Device: Abbott: Merlin™ Patient Care System (PCS) Software Model 3330 v25.0.X–v25.3.X

GTIN 05414734509725

When used with: Abbott Gallant™, Neutrino™ NxT, Entrant™ devices

TGA Reference:

Australian Register of Therapeutic Goods (ARTG): 124262

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Note:

1. In Australia; Neutrino™ NxT and Entrant ™ are currently approved but not commercially launched (Only Gallant is commercially available).
2. In New Zealand; Only Gallant and Entrant are Medsafe WAND notified however only Entrant has been commercially launched at limited accounts.

Advisory grade TGA:

Class II

Class II- A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

ANZDACC Advisory Grade:

Class II

Description:

There has been a programmer software anomaly that may be encountered in a very specific circumstance when executing a pacing capture Decrement Test in-clinic on a Gallant ™, Neutrino ™ NxT, or Entrant ™TM device using an Abbott Merlin™ Patient Care System (PCS) programmer.

If a user presses the “Hold to Test” button and releases the button prior to the first voltage decrement (within a narrow time window approximately 2.5 seconds after test initiation), the programmer may continue to execute the Decrement Test instead of terminating the test and restoring the permanent programmed pacing parameters. Under this scenario, the Decrement Test will continue running until an output of 0.25V is reached or until telemetry communication is broken. For pacemaker dependent patients, there is a potential for this scenario to cause a transient asystole until permanent parameters are restored if the voltage is below the patient’s capture threshold.

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

Abbott has developed updated Merlin™ PCS software which corrects this issue, which is expected to be available beginning in June 2022.

Number of devices affected in Australia and New Zealand:

366 customer Merlin Programmers in Australia, 52 in New Zealand. 113 programmers with commercial sales team across ANZ. A total of 531.

Number of implanted Gallant™ devices in Australia: <1000

Number of implanted Entrant™ devices in New Zealand: 1

Presentation:

This would present during in clinic follow up, as described above.

This could occur if the user decided not to carry on with the test, intentionally releasing the "Hold to Test" button. This could also occur unintentionally, if the touch screen only intermittently recognises the finger touching the button. This 'intermittent recognition of a button press' is not part of this notification, it is simply a nuance of the touch screen.

Rate of occurrence:

Twenty-one (21) complaints have been received for this issue out of approximately 38,000 implanted devices globally. Sixteen (16) of the complaints occurred during an LV Capture Test where there is an increased likelihood of testing a vector with an elevated capture threshold.

Recommendation:

Ensure programmers are updated once the update is available.

These are the recommendations for conducting Decrement Tests prior to the programmer software upgrade.

- For patients who are known to be pacemaker dependent, consider performing the Decrement Test while the patient is in the supine position.
- Start the Decrement Test at a value significantly higher than the anticipated threshold, based on previous testing.
- When performing a Decrement Test, do not release the "Hold to Test" button prior to the first voltage decrement.

If the Decrement Test continues after releasing the "Hold to Test" button, breaking telemetry communication will end temporary pacing settings and restore permanent parameters.

- When using Merlin™ PCS, use one of the following options depending on the telemetry mode:

- When using the wireless telemetry, “BLE”, disconnect the BLE dongle from the USB port.
- When using inductive telemetry, move the inductive wand more than 6 inches away from the device for at least 2 seconds.
- Alternatively, telemetry may be broken by powering down the programmer.

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