Voluntary Medical Device Recall
Urgent

MERLIN™ PATIENT CARE SYSTEM (PCS) 3650
SOFTWARE MODEL 3330 V28.0.X – V28.1.X REV 1
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 be encountered in a very specific circumstance during finalization of the 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. A specific sequence of programmer actions combined with a loss of telemetry during a small window (<2 seconds) may cause the finalization step to fail. If this occurs, the Merlin™ PCS 3650 Programmer displays a “Loss of telemetry detected” window, and there is no pacing. Atrial sense markers coincident to intrinsic QRS complexes may be observed. Subsequent attempts to finalize the device will also result in a “Loss of telemetry detected” window. Full functionality, including ability to finalize the device and restore pacing, is 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.

Patient Management Recommendations:
Updated Merlin™ PCS 3650 programmer software (version 28.2.4 rev 1 or higher) corrects this issue. Your Abbott Representative will upgrade programmer software beginning by mid-year 2025.

In consultation with Abbott CRM’s Medical Advisory Board (MAB), Abbott is providing the following recommendations for implanting AVEIR DR LPs prior to the programmer software upgrade:

- Prior to finalization, ensure robust telemetry connection.
- For pacemaker dependent patients:
  - Consider backup pacing support through implant finalization.
  - During a new AVEIR DR system implant, consider implanting and finalizing the RA LP first before the RV LP if appropriate for the patient, as this order of finalization does not allow the issue to occur.
- If this issue occurs during the finalization step of an AVEIR DR system, contact Abbott Technical Services as device restoration will be required.

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 your local Abbott representative. Should you have any questions about this notice, please contact your local Abbott Representative.

A list of Abbott advisories is available at https://www.cardiovascular.abbott/int/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

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management