGEMENT WANTED TO SUBMIT THIS FOR REVIEW TO VALIDATE THAT ECG WAVES WERE TRULY BEING SEEN ON THE CENTRAL PRIOR TO PATIENT DEATH. A FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND COLLECTED THE LOGS. THE PATIENT'S RETROSPECTIVE DATA WAS RETRIEVED. THE COMPLAINT WAS ESCALATED FOR TECHNICAL INVESTIGATION, AND THE PROVIDED LOGS WERE REVIEWED BY A BUSINESS UNIT PRODUCT SUPPORT ENGINEER (PSE). WHEN REVIEWING THE CLINICAL AUDIT LOG DURING THE INCIDENT TIME FRAME, THERE ARE MANY INDIVIDUAL ¿ECG LEAD OFF¿ TECHNICAL INOPS, INCLUDING ¿LA LEAD OFF¿ AND ¿LL LEAD OFF¿, ¿ECG LEADS OFF¿ INOPS, ¿!!ECG LEADS OFF¿ INOPS (ESCALATED INOPS TO YELLOW LEVEL), AND ONE ¿LEADSET UNPLUGGED¿ INOP LEADING UP TO THE INCIDENT TIMEFRAME REPORTED AS APPROXIMATELY 02:24 ON (B)(6) 2023. THE ¿LEADSET UNPLUGGED¿ INOP OCCURRED AT 23:16:23 AND REMAINED UNRESOLVED UNTIL 02:10:57, WHEN THE DEVICE BATTERY WAS REMOVED AND REINSERTED, AND THE DEVICE POWER CYCLED. WHEN THE DEVICE COMPLETED THE BOOT-UP CYCLE, A ¿LEADSET UNPLUGGED¿ INOP WAS GENERATED AT 02:11:55 AND REMAINED IN EFFECT UNTIL THE DEVICE WAS PUT INTO ¿STANDBY¿ AT 02:26:30 ON (B)(6) 2023. THE LEADSET UNPLUGGED CONDITION WAS NOT RESOLVED; THEREFORE, ECG MEASUREMENTS AND PHYSIOLOGICAL ALARMS WERE NOT AVAILABLE, AND THE PATIENT WAS NOT MONITORED FROM 23:16:23 ON (B)(6) 2023, THROUGH 02:11:55 ON (B)(6) 2023. THE NOTED TECHNICAL INOPS RELATED TO ¿ECG LEADS OFF¿ CAN BE THE RESULT OF POOR SKIN PREP, POOR ELECTRODE PLACEMENT, OR POOR CONDITION OF ELECTRODES (ADHESIVE NOT HOLDING/DRY ELECTRODE GEL). THE ¿LEADSET UNPLUGGED¿ TECHNICAL INOP INDICATES EITHER THE LEAD SET IS NOT RECOGNIZED BY THE MX40, OR IT IS DISCONNECTED FROM THE DEVICE/NOT PROPERLY SEATED ONTO THE MX40 CONNECTOR. THE PICTURES OF THE PATIENT CABLE CONNECTOR AND MX40 CONNECTOR DO NOT SHOW ANY CORROSION THAT COULD HAVE IMPACTED THE CONNECTION/COMMUNICATION BETWEEN THE DEVICE AND PATIENT CABLE. THE PICTURES DO SHOW THAT THE DEVICE AND PATIENT CABLE ARE NOT VERY CLEAN, BUT NOT SO DIRTY THAT IT COULD IMPACT FULL SEATING OF THE PATIENT CABLE ONTO THE MX40 CONNECTOR. ALSO, WITH THE ALARMS REMINDERS TURNED ON WITH THE SETTING OF 2 MINUTES, THERE WOULD HAVE BEEN REMINDERS FOR THE ¿LEADSET UNPLUGGED¿ INOP EVERY TWO MINUTES. USERS WERE AWARE OF THIS CONDITION AND ACKNOWLEDGED THE INOP AT 23:21:46, AGAIN AFTER THE BATTERY REBOOT AT 02:18:36 AND FINALLY SOMEONE ENTERED STANDBY FROM THE MANAGE PATIENT APPLICATION AT THE PIC IX AT 02:26:30. BASED ON THE FOREGOING INVESTIGATION, THE MX40 AND PIC IX DEVICES WERE OPERATING PROPERLY. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE DEVICE WAS FUNCTIONING AS INTENDED, AND THERE IS NO MALFUNCTION ON THE DEVICE. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

{{datachunk}}Event469:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231031

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00871

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THE ALARMS DO NOT WORK. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THERE WAS NO FUNCTIONAL TESTING DONE. THE DEVICE WAS NOT RETURNED FOR EVALUATION. THE CAUSE OF THE REPORTED PROBLEM WAS NOT CONFIRMED. H3 OTHER TEXT : DEVICE NOT RETURNED FOR EVALUATION.

{{datachunk}}Event470:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230125

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:81 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07539

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

B3: DATE IS APPROXIMATE. MONTH AND YEAR ARE CONFIRMED VALID. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS

## DSI MAUDE Problems Summary

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EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD MOVED TOWARDS THE STERNOTOMY INCISION SIX MONTHS POST IMPLANT AND CONTINUED TO MOVE A LITTLE CLOSER TO THE HEALED SITE FOR SEVERAL MONTHS AFTER THAT. THE ICM REMAINS IN USE. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event471:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20191125

event\_location:

remedial\_action:[""]

patient.patient\_age:86 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

## DSI MAUDE Problems Summary

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report\_number:9614453-2023-04210

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR UNDERSENSING. IT WAS NOTED THE ICM HAD REACHED END OF SERVICE (EOS). IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT LAST CLEARED WENT BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event472:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20200923

event\_location:

remedial\_action:[""]

patient.patient\_age:63 YR

patient.patient\_sex:Female

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04212

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR OVERSENSING ON TACHYCARDIA EPISODES. IT WAS NOTED THE ICM HAD REACHED END OF SERVICE (EOS). IT WAS FURTHER NOTED THAT THE REMOTE MONITORING TRANSMISSION LAST CLEARED WENT BACK TO THE DATE OF IMPLANT. THE REPORT ALSO CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event473:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["No Audible Alarm","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231024

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 PATIENT WEARABLE MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00870

mdr\_text.text:A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE BY TELEPHONE SUPPORT WITH THE CUSTOMER AND CONFIRMED THE SPEAKER MALFUNCTION ISSUE AS REPORTED. THE RSE DETERMINED THE DEVICE WOULD REQUIRE REPLACEMENT, AND THE RSE ARRANGED FOR A REPLACEMENT DEVICE TO BE SENT TO THE CUSTOMER SITE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. THE DEVICE REMAINS AT THE CUSTOMER SITE.

D4 SERIAL NUMBER WAS CORRECTED FROM (B)(6). H4 MANUFACTURE DATE WAS CORRECTED FROM 05/22/2018 TO 01/14/2013.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. SECTION E REPORTING INSTITUTION / REPORTER PHONE # (B)(6).

THE CUSTOMER REPORTED THE DEVICE HAS A SPEAKER MALFUNCTION. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event474:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00601

mdr\_text.text:BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE THE DISTORTED SOUND WITH THE SPEAKER. THE CUSTOMER WAS PROVIDED WITH A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. AFTER SPEAKER REPLACEMENT THE DEVICE WAS RETURNED TO FUNCTIONAL USE WITH NO FURTHER ISSUES IDENTIFIED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. E1: REPORTING INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6).

THE SPEAKER IS DEFECTIVE, THE CUSTOMER WANTS TO RECEIVE A QUOTE FOR ORDERING A NEW SPEAKER. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED. A NEW SPEAKER ASSEMBLY WAS SHIPPED TO THE CUSTOMER.

{{datachunk}}Event475:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction



## DSI MAUDE Problems Summary

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date\_of\_event:20231027

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00606

mdr\_text.text:A PHILIPS REMOTE SERVICE ENGINEER (RSE) REMOTELY INTERVIEWED THE CUSTOMER WHO WAS ONSITE. THE CUSTOMER CONFIRMED THERE WAS NO BEEPING SOUND COMING FROM THE SPEAKER AND THERE WAS AN INOPERATIVE MESSAGE PRESENT, BUT NO AUDIO PRESENT DURING THIS MESSAGE. THE CUSTOMER TESTED THE UNIT WITH AN ARTIFICIAL ECG ON THE MONITOR. THE UNIT WOULD SOMETIMES WORK INDEPENDENTLY DURING PATIENT TRANSPORT. THE DEVICE REMAINS AT THE CUSTOMER'S SITE. A REPLACEMENT SPEAKER ASSEMBLY WAS ORDERED, THE CUSTOMER STATED THEY WILL TAKE RESPONSIBILITY FOR THE REPAIR OF THE UNIT.

THE CUSTOMER REPORTED THE X2 ALARM VOLUME IS SET TO FIVE; HOWEVER, IT DOES NOT GIVE OFF AN ALARM SOUND. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED. A REPLACEMENT SPEAKER ASSEMBLY WAS ORDERED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. H3 OTHER TEXT : THE CUSTOMER IS REPAIRING THE DEVICE.

{{datachunk}}Event476:

adverse\_event\_flag:Y

product\_problems:["Overheating of Device"]

event\_type:Injury

date\_of\_event:20231026

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Burn(s)"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00873

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED THE DEVICE GETS TOO HOT AND MAY HAVE BURNED A PATIENT ON THE RIGHT SHOULDER. THERE IS INSUFFICIENT INFORMATION PROVIDED TO DETERMINE THE SEVERITY OF THE BURN.

A PHILIPS PRODUCT SPECIALIST ENGINEER (PSE) INSPECTED THE DEVICE AND FOUND VISIBLE CORROSION ON PIN 4. USING A FLUKE HART SCIENTIFIC 1504 THERMOMETER READOUT THE PSE PERFORMED A TEMPERATURE TEST ON THE BATTERIES WHICH RETURNED RESULTS OF THE BATTERIES WAS 82 DEGREES FAHRENHEIT VERSUS AMBIENT TEMP OF 72 DEGREES FAHRENHEIT. THE REPORTING INSTITUTION WOULD NOT DISCLOSE FURTHER INFORMATION RELATED TO THE REPORTED EVENT; HOWEVER, ANALYSIS OF THE RETURNED DEVICE REVEALED NO ANOMALIES RELATED TO TEMPERATURE. BASED ON THIS INFORMATION, THE EXTENT OF THE BURN REMAINS UNKNOWN AT THIS TIME, AND IT DOES NOT APPEAR THERE WAS ANY DEVICE MALFUNCTION WHICH WOULD CAUSE A BURN. WITH THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS NOT CONFIRMED. THE LAB TESTS SHOWS DEVICE FUNCTIONED AS INTENDED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event477:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

## DSI MAUDE Problems Summary

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event\_type:Death

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00872

mdr\_text.text:THE FIELD SERVICE ENGINEER (FSE) STATES THAT THE CUSTOMER REPORTS MX40 CONNECTIVITY ISSUES. FSE CHECKED AND FOUND THAT ONE OF THE CUSTOMERS ACCESS POINT WAS WRONGLY CONFIGURED. PER RESOLUTION THE UNIT CONFIGURATION WAS CLONED, WHICH RESOLVED THE PROBLEM. BASED ON THE INFORMATION PROVIDED IN THE CASE, THE ENGINEER REPORTS THAT THE SYSTEM WAS RECONFIGURED, WHICH ISSUE RESOLVED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED THE MX40 WAS INVOLVED IN A PATIENT SAFETY INCIDENT RESULTING IN DEATH AND FURTHER INVESTIGATING IS NEEDED.

{{datachunk}}Event478:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231025

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00597

mdr\_text.text:REMOTE SERVICE ENGINEER (RSE) RECOMMENDED REPLACEMENT OF THE SPEAKER. THE CUSTOMER AGREED AND REQUESTED FOR PARTS TO BE SHIPPED UNDER CONTRACT. A REPLACEMENT SPEAKER WAS ORDERED AND SHIPPED TO THE CUSTOMER SITE. BASED ON THE INFORMATION AVAILABLE AND THE COMMUNICATION CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

IT WAS REPORTED THE THERE WAS NO SOUND FROM THE SPEAKER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event479:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231024

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00874

mdr\_text.text:PHILIPS AUTHORIZED REPAIR FACILITY INDICATE THAT THE SYSTEM SPEAKER PRODUCED NO SOUND AND WAS DEFECTIVE. THE SYSTEM SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED THAT DURING BENCH TESTING THE DEVICE DID NOT PRODUCE SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event480:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00151

## DSI MAUDE Problems Summary

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mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 11 DAYS OF THE 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 22. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event481:

adverse\_event\_flag:N

product\_problems:["Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20231112

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07478

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE,

A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DID NOT DETECT VENTRICULAR TACHYCARDIA (VT). IT WAS FURTHER REPORTED THAT THE DEVICE INTERROGATED BACK TO THE DATE OF IMPLANT RATHER THAN LAST SESSION WITH THE REMOTE MONITOR. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event482:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231108

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04184

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN



## DSI MAUDE Problems Summary

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ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event483:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231108

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04185

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). IT AS JUST SHOWING TO PICK UP THE READER AND GOES BACK TO THE MAIN SCREEN. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event484:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231025

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00861

mdr\_text.text:IT WAS REPORTED, THAT DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. THERE WAS NO PATIENT OR USER HARM REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST, AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event485:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231115

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04187

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. REFERRED THE PATIENT TO CLINIC AND TO BRING THE MONITOR TO HAVE THE DEVICE INTERROGATED IN THE OFFICE. THE ICM REMAINS IN THE PATIENT. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event486:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231019

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00146

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR THE FULL PRESCRIBED 3-DAY WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 15. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event487:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231024

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00147

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 13 DAYS OF THE 14-DAYS PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO

CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event488:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231018

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00149

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR 5 DAYS OF THE 7-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 15. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED

## DSI MAUDE Problems Summary

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IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event489:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231020

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00150

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.



THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE. THE HEALTHCARE PROVIDER (HCP) WAS IMMEDIATELY NOTIFIED, AND IRHYTHM LEARNED THAT THE HCP WAS ALREADY AWARE OF THE PATIENT'S ARRHYTHMIA AND WAS TREATING IT. THERE WERE NO DELAYS IN TREATMENT, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE AT DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA FOUND THAT THE PATIENT WORE THE AT DEVICE FOR THE FULL 14-DAY PRESCRIBED WEAR PERIOD. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 24. THE INVESTIGATION REVEALED A POTENTIAL ALGORITHM SENSITIVITY ISSUE WITH THE DEVICE, AS THERE WERE NO ERRORS OR ISSUES OBSERVED AROUND THE TIME THE MISSED EPISODE OCCURRED. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event490:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System"]

event\_type:Death

date\_of\_event:20231020

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00865

## DSI MAUDE Problems Summary

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mdr\_text.text:THE PRODUCT SUPPORT ENGINEER (PSE) IDENTIFIED THAT THERE IS RADIO FREQUENCY DATA ACQUISITION (RFDA) AND DEVEBDEBUG LOG DATA FOR BED LABEL TELE-8 IN THE REPORTED INCIDENT TIMEFRAME. THERE IS AUDIT LOG DATA FOR THE INCIDENT TIMEFRAME AND DEVICE IN QUESTION. THE MX40 PWM LOGS WERE NOT COLLECTED. THE RFDA LOG SHOWS THAT THERE ARE SIGNAL ISSUES DURING THE REPORTED TIMEFRAME (MX40 TO PIC IX), BUT THE MX40 REMAINED CONNECTED TO THE PIC IX. THE RFDA LOG SHOWS THE CONNECTION BETWEEN DEVICE TELE-8 (BED LABEL HTG1-8) AND THE PATIENT INFORMATION CENTER IX (PIC IX) BEING ABORTED AT 06:27:24 ON (B)(6) 2023, AT WHICH TIME THE PATIENT WAS DISCHARGED FROM THE PIC IX. THE DEVICE DEBUG LOG SHOWS A BATTERY CHANGE FOR DEVICE/BED LABEL TELE-8/HTG1-8 AT 09:58:05 ON (B)(6), 2023. NO OTHER ACTIVITY WAS CAPTURED DURING THE INCIDENT TIMEFRAME. THE AUDIT LOG SHOWS ONGOING ACTIVITY FOR DEVICE LABEL/BED LABEL TELE-8/HTG1-8 THROUGHOUT THE TIMEFRAME OF 01:30 THROUGH 06:27 ON OCTOBER 20, 2023. PHYSIOLOGICAL ALARMS WERE BEING PROVIDED FOR ASYSTOLE, VENT FIB/TACHY, HR LOW LIMIT VIOLATIONS, AFIB, PAUSE, AND IRREGULAR HR EVENT AS THE PATIENT'S CONDITION CHANGED. TECHNICAL INOP ALARMS WERE PROVIDED FOR TELE WEAK SIGNAL, CANNOT ANALYZE ECG, AND ECG LEADS OFF (R LEAD (RIGHT ARM) EVENTS. THE AUDIT LOG SHOWS THE PATIENT WAS DISCHARGED AT 06:27:24 ON (B)(6), 2023. THE AUDIT LOG SHOWS THE PATIENT WAS READMITTED AT 08:12:34 ON (B)(6), 2023. NO FURTHER ACTIVITY FOR DEVICE/BED TELE-8/HTG1-8 IS CAPTURED. THE READMIT MAY HAVE BEEN TO REVIEW DATA. THE AUDIT LOG DATA ENDS AT 08:12:34 ON (B)(6), 2023. THE LOGS INDICATE THAT THE PHILIPS EQUIPMENT IS PERFORMING AS SPECIFIED. IT IS FURTHER DETERMINED THAT THE PHILIPS DEVICE DID NOT CAUSE OR CONTRIBUTE TO THE PATIENT DEATH. THE CUSTOMER IS USING TUNSTALL NURSE CALL SYSTEM. THIS SECONDARY ALARMING SYSTEM IS ALLEGED TO NOT HAVE ALARMED. ADDITIONAL INFORMATION REGARDING THE TUNSTALL SYSTEM HAS BEEN REQUESTED. A FOLLOW-UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETED.

THE LOGS INDICATE THAT THE PHILIPS EQUIPMENT IS PERFORMING AS SPECIFIED. IT IS FURTHER DETERMINED THAT THE PHILIPS DEVICE DID NOT CAUSE OR CONTRIBUTE TO THE PATIENT DEATH. THE CUSTOMER IS USING TUNSTALL NURSE CALL SYSTEM (A NON-PHILIPS PRODUCT). THIS SECONDARY ALARMING SYSTEM IS ALLEGED TO NOT HAVE ALARMED. ADDITIONAL INFORMATION REGARDING THE TUNSTALL SYSTEM WAS REQUESTED, HOWEVER NO ADDITIONAL INFORMATION WAS RECEIVED. THE PHILIPS PRODUCT SUPPORT ENGINEERING (PSE) LOG REVIEW INDICATES AND THE CUSTOMER WAS CERTAIN THE ALARMS WERE BEING GENERATED AT THE PATIENT INFORMATION CENTER IX (PIC IX). THIS CONFIRMS ALARMING AT THE MX40 DEVICE AS THE PIC IX RECEIVES THE INFORMATION FROM THE MX40. THE SECONDARY ALARMS WERE NOT BEING SENT TO THE NON-PHILIPS NURSE CALL SYSTEM. PER THE PSE, THE IFU STATES 'THE PAGING SYSTEM IS A SECONDARY ALARM NOTIFICATION SYSTEM AND IS NOT INTENDED FOR PRIMARY NOTIFICATION OF ALARMS, PHYSIOLOGICAL DATA, OR DEMOGRAPHIC DATA. RECEIPT BY THE EXTERNAL SOFTWARE DEVICE OF ALERTS IS NOT CONFIRMED, AND DELIVERY TO THE PAGING DEVICE IS NOT GUARANTEED.' THE CLINICAL AUDIT LOG REVIEW REVEALED THE PHILIPS DEVICES WERE PERFORMING AS SPECIFIED AND MANUFACTURER-SPECIFIC PERFORMANCE IS TO BE ADDRESSED BY THE CUSTOMER WITH THAT MANUFACTURER.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE

## DSI MAUDE Problems Summary

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INVESTIGATION IS COMPLETE. REPORTING INSTITUTION PHONE#: (B)(6).

IT WAS REPORTED A PATIENT BEING MONITORED BY A TELEMETRY DEVICE PASSED AWAY. THE CUSTOMER INDICATED THE CENTRAL STATION WAS ALARMING; HOWEVER, THE SECONDARY ALARM FORWARDING TO THE NURSE CALL WAS NOT ALARMING. THE CUSTOMER REQUESTED ONSITE ASSISTANCE GATHERING THE DEVICE LOGS. DEVICE LOGS WERE RETRIEVED AND PROVIDED TO THE PRODUCT SUPPORT ENGINEER FOR EVALUATION. THE PATIENT INFORMATION CENTER IX IN USE DURING THIS EVENT IS REPORTED IN MFR NUMBER 1218950-2023-00863.

{{datachunk}}Event491:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231031

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00866

mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPRODUCED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED.

## DSI MAUDE Problems Summary

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THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event492:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230921

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00589

mdr\_text.text:THE CUSTOMER REPORTED MACHINE DID NOT ALARM WHEN THE BLOOD OXYGEN BAND FELL OFF WHEN THE PATIENT MONITOR WAS USED FOR THE CHILD. THE DEVICE WAS IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT/USER INJURY/HARM.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. E1: REPORTER INSTITUTION PHONE NUMBER: (B)(6). E2: REPORTER PHONE NUMBER: (B)(6).

THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY BLOOD OXYGEN PROBE. THERE IS NO INFORMATION IF THE MALFUNCTIONING PROBE IS A PHILIPS PRODUCT, NOR ANY ADDITIONAL PRODUCT INFORMATION WAS PROVIDED. THE HOSPITAL EQUIPMENT DEPARTMENT REPLACED THE PROBE AND THE EQUIPMENT RETURNED TO NORMAL USE. HOWEVER, THE ISSUE WAS NOT CAUSED BY

## DSI MAUDE Problems Summary

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A MALFUNCTION OF THE INTELLIVUE MP5, BUT OF A MALFUNCTIONING BLOOD OXYGEN PROBE OF UNKNOWN ORIGIN. H3 OTHER TEXT : NO ADDITIONAL INFORMATION.

{{datachunk}}Event493:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:20231022

event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04159

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM

BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED ARTIFACT ON A TACHYCARDIA EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event494:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231106

event\_location:

remedial\_action:[""]

patient.patient\_age:62 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04160

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS EXPLANTED.

IT WAS REPORTED THAT THE READER WAS NOT READING THE IMPLANTABLE CARDIAC MONITOR (ICM). IT WAS MENTIONED THAT THE PROGRESS BAR DID NOT COME. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE

## DSI MAUDE Problems Summary

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COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. ANALYSIS OF THE DEVICE REVEALED, NORMAL BATTERY DEPLETION. THIS DEVICE EXCEEDS NOMINAL EXPECTED LONGEVITY OF 36 MONTHS. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM, BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK, BECAUSE THE INFORMATION IS CURRENTLY, UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event495:

adverse\_event\_flag:N



## DSI MAUDE Problems Summary

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product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:10 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Skin Inflammation/ Irritation"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00071

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT GOT BLISTERS AND A POSSIBLE ALLERGIC REACTION. THE SENSOR WAS RETURNED FOR INVESTIGATION. THE SENSOR WAS INVESTIGATED. DEVICE WAS ABLE TO CHARGE, AND DEVICE INVESTIGATION FOUND THAT THE TEMPERATURE FOR THE DEVICE WAS WITHIN NORMAL LIMITS. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE ELECTRODE WAS NOT RETURNED. ALLEGATION IS CONFIRMED AS THE IMAGE OF PATIENT SKIN IRRITATION SHOWS AND ANY SKIN IRRITATION IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARSII, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

IT WAS REPORTED BY THE PATIENT'S MOTHER THAT HER DAUGHTER COMPLAINED THE DEVICE WAS BURNING HER. UPON REMOVING THE DEVICE, THE MOTHER NOTICED BURN MARKS ON THE DEVICE CONNECTORS AND ALSO SMALL RED BLISTERS ON THE CHILD'S SKIN. SHE WAS UNSURE IF THERE WAS AN ALLERGIC REACTION OR IF THE SKIN APPEARANCE WAS FROM THE DEVICE ITSELF BECAUSE OF THE BURN MARKS ON THE CONNECTORS. THE MOTHER REPORTED THAT THE PATIENT RECEIVED MEDICAL TREATMENT AND WAS PRESCRIBED AN OINTMENT. THE MOTHER ALSO EXPRESSED CONCERN THAT THE INJURY WAS NOT BEING TAKEN SERIOUSLY. SUBSEQUENTLY, ADDITIONAL FOLLOW-UP INFORMATION WAS RECEIVED FROM THE PATENT'S MOTHER STATING THAT OINTMENT WAS NOT PRESCRIBED, BUT RATHER AN OINTMENT WAS APPLIED TO SKIN BY A SCHOOL NURSE. SHE DIDN'T KNOW WHAT

## DSI MAUDE Problems Summary

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OINTMENT WAS APPLIED. THE MOTHER ALSO STATED THAT THE PATIENT DID NOT HAVE A KNOWN PRIOR SKIN SENSITIVITY. ALCOHOL WIPES WERE USED PRIOR TO APPLYING THE PATCH. THIS IS RELATED TO MFR 2133409-2023-00072.

{{datachunk}}Event496:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:10 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Burn(s)"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00072

mdr\_text.text:IT WAS REPORTED BY THE PATIENT'S MOTHER THAT HER DAUGHTER COMPLAINED THE DEVICE WAS BURNING HER. UPON REMOVING THE DEVICE, THE MOTHER NOTICED BURN MARKS ON THE DEVICE CONNECTORS AND ALSO SMALL RED BLISTERS ON THE CHILD'S SKIN. SHE WAS UNSURE IF THERE WAS AN ALLERGIC REACTION OR IF THE SKIN APPEARANCE WAS FROM THE DEVICE ITSELF BECAUSE OF THE BURN MARKS ON THE CONNECTORS. THE MOTHER REPORTED THAT THE PATIENT RECEIVED MEDICAL TREATMENT AND WAS PRESCRIBED AN OINTMENT. PATIENT MOTHER ADVISED PATIENT TOOK A SHOWER EARLIER IN THE DAY THAT WAS THE PRIOR WATER EXPOSER BEFORE THE EVENT OCCURRED. THIS IS RELATED TO MFR 2133409-2023-00072.

IT WAS REPORTED DEVICE GOT HOT AND LEAVED BURNS ON THE PATIENT. THE DEVICE WAS RETURNED FOR INVESTIGATION. DEVICE WAS ABLE TO CHARGE, AND DEVICE INVESTIGATION FOUND THAT THE TEMPERATURE FOR THE DEVICE WAS WITHIN NORMAL LIMITS. ENGINEERING EVALUATION WAS

## DSI MAUDE Problems Summary

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UNABLE TO BE PERFORMED AS THE ELECTRODE WAS NOT RETURNED. ALLEGATION IS CONFIRMED AS THE IMAGE OF PATIENT SKIN IRRITATION SHOWS AND ANY SKIN IRRITATION IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE.

{{datachunk}}Event497:

adverse\_event\_flag:Y

product\_problems:["Biocompatibility"]

event\_type:Injury

date\_of\_event:20231002

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Skin Inflammation/ Irritation"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00073

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT WAS EXPERIENCING RED, ITCHY SKIN DUE TO THE ADHESIVE. THE PATIENT REPORTED THAT THEY WERE PRESCRIBED STEROID CREAM TO TREAT THE SKIN IRRITATION. THE PATIENT PREPPED HER SKIN WITH SOAP AND WATER. THERE WERE PRIOR HISTORY OF SKIN SENSITIVITIES/ALLERGIES. THE PATIENT WAS OFFERED TO SWITCH TO THE LWA (LEAD WIRE ADAPTOR) OR FLEX ADAPTER WITH CLOTH ELECTRODES. A REPLACEMENT DEVICE WAS ALSO OFFERED HOWEVER, THE PATIENT WANTED TO FOLLOW UP WITH THEIR DOCTOR. THE PATIENT'S DOCTOR ADVISED THAT PATIENT SHOULD CONTINUE SERVICE AND WAS SET UP WITH FLEX DEVICE AND CLOTH ELECTRODES.

IT WAS REPORTED THAT THE PATIENT EXPERIENCED RED, ITCHY SKIN DURING SERVICE. THE ELECTRODE DID NOT RETURN HOWEVER, THE SENSOR DID. DEVICE WAS ABLE TO CHARGE, AND DEVICE INVESTIGATION FOUND THAT THE TEMPERATURE FOR THE DEVICE WAS WITHIN NORMAL LIMITS.

## DSI MAUDE Problems Summary

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DEVICE WAS OPENED AND CONFIRMED THAT THERE WAS NO INTERNAL DAMAGE OR CORROSION ON THE INSIDE OF THE DEVICE. ENGINEERING EVALUATION ON SKIN IRRITATION IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARSII, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

{{datachunk}}Event498:

adverse\_event\_flag:N

product\_problems:["Break", "Electrical /Electronic Property Problem"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:12 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00074

mdr\_text.text:THE PATIENT REPORTED THAT THE CHARGER PLUG WAS PLUGGED INTO THE OUTLET AND BROKE WHEN THE PATIENT WENT TO REMOVE IT FROM THE WALL. THE DEVICE WAS NOT RETRURNED. THE CAUSE OF THE ISSUE WAS THE SUPPLIER USAGE OF AN ULTRASONIC WELDING TOOL THAT WAS NOT EFFECTIVE DUE TO IT BEING LIMITED TO THE NUMBER OF CYCLES IT COULD BE USED TO MANUFACTURE THE COMPONENT. THIS CAUSED AN INCONSISTENT WELD PATTERN ON THE COMPONENT. A USER CANNOT DETECT IF THE WELDED JOINT IS ADEQUATE AND HAS NO INDICATION THE DEVICE MAY FAIL DURING NORMAL USE. WHEN THE FAILURE OCCURS, THE WALL ADAPTER

SEPARATES INTO TWO PIECES. THE USER CAN EASILY DETECT THIS EVENT AND AT THIS POINT THE DEVICE IS NO LONGER FUNCTIONAL AND CANNOT BE USED. PHILIPS AM&D ARE CONTINUING TO MONITOR THE ISSUE.

PATIENT CALLED IN BECAUSE SHE HAD THE MONITOR CHARGER PLUGGED INTO THE WALL. SHE WENT TO PULL IT OUT AND THE PRONGS HAVE GOTTEN STUCK IN THE OUTLET. PATIENT GOT IT OUT OF OUTLET, BUT NEEDS REPLACEMENT CHARGER. A REPLACEMENT CHARGER WAS SENT. NO PATIENT HARM WAS REPORTED.

{{datachunk}}Event499:

adverse\_event\_flag:Y

product\_problems:["Biocompatibility"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:53 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Skin Tears","Blister","Skin Inflammation/ Irritation"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00075

mdr\_text.text:IT WAS REPORTED THE PATIENT EXPERIENCED SEVERE SKIN IRRITATION CAUSING A TEAR, BLISTERS AND REDNESS. THE DEVICE WAS NOT RETURNED. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE ELECTRODE/DEVICE WAS NOT RETURNED. ALLEGATION IS UNABLE TO BE CONFIRMED AS THERE ARE NO IMAGES OF PATIENT SKIN IRRITATION, AND ANY SKIN IRRITATION IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARSII, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO

## DSI MAUDE Problems Summary

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ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

PATIENT REPORTED THEY WERE EXPERIENCING SKIN BLISTERS THAT WERE THE SIZE OF THE UNIVERSAL PATCH. THE SKIN APPEARED WITH RED RAISED SKIN WITH A TEAR NEAR WERE THE TOP OF THE PATCH WOULD BE ON THE SKIN AND NEAR THE BOTTOM IT WAS VERY RED AND COMPLETELY BLISTERED. THE PATIENT WENT TO EMERGENCY ROOM (ER) AND WAS DIAGNOSED WITH ALLERGIC CONTACT DERMATITIS DUE TO THE ADHESIVE ON PATCH. THE PATIENT WAS PRESCRIBED HYDROCORTISONE. LEAD WIRE ADAPTER (LWA) AND FLEX WAS OFFERED AND THE PATIENT TOOK A BREAK IN SERVICE UNTIL SKIN COMPLETELY HEALED. THE PATIENT HAS A HISTORY OF ALLERGIES.

{{datachunk}}Event500:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231008

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00137

mdr\_text.text:THE DEVICE WAS WORN FOR THE 14-DAY PRESCRIBED WEAR-PERIOD. THE DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT AND STOPPED TRANSMITTING ASYMPTOMATIC EVENTS ON DAY 7. THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS

SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 32. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO THE STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. IRHYTHM WAS INFORMED THAT THE PATIENT WILL BE TREATED WITH A PACEMAKER. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event501:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231018

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00141

mdr\_text.text:THE DEVICE WAS WORN FOR THE 14-DAY PRESCRIBED WEAR-PERIOD. THE DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT AND STOPPED TRANSMITTING ASYMPTOMATIC EVENTS ON DAY 13. THE HCP ACCOUNT WAS NOTIFIED ON DAY 13 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 27. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO THE STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM WAS INFORMED THAT THE PATIENT WILL BE TREATED WITH A PACEMAKER. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event502:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231103

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00586

mdr\_text.text:IT WAS REPORTED THE INTELLIVUE X2 MEASUREMENT SERVER HAD A DEFECTIVE SPEAKER. THERE WAS NO MORE SOUND AND NO INOP MESSAGE. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THE SPEAKER FAILURE PARTS REQUEST FROM THE CUSTOMER TO RESOLVE THE ISSUE (453564238621-MS\_X2 ASSY CBL X2/MP2 SPEAKER ASSEMBLY) A NEMO (NON ENGINEERING MATERIAL ONLY) SERVICE WAS AGREED UPON. THE CUSTOMER ORDERED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. E1: REPORTING INSTITUTION PHONE: (B)(6). E1: REPORTER PHONE # (B)(6).

{{datachunk}}Event503:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231017

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP50

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00578

mdr\_text.text:A PHILIPS REMOTE SERVICE ENGINEER (RSE) INTERVIEWED THE CUSTOMER. CUSTOMER'S BIOMED MENTIONED THAT THE DEVICE IS GOING TO BE RETURNED FOR BENCH REPAIR. HOWEVER, THE MP50 WAS NEVER RETURNED FOR BENCH REPAIR. BASED ON THE INFORMATION AVAILABLE, THE EXACT CAUSE FOR THE REPORTED ISSUE COULD NOT BE ESTABLISHED AS THE DEVICE WAS NOT RETURNED FOR EVALUATION. THE EXACT CAUSE IS UNKNOWN.

IT WAS REPORTED THAT THE DEVICE DISPLAYED A SPEAKER MALFUNCTION INOP AND WAS NOT MAKING ANY SOUND. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED THAT THE DEVICE DISPLAYED A SPEAKER MALFUNCTION INOP AND WAS NOT MAKING ANY SOUND. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event504:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230602

event\_location:

remedial\_action:[""]

patient.patient\_age:54 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04146

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD REACHED END OF SERVICE (EOS). THE ICM WAS EXPLANTED AND REPLACED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD MISSED NIGHTLY AUDITS. IT WAS ALSO REPORTED THAT REMOTE MONITOR WAS UNRESPONSIVE WHEN THE ACCEPT BUTTON WAS PRESSED. IT WAS FURTHER REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL FOR THE MISSED DAILY WIRELESS AUDIT. NO SPECIFIC TROUBLESHOOTING INDICATED FOR THE ISSUE WITH PRESSING THE ACCEPT BUTTON AND NO TELEMETRY. THE PATIENT WAS REFERRED TO THE CLINIC. THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT HAVE ANY SUCCESSFUL WIRELESS TRANSMISSIONS SINCE THE DATE OF THE CALL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event505:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231013

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00136

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO THE STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. IRHYTHM WAS INFORMED THAT THE PATIENT WILL BE TREATED WITH A PACEMAKER. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE DEVICE WAS WORN FOR 13 DAYS OF THE 14 DAYS PRESCRIBED WEAR-PERIOD. THE DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT AND STOPPED TRANSMITTING ASYMPTOMATIC EVENTS ON DAY 8. THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 24. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event506:

adverse\_event\_flag:Y

product\_problems:

event\_type:Injury

date\_of\_event:20231103

event\_location:

remedial\_action:[""]

patient.patient\_age:46 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:BOSTON SCIENTIFIC BODYGUARDIAN MINI PLUS

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BOSTON SCIENTIFIC CARDIAC DIAGNOSTIC TECHNOLOGIES, INC.

report\_number:MW5148180

mdr\_text.text:BOSTON SCIENTIFIC BODYGUARDIAN MINI PLUS (BS) - SERIAL NUMBER: (B)(6) - 30-DAY STUDY FOR CARDIAC ISSUES THAT CAN LEAD TO STROKE/HEART ATTACK/DEATH. I AM A 46-YEAR-OLD MALE WHO IS VERY TECH-SAVVY. I CONFIRMED THIS ISSUE IS PREVALENT, AND THE LOCAL STAFF ARE HAVING DIFFICULTY ESCALATING THIS VERY SERIOUS ISSUE WITHIN THEIR HOSPITAL/HEALTH SYSTEM AND THEIR VENDOR (BOSTON SCIENTIFIC). I PICKED UP THE BS DEVICE FOR A 30-DAY STUDY FROM (B)(6) HOSPITAL ON (B)(6) 2023. IT WAS WORKING WHEN I LEFT THE FACILITY. THE MONITOR IS SUPPOSED TO LAST 3-4 DAYS, BUT NOT 12 HOURS, AND WHEN THE BATTERY DRAINS AND THEN IS CHARGED, IT NO LONGER CONNECTS TO THE ANDROID PHONE. THE FIRST TIME THIS HAPPENED, I CALLED BOSTON SCIENTIFIC SUPPORT AND IT TOOK 40-60 MINUTES (THEIR LOG SHOULD HAVE THE EXACT TIME) TO CLEAR THE CACHE ON THE PHONE AND RECONNECT THE DEVICE. I WAS ADVISED TO SEE IF THE MONITOR WOULD LAST 3-4 DAYS, IT DID NOT. I CALLED BS AGAIN THE NEXT DAY, AND THEY SAID THEY WOULD SEND A REPLACEMENT MONITOR. I HAVE YET TO RECEIVE THE MONITOR, NOW ON THE 8TH DAY SINCE THE START OF THE CARDIAC STUDY. I AM AN ENGINEER WHO WORKED AT A BIG TECH COMPANY FOR 15+ YEARS AND A TECH ENTREPRENEUR/EXPERT, AND I HAVE DIFFICULTY GETTING THE BS DEVICES TO WORK. (THEY ARE NOT WORKING). I AM AT RISK OF A CARDIOVASCULAR EVENT (STROKE/HEART ATTACK, DISABILITY, DEATH). WHAT ABOUT OPEN HEART SURGERY? VALVE REPLACEMENT? BYPASS? WHAT ABOUT AN ELDERLY PERSON? HOW MANY PATIENTS HAVE HAD ADVERSE EVENTS (STROKE, DISABILITY, DEATH)? SUBMITTING FDA COMPLAINT. PLEASE LOOK INTO THIS. I EXPECT SEVERAL ADVERSE EVENTS, AND THIS DEVICE NEEDS TO BE FIXED/RECALLED ASAP. FEEL FREE TO CONTACT ME IF REQUIRED.

{{datachunk}}Event507:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210726

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04124

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED OVERSENSING ON A TACHYCARDIA EPISODE. IT WAS ALSO NOTED THERE WERE INVALID HISTOGRAMS ON THE REMOTE MONITORING REPORT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event508:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20231008

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00134

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO THE STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM WAS INFORMED THAT THE PATIENT WOULD BE TREATED WITH A PACEMAKER. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE DEVICE WAS RETURNED TO IRHYTHM, AND THE CLINICAL DATA WAS DOWNLOADED. A REVIEW OF THE CLINICAL DATA REVEALED THE DEVICE WAS WORN FOR THE FULL 14 DAY PRESCRIBED WEAR-PERIOD. THE DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT AND STOPPED TRANSMITTING ASYMPTOMATIC EVENTS ON DAY 10. THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. AS DESCRIBED IN PRODUCT LABELING,



THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING (B)(4) PATIENT TRIGGERS AND (B)(4) ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event509:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20220208

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cyanosis","Insufficient Information"]

device.brand\_name:INTELLIVUE MP50

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00580

mdr\_text.text:THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND ASSISTED IN PULLING THE LOGS OF THE BEDSIDE MONITOR. THE CUSTOMER LEARNED TO PULL ALL THE LOGS. A REVIEW OF MONITOR ACTIVITY WAS PERFORMED, REVEALING ANESTHESIA HAD SILENCED THE ALARMS. IT WAS INDICATED BY THE CUSTOMER THAT THE DEVICE APPEARED TO BE FUNCTIONING PROPERLY AND THE REPORTED ISSUE WAS ENTIRELY DUE TO USE ERROR. THE RISK MANAGEMENT DEPARTMENT AT THE HOSPITAL

## DSI MAUDE Problems Summary

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INDICATED: "THIS CASE SEEMS TO BE A DIRECT RESULT OF A LACK OF MEDICAL CARE UNDER THE ANESTHESIOLOGIST'S WATCH AND NOT DUE TO A PRE-EXISTING CONDITION." THIS INFORMATION SUPPORTS THE CONCLUSION THAT THE DEVICE FUNCTION DID NOT CAUSE OR CONTRIBUTE TO THE REPORTED EVENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE USER, AND THERE WAS NO MALFUNCTION OF THE DEVICE. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MP50 INDICATING THAT THE CUSTOMER WANTED ALL LOGS PULLED FROM THE MONITOR. THERE WAS A PATIENT INCIDENT ON (B)(6) 2022, AND THE MONITOR HAD NOT BEEN USED SINCE THE INCIDENT. DURING A ROUTINE PROCEDURE WHILE MONITORING ANESTHESIA, THE PATIENT BECAME CYANOTIC, REQUIRING RESUSCITATION. THE PATIENT WAS MOVED TO A HIGHER LEVEL OF CARE DUE TO A CEREBROVASCULAR ACCIDENT (CVA) AND HAS SOME RESIDUAL DEFICITS, WHICH REQUIRE REHABILITATION.

A FOLLOW UP REPORT WILL BE SUBMITTED AFTER PHILIPS OBTAINS MORE INFORMATION CONCERNING THIS EVENT.

BIOMED CALLED TO REQUEST FSE ONSITE TO PULL THE LOGS OF THE BEDSIDE MONITOR. THERE WAS A PATIENT INCIDENT ON (B)(6) 2022. THE MONITOR HAS NOT BEEN USED SINCE THE INCIDENT. IT WAS REPORTED THERE WAS A PATIENT INCIDENT RESULTING IN HARM; HOWEVER, THERE IS INSUFFICIENT INFORMATION TO DETERMINE THE TYPE OF HARM OR WHETHER THE HARM WAS RELATED TO A PHILIPS DEVICE.

{{datachunk}}Event510:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231026

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00856

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST, AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event511:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231016

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00579

## DSI MAUDE Problems Summary

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mdr\_text.text:THE PHILIPS REMOTE SERVICE ENGINEER (RSE) ASSISTED THE CUSTOMER WITH THEIR REQUEST FOR A QUOTE FOR A NEW SPEAKER MODULE. THE CUSTOMER DID NOT ACCEPT THE QUOTE. THEREFORE, THE REPORTED PROBLEM COULD NOT BE CONFIRMED, AND THE ROOT CAUSE COULD NOT BE IDENTIFIED. H3 OTHER TEXT : SEE H10.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. E1: REPORTER PHONE NUMBER: (B)(6). E1: REPORTING INSTITUTION PHONE NUMBER: (B)(6).

THE CUSTOMER REPORTED THE DEVICE DISPLAYS A SPEAKER MALFUNCTION ERROR MESSAGE AND DOES NOT PRODUCE AUDIBLE SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event512:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electromagnetic Interference","Over-Sensing","Under-Sensing","Positioning Problem"]

event\_type:Malfunction

date\_of\_event:20231024

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07290

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED

## DSI MAUDE Problems Summary

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BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE POSITIVES EPISODES DUE TO OVERSENSING ARTIFACT/NOISE AND UNDERSENSING. IT WAS FURTHER REPORTED THAT THERE WAS SUBOPTIMAL ELECTRODE CONNECTION, ELECTROMAGNETIC INTERFERENCE/MYOPOTENTIAL INTERFERENCE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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PRODUCT EVENT REPORT: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event513:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:20231030

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04059

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS UNABLE TO ESTABLISH TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT HAVE ANY SUCCESSFUL WIRELESS TRANSMISSIONS SINCE THE DATE OF THE CALL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event514:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:20231031

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:62 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04060

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.



## DSI MAUDE Problems Summary

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{{datachunk}}Event515:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230928

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07255

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH

## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE DEVICE REPORT DID NOT GENERATE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event516:

adverse\_event\_flag:N

product\_problems:["Decreased Sensitivity","Human-Device Interface Problem"]

event\_type:Malfunction

date\_of\_event:20230109

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07257

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED DIMINISHED R WAVES ON A PAUSE EPISODE. ON FURTHER REVIEW IT WAS ALSO NOTED THAT THE ICM HAD BEEN IMPLANTED APPROXIMATELY FOUR MONTHS PAST THE USE BY DATE. IT WAS ALSO REPORTED THAT THERE WERE FAILED TRANSMISSIONS THAT WERE NOT CONNECTED TO A NETWORK CONNECTION ISSUE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED DIMINISHED RIGHT VENTRICULAR SENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION

AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event517:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231030

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04064

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). IT WAS FURTHER REPORTED THAT THE REMOTE MONITOR HAD MISSED DAILY WIRELESS AUDITS (DWA). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT HAVE ANY SUCCESSFUL TRANSMISSIONS SINCE THE DATE OF THE CALL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event518:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231016

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00850

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE DID NOT PRODUCE SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event519:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231025

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00852

## DSI MAUDE Problems Summary

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mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event520:

adverse\_event\_flag:Y

product\_problems:["Migration or Expulsion of Device"]

event\_type:Injury

date\_of\_event:20231103

event\_location:

remedial\_action:[""]

patient.patient\_age:53 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Infection"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07218

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED AN INFECTION WITH THE ICM BEING EXPOSED FROM THE POCKET. THE ICM HAD BEEN IMPLANTED APPROXIMATELY TWO WEEKS. THE ICM WAS REMOVED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event521:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231017

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI



## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00572

mdr\_text.text:REPORTING INSTITUTION PHONE NUMBER: (B)(6). REPORTER PHONE NUMBER: (B)(6).  
PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND  
THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE  
INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT NO SOUND WAS COMING FROM THE INTELLIVUE MULTI  
MEASUREMENT SERVER X2 WHEN IT WAS DISCONNECTED FROM THE HOST MONITOR. THE DEVICE WAS  
NOT IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. THERE WAS NO PATIENT  
INVOLVEMENT.

PHILIPS RECEIVED A COMPLAINT ON AN INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING  
THAT NO ALARM SOUNDS WERE TRIGGERED. THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED:  
THE PHILIPS FIELD SERVICE ENGINEER (FSE) SUGGESTED TO THE CUSTOMER THAT THE QRS TONE COULD  
HAVE BEEN SWITCHED OFF IN CONFIGURATION SETTINGS, BUT FOUND NO FAULT IN THE  
CONFIGURATION. NO VISUAL DEFECT WAS DETECTED. THE FSE RECOMMENDED TO THE CUSTOMER TO  
SEND IN THE MONITOR TO THE PHILIPS BENCH FOR ANALYSIS AND REPAIR. BASED ON THE  
INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM IS  
UNKNOWN, AS THE DEVICE WAS NOT RETURNED FOR REPAIR. THE REPORTED PROBLEM WAS  
CONFIRMED. BASED ON THE INFORMATION AVAILABLE AND RESULTS OF ADDITIONAL ANALYSIS, NO  
FURTHER ACTION IS NECESSARY AT THIS TIME. DUE TO THE LACK OF AVAILABLE INFORMATION, THE  
EXACT CAUSE FOR THE REPORTED ISSUE REMAINS UNKNOWN AND A MALFUNCTION OF THE DEVICE  
CANNOT BE RULED OUT. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT  
THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event522:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231017

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00571

mdr\_text.text:REPORTING INSTITUTION PHONE NUMBER: (B)(6). REPORTER PHONE NUMBER: (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT NO SOUND WAS COMING FROM THE INTELLIVUE MULTI MEASUREMENT SERVER X2 WHEN IT WAS DISCONNECTED FROM THE HOST MONITOR. THE DEVICE WAS NOT IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. THERE WAS NO PATIENT INVOLVEMENT.

PHILIPS RECEIVED A COMPLAINT ON AN INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT NO ALARM SOUNDS WERE TRIGGERED. THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED: THE PHILIPS FIELD SERVICE ENGINEER (FSE) SUGGESTED TO THE CUSTOMER THAT THE QRS TONE COULD HAVE BEEN SWITCHED OFF IN CONFIGURATION SETTINGS BUT FOUND NO FAULT IN THE CONFIGURATION. NO VISUAL DEFECT WAS DETECTED. THE FSE RECOMMENDED TO THE CUSTOMER TO SEND IN THE MONITOR FOR ANALYSIS AND REPAIR. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM IS UNKNOWN, AS THE DEVICE WAS NOT RETURNED FOR REPAIR. THE REPORTED PROBLEM WAS CONFIRMED. BASED ON THE INFORMATION AVAILABLE AND RESULTS OF ADDITIONAL ANALYSIS, NO FURTHER ACTION IS NECESSARY AT THIS TIME. DUE TO THE LACK OF AVAILABLE INFORMATION, THE EXACT CAUSE FOR THE REPORTED ISSUE REMAINS UNKNOWN AND A MALFUNCTION OF THE DEVICE CANNOT BE RULED OUT. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event523:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231027

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04044

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM) WHEN INITIATING A TRANSMISSION. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL AND THE BAR DID NOT APPEAR. THE PATIENT WAS REFERRED TO THE CLINIC. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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{{datachunk}}Event524:

adverse\_event\_flag:N

product\_problems:["Defective Alarm","No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231010

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP70

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00574

mdr\_text.text:THE CUSTOMER REPORTED THAT THE INTELLIVUE MP70 PATIENT MONITOR FAILED TO GENERATE AN ALARM. IT IS UNKNOWN WHETHER THE DEVICE WAS IN USE AT THE TIME OF THE REPORTED EVENT. NO DEATH OR PATIENT INJURY OR HARM WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MP70 INDICATING THAT THE MP70 DID NOT ALARM. A FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND FILED A PATIENT INCIDENT REPORT WITH PHILIPS. THROUGH THE FSE'S TESTING AND THE CUSTOMER'S OWN TESTING, THE ISSUE COULD NOT BE REPLICATED. THE DEVICE PASSED FUNCTIONAL CHECKS AND ALARMED AS INTENDED. THE CUSTOMER WAS ASKED FOR ADDITIONAL INFORMATION TO COMPLETE THE INVESTIGATION BUT ADVISED THAT THEY DID NOT WANT TO PURSUE THE ISSUE ANY FURTHER AND REQUESTED THE CASE BE CLOSED. THE CUSTOMER SEES THIS ISSUE AS RESOLVED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, PHILIPS WAS UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. BASED ON THE INFORMATION AVAILABLE AND RESULTS OF ADDITIONAL ANALYSIS, NO FURTHER ACTION IS NECESSARY AT THIS TIME. THE DEVICE WAS CONFIRMED TO BE

## DSI MAUDE Problems Summary

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OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. THE DEVICE REMAINS AT THE CUSTOMER SITE.

