ANZCDACC Management Recommendations for Abbott Product Defect Correction August 2023

Device:
GALLANT™, NEUTRINO™ NXT, and ENTRANT™ ICDs and CRT-Ds manufactured prior to April 2022
(Models CDVRA500Q, CDDRA500Q, CDHFA500Q, CDVRA600Q, CDDRA600Q, CDHFA600Q, CDVRA300Q, CDDRA300Q, and CDHFA300Q)

Note: No affected NEUTRINO™ NXT or ENTRANT™ ICDs and CRT-Ds were implanted in Australia.
No affected GALLANT™ or NEUTRINO™ NXT ICDs and CRT-Ds were implanted in NZ.

TGA Reference:
RC-2023-RN-00734-1
Australian Register of Therapeutic Goods (ARTG):
336475, 341252, 336476, 341253, 341254, 336479, 336477, 336478, 336480
NZ WAND #:
200713-WAND-6V1ACH, 200713-WAND-6V1AIK, 200713-WAND-6V1ACZ, 230509-WAND-7165FH, 200720- WAND-6V2SWF, 200720-WAND-6V2SUX, 230509-WAND-7165EK, 230509-WAND-7165F2, 200720-WAND-6V2SVH
Medsafe Reference:
31671

Advisory grade TGA:
Class II
(Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not class I.)

Description:
An electrical circuit component in these devices may have a rare issue, which if present, will disable Bluetooth telemetry (and therefore a loss of remote monitoring). In a subset of instances, this may place the Bluetooth circuitry into a higher-than-normal current consumption mode leading to reduced device longevity due to power consumption.

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.

If unrecognised, however, high current consumption could result in a lack of therapy and device communications. 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.

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

Abbott 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 these devices 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. Upon further questioning, Abbott has stated this “moderately elevated current consumption” has a “negligible” effect on battery longevity.
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 72% of implanted devices manufactured with prior firmware version pr00.10.87.00 have already been upgraded to device firmware version pr00.10.87.04 in Australia.

Number of devices affected in Australia and New Zealand:
Higher risk group: 2 in Australia, 0 in NZ.
Abbott confirmed that both patients in the higher risk group have now had their firmware updated.
Lower risk group: 1020 in Australia, 12 in NZ.
For New Zealand, all (12) of the impacted devices have been upgraded to the latest firmware version.

Presentation:
In-clinic:
Presuming there is still battery remaining, the issue is 100% detectable during a programmer interrogation in-clinic by the presence of a “Bluetooth Malfunction” alert and loss of Bluetooth connectivity.

Remote monitoring:
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 and compliance report of Merlin.net; however, this list includes devices lost to transmitter follow-up for any reason and not solely for this issue.
As the described issue causes communication breakdown between the device and transmitter, the issue will most likely present as "no alert checks" in the “Patients with Disconnected Transmitters” list.

Rate of occurrence:
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 high current consumption and reduced device longevity.

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 rate 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.

ANZCDACC Recommendation:

- Prophylactic device replacement is NOT recommended
    - The risk of mortality for patients after firmware upgrade is estimated to be less than the risk of patient mortality due to complications associated with device replacement.
- Determine the firmware version of devices followed at your clinic by reviewing the instructions in Appendix A.
- 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
    - Prioritise in-clinic firmware upgrade for the specific devices from the 1,500 device sub-group
    - For remaining patients, schedule the next follow-up in-clinic to complete the firmware upgrade
- Educate patients who are affected by this advisory to contact the clinic (or Abbott on 1800 899 081 (Aust.) or 0800 785 833 (NZ) if they are unable to resolve a related Bluetooth connection problem notification on their phone or if they hear an audible tone from their device.
    - Demonstrate the device's audible tone if seen in-clinic.
- 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:
    1. determine whether the loss of Bluetooth communication is related to this issue, and if so,
    2. determine whether they can recover normal Bluetooth (BLE) functionality and normal current consumption
- The device's battery longevity estimate can be used in all cases to determine follow up intervals and generator change timing.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead

function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA;

Online	https://www.tga.gov.au/reporting-problems

In New Zealand, report to Medsafe;

Post	Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.
Email	devices@moh.govt.nz
Fax	04 819 6806

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:

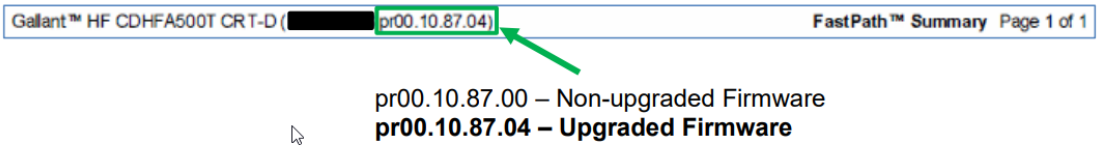

Image 1: Firmware version displayed in the footer of a Merlin™ PCS 3650 or Merlin™2 PCS programmer reports

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 v25.4.1 or higher.


?
Tools
I
II
Markers
EGM
EGM
PDF
PDF Only
Interrogate
Interrogate Monitors
For ICM devices, place magnet for 3 seconds, remove and select Interrogate Monitors.
Merlin™
Patient Care System
Abbott
Aug 11, 2023 9:57 AM
3330 v26.0.1 rev 2