



URGENT MEDICAL DEVICE CORRECTION

FOR A SUBSET OF GALLANT™, NEUTRINO™,
AND ENTRANT™ ICDs AND CRT-Ds
MANUFACTURED PRIOR TO APRIL 2022

MODELS CDVRA500Q, CDDRA500Q, CDHFA500Q, CDVRA600Q,
CDDRA600Q, CDHFA600Q, CDVRA300Q, CDDRA300Q, AND CDHFA300Q

August 2023

Dear Physician or Healthcare Professional:

Summary:

Abbott is informing customers of a rare potential for a Bluetooth (BLE) circuit component issue on a subset of Gallant™, Neutrino™, and Entrant™ Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) manufactured prior to April 2022. This issue has been associated with a risk of loss of Bluetooth communication (and therefore a loss of remote monitoring), higher-than-normal current consumption, and reduced device longevity.

There have been no reports of serious harm to patients due to this issue.

If a device experiences this issue, primary device functions, including pacing, sensing, shock delivery, and inductive telemetry, remain available during the period of remaining battery life. The device audible ERI (Elective Replacement Indicator) alert remains active in devices affected by this issue.

Among 67,000 devices distributed globally, 16 implanted devices are known to have lost Bluetooth communication due to this issue. Of these, 9 (0.013%) have experienced higher-than-normal current consumption and reduced device longevity. Approximately 78% of all devices distributed globally already have been risk mitigated through routine programmer interrogation, which deploys a firmware upgrade.

A sub-group of approximately 1,500 devices are more likely to manifest this issue as compared to the remaining 65,500 devices. The estimated risk of potential loss of therapy leading to harm is 0.06% and 0.0007%, respectively, in these two sub-groups, if the firmware is not upgraded.

Patient Management Recommendations:

Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott is providing the following guidelines:

- **Prophylactic device replacement is NOT recommended** as the new firmware version pr00.10.87.04 eliminates the potential for loss of therapy between follow-ups due to unrecognized decreased device longevity
- **Determine the firmware version of devices** followed at your clinic by reviewing the instructions in Appendix A and the device list in Appendix B
- **For patients with firmware version pr00.10.87.00 or with firmware version undetermined, upgrade devices to device firmware version pr00.10.87.04** by interrogating patients in-clinic with Merlin™ PCS 3650 programmer Model 3330 software version 25.4.1 rev 1 or higher or any Merlin™ 2 PCS MER3700 programmer
 - **Prioritize in-clinic firmware upgrade for the specific devices from the 1,500 device sub-group** listed in Appendix B
 - **For remaining patients, schedule the next follow-up in-clinic** to complete the firmware upgrade
- **Following firmware upgrade, continue to follow patients routinely** at the recommended interval per the device User's Manual
- **If a device experiences a loss of Bluetooth communication**, contact Abbott Technical Support for troubleshooting to determine whether the loss of Bluetooth communication is related to this issue

Action Abbott Has Taken:

Abbott has developed upgraded device firmware version pr00.10.87.04, which eliminates the potential for devices affected by this issue from entering the high current consumption mode should the Bluetooth (BLE) circuit component issue occur.

If the issue occurs in the devices affected after the firmware has been upgraded, a moderately elevated current consumption is ensured, providing sufficient time (typically years) for the issue to be detected and device replacement planned electively, as appropriate. The battery longevity is accurately displayed for these devices. With the assistance of Abbott Technical Support, it may be possible to recover normal Bluetooth (BLE) functionality and normal current consumption.



Merlin™ PCS 3650 programmer Model 3330 software version 25.4.1 rev 1 or higher or any Merlin™ 2 PCS MER3700 programmer facilitates the download of device firmware version pr00.10.87.04 through an automatic prompt to the user during in-clinic interrogation. All device settings and therapies remain active during the firmware download.

This programmer software and upgraded device firmware were made available to clinics starting March 2022. Based on Merlin.net remote monitoring data, Abbott estimates approximately 78% of implanted devices manufactured with prior firmware version pr00.10.87.00 have already been upgraded to device firmware version pr00.10.87.04 worldwide.

Issue Details and Detection of Affected Devices:

An electrical circuit component in the devices manufactured prior to April 2022 may have a rare issue, which if present, will disable Bluetooth telemetry and, in a subset of instances, place the Bluetooth circuitry into a higher-than-normal current consumption mode leading to reduced device longevity due to power consumption.

Importantly, the device audible ERI (Elective Replacement Indicator) alert remains functional for all patients.