{{datachunk}}Event525:

adverse\_event\_flag:N

product\_problems:["Device Emits Odor"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:38 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00068

mdr\_text.text:IT WAS REPORTED THAT THE DEVICE SMELT LIKE SMOKE AND WAS NOT WORKING. THE DEVCIE WAS RETURNED FOR ENGINEERING INVESTIGATION. THE DEVICE WAS INVESTIGATED AND THE ENGINEERING EVALUATION CONFIRMED THE REPORTED ALLEGATION OF "BURNING SMELL"; HOWEVER, IT COULD NOT REPLICATE THE REPORTED ALLEGATION OF "NOT ABLE TO ACCESS FUNCTIONS". MONITOR WAS RESPONSIVE TO TOUCH STROKES, NO ISSUE WITH APPLICATION AND TOUCH SCREEN INTERFACE. THE USB-A TO USB-C CHARGE CORD WAS FOUND TO BE DEFECTIVE. THE MOST LIKELY ROOT CAUSE OF THE BURNING SMELL IS FROM AN ELECTRICAL FAULT WITHIN THE CORD RESULTING IN A DEFECTIVE USB-A TO USB-C MONITOR CHARGING CORD.

IT WAS REPORTED THAT THE MONTIOR HAS A BURNING SMELL AND THE MONITOR IS NOT WORKING. THERE WAS NO PATIENT HARM REPORTED. A REPLACEMENT MONITOR WAS SENT TO THE PATIANT. THE DEVICE RETURNED AND IT WAS CONFIRMED THAT THE BURNING SMELL WAS LIKELY DUE TO A ELECTRICAL FAULT DUE TO THE MONITOR CHARGING CORD.

{{datachunk}}Event526:

adverse\_event\_flag:N

product\_problems:["Melted","Overheating of Device"]

event\_type:Malfunction

date\_of\_event:20231022

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00069

mdr\_text.text:IT WAS REPORTED THAT THE DEVICE HOT TO THE TOUCH AND THE DEVICE AND CHARGER WERE MELTED SOME. THE DEVICE RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS ABLE TO CONFIRM THE REPORTED COMPLAINT OF "MONITOR PARTIALLY DAMAGED BY CHARGING". NO CHARGING CABLE WAS RETURNED FOR ROOT CAUSE INVESTIGATION. THE MOST LIKELY ROOT CAUSE OF THE REPORTED EVENT IS THE DUE TO AN ELECTRICAL FAULT WITHIN USB-A/USB-C CHARGING CORD.

IT WAS REPORTED THAT THE PATIENT WAS TAKING THE MONIOR OFF THE CHARGER AND THE MONITOR WAS HOT TO THE TOUCH AND THE CHARGER AND MONITOR WERE PARTICALLY MELTED. A REPLACEMENT MONITOR WAS NOT SENT AS THE PATIENT ENDED SERVICE EARLY. NO PATIENT HARM WAS REPORTED.

{{datachunk}}Event527:

adverse\_event\_flag:Y

product\_problems:["Biocompatibility"]

## DSI MAUDE Problems Summary

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event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:30 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Skin Inflammation/ Irritation"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00070

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT WAS EXPERIENCING SKIN IRRITATION UNDER THE PATCH. OTHER ELECTRODE OPTIONS WERE OFFERED TO THE PATIENT HOWEVER, THE PATIENT WANTED TO KEEP USING THE UNIVERSAL PATCH. THE PATIENT WAS PRESCRIBED A STEROID OINTMENT FOR THE SKIN IRRITATION AND CONTINUED WITH SERVICE.

IT WAS REPORTED THAT THE PATIENT EXPERIENCED AN ALLERGIC REACTION WHILE WEARING THE UNIVERSAL PATCH. THE UNIVERSAL PACTH WAS NOT RETURNED. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE ELECTRODE WAS NOT RETURNED. ALLEGATION IS CONFIRMED THROUGH THE NEED FOR A PRESCRIPTION AND IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARSII, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

{{datachunk}}Event528:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231009

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00843

mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT HE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE VENT OR HARM WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event529:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231012

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00848

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

BIOMED STATED THAT THEY ARE GETTING SPEAKER MALFUNCTION ON THE MX40, AND NO SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event530:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231019

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00849

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL WHEN THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM REPORTED.

{{datachunk}}Event531:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20231012

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP70

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

## DSI MAUDE Problems Summary

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report\_number:9610816-2023-00569

mdr\_text.text:THE CUSTOMER REPORTED MONITOR NEEDS TO BE ADJUSTED FOR ALARMING CORRECTLY. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

THE PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND FOUND THAT AT SOME POINT, THE MONITOR WAS PLACED INTO HOSPICE MODE (NO ALARMS). THE CUSTOMER WANTED ¿NORMAL¿ VITAL BEEPING. THE FSE WENT INTO THE CONFIGURATION MODE IN THE PROFILE SETTINGS AND RETURNED IT TO REGULAR SERVICE NOISES. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event532:

adverse\_event\_flag:Y

product\_problems:

event\_type:Injury

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Erythema","Hypersensitivity/Allergic reaction","Itching Sensation","Skin Inflammation/ Irritation"]

device.brand\_name:MINI HEART MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BOSTON SCIENTIFIC CARDIAC DIAGNOSTIC TECHNOLOGIES, INC.

report\_number:MW5147889

mdr\_text.text:PATIENT CALLED TO REPORT AN ADVERSE EVENT INVOLVING HER BOSTON SCIENTIFIC MINI HEART MONITOR. PATIENT STATED AFTER ABOUT 2 WEEKS OF USE, SHE STARTED ITCHING UNDER THE PAD. PATIENT STATED SHE CALLED THE MANUFACTURER AND WAS SENT ANOTHER PAD THAT WAS

## DSI MAUDE Problems Summary

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HYPOALLERGENIC. SHE SAID WHEN SHE REMOVED THE OLD PAD TO PUT ON THE NEW PAD, SHE NOTICED DRIED BLOOD AROUND THE PATCH. PATIENT SAID SHE CONTACTED THE MANUFACTURER AND WAS TOLD SHE WOULD RECEIVE A CALL BACK AND THAT SHE WAITED 3 DAYS AND NEVER HEARD FROM ANYONE. PATIENT SAID SHE DECIDED TO TAKE OFF THE MONITOR HERSELF BECAUSE OF THE IRRITATION AND FOUND BLEEDING SORES UNDER THE PATCH WITH BLOOD AROUND THE EDGES. PATIENT SAID HER SKIN WAS RAW AND RED. REFERENCE REPORT: MW5147890.

{{datachunk}}Event533:

adverse\_event\_flag:Y

product\_problems:

event\_type:Injury

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Hemorrhage/Blood Loss/Bleeding","Itching Sensation","Localized Skin Lesion","Skin Inflammation/ Irritation"]

device.brand\_name:MINI HEART MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BOSTON SCIENTIFIC CARDIAC DIAGNOSTIC TECHNOLOGIES, INC.

report\_number:MW5147890

mdr\_text.text:PATIENT CALLED TO REPORT AN ADVERSE EVENT INVOLVING HER BOSTON SCIENTIFIC MINI HEART MONITOR. PATIENT STATED AFTER ABOUT 2 WEEKS OF USE, SHE STARTED ITCHING UNDER THE PAD. PATIENT STATED SHE CALLED THE MANUFACTURER AND WAS SENT ANOTHER PAD THAT WAS HYPOALLERGENIC. SHE SAID WHEN SHE REMOVED THE OLD PAD TO PUT ON THE NEW PAD, SHE NOTICED DRIED BLOOD AROUND THE PATCH. PATIENT SAID SHE CONTACTED THE MANUFACTURER AND WAS TOLD SHE WOULD RECEIVE A CALL BACK AND THAT SHE WAITED 3 DAYS AND NEVER HEARD FROM ANYONE. PATIENT SAID SHE DECIDED TO TAKE OFF THE MONITOR HERSELF BECAUSE OF THE IRRITATION AND FOUND BLEEDING SORES UNDER THE PATCH WITH BLOOD AROUND THE EDGES.

PATIENT SAID HER SKIN WAS RAW AND RED. REFERENCE REPORT MW5147889.

{{datachunk}}Event534:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20220909

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03994

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON A TACHYCARDIA EPISODE. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED UNDERSENSING ON PAUSE AND BRADYCARDIA EPISODES. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT DID NOT GENERATE ON THE NETWORK AND HAD TO BE RETRIEVED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT.

## DSI MAUDE Problems Summary

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IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event535:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230929

event\_location:

remedial\_action:[""]

patient.patient\_age:94 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03998

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE

## DSI MAUDE Problems Summary

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EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED LOSS OF R WAVE SENSED SIGNAL ON A PAUSE EPISODE. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT INTERROGATED BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event536:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231018

event\_location:

remedial\_action:[""]

patient.patient\_age:42 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04002

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD A TELEMETRY ISSUE WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. CALLER WAS REFERRED TO CLINIC AND ADVISED TO BRING THE REMOTE MONITOR. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event537:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:20231018

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-07147

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD TELEMETRY ISSUE WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event538:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231024

event\_location:

remedial\_action:[""]

patient.patient\_age:59 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04003

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD A TELEMETRY ISSUE WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS REFERRED TO THE CLINIC. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event539:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-04006

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. ELECTROMAGNETIC INTERFERENCE WAS REMOVED BUT STILL THE SAME ISSUE. THE PATIENT WAS REFERRED TO THE CLINIC. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event540:

adverse\_event\_flag:Y

product\_problems:["Overheating of Device"]

event\_type:Injury

date\_of\_event:20231012

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Burn(s)"]

device.brand\_name:INTELLIVUE NMT MODULE

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00564

mdr\_text.text:THE CLINICAL APPLICATION SPECIALIST (CAS) SPOKE TO THE CUSTOMER, AND THE CUSTOMER STATED THAT THE SITE WAS ROTATED, AND ELECTRODES WERE CHANGED. A PHILIPS FIELD SERVICE ENGINEER (FSE) WAS DISPATCHED TO PERFORM TESTING ON THE DEVICE. THE FSE VISITED THE SITE TWO TIMES, AND AFTER TALKING TO CLINICAL ENGINEERS AND THE CUSTOMERS BIOMEDICAL MANAGEMENT, THE FSE WAS TOLD THAT AT THIS POINT, THERE IS NO ACTION NEEDED FROM THE PHILIPS TEAM REGARDING PATIENT INJURY INVESTIGATION. THE CUSTOMER SITE ADVISED THAT THEY ARE DOING THEIR OWN INVESTIGATION AND WILL REACH OUT TO THE PHILIPS TEAM IF NEEDED. H3 OTHER TEXT : CUSTOMER REFUSES INVESTIGATION OF DEVICE

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THE PATIENT DEVELOPED A BURN AT THE NMT ELECTRODE SITE, POSSIBLY FROM THE MODULE TEMPERATURE BEING SET TOO HIGH.

{{datachunk}}Event541:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231012

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00563

mdr\_text.text:A GOOD FAITH EFFORT (GFE) CONDUCTED WAS NOT ABLE TO CONFIRM IS THERE WAS SOUND ON THE DEVICE AS THE CUSTOMER DID NOT RESPOND TO REQUESTS FOR ADDITIONAL INFORMATION. A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THE SPEAKER FAILURE. THE RSE DETERMINED THAT PART LOUDSPEAKER NEEDED TO BE REPLACED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. H3 OTHER TEXT : DEVICE NOT RETURNED.

IT WAS REPORTED THE INTELLIVUE MX800 MONITOR IS GETTING A SPEAKER MALFUNCTION INOP ERROR MESSAGE. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event542:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20231009

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00565

mdr\_text.text:A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER. THE RSE INFORMED THE CUSTOMER THAT THE SITUATION DESCRIBED SOUNDS LIKE AN UNDESIRABLE SETTING ON THE AFFECTED HOST MONITOR, WHICH CAUSES THE SETTINGS TO BE ADOPTED BY THE PARAMETER SERVER. AN EMAIL WAS SENT TO THE CUSTOMER REGARDING THE TRANSPORT CONCEPT, INFORMING THE CUSTOMER THAT THE SETTING SHOULD BE CHECKED AND HOW TO DO THIS. A GOOD FAITH EFFORT (GFE) WAS MADE TO OBTAIN FURTHER DETAILS OF THE ISSUE AND THE RESOLUTION, BUT NO RESPONSE WAS RECEIVED. BASED ON THE AVAILABLE INFORMATION, THE EXACT CAUSE FOR THE REPORTED ISSUE COULD NOT BE ESTABLISHED.

IT WAS REPORTED THAT ALARMS WERE TURNED OFF AFTER TRANSPORT. SPO2 AND TEMP WERE SWITCHED OFF AFTER THE X2 WAS REATTACHED TO THE DOCKING STATION. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

IT WAS REPORTED THAT ALARMS WERE TURNED OFF AFTER TRANSPORT. SPO2 AND TEMP WERE SWITCHED OFF AFTER THE X2 WAS REATTACHED TO THE DOCKING STATION. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event543:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231011

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00841

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THERE WAS NO SPEAKER SOUND AT START UP TEST, DUE TO A DEFECTIVE SPEAKER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE.

{{datachunk}}Event544:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231012

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI



## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00844

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER WAS DEFECTIVE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event545:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231028

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06985

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE

EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING R-WAVES OR PREMATURE VENTRICULAR CONTRACTIONS (PVC)'S WHICH RESULTED IN FALSE PAUSE EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event546:

adverse\_event\_flag:N

product\_problems:["Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20231030

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06991

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS INTERROGATED BUT NO EPISODES WERE RECORDED DUE TO A SUSPECTED SENSING FAILURE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event547:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231010

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00837

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND AT START UP TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event548:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20231030

event\_location:

remedial\_action:[""]

patient.patient\_age:64 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03954

mdr\_text.text:B3: DATE IS APPROXIMATE. MONTH AND YEAR ARE CONFIRMED VALID. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE PHYSICIAN INTENDED TO REMOVE THE IMPLANTABLE CARDIAC MONITOR (ICM) AS IT HAD REACHED END OF SERVICE (EOS), HOWEVER THE DEVICE COULD NOT BE FOUND. IT WAS CONFIRMED THAT THE DEVICE WAS STILL TRANSMITTING SO THE DEVICE WAS STILL IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event549:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231011

event\_location:

remedial\_action:[""]

patient.patient\_age:46 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03960

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) COULD NOT BE LOCATED WITH THE REMOTE MONITOR AND WAS UNABLE TO ESTABLISH TELEMETRY. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event550:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231030

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00840

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED AUDIBLE SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS UNKNOWN. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING AS SPEAKER PRODUCED AUDIBLE SOUND, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) REPORTED THE SPEAKER IS NOT WORKING/NOT CONNECTING. THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event551:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231026

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:90 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06951

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO



## DSI MAUDE Problems Summary

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THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE PAUSE EPISODES DUE TO UNDERSENSING AND LOSS OF SIGNAL. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event552:

adverse\_event\_flag:N

product\_problems:["Display or Visual Feedback Problem"]

event\_type:Malfunction

date\_of\_event:20231020

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2023-00831

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM AS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THE SPEAKER WAS NOT WORKING AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THE TOUCHSCREEN IS NOT WORKING. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event553:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230129

event\_location:

remedial\_action:[""]

patient.patient\_age:83 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03914

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER NOTED THAT THE EVENT COUNTERS WERE EQUAL TO THE LIFETIME COUNTERS. THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event554:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231024

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03915

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR UNDERSENSING. IT WAS FURTHER REPORTED THAT THE REPORT LAST CLEARED GOES BACK TO THE DATE OF IMPLANT DESPITE CLEARING THE DEVICE. THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event555:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20231025

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06902

mdr\_text.text:IT WAS IDENTIFIED DURING AN INTERNAL DATA REVIEW THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event556:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:Y

product\_problems:["Migration or Expulsion of Device"]

event\_type:Injury

date\_of\_event:20230916

event\_location:

remedial\_action:[""]

patient.patient\_age:79 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Wound Dehiscence","Pain"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06909

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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REFERENCE REPORT: (B)(4). MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT IMMEDIATELY AFTER THE IMPLANT PROCEDURE THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT FELL FROM THE CART TO THE FLOOR ON THE OPPOSITE SIDE THAT THE DEVICE WAS PLACED. THE PATIENT FELT A STRONG JARRING DUE TO THE FALL. IT WAS NOTED A FEW DAYS LATER THAT THE PATIENT EXPERIENCED A LUMP AND PAIN AT THE INCISION SITE. IT WAS FOUND THAT THE ICM WAS PARTIALLY EXPOSED THOROUGH THE CHEST, WOUND DEHISCENCE WITH NO DRAINAGE OR BLEEDING. THE ICM WAS REMOVED AND DISPOSED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event557:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231020

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:4003409

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00830

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER BIOMED REPORTED THAT THE FRONT BEZEL IS BROKEN, THERE ARE NO SOUNDS COMING FROM THE DEVICE DURING BOOTUP, AND THE TOUCHSCREEN IS INTERMITTENT. THE DEVICE IS PENDING BENCH REPAIR. THE DEVICE WAS NOT IN USE.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event558:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231006

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:



## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00557

mdr\_text.text:THE CUSTOMER REPORTED LOUDSPEAKER ERROR. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

A PHILIPS BENCH REPAIR TECHNICIAN (BRT) EVALUATED THE DEVICE AND CONFIRMED THE ISSUE. THE BRT DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. THE SPEAKER WAS DETERMINED TO HAVE CAUSED THE REPORTED PROBLEM. REPLACING THE SPEAKER RESOLVED THE ISSUE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THERE WAS A LOUDSPEAKER ERROR. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED. IT WAS DETERMINED THAT THE DEVICE FAILED TO MEET SPECIFICATIONS.

{{datachunk}}Event559:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231013

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00558

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MP5 INDICATING THAT THE SPEAKER DID NOT WORK AND THE DEVICE WAS UNABLE TO PRODUCE SOUND. A PHILIPS REMOTE SERVICE ENGINEER SPOKE TO THE CUSTOMER BIOMED AND CONFIRMED THE REPORTED ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE CUSTOMER WAS PROVIDED WITH THE PART NUMBER FOR A REPLACEMENT SPEAKER ASSEMBLY. THE CUSTOMER HAS ORDERED THE PART TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. THE DEVICE REMAINS AT THE CUSTOMER SITE.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION ON THE INTELLIVUE MP5 PATIENT MONITOR. NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. THERE WAS NO PATIENT INVOLVEMENT AND NO ADVERSE EVENT.

{{datachunk}}Event560:

adverse\_event\_flag:N

product\_problems:["Melted","Temperature Problem"]

event\_type:Malfunction

date\_of\_event:20230920

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00065

mdr\_text.text:IT WAS REPORTED THE MONITOR CHARGING PORT WAS MELTED AND THE MONITOR WAS NOT WORKING. THE MONITOR AND CHARGER CORD WAS RETURNED FOR INVESTIGATION. BOM: (B)(4), PRODUCT MODEL: UNIT, C6M, A13, V, SERIAL NUMBER: (B)(6) IS NOT LIKELY THE ROOT CAUSE OF THIS ALLEGATION. PRODUCT INFORMATION UPDATED TO CHARGE CORD, RED FOR A10E PHONE. OVERHEATING AND MELTING OF THE CHARGE CABLE IS A KNOWN PRODUCT DEFECT AND PHILIP'S AM&D IS DOING FURTHER INVESTIGATING.

IT WAS REPORTED THAT THE PATIENT'S DAUGHTER CALLED AND STATED THAT C6 MONITOR CHARGING PORT HAD MELTED AND THE MONITOR IS NO LONGER WORKING. THE DEVICE WAS RETURNED AND A REPLACEMENT WAS NOT SENT. THERE WAS NO REPORT OF PATIENT HARM OR INJURY.

{{datachunk}}Event561:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231006

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00832

## DSI MAUDE Problems Summary

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mdr\_text.text:PHILIPS RECEIVED A COMPLAINT THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE IS READING SPEAKER MALFUNCTION. THE DEVICE WAS TESTED AND NO AUDIBLE SOUND WAS EMITTED FROM THE DEVICE, CONFIRMING THE SPEAKER MALFUNCTION AS REPORTED. THE DEVICE FAILED TO WORK AS INTENDED AND WAS CAUSED BY A MALFUNCTION OF THE DEVICE SPEAKER ASSEMBLY. THE SPEAKER ASSEMBLY WAS REPLACED AND FOLLOWING OPERATIONAL TESTS, THE DEVICE WAS RETURNED TO THE CUSTOMER. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THE UNIT IS READING SPEAKER MALFUNCTION. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event562:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20231022

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06931

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY

## DSI MAUDE Problems Summary

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PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE EPISODES DUE TO OVERSENSING. THE ICM REMAINS IN SUE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event563:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm","Alarm Not Visible"]

event\_type:Malfunction

date\_of\_event:20231002

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00834

mdr\_text.text:A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT TO THE CUSTOMER SITE AND DETERMINED THE ISSUE WAS RELATED TO SOFTWARE DEFECTS. THE FSE UPGRADED THE MX40 TO RESOLVE THE REPORTED ISSUE. THE DEVICE REMAINS AT THE CUSTOMER SITE.

A PHILIPS FIELD SERVICE ENGINEER (FSE) REPORTED ON BEHALF OF THE CUSTOMER THAT AUDIBLE AND VISUAL NOTIFICATIONS ARE AFFECTED DUE TO BATTERY CONSUMPTION. THE FSE UPGRADED THE SOFTWARE AND CONFIRMED THE UNIT IS WORKING PROPERLY. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

A PHILIPS FIELD SERVICE ENGINEER (FSE) REPORTED ON BEHALF OF THE CUSTOMER THAT AUDIBLE AND VISUAL NOTIFICATIONS ARE AFFECTED DUE TO BATTERY CONSUMPTION. THE FSE UPGRADED THE SOFTWARE AND CONFIRMED THE UNIT IS WORKING PROPERLY. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

{{datachunk}}Event564:

adverse\_event\_flag:N

product\_problems:["Melted","Temperature Problem"]

event\_type:Malfunction

date\_of\_event:20231019

event\_location:

remedial\_action:[""]

patient.patient\_age:61 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00067

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT WENT TO CHARGE THEIR MONITOR AND THE MONITOR CHARGER STARTED SMOKING. THE MONITOR AND CHARGING CORD WERE RETURNED FOR INVESTIGATION. BOM: 02-01894, PRODUCT MODEL: UNIT, C6M, A10E, U, SERIAL NUMBER: (B)(6) IS NOT LIKELY THE ROOT CAUSE OF THIS ALLEGATION. PRODUCT INFORMATION UPDATED TO CHARGE CORD, RED FOR A10E PHONE. OVERHEATING AND MELTING OF THE CHARGE CABLE IS A KNOWN PRODUCT DEFECT AND PHILIP'S AM&D IS DOING FURTHER INVESTIGATION.

THE PATIENT REPORTED THAT THEY WENT TO CHARGE THEIR C6 MONITOR AND IT STARTED SMOKING. THE PATIENT IMMEDIATELY AND WAS ADVISED BY HER PHYSICIAN TO CALL AND GET A REPLACEMENT MONITOR AND CHARGER. NOTHING WAS DAMAGED BY THE SMOKING MONITOR AND THE PATINET WAS NOT INJURED. A REPLACEMENT MONITOR AND CHARGER WAS SENT TO THE PATIENT.

{{datachunk}}Event565:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20231003

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP70

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00552

## DSI MAUDE Problems Summary

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mdr\_text.text:THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND FILED A PATIENT INCIDENT REPORT WITH PHILIPS. THE PHOTOS AND LOGS WERE TAKEN FOR ESCALATION. WHEN THE PROVIDED LOGS AND PHOTOS WERE PROVIDED FOR ESCALATION, THE PRODUCT SUPPORT ENGINEER (PSE) ADVISED THERE WAS NOT SUFFICIENT INFORMATION TO COMPLETE THE INVESTIGATION. THE CUSTOMER WAS ASKED FOR ADDITIONAL INFORMATION TO COMPLETE THE INVESTIGATION BUT ADVISED THAT THEY DID NOT WANT TO PURSUE THE ISSUE ANY FURTHER AND REQUESTED THE CASE BE CLOSED. THROUGH THE FSE'S TESTING AND THEIR OWN TESTING, THE ISSUE COULD NOT BE REPLICATED. THE DEVICES PASSED FUNCTIONAL CHECKS AND ALARM AS INTENDED. THE CUSTOMER SEES THIS ISSUE AS RESOLVED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED.

IT WAS REPORTED THE INTELLIVUE MP70 DID NOT ALARM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED THE INTELLIVUE MP70 DID NOT ALARM. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event566:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231003

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI



## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00554

mdr\_text.text:THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) PERFORMED TROUBLE SHOOTING AS ADVISED BY THE PHILIPS RSE. TROUBLESHOOTING ESTABLISHED THE SPEAKER MALFUNCTION ERROR WAS EITHER THE MX700 OR X2. THE BIOMED STOPPED FURTHER TROUBLESHOOTING AND REQUESTED TO CLOSE THE CASE. NO FURTHER INFORMATION PROVIDED. THE PHILIPS RSE PROVIDED THEIR ANALYSIS FINDINGS HOWEVER WE ARE UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE BECAUSE THE CUSTOMER REJECTED FURTHER REMOTE TROUBLESHOOTING. THE CUSTOMER REQUESTED THE CASE BE CLOSED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED AND THERE WAS NO AUDIBLE ALERT COMING FROM THE DEVICE.

{{datachunk}}Event567:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231018

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 2.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00823

## DSI MAUDE Problems Summary

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mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. FUNCTIONAL TESTS WERE PERFORMED AND IT WAS DETERMINED THE SPEAKER DID PRODUCE AUDIBLE SOUND. THE CUSTOMER'S REPORTED PROBLEM COULD NOT BE CONFIRMED. A REPLACEMENT DEVICE WAS SHIPPED TO THE CUSTOMER.

THE CUSTOMER REPORTED THAT THERE WAS A SPEAKER MALFUNCTION. IT IS UNKNOWN IF THE UNIT WAS IN CLINICAL USE OR NOT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THE CUSTOMER REPORTED THAT THERE WAS A SPEAKER MALFUNCTION. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THE WORK ORDER (B)(4) INDICATES A MATERIAL ONLY WAS REQUIRED TO RESOLVE THE REPORTED PROBLEM. THE FAULTY UNIT WAS REPLACED WITH PART NO (453564262531),TELE MX40, 2.4 GHZ, ECG ONLY. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED. A REPLACEMENT UNIT ( MX40, 2.4 GHZ, ECG.) WAS SHIPPED TO THE CUSTOMER. WE WILL CONSIDER THAT THE CUSTOMER RESOLVED THE ISSUE USING THE REPLACEMENT FROM PHILIPS. AND THE DEVICE REMAINS IN USE AT THE CUSTOMER SITE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. PHONE NUMBER PROVIDED: (B)(6).

{{datachunk}}Event568:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231017

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00822

mdr\_text.text:NO FUNCTIONAL TESTING WAS PERFORMED, THE DEVICE WILL NOT BE EVALUATED BY THE PHILIPS AUTHORIZED REPAIR FACILITY. BASED ON THE INFORMATION AVAILABLE THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. H3 OTHER TEXT : DEVICE WAS NOT RETURNED FOR EVALUATION AND THE CUSTOMER WAS SENT A REPLACEMENT DEVICE.

THE CUSTOMER REPORTED THAT THERE WAS NO SOUND COMING FROM THE SPEAKER THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event569:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231018

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00825

## DSI MAUDE Problems Summary

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mdr\_text.text:THE FIELD ENGINEER RECEIVED THE EXCHANGED PART. THE UNIT TRANSFER LICENSES AND CONFIGURATION WAS DONE, THE INSPECTION AND THE RECOMMENDED MANUFACTURE T&V TEST PASSED. CONSUMED PARTS ORDERED IS ((B)(4)) AGAINST WORK ORDER - (B)(4) DELIVERED ON WORK ORDER (B)(4). BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED. BASED ON THE FINDINGS PROVIDED IN THE CASE, A REPLACEMENT WAS ORDERED AND SHIPPED TO THE CUSTOMER SITE. THE REPORTS VERIFIES DEVICE IS RESTORED AND WORKING PROPERLY. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE DEVICE SPEAKER WILL NOT SOUND FOR AN ALARM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event570:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231016

event\_location:

remedial\_action:[""]

patient.patient\_age:45 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03879

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED A TACHYCARDIA EPISODE WHICH HAD SOME ARTIFACT/NOISE PRESENT ALONG WITH UNDERSENSING OF TRUE VENTRICULAR COMPLEXES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event571:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230704

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06853

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED PAUSE EPISODES WHICH APPEARED TO BE UNDERSENSING. IT WAS FURTHER REPORTED THAT THE COUNTERS WENT BACK TO THE DATE OF IMPLANT DESPITE HISTORICAL CLEARING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event572:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20231009

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Infection"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03887

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED AN INFECTION. THE ICM WAS EXPLANTED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS

REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event573:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231007

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI



## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00551

mdr\_text.text:E1; REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6). A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND CONFIRMED THE PROBLEM. THE FSE REPLACED THE SPEAKER TO RESOLVE THE ISSUE. ILLANCE AND RISK MANAGEMENT PROCESSES. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED SPEAKER FAILURE. THERE WAS NO SOUND. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event574:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231023

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00816

mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) REPORTED THAT WHEN THE MX40 POWERS ON, AN ERROR OF "SPEAKER MALFUNCTION" APPEARS ON THE SCREEN. THE BIOMED CONFIRMED THAT WHEN THE MX40 IS TURNED ON, NO SOUND CAN BE HEARD FROM THE MODULE'S SPEAKER. THE BIOMED

## DSI MAUDE Problems Summary

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WOULD LIKE TO SEND TO THE PHILIPS REPAIR BENCH FOR REPAIR. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event575:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Death

date\_of\_event:20230518

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest"]

device.brand\_name:MX40 PATIENT WEARABLE MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00818

mdr\_text.text:THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED: THE PHILIPS REMOTE SERVICE ENGINEER (RSE) EXTRACTED AND ANALYZED THE LOGS, AND THE DEVICE WAS WORKING AS DESIGNED. THE COMPLAINT WAS ESCALATED TO THE PRODUCT SUPPORT ENGINEER (PSE) FOR TECHNICAL

## DSI MAUDE Problems Summary

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INVESTIGATION AND THE RESULTS INDICATE FOR TIMEPOINT OF (B)(6) 2023 AT AROUND 04:30 A.M., THE TEL11 OF BED LABEL 441 HAD CARDIAC ALERTS WHICH WERE SILENCED AT THE PATIENT INFORMATION CENTER IX (PIC IX). THE MX40 WAS ASSOCIATED TO THE PICIX FROM 03:52 A.M. UNTIL 07:10. MX40 WAS SENDING ALARMS TO THE PIC IX UNTIL AN ECG LEADS OFF CONDITION OCCURRED. THE AUDIT LOG SHOWS THAT PREMATURE VENTRICULAR CONTRACTION (PVC) ALARMS WERE BEING PROVIDED UNTIL THE ECG LEADS OFF CONDITION OCCURRED. ALSO NOTE THAT ECG LEADS OFF WAS SET AS A !!! RED TECHNICAL INOP ALARM. NO FURTHER ECG RELATED PHYSIOLOGICAL ALARMS WOULD BE PROVIDED UNTIL THE ECG LEADS OFF CONDITION WAS RESOLVED. THE MX40 WAS FUNCTIONING AS INTENDED. THE REPORTED PROBLEM WAS NOT CONFIRMED. INFORMATION WAS PROVIDED TO THE CUSTOMER TO RESOLVE THE ISSUE.

THE CUSTOMER REPORTED THE DEATH OF A 68-YEAR-OLD POST-OP REPAIR/REPLACEMENT OF AN ASCENDING AORTIC ANEURYSM. THE SURGERY TOOK PLACE ON (B)(6) 2023, THE PATIENT WAS ADMITTED TO THE INTENSIVE CARE UNIT (ICU) THEREAFTER AND ON (B)(6) 2023, THE PATIENT STARTED TO EXPERIENCE NAUSEA, VOMITING AND FEVER, ALTHOUGH HEMODYNAMICS WERE REPORTEDLY STILL STABLE. AT APPROXIMATELY 04:00 ON (B)(6) 2023, THE NURSE NOTICED ABNORMAL TRACE ON THE CENTRAL STATION AND SUBSEQUENTLY WENT TO THE PATIENT'S ROOM AND FOUND THE PATIENT IN CARDIAC ARREST. THE ON-CALL RESUSCITATOR WAS CALLED BUT UNFORTUNATELY THE PATIENT WAS DECLARED DEAD AT 06:00. THE PATIENT INFORMATION CENTER IX, CATALOG ITEM 866389, SERIAL NUMBER (B)(6), IN USE DURING THIS EVENT WAS REPORTED IN MFR REPORT NUMBER 1218950-2023-00417.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event576:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20231004

event\_location:

remedial\_action:[""]

patient.patient\_age:83 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["Unspecified Infection"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03856

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED AN INFECTION AT THE INCISION SITE. IT WAS FURTHER REPORTED THAT THERE WAS A SORE/SMALL WOUND NOTED OVER THE DEVICE. THE ICM WAS REMOVED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event577:

adverse\_event\_flag:Y

product\_problems:["Unable to Obtain Readings"]

event\_type:Injury

date\_of\_event:20231018

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Arrhythmia","Insufficient Information"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00545

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2, SERIAL NUMBER UNKNOWN. ON (B)(6) 2023, AT 9:16 AM IN ROOM 5 OF THE EMERGENCY DEPARTMENT (B)(6), A PATIENT WAS BEING MONITORED VIA X2 CONNECTED TO AN INTELLIVUE MX450 PATIENT MONITOR WITH ECG AND SPO2. PARAMETERS SUCH AS SPO2 CAME THROUGH, HOWEVER, THE ECG DID NOT AND GAVE A FLAT LINE. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE EVENT. FORTUNATELY, THE PATIENT DID NOT DIE DUE TO APPROPRIATE ACTIONS BY THE NURSE (A DEFIBRILLATOR WAS CONNECTED TO MONITOR THE RHYTHM). WHEN THE DEFIBRILLATOR WAS CONNECTED, THE PATIENT TURNED OUT TO HAVE A LIFE-THREATENING CARDIAC ARRHYTHMIA, WHICH HAD NOT BEEN DETECTED BY THE X2. THE PATIENT WAS THEN TRANSFERRED TO ROOM 2 FOR FURTHER MONITORING. A PHILIPS CLINICAL APPLICATION SPECIALIST (CAS) WENT ONSITE TO COLLECT ADDITIONAL INFORMATION ABOUT THE CASE. THE CAS REPORTED THAT ON OCTOBER 11TH, 2023, THE MX450 MONITORS IN THE ER WERE UPGRADED TO SOFTWARE REV P.01.01. THE X2 MONITORS HAD TO BE UPDATED TO REV M.04.05 SOFTWARE TO BE COMPATIBLE WITH THE NEWLY UPGRADED MX450 MONITORS. EVER SINCE THE UPGRADE, THERE HAVE BEEN OBSERVATIONS OF FAILED ECG DURING MONITORING, RESULTING IN IMPROPER MONITORING OF THE PATIENT. THE ISSUES ONLY OCCURRED WHEN THE X2 WAS USED IN COMBINATION WITH THE MX450. THE CAS RETRIEVED THE DEVICE STRIP LOGS FROM THE CUSTOMER TO BE EVALUATED BY A PHILIPS PRODUCT SUPPORT ENGINEER (PSE). THE PHILIPS PSE EVALUATED THE DEVICE STRIPS AND DISCOVERED THE ECG STRIP REPORT SHOWED BOTH THE ECG AND THE RESPIRATION MEASUREMENT WERE IN INOP CONDITION, WHICH MEANT NO PHYSIOLOGICAL ALARM CAN BE GENERATED BY THE MONITOR. THE ALARM LOG DOCUMENTED INOP CONDITIONS IN THE ECG PARAMETER FOR BOTH BEDS AT THE TIME OF THE EVENT ((B)(6) 2023 @ ~09:00). PHILIPS HAD INVESTIGATED THE ¿LEADS OFF¿ CONDITION WITH THE X2 HARDWARE IN 2016. BASED ON INVESTIGATIONS AT SEVERAL CUSTOMER SITES, LIQUID CAN ENTER THE ECG CABLE WHEN THE CABLES ARE OFF A PATIENT AND CLEANED, OR IF THEY COME IN CONTACT WITH FLUIDS WHEN THEY ARE CONNECTED TO A PATIENT. LIQUID THAT ENTERS THE CABLES MAY CAUSE A CONDUCTIVE

## DSI MAUDE Problems Summary

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CONNECTION BETWEEN THE LEAD AND CABLE SHIELD, REFERRED TO AS "SHUNT IMPEDANCE". THE SHUNT IMPEDANCES BETWEEN CONDUCTORS AND SHIELD INSIDE THE CABLE ARE CAUSED BY CONDUCTIVE LIQUIDS ENTERING THE ELECTRODE CONNECTORS (GRABBERS OR SNAPS) OR THE CONNECTORS BETWEEN LEAD SETS AND THE TRUNK CABLE. IN COMBINATION WITH THE NORMAL SERIES RESISTANCE OF THE CABLE ITSELF, A POOR ELECTRODE-TO-SKIN CONTACT AND/OR POOR ELECTRODES WITH A RELATIVE HIGH DC-OFFSET VOLTAGE, THE ECG SIGNAL MIGHT GET LOST RESULTING IN A ¿LEADS OFF¿ INOP. BASED ON THESE FINDINGS, ECG CABLES WERE IMPROVED AT THE GRABBER SIDE TO BE LESS SENSITIVE TO FLUID INGRESS. ALSO, AN ECG FIRMWARE UPDATE HAD BEEN INTRODUCED TO BE MORE TOLERANT IN TERMS OF SHUNT IMPEDANCE CAUSED BY FLUID INGRESS IN THE ECG CABLE. IN CONCLUSION, THE ECG EXAMPLE PREVIOUSLY MENTIONED ABOVE APPEARS TO BE THE RESULT OF A COMPROMISED ECG CABLES THAT WERE BEING USED. BASED ON THE INFORMATION AVAILABLE AND THE DEVICE LOGS PROVIDED, THE CAUSE OF THE REPORTED PROBLEM WAS DUE TO THE CUSTOMER NEGLIGENCE TO OBSERVE PHILIPS SERVICE BULLETIN SB86202447A. THE SERVICE BULLETIN SB86202447A POINTS TO A FIRMWARE UPDATE E.01.22, TO FIX ISSUES INVOLVING FAILED ECG DURING MONITORING AND COUNTERACTS HAPPENINGS THAT MAY OCCUR WITH ECG CABLES PARTICULARLY FLUID INGRESS. THE X2 WAS OPERATING ON SOFTWARE M.04.05 AND NOT THE LATEST FIRMWARE VERSION E.01.22. THE PSE ADVISED THE CUSTOMER TO CHECK ALL OTHER X2'S IN THIS DEPARTMENT FOR THE LAST FW VERSION OF THE ECG MEASUREMENT. FURTHERMORE, THE CLINICIANS WERE INSTRUCTED TO CAREFULLY CHECK THEIR ECG ACCESSORIES, ESP. TRUNK CABLE AND LEAD SET FOR OBVIOUS DAMAGE AND MOISTURE RESIDUALS AT ELECTRIC CONNECTORS BEFORE EACH USE. AFTER CLEANING CABLES, ONLY COMPLETELY DRIED CABLES SHOULD BE USED ON THE PATIENT; NEVER IMMERSE CABLES INTO CLEANING/DISINFECTION AGENT. BASED ON THE INFORMATION IN THE CASE AND THE DEVICE LOGS PROVIDED, THE PSE CONCLUDED THIS EVENT WAS A RESULT OF A COMPROMISED ECG CABLE THAT WAS BEING USED. COMPROMISED CABLES WOULD GIVE POOR SKIN CONTACT AND/OR POOR ELECTRODES WITH A RELATIVELY HIGH DC-OFFSET VOLTAGE; AS A RESULT, PRODUCING THE ECG SIGNAL TO GET LOST, RESULTING IN A ¿LEADS OFF¿ INOP. IF THE CUSTOMER HAD THE LATEST VERSION E.01.22 INSTALLED ON THE X2 MONITOR, THERE WOULD NOT HAVE BEEN ANY ISSUES WITH THE ECG MONITORING. THE ECG FIRMWARE UPDATE HAD BEEN INTRODUCED TO BE MORE TOLERANT IN TERMS OF SHUNT IMPEDANCE CAUSED BY FLUID INGRESS IN THE ECG CABLE. FURTHERMORE, THE PSE'S REPORT CONCLUDES THAT THESE ECG FAILURES WERE NOT RELATED TO THE UPDATE OF THE X2'S THE CUSTOMER HAD DONE. THE PSE REFERENCED THE SERVICE BULLETIN SB86202447A FOR FURTHER DETAILS REGARDING THE ECG FIRMWARE UPDATE. THE CAS WILL BE UPGRADING THE ECG FIRMWARE ON THE X2¿S FOR THE WHOLE DEPARTMENT. THE DEVICE REMAINS AT THE CUSTOMER SITE. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED.

REPORTING INSTITUTION PHONE NUMBER: (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MULTI MEASUREMENT SERVER X2 FAILED TO MEASURE ECG, RESULTING IN THE FLATLINING OF THE ECG WAVEFORM, ON (B)(6) 2023 AT 9:16 A.M. FOR A PATIENT IN THE EMERGENCY DEPARTMENT. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED EVENT. THE PATIENT PASSED AWAY.

## DSI MAUDE Problems Summary

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DURING THE INVESTIGATION IT WAS CONFIRMED THAT THE PATIENT HAD A LIFE-THREATENING ARRHYTHMIA EVENT, BUT SURVIVED. THE INVESTIGATION IS ONGOING.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MULTI MEASUREMENT SERVER X2 FAILED TO MEASURE ECG, RESULTING IN THE FLATLINING OF THE ECG WAVEFORM, ON (B)(6) 2023 AT 9:16 A.M. FOR A PATIENT IN THE EMERGENCY DEPARTMENT. THE PATIENT HAD A LIFE-THREATENING CARDIAC ARRHYTHMIA, BUT SURVIVED.

{{datachunk}}Event578:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20231024

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06796

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS INTERROGATED WITH A DIAGNOSTIC MOBILE PROGRAMMER APPLICATION AND 'INPUT INVALID' ERROR MESSAGES WERE DISPLAYED HENCE, THE OPERATION COULD NOT BE COMPLETE. THE APPLICATION WAS ERASED AND THE ICM WAS RE-INTERROGATED WHICH RESULTED IN AN ELECTRICAL RESET. THE RESET DISPLAY WAS CLEARED AND EPISODES ANALYSIS WAS PERFORMED AS EXPECTED. IT WAS NOTED THAT ON CHECKING THE PARAMETERS SCREEN THEREAFTER, FURTHER 'INPUT INVALID' ERROR MESSAGES WERE DISPLAYED. THE ICM REMAINS IN USE. THE DIAGNOSTIC MOBILE PROGRAMMER APPLICATION REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF

THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event579:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate","Battery Problem","Reset Problem"]

event\_type:Malfunction

date\_of\_event:20231025

event\_location:

remedial\_action:[""]

patient.patient\_age:62 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ



## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03865

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. ANALYSIS OF THE RETURNED DEVICE WAS INCONCLUSIVE. HYBRID ANALYSIS REVEALED THAT THE CAUSE OF THE REPORTED NO-TELEMETRY CONDITION WAS BATTERY DEPLETION BELOW THE OPERATING THRESHOLD OF THE DEVICE. A HIGH CURRENT CONDITION WAS BRIEFLY OBSERVED BUT WAS NOT REPEATABLE. IT IS UNKNOWN IF THIS BRIEF HIGH CURRENT DRAIN CONDITION WAS AN ARTIFACT OF AN ANALYSIS STEP OR REAL. NO CONCLUSION CAN BE MADE AS TO THE CAUSE OF THE PREMATURE BATTERY DEPLETION. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD EXPERIENCED AN ELECTRICAL RESET.

MEDTRONIC SUBMITS THIS REPORT TO COMPLY WITH FDA REGULATIONS 21 CFR PARTS 4 AND 803. MEDTRONIC HAS MADE REASONABLE EFFORTS TO PROVIDE AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. MEDTRONIC WILL SUBMIT A SUPPLEMENTAL REPORT IF ADDITIONAL RELEVANT INFORMATION BECOMES KNOWN.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS EXPLANTED.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY DURING INTERROGATION ATTEMPTS WITH DIFFERENT DEVICES. IT WAS NOTED THE ICM HAD EXPERIENCED EARLY BATTERY DEPLETION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN

REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event580:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230928

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00813

mdr\_text.text:THE CUSTOMER REPORTED THE MX40 TELEMETRY DEVICE DISPLAYS A SPEAKER MALFUNCTION ERROR MESSAGE. THE MX40 WAS IN USE MONITORING A PATIENT SO THE BIOMED WAS UNABLE TO TEST THE DEVICE. THE REMOTE SERVICE ENGINEER (RSE) RECOMMENDED THE BIOMED TO SWITCH OUT THE POSSIBLE DEFECTIVE MX40 OFF THE PATIENT AND PERFORM A FACTORY RESET ON THE MODULE AND THEN RUN A PATIENT SIMULATOR ON THE DEVICE TO DETERMINE IF ANY SOUND IS COMING FROM THE SPEAKER. BIOMED STATES THAT HE WILL PERFORM TEST BUT REQUESTED THE CASE TO BE CLOSED WITHOUT FURTHER TROUBLESHOOTING FROM PHILIPS SIDE. THE RSE INFORMED THE BIOMED TO CONTACT PHILIPS IF ADDITIONAL ASSISTANCE IS NEEDED. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

{{datachunk}}Event581:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20231010

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00814

mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE UNIT HAS A CONSTANT SPEAKER MALFUNCTION ERROR MESSAGE, NO SOUND IS COMING FROM THE DEVICE AT ALL. THE DEVICE WAS NOT IN USE.

THE DEVICE WAS RECEIVED AT THE PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH EVALUATION. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO AUDIO ALARM. THE SPEAKER HAD NO SOUND AT START UP TEST. AND FAILED AT MANUAL POWER ON TEST. NO SOUND, DEFECTIVE SPEAKER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED.

{{datachunk}}Event582:

adverse\_event\_flag:Y

product\_problems:["Incorrect Measurement"]

event\_type:Death

date\_of\_event:20230928

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00544

mdr\_text.text:IT WAS REPORTED DURING MONITORING OF A PATIENT WITH GSW X3 TO THE HEAD THE ARTERIAL LINE MEASUREMENT DID NOT DISPLAY ON THE X2 MONITOR. THE CAUSE OF THE ISSUE WAS FOUND TO BE THE X2 DID NOT REGISTER THE ART/TEMP MEASUREMENT BOARD, SO IT WAS RECOMMENDED TO REPLACE THE BOARD. THE DEVICE WAS IN USE AT TIME OF THE EVENT AND THE PATIENT DIED.

THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND CONFIRMED THE PROBLEM THAT ARTERIAL BLOOD PRESSURE (ABP) SHOULD HAVE DISPLAYED. THE FSE DETERMINED THAT THE CAUSE OF THE ISSUE WAS THAT THE X2 MONITOR DID NOT REGISTER THE ECG/TEMPERATURE MEASUREMENT BOARD. THE CUSTOMER WAS ADVISED TO REPLACE ECG/TEMP MEASUREMENT BOARD AND ENSURE IT IS DETECTED BY THE X2 MONITOR. THE CUSTOMER WAS ADVISED TO REPLACE THE PARAMETER BOARD. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE DEVICE WAS SENT TO PHILIPS BENCH REPAIR. A PHILIPS BENCH REPAIR TECHNICIAN (BRT) EVALUATED THE DEVICE AND CONFIRMED THE ISSUE; PRESSURE LINE WILL NOT OPERATE DUE TO A FAULTY PARAMETER BOARD AND MAIN BOARD. THE CAUSE OF THE REPORTED PROBLEM WAS THE PARAMETER BOARD AND MAIN BOARD. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE PARAMETER BOARD AND MAIN BOARD. THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event583:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20230930

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00549

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX800 PATIENT MONITOR INDICATING THAT THE YELLOW ALARM WENT OFF INSTEAD OF RED. A REMOTE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND EXPLAINED THAT THE HEART RATE (HR) NEEDED TO BE ABOVE THE SET LIMIT FOR A VENTRICULAR TACHYCARDIA (V-TACH). THE PATIENT HAD PREMATURE VENTRICULAR CONTRACTIONS (PVCs), WHICH IS WHY THE CUSTOMER GOT THE YELLOW ALARM. THE RSE ADVISED THAT THERE HAD TO BE A HR VIOLATION AS WELL IN ORDER TO GET THE RED ALARM FOR V-TACH. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE DEVICE WAS FUNCTIONING AS INTENDED, AND THERE WAS NO MALFUNCTION OF THE DEVICE. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MX800 PATIENT MONITOR ISSUED A YELLOW ALARM INSTEAD OF THE EXPECTED RED ALARM. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO ADVERSE PATIENT OR USER EVENT WAS REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MX800 PATIENT MONITOR ISSUED A YELLOW ALARM INSTEAD OF THE EXPECTED RED ALARM. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event584:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231020

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00815

mdr\_text.text:THE CUSTOMER REPORTED THERE WAS A SPEAKER MALFUNCTION ERROR AND THERE WAS NO SOUND. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE DEVICE WAS SENT TO PHILIPS BENCH REPAIR FOR EVALUATION. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED; RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, PHILIPS WAS UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING, IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT; THEREFORE, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event585:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20210208

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03838

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.



## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event586:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231009

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00806

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD NO AUDIO. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT SPEAKER HAS BEEN TESTED WITH THE CERTIFICATION FAILED DUE TO DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event587:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231012

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00808

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD NO SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE NO SPEAKER SOUND AT START UP TEST DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event588:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231012

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00811

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE DID NOT PRODUCE SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event589:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230930

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00126

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. IRHYTHM WAS INFORMED THAT THE PATIENT HAS AN UPCOMING APPOINTMENT AND WILL BE TREATED WITH A LIFE VEST AND AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD). NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE DEVICE WAS WORN FOR APPROXIMATELY 10 DAYS OF THE 14-DAY PRESCRIBED WEAR-PERIOD. THE DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT AND STOPPED TRANSMITTING ASYMPTOMATIC EVENTS ON DAY 8. THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 22. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event590:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:2182207-2023-02180

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) COULD NOT BE INTERROGATED AFTER IMPLANTATION. IT WAS INDICATED THAT THE ICM WAS REMOVED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event591:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231003

event\_location:

remedial\_action:[""]

patient.patient\_age:67 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03811

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT T-WAVE OVERSENSING (TWOS) ON AN ATRIAL FIBRILLATION (AF) EPISODE. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED UNDERSENSING ON A PAUSE EPISODE. IT WAS ALSO NOTED THAT



## DSI MAUDE Problems Summary

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THE DEVICE DEFAULT REPORT SHOWED THAT COUNTERS WENT BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event592:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230811

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00543

mdr\_text.text:ON 20OCT2023, ADDITIONAL INFORMATION WAS RECEIVED INDICATING THAT THIS REPORT, WITH THE EVENT DATE OF (B)(6) 2023, WAS CREATED FOR ADDITIONAL INVESTIGATION OF AN EVENT THAT OCCURRED ON (B)(6) 2023 (ADDRESSED IN MFR REPORT NUMBER 1218950-2023-00620); NO ROOT CAUSE COULD BE DETERMINED AT THAT TIME, AND THE CUSTOMER DID NOT REQUEST FURTHER INVESTIGATION AT THAT TIME, BUT DID SO LATER ON (B)(6) 2023. ALLEGATION AGAINST THE MX700 WAS INDICATED ON (B)(6) 2023. SEE MFR REPORT NUMBER 1218950-2023-00660 FOR THE ALLEGATION AGAINST THE PHILIPS PATIENT INFORMATION CENTER IX.. THE FOLLOWING FUNCTIONAL TESTS AND COMMUNICATION WERE PERFORMED: A PHILIPS FIELD SERVICE ENGINEER (FSE) AND A CLINICAL SPECIALIST (CS) WENT TO THE CUSTOMER SITE TO EVALUATE THE DEVICE AND TO DETERMINE A ROOT CAUSE OF THE CUSTOMER'S ALLEGATION THAT "ON (B)(6) 2023 AT 8:57AM PATIENT ASSIGNED TO BED 3411 IN NICU DEPARTMENT HAD A HEART RATE (HR) OF 310 BPM BUT NO ALARM FROM PIIC IX COMPUTER WAS DISPLAYED. HR HIGH LIMIT WAS SET TO 200." THE FSE AND CS REVIEWED AUDIT LOGS

## DSI MAUDE Problems Summary

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FROM (B)(6) 2023 AND TESTED THE DEVICE TO ENSURE THE MX700 MONITOR WAS ALARMING APPROPRIATELY. THE FSE STATED THAT LOOKING AT THE AUDIT LOGS ACROSS MULTIPLE DAYS, THE BABY ALARMED CONSISTENTLY, THEN THERE WAS ABOUT AN HOUR GAP DURING THE EVENT WHERE THE BABY DID NOT ALARM AT ALL DURING THE TIME FRAME IN QUESTION. THE BABY HAD AND HAS CONTINUED TO ALARM WITHOUT ISSUE. THIS WAS ALSO VALIDATED ON-SITE USING A CHICKEN HEART TO GENERATE MULTIPLE ALARMS AT ALL DIFFERENT LIMITS, USING THE MONITOR IN QUESTION. THE FSE AND CS BELIEVED THIS ANOMALY IS DUE TO SOMETHING CUSTOMER RELATED AND NOT THE MONITOR. RESULTS OF FUNCTIONAL TESTING AND LOG REVIEW DETERMINED THE MX700 MONITOR WAS ALARMING PER SPECIFICATIONS AND THE EVENT MAY HAVE BEEN AN ANOMALY NOT RELATED TO THE DEVICE, BUT MORE LIKELY USER ERROR. THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS. THE LACK OF ALARM OCCURRED WAS CONSIDERED AN ANOMALY NOT RELATED TO THE DEVICE, BUT THE ROOT CAUSE IS UNKNOWN. EXTENSIVE TESTS WERE PERFORMED AND THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS. THERE WAS NO PATIENT HARM. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THE PATIENT'S HEART RATE EXCEEDED THE HIGH LIMIT, BUT NO ALARM GENERATED ON THE PHILIPS PATIENT INFORMATION CENTER IX (PIC IX) COMPUTERS IN NEONATAL INTENSIVE CARE UNIT (NICU) DEPARTMENT. THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

{{datachunk}}Event593:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230614

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00799

mdr\_text.text:IT WAS REPORTED THE DEVICE PRESENTED WITH THE FOLLOWING: SPEAKER MALFUNCTION INOP - NO SOUND. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE FEILD SERVICE ENGINEER WENT ON SITE AND STATED THAT THE FAULTY MX40 MONITOR NEEDED TO BE REPLACED. THE CUSTOMER WAS PROVIDED A REPLACEMENT MX40.

{{datachunk}}Event594:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20231011

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP60

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00537

mdr\_text.text:A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND FOUND THAT THE SYSTEM WAS WORKING CORRECTLY. THE SERVICE STAFF ALSO REPORTED THAT THEY HAVE NOT HAD ANY PROBLEM WITH THE EQUIPMENT SINCE THE INITIAL REPORT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS CONFIRMED TO BE OPERATING PER

## DSI MAUDE Problems Summary

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SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. E1:  
REPORTING INSTITUTION PHONE: # (B)(6). E1: REPORTER PHONE # (B)(6).

IT WAS REPORTED THE INTELLIVUE MP60 MONITOR DID FAIL FOR AN SATURATION ALARM.THE DEVICE  
WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event595:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210903

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03788

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING  
REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED  
BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY  
PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE  
EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT  
INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS  
REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS  
EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE  
EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN

## DSI MAUDE Problems Summary

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ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON TACHYCARDIA EPISODES. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS ALSO NOTED THAT THE REMOTE MONITORING REPORT CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event596:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20230201

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00795

## DSI MAUDE Problems Summary

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mdr\_text.text:THE CUSTOMER PROVIDED PICTURES OF THE BATTERY. THE REMOTE SUPPORT ENGINEER (RSE) IDENTIFIED THE BATTERY TERMINALS LOOK WORN. BASED ON THE INFORMATION PROVIDED AND STATEMENTS BY THE CUSTOMER THE PRODUCT SUPPORT ENGINEER (PSE) BELIEVES THE BATTERY WAS NOT CORRECTLY CLEANED AS THERE WAS STILL RESIDUAL ON THE CONTACT. THE CUSTOMER STATED THAT THE BATTERY SHOWED FULLY CHARGED ON THE CHARGER AND AFTER SCRAPING OVER THE CONTACTS WITH A FINGERNAIL THE BATTERY STARTED TO FUNCTION AGAIN IN THE TELEMTRY MONITOR. THE CUSTOMER WAS ADVISED OF THE APPROVED CLEANING METHODS IN THE INSTRUCTIONS FOR USE (IFU). THE CUSTOMER WAS ALSO ADVISED TO REPLACE THE BATTERY DUE TO VISIBLE WEAR.

THE CUSTOMER REPORTED THE BATTERY FAILED WITHOUT ALARMING FOR LOW BATTERY, WHICH RESULTED IN A LOSS OF TELEMTRY MONITORING. THE BATTERY DID NOT WORK IN A TELEMTRY MONITOR BUT WAS SHOWING FULLY CHARGED ON THE CHARGER. THE CONTACT WAS SCRAPED OVER WITH A FINGERNAIL AND THE BATTERY STARTED TO FUNCTION AGAIN IN THE TELEMTRY MONITOR. THE CUSTOMER STATED IT APPEARS THE CHARGER DOESN'T HAVE A TERMINAL FOR THIS CONTACT. IN ADDITION, THE CUSTOMER REPORTS THE TERMINALS ON THE BATTERY LOOK CLEAN, THERE ARE NO DEPOSITS THAT CAN BE SEEN, THE BATTERY IS LESS THAN A YEAR OLD, AND THE UNITS ARE BEING CLEANED WITH ALCOHOL SANI CLOTHS. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event597:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231003

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00539

mdr\_text.text:A CUSTOMER BIOMEDICAL ENGINEER (BIOMED) REPORTED THAT THERE WAS A SPEAKER MALFUNCTION ERROR MESSAGE ALERTING AT THE PHILIPS PATIENT INFORMATION CENTER IX (PIC IX) AND THE MX700 BEDSIDE MONITOR. THERE WAS VISUAL ALARMING ONLY AT THE MX700; NOT AUDIBLE ALARMING. THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

TROUBLESHOOTING/INVESTIGATION THE SPEAKER MALFUNCTION AT THE CENTRAL AND AT THE BEDSIDE WAS PERFORMED THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED), AS ADVISED BY THE PHILIPS REMOTE SERVICE ENGINEER (RSE). TROUBLESHOOTING ESTABLISHED THE SPEAKER MALFUNCTION ERROR WAS EITHER THE MX700 OR X2. THE BIOMED STOPPED FURTHER TROUBLESHOOTING AND REQUESTED TO CLOSE THE CASE. NO FURTHER INFORMATION PROVIDED. THE PHILIPS RSE WAS PROVIDED THE ANALYSIS FINDINGS HOWEVER PHILIPS WAS UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE BECAUSE THE CUSTOMER REJECTED FURTHER REMOTE TROUBLESHOOTING. THE CUSTOMER REQUESTED THE CASE BE CLOSED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. H3 OTHER TEXT : DEVICE NOT AVAILABLE; CUSTOMER REJECTED FURTHER REMOTE TROUBLESHOOTING.

{{datachunk}}Event598:

adverse\_event\_flag:N

product\_problems:["Device Fell"]

event\_type:Malfunction

date\_of\_event:20231003

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP70

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00540

mdr\_text.text:THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED: THE REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER, AND THE CUSTOMER STATED THAT THE ARM ON THE WALL BROKE, AND THE MP70 HAD A LOT OF PHYSICAL DAMAGE. THE CUSTOMER WAS CHECKING WHAT OPTIONS WERE AVAILABLE TO HAVE THE UNIT REPAIRED. THE RSE INFORMED THE CUSTOMER THAT THE UNIT IS END OF LIFE, AND WE NO LONGER HAVE ANY PARTS OR OFFER ANY REPAIRS. THE RSE SENT THE END OF LIFE LETTER SERVICE BULLETIN (SB) (B)(4) TO THE CUSTOMER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM IS UNKNOWN. THE REPORTED PROBLEM WAS CONFIRMED WE ARE UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE, BECAUSE THE CUSTOMER WAS PROVIDED THE END OF LIFE LETTER (B)(4). IT IS UNKNOWN HOW THE CUSTOMER DECIDED TO PROCEED WITH THE DEVICE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. H3 OTHER TEXT : DEVICE WAS DETERMINED TO BE END OF LIFE.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE ARM ON THE WALL BROKE AND THE MP70 FELL, RESULTING IN A LOT OF PHYSICAL DAMAGE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event599:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20231013

event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR



## DSI MAUDE Problems Summary

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patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06624

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A PARTIAL ELECTRICAL RESET. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. IT WAS FURTHER NOTED AS A RESULT A NUMBER OF THE DETECTED EPISODES SHOWED QUESTION MARKS IN THE REPORT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event600:

adverse\_event\_flag:Y

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20231013

event\_location:

remedial\_action:[""]

patient.patient\_age:64 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Pain"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

## DSI MAUDE Problems Summary

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report\_number:9614453-2023-03767

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE DEVICE WAS REPOSITIONED.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED BY THE PATIENT THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) MIGRATED WITHIN IN THE CHEST AND HAD MOVED A COUPLE OF INCHES IN THE BREAST AREA. IT WAS NOTED THAT IT WAS NOW PAINFUL DUE TO THE NEW POSITION RIGHT WHERE THE BRA UNDERWIRE SITS. THE ICM REMAINS IN USE. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event601:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230923

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00532

mdr\_text.text:THE CUSTOMER REACHED OUT TO PHILIPS VIA A CUSTOMER FEEDBACK EXPRESSING A CUSTOMER DISSATISFACTION. A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT TO THE CUSTOMER SITE TO EVALUATE THE ALLEGED MALFUNCTIONING DEVICE. HE WAS INFORMED BY A NURSE MANAGER THAT "AT 8:15P ON (B)(6) 2023, BED #7 HAD A 16-BEAT RUN OF VENTRICULAR TACHYCARDIA (VT) AND NO ALARMS WERE ACTIVATED." THERE WAS A CONCERN THIS ISSUE COULD CAUSE THE RHYTHM TO GO UNNOTICED IN A CARDIAC EMERGENCY. THIS ALLEGATION WAS MADE IN THE EVENT OF A POTENTIALLY SERIOUS INJURY WAS TO OCCUR, WHICH DID NOT HAPPEN. THE INTELLIVUE MX800 MONITOR WAS USED IN COMBINATION WITH AN INTELLIVUE X3 AND PICIX C.03.08 SYSTEM. THE FSE REVIEWED ALARMS, RESET THE ALARMS, TESTED BUT FOUND NO ISSUES WITH THE PIC IX SPEAKERS AND MADE SURE THE MONITOR WAS WORKING ON ALL PATIENTS AT THE TIME. ALARM REVIEWING REVEALED THAT ALL RED AND YELLOW ALARMS WERE OFF, WHICH PROMPTED A CHECK OF ALL PATIENT ALARMS. IT WAS FOUND ALL RED AND YELLOW ALARMS WERE OFF FOR THE CCU. RESULTS OF FUNCTIONAL TESTING INDICATED NO MALFUNCTION OF THE DEVICES. THE COMPLAINT WAS ESCALATED FOR A TECHNICAL INVESTIGATION. A PHILIPS PRODUCT SUPPORT ENGINEER REVIEWED THE AUDIT LOGS FOR BOTH 8:15 P.M. (20:15) AND 8:15 A.M. AND FOUND THE FOLLOWING: -THERE WERE SEVERAL ECG ALARMS ACTIVE AROUND 20:15: ¿ \*AFIB ACTIVE FROM 20:08 UNTIL 20:15 ¿ \*AFIB ACTIVE FROM 20:15 UNTIL 20:16 FURTHERMORE THERE WERE SEVERAL SPO2 ALARMS PRESENT IN THIS TIME FRAME. SINCE WE DO NOT HAVE CLINICAL DATA AVAILABLE, WE CANNOT JUDGE, WHETHER THE CORRECT ALARM WOULD HAVE BEEN \*AFIB, \*RUN PVCs HIGH, \*SVT OR ANY OTHER ECG ALARM. HOWEVER, THERE WAS DEFINITELY AN ECG ALARM ACTIVATED AT THE TIME OF THE ALLEGED EVENT AND THAT YELLOW ALARM SOUNDS WERE CONTINUOUSLY PLAYED AT THE CENTRAL STATION. WHAT WE DO NOT KNOW IS WHAT THE LOUDNESS OF THE ALARM SOUNDS WERE AT THIS POINT OF TIME ¿ NEITHER AT THE CENTRAL STATION, NOR AT THE BEDSIDE MONITOR. ESPECIALLY, IF THEY WERE LOUD ENOUGH FOR THE RESPECTIVE CLINICAL ENVIRONMENT. (B)(6) 2023 20:18:11 MY INSTITUTION CCU 7 SPO2 PULSE? GENERATED AT 20:18:04. PIC IX: VHAWRXMD-CCU LOGGED INOP (B)(6) 2023 20:17:00 MY INSTITUTION CCU 7 AFIB GENERATED AT 20:16:53. PIC IX: VHAWRXMD-CCU YELLOW ALARM (B)(6) 2023 20:17:00 MY INSTITUTION CCU 7 END AFIB ENDED. PIC IX: VHAWRXMD-CCU YELLOW ALARM (B)(6) 2023 20:15:15 MY INSTITUTION CCU 7 END AFIB GENERATED AT 20:15:08. PIC IX: VHAWRXMD-CCU YELLOW ALARM (B)(6) 2023 20:15:15 MY INSTITUTION CCU 7 AFIB ENDED. PIC IX: VHAWRXMD-CCU YELLOW ALARM (B)(6) 2023 08:16:11 MY INSTITUTION CCU 7 AFIB ENDED. PIC IX: VHAWRXMD-CCU YELLOW ALARM (B)(6) 2023 08:09:27 MY INSTITUTION CCU 7 END AFIB GENERATED AT 08:09:27 PIC IX: VHAWRXMD-CCU YELLOW ALARM BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE PROBLEM SEEMS TO BE AN ISSUE OF ALARM MANAGEMENT. THE REPORTED PROBLEM WAS

## DSI MAUDE Problems Summary

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NOT CONFIRMED. A CLINICAL ASSESSMENT PERFORMED BY A POST MARKET SURVEILLANCE CLINICAL EXPERT CONCLUDED THAT BASED ON PSE'S ANALYSIS FINDINGS OF SEVERAL ECG ALARMS WERE ACTIVE AT THE TIME OF THE REPORTED EVENT, INDICATION THAT YELLOW ALARMS WERE GENERATED AT THE CENTRAL STATION, EVEN THOUGH IT IS UNKNOWN WHAT THE ALARM VOLUME WAS SET TO; PREVIOUS TESTING FOUND NO ISSUES WITH SPEAKERS. MOREOVER, PRIOR STATEMENT FROM THE NURSE MANAGER INDICATED THAT RED AND YELLOW ALARM WERE AUDIBLY TURNED OFF. THUS, IT DOES NOT APPEAR THERE WAS A DEVICE MALFUNCTION, AND NO HARM WAS DONE TO A PATIENT OR USER. THE ENGINEERS PROVIDED THEIR ANALYSIS FINDINGS CONFIRMING THAT AN ECG ALARM WAS ACTIVATED AT THE TIME OF THE ALLEGED EVENT AND THAT YELLOW ALARM SOUNDS WERE CONTINUOUSLY PLAYED AT THE CENTRAL STATION; HOWEVER IT CANNOT BE DETERMINED IF THE VOLUME WAS LOUD ENOUGH (NEITHER AT THE CENTRAL STATION, NOR AT THE BEDSIDE MONITOR) FOR THE RESPECTIVE CLINICAL ENVIRONMENT. THERE WAS NO MALFUNCTION OF THE DEVICE.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

IT WAS REPORTED NO ALARMS WERE ACTIVATED. THE INTELLIVUE MX800 MONITOR WAS USED IN COMBINATION WITH AN INTELLIVUE X3 AND PICIX C.03.08 SYSTEM. USER WAS EXPECTING THE ALARM SOUND. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event602:

adverse\_event\_flag:Y

product\_problems:["Melted","Smoking"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:55 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

## DSI MAUDE Problems Summary

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report\_number:2133409-2023-00066

mdr\_text.text:IT WAS REPORTED THAT THE MONITOR CAUGHT FIRE WHEN PLUGGED INTO THE CHARGER. THE DEVICE WAS NOT RETURNED. ENGINEERING EVALUATION WAS UNABLE TO PERFORMED AS THE DEVICE WAS NOT RETURNED FOR TESTING. THIS FAILURE MODE DESCRIPTION ALIGNS WITH A KNOWN EXISTING FAILURE WHICH IS BEING INVESTIGATED BY PHILIPS AM&D.

IT WAS REPORTED THAT THE PATIENT PLUGGED THE MONITOR INTO THE CHARGER AND TOOK A SHOWER. WHEN THE PATIENT CAME OUT OF THE SHOWER IT WAS NOTED THAT THE MONITOR CHARGING CORD WAS MELTED INTO THE MONITOR AND BOTH WERE SMOKING. NO PATIENT HARM WAS REPORTED. A REPLACEMENT MONITOR AND CHARGER WAS SENT.

{{datachunk}}Event603:

adverse\_event\_flag:Y

product\_problems:["Defective Alarm"]

event\_type:Injury

date\_of\_event:20230609

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00535

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX800 PATIENT MONITOR INDICATING THAT IT DID NOT SOUND RED ALERT FOR ARTERY. THE PATIENT WENT INTO CARDIAC ARREST, BUT THERE IS NO FURTHER INFORMATION REGARDING THE CLINICAL OUTCOME AVAILABLE. A FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND CARRIED OUT A CHECK ON THE MONITOR. THE FSE FOUND THAT THE MONITOR WAS CONFIGURED TO ALARM ARTERY AS NOT A SERIOUS ALARM. THE FSE

## DSI MAUDE Problems Summary

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RE-EXAMINED THE EVENTS AND FOUND THAT THE ALARM APPEARED REGULARLY AS YELLOW. THE CURRENT CONFIGURATION WAS CONFIRMED BY THE FSE, AND ONCE CONFIRMED, THE ALARM REGULARLY SOUNDED. THE FSE VERIFIED THAT THE MONITOR WAS READY FOR CLINICAL USE. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE FSE CHANGED THE CONFIGURATION TO RESOLVE THE CUSTOMER'S ISSUE. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

E1; REPORTER INSTITUTION PHONE NUMBER (B)(6). E1: REPORTER PHONE NUMBER (B)(6). A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED THAT THE DEVICE DID NOT SOUND A RED ALERT FOR ARTERY AND WAS NOT RECORDED. THE PATIENT SUFFERED FROM A CARDIAC ARREST.

{{datachunk}}Event604:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20211021

event\_location:

remedial\_action:[""]

patient.patient\_age:50 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06588

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED PAUSE EPISODES DUE TO UNDERSENSING R-WAVES. IT WAS FURTHER REPORTED THAT THE COUNTERS WENT BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL DEVICE CLEARING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.



## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event605:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20200319

event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03751

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT UNDERSENSING. IT WAS FURTHER NOTED THAT THE COUNTERS WENT BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING . THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event606:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20231003

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03753

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event607:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction  
date\_of\_event:20231013  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:NA  
patient.patient\_sex:  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:INTELLIVUE MX40 2.4GHZ  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS  
report\_number:1218950-2023-00788  
mdr\_text.text:(B)(6).

BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED SPEAKER MALFUNCTION WITH NO SOUND WAS CONFIRMED; SPEAKER RELATED. AS OF 26JAN2024, MULTIPLE ATTEMPTS (5) WERE MADE TO HAVE THE CUSTOMER APPROVE THE QUOTE FOR REPAIR OF THE DEVICE WAS UNSUCCESSFUL; THE CUSTOMER DID NOT RESPOND. THE DEVICE WAS RETURNED BACK TO THE CUSTOMER UNREPAIRED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) REPORTED THERE WAS A SPEAKER MALFUNCTION WITH NO AUDIO. THE BIOMED CONFIRMED THERE WAS NO AUDIO FROM THE DEVICE; THE DEVICE WILL BE RETURNED FOR FURTHER INVESTIGATION. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR HARM REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event608:  
adverse\_event\_flag:N  
product\_problems:["No Audible Prompt/Feedback"]  
event\_type:Malfunction

date\_of\_event:20230927

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00789

mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO PATIENT INVOLVEMENT.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST, AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event609:

adverse\_event\_flag:N

product\_problems:["Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20231013

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:25 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06617

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED AN ISSUE WITH DIAGNOSTIC DATA COLLECTION. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) RECORDED EVENTS HOWEVER WHEN VIEWED ON THE REMOTE MONITORING NETWORK, NO ELECTROCARDIOGRAM (ECG)'S WERE

AVAILABLE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event610:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230928

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00791

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST, TOUCH INOP DUE TO CRACKED SCREEN AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event611:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231016

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL



report\_number:9614453-2023-03731

mdr\_text.text:IT WAS REPORTED THAT ON THE DAY OF THE IMPLANT PROCEDURE THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE PAUSE EPISODES DUE TO LOSS OF CONTACT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event612:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electromagnetic Interference","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20230422

event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03733

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE POSITIVE TACHYCARDIA EPISODES DUE TO NOISE/ELECTROMAGNETIC INTERFERENCE. THE ICM HAD REACHED END OF SERVICE (EOS). THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event613:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231003

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03734

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING ON A TACHYCARDIA EPISODE. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event614:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20231016

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03735

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE

BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THAT DURING A PROCEDURE TO IMPLANT A NEW ICM, THE OLDER ONE COULD NOT BE LOCATED AND THEREFORE REMAINED IMPLANTED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event615:

adverse\_event\_flag:N

product\_problems:["Delayed Alarm"]

event\_type:Malfunction

date\_of\_event:20230926

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00785

mdr\_text.text:THE CUSTOMER REPORTED THAT THERE WAS AN 8 SECOND PAUSE TO RECEIVE THE ASYSTOLE ALARM. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

## DSI MAUDE Problems Summary

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A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND CONFIRMED THE ISSUE OF ALARMING TELEMETRY INCORRECT, ONE-STAR ALARM IS 4 SECONDS. ALARMS SHOULD BE TRIGGERED FROM 3.5 SECONDS ONWARDS AS A 3-STAR ALARM AND ON THE BELL SYSTEM. SHE ADDED THAT THE PROBLEM IS THAT USERS ACCIDENTALLY DISCOVERED THAT THE; ALARM PAUSE IN THE ALARM LOG WAS RECORDED AT >4SEC IN THE ALARM STRIP ON (B)(6) 2023, IN THE MX-40 AT 04:19:18 TELE18- 4 SEC. THE CUSTOMER CLAIMED THE MALFUNCTION COULD CAUSE OR CONTRIBUTE TO HARM OR INJURY IF IT RECURS. THE ALLEGATION WAS MADE IN THE EVENT A POTENTIALLY SERIOUS INJURY WAS TO OCCUR, WHICH DID NOT HAPPEN. THE RSE CONFIRMED THAT THERE WAS NO NEGATIVE EFFECT ON THE PATIENT, THE ISSUE WAS DISCOVERED ACCIDENTALLY AND ESCALATED TO MANAGEMENT. THE COMPLAINT WAS ESCALATED FOR TECHNICAL INVESTIGATION. A PHILIPS PRODUCT SPECIALIST ENGINEER (PSE) AND A CLINICAL APPLICATION SPECIALIST (CAS) REVIEWED THE STRIPS PROVIDED BY THE CUSTOMER. RESULTS SHOWED THAT THE EVENTS IN THE STRIPS WERE COMBINED BECAUSE THE PATIENT TRANSITIONED FROM PAUSE TO ASYSTOLE. THE CUSTOMER WAS LOOKING AT THE PAUSE STRIP AND SEEING THE LONG TIME BETWEEN BEATS, AND EXPECTED AN ASYSTOLE ALARM, WHEN IN FACT, THE ASYSTOLE ALARM STRIP IS A DIFFERENT, SEPARATE STRIP. FOR TELE 18 THE CUSTOMER ONLY SENT THE PAUSE STRIP. THE AUDIT LOG CAPTURED THE ASYSTOLE ALARM OCCURRING ONE SECOND LATER. THE CHANGES IN THE PATIENT'S CONDITION WERE RECOGNIZED BY THE MONITOR AND ALARMS WERE GENERATED AS APPROPRIATE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A MISINTERPRETATION ON THE PART OF THE CUSTOMER REGARDING ALARMS STRIPS, AS THEY WERE LOOKING AT THE PAUSE STRIP AND EXPECTING AN ASYSTOLE ALARM, WHEN IN FACT, THE ASYSTOLE ALARM STRIP IS A DIFFERENT, SEPARATE STRIP. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS. THE CHANGES IN THE PATIENT'S CONDITION WERE RECOGNIZED BY THE MONITOR AND ALARMS WERE GENERATED AS APPROPRIATE. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event616:

adverse\_event\_flag:N

product\_problems:["Delayed Alarm"]

event\_type:Malfunction

date\_of\_event:20230918

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00784

mdr\_text.text:A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND CONFIRMED THE ISSUE OF ALARMING TELEMETRY INCORRECT, ONE-STAR ALARM IS 4 SECONDS. ALARMS SHOULD BE TRIGGERED FROM 3.5 SECONDS ONWARDS AS A 3-STAR ALARM AND ON THE BELL SYSTEM. SHE ADDED THAT THE PROBLEM IS THAT USERS ACCIDENTALLY DISCOVERED THAT THE \*ALARM PAUSE IN THE ALARM LOG WAS RECORDED AT >4SEC IN THE ALARM STRIP ON (B)(6) 2023, IN THE MX-40 AT 04:19:18 TELE18- 4 SEC. THE CUSTOMER CLAIMED THE MALFUNCTION COULD CAUSE OR CONTRIBUTE TO HARM OR INJURY IF IT RECURS. THE ALLEGATION WAS MADE IN THE EVENT A POTENTIALLY SERIOUS INJURY WAS TO OCCUR, WHICH DID NOT HAPPEN. THE RSE CONFIRMED THAT THERE WAS NO NEGATIVE EFFECT ON THE PATIENT, THE ISSUE WAS DISCOVERED ACCIDENTALLY AND ESCALATED TO MANAGEMENT. THE COMPLAINT WAS ESCALATED FOR TECHNICAL INVESTIGATION. A PHILIPS PRODUCT SPECIALIST ENGINEER (PSE) AND A CLINICAL APPLICATION SPECIALIST (CAS) REVIEWED THE STRIPS PROVIDED BY THE CUSTOMER. RESULTS SHOWED THAT THE EVENTS IN THE STRIPS WERE COMBINED BECAUSE THE PATIENT TRANSITIONED FROM PAUSE TO ASYSTOLE. THE CUSTOMER WAS LOOKING AT THE PAUSE STRIP AND SEEING THE LONG TIME BETWEEN BEATS, AND EXPECTED AN ASYSTOLE ALARM, WHEN IN FACT, THE ASYSTOLE ALARM STRIP IS A DIFFERENT, SEPARATE STRIP. FOR TELE 18 THE CUSTOMER ONLY SENT THE PAUSE STRIP. THE AUDIT LOG CAPTURED THE ASYSTOLE ALARM OCCURRING ONE SECOND LATER. THE CHANGES IN THE PATIENT'S CONDITION WERE RECOGNIZED BY THE MONITOR AND ALARMS WERE GENERATED AS APPROPRIATE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A MISINTERPRETATION ON THE PART OF THE CUSTOMER REGARDING ALARMS STRIPS, AS THEY WERE LOOKING AT THE PAUSE STRIP AND EXPECTING AN ASYSTOLE ALARM, WHEN IN FACT, THE ASYSTOLE ALARM STRIP IS A DIFFERENT, SEPARATE STRIP. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS. THE CHANGES IN THE PATIENT'S CONDITION WERE RECOGNIZED BY THE MONITOR AND ALARMS WERE GENERATED AS APPROPRIATE. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT THERE WAS AN 8 SECOND PAUSE TO RECEIVE THE ASYSTOLE ALARM. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

## DSI MAUDE Problems Summary

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PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event617:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230927

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00786

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THE DEVICE DISPLAYS A SPEAKER INOP ERROR MESSAGE AND IS WITHOUT AUDIO. THERE WAS NO PATIENT INVOLVEMENT.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.



## DSI MAUDE Problems Summary

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{{datachunk}}Event618:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231004

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00771

mdr\_text.text:DURING EVALUATION AT PHILIP'S BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event619:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20231004

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00770

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIP'S BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event620:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231010

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00777

mdr\_text.text:ADDITIONAL INFORMATION WAS RECEIVED, IT WAS REPORTED THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT. NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS.

THE CUSTOMER REPORTED THE TELEMETRY DEVICE HAS A SPEAKER MALFUNCTION ERROR MESSAGE AND NO AUDIBLE SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event621:

adverse\_event\_flag:N

product\_problems:["Defective Alarm","No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230925

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00776

mdr\_text.text:THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND STATED THE CAUSE OF THE REPORTED PROBLEM WAS NOT CONFIRMED. THE FSE PULLED LOGS ASSOCIATED WITH THE EVENT AND PROVIDED THE CUSTOMER WITH LOGS, SO THEY CAN REVIEW THE LOGS. WE ARE UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE. THE CUSTOMER ONLY REQUESTED FOR THE LOGS TO BE PULLED SO THEY COULD REVIEW. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. H3 OTHER TEXT : REFER TO H10.

THE CUSTOMER REPORTED THAT THE DEVICE DID NOT ALARM ASYSTOLE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM. IT IS UNKNOWN IF THE DEVICE IS WORKING TO SPECIFICATION.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION

THE CUSTOMER REPORTED THAT THE DEVICE DID NOT ALARM ASYSTOLE. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event622:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230925

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00779

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

{{datachunk}}Event623:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231004

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00775

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE DID NOT PRODUCE SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event624:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231002

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00529

## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED THAT THERE IS A LOUDSPEAKER PROBLEM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

ADDITIONAL INFORMATION WAS PROVIDED THAT THE DEVICE DID NOT PRODUCE SOUND. A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT TO THE CUSTOMER'S SITE TO EVALUATE THE DEVICE. THE FSE DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE SPEAKER WAS REPLACED TO RESOLVE THE ISSUE.

{{datachunk}}Event625:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231004

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00780

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE

## DSI MAUDE Problems Summary

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SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT PHILIP'S BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event626:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:20231002

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06471

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED NOISE. CORRECTION: INITIAL G3 = 02 OCT 2023. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN



## DSI MAUDE Problems Summary

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ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT

DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED NOISE ON A TACHYCARDIA EPISODE. IT WAS ALSO REPORTED THAT THE REMOTE MONITORING REPORT HAD DIFFERENT REFERENCE POINTS FOR THE ELECTROCARDIOGRAM (ECG) GRAPH, INDICATING THERE WERE DIFFERENT AM PLITUDES FOR THE SAME EPISODES WHEN VIEWED ON DIFFERENT REPORTS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event627:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230607

event\_location:

remedial\_action:[""]

patient.patient\_age:88 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03690

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY WITH THE REMOTE MONITOR. IT WAS REPORTED THAT THAT THE REMOTE MONITOR HAD MISSED DAILY WIRELESS AUDIT. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE MONITOR REMAINED SET UP. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

IT WAS FURTHER REPORTED THAT ONE DAY PRIOR TO THE EVENT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT WAS IMPLANTED WITH A IMPLANTABLE PULSE GENERATOR (IPG).

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH

## DSI MAUDE Problems Summary

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ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event628:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230920

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00766

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

## DSI MAUDE Problems Summary

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DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.

{{datachunk}}Event629:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230915

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Bradycardia"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00767

mdr\_text.text:THE ENGINEER CONFIRMED THAT ALARMS WERE PROVIDED (AT THE PIC IX) FOR BED/DEVICE LABEL H1-1 / MX40-8 DURING THE REPORTED INCIDENT TIMEFRAME OF 07:40 ON (B)(6) 2023. PHYSIOLOGICAL ALARMS FOR PAUSE, XBRADY, AND ASYSTOLE CONDITIONS WERE PROVIDED. THE TELE WEAK SIGNAL GIVEN AT 07:46:01 TECHNICAL INOP DID NOT RESULT IN LOSS OF CONNECTION/ASSOCIATION BETWEEN THE MX40 AND PIC IX.THE AUDIT LOG ALSO SHOWS A LOSS OF CONNECTION/ASSOCIATION BETWEEN .THE MX40 AND PIC IX AT 10:13:12 (MORE THAN 2 HOURS AFTER THE INCIDENT TIMEFRAME). ¿TELE: SERVICE BATTERY¿ TECHNICAL INOP INDICATES THE BATTERY HAS EXCEEDED THE MAXIMUM CHARGE CYCLE LIMIT AND REACHED THE END OF ITS USEFUL LIFE. IT IS A MESSAGE TO THE USER TO REPLACE THE BATTERY. THE BATTERY WILL STILL POWER THE MX40, BUT PERFORMANCE CAN BE IMPACTED. PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE CENTRAL HAD NOT GIVEN ALARM. THE DEVICE WAS IN USE IN TELEMETRY MODE.

## DSI MAUDE Problems Summary

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A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND REVIEWED THE AUDIT LOGS. THE PATIENT WAS WEARING THE MX40 MONITOR DURING THE INCIDENT ON BED LABEL H1-1. THE CUSTOMER WAS INFORMED THAT ACCORDING TO THE LOG FILES, THE CENTRAL HAS ALARMED AS EXPECTED. FURTHERMORE THE RSE STATED "WE HAD CONVERSATION WITH OUR CLINICAL APPLICATION SPECIALIST (CAS), CHECKED THE CURVES PROVIDED BY CUSTOMER AND ONCE MORE CHECKED THE LOG FILES TOO. WE COULDN'T FIND ANY PROBLEMS REGARDING THE FUNCTION OF OUR EQUIPMENT AND REPORTED THIS TO CUSTOMER ACCORDINGLY." A GOOD FAITH EFFORT (GFE) CONDUCTED CONFIRMED THAT THE CUSTOMER WAS EXPECTING A BRADY AND ASYSTOLE ALARM, AND ALLEGED THESE ALARMS WERE NOT GENERATED BY THE CENTRAL. ACCORDING TO CUSTOMER, DEVICE DIDN'T ALARM IMMEDIATELY BUT INSTEAD A MOMENT LATER. THE PATIENT WAS IN TELEMETRY DUE TO BRADYCARDIA SO EVERYONE WAS AWARE OF PATIENT'S CONDITION. THE TELE WEAK SIGNAL GIVEN AT 07:46:01 TECHNICAL INOP DID NOT RESULT IN LOSS OF CONNECTION/ASSOCIATION BETWEEN THE MX40 AND PIC IX. THE AUDIT LOG ALSO SHOWS A LOSS OF CONNECTION/ASSOCIATION BETWEEN THE MX40 AND PIC IX AT 10:13:12 (MORE THAN 2 HOURS AFTER THE INCIDENT TIMEFRAME). THE TELE: SERVICE BATTERY TECHNICAL INOP INDICATES THE BATTERY HAS EXCEEDED THE MAXIMUM CHARGE CYCLE LIMIT AND REACHED THE END OF ITS USEFUL LIFE. IT IS A MESSAGE TO THE USER TO REPLACE THE BATTERY. THE BATTERY WILL STILL POWER THE MX40, BUT PERFORMANCE CAN BE IMPACTED. THE RFDA LOG SHOWS A LOSS OF ASSOCIATION BETWEEN THE MX40 AND PIC IX FOLLOWED BY RE ASSOCIATION AT 20:01:31 ON (B)(6), 2023. DURING A BATTERY CHANGE. THERE WERE NO LOSSES OF CONNECTION/ASSOCIATION BETWEEN THE MX40 AND PIC IX DURING THE REPORTED INCIDENT TIMEFRAME. IT ALSO SHOWS A LOSS OF ASSOCIATION BETWEEN THE MX40 AND PIC IX FOLLOWED BY RE ASSOCIATION AT 10:13:12 ON (B)(6), 2023 DUE TO A WEAK SIGNAL, AND A LOSS OF ASSOCIATION BETWEEN THE MX40 AND PIC IX WHEN THE MX40 WAS PUT INTO STANDBY MODE AT 10:37:01. THE DEVICE DEBUG LOG SHOWS AN MX40 REBOOT EVENT AT 20:02:25 ON (B)(6), 2023. WHEN THE BATTERY WAS CHANGED; A LOSS OF CONNECTION/ASSOCIATION WITH THE PIC IX AT 10:13:27 RELATED TO POOR SIGNAL STRENGTH AND THAT THE MX40 WAS PUT INTO STANDBY MODE AT 10:37:01 ON (B)(6), 2023. NOTE: BASED ON BATTERY VOLTAGES CAPTURED IN THE LOG (REBOOT EVENTS), IT CAN BE DETERMINED THE CUSTOMER IS USING THE PHILIPS RECHARGEABLE LI-ION BATTERY. PATIENT WEARING MONITOR (PWM) LOG REVIEW CAN FURTHER CONFIRM BATTERY CHANGE/REBOOT EVENTS. ANALYSIS RESULTS INDICATE THAT THE MX40 PERFORMS THE MEASUREMENT ANALYSIS, GENERATES THE ALARMS AND SENDS THEM TO THE PIC IX. IT WAS CONFIRMED THAT THE MX40 WAS CONNECTED TO THE PIC IX AND PROVIDING PHYSIOLOGICAL ALARMS DURING THE REPORTED INCIDENT TIMEFRAME. IN ADDITION, THE PSE STATED "I CONFIRM THAT ALARMS WERE PROVIDED (AT THE PIC IX) FOR BED/DEVICE LABEL H1-1 / MX40-8 DURING THE REPORTED INCIDENT TIMEFRAME OF 07:40 ON (B)(6) 2023. PHYSIOLOGICAL ALARMS FOR PAUSE, XBRADY, AND ASYSTOLE CONDITIONS WERE PROVIDED." BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE USER LACK OF ALARM AWARENESS. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE ENGINEERS PROVIDED THEIR ANALYSIS FINDINGS. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO ALARM FAILURE WAS IDENTIFIED. PHILIPS MX40 PATIENT WEARABLE MONITOR HAS NOT CAUSED OR CONTRIBUTED TO THE EVENT. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event630:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230911

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00115

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT DESCRIBED IN THE PRODUCT LABELING. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. FOLLOW-UP WITH THE ACCOUNT CONFIRMED THEY WERE ALREADY AWARE OF THE ARRHYTHMIA, NO TREATMENT WAS REQUIRED, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event631:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20231002

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00769

mdr\_text.text:DURING EVALUATION AT PHILIP'S BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event632:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230921

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00772

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST, FAILED AT MANUAL POWER ON TEST. AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED WITH A REPLACEMENT DEVICE (TELE PWM,802.11A/B/G,ECG ) WHICH RESOLVED THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event633:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230921

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00773

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE.BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event634:

adverse\_event\_flag:N

product\_problems:["Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20231011

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03669

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. ANALYSIS OF THE DEVICE REVEALED NORMAL BATTERY DEPLETION. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INVALID COUNTERS AND THE CARDIAC COMPASS CONTAINED INVALID DATA DUE TO THE BATTERY STATUS AT END OF SERVICE (EOS). THE HISTOGRAMS WERE ALSO INVALID. IT WAS NOTED THAT THE EPISODES WERE IN COUNTERS BUT NOT AVAILABLE TO VIEW IN THE EPISODE LIST. IT WAS FURTHER REPORTED THAT THE TRANSMISSION INTERROGATE BACK TO THE IMPLANT DATE. THE MONITOR REMAINS IN USE. THE ICM REMAINS I USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY HAVE NOT BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO

## DSI MAUDE Problems Summary

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CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) IS NO LONGER IN USE.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event635:

adverse\_event\_flag:N

product\_problems:["Device Alarm System","Mechanical Problem"]

event\_type:Malfunction

date\_of\_event:20230915

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00760

mdr\_text.text:THE CUSTOMER REPORTED THAT THERE WAS A DAMAGED CASE. IN ADDITION, IT WAS STATED THAT THE DEVICE DID NOT ALARM/ALERT AS INTENDED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE PHILIPS AUTHORIZED REPAIR FACILITY EVALUATED THE DEVICE AND WAS UNABLE TO REPLICATE THE REPORTED PROBLEM. IT WAS CONFIRMED THE SPEAKER PRODUCED SOUND. AFTER TESTING IT WAS DETERMINED THAT THE SPEAKER WAS FUNCTIONING AS DESIGNED. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THE MX40 COULD NOT PROVIDE ALARMING DUE TO A BROKEN CASE & UNABLE TO HOLD BATTERIES. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event636:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231005

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 802.11A/B/G

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00761

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED THAT THE BUZZER/ALARM SPEAKER NO LONGER WORKS. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. A REPLACEMENT DEVICE WAS SENT TO THE CUSTOMER.

THE DEVICE WAS SENT TO PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH FOR EVALUATION. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND AT START UP TEST AND FAILED AT MANUAL POWER ON TEST. THE SPEAKER WAS DEFECTIVE. THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT MX40 DEVICE TO RESOLVE THE ISSUE. SECTION H COMPONENT CODES CHANGED.

{{datachunk}}Event637:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230920

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00762

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD NO AUDIO SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE NO SPEAKER SOUND AT START UP TEST DUE TO A DEFECTIVE SPEAKER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event638:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230920

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2023-00763

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE DID NOT PRODUCE SOUND. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THE MONITOR DID NOT PRODUCE SOUND DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event639:

adverse\_event\_flag:Y

product\_problems:["Use of Device Problem"]

event\_type:Death

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00122

mdr\_text.text:AS OF THE TIME OF THE PATIENT'S PASSING, THE AT DEVICE WAS NOT SENT BACK FOR EVALUATION. FOR TRANSPARENCY, THE COMPANY ALSO RECEIVED A GENERAL INQUIRY FROM THE PATIENT REGARDING THE GATEWAY DURING THE WEAR PERIOD. CUSTOMER CARE IDENTIFIED A POTENTIAL REGISTRATION DISCREPANCY AND CREATED A SUPPORT TICKET TO VERIFY WITH THE HCP LOCATION WHETHER THE DEVICE WAS ACCURATELY REGISTERED. A COMPANY REPRESENTATIVE WAS NOTIFIED BY THE HCP LOCATION THAT THE AT DEVICE WAS REGISTERED TO THE WRONG PATIENT



AFTER THE PATIENT HAD PASSED AWAY. ADDITIONAL INFORMATION ABOUT THE CAUSE OF THE PATIENT'S DEATH WAS UNAVAILABLE FROM THE HCP LOCATION AT THE TIME, AND THE COMPANY REPRESENTATIVE WAS INFORMED THAT THE PATIENT'S FAMILY DECLINED TO DISCUSS WITH THE HCP LOCATION. THE INVESTIGATION ALSO CONFIRMED THE AT DEVICE REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT DURING THE PRESCRIBED WEAR PERIOD. THE COMPANY CONTACTED THE HCP REPRESENTATIVE, AS WELL AS THE PATIENT (INCORRECTLY) IDENTIFIED IN THE PHYSICIAN ORDER AND NOTIFIED THEM THAT THE ASYMPTOMATIC TRANSMISSION LIMIT WAS APPROACHING. THE COMPANY SENT A REPLACEMENT DEVICE TO THE PATIENT IDENTIFIED IN THE PHYSICIAN ORDER (REGISTRATION) AS WEARING THE DEVICE THAT WAS NEARING THE TRANSMISSION LIMIT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. H3 OTHER TEXT: SINGLE USE DEVICE NOT RETURNED.

IT WAS REPORTED THAT THE PATIENT PASSED AWAY WHILE WEARING THE AT DEVICE. AFTER AN INVESTIGATION, IT WAS CONFIRMED THAT THE PHYSICIAN ORDER (I.E., REGISTRATION) SUBMITTED TO IRHYTHM (THE COMPANY) FOR THE PROVISION OF AMBULATORY MCT SERVICES WITH THE AT DEVICE CONTAINED AN ERROR. SPECIFICALLY, THE PHYSICIAN ORDER CONTAINING THE AT DEVICE SERIAL NUMBER IDENTIFIED THE INCORRECT PATIENT (I.E., IT INCLUDED INCORRECT PATIENT INFORMATION, SUCH AS NAME AND DATE OF BIRTH). CONSEQUENTLY, MEDICAL DOCTOR NOTIFICATIONS (ALSO REFERRED TO AS EVENT NOTIFICATIONS OR MDNS) FOR ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD WERE PROVIDED FOR THE PATIENT (INCORRECTLY) IDENTIFIED BY THE PROVIDER.

{{datachunk}}Event640:

adverse\_event\_flag:N

product\_problems:["Melted","Overheating of Device"]

event\_type:Malfunction

date\_of\_event:20230920

event\_location:

remedial\_action:[""]

patient.patient\_age:30 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00062

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT STARTING CHARGING THE MONITOR HOWEVER THE MONITOR CHARGER MELTED. THE MONITOR WAS DAMAGED AND THE CHARGING CORD WAS VERY DIFFICULT TO REMOVE FROM THE DEVICE. THE PATIENT STOPPED USING THE DEVICE AND A REPLACEMENT WAS SENT. THE PATIENT STATED THAT THERE WAS NO HARM OR PROPERTY DAMAGE.

IT WAS REPORTED THAT THE MONITOR CHARGER MELTED AND CAUSED DAMAGE TO THE MONITOR. THE DEVICE WAS RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS ABLE TO CONFIRM DEVICE MELT. NO INTERNAL DEVICE WAS OBSERVED DURING EVALUATION. IT IS MOST PROBABLE THAT THE DEVICE MELT WAS CAUSED BY AN EXTERNAL HEAT SOURCE. AM&D PHILIPS IS DOING FURTHER INVESTIGATION FRO MCOT USB-A/USB-C CABLES OVERHEATING.

{{datachunk}}Event641:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Chest Pain"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

## DSI MAUDE Problems Summary

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report\_number:2133409-2023-00064

mdr\_text.text:THE PATIENT REPORTED THAT THE SENSOR WAS PLACED AT THEIR DOCTOR'S OFFICE ONTOP OF HER IMPLANTED DEFIBRILLATOR. ONCE THEY GOT HOME THE PATIENT STARTED FEELING PAIN ON THEIR CHEST, LEGS, STOMACH AND STARTED EXPERIENCING A HEADACHE. THE PATIENT REMOVED THE DEVICE INSTANTLY AND WAS SUGGESTED TO SEEK MEDICAL ATTENTION. THE PATIENT WENT TO THE EMERGENCY ROOM (ER) DUE TO SEVERE CHEST PAINS. THE DEVICE IS EXPECTED TO BE RETURNED.

IT WAS REPORTED THE PATIENT EXPERIENCED PAIN AFTER THE MCOT C6 SENSOR WAS PLACED ONTOP OF THEIR DEFIBRILLATOR. THE DEVICE WAS RETURNED FOR INVESTIGATION. DEVICE WAS INSPECTED FOR GENERAL PHYSICAL INTEGRITY AND FOUND THE BLUE SEAL ON THE SENSOR DAMAGED FROM CUSTOMER PRY MARKS. ENGINEERING EVALUATION COULD NOT REPLICATE THE REPORTED EVENT. THE SENSOR IS UNLIKELY TO HAVE CAUSED OR CONTRIBUTED TO THE REPORTED PATIENT SYMPTOMS. PER THE IFU, "THE ECG RECORDER IS NOT INTENDED FOR USE ON PATIENTS WITH IMPLANTED PACEMAKERS." A DEFINITIVE ROOT CAUSE COULD NOT BE DETERMINED.

{{datachunk}}Event642:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230906

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00112

## DSI MAUDE Problems Summary

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mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT DESCRIBED IN THE PRODUCT LABELING. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. FOLLOW-UP WITH THE ACCOUNT CONFIRMED THEY WERE ALREADY AWARE OF THE ARRHYTHMIA AND HANDLING THE ISSUE. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE DEVICE WAS WORN FOR APPROXIMATELY 7 DAYS OF THE 14-DAY PRESCRIBED WEAR-PERIOD. THE DEVICE LAST TRANSMITTED AND REACHED THE MAXIMUM TRANSMISSION LIMIT 3 DAYS AFTER IT WAS ACTIVATED. THE HCP ACCOUNT WAS NOTIFIED ON DAY 3 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS SHIPPED. THERE WAS NO PATIENT NOTIFICATION PERFORMED AT THAT TIME AS THE ACCOUNT REQUESTED THAT THE PATIENT NOT BE CONTACTED UNLESS THEY NEEDED TO GO TO THE EMERGENCY ROOM. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 19. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event643:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230418

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00757

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THERE WERE NO AUDIBLE TONES COMING FROM THE MX40 DEVICE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. BASED ON THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING, IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT; THEREFORE, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED.

{{datachunk}}Event644:

adverse\_event\_flag:N

product\_problems:["Device Fell"]

event\_type:Malfunction

date\_of\_event:20230927

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00519

mdr\_text.text:THE CUSTOMER REPORTED THAT THE DEVICE FELL DUE TO THE MOUNTING ISSUE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

THE REMOTE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND DETERMINED THAT THE DEVICE ATTACHED TO AN ARM AND BY WEAR AND TEAR THE FASTENING SYSTEM DID NOT HOLD ANYMORE, THE MONITOR FELL. THE CUSTOMER ADVISED THAT THE DEVICE WAS PUSHED INTO THE SUPPORT PIN BUT DOES NOT CLIP ANYMORE. THE RSE DETERMINED THAT THE FASTENING SYSTEM AND SCREEN REQUIRED REPLACEMENT. THE CUSTOMER WAS PROVIDED A REPLACEMENT QUICK MOUNT AND DISPLAY TO RESOLVE THE ISSUE.

{{datachunk}}Event645:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230911

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00114

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT DESCRIBED IN THE PRODUCT LABELING. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS SHIPPED. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE DEVICE WAS WORN FOR APPROXIMATELY THE 14-DAY PRESCRIBED WEAR-PERIOD. THE DEVICE LAST TRANSMITTED AND REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT EIGHT DAYS AFTER IT WAS ACTIVATED. THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 PRIOR TO THE NOTED ARRHYTHMIA, THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event646:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20210422

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06377

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT INTERROGATED BACK TO THE DATE OF IMPLANT INSTEAD OF THE MOST RECENT REPORT OR INTERROGATION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.



## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event647:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20231005

event\_location:

remedial\_action:[""]

patient.patient\_age:61 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03631

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event648:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230926

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00520

mdr\_text.text:(B)(6). THE REMOTE SERVICE ENGINEER (RSE) SPOKE WITH THE CUSTOMER, AND THE CUSTOMER ADVISED THAT THE SPEAKER PRODUCED NO SOUND. THE RSE DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

IT WAS REPORTED THE DEVICE WAS IN THE WORKSHOP AND DURING THE REPAIR WORK A TORN SPEAKER CABLE WAS IDENTIFIED AND CHIPPED BLACK POTTING COMPOUND WITH SOLDER CONTACT. THE DEVICE DID NOT HAVE AUDIBLE SOUND BECAUSE THE CONTACT ON THE SPEAKER IS DEFECTIVE. THE FAULT WAS DETECTED WITH DEVICE IN A PARTIALLY DISMANTLED CONDITION. PREVIOUSLY, THERE WAS NO EVIDENCE OR REPORT OF A SPEAKER PROBLEM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event649:

adverse\_event\_flag:N

product\_problems:["Device Alarm System","Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230918

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00521

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THE POWER SUPPLY OF THE MONITOR, ON WHICH THE DEVICE WAS DOCKED, FAILED. THE CUSTOMER REPORTED THAT THE MODULE SUPPOSEDLY GAVE NO ALARM. THE DEVICE WAS SENT TO PHILIPS BENCH REPAIR. A PHILIPS BENCH REPAIR TECHNICIAN (BRT) EVALUATED THE DEVICE AND WAS UNABLE TO CONFIRM THE ISSUE. THERE WERE NO FUNCTIONAL DEFECTS FOUND. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED POWER SUPPLY OF THE MONITOR, ON WHICH THE DEVICE WAS DOCKED, FAILED. THE MODULE SUPPOSEDLY GAVE NO ALARM. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event650:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20201128

event\_location:

remedial\_action:[""]

patient.patient\_age:32 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

## DSI MAUDE Problems Summary

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report\_number:9614453-2023-03606

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT UNDERSENSING ON STORED EPISODES. IT WAS FURTHER NOTED THAT THE DEVICE INTERROGATION WENT BACK TO DATE OF IMPLANT. THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event651:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230915

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00513

mdr\_text.text:THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND FOUND THAT THE DEVICE LOUDSPEAKER WAS DEFECTIVE. THE FSE REPLACED THE LOUDSPEAKER TO RESOLVE THE ISSUE. AFTER THE REPLACEMENT OF THE SPEAKER THE DEVICE WAS OPERATIONAL TO ITS SPECIFICATIONS. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. E1: REPORTING INSTITUTION PHONE: # (B)(6). E1: REPORTER PHONE # (B)(6).

IT WAS REPORTED THE INTELLIVUE MP5 LOUDSPEAKER HAD NO SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event652:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230926

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00512

mdr\_text.text:THE CUSTOMER REPORTED LOUDSPEAKER FAULT. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED. THE CUSTOMER REQUESTED A PARTS ORDER ONLY. THE DEVICE WILL NOT BE RETURNED FOR EVALUATION AND NO ON-SITE ENGINEER IS REQUESTED; THE CUSTOMER WILL REPAIR THE DEVICE. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS UNABLE TO BE CONFIRMED. A SPEAKER ASSEMBLY WAS ORDERED AND SHIPPED TO THE CUSTOMER.

H3 OTHER TEXT : SEE B5.

{{datachunk}}Event653:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230919

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00750

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST, AND SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED



## DSI MAUDE Problems Summary

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PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.

{{datachunk}}Event654:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230919

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00751

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND, AND THE SPEAKER WAS DEFECTIVE. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event655:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230919

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00754

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event656:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230919

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00753

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO PATIENT INVOLVED.

{{datachunk}}Event657:

adverse\_event\_flag:Y

product\_problems:["Image Display Error/Artifact"]

event\_type:Injury

date\_of\_event:20230918

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:10 LEAD ECG TRUNK AAMI/IEC 2M

INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DRX

DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00516

mdr\_text.text:A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

S REPORTED WHILE A PATIENT WAS BEING MONITORED WITH CONTINUOUS ECG MONITORING, DOCTORS HAD A WRONG READING OF THE ECG SIGNAL. THE CUSTOMER REPORTED IT LOOKS LIKE THE PATIENT HAS BEEN TREATED WITH THE WRONG THERAPY. THERE WERE NO SPECIFIC DETAILS PROVIDED ABOUT THE EVENT AND WHAT THE ALLEGED WRONG THERAPY GIVEN TO THE PATIENT AT TIME OF REPORT.

IT HAS BEEN CONFIRMED THE ECG ARTIFACT ISSUE HAD NO ACTUAL IMPACT TO PATIENT AND THERE WAS NO HARM TO THE PATIENT NOR INTERVENTION WAS REQUIRED; HOWEVER, THE ISSUE CAUSED THE OPERATOR TO ¿CONSIDER¿ THE SITUATION CRITICAL FOR THE PATIENT. TESTS OF THE DEVICE FOUND THAT WORN TRUNK CABLES RESULTED IN ARTIFACT, WHICH TRIGGERED VTACH/VFIB OR ASYSTOLE RED ALARMS. BASED ON THIS ECG INTERPRETATION, THE PARAMEDICS ADMINISTERED THE FIRST ROUND OF THERAPY. WHEN THE PARAMEDICS NOTED THE MONITOR DISPLAY AND THE PATIENT¿S CONDITION DID NOT MATCH, A 12-LEAD ECG WAS ACQUIRED WITH A DIFFERENT DEVICE, WHICH REVEALED THE PATIENT WAS NOT IN AN ARRHYTHMIA. FURTHER INFORMATION ON SPECIFIC MEDICATIONS ADMINISTERED AND THERAPIES INITIATED WAS NOT AVAILABLE. THOUGH TYPICAL ADVANCED CARDIOVASCULAR LIFE SUPPORT (ACLS) MEDICATIONS SUCH AS EPINEPHRINE AND AMIODARONE ARE ADMINISTERED FOR THE NOTED ARRHYTHMIAS ABOVE AND CAN INDUCE ADVERSE REACTIONS, BUT IT WAS INDICATED THERE WAS NO HARM TO THE PATIENT. ALTHOUGH, THE CASE WAS ORIGINALLY LOGGED UNDER THE MONITOR BUT THE DEFECT IS WITH THE CABLE. AS PER THE

## DSI MAUDE Problems Summary

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INVESTIGATION DONE BY THE TECHNICIAN, THE MONITOR HAD NO MALFUNCTION BUT THE CABLE. THE DEVICE ISSUE WAS RESOLVED WITH THE REPLACEMENT OF M1663A ECG TRUNK CABLE. THE PATIENT'S CURRENT STATE REMAINS UNKNOWN TO PHILIPS. THE ENGINEER HAD REPLACED THE M1663A ECG TRUNK CABLE AND THE DEFECTIVE M1663A ECG TRUNK CABLE WAS SCRAPPED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS DUE TO A DEFECTIVE ECG TRUNK CABLE. THE REPORTED PROBLEM WAS CONFIRMED.

IT WAS REPORTED WHILE A PATIENT WAS BEING MONITORED WITH CONTINUOUS ECG MONITORING, DOCTORS HAD A WRONG READING OF THE ECG SIGNAL. THE CUSTOMER REPORTED IT LOOKS LIKE THE PATIENT HAS BEEN TREATED WITH THE WRONG THERAPY. THERE WERE NO SPECIFIC DETAILS PROVIDED ABOUT THE EVENT AND WHAT THE ALLEGED WRONG THERAPY GIVEN TO THE PATIENT WAS.

MULTIPLE GOOD FAITH EFFORTS HAS BEEN MADE TO FIND OUT ABOUT THE ACTUAL PATIENT HARM BUT NO FURTHER INFORMATION COULD BE OBTAINED. TESTS OF THE DEVICE FOUND THAT WORN TRUNK CABLES RESULTED IN ARTIFACT, WHICH TRIGGERED VTACH/VFIB OR ASYSTOLE RED ALARMS. BASED ON THIS ECG INTERPRETATION, THE PARAMEDICS ADMINISTERED THE FIRST ROUND OF THERAPY. WHEN THE PARAMEDICS NOTED THE MONITOR DISPLAY AND THE PATIENT'S CONDITION DID NOT MATCH, A 12-LEAD ECG WAS ACQUIRED WITH A DIFFERENT DEVICE, WHICH REVEALED THE PATIENT WAS NOT IN AN ARRHYTHMIA. FURTHER INFORMATION ON SPECIFIC MEDICATIONS ADMINISTERED AND THERAPIES INITIATED WAS NOT AVAILABLE. THOUGH TYPICAL ADVANCED CARDIOVASCULAR LIFE SUPPORT (ACLS) MEDICATIONS SUCH AS EPINEPHRINE AND AMIODARONE ARE ADMINISTERED FOR THE NOTED ARRHYTHMIAS ABOVE AND CAN INDUCE ADVERSE REACTIONS, BUT IT WAS INDICATED THERE WAS NO HARM TO THE PATIENT. ALTHOUGH, THE CASE WAS ORIGINALLY LOGGED UNDER THE MONITOR BUT THE DEFECT IS WITH THE CABLE. AS PER THE INVESTIGATION DONE BY THE TECHNICIAN, THE MONITOR HAD NO MALFUNCTION BUT THE CABLE. THE DEVICE ISSUE WAS RESOLVED WITH THE REPLACEMENT OF M1663A ECG TRUNK CABLE. THE PATIENT'S CURRENT STATE REMAINS UNKNOWN TO PHILIPS. THE ENGINEER HAD REPLACED THE M1663A ECG TRUNK CABLE AND THE DEFECTIVE M1663A ECG TRUNK CABLE WAS SCRAPPED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS DUE TO A DEFECTIVE ECG TRUNK CABLE. THE REPORTED PROBLEM WAS CONFIRMED.

{{datachunk}}Event658:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230929

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:57 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03587

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON A TACHYCARDIA EPISODE. IT WAS FURTHER REPORTED THE ICM EXPERIENCED UNDERSENSING. IT WAS ALSO REPORTED THAT THE REMOTE MONITORING REPORT LAST CLEARED INTERROGATED BACK TO DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE

## DSI MAUDE Problems Summary

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REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event659:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230930

event\_location:

remedial\_action:[""]

patient.patient\_age:45 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03588

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT LAST CLEARED INTERROGATED BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE,



A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event660:

adverse\_event\_flag:N

product\_problems:["Appropriate Term/Code Not Available"]

event\_type:Malfunction

date\_of\_event:20230901

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2023-02900

mdr\_text.text:A VOLUNTARY MEDWATCH FORM 3500 WAS RECEIVED (REPORT # MW5145795). MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION

AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS REMOVED FROM THE PATIENT DUE TO AN UNKNOWN REASON. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event661:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230624

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03591

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING, RESULTING IN PAUSE AND BRADYCARDIA EPISODES. IT WAS FURTHER REPORTED THAT THE COUNTERS DID NOT CLEAR AFTER THE LAST INTERROGATION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event662:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230915

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00510

mdr\_text.text:A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED A ¿SPEAKER MALFUNCTION¿ INOP MESSAGE WAS DISPLAYED ON THE DEVICE, BUT THE DEVICE DID NOT PRODUCE SOUND. THE RSE STATED THAT THE SPEAKER ASSEMBLY NEEDED TO BE REPLACED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

IT WAS REPORTED THAT THERE WAS A SPEAKER MALFUNCTION. THE SPEAKER IS NOT MAKING ANY NOISE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event663:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230824

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03593

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY

## DSI MAUDE Problems Summary

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PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event664:

adverse\_event\_flag:N

product\_problems:["Audible Prompt/Feedback Problem"]

event\_type:Malfunction

date\_of\_event:20230915

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00743

mdr\_text.text:A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THEY ARE GETTING A SPEAKER MALFUNCTION ERROR. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

H3: AND H6 AFTER FURTHER INVESTIGATION IT WAS CONFIRMED THAT THIS COMPLAINT IS A DUPLICATE REPORT. PLEASE REFER TO MFG 1218950-2023-00502 FOR COMPLETE INVESTIGATION.

{{datachunk}}Event665:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Death

date\_of\_event:20230905

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest","Perforation","Insufficient Information"]

device.brand\_name:MX40 PATIENT WEARABLE MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00746

mdr\_text.text:THE REMOTE SUPPORT ENGINEER (RSE) PULLED THE AUDIT LOGS OF THE SYSTEM FOR THE REVIEW TO DETERMINE THE CAUSE OF THE REPORTED ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A USER ERROR IN PATIENT DISCHARGE. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS. THE MX40 PATIENT WEARABLE MONITOR HAS NOT CAUSED OR CONTRIBUTED TO THE REPORTED ISSUE, AS THE DEVICE WAS WORKING AS INTENDED.

THE PATIENT INFORMATION CENTER IX IN USE DURING THIS EVENT WAS REPORTED IN MFR REPORT NUMBER 1218950-2023-00670.

SECTION E REPORTER PHONE #: (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED A PATIENT ON THE TELEMETRY WARD PASSED AWAY ON (B)(6) 2023. THE PATIENT WAS PROBABLY ON TELEMETRY FOR ABOUT FIVE DAYS BEFORE THEIR DEATH.

{{datachunk}}Event666:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Death

date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:NA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest","Insufficient Information"]

device.brand\_name:MX40 PATIENT WEARABLE MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00747

mdr\_text.text:PER THE RESPONSE RECEIVED VIA THE CUSTOMER THE PHILIPS REMOTE SERVICE ENGINEER (RSE) STATED THAT THE DATA FOR THE SECOND DEATH MENTIONED IS NOT MADE AVAILABLE DESPITE ASKING FOR IT. HOWEVER, THE RSE CONFIRMED THAT THE CUSTOMER WANTED THE DATA FROM THE UNIT FOR REVIEW, AND THERE WAS NO IMPLICATION OF A FAULT. BASED ON THE INFORMATION PROVIDED IN THE CASE, THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED.

THE CUSTOMER REPORTED THAT THE MX40 PATIENT WEARABLE MONITOR WAS INDICATING THE DEATH ON A PATIENT WEARING THE DEVICE.

SECTION E REPORTER PHONE #: (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED RECENTLY A PATIENT EXPIRED. NO ADDITIONAL DETAILS HAVE BEEN PROVIDED AT THIS TIME AND IT IS UNCLEAR IF THIS EVENT HAS ALREADY BEEN REPORTED.

{{datachunk}}Event667:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20200902



## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03566

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT VENTRICULAR OVER SENSING. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTE RRIGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event668:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20191115

event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03569

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE

## DSI MAUDE Problems Summary

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APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON TACHYCARDIA EPISODES. IT WAS ALSO REPORTED THAT THE ICM EXPERIENCED UNDERSENSING ON PAUSE EPISODES. THE ICM HAD REACHED END OF SERVICE (EOS). IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event669:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20220418

event\_location:

remedial\_action:[""]

patient.patient\_age:51 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03570

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS

## DSI MAUDE Problems Summary

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REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE INTERROGATED BACK TO THE IMPLANT DATE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event670:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230929

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00727

## DSI MAUDE Problems Summary

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mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED; THE SPEAKER WAS DEFECTIVE. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) REPORTED THAT THE MX40 DISPLAYS AN ERROR OF SPEAKER MALFUNCTION, AND NO SOUND IS MADE FROM THE SPEAKER. THE BIOMED CONFIRMED THAT NO SOUND WAS COMING FROM THE MX40 WHEN IN USE. THE BIOMED WOULD LIKE TO SEND TO THE BENCH FOR REPAIR.

{{datachunk}}Event671:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230927

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00728

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO

## DSI MAUDE Problems Summary

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SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) REPORTED THAT THE DEVICE GAVE A SPEAKER MALFUNCTION ERROR MESSAGE AND WOULD NOT PRODUCER SOUND. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT, OR HARM WAS REPORTED.

{{datachunk}}Event672:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231002

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00735

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, PHILIPS WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE

## DSI MAUDE Problems Summary

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SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING, IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT; THEREFORE, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED THAT THE DEVICE HAD A SPEAKER MALFUNCTION ERROR MESSAGE, AND THE SPEAKER WOULD NOT PRODUCE SOUND. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT OR HARM WAS REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event673:

adverse\_event\_flag:N

product\_problems:["Alarm Not Visible"]

event\_type:Malfunction

date\_of\_event:20230918

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00733

mdr\_text.text:A PHILIPS REMOTE SERVICE ENGINEER (RSE) VERIFIED THAT THERE WAS AN INOPERATIVE (INOP) ALARM STATING SOME ECG ALARMS WERE OFF. THE RSE INSTRUCTED HE CUSTOMER BIOMEDICAL ENGINEER (BIOMED) TO ENTER THE ECG SETUP MENU BY TOUCHING HEART RATE (HR>ARRHYTHMIA>TURN ARRHYTHMIA ON), AND RECOMMENDED ATTEMPTING TO ACTIVATE A RED LEVEL ALARM ON A SIMULATOR WHILE ASSIGNED TO SECTOR ON THE PHILIPS INFORMATION CENTER IX (PIC IX). THE BIOMED PUT A HOLD ON THE RECOMMENDED STEPS SUGGESTED BY THE RSE FOR THE

## DSI MAUDE Problems Summary

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FOLLOWING DAY AND WOULD CALL BACK TO CONFIRM. THEY STATED THE MX40 WAS BACK IN SERVICE AND NOT HAVING ANY ISSUES NOW. FURTHER DETAILS WERE REQUESTED, BUT NOT ABLE TO BE PROVIDED, AS THE REPAIR WAS FROM ANOTHER BIOMED ON SITE AND NOT THE CASE OWNER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS UNKNOWN. THE REPORTED PROBLEM WAS NOT CONFIRMED. PHILIPS WAS UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE BECAUSE THE CUSTOMER TOOK RESPONSIBILITY TO CORRECT/REPAIR THE DEVICE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT MX40 1.4 GHZ SMART HOPPING DEVICE ALARMS WERE NOT DISPLAYING. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; THIS WAS NOTICED WHILE USING A SIMULATOR. NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event674:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230925

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00734

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE REPORTED PROBLEM WAS CONFIRMED. RESULTS OF FUNCTIONAL TESTING



## DSI MAUDE Problems Summary

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INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING REPAIR EVALUATION AT THE PHILIPS REPAIR BENCH, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event675:

adverse\_event\_flag:Y

product\_problems:["Moisture Damage","Smoking"]

event\_type:Malfunction

date\_of\_event:20230907

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Superficial (First Degree) Burn"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00060

mdr\_text.text:IT WAS REPORTED THAT THE MONITOR WAS DAMAGED DUE TO A SMOKING CHARGING CORD. THE MONITOR NO LONGER FUNCTIONED. THE MONITOR AND THE CHARGING CORD WAS RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS ABLE TO CONFIRM THE REPORTED COMPLAINT OF "MONITOR DAMAGED DUE TO A SMOKING CORD". THE MOST LIKELY ROOT CAUSE OF THE REPORTED EVENT IS THE DUE TO AN ELECTRICAL FAULT WITHIN USB-A/USB-C CHARGING CORD. THE COMPONENT FAILURE IS FURTHER BEING INVESTIGATED BY PHILIP'S AM&D.

## DSI MAUDE Problems Summary

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THE PATIENT REPORTED THAT THE MONITOR WAS DAMAGED DUE TO A SMOKING CHARGING CORD. THE PATIENT REACTED AND THREW WATER ON THE SMOKING CHARGING CODE. THE MONITOR NO LONGER FUNCTIONS DUE TO THE WATER AND CHARGING PORT IS DAMAGED. THE PATIENT REPORTED THAT SHE RECEIVED A SMALL BRUN. THE PATIENT DID NOT REQUIRE MEDICAL ATTENTION. THE DEVICIE WAS RETURNED.

{{datachunk}}Event676:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230926

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00505

mdr\_text.text:UPDATED FOR HEALTH IMPACT GRID AND AND EVALUATION CODE GRID.

IT WAS REPORTED IF THE INTELLIVUE X2 MEASUREMENT SERVER IS DISCONNECTED FROM THE MX450, NO ALARM SOUNDS ARE TRIGGERED ON THE X2. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

PHILIPS FIELD SERVICE ENGINEER (FSE) COULD FIND NO ISSUE WITH THE DEVICE. THE DEVICE WAS OPERATING AS NORMAL. THE FSE SUGGESTED TO THE CUSTOMER THAT THE QRS TONE COULD HAVE BEEN SWITCHED OFF IN CONFIGURATION SETTINGS. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS UNKNOWN. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS

## DSI MAUDE Problems Summary

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AND NO FAILURE WAS IDENTIFIED.

IT WAS REPORTED IF THE INTELLIVUE X2 MEASUREMENT SERVER IS DISCONNECTED FROM THE MX450, NO ALARM SOUNDS ARE TRIGGERED ON THE X2. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. E1: REPORTING INSTITUTION PHONE: # (B)(6). E1: REPORTER PHONE #: (B)(6).

{{datachunk}}Event677:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230907

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:CIC PRO

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:CRITIKON DE MEXICO S. DE R.L. DE C.V.

report\_number:3008729547-2023-00009

mdr\_text.text:THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARMS AT THE CIC PRO. THERE WAS NO RELATED ADVERSE PATIENT IMPACT.

LEGAL MANUFACTURER: HCS TOWER - 8200 W TOWER AVE USA MILWAUKEE, WI 53223 A1-6: NOT PROVIDED BY CUSTOMER. INVESTIGATION FINDINGS: THE CUSTOMER REPORTED A LOSS OF AUDIBLE ALARM FUNCTION ON THE CIC PRO. ON FOLLOW-UP WITH THE CUSTOMER, THERE WAS NO RELATED ADVERSE PATIENT CONSEQUENCE, NOR ALLEGATION THAT THE ISSUE LED TO A MISSED PATIENT EVENT OR DELAY IN TREATMENT. THE BIOMEDICAL ENGINEER REBOOTED THE CIC PRO WHICH RESTORED THE

AUDIO FUNCTION. PER REVIEW WITH GE HEALTHCARE (GEHC) ENGINEERING, THIS EVENT WAS DETERMINED TO BE RELATED TO A PREVIOUSLY INVESTIGATED ISSUE WHEREIN THE CIC PRO MAY LOSE AUDIBLE ALARM FUNCTION. THE VISUAL ALARMS ARE STILL PRESENT AND ACTIVE. IF THE PATIENT IS ALSO CONNECTED TO A BEDSIDE DEVICE, THE ALARMS AT THE BEDSIDE MONITOR ARE UNAFFECTED. GEHC ATTEMPTED TO REPRODUCE THE ISSUE WITH SIMILAR DEVICES IN THE TEST LAB, REVIEWED DEVICE PERFORMANCE LOG FILES FOR OTHER DEVICES THAT SHOWED THE SAME ISSUE, AND PERFORMED EXTENSIVE HISTORICAL DATA ANALYSIS ALONG WITH TECHNICAL DESIGN REVIEW. GEHC WAS UNABLE TO DETERMINE A DEFINITIVE ROOT CAUSE FOR THE LOSS OF AUDIBLE ALARM FUNCTION. GEHC CONTINUES TO EVALUATE INCOMING COMPLAINTS AND INVESTIGATE WHERE APPROPRIATE.

{{datachunk}}Event678:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 802.11A/B/G

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00738

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

## DSI MAUDE Problems Summary

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THE CUSTOMER REPORTED THAT A SPEAKER MALFUNCTION ERROR MESSAGE DISPLAYS ON SCREEN, AND THERE IS NO SOUND. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

{{datachunk}}Event679:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230913

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 2.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00739

mdr\_text.text:THE CUSTOMER REPORTED THE TELEMETRY DEVICE HAS WATER DAMAGE AND NO AUDIBLE SOUND. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THE DEVICE HAD NO SOUND. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME OF THE EVENT. THERE WAS NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

THE CUSTOMER RETURNED THE DEVICE TO THE PHILIPS AUTHORIZED REPAIR FACILITY (RFT) FOR BENCH EVALUATION. THE REPAIR FACILITY TECHNICIAN (RFT) PERFORMED FUNCTIONAL TESTING AND

## DSI MAUDE Problems Summary

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CONFIRMED THE CUSTOMER'S REPORTED ISSUE. IT WAS DETERMINED THE SPEAKER WAS FAULTY. THE RFT SENT THE CUSTOMER A REPLACEMENT DEVICE.

{{datachunk}}Event680:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20231003

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00741

mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION. IT IS UNCLEAR IF THE SPEAKER WAS UNABLE TO PRODUCE SOUND, OR IF THE ISSUE WAS ONLY AN INOPERATIVE ERROR MESSAGE WITH SOUND PRESENT. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. NO ADVERSE EVENT OR HARM WAS REPORTED.

FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO AUDIO SOUND; THE SPEAKER HAD NO SOUND DURING THE START-UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED, AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED, THE COMPLAINT FILE WILL BE REOPENED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event681:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20210814

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06216

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE

## DSI MAUDE Problems Summary

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BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED T-WAVE OVERSENSING (TWOS). IT WAS FURTHER REPORTED THAT DEVICE INTERROGATED EPISODES BACK TO IMPLANT DATE THOUGH IT HAD BEEN REMOTELY INTERROGATED SINCE THEN. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event682:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20220831

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06222

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS



## DSI MAUDE Problems Summary

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EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE DEVICE INTERROGATED BACK TO DATE OF IMPLANT RATHER THAN LAST SESSION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event683:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230923

event\_location:

remedial\_action:[""]

patient.patient\_age:59 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

## DSI MAUDE Problems Summary

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report\_number:9614453-2023-03535

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED A FALSE PAUSE EPISODE DUE TO UNDERSENSING R-WAVES OR PREMATURE VENTRICULAR CONTRACTIONS (PVC)'S. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event684:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230926

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03536

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE ATRIAL FIBRILLATION (AF) EPISODES DUE TO PREMATURE VENTRICULAR CONTRACTIONS (PVC) UNDERSENSING AND DETECTED FALSE TACHYCARDIA EPISODES DUE TO T-WAVE OVERSENSING (TWOS).

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC

## DSI MAUDE Problems Summary

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OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED T-WAVE OVERSENSING (TWOS). THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event685:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20230224

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03537

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT OVERSENSING. IT WAS FURTHER NOTED THAT THE DEVICE INTERROGATED BACK TO DATE OF IMPLANT INSTEAD OF MOST RECENT FULL REPORT. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF

## DSI MAUDE Problems Summary

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THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event686:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210222

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06237

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON TACHYCARDIA EPISODES. IT WAS ALSO REPORTED THAT THE DEVICE EXPERIENCED UNDERSENSING DURING PAUSE AND BRADYCARDIA EPISODES. IT WAS FURTHER REPORTED THAT THE TRANSMISSION LAST CLEARED WENT BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event687:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20191212

event\_location:

remedial\_action:[""]

patient.patient\_age:84 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03540

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT INTERROGATED BACK TO THE DATE OF IMPLANT. THE ICM HAD MET RECOMMENDED REPLACEMENT TIME (RRT). THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event688:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210817

event\_location:

remedial\_action:[""]

patient.patient\_age:59 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06240

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.



## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCE A PAUSE EPISODE, RELATED TO IMPLANT. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT INTERROGATED BACK TO THE DATE OF IMPLANT AND DID NOT REFLECT CURRENT INTERROGATION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event689:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20220819

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03543

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDER SENSED R-WAVES ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY HAVE NOT BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT

## DSI MAUDE Problems Summary

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DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event690:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230607

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00729

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE TECHNICIAN PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE DEVICE BEEP AND SOUND TESTING AND THERE WAS NO AUDIO DURING THE START-UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAILED SPEAKER. THE REPORTED

## DSI MAUDE Problems Summary

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PROBLEM WAS CONFIRMED. THE TECHNICIAN REPLACED THE DEVICE SPEAKER - FOXLINK D SPEAKER - 453665031201. THE DEVICE PASSED ALL FUNCTIONAL TESTING. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event691:

adverse\_event\_flag:Y

product\_problems:["Sparking"]

event\_type:Injury

date\_of\_event:20230611

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Shock from Patient Lead(s)"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00063

mdr\_text.text:IT WAS REPORTED WHEN PATIENT WAS BEING DEFIBRILLATED SPARKS CAME OUT OF THE SENSOR. THE SENSOR WAS RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION COULD NOT REPLICATE THE REPORTED EVENT OF "THE SENSOR WAS NOT CHARGING AND SPARKS COMING OUT OF THE SENSOR." PER THE PATIENT EDUCATION GUIDE (PEG) IT SPECIFICALLY STATES "REMOVE BRAEMAR TELEMETRY SYSTEM PATCH AND SENSOR BEFORE USING AN EXTERNAL DEFIBRILLATOR." ANY SPARK OBSERVED DURING DEFIBRILLATION IS MOST LIKELY THE RESULT OF THE VOLTAGE DISCHARGED BY THE AUTOMATED EXTERNAL DEFIBRILLATOR (AED) AND NOT A PRODUCT MALFUNCTION. ANY ISSUE WITH

## DSI MAUDE Problems Summary

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CHARGING IS ALSO LIKELY RESULTING FROM PATIENT DEFIBRILLATION.

IT WAS REPORTED BY PATIENT AND HER DAUGHTER THAT THE SENSOR WAS NOT CHARGING. THE DAUGHTER SAID HER MOTHER HAD BEEN DEFIBRILLATED AND THAT SPARKS CAME OUT OF THE SENSOR. THE PATIENT WAS ADVISED TO REMOVE THE BLUE CASING OF THE PATCH. THE SENSOR WAS FLASHING RED. A REPLACEMENT SENSOR WAS ORDERED IN CASE OF IT BEING DAMAGED DURING THE DEFIBRILLATION. THE PATIENT WILL TRY TO RECONNECT A FEW HOURS AFTER THE SENSOR IS CHARGED.

{{datachunk}}Event692:

adverse\_event\_flag:N

product\_problems:

event\_type:Malfunction

date\_of\_event:20230916

event\_location:

remedial\_action:[""]

patient.patient\_age:28835 DA

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Wound Dehiscence","Fall","Pain"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:17867753

mdr\_text.text:THE PATIENT HAS THE REVEAL LINQ INSERTABLE CARDIAC MONITOR PLACED A FEW DAYS BEFORE. PATIENT SUSTAINED A FALL FROM THE CART TO THE FLOOR IMMEDIATELY FOLLOWING THE PROCEDURE ON THE OPPOSITE SIDE THAT THE DEVICE WAS PLACED. PATIENT FELT A STRONG JARRING DUE TO THE FALL. THE PATIENT WAS DISCHARGED HOME. PATIENT NOTICED A LUMP AND PAIN AT THE SITE WHERE THE IMPLANTABLE LOOP RECORDER WAS PLACED, RETURNED TO THE EMERGENCY DEPARTMENT (ED). MD FOUND THE REVEAL LINQ INSERTABLE CARDIAC MONITOR PARTIALLY EXPOSED THROUGH THE CHEST, WOUND DEHISCENCE, NO DRAINAGE OR BLEEDING. THE REVEAL LINQ INSERTABLE CARDIAC MONITOR WAS REMOVED WITHOUT DIFFICULTY AND DISPOSED OF IN MEDICAL

WASTE. PATIENT FELT BETTER UPON REMOVAL OF DEVICE.

{{datachunk}}Event693:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230918

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00725

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THEMX40 PATIENT WEARABLE MONITOR DEVICE DID NOT PRODUCE SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND DUE TO A DEFECTIVE SPEAKER. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE.

{{datachunk}}Event694:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20230730

event\_location:

remedial\_action:[""]

patient.patient\_age:43 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03498

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: B3 MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE

## DSI MAUDE Problems Summary

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EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR OVER AND UNDERSENSING ON ALL EPISODES RESULTING IN POSSIBLE FALSE EPISODES.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON TACHYCARDIA EPISODES. IT WAS ALSO REPORTED THE ICM EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS ALSO REPORTED THAT THE DEVICE DEFAULT REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF



THIS EVENT.

{{datachunk}}Event695:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230907

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00722

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND AT START UP TEST, AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event696:

adverse\_event\_flag:N

product\_problems:["Device Fell"]

event\_type:Malfunction

date\_of\_event:20230913

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP50

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00498

mdr\_text.text:A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT TO THE CUSTOMER'S SITE TO EVALUATE THE DEVICE IN QUESTION. THE FSE CONFIRMED THE MP50 WAS DROPPED DURING TRANSPORT UNMOUNTED TO ANY FIXTURE. THE STAFF PUT THE MP50 DIRECTLY ON THE BED RESULTING IN ITS FALL CAUSING DISPLAY AND MAIN UNIT FRAME DAMAGE. THE FSE REPAIRED THE UNIT, CONDUCTED A HEAT RUN, AND INSPECTED IT THOROUGHLY. THE UNIT PASSED PERFORMANCE VERIFICATION TESTING AND RETURNED TO NORMAL OPERATION. THE DEVICE REMAINS IN USE AT THE CUSTOMER'S SITE.

THE PHILIPS FIELD SERVICE ENGINEER (FSE) REPORT THE ISSUE ON THE CUSTOMER'S BEHALF. IT WAS REPORTED THAT THE MP50 FELL. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED. THE FSE CONFIRMED THAT THE DISPLAY AND MAIN UNIT FRAME WERE DAMAGED BECAUSE THE MP50 WAS DROPPED. THE FSE REPAIRED THE PART, INSPECTED IT, AND CARRIED OUT A HEAT RUN, AND CONFIRMED NORMAL OPERATION.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event697:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N  
product\_problems:["No Audible Prompt/Feedback"]  
event\_type:Malfunction  
date\_of\_event:20230123  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:  
patient.patient\_sex:  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH  
report\_number:9610816-2023-00495  
  
mdr\_text.text:A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THE ¿SPEAKER MALFUNCTION¿ INOP MESSAGE WAS DISPLAYED ON THE DEVICE. THE RSE DETERMINED THAT THE SPEAKER ASSEMBLY NEEDED TO BE REPLACED. A GOOD FAITH EFFORT (GFE) CONDUCTED COULDN'T CONFIRMED IF THE X2 DEVICE WAS COMPLETELY OUT OF SOUND. THE SOUND WORKED ON THE CENTRAL AND ON THE HOST MONITOR THE X2 WAS CONNECTED TO. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.  
  
THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2. THE DEVICE WAS COMPLETELY OUT OF SOUND. THE DEVICE WAS NOT IN USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT OCCURRED.

{{datachunk}}Event698:

adverse\_event\_flag:N  
product\_problems:["Reset Problem"]  
event\_type:Malfunction  
date\_of\_event:20230925

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06115

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED A POWER ON RESET (POR). THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event699:  
adverse\_event\_flag:Y  
product\_problems:["Communication or Transmission Problem"]  
event\_type:Injury  
date\_of\_event:20230905  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:NA  
patient.patient\_sex:  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["Shock from Patient Lead(s)"]  
device.brand\_name:PATIENT CONNECTOR

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2023-02792

mdr\_text.text:CORRECTION: H6 EVAL CODE CONCLUSION MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: PERFORMANCE DATA COLLECTED FROM THE MOBILE PROGRAMMER WAS RECEIVED AND ANALYZED. ANALYSIS OF THE PRODUCT DATA /DATABASE WAS ABLE TO CONFIRM THE CUSTOMER COMMENT THAT THE MOBILE PROGRAMMER PATIENT CONNECTOR WAS USED TO SUSPEND THERAPIES FROM THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) BEFORE AN RADIOFREQUENCY (RF) ABLATION PROCEDURE AND THE PATIENT CONNECTOR LOST TE LEMETRY WITH THE ICD DURING THE PROCEDURE WITH THERAPIES REACTIVATED RESULTING IN THE PATIENT RECEIVING AN INAPPROPRIATE SHOCK DUE TO RF NOISE. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA

## DSI MAUDE Problems Summary

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3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE MOBILE PROGRAMMER PATIENT CONNECTOR WAS USED TO SUSPEND THERAPIES FROM THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) BEFORE AN RADIOFREQUENCY (RF) ABLATION PROCEDURE. THE PATIENT CONNECTOR LOST TELEMETRY WITH THE ICD DURING THE PROCEDURE AND THERAPIES WERE REACTIVATED. THE PATIENT RECEIVED AN INAPPROPRIATE SHOCK DUE TO RF NOISE. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN

## DSI MAUDE Problems Summary

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ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event700:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230906

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00490

mdr\_text.text:A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED A ¿SPEAKER MALFUNCTION¿ INOP MESSAGE WAS DISPLAYED ON THE DEVICE. THE RSE



## DSI MAUDE Problems Summary

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DETERMINED THE MAIN BOARD NEEDED TO BE REPLACED. THE CUSTOMER ORDERED AND WAS PROVIDED A REPLACEMENT MAIN BOARD TO RESOLVE THE ISSUE.

THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MX700 PATIENT MONITOR. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event701:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220427

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00073

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 22. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE

TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event702:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230227

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

## DSI MAUDE Problems Summary

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report\_number:3007208829-2023-00099

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 9 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 35. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN (B)(6) 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event703:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230501

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00103

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 31. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN

## DSI MAUDE Problems Summary

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TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event704:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230131

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00110

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 3 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 14. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS

MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

{{datachunk}}Event705:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230906

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2023-00708

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD NO AUDIO SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THERE WAS NO SPEAKER SOUND AT START UP TEST, DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event706:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00716

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

## DSI MAUDE Problems Summary

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DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event707:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00713

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND DURING THE START-UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.



## DSI MAUDE Problems Summary

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{{datachunk}}Event708:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00718

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event709:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00717

mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event710:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00715

mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event711:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00712

mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND DURING THE START-UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event712:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Death

date\_of\_event:20230820

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00053

## DSI MAUDE Problems Summary

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mdr\_text.text:THIS SUPPLEMENTAL REPORT IS BEING SUBMITTED TO CORRECT THE PREVIOUSLY REPORTED INVESTIGATION FINDINGS AND CODES BASED ON AN ADDITIONAL REVIEW OF THE COMPLAINT. A REVIEW OF THIS COMPLAINT DISCOVERED THAT THE PATIENT WAS PRESCRIBED A ZIO AT DEVICE THAT WAS PLACED IN CLINIC BY THEIR PHYSICIAN. ON DAY 3 IRHYTHM CALLED THE PATIENT TO FOLLOW UP ON THE ¿NO CONNECTION 24 HOURS¿ STATUS, THE PATIENT STATED HE WAS IN A REMOTE AREA AND WOULD BE FOR 2 - 3 WEEKS, BUT HE WOULD TRAVEL INTO BETTER SERVICE AREAS FROM TIME TO TIME. DURING THE CALL, IRHYTHM CUSTOMER CARE PERFORMED TROUBLESHOOTING OF THE ZIO DEVICE AND CONFIRMED THAT THE DEVICE WOULD TRANSMIT IN A BETTER SERVICE AREA. THERE WERE NO KNOWN ZIO PATCH ISSUES AT THAT TIME. THE ZIO AT WAS RETURNED TO IRHYTHM FOR EVALUATION. AVAILABLE DEVICE DATA INDICATES THAT THE PATCH WAS REMOVED FROM THE PATIENT ON DAY 11. THERE WERE ACTIONABLE ARRHYTHMIAS IDENTIFIED THAT DID NOT MEET AUTO-DETECTION CRITERIA DURING DAY 6. THE END-OF-LIFE EVENT OCCURRED ON DAY 10 AND DID NOT TRANSMIT DUE TO THE CELLULAR CONNECTIVITY ISSUE. THE EVENTS WERE FOUND WHILE PREPARING THE FINAL REPORT. THE INVESTIGATION DID NOT FIND EVIDENCE THAT THE DEVICE CAUSED OR CONTRIBUTED TO THE PATIENT'S DEATH. HOWEVER, DID CONFIRM THE REPORTED CONNECTION ISSUE, AS A CONNECTION GAP WAS NOTED FROM DAY 2 THROUGH DAY 6 DURING THE PATIENT¿S WEAR PERIOD. ADDITIONALLY, A BLUETOOTH ERROR WAS ALSO NOTED ON DAY 5, THE ERROR WAS NOT DETECTED AT THE TIME OF WEAR BECAUSE THE PATIENT WAS IN AN AREA THAT DID NOT HAVE CELLULAR CONNECTION. THIS EVENT IS BEING REPORTED OUT OF AN ABUNDANCE OF CAUTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPIRED DURING THEIR PRESCRIBED ZIO AT WEAR PERIOD. IRHYTHM ATTEMPTED TO GATHER MORE INFORMATION ABOUT THE CAUSE OF DEATH FROM THE ACCOUNT, BUT NO FURTHER DETAILS WERE PROVIDED.

A REVIEW OF THIS COMPLAINT DISCOVERED THAT THE PATIENT WAS PRESCRIBED A ZIO AT DEVICE THAT WAS PLACED IN CLINIC BY THEIR PHYSICIAN. ON DAY 3 IRHYTHM CALLED THE PATIENT TO FOLLOW UP ON THE ¿NO CONNECTION 24 HOURS¿ STATUS, THE PATIENT STATED HE WAS IN A REMOTE AREA AND WOULD BE FOR 2 - 3 WEEKS, BUT HE WOULD TRAVEL INTO BETTER SERVICE AREAS FROM TIME TO TIME. DURING THE CALL, IRHYTHM CUSTOMER CARE PERFORMED TROUBLESHOOTING OF THE ZIO DEVICE AND CONFIRMED THAT THE DEVICE WOULD TRANSMIT IN A BETTER SERVICE AREA. THERE WERE NO KNOWN ZIO PATCH ISSUES AT THAT TIME. THE ZIO AT WAS RETURNED TO IRHYTHM FOR EVALUATION. AVAILABLE DEVICE DATA INDICATES THAT THE PATCH WAS REMOVED FROM THE PATIENT ON DAY 11. THERE WERE ACTIONABLE ARRHYTHMIAS IDENTIFIED THAT DID NOT MEET AUTO-DETECTION CRITERIA DURING DAY 6. THE END-OF-LIFE EVENT OCCURRED ON DAY 10 AND DID NOT TRANSMIT DUE TO THE CELLULAR CONNECTIVITY ISSUE. THE EVENTS WERE FOUND WHILE PREPARING THE FINAL REPORT. THE CAUSE OF THE REPORTED EVENT CANNOT BE DETERMINED. THE INVESTIGATION DID NOT FIND EVIDENCE THAT THE DEVICE CAUSED OR CONTRIBUTED TO THE PATIENT'S DEATH, AS IT FUNCTIONED AS INTENDED. HOWEVER, DID CONFIRM THE REPORTED CONNECTION ISSUE, AS A CONNECTION GAP WAS NOTED FROM DAY 2 THROUGH DAY 6 DURING THE

PATIENT'S WEAR PERIOD. THERE WERE NO ARRHYTHMIAS NOTED THAT MET DETECTION DURING THIS TIME. THIS EVENT IS BEING REPORTED OUT OF AN ABUNDANCE OF CAUTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event713:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20221008

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00086

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 22. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE

## DSI MAUDE Problems Summary

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TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRs FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event714:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20221105

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00090

## DSI MAUDE Problems Summary

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mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE (ZIO AT PATCH AND GATEWAY) WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 30. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND THE HCP CHOSE NOT TO ACCEPT A REPLACEMENT DEVICE.

{{datachunk}}Event715:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220924

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:



## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00083

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 18. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH 2TRIGGER OFF2 ICONS. THE REPRESENTATIVE WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event716:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230221

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00098

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 4 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 15. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A

## DSI MAUDE Problems Summary

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TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

{{datachunk}}Event717:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230116

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00092

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 10 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 23. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A

REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE REPRESENTATIVE WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND THE REPRESENTATIVE CHOSE NOT TO ACCEPT A REPLACEMENT DEVICE SINCE THE PATIENT RECEIVED AN IMPLANTABLE DEVICE.

{{datachunk}}Event718:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220306

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00072

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT BUT FAILED TO REACH THE ACCOUNT AFTER LEAVING VOICEMAILS ON DAY(S) 35, 39, AND 40. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event719:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20221104

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00105

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 4 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE PATIENT TRIGGERED MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH 2TRIGGER OFF2 ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE PATIENT TRIGGERED TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event720:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230130

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, IN

report\_number:3007208829-2023-00093

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 2 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. HOWEVER, THE PATIENT RETURNED THE MONITOR BACK UNUSED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 17. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT

TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN (B)(6) 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event721:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20221013

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00085

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND



NOTIFIED THE HCP ON DAY 17. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event722:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20211105

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00109

mdr\_text.text:PER IRHYTHM PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. . THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS.

{{datachunk}}Event723:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220612

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00077

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 9 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH 2TRIGGER OFF2 ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS SENT.

{{datachunk}}Event724:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction  
date\_of\_event:20220922  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:  
patient.patient\_sex:Female  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["Unspecified Heart Problem"]  
device.brand\_name:ZIO AT  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC  
report\_number:3007208829-2023-00116

mdr\_text.text:PER IRHYTHM PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 107. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS.

{{datachunk}}Event725:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230501

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00104

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 5 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 34. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

{{datachunk}}Event726:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230219

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00096

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR

PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND 2 TRIGGER OFF 2 ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 4 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 15. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event727:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230619

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06045

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. IT WAS FURTHER REPORTED THAT THE CURRENT COUNTERS WERE EQUAL TO THE LIFETIME COUNTERS ON THE REMOTE MONITORING REPORT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event728:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230914



## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03445

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY HAVE NOT BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR DID NOT WENT TO TELEMETRY STEP AND WAS NOT ABLE TO SEND TRANSMISSION WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT HAVE ANY SUCCESSFUL WIRELESS TRANSMISSIONS SINCE THE DATE OF THE CALL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE

BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event729:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230830

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00707

mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

RESULTS OF DIAGNOSTIC/FUNCTIONAL TESTING PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY CONFIRMED THAT THERE WAS NO SPEAKER SOUND AT THE START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED, AND THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED; THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event730:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230920

event\_location:

remedial\_action:[""]

patient.patient\_age:93 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03447

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR WAS UNABLE TO ESTABLISH TELEMTRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). CALLED PATIENT TO CONNECT NEW READER. WALKED PATIENT THROUGH THE PAIRING PROCESS. THE PATIENT WAS NOT ABLE TO START TELEMTRY. NO ERROR CODES. ADVISED TO DO OVER THE SHIRT, SKIN TO SKIN, AND USE A DRY WASH CLOTH. THE PATIENT WAS REFERRED TO CLINIC. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH

## DSI MAUDE Problems Summary

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ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event731:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230904

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03448

mdr\_text.text:B3: DATE IS APPROXIMATE. MONTH AND YEAR ARE CONFIRMED VALID. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT

DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS UNABLE TO ESTABLISH TELEMTRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). THE PATIENT MANAGEMENT DATABASE CONFIRMED THAT THE REMOTE MONITOR DID NOT HAVE ANY SUCCESSFUL WIRELESS TRANSMISSIONS SINCE THE DATE OF THE CALL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event732:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230905

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00489

## DSI MAUDE Problems Summary

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mdr\_text.text:THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND DETERMINED THAT THE MAIN BOARD REQUIRED REPLACEMENT. THE FSE REPLACED THE MAIN BOARD TO RESOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE MAIN BOARD.

THE CUSTOMER REPORTED DEVICE DOES NOT START - NO SOUND AS WELL. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event733:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230901

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00697

mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE UNIT HAS A SPEAKER MALFUNCTION. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE RFT CONFIRMS THAT THE SPEAKER PRODUCED AUDIBLE SOUND. HOWEVER, THE DISPLAY TOUCH SCREEN WAS FAULTY. THE UNIT WAS REPAIRED AND WAS RETURNED AND THE SALESFORCE REPAIR CASE WAS CLOSED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE

## DSI MAUDE Problems Summary

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REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event734:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230829

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00695

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY CONFIRMED THAT THE SPEAKER HAD NO SOUND, DUE TO A DEFECTIVE SPEAKER. A PHILIPS BENCH REPAIR TECHNICIAN (BRT) REPLACED THE SPEAKER TO SOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event735:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20200212

event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03427

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH



## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM HAD REACHED END OF SERVICE (EOS). IT WAS FURTHER NOTED THAT THE REMOTE MONITORING REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION NOTED. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event736:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230922

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00482

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING ¿EQUIPMENT DISPLAYS A SPEAKER MALFUNCTION INOP ERROR MESSAGE.¿ IT IS UNKNOWN IF THE DEVICE WAS IN USE AT THE TIME OF THE EVENT. NO ADVERSE EVENT OCCURRED. A GOOD FAITH EFFORT (GFE) CONDUCTED FOR ADDITIONAL INFORMATION WAS NOT SUCCESSFUL. IT IS UNKNOWN IF THE DEVICE AS IN STANDALONE MODE OR HAD SOUND. A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THE SPEAKER PROBLEM. THE RSE DETERMINED THE SPEAKER ASSEMBLY NEEDED TO BE REPLACED. THE CUSTOMER ORDERED A

## DSI MAUDE Problems Summary

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REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. H3 OTHER TEXT : DEVICE NOT RETURNED.

IT WAS REPORTED THE INTELLIVUE X2 DISPLAYS A SPEAKER MALFUNCTION INOP ERROR MESSAGE. A LOSS OF AUDIO CANNOT BE RULED OUT BASED ON INFORMATION CURRENTLY AVAILABLE. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. (B)(6).

{{datachunk}}Event737:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230914

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00477

mdr\_text.text:IT WAS REPORTED THE INTELLIVUE MULTI MEASUREMENT SERVER X2 SPEAKER IS DAMAGED. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A PHILIPS REMOTE SERVICE ENGINEER (RSE) INTERVIEWED THE CUSTOMER. THE CUSTOMER CONFIRMED THERE WAS NO SOUND AT ALL AND THERE WAS AN INOPERATIVE SPEAKER INOP MESSAGE

## DSI MAUDE Problems Summary

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PRESENT. THE CUSTOMER WAS PROVIDED WITH A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. AFTER SPEAKER REPLACEMENT THE DEVICE WAS RETURNED TO FULL FUNCTIONALITY WITH NO FURTHER ISSUES IDENTIFIED. THE DEVICE REMAINS AT THE CUSTOMER SITE. E1: (B)(6). H3 OTHER TEXT : DEVICE NOT RETURNED.

{{datachunk}}Event738:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210127

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05985

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR

## DSI MAUDE Problems Summary

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SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE INTERROGATION BACK TO DATE OF IMPLANT INSTEAD OF MOST RECENT FULL REPORT OR PROGRAMMER INTERROGATION. IT WAS ALSO REPORTED THAT THE REMOTE MONITORING REPORT CONTAINED INVALID HISTOGRAMS. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event739:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20230908

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Infection","Pain"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:2182208-2023-02757

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED AN INFECTION. THE ICM WAS REMOVED HAVING BEEN IMPLANTED APPROXIMATELY TWENTY DAYS. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

## DSI MAUDE Problems Summary

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THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT SIGNS OF INFECTION WERE OBSERVED ONE WEEK AFTER IMPLANT OF THE DEVICE. THE PATIENT WAS TREATED WITH ANTIBIOTICS. NO IMPROVEMENT WAS NOTED AND THE PATIENT WAS IN PAIN. THE ICM WAS THEN REMOVED.

{{datachunk}}Event740:

adverse\_event\_flag:N

product\_problems:["Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20230915

event\_location:

remedial\_action:[""]

patient.patient\_age:41 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-06006

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT DURING THE IMPLANTABLE CARDIAC MONITOR (ICM) IMPLANT PROCEDURE, THE DEVICE DID NOT SHOW ANY SENSING OR REAL TIME AMPLITUDE COUNTING ON THE PROGRAMMER SCREEN. THE ICM WAS RE-POSITIONED AND RE-PROGRAMMED HOWEVER THIS DID NOT RESOLVE THE ISSUE. THE ICM WAS REMOVED AND A NEW ICM IMPLANTED WITH SENSING VISIBLE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA

## DSI MAUDE Problems Summary

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3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event741:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230901

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00691

mdr\_text.text:THE CUSTOMER REPORTED A SPEAKER MALFUNCTION WITH THE SYSTEM. THE DEVICE WAS NOT IN USE.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED,



## DSI MAUDE Problems Summary

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THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event742:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230828

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00692

mdr\_text.text:REPORTING ADDRESS STATE: WI.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY CONFIRMED THAT THE SPEAKER HAD NO SOUND, DUE TO A DEFECTIVE SPEAKER. A PHILIPS BENCH REPAIR TECHNICIAN (BRT) REPLACED THE SPEAKER TO SOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT

OR HARM WAS REPORTED.

