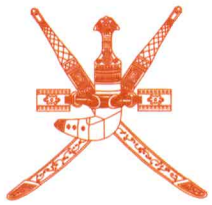
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط



To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 191 **dated** 17/9/2023 **Regarding FSCA of A Subset of Gallant™, Neutrino™ Nxt, and Entrant™ Icds and Crt-Ds from (mfr: Abbott).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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سلطنة عُمان
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Circular No. 191 / 2023

01-03-1445 H
17-09-2023

FSCA of A Subset of Gallant™, Neutrino™ Nxt, and Entrant™ Icds and Crt-Ds from Abbott.

Source	Abbott through their local agent Muscat Pharmacy & Stores LLC.
Product	A Subset of Gallant™, Neutrino™ Nxt, and Entrant™ Icds and Crt-Ds.
Description	Active Implantable Devices.
Manufacturer	Abbott.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Manufactured prior to April 2022 MODELS: CDVRA500Q, CDDRA500Q, CDHFA500Q, CDVRA600Q, CDDRA600Q, CDHFA600Q, CDVRA300Q, CDDRA300Q, AND CDHFA300Q
Reason	A risk of loss of Bluetooth Communication (and therefore a loss of remote monitoring), higher-than-normal current consumption, and reduced device longevity, due to a Bluetooth (BLE) circuit component issue.
Action	1. Please refer to the attachment for recommended patient management. 2. Device firmware version pr00.10.87.04 has been developed. Please refer to the attachment for upgrading the device firmware. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
Directorate General of Pharmaceutical Affairs & Drug Control
ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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FA-Q122-CRM-2 URGENT Field Safety Notice

FOR A SUBSET OF 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

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 9 events reported to Abbott which led to early device replacement caused by this issue without clinical consequences for the patients.

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 high 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 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.

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 25.8.2 rev 1 or higher or Merlin™ 2 PCS MER3700 programmer software version 1.8.2 rev 1 or higher
    - **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 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

Abbott

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 25.8.2 rev 1 or higher or Merlin™ 2 PCS MER3700 programmer software version 1.8.2 rev 1 or higher is necessary for 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 June 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 these devices 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 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.

Should you have any questions about this notice, please contact Abbott Technical Support. A list of Abbott advisories is available at https://www.cardiovascular.abbott/int/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,

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 v25.8.2. rev. 1 or higher.

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