

Date: May 14, 2026

Canadian Heart Rhythm Society Device Committee

RE: Interruption in pacing capture threshold testing of Abbott AVEIR LP with MERLIN 3650 Patient Care System (software models V25.0.4 – V28.8.4)

Nature of the Advisory:

While performing Pacing Capture Threshold testing (PCT) of the Abbott Aveir leadless pacemaker (LP) through a Merlin 3650 Programmer (software models V25.0.4 – V28.8.4), loss of telemetry can result in the Aveir LP pacing at its last temporarily programmed output. If loss of telemetry occurs when the PCT is pacing at a sub-threshold output, then pacing may continue at this output. Cancelling the PCT usually restores the pacing output to pre-testing values, but in this setting, sub-threshold pacing may persist and result in presyncope or syncope in pacing-dependent patients. Full disconnection of the Aveir LP from the Merlin PCS will restore normal pacing settings after a short delay.

Scope of the problem:

There have been 4 complaints worldwide that have been received by Abbott of this abnormal PCT behaviour. Three incidents were not associated with any clinical symptoms but may have prolonged the duration of the procedure. One incident resulted in transient asystole in a pacing-dependent patient. The occurrence of this event during a PCT test is estimated at 0.001%.

A software update has been developed for the Merlin PCS 3650 (v28.9.4 Rev 1 or higher) which addresses this specific PCT behaviour. This software update is available starting **May 12, 2026** and completely resolves this advisory issue.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients with a device affected by this advisory be notified about this potential issue.
- All Merlin 3650 PCS programmers that may be used clinically during implantation or follow-up of Aveir LP should be upgraded to v28.9.4 Rev1 or higher. Once the software update has been installed on all applicable programmers, the advisory may be considered resolved.
- The CHRS device committee may update these recommendations should more data become available.

CHRS Device Committee

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