{{datachunk}}Event743:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220806

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00078

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE (ZIO AT PATCH AND GATEWAY) WAS OFFERED.

## DSI MAUDE Problems Summary

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IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 28. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN (B)(6) 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event744:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220903

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00079

mdr\_text.text:THIS SUPPLEMENTAL REPORT IS BEING SUBMITTED TO CORRECT SECTION D3. MANUFACTURER NAME. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR

## DSI MAUDE Problems Summary

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SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND THE HCP CHOSE NOT TO ACCEPT A REPLACEMENT DEVICE SINCE THE PATIENT WAS HOSPITALIZED AT THE TIME FOR AN UNRELATED EVENT.

THE HCP ACCOUNT WAS NOTIFIED ON 5 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 28. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR

{{datachunk}}Event745:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220907

event\_location:

remedial\_action:["Modification/Adjustment"]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00080

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 8 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 28. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN (B)(6) 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH 2TRIGGER OFF2 ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event746:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20210726

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:RHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00067

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 5 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 29. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACHED, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO,

## DSI MAUDE Problems Summary

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UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event747:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20221016

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00087

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 11 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 22. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN (B)(6) 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION

## DSI MAUDE Problems Summary

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BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND THE HCP CHOSE NOT TO ACCEPT A REPLACEMENT DEVICE SINCE THE PATIENT WAS ALREADY SCHEDULED TO RECEIVE A PACEMAKER.

{{datachunk}}Event748:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20210908

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00070



mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 13 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND ATTEMPTED TO CONTACT THE ACCOUNT MULTIPLE TIMES, BUT WAS UNSUCCESSFUL. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event749:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230319

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00100

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE (ZIO AT PATCH AND GATEWAY) WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event750:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230323

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00101

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 3 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE (ZIO AT PATCH AND GATEWAY) WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 17. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE

INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

{{datachunk}}Event751:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220603

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00075

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 23. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING

## DSI MAUDE Problems Summary

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EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND THE HCP CHOSE NOT TO ACCEPT A REPLACEMENT DEVICE SINCE THE PATIENT RECEIVED A PACEMAKER.

{{datachunk}}Event752:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230423

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00102

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 28. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event753:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220525

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]  
patient.patient\_age:  
patient.patient\_sex:Male  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["Unspecified Heart Problem"]  
device.brand\_name:ZIO AT  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC  
report\_number:3007208829-2023-00074

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 24. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event754:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230115

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00091

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP/REPRESENTATIVE WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 9 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM



## DSI MAUDE Problems Summary

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THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN (B)(6) 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event755:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20210630

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00066

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE

WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ǂTRIGGER OFFǂ ICONS. THE REPRESENTATIVE WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS OFFERED.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 10 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 31. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDAǂS POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR SUBMISSION MATERIALS ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event756:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20210908

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

## DSI MAUDE Problems Summary

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device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00069

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ǂTRIGGER OFFǂ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDAǂS POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN (B)(6) 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event757:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230214

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00095

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 14. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE

NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

{{datachunk}}Event758:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230221

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00097

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

## DSI MAUDE Problems Summary

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THE HCP ACCOUNT WAS NOTIFIED ON DAY 11 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 22. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event759:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback","Audible Prompt/Feedback Problem"]

event\_type:Malfunction

date\_of\_event:20230901

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00696

## DSI MAUDE Problems Summary

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mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE SYSTEM HAS A SPEAKER MALFUNCTION ERROR. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

NO DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED. THE DEVICE WAS NOT RETURNED FOR EVALUATION AS OF >70 DAYS, SO THE REPORTED PROBLEM WAS NOT CONFIRMED. BASED ON THE INFORMATION AVAILABLE, NO FURTHER ACTION IS NECESSARY AT THIS TIME. THE CUSTOMER WAS PROVIDED A REPLACEMENT MX40 DEVICE ON PARTS SUPPLY ORDER, HOWEVER, AS OF 14NOV2023, THERE IS NO ADDITIONAL INFORMATION AVAILABLE AS THE DEVICE HAS NOT BEEN RECEIVED FOR EVALUATION. THE CAUSE OF THE REPORTED ALLEGATION IS UNDETERMINED.

PHILIPS RECEIVED A COMPLAINT ON THE MX40 PATIENT WEARABLE MONITOR INDICATING THAT THE DEVICE IS GIVING A SPEAKER MALFUNCTION AND CONFIRMED NO SOUND. THE DEVICE WAS IN USE ON PATIENT AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event760:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230828

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00694

## DSI MAUDE Problems Summary

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mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY CONFIRMED THAT THE SPEAKER HAD NO SOUND, DUE TO A DEFECTIVE SPEAKER. A PHILIPS BENCH REPAIR TECHNICIAN (BRT) REPLACED THE SPEAKER TO SOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event761:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220915

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00082

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 2 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 22. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A



REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRs FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH 2TRIGGER OFF2 ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND THE HCP CHOSE NOT TO ACCEPT A REPLACEMENT DEVICE SINCE THE PATIENT RECEIVED A PACEMAKER.

{{datachunk}}Event762:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220602

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00076

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ǂTRIGGER OFFǂ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS OFFERED.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 23. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDAǂS POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event763:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20220904

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00081

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 34. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH 2TRIGGER OFF2 ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

{{datachunk}}Event764:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20221016

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00088

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 11 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE (ZIO AT PATCH AND GATEWAY) WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO,

## DSI MAUDE Problems Summary

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UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event765:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230119

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00094

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, AN APPROACHING TRANSMISSION LIMIT AND A TRANSMISSION LIMIT BEING REACHED WOULD PROMPT CONTACT TO THE HCP ACCOUNT, IN TANDEM WITH PRECAUTIONS DISCUSSED IN THE LABELING AND ¿TRIGGER OFF¿ ICONS PRESENTED TO HCP ACCOUNTS ON THE ZIO AT DAILY REPORTS WHEN A TRANSMISSION LIMIT HAD BEEN REACHED. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC

TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS SENT.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS SHIPPED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY <DAY>. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN (B)(6) 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR

{{datachunk}}Event766:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20210826

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:RHYTHM TECHNOLOGIES, INC

## DSI MAUDE Problems Summary

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report\_number:3007208829-2023-00068

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 11 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 29. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRs FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ıTRIGGER OFFı ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event767:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20221004

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00084

mdr\_text.text:NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH ¿TRIGGER OFF¿ ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND THE HCP CHOSE NOT TO ACCEPT A REPLACEMENT DEVICE.

THE HCP ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 20. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA¿S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR.

{{datachunk}}Event768:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]



## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20221021

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00089

mdr\_text.text:THE HCP ACCOUNT WAS NOTIFIED ON DAY 10 THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE ZIO AT PATCH AND GATEWAY WAS OFFERED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 29. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE CLINICIAN TO INFORM THE CLINICIAN THAT A REPLACEMENT ZIO AT PATCH AND GATEWAY WILL BE SENT, UNLESS A CLINICIAN REPRESENTATIVE DETERMINES A REPLACEMENT IS NOT NEEDED. IN KEEPING WITH FDA'S POSITION ON REPORTING EXPECTATIONS AS COMMUNICATED TO THE COMPANY IN MAY 2023, IRHYTHM ALIGNED TO A REPORTING APPROACH FOR MDNS THAT WERE NOT COMMUNICATED DURING THE WEAR PERIOD DUE TO A MAXIMUM TRANSMISSION LIMIT BEING REACH, AND AGREED TO TREAT THESE INSTANCES AS MALFUNCTION MDRS FOR REPORTING PURPOSES. MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. CERTAIN TERMS INCLUDED IN FORM FDA 3500A AND RELATED MDR "

NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET THE CRITERIA FOR MEDICAL DOCTOR NOTIFICATION (MDN) (ARRHYTHMIAS OF CLINICAL INTEREST DURING THE PRODUCT WEAR PERIOD) FOR THE HCP LOCATION, BUT THAT WAS NOT CONVEYED TO THE HCP LOCATION DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT FOR THE ZIO AT DEVICE, PROMPTING A CONTACT TO THE HCP ACCOUNT. ALSO, UNDER THE PROCESS IN PLACE AT THE TIME OF THIS EVENT, WHEN A TRANSMISSION LIMIT HAD BEEN

## DSI MAUDE Problems Summary

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REACHED, THE ZIO AT DAILY REPORT WOULD REFLECT THAT TO THE HCP ACCOUNT THROUGH 2TRIGGER OFF2 ICONS. THE HCP WAS NOTIFIED THAT THE DEVICE HAD MET THE ASYMPTOMATIC TRANSMISSION LIMIT, PRIOR TO THE NOTED ARRHYTHMIA, AND A REPLACEMENT DEVICE WAS OFFERED.

{{datachunk}}Event769:

adverse\_event\_flag:N

product\_problems:["Fire","Overheating of Device"]

event\_type:Malfunction

date\_of\_event:20230905

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00058

mdr\_text.text:IT WAS REPORTED THAT THE SENSOR BURNED THROUGH AN ENVELOP. IT NEVER OVERHEATED PRIOR TO BURNING THROUGH THE PAPER. THE DEVICE WAS RETURNED FOR INVESTIGATION. DEVICE FAILED VISUAL INSPECTION DUE TO THE MELTING OF THE DEVICE. INTERNAL DAMAGE CONFIRMS THAT THERE WAS DAMAGE THAT WAS CAUSED BY A SPARK ON THE SENSOR. UNABLE TO CONFIRM WHERE THE SPARK ORIGINATED AT DUE TO THE DAMAGE OF THE DEVICE.

THE PATIENT REPORTED THAT THEY LAID THE SENSOR ON AN ENVELOPE AND THE SENSOR BURNED THROUGH THE PAPER. THE SENSOR WAS NOT HOT PRIOR TO SETTING IT DOWN. THERE WAS NO HARM TO THE PATIENT REPORTED. THE SENSOR WAS REPLACED.

{{datachunk}}Event770:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230913

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00476

mdr\_text.text:THE REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND DETERMINED THAT THE SPEAKER NEEDED TO BE REPLACED. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. H3 OTHER TEXT : DEVICE NOT RETURNED.

IT WAS REPORTED THE INTELLIVUE PATIENT MONITOR MX800 IS DISPLAYING A SPEAKER MALFUNCTION ERROR MESSAGE AND IS NOT PRODUCING ANY AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event771:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230829

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00685

mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.

RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event772:

adverse\_event\_flag:N

product\_problems:["Thermal Decomposition of Device","Melted"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:64 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00059

mdr\_text.text:THE DEVICE RETURNED WITH PHYSICAL DAMAGE ON THE TOP OF THE MONITOR. THE DAMAGE APPEARED TO BE CAUSED BY OVERHEAT. THE PATIENT NEVER REPORTED ANY TECHNICAL OR PHYSICAL FAILURES OF THE MONITOR DURING USE.

THE DEVICE WAS RETURNED WITH PHYSICAL DAMAGE NEAR THE CAMERA. THE PATIENT DID NOT REPORT ANY TECHNICAL ISSUES OR MALFUNCTIONS DURING USE. THE DEVICE WAS INVESTIGATED. ENGINEERING EVALUATION WAS ABLE TO CONFIRM DEVICE MELT. NO INTERNAL DEVICE WAS OBSERVED DURING EVALUATION. IT IS MOST PROBABLE THAT THE DEVICE MELT WAS CAUSED BY AN EXTERNAL HEAT SOURCE.

{{datachunk}}Event773:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230918

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03387

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). THE PATIENT WAS USING THE NEW MONITOR. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS REFERRED TO CLINIC FOR DEVICE INTERROGATION. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event774:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230830

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00479

mdr\_text.text:A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE TO EVALUATE THE DEVICE AND CONFIRMED THE SPEAKER WAS COMPLETELY OUT OF SOUND WHEN THE UNIT WAS TURNED ON. THERE WAS NO PRESENCE OF A SPEAKER INOPERATIVE MESSAGE PRESENT. THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE THE SPEAKER ASSEMBLY. THE SPEAKER WAS REPLACED AND DEVICE WAS RETURNED TO FUNCTIONAL USE WITH NO FURTHER ISSUES IDENTIFIED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

IT WAS REPORTED THAT THE INTELLIVUE MULTI MEASUREMENT SERVER X2 HAD A FAULTY SPEAKER. A LOUDSPEAKER FAILURE WAS DISPLAYED. THE DEVICE WAS NOT IN USE MONITORING A PATIENT AT THE TIME OF THE EVENT. NO ADVERSE EVENT INVOLVING A PATIENT OR USER WAS REPORTED.

{{datachunk}}Event775:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230831

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00687

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THERE IS SPEAKER MALFUNCTION WITHIN THE BOX AND THERE IS NO AUDIBLE SOUND. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

THE CUSTOMER WAS PROVIDED INSTRUCTIONS TO RETURN THE DEVICE TO BENCH REPAIR; HOWEVER, THE CUSTOMER DID NOT RETURN THE DEVICE FOR EVALUATION. THE CAUSE OF THE REPORTED ALLEGATION IS UNABLE TO BE DETERMINED. H3 OTHER TEXT : DEVICE NOT RETURNED.

{{datachunk}}Event776:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230830

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING



## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00686

mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE UNIT IS NOT MAKING ANY TONES OR NOISES. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event777:

adverse\_event\_flag:Y

product\_problems:["Defective Alarm","No Audible Alarm"]

event\_type:Injury

date\_of\_event:20230827

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00688

mdr\_text.text:THE CUSTOMER REPORTED THAT THE SYSTEM DID NOT ALARM. THE PATIENT EXPERIENCED CARDIAC ARREST.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE LIMITED INFORMATION PROVIDED WAS REVIEWED BY A PHILIPS CLINICAL SPECIALIST AND A PHILIPS MEDICAL SAFETY MANAGER NOTED BELOW: THE STRIPS PROVIDED SHOW SOME BEATS LABELED ¿A¿. IF THE SIGNAL QUALITY IS NOT GOOD, THE ALGORITHM WILL ASSIGN THE BEAT LABEL ¿A¿ FOR ARTIFACT. GOOD SKIN PREPARATION IS CRUCIAL TO SUCCESSFUL MONITORING. A CLEAN SIGNAL IS INTEGRAL TO ACCURATE ARRHYTHMIA MONITORING. A NOISY SIGNAL MAKES IT DIFFICULT TO DETECT AND CLASSIFY BEATS ACCURATELY, THUS AFFECTING EVENT DETECTION AND ALARM GENERATION. (STAR APP NOTE PAGE 2). THE FOLLOWING ARE SOME POSSIBLE CAUSES OF NOISY ECG SIGNALS: POOR SKIN PREPARATION; DRIED ELECTRODE GEL; DETACHED ELECTRODES; BROKEN LEAD WIRES; MUSCLE ARTIFACT CAUSED BY SHIVERING, MOVEMENT, OR TREMORS; BASELINE WANDER CAUSED BY EXCESSIVE CHEST MOVEMENT OR THE OFFSET DIFFERENCES BETWEEN TWO BRANDS OF ELECTRODES; RESPIRATION ARTIFACT CAUSED BY THORACIC OR ABDOMINAL MOVEMENT OF BOTH SPONTANEOUS AND VENTILATED BREATHING PATTERNS; AND INTERFERENCE FROM EQUIPMENT. IF 20 OF THE LAST 30 SECONDS ARE CLASSIFIED AS EITHER NOISY OR QUESTIONABLE (DISPLAYED BY DELAYED BEAT ANNOTATIONS AS PREDOMINANTLY ¿A¿ OR ¿?¿), A CANNOT ANALYZE ECG INOP/TECHNICAL ALARM IS GENERATED. WHEN THE ALGORITHM CANNOT RELIABLY ANALYZE THE ECG DATA, PER THE IFU, THE SYSTEM IS DESIGNED TO PROVIDE/DISPLAY A "CANNOT ANALYZE ECG INOP". THE INTELLIVUE MX400-800 IFU SAYS TO CHECK THE ECG SIGNAL QUALITY OF THE SELECTED PRIMARY AND SECONDARY LEADS. IF NECESSARY, IMPROVE LEAD POSITION OR REDUCE PATIENT MOTION. BASED ON THE REVIEW OF THE AUDIT LOG, THE SYSTEM DID NOT GENERATE AN ASYSTOLE ALARM. THE INFORMATION PROVIDED STATES THE PATIENT WAS HAVING MUSCULAR CONVULSIONS WITH THE ARREST. THIS IS MOST LIKELY RESULTED IN THE STAR ALGORITHM CLASSIFYING SOME BEATS AS ARTIFACT (IDENTIFIED AS BEATS LABELED ¿A¿) . BASED ON THE AVAILABLE INFORMATION, WE CANNOT CONFIRM THE SYSTEM DISPLAYED THE ¿CANNOT ANALYZE ECG INOP¿, BUT WHEN THE ALGORITHM CANNOT RELIABLY ANALYZE THE ECG DATA, PER THE IFU, A "CANNOT ANALYZE ECG INOP¿ IS DISPLAYED. THE INFORMATION PROVIDED STATES THE PATIENT WAS HAVING MUSCULAR CONVULSIONS WITH THE ARREST. THIS IS MOST LIKELY RESULTED IN THE STAR ALGORITHM CLASSIFYING SOME BEATS AS ARTIFACT (IDENTIFIED AS BEATS LABELED ¿A¿) .

{{datachunk}}Event778:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction  
date\_of\_event:20230906  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:  
patient.patient\_sex:  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:MX40 1.4 GHZ SMART HOPPING  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS  
report\_number:1218950-2023-00690  
mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THERE WAS NO SPEAKER SOUND AT START UP TEST, DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event779:  
adverse\_event\_flag:N  
product\_problems:["Over-Sensing","Under-Sensing"]  
event\_type:Malfunction  
date\_of\_event:20230202  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:78 YR  
patient.patient\_sex:Male  
patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03366

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR OVER AND UNDERSENSING ON TACHYCARDIA EPISODES. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING TRANSMISSION DATED BACK TO IMPLANT RATHER THAN LAST CLEARED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT

## DSI MAUDE Problems Summary

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DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event780:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20230918

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["Hematoma"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05936

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT

## DSI MAUDE Problems Summary

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INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER NOTED THAT THE HEMATOMA BLOOD TINGED INCISION SITE WAS DUE TO THE PRESENCE OF ANTICOAGULATION.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED A HEMATOMA AT THE INCISION SITE, APPROXIMATELY ELEVEN DAYS POST IMPLANT. THE HEMATOMA WAS DRAINED AND THE PATIENT PRESCRIBED ANTIBIOTICS. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. THE ICM REMAINS IN USE. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event781:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230906

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00679

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THERE WAS NO SPEAKER SOUND AT START UP TEST DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event782:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230906

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00680

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THERE WAS NO SPEAKER SOUND AT START UP TEST DUE TO A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event783:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230905

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:



## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00475

mdr\_text.text:THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

SECTION A PATIENT INFORMATION, B5 DESCRIBE EVENT OR PROBLEM, AND H6 HEALTH IMPACT CODE WERE CORRECTED AS IT WAS INDICATED THE DEVICE WAS IN CLINICAL USE. A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT TO THE CUSTOMER'S SITE AND IDENTIFIED THE SPEAKER SOLDERING POINT WAS BROKEN. THE SPEAKER WAS REPLACED, AND THE CONFIGURATION WAS INSTALLED. THE DEVICE PASSED TESTING AND REMAINS IN USE AT THE CUSTOMER'S SITE.

IT WAS REPORTED THAT THE INTELLIVUE MP2 HAD A LOUDSPEAKER ERROR. THERE IS NO ALARM SOUND FROM LOUDSPEAKER. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT TO THE CUSTOMER'S SITE AND IDENTIFIED THE SPEAKER SOLDERING POINT WAS BROKEN. THE SPEAKER WAS REPLACED, AND THE CONFIGURATION WAS INSTALLED. THE DEVICE PASSED TESTING.

SECTION E REPORTING INSTITUTION PHONE # (B)(6) PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event784:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230830

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 802.11A/B/G

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00682

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF THE FUNCTIONAL TESTING INDICATE THAT SPEAKER PRODUCED AUDIBLE SOUND. THE CUSTOMER'S ALLEGATION WAS UNABLE TO BE CONFIRMED; THEREFORE, THE ROOT CAUSE OF THE CUSTOMER'S ALLEGATION IS UNKNOWN. THE CUSTOMER RECEIVED A REPLACEMENT DEVICE.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION, THE SPEAKER IS NOT WORKING. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event785:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20230825

event\_location:

remedial\_action:[""]

patient.patient\_age:41 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Caustic/Chemical Burns"]

device.brand\_name:C6 MCOT PPM

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00057

mdr\_text.text:THE PATIENT REPORTED THEY WERE EXPERIENCING SEVERE SKIN BURNS WHILE USING HE C6 SENSOR WITH FLEX ADAPTOR. THE PATIENT STATED THEY HAD LUMPS AND BURNS FROM THE METAL ATTACHMENT. THE PATIENT FOLLOWED THE RECOMMENDED SKIN PREP. PATIENT REPORTED THAT THEY ARE NO LONGER WANTING TO CONTINUE WITH SERVICE. THE PATIENT USED SULFADIAZINE CREAM ON THE SEVERE SKIN BURNS.

{{datachunk}}Event786:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:20230901

event\_location:

remedial\_action:[""]

patient.patient\_age:96 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03346

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT

INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) COULD NOT BE INTERROGATED WITH TWO PROGRAMMERS. IT WAS CONFIRMED THE ICM HAD BEEN IMPLANTED BEYOND THE THREE YEAR LONGEVITY. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event787:

adverse\_event\_flag:N

product\_problems:["Battery Problem","Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230906

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03348

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS CONFIRMED THAT THE ICM HAD REACHED END OF SERVICE (EOS).

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE,

## DSI MAUDE Problems Summary

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A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY WITH THE REMOTE MONITOR. IT WAS REPORTED THAT THE PROGRESS BAR ON THE REMOTE MONITOR SCREEN WAS NEVER FILLED UP WITH GREEN SUCCESSFULLY. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event788:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230907

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03349

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE

EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR TELEMETRY WAS NOT SUCCESSFUL WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS ADVISED TO SET AN APPOINTMENT WITH THE CLINIC AND BRING THE MONITOR TO GET ASSISTANCE. THE REMOTE MONITOR REMAINS IN USE AND THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event789:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230913

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03350

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO GREEN LIGHT ON READER AND NOTHING SHOWING IN THE SCREEN ON TELEMETRY PHASE WHILE TRYING TO SEND MANUAL TRANSMISSION WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event790:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230913

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Male



## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03351

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD A TELEMETRY ISSUE WITH THE IMPLANTABLE CARDIAC MONITOR (ICM) WHEN USING A NEW READER. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE CALLER WAS REFERRED TO CLINIC. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE,

MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD REACHED END OF SERVICE (EOS).

{{datachunk}}Event791:

adverse\_event\_flag:Y

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230829

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Hypoxia","Insufficient Information","No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP70

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00473

## DSI MAUDE Problems Summary

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mdr\_text.text:A PHILIPS TECHNICAL CONSULTANT (TC) WENT ONSITE TO EVALUATE THE DEVICE IN QUESTION. PER THE TC, THERE WAS NO PATIENT INJURY, AS THE STAFF WERE ABLE TO ASSIST BEFORE THE PATIENT WAS INJURED. THE TC CHECKED THE ALARMS OF THE PATIENT ROOM BY RUNNING A DEMO AND ELECTRICAL SAFETY TESTS. THE TC CONFIRMED THE FOLLOWING: THE UNIT WAS OPERATING IN SOLO MODE AT THE TIME OF THE EVENT; ON (B)(6), THE ALARMS HAD BEEN SHUT OFF BY NURSING STAFF; ON (B)(6) 2023, AT APPROXIMATELY 1700 THE PATIENT HAD A DESATURATION EVENT, BUT THERE WAS NO ALARM. INITIALLY, THE TC THOUGHT THE ALARM HAD BEEN SILENCED AT THE BEDSIDE, BUT THEN REALIZED THAT THE ALARM WAS DISABLED. THE PATIENT DESATURATED TO 50% AND THERE WAS A DELAY IN RECOGNITION BY MONITOR TECHNICIANS AND NURSING STAFF BECAUSE, ONCE AGAIN, THE ALARM HAD BEEN DISABLED. THE CUSTOMER PROVIDED THE CLINICAL AUDIT LOGS TO BE EVALUATED BY THE PHILIPS PRODUCT SUPPORT ENGINEER (PSE). THE TC DETERMINED THERE WAS NO ISSUE FOUND WITH THE MONITOR. THE PHILIPS PSE CONFIRMED THERE WAS A DESATURATION ALARM GENERATED AT 17:09. THE CUSTOMER ACKNOWLEDGED THE ALARM SHOWN ON THE OVERVIEW AT 17:09:44. THE PSE REPORTED OTHER ALARMS WERE BEING PLAYED UNTIL THERE WAS ANOTHER ACKNOWLEDGEMENT AT 17:12:45 ON THE (B)(6) BEDSIDE. THEN AT 17:12:50, THERE WAS A REMINDER OF THE RED ALARM UNTIL IT WAS PAUSED AT 17:12:54. ON THE PIC STATIONS 3SOVER1 AND PCUSRV, THE DESATURATION ALARM WAS PLAYED. THEY DIDN'T HEAR IT ON THE BEDSIDE UNTIL 17:15:59 WHEN THE ALARMS WERE RESUMED; THEY HEARD THE ALARMS ON THE BEDSIDE AT THAT TIME. THE PSE IDENTIFIED THIS SITUATION AS A USER ISSUE AND NOT A DEVICE ISSUE. BASED ON THE INFORMATION AVAILABLE, AND THE LOGS PROVIDED BY THE CUSTOMER, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE NURSES TURNING OFF SPO2 ALARMS ON MONITOR AND THE WORKFLOW. THE ALARMS WERE VISIBLE ON THE CLINICAL LOGS. BASED ON THE INFORMATION AVAILABLE AND RESULTS OF ADDITIONAL ANALYSIS, NO FURTHER ACTION IS NECESSARY AT THIS TIME. THE NURSING MANAGER HAS CORRECTED THE WORKFLOW BY ADJUSTING THE OXYGEN AND CORRECTION OF ALARMS TO PREVENT FUTURE ISSUES. THE PATIENT WAS DISCHARGED A FEW DAYS LATER WITHOUT ISSUE. THE DEVICE REMAINS AT THE CUSTOMER SITE. NO FURTHER INVESTIGATION OR ACTION IS WARRANTED AT THIS TIME.

A FOLLOW UP REPORT WILL BE SUBMITTED AFTER PHILIPS OBTAINS MORE INFORMATION CONCERNING THIS EVENT. E1: REPORTING ADDRESS STATE: (B)(6).

IT WAS REPORTED THE CUSTOMER REQUESTED AN ASSESSMENT TO DETERMINE WHERE A DESATURATION ALARM WAS SILENCED/ACKNOWLEDGED. SUBSEQUENTLY THE PATIENT REQUIRED THE RAPID RESPONSE TEAM DUE TO DESATURATION. THE RECORD INDICATES PATIENT HARM, BUT FURTHER INFORMATION ABOUT THE HARM IS NOT PROVIDED.

{{datachunk}}Event792:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230829

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00676

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED

THE CUSTOMER REPORTED THAT THE SYSTEM SPEAKER IS FAULTY AND PRODUCES NO SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event793:

adverse\_event\_flag:Y

product\_problems:["Unexpected Shutdown"]

event\_type:Death

date\_of\_event:20230905

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Stomach Ulceration","Insufficient Information"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00678

mdr\_text.text:A PHILIPS REMOTE SUPPORT ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND GATHERED AUDIT LOGS FOR ANALYSIS. THE CUSTOMER ALLEGED THE PATIENT DIED WEARING TEL8 DURING THE HOURS OF 3-6AM, ON (B)(6) 2023 AT THE CORONARY CARE UNIT (CCU). THE RSE STATED THAT "THE CUSTOMER WANTS TO KNOW WHAT HAPPENED. THE UNIT WAS OFFLINE ACCORDING TO THE LOGS BETWEEN 01:00 AND 03:43, SO I THINK THE CUSTOMER KNOWS THIS AND IS WONDERING WHY IT WASN'T WORKING DURING THIS TIME. THEY HAVE NO ACCURATE TIME OF DEATH AND THERE IS NO ASYSTOLE IN THE LOGS SO THE DEATH MUST HAVE HAPPENED DURING THIS TIME.""LOOKING AT THE DATA IT APPEARS THE PATIENT WAS DISCHARGED. I THINK THIS WAS USER ERROR." THE RSE CONFIRMED THAT THERE WAS NO MALFUNCTION FOUND WITH THE TELEMETRY 8. WHAT CAUSED THE ISSUE TO OCCUR WAS AN USER ERROR DISCHARGING THE PATIENT AND NOT HAVING THEM MONITORED DURING THE INCIDENT. THE COMPLAINT WAS ESCALATED FOR TECHNICAL INVESTIGATION AND IS PENDING RESULTS OF THE PRODUCT SUPPORT ENGINEER (PSE) TO PERFORM AN ANALYSIS ON THE AUDIT LOGS. PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT PATIENT DIED WEARING TEL8 DURING THE HOURS OF 3-6AM IN CCU.

A PHILIPS REMOTE SUPPORT ENGINEER (RSE) SPOKE WITH THE CUSTOMER AND GATHERED AUDIT LOGS FOR ANALYSIS. THE CUSTOMER ALLEGED THE PATIENT DIED WEARING TEL8 DURING THE HOURS OF 3-6AM, ON (B)(6) 2023 AT THE CORONARY CARE UNIT (CCU). THE RSE STATED THAT "THE CUSTOMER WANTS TO KNOW WHAT HAPPENED. THE UNIT WAS OFFLINE ACCORDING TO THE LOGS BETWEEN 01:00 AND 03:43, SO I THINK THE CUSTOMER KNOWS THIS AND IS WONDERING WHY IT WASN'T WORKING DURING THIS TIME. THEY HAVE NO ACCURATE TIME OF DEATH AND THERE IS NO ASYSTOLE IN THE LOGS SO THE DEATH MUST HAVE HAPPENED DURING THIS TIME." HE ADDED THAT "LOOKING AT THE DATA IT APPEARS THE PATIENT WAS DISCHARGED. I THINK THIS WAS USER ERROR." THE

## DSI MAUDE Problems Summary

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COMPLAINT WAS ESCALATED FOR A TECHNICAL INVESTIGATION. A PHILIPS PRODUCT SUPPORT ENGINEER (PSE) ANALYZED AUDIT LOGS, START DATE LOGS (RFDA AND DEVIDEBUG). THE MX40, SERIAL NUMBER (B)(6) IS A 2.4GHZ ECG ONLY DEVICE, OPERATING ON SW REVISION B.06.59. THE CUSTOMER IS USING THE BATTERY ADAPTER TRAY AND AA BATTERIES. CONDITION OF THE BATTERY ADAPTER TRAY AND DEVICE BATTERY COMPARTMENT IS NOT KNOWN. THE DISCONNECT MAY BE THE RESULT OF EITHER THE BATTERIES BEING DISLODGED OR REMOVED. WHEN THE DEVICE WENT OFFLINE, A ¿NO DATA TELE¿ TECHNICAL INOP (VISUAL AND AUDIBLE ALARM) WOULD HAVE BEEN PROVIDED AT THE PATIENT SECTOR OF THE PIC IX. USERS SHOULD HAVE RECOGNIZED THIS CONDITION AT THE PIC IX. A REQUEST FOR PICTURES OF THE BATTERY ADAPTER TRAY THAT WAS IN USE AS WELL AS PICTURES OF THE MX40 BATTERY COMPARTMENT WAS SENT, BUT NO DATA COULD BE OBTAINED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE REPORTED PROBLEM WAS CAUSED BY A CLINICAL WORKFLOW/USE ERROR. IN ADDITION, THE FACT THAT THE UNIT WAS OFFLINE WOULD PROMPT AN INOP AT THE CENTRAL STATION ALERTING THE USER. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS. THE MX40 PATIENT WEARABLE MONITOR HAS NOT CAUSED OR CONTRIBUTED TO THE REPORTED ISSUE, AS THE DEVICE WAS WORKING AS INTENDED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

CLINICAL REASSESSMENT WAS PERFORMED BASED ON NEW INFORMATION RECEIVED IN THE COMPLAINT RECORD. ADDITIONAL INFORMATION INDICATED THE PATIENT PASSED AWAY FROM 'PEPTIC PERFORATION', IF ADDITIONAL INFORMATION IS OBTAINED, PLEASE REQUEST REASSESSMENT OF THE RECORD BY THE PMS CLINICAL EXPERT.

{{datachunk}}Event794:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230915

event\_location:

remedial\_action:[""]

patient.patient\_age:68 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03331

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD MIGRATED TO THE PATIENT'S ABDOMEN (OBSERVED ON XRAY). THE ICM HAD BEEN IMPLANTED SIX YEARS AND EIGHT MONTHS. THE BATTERY WAS NO LONGER FUNCTIONING. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC

## DSI MAUDE Problems Summary

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OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event795:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230825

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00671

mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE SPEAKER NOT WORKING. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THERE WAS NO SPEAKER SOUND AT THE START UP TEST, AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING



## DSI MAUDE Problems Summary

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CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event796:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230912

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00468

mdr\_text.text:THE PHILIPS REMOTE SUPPORT (RSE) CONTACTED THE CUSTOMER AND THEY CONFIRMED THAT NO SOUND WAS COMING FROM THE DEVICE. THE RSE SENT OUT AN REPLACEMENT SPEAKER TO THE CUSTOMER TO SOLVE THE REPORTED ISSUE. E1: REPORTER INSTITUTION PHONE NUMBER: (B)(6). E1: REPORTER PHONE NUMBER: (B)(6). H3 OTHER TEXT : PHILIPS REMOTE SUPPORT ONLY- MATERIAL ONLY.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION NO SOUND COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event797:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230825

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00672

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT THE SPEAKER DOES NOT WORK. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event798:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230825

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00673

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE SPEAKER DOES NOT WORK.THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event799:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230823

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00466

mdr\_text.text:ADDITIONAL INFORMATION WAS RECEIVED THAT THE SPO2 WAS LOST IN ISOLATION AND THE DEVICE DISPLAYED A SPO2 MALFUNCTION ERROR MESSAGE, SO THE ISSUE WAS EASILY DETECTED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE PARAMETER BOARD. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE PARAMETER BOARD AND REMAINS IN USE AT THE CUSTOMER'S SITE.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED THAT THE SPO2 WAVEFORM DOES NOT APPEAR, THE BASELINE APPEARS, AND THERE IS NO INOP (INOPERABLE) MESSAGE. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED. A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT TO THE CUSTOMER'S SITE TO EVALUATE THE DEVICE. THE FSE NOTED THERE WAS NO CHANGE EVEN IF THE BATTERY IS REMOVED AND THE POWER IS TURNED OFF. THE PARAMETER BOARD WAS REPLACED, AND IT WAS CONFIRMED THIS RESOLVED THE ISSUE.

{{datachunk}}Event800:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Overheating of Device"]

event\_type:Malfunction

date\_of\_event:20230821

event\_location:

remedial\_action:[""]

patient.patient\_age:28 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00051

mdr\_text.text:IT WAS REPORTED THAT THE DEVICE MELTED. THE DEVICE WAS RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS ABLE TO CONFIRM DEVICE MELT. NO INTERNAL DEVICE WAS OBSERVED DURING EVALUATION. IT IS MOST PROBABLE THAT THE DEVICE MELT WAS CAUSED BY AN EXTERNAL HEAT SOURCE.

THE PATIENT REPORTED THAT THE MONITOR MELTED. NO PATIENT HARM WAS REPORTED.

{{datachunk}}Event801:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20221101

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00622

mdr\_text.text:THE PHILIPS AUTHORIZED REPAIR FACILITY TESTING OF THE DEVICE SPEAKER INDICATE THAT THERE WAS NO SPEAKER SOUND AT START UP TEST, AND SPEAKER WAS DEFECTIVE. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE HAD NO SPEAKER SOUND AT THE START-UP TEST, AND THE SPEAKER HAD NO AUDIO SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT. THERE WAS NO REPORTED ADVERSE EVENT.

{{datachunk}}Event802:

adverse\_event\_flag:N

product\_problems:["Inaudible or Unclear Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230628

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00661

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event803:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230309

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00662

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE REPAIR FACILITY TECHNICIAN (RFT) PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER HOWEVER WAS UNABLE TO TEST THE SPEAKER IN THE DEVICE. THE RFT FOUND THAT THE DEVICE SPEAKER WAS PRODUCING AUDIO WHEN PERFORMING TESTING WITH THE MT56060 TOOL. THE RFT PROACTIVELY REPLACED THE DEVICE SPEAKER - FOXLINK D SPEAKER - 453665031201. THE DEVICE PASSED ALL FUNCTIONAL TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT THE BENCH, IT WAS IDENTIFIED THAT THE DEVICE HAD SPEAKER ISSUE. NO PATIENT INVOLVEMENT.

{{datachunk}}Event804:

adverse\_event\_flag:Y

product\_problems:["Communication or Transmission Problem","Adverse Event Without Identified Device or Use Problem"]

event\_type:Malfunction

date\_of\_event:20230913

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Asystole","Insufficient Information"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS



## DSI MAUDE Problems Summary

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report\_number:1218950-2023-00666

mdr\_text.text:ADDITIONAL INFORMATION WAS RECEIVED THAT THE PATIENT FLATLINED FOR A FEW MOMENTS, THE PATIENT WAS REVIVED. THERE WAS NO HARM REPORTED, THE CUSTOMER ISSUE IS DATA LOSS. THIS IS PRESUMED TO HAVE OCCURRED BETWEEN THE TIMES THE PATIENT WAS TRANSFERRED FROM A LOW ACUITY BED TO A HIGHER ACUITY BED. THE STAFF FOLLOWED THEIR USUAL TRANSFER PROCESS ON THE MP30 IN, WHEN THE PATIENT ARRIVED THE STAFF REPORTED THERE WAS SOME KIND OF ERROR MESSAGE ON THE SCREEN RELATING TO EQUIPMENT PAIRED, BUT THEY CANNOT BE SURE, SOMETHING LIKE ¿DUAL OR TOO MANY MONITORS/EQUIPMENT¿. WHILE THE PATIENT WAS IN THE LOW ACUITY BED THE PATIENT HAD EPISODES OF ASYSTOLE, THESE ALARMED AT THE PIC AND THE STRIP RECORDER AT THE PIC RECORDED A STRIP. AFTER THE EVENT AND ONCE THE PATIENT WAS IN MOVED TO THE HIGH ACUITY BED, THE DOCTORS WENT TO THE PIC TO REVIEW THE PATIENT ECG AND ASYSTOLE ALARMS AND THERE WAS NO ECG TRACE DATA AVAILABLE. THE PATIENT RECOVERED AND WAS DISCHARGED FROM THE HOSPITAL.

THE DEVICE LOGS AND PATIENT STRIPS PROVIDED WERE REVIEWED BY THE PRODUCT SUPPORT ENGINEER (PSE) AND CLINICAL EXPERT. THE AUDIT LOG SHOWS ALARMS WERE PROVIDED FOR \*\*\*XBRADY, ASYSTOLE, AND HR LOW LIMIT VIOLATIONS DURING THE INCIDENT TIMEFRAME. ALARMS WERE BEING SILENCED. THE TIMESTAMP WAS REMOVED FROM THE PATIENT STRIPS PROVIDED, BUT THE FLAT LINE (ASYSTOLE) IS CONSISTENT WITH THE \*\*\*ASYSTOLE EVENT DURING THE INCIDENT TIMEFRAME. THE PATIENT HAD GONE INTO ASYSTOLE AND WAS TREATED ACCORDINGLY, WITH ALL ALARMS AND STRIPS GENERATING APPROPRIATELY. THE PATIENT WAS TRANSFERRED TO ANOTHER BED AND THE USERS RECEIVED SOME TYPE OF ERROR INDICATING 'DUAL OR TOO MANY MONITORS/EQUIPMENT'. AFTER THE EVENT, WHEN THE PHYSICIAN WANTED TO REVIEW THE ECG AND ALARMS, THERE WAS NO ECG TRACE DATA AVAILABLE. BASED ON THIS INFORMATION, THE DEVICE DID NOT CAUSE OR CONTRIBUTE A DEATH OR SERIOUS INJURY AND THIS COMPLAINT IS RELATED TO DATA LOSS. PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED A PATIENT INCIDENT OCCURRED AT 8:00 AM. THE CUSTOMER IS REQUESTING ASSISTANCE RETRIEVING LOG DATA. ADDITIONAL EVENT INFORMATION HAS BEEN REQUESTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

B1: TYPE OF REPORT WAS CHANGED FROM ADVERSE EVENT TO PRODUCT PROBLEM H1: CHANGED TYPE OF REPORTED COMPLAINT FROM SERIOUS INJURY TO PRODUCT PROBLEM

THE INFORMATION PROVIDED WAS REVIEWED BY A PHILIPS PRODUCT SUPPORT ENGINEER. THE DATA INDICATES THAT THE MX40 PWM (TEL 25) WAS MOVED FROM SECTOR BED40A TO SECTOR BED63 AT THE PIC IX AT 09:46:42 ON (B)(6) 2023, WHICH WAS AFTER THE INCIDENT TIMEFRAME. THERE WAS ADDITIONAL ACTIVITY IN THE LOGS INDICATING A PATIENT DISCHARGE AND READMIT FOLLOWING THE INCIDENT TIMEFRAME. IN ADDITION, THE PICTURES SUPPLIED SHOW GAPS IN WAVE DATA THAT ARE

## DSI MAUDE Problems Summary

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LIKELY RELATED TO THE DEVICE GOING OFFLINE (MX40 NOT CONNECTED TO THE PIC IX, MX40 POWERED OFF, MX40 IN STANDBY MODE) AND OTHER EQUIPMENT AND PATIENT DISCHARGE AND READMIT ACTIVITIES. THE PICTURES DO NOT CAPTURE TIMEFRAMES OF THE GAPS IN GENERAL REVIEW DATA AROUND THE TIME OF THE INCIDENT. THERE WAS A DISCONNECT/RECONNECT AT 09:01:46-9:02:50 ON (B)(6) 2023 FOR A BATTERY CHANGE AND A DISCONNECT/RECONNECT AT 09:46:28 WHEN THE DEVICE WAS ASSIGNED TO THE NEW SECTOR. DURING THE PERIODS THE DEVICE WAS OFFLINE, A ¿NO DATA TELE¿ TECHNICAL INOP WOULD BE PROVIDED AT THE PATIENT SECTOR OF THE PIC IX. THE AUDIT LOG REVEALS THAT THE USER ANNOTATED THE ALARM STRIP FROM 08:30:06 AT 09:23:18 INDICATING THE FULL DISCLOSURE DATA WAS STILL AVAILABLE. THE INFORMATION PROVIDED IS NOT CONSISTENT WITH A MALFUNCTION OF THE PRODUCT. FULL DISCLOSURE DATA AVAILABILITY AT THE PATIENT INFORMATION CENTER IX (PIC IX) IS BASED ON MONITOR CONNECTION TO THE PIC IX SO THAT WAVES/DATA CAN BE STORED. THE LOGS DO NOT SHOW A GAP IN DATA DURING THIS INCIDENT TIME FRAME. FULL DISCLOSURE DATA CAN BE RETRIEVED FOR UP TO 7 DAYS. DATA THAT IS DISCHARGED PRIOR TO ADMISSION CANNOT BE RETRIEVED. ONCE THE PATIENT HAS BEEN TRANSFERRED TO A NEW BED THE PREVIOUS UNIT DATA CAN BE ACCESSED FROM THE PRIOR UNIT DATA MENU IN REVIEW APPLICATIONS. PIC IX IFU C.03 PART NUMBER 4535 648 21841 PG.224 INFORMATION WAS PROVIDED TO THE CUSTOMER TO RESOLVE THIS ISSUE.

{{datachunk}}Event805:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230719

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2023-00667

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE DEVICE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE THIRD PARTY SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION

{{datachunk}}Event806:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230824

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 PATIENT WEARABLE MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00665

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND.

## DSI MAUDE Problems Summary

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BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED THE REPORTED PROBLEM WAS UNABLE TO BE REPLICATED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS A SPEAKER MALFUNCTION AT THE TIME OF THE EVENT. ADDITIONAL INFORMATION WAS REQUESTED TO CONFIRM IF THE SPEAKER PRODUCED AUDIBLE SOUND DURING THE EVENT, BUT THIS WAS NOT CONFIRMED BY THE CUSTOMER. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THE MX40 TELEMETRY DEVICE HAS A SPEAKER MALFUNCTION. IT IS UNKNOWN IF THE DEVICE PRODUCED AUDIBLE SOUND. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. THE CUSTOMER RECEIVED A REPLACEMENT DEVICE.

{{datachunk}}Event807:

adverse\_event\_flag:N

product\_problems:["No Device Output"]

event\_type:Malfunction

date\_of\_event:20221202

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00669

## DSI MAUDE Problems Summary

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mdr\_text.text:RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND ON THE CERTIFICATION TOOL STATION. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THERE WAS NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THE UNIT DOES NOT HAVE ANY SOUND, NO ADDITIONAL INFORMATION AVAILABLE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event808:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230722

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00047

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE

## DSI MAUDE Problems Summary

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WEAR PERIOD. THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSIONS LIMIT. NO ADVERSE EVENTS SUCH AS DEATH OR SERIOUS INJURY ARE KNOWN TO HAVE OCCURRED. THE DEVICE WAS APPROACHING THE MAXIMUM TRANSMISSION LIMIT FOUR DAYS AFTER IT WAS ACTIVATED. IRHYTHM CONTACTED THE PATIENT'S HEALTHCARE PROVIDER (HCP) TO NOTIFY THAT THE DEVICE WAS REACHING THE MAXIMUM TRANSMISSION LIMIT. AFTER THE THIRD NOTIFICATION ATTEMPT, A SECOND DEVICE WAS SHIPPED TO THE PATIENT. THE FOLLOWING DAY, THE HCP CONTACTED IRHYTHM AND DECLINED THE SECOND MONITOR TO BE SENT SINCE THE PATIENT WAS ALREADY IN THE HOSPITAL FOR NON-CARDIAC RELATED ISSUES. THE FIRST PATCH DEVICE WAS RETURNED AND DURING PREPARATION OF THE FINAL REPORT, IRHYTHM BECAME AWARE OF AN ARRHYTHMIA THAT OCCURRED FOUR DAYS AFTER THE DEVICE HAD REACHED THE MAXIMUM TRANSMISSION LIMIT . AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER ZIO AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21 CFR 803 AS A PRODUCT PROBLEM / MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

IT WAS REPORTED THAT THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. INVESTIGATION CONFIRMED THAT THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSIONS LIMIT DESCRIBED IN THE PRODUCT LABELING. THE HEALTHCARE PROVIDER (HCP) ACCOUNT WAS NOTIFIED THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, AND A REPLACEMENT DEVICE WAS DISPATCHED TO THE PATIENT, ACCORDING TO STANDARD PROCESS. NO ADVERSE EVENTS SUCH AS DEATH OR SERIOUS INJURY ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event809:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electromagnetic Interference"]

event\_type:Malfunction

date\_of\_event:20230729

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:36 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05770

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING ASSOCIATED WITH THE RIGHT VENTRICULAR LEAD.

ANALYSIS OF THE DEVICE MEMORY OBSERVED NOISE ON THE ELECTROGRAM WAVEFORMS.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE

## DSI MAUDE Problems Summary

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COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED FALSE VENTRICULAR TACHYCARDIA (VT)'S DUE TO ARTIFACT, MOST LIKELY CAUSED BY EXTERNAL INTERFERENCE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event810:



## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230914

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05775

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED FALSE ASYSTOLE DUE TO UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED RIGHT VENTRICULAR UNDERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT.

## DSI MAUDE Problems Summary

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ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED FALSE PAUSE EPISODES DUE TO UNDERSENSING R WAVES. THE ICM HAD BEEN IMPLANTED EIGHT DAYS AGO. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH

## DSI MAUDE Problems Summary

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{{datachunk}}Event811:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230910

event\_location:

remedial\_action:[""]

patient.patient\_age:90 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03297

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS

## DSI MAUDE Problems Summary

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¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON A PAUSE EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event812:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20230809

event\_location:

remedial\_action:[""]

patient.patient\_age:43 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03298

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OCCASIONAL VENTRICULAR OVERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE DEFAULT

## DSI MAUDE Problems Summary

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REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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CORRECTION: B3 MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event813:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230701

event\_location:

remedial\_action:[""]

patient.patient\_age:94 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03300

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER NOTED THAT THE COUNTERS WENT BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE INTERROGATION. THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event814:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Death

date\_of\_event:20230823

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00659

mdr\_text.text:SEVERAL ATTEMPTS WERE MADE TO CONTACT THE CUSTOMER DIRECTLY FOR ADDITIONAL INFORMATION AND CLARIFICATION OF THE EVENT. THE CUSTOMER HAS NOT PROVIDED THE REQUESTED INFORMATION AND NO FURTHER DETAILS WERE PROVIDED. THE CUSTOMER RETURNED THE DEVICE TO BENCH REPAIR DUE TO THE TOUCHSCREEN NOT WORKING. IT WAS REPORTED THE DEVICE WAS INVOLVED IN A DEATH AND IN ADDITION THE TOUCH SCREEN IS MALFUNCTIONING. THEREFORE, THE TOUCHSCREEN ISSUE HAS NOT BEEN ALLEGED TO HAVE CAUSED OR CONTRIBUTED TO THE PATIENT'S DEATH. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING CONFIRM THE TOUCHSCREEN DID NOT WORK DUE TO CORROSION ON THE FLEX CABLE. THE DEVICE PRODUCED AUDIBLE SOUND AND NO OTHER ISSUES WERE IDENTIFIED. DUE TO THE LIMITED INFORMATION AVAILABLE THE ROOT CAUSE OF THE CUSTOMER'S ALLEGATION IS UNABLE TO BE DETERMINED.

IT WAS REPORTED THE PATIENT WAS BEING MONITORED BY AN MX40 TELEMETRY DEVICE WHEN THEY PASSED AWAY. ADDITIONAL INFORMATION HAS BEEN REQUESTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event815:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230914

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:53 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["Impaired Healing"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03304

mdr\_text.text:IT WAS REPORTED THAT APPROXIMATELY SIX WEEKS POST IMPLANT OF THE IMPLANTABLE CARDIAC MONITOR (ICM), THE LOWER PORTION OF THE INCISION NEVER SEEMED TO FULLY CLOSE. IT WAS FURTHER REPORTED THAT THE ICM WAS PROTRUDING AND THE CORNER OF IT COULD BE FELT WHEN THE PATIENT RAN THEIR HAND OVER IT. THE ICM REMAINS IN USE. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: H10 PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. THE DEVICE

## DSI MAUDE Problems Summary

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PASSED ALL FUNCTIONAL TESTING ON THE BENCH AND PASSED AUTOMATED FUNCTIONAL TESTING AT MEDTRONIC TEMPE CAMPUS AFTER BENCH TESTING. NO HYBRID ANOMALIES WERE IDENTIFIED. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. THE DEVICE PASSED ALL FUNCTIONAL TESTING ON THE BENCH AND PASSED FF AT MTC AFTER BENCH TESTING. NO HYBRID ANOMALIES WERE IDENTIFIED. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT PULLED THE DEVICE OUT AS IT WAS PROTRUDING.

