Date – August 18, 2023

Canadian Heart Rhythm Society
Device Committee

RE: BLUETOOTH FUNCTION ON GALLANT™, NEUTRINO™, AND ENTRANT™ ICDs AND CRT-Ds MANUFACTURED PRIOR TO APRIL 2022

Nature of the Advisory:

Abbott has identified an issue with the Bluetooth electrical circuit component of a subset of Gallant™, Neutrino™, and Entrant™ Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) manufactured prior to April 2022.

If a device experiences this issue, all device functionality remains normal except for the loss of Bluetooth telemetry. This typically results in a loss of remote monitoring capability.

In a subset of instances, the abnormality in the Bluetooth circuitry leads to a higher-than-normal current consumption mode leading to reduced device longevity due to accelerated power consumption. The time from Bluetooth loss to ERI (Elective Replacement Indicator) has been approximately 1 month for the 9 devices which experienced high current consumption.

Importantly, the primary device functions, including pacing, sensing, shock delivery, and inductive telemetry (e.g., ability to perform in-clinic interrogation), are unaffected during the period of remaining battery life. The device audible ERI (Elective Replacement Indicator) alert remains active in devices affected by this issue.

Scope of the problem:

Abbott has observed a total of 16 implanted devices out of 67,000 to have lost Bluetooth communication due to this issue. Of these, 9 (0.013%) have experienced high current consumption and reduced device longevity.

A total of 67,000 devices are potentially affected by this communication, with a sub-group of approximately 1,500 devices being more likely to manifest this issue as compared to the remaining 65,500 devices.

In Canada there are an estimated 773 potentially affected devices, of which 64 are in the higher risk sub-group. Of the 773 devices, approximately 405 have already received a firmware upgrade, 133 have non-upgraded firmware, and 235 have unknown firmware status.

How to identify the problem:

The issue potentially manifests as:

1. In-person interrogation reveals a “Bluetooth Malfunction” alert and loss of Bluetooth connectivity.
2. Remotely monitored patients who lose Bluetooth function and see a connection problem notification on their phone and will appear on the clinic’s “Patients with Disconnected Transmitters” list or compliance report of Merlin.net.

Problem Mitigation:

Abbott has developed a device firmware update 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.

The updated programmer software and upgraded device firmware were made available to clinics in Canada starting August 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.

Following firmware upgrade, the risk of accelerated battery drain is minimised, providing sufficient time (typically years) for the issue to be detected and device replacement planned electively, as appropriate. In addition, Abbott Technical Support may be able to recover normal Bluetooth functionality and normal current consumption.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue.
- No prophylactic replacement is recommended at this stage.
- Patients should have their device firmware version determined
- **Patients with firmware version pr00.10.87.00 or with an undetermined firmware version, will require their devices to be upgraded to firmware version pr00.10.87.04**
    - This is accomplished by in-clinic interrogation with Merlin™ PCS 3650 programmer Model 3330 software version 25.4.1 rev 1 or higher or any Merlin™ 2 PCS MER3700 programmer
    - Consider prioritizing patients with devices in the “higher risk” sub-group
    - For remaining patients, firmware upgrade can occur at the next scheduled follow-up
- **Following firmware upgrade,** patients should be followed in-person or via remote monitoring at their usual follow-up schedule
- Contact Abbott Technical Support **if a device experiences a loss of Bluetooth communication**

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