URGENT MEDICAL DEVICE CORRECTION

MERLIN™ 3650 PATIENT CARE SYSTEM (PCS)
SOFTWARE MODEL 3330 V25.0.X – V28.7.X
GTIN 05414734509725
WHEN USED WITH AVEIR™ LEADLESS SYSTEM

May 2026

Dear Physician or Healthcare Professional:

Abbott is reaching out to customers to inform about a Merlin™ PCS 3650 programmer software update that addresses a software behavior that may occur during Pacing Capture Threshold (PCT) test of an AVEIR™ Leadless Pacemaker (LP). If intermittent loss of telemetry occurs during PCT test, the programmer may not successfully communicate the command to terminate the test, potentially leaving the LP in sub-threshold pacing until telemetry is fully disconnected. This issue can only occur during a PCT test, which is performed during implant or in clinic follow-up.

Risk to Health:
Four (4) related complaints have been reported globally. Three (3) involved no reported symptoms and were associated with minor impact such as procedure delay. One (1) involved a pacer dependent patient who experienced transient asystole due to prolonged sub-threshold pacing. This issue may cause loss of capture, and in pacemaker-dependent patients, may cause dizziness or syncope. There were no permanent patient injuries reported, and in all cases the issues were resolved within the same session.

The estimated occurrence rate per PCT test is 0.001%.

Action Abbott has taken:
Abbott has developed updated Merlin™ PCS 3650 programmer software (v28.9.1 rev 1 or higher) that resolves this behavior. Beginning with this notification, your Abbott Representative will upgrade programmer software to this software version.

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 with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Should you have any questions about this notice, contact Abbott Technical Services at 1-800-722-3774 (U.S.).

A list of Abbott advisories is available at https://www.cardiovascular.abbott/us/en/hcp/product-advisories.html.
We sincerely apologize for any difficulties or inconvenience that this may cause you and your patients. Patient safety remains Abbott's top priority, Abbott is committed to delivering high-quality products and support, and we appreciate your partnership in this process.

Sincerely,

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management