CORRECTION: D6B MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event816:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230911

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00465

mdr\_text.text:THE DEVICE WAS EVALUATED AT THE BENCH AND THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE A SPEAKER ISSUE. THE BENCH SERVICE ENGINEER REPLACED THE SPEAKER ASSEMBLY TO RESOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE DEVICE REMAINS AT CUSTOMER SITE. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION, IT IS UNKNOWN OF STILL SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event817:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20230821

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00655

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED THAT THE DEVICE SPEAKER MALFUNCTIONED, AND THEY CANNOT HEAR SOUND FROM THE SPEAKER. A PHILIPS REMOTE SERVICE TECHNICIAN (RSE) SPOKE TO THE CUSTOMER BIOMEDICAL ENGINEER (BIOMED). THE DEVICE WAS POWERED ON BY THE BIOMED DURING THE CONVERSATION, CONFIRMED NO SOUND WAS HEARD FROM DEVICE. IT WAS AGREED TO SUBMIT A REQUEST FOR AN EXCHANGE REPLACEMENT OF THE DEVICE. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event818:

adverse\_event\_flag:Y

product\_problems:["Telemetry Discrepancy"]

event\_type:Death

## DSI MAUDE Problems Summary

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date\_of\_event:20230818

event\_location:

remedial\_action:[""]

patient.patient\_age:89 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00654

mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THE DEVICE WAS DROPPING TELE SIGNAL. ALLEGEDLY DID NOT ALARM CLINICAL STAFF. A PATIENT DEATH WAS REPORTED .

INSPECTION OF THE DEVICE BY THE PHILIPS FIELD SERVICE PERSONNEL AND CLINICAL ENGINEERING REVEALED FLUID INTRUSION IN THE BATTERY TRAY. PRODUCT SUPPORT ENGINEER STATED THE BATTERY ADAPTER TRAY SHOWS WEAR AND SOME SEPARATION OF THE FLEX CIRCUIT FROM THE TRAY & BATTERY COMPARTMENT SHOWS CHEMICAL RESIDUE. THE COMPLAINT WAS ESCALATED FOR TECHNICAL INVESTIGATION AND THE RESULTS INDICATE THAT THE DEVICE WENT OFFLINE DUE TO SOME TYPE OF BATTERY INTERRUPTION. DURING THIS TIME, A ¿NO DATA TELE¿ TECHNICAL INOP WOULD HAVE BEEN DISPLAYED IN THE PATIENT SECTOR AND AN AUDIBLE TONE WOULD HAVE BEEN PROVIDED. THE DEVICE WENT BACK ONLINE AT 04:49 ON 18-AUG-2023 WHEN BATTERIES WERE REPLACED. THE BATTERY ADAPTER TRAY SHOWS WEAR AND SOME SEPARATION OF THE FLEX CIRCUIT FROM THE TRAY, BUT THIS IS NOT SIGNIFICANT ENOUGH TO PREVENT THE DEVICE FROM FUNCTIONING. THE PICTURE OF THE INSIDE OF THE BATTERY COMPARTMENT SHOWS CHEMICAL RESIDUE. THERE DOES NOT APPEAR TO BE ENOUGH RESIDUE TO PREVENT CONTACT WITH THE BATTERY ADAPTER TRAY. IT WAS ALSO NOTED THAT THE MX40 WAS TESTED BY THE PHILIPS TECHNICAL CONSULTANT WHO WAS ON SITE AND THE DEVICE WAS OPERATION AFTER THE EVENT, NO ISSUES WERE FOUND, BUT THIS WAS AFTER THE DEVICE WAS CLEANED AND BATTERY TRAY REPLACED BY THE BIOMED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS DUE TO SOME TYPE OF BATTERY INTERRUPTION. THE REPORTED PROBLEM WAS CONFIRMED. THE PRODUCT SUPPORT ENGINEER PROVIDED THEIR ANALYSIS FINDINGS. REVIEW OF

## DSI MAUDE Problems Summary

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THE LOG INFORMATION PROVIDED INDICATES THAT THE DEVICE WENT OFFLINE DUE TO SOME TYPE OF BATTERY INTERRUPTION. DURING THIS TIME, A ¿NO DATA TELE¿ TECHNICAL INOP WOULD HAVE BEEN DISPLAYED IN THE PATIENT SECTOR AND AN AUDIBLE TONE WOULD HAVE BEEN PROVIDED. THE DEVICE WENT BACK ONLINE AT 04:49 ON 18-AUG-2023 WHEN BATTERIES WERE REPLACED. THE PICTURE OF THE INSIDE OF THE BATTER COMPARTMENT SHOWS CHEMICAL RESIDUE. THERE DOES NOT APPEAR TO BE ENOUGH RESIDUE TO PREVENT CONTACT WITH THE BATTERY ADAPTER TRAY. IT WAS ALSO NOTED THAT THE MX40 WAS TESTED BY THE PHILIPS TECHNICAL CONSULTANT WHO WAS ON SITE AND THE DEVICE WAS OPERATION AFTER THE EVENT, NO ISSUES WERE FOUND, BUT THIS WAS AFTER THE DEVICE WAS CLEANED AND BATTERY TRAY REPLACED BY THE BIOMED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event819:

adverse\_event\_flag:N

product\_problems:["Audible Prompt/Feedback Problem"]

event\_type:Malfunction

date\_of\_event:20230825

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00658

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT SPEAKER PRODUCED AUDIBLE SOUND AT BOOT UP. SPEAKER WAS NOT DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS NOT CONFIRMED. THE SPEAKER

WAS CONFIRMED TO BE FUNCTIONING AS INTENDED, AS SPEAKER PRODUCED AUDIBLE SOUND DURING TESTING. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT THE SPEAKER IS NOT WORKING. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event820:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20220407

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03258

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OCCASIONAL VENTRICULAR OVER SENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE



## DSI MAUDE Problems Summary

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REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event821:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230205

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05693

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING DURING PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE SESSION MANAGEMENT REPORT WENT BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE,

A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event822:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230328

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL XT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03260

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) COULD NOT CONNECT TO THE PATIENT ACTIVATOR. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CONTINUATION OF B3: EVENT DATE IS YEAR VALID ONLY MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY HAVE NOT BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS

## DSI MAUDE Problems Summary

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REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE ICM WAS WORKING AS INTENDED. THE REMOTE MONITOR WAS REPLACED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN

## DSI MAUDE Problems Summary

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ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event823:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230908

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03262

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED A FALSE POSITIVE PAUSE EPISODE DUE TO UNDERSENSING R WAVES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY HAVE NOT BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event824:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230816

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03263

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH

## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD TELEMETRY ISSUE WITH THE REMOTE MONITOR. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE REMOTE MONITOR REMAINED IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event825:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20230818

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Hypoxia"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00460

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE. H3 OTHER TEXT : THE CUSTOMER REJECTED REPAIR QUOTE.

IT WAS REPORTED THE PATIENT DESATURATED INTO THE 30S AND 40S AND THE DEVICE FAILED TO GENERATE AN ALARM. THE BIOMED HAS BEEN UNABLE TO CONFIRM THE ALARMS ARE FAILING AS THEY ARE UNABLE TO RECREATE THE ALARM ISSUE. AN OXYGEN DESATURATION TO 30% OR 40% REPRESENTS A CHANGE IN THE PATIENT'S CLINICAL CONDITION WHICH CAN BE CONSIDERED LIFE-THREATENING AND TYPICALLY REQUIRES INTERVENTION TO PRECLUDE PERMANENT IMPAIRMENT;



## DSI MAUDE Problems Summary

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THEREFORE, THIS EVENT MEETS CRITERIA FOR A SERIOUS INJURY BASED ON THE INFORMATION RECEIVED. DETAILS OF THE EVENT ARE INCOMPLETE AND ADDITIONAL INFORMATION HAS BEEN REQUESTED.

A PHILIPS REMOTE SERVICE ENGINEER (RSE) THE CUSTOMER REQUESTED THE CENTRAL STATION AND MONITOR LOGS BE PULLED. PHILIPS PROVIDE A QUOTE FOR ONSITE SERVICE; HOWEVER, THE CUSTOMER CANCELLED THE ONSITE SERVICE. REQUESTS WERE MADE FOR ADDITIONAL INFORMATION AND NO INFORMATION WAS RECEIVED. THE ROOT CAUSE IS UNABLE TO BE DETERMINED WITH THE INFORMATION AVAILABLE; HOWEVER, THE SUSPECTED CAUSE IS POSSIBLE USER ERROR AS ISSUE CANNOT BE RECREATED.

{{datachunk}}Event826:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230823

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00462

mdr\_text.text:IT WAS REPORTED THAT THERE WAS A SPEAKER MALFUNCTION INOP. THE SPEAKER IS NOT WORKING AND NO ALARMS NOISE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO PATIENT INVOLVEMENT.

A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER(BIOMED) AND CONFIRMED A ¿SPEAKER MALFUNCTION¿ INOP MESSAGE WAS DISPLAYED ON THE DEVICE AND THE SPEAKER FAILURE

## DSI MAUDE Problems Summary

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TO PRODUCE SOUND. THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE CUSTOMER WAS PROVIDED REPLACEMENT PARTS TO RESOLVE THE ISSUE.

{{datachunk}}Event827:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230822

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP5

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00461

mdr\_text.text:IT WAS REPORTED THAT THE INTELLIVUE MP5 INDICATING THAT THE AUDIO ALARM OF THE LOUDSPEAKER DID NOT WORK ANYMORE, OR VERY POORLY. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

THE REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. IT WAS DETERMINED THAT THE SPEAKER REQUIRED REPLACEMENT. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. THE DEVICE REMAINS AT CUSTOMER SITE.

{{datachunk}}Event828:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Communication or Transmission Problem"]  
event\_type:Malfunction  
date\_of\_event:20230824  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:30 YR  
patient.patient\_sex:Male  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:REVEAL LINQ  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL  
report\_number:9614453-2023-03215

mdr\_text.text:IT WAS REPORTED THAT NEARLY FIVE YEARS AFTER THE IMPLANT PROCEDURE THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY WITH THE REMOTE MONITOR. THE REMOTE MONITOR WAS SHOWING THE TELEMETRY SYMBOL ON THE SCREEN. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS

## DSI MAUDE Problems Summary

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CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event829:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230901

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03217

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY WITH THE REMOTE MONITOR. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event830:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230824

event\_location:

remedial\_action:[""]

patient.patient\_age:84 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03219

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY

## DSI MAUDE Problems Summary

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PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY WITH THE REMOTE MONITOR. IT WAS FURTHER NOTED THAT THE MONITOR WAS MISSING DAILY WIRELESS AUDIT DUE TO A CPAD NEAR THE MONITOR. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event831:

adverse\_event\_flag:N

product\_problems:["Thermal Decomposition of Device","Melted","Device Emits Odor"]

event\_type:Malfunction

date\_of\_event:20230823

event\_location:

remedial\_action:[""]

patient.patient\_age:43 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00053

mdr\_text.text:PATIENT REPORTED THAT THE SENSOR THAT WAS IN THE UNIVERSAL PATCH GAVE AN AWFUL SMELL. THE PATIENT ALSO STATED THAT THERE WERE BURN MARKS ON THE PATCH AND THE SENSOR STARTED TO MELT ONTO THE PATCH. THE PATIENT STATED THAT THEY REMOVED THE PATCH AND SENSOR AND DISCONTINUED MONITORING. THE PATIENT WAS NOT HARMED. A REPLACEMENT DEVICE WAS OFFERED HOWEVER, THE PATIENT DECLINED. THE DEVICE IS EXPECTED TO BE RETURNED.

IT WAS REPORTED THAT THE SENSOR GAVE AN AWFUL SMELL AND IT WAS NOTED THAT THERE WERE BURN MARKS ON THE PATCH AND SENSOR. THE SENSOR WAS RETURNED AND INVESTIGATED. ENGINEERING EVALUATION COULD NOT REPLICATE THE REPORTED EVENT; HOWEVER, OBJECTIVE EVIDENCE PROVIDED FROM THE PATIENT DOES SHOW INDICATION OF EXCESS HEAT EXPERIENCED BETWEEN THE DEVICE CONTACT TERMINALS AND UNIVERSAL PATCH CRADLE. THE ROOT CAUSE OF THIS FAILURE MODE IS LIKELY DUE TO AN ACCUMULATION OF MOISTURE AND OR PATIENT SWEAT AT THE JUNCTURE WHILE DEVICE WAS IN USE. DEVICE ALLEGATION IS THEREFORE CONFIRMED FOR EXCESS HEAT RESULTING IN BURN MARKS.

{{datachunk}}Event832:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230908

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03220

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.



## DSI MAUDE Problems Summary

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IT WAS REPORTED BY THE PATIENT THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY WITH THE REMOTE MONITOR. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event833:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230906

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03221

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF

REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT CONTAINED INVALID HISTOGRAMS AND THAT THE EPISODE LIST WAS INCORRECT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event834:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230805

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00049

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. THE HCP

## DSI MAUDE Problems Summary

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ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS DECLINED. DUE TO THE PATIENT'S ARRHYTHMIA FREQUENCY, THE PHYSICIAN ORDERED AN ADDITIONAL DIAGNOSTIC TEST. THE RESULTS OF THE ADDITIONAL TESTING ARE UNKNOWN. NO TREATMENT WAS REQUIRED, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. NO TREATMENT WAS REQUIRED, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE PATIENT INITIATED TWO SYMPTOMATIC TRANSMISSIONS AND WORE THE DEVICE FOR 13 DAYS OF THE 14 DAYS PRESCRIBED. THE DEVICE LAST TRANSMITTED AND REACHED THE MAXIMUM TRANSMISSION LIMIT EIGHT DAYS AFTER IT WAS ACTIVATED. THE HEALTHCARE PROVIDER (HCP) ACCOUNT WAS NOTIFIED ON DAY 6 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 21. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event835:

adverse\_event\_flag:N

product\_problems:["Failure to Transmit Record"]

event\_type:Malfunction

date\_of\_event:20230809

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Heart Problem"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:RHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00048

mdr\_text.text:THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT. NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED. THE DEVICE LAST TRANSMITTED AND REACHED THE MAXIMUM TRANSMISSION LIMIT EIGHT DAYS AFTER IT WAS ACTIVATED. THE HCP ACCOUNT WAS NOTIFIED ON DAY 7 THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT, AND A REPLACEMENT DEVICE WAS DECLINED. IRHYTHM BECAME AWARE OF THE ARRHYTHMIA WHILE PREPARING FINAL REPORT AND NOTIFIED THE HCP ON DAY 17. AS DESCRIBED IN PRODUCT LABELING, THE ZIO AT DEVICE HAS A MAXIMUM THRESHOLD OF TRANSMITTING 100 PATIENT TRIGGERS AND 500 ASYMPTOMATIC TRANSMISSIONS DURING WEAR. WHEN THE DEVICE WAS WORN FOR APPROXIMATELY 10 DAYS OF THE 14-DAY PRESCRIBED WEAR-PERIOD. A PATIENT IS APPROACHING THE LIMIT FOR EITHER TRANSMISSION TYPE, IRHYTHM REACHES OUT TO THE ACCOUNT TO DETERMINE WHETHER TO SEND ANOTHER AT DEVICE TO THE PATIENT. PATIENT-TRIGGERED SYMPTOMATIC TRANSMISSIONS ARE STILL ABLE TO BE TRANSMITTED BEYOND THIS LIMIT BY PRESSING THE LARGE CENTRAL BUTTON LOCATED ON THE OUTER DEVICE HOUSING. THIS EVENT IS BEING REPORTED PER 21CFR 803 AS A PRODUCT PROBLEM /MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN)REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. THE INVESTIGATION CONFIRMED THE ZIO AT REACHED THE ASYMPTOMATIC MAXIMUM TRANSMISSION LIMIT DESCRIBED IN THE PRODUCT LABELING. THE HCP ACCOUNT WAS NOTIFIED THAT THE DEVICE WAS APPROACHING THE ASYMPTOMATIC TRANSMISSION LIMIT PRIOR TO REACHING THE LIMIT, ACCORDING TO STANDARD PROCESS, AND A REPLACEMENT DEVICE WAS DECLINED. FOLLOW-UP WITH THE ACCOUNT CONFIRMED THEY WERE ALREADY AWARE OF THE ARRHYTHMIA, AND NO TREATMENT WAS REQUIRED, AND NO ADVERSE EVENTS, SUCH AS DEATH OR SERIOUS INJURY, ARE KNOWN TO HAVE OCCURRED.

{{datachunk}}Event836:

adverse\_event\_flag:N

product\_problems:["Excessive Heating"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:63 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00054

mdr\_text.text:THE PATIENT REPORTED THAT THE MONITOR CHARGING PLUG WAS HOT TO THE TOUCH AND CAUSED DAMAGED TO THEIR WALL OUTLET. THE PATIENT STATED THAT THE POWERSTRIP THAT THEY PLUGGED THE CHARGER INTO NO LONGER WORKS. THERE WAS NO PATIENT HARM REPORTED. THE DEVICE IS EXPECTED TO BE RETURNED AND A REPLACEMENT KIT WAS SENT.

IT WAS REPORTED THAT WHEN THE MCOT MONITOR WAS PLUGGED IN IT BECAME HOT TO THE TOUCH AND MESSED THE PATIENT'S OUTLET. THE DEVICE WAS NOT RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE WALL CHARGER WAS NOT RETURNED. PATIENT NOTED THE USE OF A "POWER STRIP". PER THE PHILIPS PATIENT EDUCATION GUIDE THE DEVICE IS TO BE PLUGGED INTO A SINGULAR OUTLET AND EXTENSION CORDS OR POWER STRIPS SHOULD NOT BE USED. UNABLE TO CONFIRM ALLEGATION AS EVIDENCE WAS NOT PROVIDED. ROOT CAUSE UNKNOWN. MONITOR SN: (B)(6)/ BOM: 02-02118 / UDI: (B)(4) WAS PRESENT DURING THE TIME OF THE EVENT ALTHOUGH IT IS NOT THOUGHT TO HAVE CAUSED OR CONTRIBUTED TO THE ALLEGATION AS THE EVENT HAPPENS BETWEEN THE WALL CHARGER AND THE OUTLET.

## DSI MAUDE Problems Summary

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{{datachunk}}Event837:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230830

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00644

mdr\_text.text:A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.  
REPORTING ADDRESS STATE: (B)(6). REPORTER PHONE #: (B)(6).

THE CUSTOMER REPORTED THAT THERE WAS AN ERROR MESSAGE LOUDSPEAKER FAULT ON THE CENTRAL STATION FROM THE MX40 DEVICE. IT WAS CONFIRMED THAT THERE WAS NO AUDIO FROM THE MX40. A REPLACEMENT MX40 DEVICE WAS ORDERED AND SENT TO THE CUSTOMER. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED. THERE WAS NO ADVERSE EVENT OR PATIENT HARM REPORTED.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event838:

adverse\_event\_flag:N  
product\_problems:["Overheating of Device"]  
event\_type:Malfunction  
date\_of\_event:20230824  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:82 YR  
patient.patient\_sex:Female  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:C6 MCOT PPM  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC  
report\_number:2133409-2023-00056  
  
mdr\_text.text:IT WAS REPORTED THE MONITOR WAS PLUGGED IN CHARGED AND THE MONITOR OVERHEATED. THE DEVICE WAS RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS ABLE TO CONFIRM DEVICE MELT. NO INTERNAL DEVICE WAS OBSERVED DURING EVALUATION. IT IS MOST PROBABLE THAT THE DEVICE MELT WAS CAUSED BY THE MCTO USB-A/ USB-C CABLES OVERHEATING AND FURTHER INTERNAL INVESTIGATION IS ON GOING.  
  
THE PATIENT REPORTED THAT WHEN THEY PLUGGED THEIR MONITOR IN WITH THE CHARGER IT STARTED TO OVERHEAT. SIZZLING SOUNDS WERE COMING FROM THE DEVICE. THERE WAS NO PATIENT HARM REPORTED. THE DEVICE WAS REPLACED.

{{datachunk}}Event839:

adverse\_event\_flag:Y  
product\_problems:["Unable to Obtain Readings"]  
event\_type:Death  
date\_of\_event:20230818

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00459

mdr\_text.text:THE CUSTOMER REPORTED THAT PATIENT EXPIRED WHILE MONITORED ON MX800 DURING SURGICAL ACTIVITY. NO RECORD OF PATIENT ACTIVITY DURING FINAL MOMENTS BEFORE PATIENT EXPIRATION.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE COMPLAINT WAS ESCALATED FOR TECHNICAL INVESTIGATION AND THE RESULTS INDICATE THAT THE MONITOR IN QUESTION WAS SET UP AS A STANDALONE MONITOR WITH NO CONNECTION TO A DATABASE, SO RECORDINGS WERE NOT AVAILABLE AFTER THE EVENT. THE PRODUCT SUPPORT ENGINEER (PSE) ADVISED THAT THIS IS NOT A PRODUCT MALFUNCTION, AND THE MONITOR WAS FUNCTIONING AS DESIGNED. THE PSE EXPLAINED THAT THE MX800 CAN BE SETUP/CONFIGURED TO SEND INFORMATION TO A DATABASE. HOWEVER, IN THIS CASE, THE MONITOR HAS NOT BEEN SET UP TO DO SO AND/OR THE CUSTOMER HAS NOT THE INFRASTRUCTURE TO RECORD DATA COMING OUT OF THE MONITOR. THE PROJECT MANAGER (PM) WAS SENT THE INFORMATION, AND HE ADVISED THAT IF WE CONSIDER THE TREND AS PATIENT ACTIVITY, WE COULD SAY THAT THE MX800 COULD RECORD THE PATIENT ACTIVITY AT 1 VALUE EVERY 12 SECONDS. IF THE USER IS CONSIDERING PATIENT ACTIVITY AS CONTINUOUS WAVES AND NUMERIC RECORDS, SO IN THAT CASE MX800 IS NOT CAPABLE OF A SUCH REPORT AS LONG AS NOT CONNECTED TO ANY DATABASE (SUCH AS PICIX). THE DEVICE WAS FUNCTIONING AS INTENDED AND THERE IS NO MALFUNCTION ON THE DEVICE. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event840:

adverse\_event\_flag:Y



## DSI MAUDE Problems Summary

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product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:58 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Superficial (First Degree) Burn"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00049

mdr\_text.text:THE PATIENT REPORTED THAT THEY WENT TO URGENT CARE FOR FIRST DEGREE BURNS UNDER THE PATCH. THE PATIENT WAS PRESCRIBED OINTMENT AND SWITCHED TO FLEX ADAPTOR AND CONTINUED WITH SERVICE. AFTER SWITCHING TO FLEX THE PATIENT RETURNED TO URGENT CARE AND RECEIVED MORE OINTMENT DUE TO FIRST DEGREE BURNS. THE PATIENT RETURNED THE KIT AND DID NOT FINISH SERVICE. THE PATIENT DOES HAVE A HISTORY OF SKIN SENSITIVITY.

THIS REPORT IS RELATED TO REPORT NUMBER 2133409-2023-00050.

IT WAS REPORTED THAT PATIENT EXPERIENCED A FIRST DEGREE BURN UNDER THE UNIVERSAL PATCH. THE UNIVERSAL PATCH WAS NOT RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE ELECTRODE/DEVICE WAS NOT RETURNED. ALLEGATION IS CONFIRMED THROUGH THE NEED FOR A PRESCRIPTION AND IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARS, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

{{datachunk}}Event841:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Battery Problem","Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230223

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03208

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM) TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE ICM HAD REACHED RECOMMENDED REPLACEMENT TIME (RRT). THE REMOTE MONITOR REMAINS IN USE. THE DEVICE REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION

AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event842:

adverse\_event\_flag:N

product\_problems:["Overheating of Device","Smoking"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00052

mdr\_text.text:PATIENT REPORTED THAT THE MONITOR WAS CHARGING AND IT STARTED SMOKING AND THE MONITOR SAID IT WAS OVERHEATING. THE PATIENT NOTED THAT THE CHARGING CORD WAS BURNING. THE DEVICE WAS RETURNED AND A REPLACEMENT WAS SENT. NO HARM OR PHYSICAL PROPERTY DAMAGE WAS REPORTED.

IT WAS REPORTED THAT THE MONITOR STARTED SMOKING AND THE MONITOR SAID IT WAS OVER HEATING. PATIENT STATED THE CHARGING CORD LOOKS LIKE IT WAS BURNING. THE DEVICE WAS RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION WAS ABLE TO CONFIRM CHARGING CORD MELTING. ROOT CAUSE IS MOST PROBABLE TO BE AN ELECTRICAL FAULT BY THE CHARGING CORD.

{{datachunk}}Event843:

adverse\_event\_flag:N

product\_problems:["Smoking"]

event\_type:Malfunction

date\_of\_event:20230817

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT PPM

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00055

mdr\_text.text:PARENT REPORTED THAT THE SENSOR WAS DAMAGED AND BEGAN SMOKING WITH ATTEMPTING TO PRY OFF THE PLASTIC COMPARTMENT. THE PATIENT WAS STRUGGLING TO REMOVE SENSOR FROM PATCH AT THE TIME OF THE EVENT. NO PATIENT HARM WAS REPORTED. THE DEVICE WAS RETURNED AND A REPLACEMENT DEVICE WAS SENT.

IT WAS REPORTED THAT THE SENSOR HAD SMOKE DAMAGE. THE DEVICE WAS RETURNED FOR INVESTIGATION. A INVESTIGATION WAS PERFORMED AND FOUND THAT THE DEVICE WAS ABLE TO CHARGE AND DEVICE WAS ABLE TO BE DOWNLOADED AND TESTED. INVESTIGATION FOUND THAT THE TEMPERATURE FOR THE DEVICE WAS WITHIN NORMAL LIMITS. INVESTIGATION IN THE LOG OF THE DEVICE FOUND MULTIPLE INITIALIZATION FAILED MESSAGES. DEVICE WAS OPENED TO CONFIRM IF THERE WAS INTERNAL DAMAGE AND CORROSION WAS IDENTIFIED ON THE PCB BOARDS ALONG WITH THE BATTERY CONTACT ON THE BOARD. THE CORROSION CAN CONTRIBUTE TO THE DEVICE NOT CHARGING AND GETTING HOT. TEMPERATURE STRESS TESTS COULD NOT DUPLICATE THE OVERHEAT OR SPARK, BUT THERE IS EVIDENCE OF SPARKS AND MELTING ON THE BATTERY AND ON THE INTERIOR AND EXTERIOR OF THE SENSOR.

{{datachunk}}Event844:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System","No Audible Alarm"]

event\_type:Injury

date\_of\_event:20230426

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Low Blood Pressure/ Hypotension","No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP60

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00451

mdr\_text.text:REPORTER PHONE NUMBER: (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MP60 PATIENT MONITOR DID NOT GENERATE A HIGH PRIORITY RED ALARM FOR A LOW NON-INVASIVE BLOOD PRESSURE (NIBP) OF 44/17 MMHG ON(B)(6) 2023. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO DEATH OR PATIENT INJURY OR HARM WAS REPORTED.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MP60 PATIENT MONITOR DID NOT GENERATE A HIGH PRIORITY RED ALARM FOR A LOW INVASIVE BLOOD PRESSURE (IBP) OF 44/17 MMHG ON 26-APRIL-2023, RESULTING IN THE IMMEDIATE NEED FOR ADJUSTMENT IN IV VASOACTIVE MEDICATIONS. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED EVENT. A SERIOUS INJURY TO THE PATIENT WAS REPORTED.

## DSI MAUDE Problems Summary

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PHILIPS HAS RECEIVED A COMPLAINT ON THE INTELLIVUE MP60, INDICATING "AT 16:37 ON APRIL 26, 2023, THE MONITOR DID NOT GENERATE A HIGH PRIORITY RED ALARM FOR A LOW INVASIVE BLOOD PRESSURE (IBP) OF 44/17 MMHG." THE DEVICE WAS IN CLINICAL USE DURING THE EVENT. THE CUSTOMER REACHED OUT TO PHILIPS VIA A NATIONAL MEDICAL PRODUCTS ADMINISTRATION REPORT (NMPA # (B)(4)) REQUESTING AN INVESTIGATION OF THIS ISSUE. THE NMPA REPORTED THAT AT 16:37 ON APRIL 26, 2023, THE PATIENT'S BLOOD PRESSURE WAS AS LOW AS 44/17MMHG, AND THE AVERAGE PRESSURE WAS 24MMHG. THE MONITOR DID NOT PROMPT A RED ALARM. THE DOCTOR WAS IN THE WARD AT THE TIME AND IMMEDIATELY ADMINISTERED VASOACTIVE DRUGS, AND THE PATIENT'S BLOOD PRESSURE WAS NORMAL 5 MINUTES LATER WITHOUT CONSEQUENCES. NO OTHER CLINICAL INFORMATION OR MEDICAL INTERVENTION WAS REPORTED. A GOOD FAITH EFFORT (GFE) WAS CONDUCTED SEVERAL TIMES, BUT NO FURTHER INFORMATION IF THE DEVICE WAS TESTED OR LOGS WERE REVIEWED AND INFORMATION REGARDING THE ALARM SETTINGS WAS PROVIDED. A PHILIPS FIELD SERVICE ENGINEER (FSE) REACHED OUT TO THE CUSTOMER, AND CONFIRMED THAT THE EVENT DATE WAS ON APRIL 26, 2023, BUT PHILIPS NEVER RECEIVED ANY FEEDBACK ON THE ISSUE AT THE TIME. THE CUSTOMER STATED THAT THIS ISSUE WAS ABOUT AN INVASIVE PRESSURE ALARM, AND IT ONLY HAPPENED ONE TIME. THE ALARM WAS NORMAL BEFORE AND AFTER THE OCCURRENCE OF THE INCIDENT, AND THE CUSTOMER ADDED THAT SINCE THE INCIDENT HAPPENED ON APRIL 26, 2023, THERE WERE NO VALUABLE CLUES TO SUPPORT THE INVESTIGATION OF THE PROBLEM. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM REMAINS UNKNOWN. THE ENGINEER COULDN'T PROVIDE ANY ANALYSIS FINDINGS BECAUSE THE CUSTOMER DID NOT RESPOND TO REQUESTS FOR ADDITIONAL INFORMATION. IT WAS CONFIRMED THE ISSUE HAS NOT RECURRED, HOWEVER, PHILIPS IS UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED. H3 OTHER TEXT : DEVICE NOT MADE AVAILABLE FOR EVALUATION

{{datachunk}}Event845:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Electromagnetic Interference","Over-Sensing","Under-Sensing","Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20230128

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05554

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED AN R-WAVE AMPLITUDE MEASUREMENT ISSUE. ANALYSIS OF THE DEVICE MEMORY INDICATED RIGHT VENTRICULAR UNDERSENSING. ANALYSIS OF THE DEVICE MEMORY OBSERVED NOISE ON THE ELECTROGRAM WAVEFORMS. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED LOW R-WAVE AMPLITUDE. THE ICM ALSO DETECTED FALSE TACHYCARDIA EPISODES DUE TO OVERSENSING WITH SOME KIND OF ELECTROMAGNETIC INTERFERENCE/ NOISE CAUSING THE OVERSENSING. THE ICM FURTHER REPORTED THAT THE ICM EXPERIENCED AN UNDER SENSED R WAVE. THE EPISODES LATER SHOW FLOATING ELECTROCARDIOGRAM (ECG) WHICH WAS LIKELY CAUSED BY MECHANICAL MANIPULATION/MOVEMENTS OF THE IMPLANT SITE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event846:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230821

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI



## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00633

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT ON THE MX40 PATIENT WEARABLE MONITOR INDICATING THAT THE DEVICE IS DISPLAYING A SPEAKER MALFUNCTION INOP WITH CONFIRMED NO SOUND. THE DEVICE WAS NOT IN USE.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT THERE WAS A SPEAKER MALFUNCTION. THE CUSTOMER CONFIRMED THAT NO SOUND WAS PRODUCED. PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event847:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20230817

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00635

mdr\_text.text:THE CUSTOMER REPORTED THAT THERE IS NO ERROR ALARM DISPLAYED. THERE IS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THERE WAS NO ACTUAL FAILURE REGARDING THAT MESSAGE BEING PRESENT. BENCH REPAIR CONFIRMED THAT THE "NO ALARM DISPLAY" MESSAGE IS PRESENT ON ALL DEVICES BEFORE CONNECTING TO THE COMMUNICATION TOWER. AFTER THE CONNECTION IS MADE AND LEAD SET HAS BEEN INSERTED THE MESSAGE IS RESOLVED. ADDITIONAL PARTS WERE REPLACED DUE TO BRINGING THE DEVICE TO CURRENT REV AND ARE NOT DUE TO ANY FAILURE OF THE DEVICE. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event848:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20230815

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:PATIENT INFORMATION CENTER IX

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00638

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE DEVICE DISPLAYS A SPEAKER MALFUNCTION. THERE WAS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION ERROR WITH THE SYSTEM AND REQUEST ASSISTANCE GETTING THE SURVEILLANCE RECONNECTED BACK TO THE PRIMARY SERVER. THE REMOTE SERVICE ENGINEER (RSE) GUIDED THE BIOMED THROUGH THE PROCESS OF REBOOTING THE STATION, THE STATION WAS RECONNECTED BUT THERE IS NO SOUND. FURTHER WORKAROUND SHOWED THAT THE RECTANGULAR SPEAKER IS SET AS DEFAULT (THE ONLY SPEAKER ON SITE) IT WAS TESTED BUT IT DID NOT GENERATE A SOUND. RSE ADVISED THE BIOMED TO GET A SPARE SPEAKER AS THE STATION SHOULD NOT BE RUNNING WITHOUT SOUND . BIOMED TAKES FULL RESPONSIBILITY OF CALLING US BACK IF ADDITIONAL SUPPORT IS NOT NEEDED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE CUSTOMER SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. BASED ON THE INFORMATION PROVIDED IN THE CASE, THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS AND THE DETAILS OF THE WORKAROUND GIVEN TO THE CUSTOMER, HOWEVER WE ARE UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE. THE CUSTOMER TAKES THE FULL RESPONSIBILITY OF CALLING BACK IF ADDITIONAL SUPPORT IS NOT NEEDED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event849:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230831

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00639

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event850:

adverse\_event\_flag:N

product\_problems:["Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20230829

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05528

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) REPORTED A PAUSE EPISODE WITH A FIVE SECOND DURATION. IT WAS NOTED THAT THE ELECTROCARDIOGRAM (ECG) HAD BEEN SUSPENDED FOR SEVEN SECONDS. THIS DISCREPANCY CHANGED THE EVENT FROM NON-CLINICALLY ACTIONABLE TO ACTIONABLE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR

## DSI MAUDE Problems Summary

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THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event851:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230822

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00632

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

## DSI MAUDE Problems Summary

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DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event852:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230831

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03141

mdr\_text.text:CORRECTION: B5, B7, D6B, H6. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR

## DSI MAUDE Problems Summary

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THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD MIGRATED INTO THE TISSUE. THE ICM WAS EXPLANTED.

B3: DATE IS APPROXIMATE. MONTH AND YEAR ARE CONFIRMED VALID. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD MIGRATED. AN ATTEMPT WAS MADE TO REMOVE THE ICM HOWEVER IT COULD NOT BE LOCATED IN THE PATIENT. IT WAS DECIDED TO LEAVE THE DEVICE IN THE PATIENT. THE ICM HAD BEEN IMPLANTED APPROXIMATELY FORTY SIX MONTHS. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event853:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction



date\_of\_event:20230828

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00448

mdr\_text.text:THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 AND NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND CONFIRMED THERE WAS NO SOUND COMING FROM THE UNIT AND THERE WAS A SPEAKER INOPERATIVE MESSAGE PRESENT. THE FSE PROVIDED THE CUSTOMER A QUOTE FOR A REPLACEMENT SPEAKER.

(B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 AND NO SOUND WAS COMING FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT THE TIME OF THE REPORTED ISSUE. NO DEATH OR PATIENT INJURY OR HARM WAS REPORTED.

{{datachunk}}Event854:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

## DSI MAUDE Problems Summary

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date\_of\_event:20230728

event\_location:

remedial\_action:[""]

patient.patient\_age:51 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03147

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS ALSO REPORTED THAT THE NETWORK SESSION MANAGEMENT ISSUE: TRANSMISSION LAST CLEARED GOES BACK TO DATE OF IMPLANT, UNEXPECTED BEHAVIOR.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED UNDERSENSESING ON A TACHYCARDIA EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event855:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230815

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00626

mdr\_text.text:THE PHILIPS AUTHORIZED REPAIR FACILITY TESTING INDICATE THAT THE SPEAKER PRODUCED HAS NO SOUND AND THE SPEAKER WAS DEFECTIVE. THE DEVICE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

THE CUSTOMER REPORTED THAT DURING AN EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

{{datachunk}}Event856:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230821

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00627

## DSI MAUDE Problems Summary

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mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THERE WAS NO SPEAKER SOUND AT START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event857:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230823

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00628

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT NO SPEAKER SOUND AT START UP TEST, FAILED AT MANUAL POWER ON TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS

## DSI MAUDE Problems Summary

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RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event858:

adverse\_event\_flag:Y

product\_problems:["No Audible Alarm"]

event\_type:Death

date\_of\_event:20230818

event\_location:

remedial\_action:[""]

patient.patient\_age:32 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Hypoxia"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00441

mdr\_text.text:THE CUSTOMER REPORTED THAT THE INTELLIVUE MX800 PATIENT MONITOR DID NOT AUDIBLY ALARM FOR A DESATURATION EVENT FOR THE PATIENT IN ROOM C23 ON (B)(6) 2023 BETWEEN 14:00 AND 14:30. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED EVENT. THE PATIENT LATER PASSED AWAY.

A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE TO EVALUATE THE DEVICE AND CONFIRMED WITH THE CUSTOMER THAT THE ALARMS WERE SILENCED DURING THE TIMES IN QUESTION. IT WAS CONFIRMED THAT THE PATIENT WAS A 32-YEAR-OLD MALE. THE COMPLAINT WAS ESCALATED FOR TECHNICAL INVESTIGATION BY A PHILIPS PRODUCT SUPPORT ENGINEER (PSE) FOR THE ALLEGATION THAT "LAST FRIDAY (B)(6) 2023 BETWEEN 14:00 AND 14:30 IN ROOM C23 OF MICU AT (B)(6) HOSPITAL A PATIENT CODED, AND THE NURSE FELT LIKE A DESATURATION (DESAT ALARM) WASN'T MAKING

## DSI MAUDE Problems Summary

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AUDIBLE NOISE IN ROOM AT MONITOR DURING RESUSCITATION OF PATIENT." THE PSE EVALUATED THE DEVICE LOGS PROVIDED BY THE CUSTOMER AND SAW SEVERAL ALARMS BEING ANNOUNCED AT THE CENTRAL STATION. THESE ALARMS WERE COMING FROM THE BEDSIDE LABELED C23 AND THERE WAS NO INDICATION THAT THERE WAS NO ALARM. THE PSE CONFIRMED THERE WERE DESAT ALARMS DURING THE MENTIONED TIMEFRAME AND STATED, "FROM WHAT I SEE, THE MONITOR WORKED AND ALARMED AS EXPECTED". BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED BY THE FSE, LOG ANALYSIS FROM OUR PSE AND CAS, IT HAS BEEN CONCLUDED THAT "THE MONITOR WORKED AND ALARMED AS EXPECTED" AND THE DEVICE DID NOT CAUSE OR CONTRIBUTE TO THE PATIENT'S DEATH. IT IS EVIDENT FROM THE AFOREMENTIONED INVESTIGATIONS THAT THE MONITOR WAS SILENCED IN THE ROOM DURING THE TIMES IN QUESTION. THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS, NO FAILURE WAS IDENTIFIED AND THE DEVICE DID NOT CAUSE OR CONTRIBUTE TO THE PATIENT'S DEATH. IT IS EVIDENT FROM THE AFOREMENTIONED INVESTIGATIONS THAT THE MONITOR WAS SILENCED IN THE ROOM DURING THE TIMES IN QUESTION. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

IT WAS STATED THAT THE PATIENT HAS DIED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MX800 PATIENT MONITOR DID NOT AUDIBLY ALARM FOR A DESATURATION EVENT FOR THE PATIENT IN ROOM C23 ON (B)(6) 2023 BETWEEN 14:00 AND 14:30. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED EVENT. THE PATIENT NEEDED TO BE RESUSCITATED.

{{datachunk}}Event859:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20230830

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Male

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03123

mdr\_text.text:CORRECTION: UPDATED CODING IN H6. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: A1 MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM



## DSI MAUDE Problems Summary

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BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION

AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event860:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230819

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00442

mdr\_text.text:THE DEVICE WAS TESTED BY THE HOSPITAL BIOMED. ADDITIONALLY, A FIELD SERVICE ENGINEER WENT ON SITE TO EVALUATE THE DEVICE. THE FSE CHANGED PARAMETERS TO INTENTIONALLY SET AN ALARM AND THE MONITOR ALARMED USING DEMO MODE. A VISUAL INSPECTION WAS PERFORMED AND CONFIGURATION WAS VERIFIED. NOTHING OBVIOUS WAS FOUND. PHILIPS PRODUCT SUPPORT ENGINEERING (PSE) PERFORMED ANALYSIS OF THE AUDIT LOGS AND

## DSI MAUDE Problems Summary

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CONFIGURATION PROVIDED BY THE CUSTOMER. HOWEVER, THE FILES PROVIDED DID NOT CLARIFY WHETHER A DESATURATION ALARM SHOULD HAVE BEEN ANNOUNCED AT THIS TIME. PSE REQUESTED RECORDING/STRIPS SHOWING THE SPO2 VALUES AT THE POINT OF TIME, BUT THE INFO WAS NOT AVAILABLE. IN GENERAL, IF THE DESAT DELAY WAS SET TO 20 SEC., THE MONITOR WOULD ONLY HAVE ALARMED FOR DESATURATION, AFTER THE AVERAGED SPO2 VALUE HIT BELOW THE DESAT LIMIT. IF THERE WAS ONE SPO2 VALUE ABOVE THE DESAT LIMIT OF 85% & THIS WOULD HAVE TRIGGERED THE DESAT DELAY TO START FRESH & AND THEREFORE NO DESAT ALARM WOULD HAVE BEEN ISSUED (CORRECT BEHAVIOR AS SPECIFIED). BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM IS UNKNOWN DUE TO THE LIMITED INFORMATION PROVIDED.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MX800 PATIENT MONITOR DID NOT ALARM FOR A DESATURATION EVENT FOR THE PATIENT IN ROOM C18 WHEN THE SPO2 READING WAS AT 84% AND THE DESAT ALARM LIMIT WAS SET TO 85%. THE EVENT OCCURRED ON (B)(6) 2023 AT 05:10. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED EVENT. NO DEATH OR PATIENT INJURY OR HARM WAS REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MX800 PATIENT MONITOR DID NOT ALARM FOR A DESATURATION EVENT FOR THE PATIENT IN ROOM C18 WHEN THE SPO2 READING WAS AT 84% AND THE DESAT ALARM LIMIT WAS SET TO 85%. THE EVENT OCCURRED ON (B)(6) 2023 AT 05:10. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED EVENT. NO DEATH OR PATIENT INJURY OR HARM WAS REPORTED.

{{datachunk}}Event861:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20230821

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00443

mdr\_text.text:THE HOSPITAL BIOMED DID AN INITIAL EVALUATION OF THE ISSUE, AND A PHILIPS FIELD SERVICE ENGINEER (FSE) PERFORMED ANOTHER EVALUATION WHEN ON SITE. THE FSE DID A VISUAL INSPECTION, CHECKED CONFIGURATION, CHANGED PARAMETERS TO INTENTIONALLY SET AN ALARM AND MONITOR ALARMED USING DEMO MODE. AS PER CUSTOMER, ONLY THE BEDSIDE MONITOR WAS NOT ALARMING, HOWEVER THE FSE CONFIRMS THE DEVICE ALARMED/ALERTED WHEN TESTED AND ON REVIEWING OF LOGS. A PHILIPS PRODUCT SUPPORT ENGINEER (PSE) PERFORMED ANALYSIS OF LOGS AND CONFIGURATION PROVIDED BY THE CUSTOMER. THE PSE CHECKED THE TIMES BETWEEN 9:10 AND 9:20 AND VERIFIED A \*\*\*DESAT ALARM AT 9:16:06 GENERATED IN ROOM D24. AT THE SAME TIME AT 9:16:06 A RED ALARM SOUND PLAYED. HOWEVER, AT 9:16:47 THE ALARM WAS ACKNOWLEDGED FROM THE CENTRAL STATION AND THEREFORE, THE ALARM SOUND STOPPED AT 9:16:47. FOR THE RESPECTIVE PATIENT MONITOR, THE ¿ALARM REMINDER¿ WAS CONFIGURED TO ¿REALARM¿. THIS MEANS THAT AFTER THE ¿REMINDER TIME¿ (IN THIS CASE: 3 MIN.) THE ALARM TONE IS REPEATED. THIS CAN BE SEEN AT 9:19:55 IN THE AUDIT LOG. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS THE USER LACK OF AWARENESS OF ALARM CONFIGURATION. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE ENGINEERS PROVIDED THE FINDINGS TO THE CUSTOMER TO RESOLVE THE ISSUE.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MX800 PATIENT MONITOR ALARMED FOR A DESATURATION EVENT FOR THE PATIENT IN ROOM D24, BUT THE ALARM CLEARED ITSELF AT THE MONITOR ON (B)(6) 2023 BETWEEN 09:16 AND 09:20. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. NO DEATH OR PATIENT INJURY OR HARM WAS REPORTED.

{{datachunk}}Event862:

adverse\_event\_flag:Y

product\_problems:["No Audible Alarm"]

event\_type:Injury

## DSI MAUDE Problems Summary

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date\_of\_event:20230817

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Asystole"]

device.brand\_name:INTELLIVUE MP50

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00444

mdr\_text.text:PHILIPS HAS RECEIVED A COMPLAINT ON THE INTELLIVUE MP50 INDICATING "MONITOR DID NOT ALARM FOR THE NEONATAL PATIENT IN BED 8 WHEN THE HEART RATE DROPPED ON 16 AUGUST 2023 AT 22:00. THE PATIENT CODED AND CLINICAL STAFF PERFORMED CARDIOPULMONARY RESUSCITATION (CPR) FOR 15 SECONDS." THE PATIENT RECOVERED. A PHILIPS FIELD SERVICE ENGINEER (FSE), CLINICAL APPLICATION SPECIALIST (CAS) AND A NATIONAL SUPPORT SPECIALIST (NSS) WENT ONSITE, LOOKED INTO THE CLINICAL AUDIT LOG IN THE PHILIPS SYSTEM AND REVIEWED THE ALARMS FOR THE MONITOR. THEY WERE ABLE TO SEE ASYSTOLE ALARMS FOR THE TIME FRAME IN QUESTION AND CONFIRMED THAT THE MONITOR DID IN FACT ALARM. MULTIPLE YELLOW AND RED ALARMS WERE GENERATED BETWEEN 22:10 AND 24:00 ON 16-AUGUST-2023 FOR BED NICU 8. A RED VTACH ALARM WAS GENERATED AT 22:27:59, FOLLOWED BY AN ASYSTOLE ALARM AT 23:12:49 WHICH WAS ACKNOWLEDGED AT THE BEDSIDE MONITOR. IN ADDITION, SEVERAL RED ALARMS WERE GENERATED AND WERE PAUSED DURING THE TIME FRAME OF 22:00 UNTIL 00:00 ON 16-AUGUST-2023, WITH THE PAUSE LASTING THREE MINUTES. FURTHERMORE, THE FSE AND BIOMED TESTED THE MONITOR USING A PATIENT SIMULATOR AND CONFIRMED THAT THE MONITOR DID ALARM AS EXPECTED. BASED ON THE INFORMATION AVAILABLE, PSE LOG REVIEW AND TESTS CONDUCTED, IT HAS BEEN DETERMINED THAT THE INTELLIVUE MP50 PATIENT MONITOR WAS FUNCTIONING/ALARMING PER SPECIFICATION. ALARMS WERE ACKNOWLEDGED BY THE STAFF. THE INTELLIVUE MP50 PATIENT MONITOR DID NOT CAUSE OR CONTRIBUTE TO THE REPORTED EVENT. THE CAUSE OF THE REPORTED PROBLEM WAS AN USER ERROR. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

THE CUSTOMER REPORTED THAT THE INTELLIVUE MP50 PATIENT MONITOR DID NOT ALARM FOR THE NEONATAL PATIENT IN BED 8 WHEN THE HEART RATE DROPPED ON (B)(6) 2023 AT APPROXIMATELY 23:10. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED EVENT. THE

## DSI MAUDE Problems Summary

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PATIENT CODED AND CLINICAL STAFF PERFORMED CPR FOR 15 SECONDS. THE PATIENT RECOVERED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event863:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20221230

event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03119

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS

¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR OVERSENSING ON TACHYCARDIA EPISODES. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT DID NOT GENERATE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event864:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20230828

event\_location:

remedial\_action:[""]

patient.patient\_age:79 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03120

## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING NOISE. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT WAS NOT GENERATING. IT WAS NOTED THAT A PREVIOUS REPORT HAD NO EPISODES RECORDED. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CONTINUATION OF D10: PRODUCT ID 977C165 LOT# SERIAL# (B)(6). IMPLANTED: (B)(6) 2018. PRODUCT ID 97715 LOT# SERIAL# (B)(6). IMPLANTED: (B)(6) 2018. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event865:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230829

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Female



## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03121

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS ADVISED TO GET A DEVICE CHECK AT THE OFFICE AND BRING THE REMOTE MONITOR. THE REMOTE MONITOR REMAINS IN USE AND THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event866:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20230829

event\_location:

remedial\_action:[""]

patient.patient\_age:90 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03122

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR HAD NO TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS REFERRED

## DSI MAUDE Problems Summary

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TO CLINIC. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event867:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230817

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00440

mdr\_text.text:IT WAS REPORTED THAT THERE WAS A LOUDSPEAKER ERROR. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THERE WAS A LOUDSPEAKER ERROR AND IT WAS PROVIDED THAT THE SPEAKER HAD NO SOUND AT ALL. THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND DETERMINED THAT THE SPEAKER WAS DEFECTIVE. THE FSE CHANGED THE SPEAKER TO RESOLVE THE ISSUE. E1; REPORTER INSTITUTION PHONE NUMBER: (B)(6). E1: REPORTER PHONE NUMBER: (B)(6).

{{datachunk}}Event868:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Appropriate Term/Code Not Available"]

event\_type:Malfunction

date\_of\_event:20230824

event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03105

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THE THE DEVICE WORKED SOMETIMES AND SOMETIMES IT DID NOT. THE ICM REMAINS IN USE. THE ICM HAS BEEN IMPLANTED OVER TWO YEARS. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED BY THE HEALTHCARE PERSONNEL THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO PERFORMANCE ISSUE.

