

March 2022

Canadian Heart Rhythm Society Device Committee

**RE: Abbott Merlin™ and Merlin™2 Patient Care System (PCS)
When used with Gallant™, Neutrino™ NxT, Entrant™ devices**

Nature of the Advisory:

Abbott has identified a software anomaly that may be encountered when performing a pacing capture Decrement Test using a Merlin Patient Care System (PCS) programmer on a Gallant, Neutrino NxT, or Entrant device.

If a user presses the “Hold to Test” button but releases the button prior to the first voltage decrement (e.g. within 2.5 seconds after test initiation), the programmer may continue to execute the Decrement Test 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 during the period where the test voltage is below the patient’s capture threshold. This asystole would last until the test terminates and the permanent parameters are restored.

Scope of the problem:

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.

Response of the CHRS Device Committee:

Abbott has developed a software update which corrects this issue. This update will be provided to clinics once approved by Health Canada.

Until the update is available, we advise not terminating a pacing capture Decrement Test within the first 3 seconds of initiation.

In the event the Decrement Test does not terminate upon releasing the “Hold to Test” button, we suggest breaking telemetry communication with the device to end temporary pacing and restore permanent parameters. Telemetry may be disrupted by:

- Disconnecting the Bluetooth Low-Energy (BLE) dongle from USB port (if BLE is being used)
- Moving inductive wand more than 6 inches (15 cm) from device for at least 2 seconds (if inductive telemetry is being used).
- Powering down programmer.

CHRS Device Committee

Jason Andrade (chair), François Philippon (past chair), Derek Exner, Clarence Khoo, Ratika Parkash, Calum Redpath, Larry Sterns, Raymond Yee