If a device experiences this issue, all device functionality remains normal except for the loss of Bluetooth (BLE) telemetry (and therefore remote monitoring) and the possibility of a higher-than-normal current consumption during the period of remaining battery life. If unrecognized, however, high current consumption could result in a lack of therapy and device communications due to accelerated power consumption. The time from Bluetooth (BLE) loss to ERI (Elective Replacement Indicator) has been approximately 1 month for the 9 devices which experienced high current consumption.

The issue is 100% detectable during a programmer interrogation by the presence of a “Bluetooth Malfunction” alert and loss of Bluetooth connectivity. Remotely monitored patients who lose Bluetooth function and see a connection problem notification on their phone may be subject to this issue. These devices will also appear on the clinic’s “Patients with Disconnected Transmitters” list or compliance report of Merlin.net; however, this list includes devices lost to transmitter follow-up for any reason and not solely for this issue.

Technical Support:

Abbott has notified applicable regulatory agencies about this matter. Please share this notification with others in your organization, as appropriate.

Adverse reactions or quality problems experienced with the use of this product should be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Should you have any questions about this notice, please contact Abbott Technical Support at 1-800-722-3774 (U.S.). A list of Abbott advisories is available at <https://www.cardiovascular.abbott/us/en/hcp/product-advisories.html>. We sincerely apologize for any difficulties or inconvenience that this may cause you and your patients. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for assisting us with this process.

Sincerely,

A handwritten signature in black ink that reads "Robert Blunt".

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management

Appendix A

Identifying Device Firmware Version

The device firmware version is visible in the footer of any programmer reports from the Merlin™ PCS 3650 or Merlin™2 PCS, as displayed in the image below:



pr00.10.87.00 – Non-upgraded Firmware
pr00.10.87.04 – Upgraded Firmware

Image 1: Firmware version displayed in the footer of a Merlin™ PCS 3650 or Merlin™2 PCS programmer reports

Identifying Merlin™ PCS 3650 Software Version

The Merlin™ PCS 3650 software version is visible on the lower right corner of the initial startup screen, as displayed in the image below. Confirm the programmer software version is 3330 v25.4.x or higher.

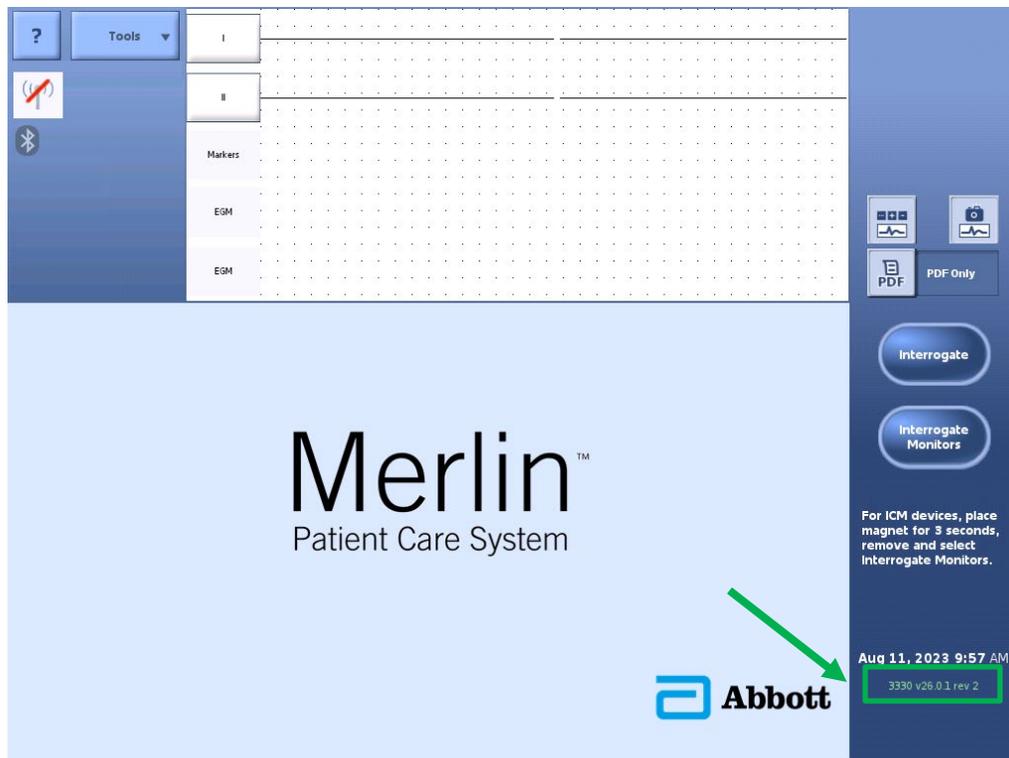


Image 2: Merlin™ PCS 3650 software version visible on the startup screen