URGENT MEDICAL DEVICE CORRECTION

MERLIN™ PATIENT CARE SYSTEM (PCS) 3650
SOFTWARE MODEL 3330 V28.0.X – V28.1.1 REV 1
GTIN 05414734509725
WHEN USED WITH AVEIR™ DR LEADLESS SYSTEM

November 2024

Dear Physician or Healthcare Professional:

Abbott is informing customers of a programmer software anomaly that may incorrectly reprogram a ventricular Aveir leadless pacer during the Finalize the New LP ("Finalization") step of the implant process for an AVEIR™ DR Leadless Pacemaker (LP) System. This can occur during an upgrade from an AVEIR VR to an AVEIR DR system or during a new AVEIR DR system implant. If telemetry is lost during a small window (<2 seconds) during Finalization of the Right Atrial (RA) LP after the Right Ventricular (RV) LP is Finalized, the programmer software anomaly configures the RV LP to incorrectly behave as an RA LP. If this occurs, the Merlin™ PCS 3650 Programmer displays a "Loss of telemetry detected" window, and there is no pacing. Additionally, atrial sense markers coincident to intrinsic QRS complexes may be observed. Subsequent attempts to finalize the device will continue to result in a "Loss of telemetry detected" window. In all cases where this occurred, full functionality, including ability to finalize the device and restore pacing, was reinstated through Abbott Technical Services intervention.

Abbott has observed this issue at a rate of approximately 0.2% for implanted AVEIR DR systems globally. There have been no reports of any harm to patients resulting from this issue. In each event, devices were subsequently restored to standard functionality.

Action Abbott has Taken:
Currently available Merlin™ PCS 3650 programmer software (version 28.2.1 rev 2) prevents this issue. Your Abbott Representative will upgrade your programmer software and work with you to ensure use of version 28.2.1 rev 2 or greater as it eliminates this issue.

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. 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