{{datachunk}}Event869:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20230815

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03106

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. THE ICM HAD REACHED END OF SERVICE (EOS). IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT DID NOT GENERATE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT

## DSI MAUDE Problems Summary

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DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event870:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Pain"]

device.brand\_name:REVEAL XT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC MED REL MEDTRONIC PUERTO RICO

report\_number:3004209178-2023-15265

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT

## DSI MAUDE Problems Summary

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INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THAT THEY EXPERIENCED EXTREME PAIN A FEW WEEKS AFTER IMPLANT. IT WAS INDICATED THIS WAS DUE TO THE DEVICE. IT WAS FURTHER INDICATED THAT THE DEVICE WAS REMOVED. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event871:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230727

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI



## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00619

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND; THE SPEAKER WAS CONFIRMED TO BE DEFECTIVE. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT THE PHILIPS REPAIR BENCH, IT WAS IDENTIFIED THAT THE DEVICE HAD NO SPEAKER SOUND AT START UP TEST. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

{{datachunk}}Event872:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230824

event\_location:

remedial\_action:[""]

patient.patient\_age:82 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Pain"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03083

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY

## DSI MAUDE Problems Summary

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PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT HAD TWO ICM'S IMPLANT, ONE ACTIVE AND ONE INACTIVE. ONE OF THE DEVICES HAD MOVED FROM BETWEEN THE PATIENT'S BREAST TO ABOVE THEIR LEFT BREAST AND WAS PROTRUDING. IT WAS FURTHER REPORTED THAT IT WAS PAINFUL WHEN BEING HUGGED. THE ICM REMAINS IN USE. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event873:

adverse\_event\_flag:N

product\_problems:["Device Sensing Problem"]

event\_type:Malfunction

date\_of\_event:20230811

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03084

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE

## DSI MAUDE Problems Summary

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BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED BY THE PATIENT THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD BEEN CONSTANTLY DETECTING ATRIAL FIBRILLATION (AF) OVER A TWENTY-FOUR HOUR PERIOD. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event874:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230807

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00434

mdr\_text.text:A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO DETERMINE IF THE SPEAKER PRODUCED SOUND, AND IT WAS PROVIDED THAT THE SPEAKER WAS COMPLETELY OUT OF SOUND. THE BENCH REPAIR TECHNICIAN (BRT) CONFIRMED THE ISSUE AND REPLACED THE SPEAKER TO RESOLVE THE SPEAKER ISSUE. THE DEVICE WAS OPERATIONAL REPLACING THE SPEAKER.

IT WAS REPORTED THAT THE LOUDSPEAKER WAS DEFECTIVE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event875:

adverse\_event\_flag:N

product\_problems:["Break"]

event\_type:Malfunction

date\_of\_event:20230822

event\_location:

remedial\_action:[""]

patient.patient\_age:81 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03088

mdr\_text.text:IT WAS REPORTED THAT BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THAT THEY FELT THE ICM WAS IN TWO PIECES. THEY FURTHER REPORTED THAT THEY COULD FEEL A 'CHIP OR SOMETHING' AND THAT IT FELT DISCONNECTED FROM THE DEVICE. THE ICM WAS IMPLANTED APPROXIMATELY SEVEN MONTHS AGO. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE

## DSI MAUDE Problems Summary

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INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event876:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230810

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00617

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THERE WAS NO SPEAKER SOUND DURING START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

## DSI MAUDE Problems Summary

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THE CUSTOMER REPORTED A SPEAKER MALFUNCTION, THERE IS NO AUDIBLE SOUND DURING ALARMING. THE DEVICE WAS REPORTED TO BE IN USE ON A PATIENT, BUT NO ADVERSE EVENT TO THE PATIENT OR USER WAS REPORTED.

{{datachunk}}Event877:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230815

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00618

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THERE WAS NO SOUND AT START UP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE SPEAKER IS DEFECTIVE. THE SPEAKER WAS REPLACED.

{{datachunk}}Event878:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:20230815

event\_location:

remedial\_action:[""]

patient.patient\_age:63 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03050

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY WITH THE REMOTE MONITOR. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS REFERRED TO THE CLINIC. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS



CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event879:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230606

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03052

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR HAD TELEMETRY ISSUES WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE REMOTE MONITOR REMAINED IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE,

## DSI MAUDE Problems Summary

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MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event880:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230821

event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03053

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY

## DSI MAUDE Problems Summary

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PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS UNABLE TO SEND A TRANSMISSION WITH THE NEW READER. IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMETRY. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE PATIENT WAS REFERRED TO THE CLINIC. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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{{datachunk}}Event881:

adverse\_event\_flag:N

product\_problems:["Battery Problem","Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230821

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03055

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE

## DSI MAUDE Problems Summary

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BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS SHOWING A PERSON HOLDING THE READER AGAINST THE IMPLANTABLE CARDIAC MONITOR (ICM); IT HAD NO TELEMETRY. IT WAS FOUND OUT THAT THE BATTERY OF THE CM HAD REACHED ITS RECOMMENDED REPLACEMENT TIME (RRT). THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event882:

adverse\_event\_flag:N

product\_problems:["Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20230822

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05295

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS

## DSI MAUDE Problems Summary

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REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DID NOT RECORD ELECTROCARDIOGRAM (ECG)'S FOR PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event883:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20230607

event\_location:

remedial\_action:[""]

patient.patient\_age:56 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-03025

mdr\_text.text:IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR OVERSENSING.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS

## DSI MAUDE Problems Summary

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CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED T-WAVE OVERSENSING (TWOS). IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT WHEN BACK TO THE DATE OF IMPLANT INSTEAD OF LAST INTERROGATION. THE ICM REMAINS IN USE. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION



## DSI MAUDE Problems Summary

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AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event884:

adverse\_event\_flag:N

product\_problems:["Overheating of Device"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:90 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 PATCH VERIZON

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00048

mdr\_text.text:IT WAS REPORTED THAT THE MONITOR CHARGER AND MONITOR ITSELF WAS BURNT AND DAMAGED. THE DEVICES RETURNED FOR INVESTIGATION. A CAPA HAS BEEN INITIATED FOR MCOT USB-A/ USB-C CABLES OVERHEATING FAILURES. ALTHOUGH UNIT,C6M,A10E,U (B)(6), 02-01894 UDI: (B)(4), WAS NAMED IN THE ALLEGATION IT HAS BEEN IDENTIFIED THAT THE CHARGING CORD IS THE SOURCE OF THIS FAILURE.

THE PATIENT'S DAUGHTER REPORTED THAT MONITOR CHARGER WAS BURNT AND DAMAGED AS WELL AS THE MONITOR ITSELF. THERE WERE NO REPORTED INJURIES. THE DEVICE WAS REQUESTED TO BE RETURNED.

{{datachunk}}Event885:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230210

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00430

mdr\_text.text:A PHILIPS REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED THIS CASE WAS A PART ORDER FROM THE CUSTOMER UNDER CONTRACT FOR A SPEAKER ASSEMBLY REPLACEMENT. BASED ON THE INFORMATION AVAILABLE, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY SPEAKER. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2, INDICATING THE LOUDSPEAKER IS FAULTY. ADDITIONAL INFORMATION WAS RECEIVED THAT THE DEVICE DID NOT HAVE AUDIBLE SOUND. THIS WAS IDENTIFIED DURING SETUP. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event886:

adverse\_event\_flag:Y

product\_problems:["Patient-Device Incompatibility"]

## DSI MAUDE Problems Summary

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event\_type:Injury

date\_of\_event:20230726

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cellulitis","Contact Dermatitis"]

device.brand\_name:ZIO AT

ZIO AT

device.device\_report\_product\_code:DSI

QYX

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00043

mdr\_text.text:THE PATIENT REPORTED SKIN IRRITATION WITH SIGNS OF SECONDARY INFECTION ALLEGED TO BE CAUSED BY ZIO AT. THE PATIENT WAS DIAGNOSED WITH CONTACT DERMATITIS AND CELLULITIS AND WAS PRESCRIBED TREATMENT BY THEIR HEALTHCARE PROVIDER. SKIN IRRITATION IS A KNOWN INHERENT RISK OF THE DEVICE. DEVICE MANUAL WARNINGS SECTION READ AS FOLLOWS: DO NOT USE THE ZIO AT PATCH ON PATIENTS WITH KNOWN ALLERGIC REACTION TO ADHESIVES OR HYDROGELS OR WITH FAMILY HISTORY OF ADHESIVE SKIN ALLERGIES. PATIENT MAY EXPERIENCE SKIN IRRITATION. IF SKIN IRRITATION SUCH AS SEVERE REDNESS, ITCHING OR ALLERGIC SYMPTOMS DEVELOP, REMOVE THE ZIO AT PATCH FROM THE PATIENT'S CHEST. THIS EVENT IS BEING REPORTED PER 21 CFR 803 AS A SERIOUS INJURY. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS, OR HAS MALFUNCTIONED. THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

THE PATIENT REPORTED SKIN IRRITATION WITH SIGNS OF SECONDARY INFECTION ALLEGED TO BE CAUSED BY ZIO AT. THE PATIENT WAS DIAGNOSED WITH CONTACT DERMATITIS AND CELLULITIS AND WAS PRESCRIBED TREATMENT BY THEIR HEALTHCARE PROVIDER.

## DSI MAUDE Problems Summary

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{{datachunk}}Event887:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230812

event\_location:

remedial\_action:[""]

patient.patient\_age:87 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02996

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH

## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON A TACHYCARDIA EPISODE. IT WAS FURTHER REPORTED THAT THE ICM EXPERIENCED UNDERSENSING ON PAUSE EPISODES. IT WAS ALSO REPORTED THAT THE REMOTE MONITORING REPORT COUNTERS WENT BACK TO IMPLANT DESPITE A COUNTER CLEARING EVENT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event888:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230803

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02970

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED NO TELEMETRY WITH THE REMOTE MONITOR. THE REMOTE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE

## DSI MAUDE Problems Summary

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COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event889:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230622

event\_location:

remedial\_action:[""]

patient.patient\_age:84 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02971

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR UNDERSENSING AND T-WAVE OVERSENSING. THE ICM REMAINS IN USE. THE PATIENT IS A PARTICIPANT IN A CLINICAL STUDY. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event890:

adverse\_event\_flag:N

product\_problems:["Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20230815

event\_location:

remedial\_action:[""]

patient.patient\_age:85 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02976

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DID NOT RECORD ELECTROCARDIOGRAM (ECG) FOR EPISODES DETECTED. IT WAS FURTHER REPORTED THERE WAS NO FULL REPORT AVAILABLE DUE TO A FAILED TRANSMISSION. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

D6B: YEAR VALID MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS



## DSI MAUDE Problems Summary

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¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS REMOVED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event891:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20200729

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02956

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER REPORTED THAT THE DEVICE INTERROGATED BACK TO DATE OF IMPLANT INSTEAD OF MOST RECENT FULL REPORT OR PROGRAMMER INTERROGATION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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{{datachunk}}Event892:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20211118

event\_location:

remedial\_action:[""]

patient.patient\_age:77 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05155

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH

## DSI MAUDE Problems Summary

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EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED INTERMITTENT R WAVE UNDERSENSING. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING TRANSMISSION LAST CLEARED GOES BACK TO DATE OF IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event893:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20220826

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

## DSI MAUDE Problems Summary

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patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00422

mdr\_text.text:THE CUSTOMER REPORTED A LOUDSPEAKER ERROR ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2. IT IS UNKNOWN IF SOUND WAS STILL COMING FROM THE DEVICE. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

THE REMOTE SERVICE ENGINEER (RSE) DETERMINED THAT THE CUSTOMER HAD A QUESTION REGARDING THE LOUDSPEAKER ERROR ALARM. THE PROBLEM WAS NOT PRESENT AT THE TIME OF THE CALL. THE USER WAS NOT ONSITE WITH THE USER TO TROUBLESHOOT. THE RSE ASKED THE CUSTOMER WHETHER THE PROBLEM WAS STILL PRESENT BUT RECEIVED NO RESPONSE BY EMAIL. WE ARE UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE, BECAUSE THE CUSTOMER DID NOT RESPOND TO REQUESTS FOR ADDITIONAL INFORMATION. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event894:

adverse\_event\_flag:Y

product\_problems:["Incorrect, Inadequate or Imprecise Result or Readings"]

event\_type:Death

date\_of\_event:20230801

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00600

mdr\_text.text:A PHILIPS PRODUCT SUPPORT ENGINEER REVIEWED THE LOG FILES PROVIDED. THE AVAILABLE LOG DATA (RFDA & DEVICE DEBUG) DOES NOT SHOW ANY LOSS OF MONITORING (LOSS OF ASSOCIATION WITH THE PIC IX) DURING THE INCIDENT TIMEFRAME. THE LOGS ALSO SHOW THAT THE DEVICE WAS PUT INTO ¿STANDBY¿ MODE AT 23:53 ON (B)(6) 2023 AND THE DEVICE WAS TAKEN OUT OF ¿STANDBY¿ MODE AT 00:40 ON (B)(6) 2023. THE ONLY WAY THE EQUIPMENT CAN GO INTO STANDBY MODE IS THROUGH USER INTERACTION. WHEN THE MX40 IS PUT INTO STANDBY (EITHER AT THE DEVICE OR AT THE PIC IX) THE MX40 RADIO IS TURNED OFF, AS A RESULT, NO MONITORING IS BEING PERFORMED, AND NO DATA IS BEING TRANSMITTED TO THE PIC IX. THE PATIENT SECTOR WILL SHOW THAT THE DEVICE IS IN ¿STANDBY.¿ THERE ARE NO OTHER LOG ENTRIES UNTIL A BATTERY REPLACEMENT WAS PERFORMED AT 08:25 ON (B)(6) 2023, WHICH WAS AFTER THE REPORTED INCIDENT TIMEFRAME. BASED ON THE LIMITED INFORMATION PROVIDED, THE DEVICE WAS OPERATING AS SPECIFIED DURING THE EVENT IN QUESTION. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE REPORTED PROBLEM WAS NOT CONFIRMED. THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS. BASED ON THE LIMITED INFORMATION PROVIDED, THE DEVICE WAS OPERATING AS SPECIFIED DURING THE EVENT IN QUESTION. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE PATIENT EXPIRED WHILE BEING MONITORED ON THIS MX40; THE ECG STOPPED WORKING.

{{datachunk}}Event895:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20220902

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00423

mdr\_text.text:THE FIELD SERVICE ENGINEER (FSE) WENT ONSITE AND CONFIRMED THAT THE SPEAKER WAS FAULTY. THE FSE REPLACED THE SPEAKER TO RESOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPLACING THE SPEAKER WAS COMPLETED. E1; REPORTER INSTITUTION PHONE NUMBER (B)(6)  
E1: REPORTER PHONE NUMBER (B)(6)

IT WAS REPORTED THAT A MESSAGE ABOUT A SPEAKER OPERATION FAULT IS BEING DISPLAYING ON THE X2. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event896:

adverse\_event\_flag:N

product\_problems:["Appropriate Term/Code Not Available"]

event\_type:Malfunction

date\_of\_event:20230809

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02927

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS SUSPECTED TO HAVE MALFUNCTIONED DUE TO PATIENT SYNCOPE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event897:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230811

event\_location:

remedial\_action:[""]

patient.patient\_age:84 YR



## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05071

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED FALSE PAUSE EPISODES DUE TO LOSS OF CONTACT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event898:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20230108

event\_location:

remedial\_action:[""]

patient.patient\_age:46 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05070

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED FALSE PAUSE EPISODES DUE TO VENTRICULAR UNDERSENSING. IT WAS FURTHER REPORTED THAT THE REMOTE

## DSI MAUDE Problems Summary

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MONITORING REPORT INTERROGATED BACK TO THE IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event899:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20211003

event\_location:

remedial\_action:[""]

patient.patient\_age:56 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02928

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AND OVERSENSING. THE ICM HAD REACHED END OF SERVICE (EOS). IT WAS FURTHER REPORTED THAT THE REPORT MONITORING REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT DESPITE A HISTORICAL COUNTER CLEARING DEVICE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE,

## DSI MAUDE Problems Summary

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MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event900:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230719

event\_location:

remedial\_action:[""]

patient.patient\_age:66 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02929

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY

## DSI MAUDE Problems Summary

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PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS ALSO REPORTED THAT THE ICM EXPERIENCED UNDERSENSING. THE REMOTE MONITORING REPORT ALTHOUGH LAST CLEARED WENT BACK TO THE DATE OF IMPLANT. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event901:

adverse\_event\_flag:N

product\_problems:["Protective Measures Problem"]

event\_type:Malfunction

date\_of\_event:20230727

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00595

mdr\_text.text:THIS RECORD HAS BEEN IDENTIFIED AS A DUPLICATE OF MANUFACTURER'S REPORT 1218950-2023-00390 AND WILL BE CLOSED. NO FURTHER ADDITIONAL INFORMATION PENDING. H3 OTHER TEXT: THE DEVICE WAS EVALUATED UNDER A DIFFERENT COMPLAINT RECORD.

THE MX40 WAS SENT IN FOR BENCH REPAIR FOR SPEAKER MALFUNCTION. THE REMOTE SERVICE ENGINEER CONFIRMED FROM BENCH REPAIR VIA EMAIL THAT THE UNIT IS UNDER REPAIR, AND UNDER EVALUATION. THE CUSTOMER WAS UPDATED WITH THIS INFORMATION. PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION WITH THE SYSTEM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event902:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Over-Sensing","Unable to Obtain Readings"]

event\_type:Malfunction

date\_of\_event:20230814

event\_location:

remedial\_action:[""]

patient.patient\_age:66 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05086

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS FURTHER REPORTED THAT THE PATIENT WAS UPGRADED TO A IMPLANTABLE PULSE GENERATOR (IPG).

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED HIGH FREQUENCY OVERSENSING WHICH CAUSED THE EPISODE TO TERMINATE BEFORE INTRINSIC SIGNALS CAME IN. THIS RESULTED IN THE DEVICE NOT ABLE TO DETERMINE THE TOTAL LENGTH OF THE EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS. HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. ANALYSIS OF THE DEVICE MEMORY INDICATED AN ISSUE WITH DIAGNOSTIC DATA COLLECTION. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event903:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20210606

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:69 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02934

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT.

IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED VENTRICULAR UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event904:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230811

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MP60

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00419

## DSI MAUDE Problems Summary

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mdr\_text.text:A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE TO EVALUATE THE DEVICE IN QUESTION. THE FSE CONFIRMED THERE WAS AN ALARM SOUND WHICH APPEARED IN THE SERVICE REPORT WITH AN ERROR. THE ISSUE WAS A FAULTY DISPLAY THAT DID NOT PRODUCE AN IMAGE. THE UNIT HAD A BAD DISPLAY. THE MONITOR WAS OBSOLETE AND OUT OF SUPPORT.

IT WAS REPORTED THAT THE CONSTANT CANNOT BE HEARD ON THE MONITOR. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF EVENT, THERE WAS NO PATIENT INVOLVEMENT.

IT WAS REPORTED THAT THE CONSTANT CANNOT BE HEARD ON THE MONITOR. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event905:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Reset Problem"]

event\_type:Malfunction

date\_of\_event:20230816

event\_location:

remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05024

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED UNDERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON

## DSI MAUDE Problems Summary

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INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED AN ELECTRICAL RESET AND UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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{{datachunk}}Event906:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20230807

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02908

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. ANALYSIS OF THE DEVICE REVEALED NORMAL BATTERY DEPLETION. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT.

## DSI MAUDE Problems Summary

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ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

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IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS EXPLANTED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS

## DSI MAUDE Problems Summary

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CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS UNABLE TO ESTABLISH TELEMETRY WITH THE REMOTE MONITOR. IT WAS FURTHER NOTED THAT THE BATTERY LIFE OF THE IMPLANT WAS DRAINED. TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event907:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20230802

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05039

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A PARTIAL POWER ON RESET OCCURRED. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY

THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED AN ELECTRICAL RESET. IT WAS FURTHER NOTED THAT QUESTIONS MARKS APPEARED IN THE COUNTERS AS A RESULT OF THE RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event908:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230727

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN



## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00593

mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE REPAIR FACILITY TECHNICIAN (RFT) PERFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. THE RFT REPLACED THE DEVICE SPEAKER - FOXLINK D SPEAKER - 453665031201. THE DEVICE PASSED ALL FUNCTIONAL TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAILED SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED THAT THE SYSTEM DISPLAYS AN ERROR MESSAGE "SPEAKER MALFUNCTION". PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

{{datachunk}}Event909:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-04982

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD REACHED END OF SERVICE (EOS).

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED AN ELECTRICAL RESET DURING ELECTROLYSIS. IT WAS FURTHER NOTED THAT THE PATIENT WAS NOT ENROLLED IN CARELINK. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event910:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20201217

event\_location:

remedial\_action:[""]

patient.patient\_age:80 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02884

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING AT IMPLANT. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event911:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20230629

event\_location:

remedial\_action:[""]

patient.patient\_age:74 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:Non Hispanic

patient.patient\_race:White

patient.patient\_problems:["Pain"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

## DSI MAUDE Problems Summary

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report\_number:9614453-2023-02885

mdr\_text.text:PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

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## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT EXPERIENCED PAIN. THE ICM WAS REMOVED. THE ICM HAD BEEN IMPLANTED ONE YEAR AND FIVE MONTHS. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event912:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise"]

event\_type:Malfunction

date\_of\_event:20230130

event\_location:

remedial\_action:[""]

patient.patient\_age:65 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-04995

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED NOISE ON TACHYCARDIA EPISODES. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT.

IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event913:

adverse\_event\_flag:N

product\_problems:["Failure to Interrogate"]

event\_type:Malfunction

date\_of\_event:20230802

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02886

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE

## DSI MAUDE Problems Summary

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EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS FURTHER NOTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD REACHED NORMAL BATTERY DEPLETION.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE REMOTE MONITOR WAS UNABLE TO ESTABLISH TELEMETRY WITH THE IMPLANTABLE CARDIAC MONITOR (ICM). TROUBLESHOOTING STEPS WERE TAKEN TO NO AVAIL. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.



## DSI MAUDE Problems Summary

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{{datachunk}}Event914:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20221214

event\_location:

remedial\_action:[""]

patient.patient\_age:73 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02887

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE

## DSI MAUDE Problems Summary

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BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON A PAUSE EPISODE ON THE DAY OF IMPLANT. IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT WHEN BACK TO THE DATE OF IMPLANT INSTEAD OF LAST INTERROGATION. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event915:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Battery Problem"]

event\_type:Malfunction

date\_of\_event:20200221

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05000

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. IT WAS FURTHER NOTED THAT THE DEVICE INTERROGATION BACK TO DATE OF IMPLANT INSTEAD OF MOST RECENT REPORT. THE ICM HAD REACHED RECOMMENDED REPLACEMENT TIME (RRT). THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event916:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20201106

event\_location:

remedial\_action:[""]

patient.patient\_age:76 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

## DSI MAUDE Problems Summary

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report\_number:9614453-2023-02883

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED UNDERSENSING ON PAUSE EPISODES. IT WAS FURTHER REPORTED THAT THE TRANSMISSION LAST CLEARED GOES BACK TO DATE OF IMPLANT AND OBSERVATIONS SHOW AN INVALID EPISODE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event917:

adverse\_event\_flag:N

product\_problems:["Under-Sensing","Battery Problem","Human-Device Interface Problem"]

event\_type:Malfunction

date\_of\_event:20220227

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-04988

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING. IT WAS FURTHER NOTED THAT THE ICM WAS IMPLANTED APPROXIMATELY SIX WEEKS BEYOND ITS USE BY DATE. IT WAS FURTHER REPORTED THAT THE DEVICE INTERROGATED BACK TO DATE OF IMPLANT INSTEAD OF MOST RECENT FULL REPORT OR PROGRAMMER INTERROGATION. THE REMOTE MONITORING REPORT CONTAINED INVALID HISTOGRAMS. THE ICM HAD REACHED END OF SERVICE (EOS). THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event918:

adverse\_event\_flag:N

product\_problems:["Signal Artifact/Noise","Over-Sensing","Under-Sensing"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20230707

event\_location:

remedial\_action:[""]

patient.patient\_age:59 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-05009

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED NOISE ON A TACHYCARDIA EPISODE. IT WAS FURTHER REPORTED THERE APPEARED TO BE SOME OVERSENSING AND UNDERSENSING AS WELL. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE

## DSI MAUDE Problems Summary

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APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event919:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20200223

event\_location:

remedial\_action:[""]

patient.patient\_age:32 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02896

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM

## DSI MAUDE Problems Summary

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BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DETECTED TACHYCARDIA EPISODES WHICH APPEARED TO BE OVERSENSING AND PAUSE EPISODES WHICH APPEARED TO BE UNDERSENSING. IT WAS FURTHER NOTED THAT THE REMOTE MONITOR REPORT GOES BACK TO THE DATE OF IMPLANT INSTEAD OF THE INTERROGATION. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event920:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230725

event\_location:



remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00585

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE TECHNICIAN PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. THE TECHNICIAN REPLACED THE DEVICE SPEAKER - FOXLINK D SPEAKER - (B)(4). THE DEVICE PASSED ALL FUNCTIONAL TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAILED SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event921:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20230726

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00587

mdr\_text.text:THE REMOTE SUPPORT ENGINEER (RSE) HAD CONVERSATIONS WITH CUSTOMER WHICH TOOK PLACE ON (B)(6) 2023.THE CUSTOMER EXPLAINED THAT HE WAS REPAIRING THE DEVICE DUE TO DAMAGE TO ITS BATTERY CASE AND MISTAKENLY DAMAGED THE SPEAKER, EXPLAINING FURTHER THAT THAT THE DEVICE NOW GIVES THE INOP MESSAGE WHEN POWERING THE DEVICE. CUSTOMER ASKED FOR PART INFORMATION TO REPLACE THE SPEAKER. THE RSE EXPLAINED TO CUSTOMER THAT THE REPAIR STRATEGY IS BENCH REPAIR OR FULL UNIT EXCHANGE ARE THE ONLY OPTIONS FROM PHILIPS. HOWEVER THE CUSTOMER WAS PROVIDED WITH THE REPLACEMENT PART NO# 453564262511 AND THE SERVICE GUIDE WITH AVAILABLE SPARE PART INFORMATION. CUSTOMER IS TAKING RESPONSIBILITY TO CORRECT/REPAIR THE DEVICE ON RESOLVING THE DAMAGED SPEAKER.THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS HOWEVER WE ARE UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE BECAUSE THE CUSTOMER IS TAKING RESPONSIBILITY TO RESOLVE THE REPORTED PROBLEM. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

PHILIPS RECEIVED A COMPLAINT FROM THE CUSTOMER THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE SPEAKER GOT DAMAGED WHILE REPAIRING DEVICE FOR A DAMAGED BATTERY CASE/NOW GIVES SPEAKER MALFUNCTION INOP MESSAGE. THE DEVICE WAS NOT IN USE.

{{datachunk}}Event922:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230725

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00586

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED.THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.

{{datachunk}}Event923:

adverse\_event\_flag:N

product\_problems:["Appropriate Term/Code Not Available"]

event\_type:Malfunction

date\_of\_event:20230724

event\_location:

remedial\_action:[""]

patient.patient\_age:75 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:9614453-2023-02862

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) STOPPED OPERATING AFTER FOUR MONTHS OF MONITORING. THE ICM WAS EXPLANTED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

CORRECTION: H6: IMF CODE MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND

## DSI MAUDE Problems Summary

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ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS RETURNED AND ANALYZED. THE CAPACITOR HAD A SHORTING/LOW RESISTANCE ISSUE. ANALYSIS OF THE HYBRID REVEALED THE NO-TELEMETRY CONDITION WAS CAUSED BY A DEPLETED BATTERY. A HIGH CURRENT DRAIN CONDITION WAS PRESENT ON THE HYBRID AND WAS ISOLATED TO THE VREF PICS CAPACITOR. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA

## DSI MAUDE Problems Summary

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3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event924:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm","Wireless Communication Problem"]

event\_type:Malfunction

date\_of\_event:20230721

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00581

mdr\_text.text:THE NATIONAL SUPPORT SPECIALIST (NSS) VISITED THE CUSTOMERS FACILITY TO INVESTIGATE THE ISSUE. THE NSS PERFORMED AN INSPECTION OF THE MEDICAL DEVICES AT THE FACILITY. VISUAL INSPECTION FOUND THAT MULTIPLE DEVICES HAD BROKEN BATTERY RETENTION TABS, CORROSION ON LEAD SETS, AND IMPROPER CLEANING DAMAGE. THE FOLLOWING FUNCTIONAL TESTS WERE PERFORMED: THE NSS CAPTURED LOGS FROM A TIME THE ISSUE OCCURRED. THE NSS ALSO STATES THAT HE WAS ABLE TO RECREATE THE ISSUE. THE NSS CONFIRMS THAT THE WHEN THE DEVICE

## DSI MAUDE Problems Summary

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IS CONNECTED TO THE NETWORK, THE APPROPRIATE ALARMS ARE SENT AND ACKNOWLEDGED. THE NSS ALSO CONFIRMS THAT THE CUSTOMER WAS NOTIFIED VIA ALARM WHEN THE DEVICES LOST CONNECTIVITY. THE NSS CONFIRMS THE DEVICE DAMAGE AS THE CAUSE OF THE ISSUE. GOOD FAITH EFFORT WAS PERFORMED TO OBTAIN ADDITIONAL DEVICE SERIAL AND PART NUMBERS HOWEVER, THIS INFORMATION WAS NOT MADE AVAILABLE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS DAMAGE TO THE MX40 DEVICE RESULTING IN INTERMITTENT ECG WAVEFORMS WHEN ALARMS OCCURRED. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER IS WORKING WITH PHILIPS SALES TEAM TO MAKE A BULK ORDER REPLACEMENT DEVICE PURCHASE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THE CUSTOMER REPORTED THAT THERE IS NO AUDIBLE ALARM ON THE SYSTEM. THE DEVICE WAS IN USE ON A PATIENT. THERE WAS NO REPORT OF PATIENT OR USER HARM.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event925:

adverse\_event\_flag:Y

product\_problems:["Adverse Event Without Identified Device or Use Problem"]

event\_type:Injury

date\_of\_event:20230728

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Appropriate Term / Code Not Available"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02864

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT POST IMPLANT OF THE IMPLANTABLE CARDIAC MONITOR (ICM), THE PATIENT EXPERIENCED BLEEDING AFTER INSERTION. THE PATIENT HAD TO RETURN TO THE CLINIC TO GET WOUND STITCHES. THE BLEEDING STOPPED WITHOUT COMPLICATIONS. THE ICM REMAINS IN USE. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event926:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20230730

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:



## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-04966

mdr\_text.text:IT WAS FURTHER REPORTED THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS EXPLANTED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS, HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED OVERSENSING. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY

¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED P WAVE OVERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event927:

adverse\_event\_flag:N

product\_problems:["Inappropriate or Unexpected Reset"]

event\_type:Malfunction

date\_of\_event:20230728

event\_location:

remedial\_action:[""]

patient.patient\_age:66 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-04967

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED A PARTIAL ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN

## DSI MAUDE Problems Summary

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REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event928:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N

product\_problems:["Material Integrity Problem"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:C6 MCOT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00045

mdr\_text.text:IT WAS REPORTED THAT THE DUAL CHARGING ADAPTER DISINTERGRATED WHEN PLUGGED INTO THE WALL OUTLET. THE DEVICE WAS NOT RETURNED FOR INVESTIGATION. ENGINEERING EVALUATION IS UNABLE TO BE PERFORMED AS THE DEVICE WAS NOT RETURNED FOR EVALUATION. THE ALLEGATION IS UNABLE TO BE CONFIRMED AS THE DEVICE WAS NOT RETURNED.

THE PATIENT REPORTED THAT THE DUEL USB CHARGING PLUG WAS DISINTERGRATING IN THE WALL OUTLET. IT BASICALLY CRUMBLES INTO PIECES. THE PATIENT WAS NOT INJURED. THE DEVICE WILL BE RETURNED AND A NEW CHARGER WAS SENT.

{{datachunk}}Event929:

adverse\_event\_flag:N

product\_problems:["Battery Problem"]

event\_type:Malfunction

date\_of\_event:20230726

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:72 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-04972

mdr\_text.text:CORRECTION: H6 PRODUCT EVENT SUMMARY: ANALYSIS OF THE RETURNED DEVICE INCLUDED REVIEW OF THE DATA RECORDED BY THE DEVICE WHILE IT WAS IN USE, AND VISUAL INSPECTION. THE DEVICE WAS TESTED FOR FUNCTIONAL PERFORMANCE: THE OPERATIONAL OUTPUT AT NOMINAL MANUFACTURING SETTINGS WAS COMPARED AGAINST A SET OF DEFINED ELECTRICAL SPECIFICATIONS, LONGEVITY CALCULATION WAS PERFORMED USING IMPLANT DURATION, DEVICE USE- THE DEVICE WAS RETURNED AND ANALYZED. RETURNED PRODUCT ANALYSIS WAS PERFORMED AND NO ANOMALIES WERE FOUND. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) WAS EXPLANTED DUE TO BATTERY DEPLETION. THE ICM IS NO LONGER IN USE. NO PATIENT COMPLICATIONS HAVE BEEN

REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event930:

adverse\_event\_flag:Y

product\_problems:["Biocompatibility"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:21 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Reaction to Medicinal Component of Device"]

device.brand\_name:MCOT C6

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00046

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT EXPERIENCED A BURNING "LIKE FIRE" REACTION AFTER REMOVING THE UNIVERSAL PATCH. MEDICAL ATTENTION WAS SOUGHT. THE DEVICE/UNIVERSAL PATCH WAS NOT RETURNED FOR INVESTIGATION. PICTURES WERE NOT PROVIDED; HOWEVER, THE PATIENT DID REQUIRE A WRITTEN PRESCRIPTION. THE CAUSE IS LIKELY DUE TO BIOCOMPATIBILITY ISSUE WITH THE UNIVERSAL PATCH ADHESIVE. MARSII, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

THE PATIENT REPORTED REDNESS OVER THE PAST COUPLE WEEKS WITH A "BURNING FIRE" FEELING AFTER CHANGING THE PATCH. THE PATIENT DROVE TO THE HOSPITAL AND WENT TO THE EMERGENCY ROOM (ER). THE ER DOCTOR SAID THE BURN ON THE PATIENT'S SKIN WAS NOT A BURN BUT A "DERMATOLOGY REACTION" DUE TO THE PATCH. THE PATCH WAS PEELING THE PATIENT'S SKIN OFF LAYER BY LAYER. THE ER DOCTOR PRESCRIBED A STEROID OINTMENT AND ANTIBIOTICS AND WAS ADVISED TO REMOVE THE DEVICE AND RETURN IT. THE PATIENT DOES NOT HAVE A HISTORY OF PRE-EXISTING SKIN SENSITIVITIES.

{{datachunk}}Event931:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230417

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00417

mdr\_text.text:IT WAS REPORTED THAT THE INTELLIVUE MULTI MEASUREMENT SERVER X2 INDICATING THAT THE LOUDSPEAKER UNIT NEEDED TO BE ORDERED. A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO CLARIFY THE CUSTOMER ALLEGATION AND TO DETERMINE IF THE SPEAKER PRODUCED ANY SOUND, BUT NO ADDITIONAL INFORMATION WAS PROVIDED. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

THE REMOTE SERVICE ENGINEER (RSE) DETERMINED THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE SPEAKER REQUIRED REPLACEMENT., AND THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. THE DEVICE REMAINS AT CUSTOMER SITE.

{{datachunk}}Event932:

adverse\_event\_flag:Y

product\_problems:["Biocompatibility"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Skin Tears","Blister","Skin Inflammation/Irritation"]

device.brand\_name:EPATCH V2 MB

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:BRAEMAR MANUFACTURING, LLC

report\_number:2133409-2023-00047



## DSI MAUDE Problems Summary

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mdr\_text.text:IT WAS REPORTED THAT THE PATIENT EXPERIENCED SKIN IRRITATION WHILE WEARING THE UNIVERSAL PATCH. THE PATCH DID NOT RETURN FOR INVESTIGATION. ENGINEERING EVALUATION WAS UNABLE TO BE PERFORMED AS THE ELECTRODE/DEVICE WAS NOT RETURNED. ALLEGATION IS CONFIRMED THROUGH IMAGES OF PATIENT SKIN IRRITATION AND IS MOST PROBABLE TO BE A BIO-INCOMPATIBILITY ISSUE WITH THE ELECTRODE ADHESIVE. MARSI, SKIN BURN, AND ASSOCIATED SYMPTOMS MAY INHERENTLY OCCUR UNDER THE COURSE OF ECG MONITORING. NO SINGLE FACTOR OR COMBINATION OF FACTORS CAN BE ATTRIBUTABLE TO ELECTRODE SKIN IRRITATION AND ASSOCIATED SYMPTOMS. THE PRODUCT LABELING ADVISES PATIENTS OF ALTERNATE OPTIONS AND OTHER STEPS TO TAKE IF SKIN IRRITATION DEVELOPS, INCLUDING HEALTHCARE PROFESSIONAL CONTACT AS NEEDED.

THE PATIENT REPORTED THAT AFTER WEARING THE SENSOR FOR 5 DAYS THE PATIENT REMOVED THE PATCH AND NOTED DAMAGED SKIN WITH RED SMALL DOTS. A NEW PATCH WAS PLACED AND AFTER 9 DAYS THE PATIENT REPORTED SHE COULD NOT MOVED THE PATCH. AFTER STRUGGLING THE PATCH WAS REMOVED AND BLOOD BLISTERS WERE NOTED. SECTIONS OF THE ADHESIVE WERE NOTED STILL ON THE PATIENT'S SKIN. THE PATIENT CALLED HER DOCTOR AND WAS PRESCRIBED TO USE AN ANTIBOTIC CREAM.

{{datachunk}}Event933:

adverse\_event\_flag:N

product\_problems:["Over-Sensing","Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230529

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

## DSI MAUDE Problems Summary

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report\_number:3008973940-2023-04921

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIMCED OVERSENSING AND UNDERSENSING. IT WAS FURTHER NOTED THAT THERE WAS A MISSING REPORT THAT FAILED TO GENERATE FROM THE REMOTE MONITOR. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event934:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20200904

event\_location:

remedial\_action:[""]

patient.patient\_age:84 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02837

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR

## DSI MAUDE Problems Summary

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SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED UNDERSENSING. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event935:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230809

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00576

mdr\_text.text:IT WAS IDENTIFIED DURING BENCH TESTING THAT THE MX40 1.4 GHZ SMART HOPPING DEVICE DID NOT PRODUCE SOUND. THE DEVICE WAS NOT IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. THERE WAS NO PATIENT INVOLVEMENT. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING

## DSI MAUDE Problems Summary

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INDICATED THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

IT WAS REPORTED THAT DURING EVALUATION OF THE MX40 MONITOR AT BENCH REPAIR, IT WAS IDENTIFIED THAT NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT IN USE MONITORING A PATIENT AT THE TIME OF THE REPORTED ISSUE. THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event936:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230511

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 1.4 GHZ, ECG AND SP02, EX

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00577

mdr\_text.text:DURING EVALUATION AT THE BENCH, IT WAS IDENTIFIED THAT THE DEVICE HAD NO SPEAKER SOUND AT START UP TEST. THERE WAS NO PATIENT INVOLVEMENT

## DSI MAUDE Problems Summary

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VISUAL INSPECTION FOUND THAT THE SPEAKER WIRES WERE TORN. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event937:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20220504

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02838

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN

## DSI MAUDE Problems Summary

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ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING ON TACHYCARDIA AND ATRIAL FIBRILLATION (AF) EPISODES. IT WAS FURTHER NOTED THAT THE EPISODES IN THE REMOTE MONITORING REPORT SHOWED DATES SINCE THE IMPLANT DATE AFTER IT WAS INTERROGATED. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event938:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20221207

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 2.4 GHZ, ECG ONLY, EXCHANGE

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00578

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO PATIENT INVOLVEMENT.

THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE TECHNICIAN PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. THE TECHNICIAN CONFIRMED THAT THE DEVICE HAD BEEN TAMPERED WITH. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE - US156K8038 TO RESOLVE THIS ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event939:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230803

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00579

mdr\_text.text:PHILIPS AUTHORIZED REPAIR FACILITY TECHNICIAN (RFT) PERFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAILED SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT.

{{datachunk}}Event940:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230720

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MP40

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00411

mdr\_text.text:THE REMOTE SERVICE ENGINEER (RSE) ADVISED THAT A QUOTE WAS PROVIDED TO THE CUSTOMER. WE ARE UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE, BECAUSE THE CUSTOMER DID NOT ACCEPT THE QUOTE FOR FURTHER SUPPORT. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED. H3 OTHER TEXT : SEE H10.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED AN ALARM SOUND PROBLEM. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event941:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230407

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX700 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00406

## DSI MAUDE Problems Summary

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mdr\_text.text:A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT FOR ONSITE SERVICE. IT REMAINS UNKNOWN IF THERE WAS STILL SOUND COMING FROM THE DEVICE. A SPEAKER MALFUNCTION INOPS WAS PRESENT. THE FSE REPLACED THE SPEAKER TO SOLVED THE ISSUE. E1: REPORTER INSTITUTION PHONE NUMBER: (B)(4). E1: REPORTER PHONE NUMBER: (B)(4).

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION FROM THE DEVICE. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event942:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20230624

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 2.4 GHZ, ECG ONLY, EXCHANGE

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00573

mdr\_text.text:PHILIPS REQUESTED ALL WAVE STRIPS, LOG FILES, PHYSIOLOGICAL DATA, ETC. ASSOCIATED WITH THIS ISSUE IN ORDER TO ESCALATE THIS ISSUE TO OUR PRODUCT SUPPORT ENGINEERS FOR A TECHNICAL INVESTIGATION. THE CUSTOMER STATES THAT THERE IS NO DATA AVAILABLE FROM THIS EVENT. DUE TO THE LACK OF DATA, WE ARE UNABLE TO PERFORM A TECHNICAL INVESTIGATION. BASED ON THE INFORMATION AVAILABLE WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. A CLINICAL ASSESSMENT WAS PERFORMED BASED ON THE INFORMATION CURRENTLY AVAILABLE IN THE COMPLAINT RECORD. IT WAS REPORTED THE DEVICE DID NOT GENERATE AN ALARM FOR "PACER SPIKES EMBEDDED INTO THE

## DSI MAUDE Problems Summary

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RHYTHM AT RANDOM AND INAPPROPRIATELY WITHOUT CAPTURING" FOR A PATIENT WITH A TEMPORARY PACEMAKER. THE ISSUE WAS REVIEWED WITH THE CLINICAL APPLICATION SPECIALIST, WHO CLARIFIED THE INTELLIVUE ALGORITHM WILL ALARM FOR PACER NOT CAPTURING OR PACER NOT PACING WHEN PACING MODE IS SWITCHED ON. BASED ON THIS INFORMATION, IT DOES NOT APPEAR AS IF THE DEVICE WOULD HAVE ALARMED FOR RANDOM PACING SPIKES AND IT CANNOT BE DETERMINED IF THIS AFFECTED THE PATIENT. THE CLINICAL EXPERT REQUESTED ADDITIONAL INFORMATION, HOWEVER GOOD FAITH EFFORT CONFIRMED THAT THIS INFORMATION AND DATA WAS NOT AVAILABLE. THE ENGINEER PROVIDED THEIR ANALYSIS FINDINGS HOWEVER WE ARE UNABLE TO CONFIRM THE FINAL DISPOSITION OF THE DEVICE BECAUSE THE CUSTOMER WAS UNABLE TO PROVIDE ADDITIONAL INFORMATION. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

THIS REPORT IS BASED ON INFORMATION PROVIDED BY HEALTH CANADA AND A QUALITY ASSURANCE REPRESENTATIVE FROM THE CUSTOMERS BIOMED TEAM, AND HAS BEEN INVESTIGATED BY THE PHILIPS COMPLAINT HANDLING TEAM. PHILIPS RECEIVED A COMPLAINT ON THE TELE MX40, 2.4 GHZ, ECG ONLY, EXCHANGE INDICATING THAT THE DEVICE WAS NOT PROPERLY ALARMING OR CAPTURING ECG WAVEFORM SPIKES FROM THE PATIENT'S PACEMAKER. THE CUSTOMER STATED THAT WHEN EXAMINING PREMATURE VENTRICULAR CONTRACTION (PVC) ALARMS THEY NOTED 6 PACER SPIKES EMBEDDED INTO THE CARDIAC RHYTHM RANDOMLY. THE CUSTOMER STATES THAT THE PHILIPS TELEMETRY MONITORS DID NOT RECOGNIZE THESE AS ISSUES AND THEREFORE DID NOT ALARM. THE CUSTOMER CONFIRMS THAT DEVICE SETTINGS WERE NOT CHANGED AND THE PROTECTIVE COVERING WAS STILL ON THE DEVICE. THERE WAS NO REPORT OF A DEATH OR SERIOUS INJURY, NOR WAS THERE A REPORT OF ANY ADVERSE IMPACT TO ANY USER OR PATIENT.

{{datachunk}}Event943:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20230715

event\_location:

remedial\_action:[""]

patient.patient\_age:56 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02798

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING. THE ICM REMAINS IN USE. THE MONITOR REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event944:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230808

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:53 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02800

mdr\_text.text:IT WAS REPORTED BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THAT THE IMPLANT HAD MOVED BELOW THE NIPPLE AREA. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

CORRECTION: UPDATED CODING IN H6. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY

INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event945:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230607

event\_location:

remedial\_action:[""]

patient.patient\_age:59 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02803

## DSI MAUDE Problems Summary

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mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON TACHYCARDIA EPISODES. THE ICM REMAINS IN USE. THE PATIENT IS A PARTICIPANT IN A STUDY. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event946:

adverse\_event\_flag:N

product\_problems:["Under-Sensing"]

event\_type:Malfunction

date\_of\_event:20230730

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:



## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02804

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING ON A TACHYCARDIA EPISODE. IT WAS FURTHER NOTED THAT THE REMOTE MONITORING REPORT SHOWED COUNTERS GOING BACK TO THE DATE OF IMPLANT. THE ICM REMAINS IN USE. THE PATIENT IS A PARTICIPANT IN A STUDY. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT

## DSI MAUDE Problems Summary

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DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event947:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230717

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX600 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00405

mdr\_text.text:THE CUSTOMER REPORTED THE DEVICE DISPLAYS A SPEAKER MALFUNCTION ERROR MESSAGE. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT, THERE WAS NO PATIENT INVOLVEMENT. PHILIPS PERFORMED REMOTE DIAGNOSTIC TESTING, THE DEVICE WAS REBOOTED WHICH DID NOT RESOLVE THE ISSUE. THE NEXT STEPS RECOMMENDED WERE ON-SITE REPAIR TO TROUBLESHOOT THE SPEAKER AND MOTHERBOARD.

## DSI MAUDE Problems Summary

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PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

A PHILIPS FIELD SERVICE ENGINEER (FSE) WENT ONSITE TO EVALUATE THE DEVICES IN QUESTION. THE FSE CONFIRMED THERE WAS INTERMITTENT SPEAKER WITH NO SOUND AND THERE WAS A SPEAKER INOPERATIVE MESSAGE PRESENT. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS CONFIRMED TO BE THE SPEAKER ASSEMBLY. AFTER SPEAKER REPLACEMENT THE DEVICE WAS RETURNED TO FUNCTIONAL USE WITH NO FURTHER ISSUES IDENTIFIED. THE DEVICE REMAINS AT THE CUSTOMER SITE. SECTION E REPORTER PHONE # (B)(6). SECTION E REPORTING INSTITUTION PHONE # (B)(6).

{{datachunk}}Event948:

adverse\_event\_flag:N

product\_problems:["Low Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230803

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00570

mdr\_text.text:DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD VERY LOW AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT OR HARM WAS REPORTED.

## DSI MAUDE Problems Summary

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THE REPORTED PROBLEM WAS CONFIRMED. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. THE RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND, BUT WAS VERY LOW. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE SPEAKER WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event949:

adverse\_event\_flag:Y

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230807

event\_location:

remedial\_action:[""]

patient.patient\_age:58 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Pain"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02781

mdr\_text.text:IT WAS REPORTED BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THAT THEY EXPERIENCED SHOOTING PAIN IN THE CHEST WHEN LYING ON THE LEFT SIDE. IT WAS FURTHER NOTED THAT THEY COULD FEEL IT RIGHT THROUGH THEIR SKIN. THE PATIENT FELT LIKE THE ICM HAD TURNED SIDEWAYS AND THE DEVICE CAN BE MOVED WITH THEIR FINGER. WHEN THE ICM WAS ORIGINALLY IMPLANTED THE PATIENT ALSO FELT IT WAS VERY PAINFUL. THE ICM REMAINS IN USE. NO FURTHER PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH

## DSI MAUDE Problems Summary

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THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event950:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230717

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2023-00561

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE ON TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event951:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230721

event\_location:

remedial\_action:[""]

patient.patient\_age:71 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02784

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED A PROBLEM WITH ITS SIGNAL. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

## DSI MAUDE Problems Summary

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MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event952:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230117

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00559

mdr\_text.text:THE PHILIPS AUTHORIZED REPAIR FACILITY TECHNICIAN (RFT) PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. THE RFT REPLACED THE DEVICE SPEAKER. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED THAT DURING THE EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

{{datachunk}}Event953:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System"]

event\_type:Death

date\_of\_event:20230711

event\_location:

remedial\_action:[""]

patient.patient\_age:78 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Bradycardia"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00567

mdr\_text.text:PHILIPS RECEIVED A COMPLAINT INDICATING THE PATIENT INFORMATION CENTER IX (PIICIX) DID NOT ALARM ON A BRADYCARDIA ALARM (EXTREME BRADY LIMIT WAS SET ON 35). THE DEVICE WAS IN CLINICAL USE DURING THE EVENT. THE PATIENT'S HEARTBEAT SLOWED DOWN SO MUCH THAT THE PATIENT EXPIRED. THE PIC IX DEVICE INVOLVED IN THIS EVENT IS REPORTED IN MFR



1218950-2023-00566.

THE LOG WAS REVIEWED BY THE CLINICAL APPLICATION SPECIALIST (CAS). THE LOG DATA SHOWS THAT A RED ASYSTOLE ALARM WAS GENERATED AT 10H37 AND THE ALARM WAS NOT ACKNOWLEDGED BY A CAREGIVER. BASED ON THIS INFORMATION AND AN AUDIT LOG REVIEW BY CLINICAL APPLICATION, THE DEVICE ALARMED PER CONFIGURATION. IT WAS NOTED A PREVIOUS ASYSTOLE ALARM HAD BEEN GENERATED BUT NEVER ACKNOWLEDGED BY THE USER. AS THE ASYSTOLE CONDITION IS HIGHER PRIORITY IN THE ALARM CHAIN, THERE WAS NO ALARM FOR EXTREME BRADY. THE ASYSTOLE ALARM WAS GENERATED FOR 1 HOUR AND 37 MINUTES. BASED ON THIS INFORMATION, THE DEVICE PERFORMED PER CONFIGURATION AND DID NOT CAUSE OR CONTRIBUTE TO THE REPORTED EVENT. THE REPORTED EVENT MAY POTENTIALLY BE RELATED TO CLINICAL WORKFLOW OR ALARM MANAGEMENT; HOWEVER, THE CAUSE REMAINS UNKNOWN.

