



Urgent Field Safety Notice

Merlin™ and Merlin™2 Patient Care System (PCS)
Software Model 3330 v25.0.X – v25.3.X
GTIN 05414734509725
Software Model MER3400 v1.1.X – v1.3.X
GTIN 05415067037121
When used with Gallant™, Neutrino™ NxT, Entrant™ devices

April 2022

Dear Physician or Healthcare Professional:

Abbott is notifying physicians of 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™ device using a Merlin™ or Merlin™2 Patient Care System (PCS) programmer. If a user presses the “Hold to Test” button and decides to stop testing by releasing 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.

As of March 2022, 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.

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

You are receiving this letter because Abbott records indicate that you currently utilize a Merlin™ or Merlin™2 PCS programmer with software versions supporting Gallant™, Neutrino™ NxT, and Entrant™ devices.

Patient Management Recommendations:

Abbott has developed updated Merlin™ and Merlin™2 PCS software which corrects this issue. Your Abbott Representative will upgrade your programmer software beginning in June 2022.

Please review the following 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 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.
- To break telemetry when using the **Merlin™2 PCS**, telemetry communication may be broken by powering down the programmer.

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 may be reported directly to Abbott. Should you have any questions about this notice, please contact your local Abbott Representative.

We sincerely apologize for any difficulties or inconvenience that this may cause. 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
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management