{{datachunk}}Event954:

adverse\_event\_flag:N

product\_problems:["Insufficient Information"]

event\_type:Injury

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Unspecified Infection","Inflammation"]

device.brand\_name:DETECTOR AND ALARM, ARRHYTHMIA

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC

report\_number:MW5131203

mdr\_text.text:THIS DEVICE WAS IMPLANTED ON (B)(6) 2014. AND WAS EXPLANTED ON (B)(6) 2016. A PROCEDURE FORM RECEIVED, STATING THAT THE IMPLANT SITE LOOKED MILDLY INFLAMED WITH TENDERNESS TO PALPATION. IT WAS ALSO RECOMMENDED, THAT THE SITE SHOULD BE GIVEN

## DSI MAUDE Problems Summary

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CONCERN FOR INFECTION. AND A CULTURE SWAB WERE SENT. THE PHYSICIAN WAS DR. (B)(6) AT (B)(6) AT THE (B)(6). NO OTHER INFORMATION IS AVAILABLE. THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event955:

adverse\_event\_flag:N

product\_problems:["Insufficient Information"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:DETECTOR AND ALARM, ARRHYTHMIA

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC

report\_number:MW5135547

mdr\_text.text:IT WAS REPORTED THAT THE DEVICE WAS EXPLANTED DUE TO DISSATISFACTION WITH THE PRODUCT. NO ADDITIONAL ADVERSE PATIENT EFFECTS WERE REPORTED. THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event956:

adverse\_event\_flag:N

product\_problems:["Pacing Problem"]

event\_type:Malfunction

date\_of\_event:

## DSI MAUDE Problems Summary

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event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Failure of Implant"]

device.brand\_name:DETECTOR AND ALARM, ARRHYTHMIA

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC

report\_number:MW5135570

mdr\_text.text:THIS DEVICE WAS IMPLANTED ON (B)(6) 2011 AND EXPLANTED ON (B)(6) 2012 DUE TO EPISODES OF 3 SECOND PAUSES. THE PROCEDURE TOOK PLACE AT (B)(6) MEDICAL CENTER WITH DR. (B)(6). THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event957:

adverse\_event\_flag:N

product\_problems:["Product Quality Problem"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Failure of Implant"]

## DSI MAUDE Problems Summary

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device.brand\_name:DETECTOR AND ALARM, ARRHYTHMIA

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:ST. JUDE MEDICAL

report\_number:MW5139423

mdr\_text.text:IT WAS REPORTED THAT THE PRODUCT WAS EXPLANTED DUE TO DISSATISFACTION WITH THE PRODUCT. NO ADDITIONAL ADVERSE PATIENT EFFECTS WERE REPORTED. THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event958:

adverse\_event\_flag:N

product\_problems:["Product Quality Problem"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Failure of Implant"]

device.brand\_name:DETECTOR AND ALARM, ARRHYTHMIA

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:ABBOTT

report\_number:MW5140548

mdr\_text.text:IT WAS REPORTED THAT THE DEVICE WAS EXPLANTED DUE TO PATIENT DISSATISFIED WITH PRODUCT. NO ADDITIONAL ADVERSE PATIENT EFFECTS WERE REPORTED. THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event959:

## DSI MAUDE Problems Summary

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adverse\_event\_flag:N  
product\_problems:["Therapeutic or Diagnostic Output Failure"]  
event\_type:Malfunction  
date\_of\_event:  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:  
patient.patient\_sex:  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["Insufficient Information"]  
device.brand\_name:BODY GUARDIAN MINI PLUS WEARABLE CARDIAC MONITOR  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:BOSTON SCIENTIFIC CORPORATION  
report\_number:MW5141019  
mdr\_text.text:STRYKER MEDICAL WAS NOTIFIED OF A POTENTIALLY REPORTABLE COMPLAINT INVOLVING A PRODUCT FOR WHICH STRYKER IS NOT THE ORIGINAL EQUIPMENT MANUFACTURER OF THE REPORTED DEVICE. THE CUSTOMER ALLEGED A HILL-ROM AND BED, L24AM3690, HAD AN INACCURATE SCALE. (B)(4). THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event960:

adverse\_event\_flag:N  
product\_problems:["Insufficient Information"]  
event\_type:Injury  
date\_of\_event:  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:REVEAL

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC

report\_number:MW5142350

mdr\_text.text:THIS DEVICE WAS IMPLANTED ON (B)(6) 2012 AND WAS EXPLANTED ON (B)(6) 2014 DUE TO AN UNKNOWN REASON. THE PHYSICIAN WAS DR. (B)(6) AT (B)(6) MEDICAL CENTER IN (B)(6). NO OTHER INFORMATION IS AVAILABLE. THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event961:

adverse\_event\_flag:N

product\_problems:["Pacing Problem"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Failure of Implant"]

device.brand\_name:DETECTOR AND ALARM, ARRHYTHMIA

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC

## DSI MAUDE Problems Summary

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report\_number:MW5143233

mdr\_text.text:THIS DEVICE WAS IMPLANTED AN (B)(6) 2011 AND WAS EXPLANTED ON (B)(6) 2012. LOOP SHOWED EPISODES OF >3 SECONDS PAUSES. PATIENT WAS UPGRADED TO DUAL CHAMBER PACEMAKER. THE PHYSICIAN WAS DR. (B)(6) AT (B)(6) MEDICAL CENTER IN (B)(6) . THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event962:

adverse\_event\_flag:N

product\_problems:["Insufficient Information"]

event\_type:Malfunction

date\_of\_event:

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Insufficient Information"]

device.brand\_name:DETECTOR AND ALARM, ARRHYTHMIA

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC

report\_number:MW5143326

mdr\_text.text:IT WAS REPORTED THAT THE DEVICE WAS EXPLANTED DUE TO DISSATISFACTION WITH THE PRODUCT. NO ADDITIONAL ADVERSE PATIENT EFFECTS WERE REPORTED. THIS REPORT REFLECTS INFORMATION RECEIVED BY FDA IN THE FORM OF A NOTIFICATION PER 803.22 (B)(2).

{{datachunk}}Event963:

adverse\_event\_flag:N

product\_problems:["No Device Output"]

## DSI MAUDE Problems Summary

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event\_type:Malfunction

date\_of\_event:20230717

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00554

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND AND THE SPEAKER WAS DEFECTIVE: BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A DEFECTIVE SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PREVIOUSLY PROVIDED A REPLACEMENT DEVICE TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event964:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20221122

event\_location:

remedial\_action:[""]



## DSI MAUDE Problems Summary

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patient.patient\_age:53 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02771

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED OVERSENSING AND UNDERSENSING. IT WAS FURTHER NOTED THAT THE I INTERROGATION WENT BACK TO THE DATE OF IMPLANT IN THE REMOTE MONITORING REPORT. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event965:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Under-Sensing"]  
event\_type:Malfunction  
date\_of\_event:20201204  
event\_location:  
remedial\_action:[""]  
patient.patient\_age:84 YR  
patient.patient\_sex:Female  
patient.patient\_ethnicity:  
patient.patient\_race:  
patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]  
device.brand\_name:REVEAL LINQ  
device.device\_report\_product\_code:DSI  
device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL  
report\_number:9614453-2023-02778

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED UNDERSENSING RESULTING IN FALSE PAUSE DETECTIONS. IT WAS FURTHER NOTED THAT THE INTERROGATION WENT BACK TO THE DATE OF IMPLANT AND THERE WAS INVALID EPISODES IN THE REMOTE MONITORING REPORT. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION

## DSI MAUDE Problems Summary

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ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event966:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem","Wireless Communication Problem"]

event\_type:Malfunction

date\_of\_event:20230629

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Syncope/Fainting"]

device.brand\_name:ZIO AT

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:IRHYTHM TECHNOLOGIES, INC

report\_number:3007208829-2023-00039

mdr\_text.text:IT WAS REPORTED THAT THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. INVESTIGATION CONCLUDED THAT THE ARRHYTHMIA WAS NOT TRANSMITTED DURING THE WEAR PERIOD BECAUSE THE GATEWAY EXPERIENCED A HARDWARE MALFUNCTION AND WAS UNABLE TO COMMUNICATE WITH THE CELL MODULE. NO ADVERSE EVENTS SUCH AS DEATH OR SERIOUS INJURY ARE KNOWN TO HAVE OCCURRED, HOWEVER THE HEALTHCARE PROVIDER (HCP) STATED THAT THERE WAS A DELAY IN INSTALLING A PACEMAKER, AND THE PATIENT LATER EXPERIENCED A SYNCOPAL EPISODE.

IT WAS REPORTED THAT THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT MET MEDICAL DOCTOR NOTIFICATION (MDN) REQUIREMENTS THAT WAS NOT TRANSMITTED DURING THE WEAR PERIOD. NO

ADVERSE EVENTS SUCH AS DEATH OR SERIOUS INJURY ARE KNOWN TO HAVE OCCURRED, HOWEVER THE HCP STATED THAT THERE WAS A DELAY IN INSTALLING A PACEMAKER, AND THE PATIENT LATER EXPERIENCED A SYNCOPAL EPISODE. THE DEVICE WAS ACTIVATED AND THE NEXT DAY, THE GATEWAY EXPERIENCED A HARDWARE MALFUNCTION AND WAS UNABLE TO COMMUNICATE WITH THE CELL MODULE. ON THE SAME DAY, THE PATIENT EXPERIENCED AN ARRHYTHMIA THAT WAS NOT TRANSMITTED DUE TO THE GATEWAY MALFUNCTION. ONCE THE DEVICE WAS RETURNED, A FINAL REPORT WAS GENERATED ON DAY 15, AND THE HCP WAS NOTIFIED OF THE ARRHYTHMIA. ON DAY 18, THE PATIENT EXPERIENCED A SYNCOPAL EPISODE AND SOUGHT CARE AT A HOSPITAL. ON DAY 19, THE HCP STATED THAT THE PATIENT WAS SENT TO THE EMERGENCY DEPARTMENT FOR A PACEMAKER. THIS EVENT IS BEING REPORTED PER 21 CFR 803 AS A PRODUCT PROBLEM / MALFUNCTION. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY IRHYTHM THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY DEFECTS OR HAS MALFUNCTIONED . THESE TERMS ARE INCLUDED IN FORM FDA 3500A AND ARE FIXED TERMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING.

{{datachunk}}Event967:

adverse\_event\_flag:N

product\_problems:["Audible Prompt/Feedback Problem"]

event\_type:Malfunction

date\_of\_event:20221115

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00557

## DSI MAUDE Problems Summary

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mdr\_text.text:THE CUSTOMER REPORTED THAT DURING THE EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

THE PHILIPS AUTHORIZED REPAIR FACILITY TECHNICIAN (RFT) PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING TESTING. THE RFT REPLACED THE DEVICE SPEAKER. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event968:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20221213

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00558

mdr\_text.text:THE CUSTOMER REPORTED THAT DURING THE EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

THE PHILIPS AUTHORIZED REPAIR FACILITY TECHNICIAN (RFT) PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TO

## DSI MAUDE Problems Summary

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RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event969:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230803

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00541

mdr\_text.text:AFTER FURTHER INVESTIGATION THIS COMPLAINT IS DEEMED NO LONGER A REPORTABLE EVENT. IT WAS REPORTED THE DEVICE PRESENTED WITH THE FOLLOWING: REMOTE SUPPORT ENGINEER TALKED WITH CUSTOMER AND THE CUSTOMER CONFIRMED THE ISSUE WAS RESOLVED. THEY CONFIRMED THAT THERE WAS NO SPEAKER MALFUNCTION. THE PRODUCT LABELING, SHIPPED WITH THE DEVICE, STATES THAT THE MOST RELIABLE METHOD OF PATIENT MONITORING COMBINES CLOSE PERSONAL SURVEILLANCE WITH CORRECT OPERATION OF MONITORING EQUIPMENT. THE REPORTED PROBLEM OF AN INOP, FLASHING LED OR OTHER INDICATOR WOULD BE IMMEDIATELY DETECTABLE TO THE USER, AS IT WOULD BE ASSOCIATED WITH INOP MESSAGES, PERFORMANCE ISSUES, LOSS OF FUNCTIONALITY, AND/OR A GENERAL LOSS OF EFFECTIVE MONITORING. THEREFORE, THE USER WOULD IMPLEMENT ALTERNATIVE METHODS OF MONITORING AND/OR TO TROUBLESHOOT THE DEVICE, PER HOSPITAL PROTOCOL. THE RECORD WAS REVIEWED AND EVALUATED TO POSE NO HEALTH OR SAFETY RISK TO PATIENTS, USERS, OR BYSTANDERS. NO DEATH, SERIOUS INJURY OR ADVERSE EVENT WAS REPORTED TO HAVE OCCURRED OR WAS ALLEGED AS A RESULT OF THIS ISSUE, NOR IS THIS ISSUE LIKELY TO CAUSE OR CONTRIBUTE TO SUCH AN EVENT IF IT WERE TO RECUR.

## DSI MAUDE Problems Summary

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PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION FROM THE DEVICE. IT IS UNKNOWN IF THE DEVICE WAS NOT USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event970:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230731

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00546

mdr\_text.text:DIAGNOSTICS TESTING WAS PERFORMED AT PHILIPS BENCH REPAIR. AND FOUND THE DEVICE DID NOT PRODUCE SOUND, DUE TO A DEFECTIVE SPEAKER. THE BENCH REPAIR TECHNICIAN REPLACED THE SPEAKER. DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event971:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230731

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00547

mdr\_text.text:DIAGNOSTICS TESTING WAS PERFORMED AT PHILIPS BENCH REPAIR AND FOUND THE DEVICE DID NOT PRODUCE SOUND DUE TO A DEFECTIVE SPEAKER. THE BENCH REPAIR TECHNICIAN REPLACED THE SPEAKER DEVICE WAS RETURNED TO THE CUSTOMER.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event972:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]



event\_type:Malfunction

date\_of\_event:20230801

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00548

mdr\_text.text:DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DIAGNOSTICS TESTING WAS PERFORMED AT PHILIPS BENCH REPAIR AND FOUND THE DEVICE DID NOT PRODUCE SOUND DUE TO A DEFECTIVE SPEAKER. THE BENCH REPAIR TECHNICIAN REPLACED THE SPEAKER DEVICE WAS RETURNED TO THE CUSTOMER.

{{datachunk}}Event973:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230801

event\_location:

remedial\_action:[""]

## DSI MAUDE Problems Summary

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patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00549

mdr\_text.text:DIAGNOSTICS TESTING WAS PERFORMED AT PHILIPS BENCH REPAIR AND FOUND THE DEVICE DID NOT PRODUCE SOUND DUE TO A DEFECTIVE SPEAKER. THE BENCH REPAIR TECHNICIAN REPLACED THE SPEAKER DEVICE WAS RETURNED TO THE CUSTOMER.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event974:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230731

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

## DSI MAUDE Problems Summary

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patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00399

mdr\_text.text:REPORTING INSTITUTION PHONE NUMBER: (B)(6). REPORTER PHONE NUMBER: (B)(6). PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

THE CUSTOMER REPORTED THAT A "SPEAKER MALFUNCTION" INOP WAS DISPLAYED ON THE INTELLIVUE MULTI MEASUREMENT SERVER X2 AND NO SOUND WAS COMING FROM THE DEVICE. IT IS UNKNOWN WHETHER THE DEVICE WAS IN USE AT THE TIME OF THE REPORTED ISSUE. NO DEATH OR PATIENT / USER INJURY OR HARM WAS REPORTED.

A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED A ¿SPEAKER MALFUNCTION¿ INOP MESSAGE WAS DISPLAYED ON THE DEVICE, BUT THE DEVICE DID NOT PRODUCE SOUND. THE RSE DETERMINED THAT THE PART (453564238621,MS\_X2 ASSY CBL X2/MP2 SPEAKER ASSEMBLY) NEEDED TO BE REPLACED. THE CUSTOMER ORDERED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE.

{{datachunk}}Event975:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230802

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

## DSI MAUDE Problems Summary

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device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00550

mdr\_text.text:DIAGNOSTICS TESTING WAS PERFORMED AT PHILIPS BENCH REPAIR AND FOUND THE DEVICE DID NOT PRODUCE SOUND DUE TO A DEFECTIVE SPEAKER. THE BENCH REPAIR TECHNICIAN REPLACED THE SPEAKER DEVICE WAS RETURNED TO THE CUSTOMER.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

{{datachunk}}Event976:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230802

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00552

## DSI MAUDE Problems Summary

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mdr\_text.text:AFTER FURTHER BENCH REPAIR INVESTIGATION THIS COMPLAINT IS DEEMED NO LONGER A REPORTABLE EVENT. IT WAS REPORTED THE DEVICE PRESENTED WITH THE FOLLOWING: SPEAKER MALFUNCTION, CONFIRMED STILL SOUND COMING FROM THE MX40 IT WAS CONFIRMED THAT THE DEVICE WAS FUNCTIONING WITH AUDIBLE SOUND. THE ISSUE WOULD BE VISUALLY DETECTABLE BY THE USER AND WOULD NOT HAVE PATIENT SAFETY IMPACT SINCE THE DEVICE WAS PROVIDING AUDIO FOR REAL TIME MONITORING AND ALARM ANNUNCIATION. THE RECORD WAS REVIEWED AND EVALUATED TO POSE NO HEALTH OR SAFETY RISK TO PATIENTS, USERS, OR BYSTANDERS. NO DEATH, SERIOUS INJURY OR ADVERSE EVENT WAS REPORTED TO HAVE OCCURRED OR WAS ALLEGED AS A RESULT OF THIS ISSUE, NOR IS THIS ISSUE LIKELY TO CAUSE OR CONTRIBUTE TO SUCH AN EVENT IF IT WERE TO RECUR.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION NO SOUND WAS COMING FROM THE DEVICE. THE DEVICE WAS NOT USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

{{datachunk}}Event977:

adverse\_event\_flag:N

product\_problems:["No Device Output","No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230717

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

## DSI MAUDE Problems Summary

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report\_number:1218950-2023-00553

mdr\_text.text:THE CUSTOMER REPORTED THAT THERE WAS NO SOUND FROM THE SPEAKER AT ALL, EVEN DURING BOOT UP. A SPEAKER INOP MESSAGE APPEARED. THERE WAS NO PATIENT INVOLVEMENT.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED SOUND. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE REPORTED PROBLEM WAS NOT CONFIRMED. ALTHOUGH THE SPEAKER WAS CONFIRMED TO BE FUNCTIONING PER SPECIFICATION DURING TESTING IT WAS INDICATED THAT THE DEVICE IS DISPLAYING A SPEAKER MALFUNCTION INOP MESSAGE AND NO SOUND AT THE TIME OF THE EVENT, THE SPEAKER HAS BEEN REPLACED PER CURRENT PROCESS. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event978:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230726

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX800 PATIENT MONITOR

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

## DSI MAUDE Problems Summary

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report\_number:9610816-2023-00400

mdr\_text.text:THE REMOTE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND DETERMINED THAT THE LOUDSPEAKER REQUIRED REPLACEMENT. BASED ON THE INFORMATION AVAILABLE THE CAUSE OF THE REPORTED PROBLEM WAS THE SPEAKER. THE CUSTOMER WAS PROVIDED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. SECTION E REPORTING INSTITUTION PHONE # (B)(4).

PHILIPS RECEIVED A COMPLAINT ON THE INTELLIVUE MX800 PATIENT MONITOR INDICATING THAT THERE WAS A BLUE ALARM, LOUDSPEAKER PROBLEM. A GOOD FAITH EFFORT (GFE) WAS PERFORMED TO DETERMINE IF THE SPEAKER PRODUCED SOUND, BUT NO ADDITIONAL INFORMATION WAS PROVIDED. IT IS UNKNOWN IF THE DEVICE WAS IN CLINICAL USE AT THE TIME OF THE EVENT, NO ADVERSE EVENT OR PATIENT HARM WAS REPORTED.

{{datachunk}}Event979:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20221031

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00555

mdr\_text.text:THE CUSTOMER REPORTED THAT DURING AN EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

## DSI MAUDE Problems Summary

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THE PHILIPS AUTHORIZED REPAIR FACILITY TECHNICIAN (RFT) PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. THE RFT REPLACED THE DEVICE SPEAKER. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

{{datachunk}}Event980:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230720

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00556

mdr\_text.text:DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE SPEAKER HAD NO SOUND. FUNCTIONAL TESTING INDICATE THAT THE SPEAKER PRODUCED NO SOUND, AND CONFIRMED THE SPEAKER WAS DEFECTIVE. THE PHILIPS BENCH REPAIR TECHNICIAN (BRT) REPLACED THE SPEAKER TO SOLVE THE ISSUE. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

DURING EVALUATION AT PHILIPS BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN CLINICAL USE AT THE TIME THE ISSUE WAS DISCOVERED; NO ADVERSE EVENT



OR HARM WAS REPORTED.

{{datachunk}}Event981:

adverse\_event\_flag:N

product\_problems:["Device Difficult to Setup or Prepare","Device Difficult to Program or Calibrate"]

event\_type:Malfunction

date\_of\_event:20230801

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ MOBILE MANAGER APP

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC, INC.

report\_number:2182208-2023-02152

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) DID NOT HAVE DATA COLLECTION ENABLED FOLLOWING PROGRAMMING WITH THE DIAGNOSTIC MOBILE PROGRAMMER APPLICATION. IT WAS ALSO REPORTED THAT THERE WAS AN ISSUE WITH THE PATIENT ENROLLMENT ON THE REMOTE MONITORING NETWORK. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT.

## DSI MAUDE Problems Summary

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IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event982:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230713

event\_location:

## DSI MAUDE Problems Summary

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remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:TELE MX40, 1.4 GHZ, ECG AND SP02, EX

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00535

mdr\_text.text:PHILIPS INITIALLY RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING DEVICE INDICATING THAT A SPEAKER MALFUNCTION ERROR WAS DISPLAYED AND THE DEVICE WAS NOT PRODUCING AUDIO. THE DEVICE WAS NOT IN USE.

THE CUSTOMER SPOKE TO A PHILIPS REMOTE SERVICE ENGINEER (RSE) AND DECIDED TO SEND THE DEVICE TO PHILIPS BENCH FOR EVALUATION. THE REPAIR FACILITY TECHNICIAN PERFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS PRODUCING AUDIO. THE DEVICE PASSED ALL FUNCTIONAL TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED WE WERE UNABLE TO REPLICATE THE REPORTED PROBLEM. THE REPORTED PROBLEM WAS NOT CONFIRMED. THE RFT PROACTIVELY REPLACED THE DEVICE SPEAKER - FOXLINK D SPEAKER - 453665031201. THE DEVICE WAS RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event983:

adverse\_event\_flag:N

product\_problems:["No Audible Alarm"]

event\_type:Malfunction

date\_of\_event:20230727

event\_location:

remedial\_action:[""]

patient.patient\_age:

## DSI MAUDE Problems Summary

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patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00394

mdr\_text.text:A FOLLOW UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.  
E1: REPORTING INSTITUTION PHONE (B)(6). E1: REPORTER PHONE (B)(6).

THE CUSTOMER REPORTED A SPEAKER MALFUNCTION. NO SOUND WAS COMING FROM THE DEVICE.  
PATIENT INVOLVEMENT IS UNKNOWN. THERE WAS NO REPORT OF PATIENT OR USER HARM.

A PHILIPS RESPONSE SERVICE ENGINEER (RSE) SPOKE TO THE CUSTOMER AND CONFIRMED A ¿SPEAKER  
MALFUNCTION¿ INOP MESSAGE WAS DISPLAYED ON THE DEVICE, BUT THE DEVICE DID NOT PRODUCE  
SOUND. THE RSE DETERMINED THAT THE SPEAKER ASSEMBLY NEEDED TO BE REPLACED. THE  
CUSTOMER ORDERED A REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. BASED ON THE INFORMATION  
AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAULTY  
SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A  
REPLACEMENT SPEAKER TO RESOLVE THE ISSUE. H3 OTHER TEXT: DEVICE NOT RETURNED.

{{datachunk}}Event984:

adverse\_event\_flag:N

product\_problems:["Device Alarm System"]

event\_type:Malfunction

date\_of\_event:20230711

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

## DSI MAUDE Problems Summary

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patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00542

mdr\_text.text:IT WAS CONFORMED THAT THE CUSTOMER DID NOT REPORT ANY FAILURE OF A  
TELEMETRY DEVICE OR DEVICE MALFUNCTION. THE FIELD SERVICE PERSONNEL RESPONSE WAS THAT  
THE CUSTOMER HAD NOT INDICATED A FAILURE OR MALFUNCTION OF A MX40 DEVICE, NO  
ADDITIONAL INFORMATION WAS PROVIDED.

THE CUSTOMER REPORTED THAT THE MX40 ALARMED FOR A "PACER NOT PACING" EVENT INSTEAD OF  
AN ASYSTOLE ON (B)(6) 2023 AT 12:27 FOR THE NON-PACED PATIENT IN ROOM 2127/2 WEST WHEN  
THERE WAS A 9 SECOND PAUSE WITH ONLY P-WAVES NOTED AND NO QRS COMPLEXES ON THE ECG  
WAVEFORM. THE DEVICE WAS IN USE AT TIME OF EVENT, NO ADVERSE EVENT WAS REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event985:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20221027

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

## DSI MAUDE Problems Summary

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device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00543

mdr\_text.text:THE PHILIPS AUTHORIZED REPAIR FACILITY TECHNICIAN (RFT) PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING TESTING UTILIZING THE SPEAKER CERTIFICATION TOOL. THE RFT REPLACED THE DEVICE SPEAKER. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED DURING AN EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

{{datachunk}}Event986:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20221031

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00544

mdr\_text.text:THE PHILIPS AUTHORIZED REPAIR FACILITY TECHNICIAN (RFT) PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING

## DSI MAUDE Problems Summary

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AUDIO WHEN PERFORMING THE STARTUP TEST. THE RFT REPLACED THE DEVICE SPEAKER. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME.

THE CUSTOMER REPORTED THAT DURING THE EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THERE WAS NO REPORTED ADVERSE EVENT TO THE PATIENT OR USER.

{{datachunk}}Event987:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230713

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MULTI MEASUREMENT SERVER X2

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDIZIN SYSTEME BÖBLINGEN GMBH

report\_number:9610816-2023-00398

mdr\_text.text:A PHILIPS BENCH REPAIR TECHNICIAN (BRT) CONFIRMED THE UNIT WAS OUT OF SOUND AND THERE WAS A SPEAKER INOPERATIVE MESSAGE PRESENT. THE BRT REPLACED THE SPEAKER ASSEMBLY TO RESOLVE THE ISSUE. AFTER SPEAKER REPLACEMENT THE DEVICE WAS RETURNED TO FUNCTIONAL USE WITH NO FURTHER ISSUES IDENTIFIED. THE DEVICE REMAINS AT THE CUSTOMER SITE.

THE CUSTOMER REPORTED THAT THE DEVICE FELL AND THE LOUDSPEAKER DOES NOT WORK ANYMORE. THE DEVICE WAS IN USE MONITORING A PATIENT AT THE TIME OF THE EVENT. NO ADVERSE EVENT INVOLVING A PATIENT OR USER WAS REPORTED.

## DSI MAUDE Problems Summary

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THE CUSTOMER REPORTED THAT THE DEVICE FELL AND THE LOUDSPEAKER DOES NOT WORK ANYMORE. IT IS UNKNOWN IF THE DEVICE WAS IN USE AT TIME OF EVENT, AND THERE WAS NO ADVERSE EVENT REPORTED.

A FOLLOW UP REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

{{datachunk}}Event988:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230711

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00532

mdr\_text.text:THE REPAIR FACILITY TECHNICIAN PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. THE RFT REPLACED THE DEVICE SPEAKER - FOXLINK D SPEAKER - (B)(4). THE DEVICE PASSED ALL FUNCTIONAL TESTING. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAILED SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED AND RETURNED TO THE CUSTOMER. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.



## DSI MAUDE Problems Summary

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PHILIPS INITIALLY RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING DEVICE INDICATING THAT THE DEVICE WILL NOT POWER ON. THE DEVICE WAS SENT TO PHILIPS BENCH WHERE THE ISSUE OF THE SPEAKER NOT FUNCTIONING WAS DISCOVERED. THERE WAS NO REPORT OF A DEATH OR SERIOUS INJURY, NOR WAS THERE A REPORT OF ANY ADVERSE IMPACT TO ANY USER OR PATIENT. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event989:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System"]

event\_type:Death

date\_of\_event:20230426

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Cardiac Arrest","Insufficient Information"]

device.brand\_name:MX40 1.4 GHZ SMART HOPPING

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00534

mdr\_text.text:IT WAS REPORTED THAT THE CUSTOMER EXPECTED PRODUCT TO ALARM IN CASE OF EMERGENCY. PERCEIVED RESULT IS THAT NO ALARMS WERE NOTICED AT THE MOMENT OF THE INCIDENT. THE PATIENT EXPIRED. A PHILIPS TECHNICAL CONSULTANT (TC) WAS CALL ON SITE TO DO A TEST AND VERIFICATION TEST FOR THE DEVICE BEING "USED" AT THE MOMENT.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION CONCERNING THIS EVENT AND THE COMPLAINT IS STILL UNDER INVESTIGATION. A FINAL REPORT WILL BE SUBMITTED ONCE THE INVESTIGATION IS COMPLETE.

G3 DATE RECEIVED BY MANUFACTURER WAS CORRECTED. THE DATE IN THE INITIAL REPORT WAS INCORRECT. DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AND THE MX40 WAS FUNCTIONAL.

## DSI MAUDE Problems Summary

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THE MX40 LOGS PROVIDED DO NOT CAPTURE ALARM EVENTS. THE MX40 PWM LOG SHOWS A BATTERY CHANGE AT 12:55 PM ON (B)(6) 2023. IT APPEARS THE DEVICE RECONNECTED TO THE PIC IX AFTER THE BATTERY CHANGE BASED ON THE SUBSEQUENT STANDBY INVOCATION, WHICH WAS PERFORMED AT THE PIC IX. BASED ON THE AVAILABLE INFORMATION, IT IS LIKELY THE MX40 WAS POWERED ON AND CONNECTED TO THE PIC IX DURING THE TIMEFRAME AROUND 01:03 AM ON (B)(6) 2023. THE DEVICE WAS PUT INTO STANDBY MODE AT 02:25 AM ON (B)(6) 2023. STANDBY WAS INVOKED AT THE PIC IX (CENTRAL). ATTEMPTS WERE MADE TO CLARIFY THE DETAILS IF THE INCIDENT INCLUDING A CLEAR DESCRIPTION OF THE INCIDENT, DATE AND TIME OF THE EVENT, EXPECTED ALARMS AND CAUSE OF DEATH, BUT THE CUSTOMER RESPONSE WAS ASKED BUT UNKNOWN (ASKU). THE CUSTOMER DID STATE THAT THE MX40 TELEMETRY WAS FUNCTIONAL AFTER TESTING. CLARIFICATION AROUND THIS STATEMENT WAS ALSO REQUESTED TO DETERMINE IF THE DEVICES DID NOT CONTRIBUTE TO THE PATIENT DEATH, BUT THERE WAS NO RESPONSE FROM THE CUSTOMER. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM IS UNKNOWN. THE PIC IX DEVICE IN USE AT THE TIME OF THE EVENT IS REPORTED IN MFR REPORT NUMBER 1218950-2023-00360. THE INTELLIVUE MX400 PATIENT MONITOR DEVICE USED DURING THIS EVENT IS REPORTED IN MFR REPORT NUMBER 9610816-2023-00517.

THE CUSTOMER REPORTED ON (B)(6) 2023, AT APPROXIMATELY 01:03 THE MONITOR FAILED TO ALARM FOR CARDIAC ARREST. THE PATIENT WAS NOT REVIVED AND EXPIRED.

{{datachunk}}Event990:

adverse\_event\_flag:Y

product\_problems:["Device Alarm System"]

event\_type:Death

date\_of\_event:20230712

event\_location:

remedial\_action:[""]

patient.patient\_age:61 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

## DSI MAUDE Problems Summary

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device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00536

mdr\_text.text:THE CUSTOMER REPORTED THAT THE DEVICE FAILED TO ALARM WHEN THE PATIENT WENT INTO CARDIAC ARREST.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION

THE PHILIPS SERVICE TEAM COLLECTED DATA ASSOCIATED WITH THIS ISSUE FOR INVESTIGATION AND VISITED THE MEDICAL FACILITY. THE FIELD SERVICE ENGINEER (FSE) PERFORMED A FULL SITE SURVEY AND CONFIRMED THAT THE AREA, DESCRIBED AS A CANTEEN AREA, WHERE THE PATIENT COLLAPSED WAS NOT SETUP FOR PHILIPS TELEMETRY. THE FSE CONFIRMS THAT THE ACCESS POINT IN THIS AREA DID NOT HAVE PHILIPS SSID ON OR ALLOW ACCESS TO PHILIPS NETWORK. THE FSE PROACTIVELY REPLACED THE CENTRAL STATION AND UPGRADED THE SOFTWARE OF ALL MX40 DEVICES ONSITE. THE FSE ALSO ADDRESSED SOME ADDITIONAL WIRELESS SETUP AND CONFIGURATION ISSUES FOR THE CUSTOMER. THE WIRELESS ISSUES ARE NOT RELATED TO ANY MALFUNCTION OF A PHILIPS PRODUCT AND WERE ESCALATED TO THE MANUFACTURER OF THE WIRELESS ACCESS POINTS, CISCO, FOR FURTHER EVALUATION. THE COMPLAINT WAS ESCALATED FOR TECHNICAL INVESTIGATION TO A PHILIPS PRODUCT SUPPORT ENGINEER (PSE) AND THE RESULTS INDICATE THE FOLLOWING: THE PIC IX CLINICAL AUDIT LOGS AND STARDATE LOGS (RFDA AND DEVICEDEBUG) WERE PROVIDED. THE FOLLOWING IS WHAT WAS FOUND IN THE LOGS FOR THE INCIDENT ON (B)(6)2023 AT 11:00 TO 12:00: THE LOGS SHOW THE FOLLOWING: 1. A BATTERY CHANGE AT 10:18 ON (B)(6)2023 FOLLOWED BY CONNECTION TO THE NETWORK/PIC. 2. THE MX40 PWM WAS PUT INTO STANDBY AT 10:50 ON (B)(6)2023. NOTE THAT WHILE THE DEVICE IS IN STANDBY, NO MONITORING IS BEING PERFORMED AND THERE IS NO COMMUNICATION TO THE NETWORK/PIC. 3. THE MX40 PWM WAS TAKEN OUT OF STANDBY AT 10:57 ON (B)(6)2023. 4. SEVEN LOSSES OF COMMUNICATION BETWEEN THE MX40 PWM AND NETWORK/PIC FOLLOWED BY RE-ESTABLISHMENT OF COMMUNICATION. THESE LOSSES OF COMMUNICATION WERE NOT RELATED TO DEVICE BATTERY CHANGES. 5. WHILE THE MX40 PWM WAS COMMUNICATING WITH THE NETWORK/PIC, MEASUREMENT DATA WAS BEING ANALYZED BY THE MX40 AND YELLOW AND RED ALARMS WERE BEING PROVIDED FOR \* PAUSE, HR LIMIT VIOLATIONS, PAIR PVCS, \*MISSED BEAT, NON-SUSTAINING VT, VTACH, XTACHY, VENT FIB/TACH, AND ASYSTOLE CONDITIONS. THE PERIODS WHEREIN COMMUNICATION BETWEEN THE MX40 PWM AND NETWORK/PIC OCCURRED INDICATE POSSIBLE NETWORK COVERAGE ISSUES. THE REPORTED PROBLEM WAS NOT CONFIRMED AS A DEVICE MALFUNCTION AS THE ISSUE WAS THE RESULT OF THE PATIENT PROCEEDING TO AN AREA THAT WAS NOT CONFIGURED FOR COVERAGE OF THE PHILIPS TELEMETRY DEVICE. THE DEVICE WAS CONFIRMED TO BE OPERATING PER SPECIFICATIONS AND NO FAILURE WAS IDENTIFIED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

{{datachunk}}Event991:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230722

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00525

mdr\_text.text:PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. E1:(B)(6).

THE CUSTOMER REPORTED A FAILURE TO ALARM ON 22 JULY FROM THE DEVICE.THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

A PHILIPS RESPONSE SERVICE ENGINEER (RSE) PERFORMED TROUBLESHOOT AND FOUND NO ISSUES WITH THE MX40. DIAGNOSIS HAS SHOWN THAT DURING MONITORING ON TELE 2, THE PATIENT WAS STOLEN FROM NB25-4 WITH X3 X070 AND PATIENT CONFLICTS WERE RESOLVED AND MOVED TO TELE 2 AGAIN. (PATIENT REMOVAL, DISCHARGE AND ADMITTED AGAIN ON TELE 2) IT WAS CONFIRMED THE DEVICES HAD NO MALFUNCTION - USER ISSUE. THIS WAS A WORKFLOW FAILURE BETWEEN TWO DEPARTMENTS. THE SYSTEM WORKS PERFECTLY. THE CUSTOMERS DEPARTMENT HEADS WERE INFORMED ACCORDINGLY. H3 OTHER TEXT: PHILIPS REMOTE SUPPORT ONLY.

{{datachunk}}Event992:

adverse\_event\_flag:N

## DSI MAUDE Problems Summary

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product\_problems:["Under-Sensing"]

event\_type:Injury

date\_of\_event:20230725

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

report\_number:3008973940-2023-04651

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

## DSI MAUDE Problems Summary

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IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED UNDERSENSING DUE TO LOSS OF CONTACT. THE ICM WAS REPOSITIONED AND REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event993:

adverse\_event\_flag:N

product\_problems:["Defective Alarm"]

event\_type:Malfunction

date\_of\_event:20230724

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00526

mdr\_text.text:THE CUSTOMER REPORTED A FAILURE TO ALARM ON 21 JULY FROM THE DEVICE. THE DEVICE WAS IN USE AT TIME OF EVENT, THERE WAS NO ADVERSE EVENT REPORTED.

PHILIPS IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION REGARDING THE REPORTED EVENT AND THE INVESTIGATION IS ONGOING. A FOLLOW-UP REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION. E1: REPORTER INSTITUTION PHONE NUMBER: (B)(6). E1: REPORTER PHONE NUMBER: (B)(6).

A PHILIPS RESPONSE SERVICE ENGINEER (RSE) PERFORMED TROUBLESHOOT AND FOUND NO ISSUES WITH THE MX40. DIAGNOSIS HAS SHOWN THAT DURING MONITORING ON TELE 2, THE PATIENT WAS STOLEN FROM NB25-4 WITH X3 X070 AND PATIENT CONFLICTS WERE RESOLVED AND MOVED TO TELE 2 AGAIN. (PATIENT REMOVAL, DISCHARGE AND ADMITTED AGAIN ON TELE 2) IT WAS CONFIRMED THE DEVICES HAD NO MALFUNCTION - USER ISSUE. THIS WAS A WORKFLOW FAILURE BETWEEN TWO

## DSI MAUDE Problems Summary

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DEPARTMENTS. THE SYSTEM WORKS PERFECTLY. THE CUSTOMERS DEPARTMENT HEADS WERE INFORMED ACCORDINGLY.

{{datachunk}}Event994:

adverse\_event\_flag:N

product\_problems:["Communication or Transmission Problem"]

event\_type:Malfunction

date\_of\_event:20230726

event\_location:

remedial\_action:[""]

patient.patient\_age:69 YR

patient.patient\_sex:Female

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02683

mdr\_text.text:IT WAS REPORTED THAT THE REMOTE MONITOR READER WAS NOT FINDING THE IMPLANT. THE IMPLANTABLE CARDIAC MONITOR (ICM) HAD NO TELEMTRY AND HAD REACHED RECOMMENDED REPLACEMENT TIME (RRT). NO TROUBLESHOOTING INDICATED. THE MONITOR REMAINS IN USE. THE ICM REMAINS IN THE PATIENT. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE,

MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event995:

adverse\_event\_flag:N

product\_problems:["Migration or Expulsion of Device"]

event\_type:Malfunction

date\_of\_event:20230727

event\_location:

remedial\_action:[""]

patient.patient\_age:70 YR

patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02684

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT



## DSI MAUDE Problems Summary

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INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED BY THE IMPLANTABLE CARDIAC MONITOR (ICM) PATIENT THAT THE DEVICE HAD MIGRATED TO THE RIGHT ABOUT TWO INCHES FROM THE ORIGINAL IMPLANT SITE. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

{{datachunk}}Event996:

adverse\_event\_flag:N

product\_problems:["Reset Problem"]

event\_type:Malfunction

date\_of\_event:20230724

event\_location:

remedial\_action:[""]

patient.patient\_age:84 YR

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC SINGAPORE OPERATIONS

## DSI MAUDE Problems Summary

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report\_number:3008973940-2023-04665

mdr\_text.text:IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXHIBITED AN ELECTRICAL RESET. THE ICM REMAINS IN USE. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

PRODUCT EVENT SUMMARY: THE DEVICE WAS NOT RETURNED FOR ANALYSIS. HOWEVER, PERFORMANCE DATA COLLECTED FROM THE DEVICE WAS RECEIVED AND ANALYZED. ANALYSIS OF THE DEVICE MEMORY INDICATED A FULL POWER ON RESET OCCURRED. ANALYSIS OF THE DEVICE MEMORY INDICATED NORMAL BATTERY DEPLETION. MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event997:

adverse\_event\_flag:N

product\_problems:["Over-Sensing"]

event\_type:Malfunction

date\_of\_event:20230725

event\_location:

remedial\_action:[""]

patient.patient\_age:57 YR

## DSI MAUDE Problems Summary

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patient.patient\_sex:Male

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:REVEAL LINQ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:MEDTRONIC EUROPE SARL

report\_number:9614453-2023-02686

mdr\_text.text:MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

IT WAS REPORTED THAT THE IMPLANTABLE CARDIAC MONITOR (ICM) EXPERIENCED T-WAVE OVERSENSING (TWOS). IT WAS FURTHER REPORTED THAT THE REMOTE MONITORING REPORT WHEN BACK TO THE BACK OF IMPLANT INSTEAD OF LAST INTERROGATION. THE ICM REMAINS IN USE. THE PATIENT WAS PARTICIPATING IN A CLINICAL STUDY. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT.

MEDTRONIC IS SUBMITTING THIS REPORT TO COMPLY WITH FDA REPORTING REGULATIONS UNDER 21 CFR PARTS 4 AND 803. THIS REPORT IS BASED UPON INFORMATION OBTAINED BY MEDTRONIC, WHICH THE COMPANY MAY NOT HAVE BEEN ABLE TO FULLY INVESTIGATE OR VERIFY PRIOR TO THE DATE THE REPORT WAS REQUIRED BY THE FDA. MEDTRONIC HAS MADE REASONABLE EFFORTS TO OBTAIN MORE

COMPLETE INFORMATION AND HAS PROVIDED AS MUCH RELEVANT INFORMATION AS IS AVAILABLE TO THE COMPANY AS OF THE SUBMISSION DATE OF THIS REPORT. THIS REPORT DOES NOT CONSTITUTE AN ADMISSION OR A CONCLUSION BY FDA, MEDTRONIC, OR ITS EMPLOYEES THAT THE DEVICE, MEDTRONIC, OR ITS EMPLOYEE CAUSED OR CONTRIBUTED TO THE EVENT DESCRIBED IN THE REPORT. IN PARTICULAR, THIS REPORT DOES NOT CONSTITUTE AN ADMISSION BY ANYONE THAT THE PRODUCT DESCRIBED IN THIS REPORT HAS ANY ¿DEFECTS¿ OR HAS ¿MALFUNCTIONED¿. THESE WORDS ARE INCLUDED IN THE FDA 3500A FORM AND ARE FIXED ITEMS FOR SELECTION CREATED BY THE FDA TO CATEGORIZE THE TYPE OF EVENT SOLELY FOR THE PURPOSE OF REGULATORY REPORTING. MEDTRONIC OBJECTS TO THE USE OF THESE WORDS AND OTHERS LIKE THEM BECAUSE OF THE LACK OF DEFINITION AND THE CONNOTATIONS IMPLIED BY THESE TERMS. THIS STATEMENT SHOULD BE INCLUDED WITH ANY INFORMATION OR REPORT DISCLOSED TO THE PUBLIC UNDER THE FREEDOM OF INFORMATION ACT. ANY REQUIRED FIELDS THAT ARE UNPOPULATED ARE BLANK BECAUSE THE INFORMATION IS CURRENTLY UNKNOWN OR UNAVAILABLE. A GOOD FAITH EFFORT WILL BE MADE TO OBTAIN THE APPLICABLE INFORMATION RELEVANT TO THE REPORT. IF INFORMATION IS PROVIDED IN THE FUTURE, A SUPPLEMENTAL REPORT WILL BE ISSUED.

{{datachunk}}Event998:

adverse\_event\_flag:N

product\_problems:["No Audible Prompt/Feedback"]

event\_type:Malfunction

date\_of\_event:20230710

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["No Clinical Signs, Symptoms or Conditions"]

device.brand\_name:INTELLIVUE MX40 2.4GHZ

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00528

## DSI MAUDE Problems Summary

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mdr\_text.text:THE DEVICE WAS SENT TO PHILIPS BENCH FOR EVALUATION. THE RFT PREFORMED DIAGNOSTIC TESTING ON THE DEVICE SPEAKER AND FOUND THAT THE DEVICE SPEAKER WAS NOT PRODUCING AUDIO WHEN PERFORMING THE STARTUP TEST. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS A FAILED SPEAKER. THE REPORTED PROBLEM WAS CONFIRMED. THE CUSTOMER WAS PROVIDED A REPLACEMENT DEVICE TELE MX40, 2.4 GHZ, ECG ONLY, EXCHANGE PART NUMBER - 453564262531, SERIAL NUMBER - (B)(6) TO RESOLVE THE ISSUE. IT HAS BEEN CONCLUDED THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

DURING EVALUATION AT BENCH REPAIR, IT WAS IDENTIFIED THAT THE DEVICE HAD NO AUDIO. THE DEVICE WAS NOT IN USE ON A PATIENT AT THE TIME OF THE EVENT.

{{datachunk}}Event999:

adverse\_event\_flag:Y

product\_problems:["Defective Alarm"]

event\_type:Death

date\_of\_event:20230704

event\_location:

remedial\_action:[""]

patient.patient\_age:

patient.patient\_sex:

patient.patient\_ethnicity:

patient.patient\_race:

patient.patient\_problems:["Ventricular Fibrillation"]

device.brand\_name:INTELLIVUE MX40 WLAN

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00530

mdr\_text.text:NEW INFORMATION RECEIVED INDICATING THAT THE EVENT INVOLVED A PATIENT DEATH. PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

## DSI MAUDE Problems Summary

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THE CUSTOMER REPORTED THAT CENTRAL UNIT DID NOT ALARM WHEN A PATIENT WENT INTO VF ARREST.

PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

A TECHNICAL INVESTIGATION WAS PERFORMED BY PHILIPS PRODUCT SUPPORT ENGINEERING. IT WAS STATED THAT LOOKING AT THE CLINICAL AUDIT LOGS WE CAN CONFIRM THE VENT FIB ALARM WAS GENERATED AROUND THE TIME MENTIONED. ADDITIONALLY, AFTER REVIEW OF THE PROVIDED PICTURES, CORROSION AT THE CENTERS OF THE BATTERY CONTACTS CAN RESULT IN INCREASED RESISTANCE/IMPACT TO CONNECTION BETWEEN THE DEVICE AND BATTERY. IT WAS ALSO NOTED THAT SOME OF THE BATTERIES BEING USED ARE OVER 4 YEARS OLD. THE PRODUCT IFU STATES THAT THE BATTERY WILL LAST FOR 4 YEARS OR 500 COMPLETE CHARGE/DISCHARGE CYCLES, AS THE BATTERY AGES, CAPACITY CAN DECREASE BY 25 & 30%. IF THIS IS NOT ACCEPTABLE, THE BATTERY SHOULD BE REPLACED AFTER TWO YEARS. EFFORTS WERE MADE TO HAVE THE FAULTY BATTERIES SENT FOR FURTHER EVALUATION BUT WAS NOT SUCCESSFUL. A GFE (GOOD FAITH EFFORT) CONFIRMED THAT THE FAULTY STANDALONE LITHIUM BATTERIES COULD NOT BE SHIPPED EITHER BY AIR OR SEA FREIGHT ACROSS BY ALL CARRIERS CONTACTED. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE CAUSE OF THE REPORTED PROBLEM WAS CORROSION AT THE CENTERS OF THE BATTERY CONTACTS DUE TO OLD BATTERIES ABOVE THE RECOMMENDED USAGE TIME. THE REPORTED PROBLEM WAS CONFIRMED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

```
{{datachunk}}Event1000:
adverse_event_flag:Y
product_problems:["Contamination","Insufficient Information"]
event_type:Death
date_of_event:20230710
event_location:
remedial_action:[""]
patient.patient_age:
patient.patient_sex:
patient.patient_ethnicity:
patient.patient_race:
patient.patient_problems:["Insufficient Information"]
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## DSI MAUDE Problems Summary

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device.brand\_name:TELE MX40, 1.4 GHZ, ECG AND SP02, EX

device.device\_report\_product\_code:DSI

device.manufacturer\_d\_name:PHILIPS MEDICAL SYSTEMS

report\_number:1218950-2023-00531

mdr\_text.text:PHILIPS IS IN PROCESS OF OBTAINING ADDITIONAL INFORMATION. A FINAL REPORT WILL BE SUBMITTED UPON COMPLETION OF THE INVESTIGATION.

THE CUSTOMER REPORTED A DEATH ASSOCIATED WITH THE DEVICE'S USE.

PHILIPS RECEIVED A COMPLAINT ON THE MX40 1.4 GHZ SMART HOPPING INDICATING THAT THE DEVICE HAD PINS CORROSION. ADDITIONAL INFORMATION RECEIVED INDICATES THAT THERE WAS NO PATIENT DEATH.

DIAGNOSTIC/FUNCTIONAL TESTING WAS PERFORMED AT THE PHILIPS AUTHORIZED REPAIR FACILITY. RESULTS OF FUNCTIONAL TESTING INDICATE THAT THE DEVICE HAD CORROSION ON PIN 4,8,10,17-19. BASED ON THE INFORMATION AVAILABLE AND THE TESTING CONDUCTED, THE REPORTED PROBLEM WAS CONFIRMED. THE REAR HOUSING SUB ASSEMBLY WAS REPLACED. THE DEVICE WAS OPERATIONAL AFTER REPAIRS WERE COMPLETED. THE INVESTIGATION CONCLUDES THAT NO FURTHER ACTION IS REQUIRED AT THIS TIME. IF ADDITIONAL INFORMATION IS RECEIVED THE COMPLAINT FILE WILL BE REOPENED.

## Configuration Data

https\_url1: api.fda.gov/device/event.json?

limit1: 1000

KEYWORD1-SEARCH:

SORT1-FIELD: date\_received

SORT1-TERM: desc

COUNT1-FIELD:

COUNT1-TERM:

data1\_fields: adverse\_event\_flag, product\_problems, event\_type, date\_of\_event, event\_location, remedial\_action, patient.patient\_age, patient.patient\_sex, patient.patient\_ethnicity, patient.patient\_race, patient.patient\_problems, device.brand\_name, device.device\_report\_product\_code, device.manufacturer\_d\_name, report\_number, mdr\_text.text

report\_title: DSI MAUDE Problems Summary

AI-WordsPerReport: 10000

AI-ModelMaxOutputTokens: 8192

AI-ModelTemperature: 0.05

AI-ModelTopP: 1

AI-ModelTopK: 2

AI-ProblemSummaryPrompt: Describe the following product problem concisely

AI-ReportSummaryPrompt: Aggregate and summarize all information; listing common items along with the count for each item. Include all important details and reference information.

AI-AnalysisPrompt: Analyze the adverse event reports dataset to uncover hidden insights and data patterns. Explore factors such as Common product problems; malfunctions; root causes; trends in adverse event occurrence; patterns in reported device issues; frequencies of remedial actions taken; correlations between reported problems and device attributes. Include a bullet list for each unique item along with the item count. Focus on utilizing available data fields to reveal meaningful insights.

SEARCH1-FIELDS:

{ date\_received: [20200101+TO+20240529], device.device\_report\_product\_code: DSI}