



IMPORTANT MEDICAL DEVICE CORRECTION
MERLIN™ PATIENT CARE SYSTEM (PCS) PROGRAMMER
SOFTWARE VERSION 24.6.1
MODEL: 3330
GTIN: 05414734509725

February 28, 2020

Dear Physician,

Abbott recently deployed Merlin™ Patient Care System (PCS) programmer software V24.6.1. After initiating the update, an anomaly was identified that may result in specific programming changes not being stored in the device. Abbott has determined there is no impact to patients, and no intervention is needed for patients.

When using programmer software V24.6.1 to make certain programming changes, the changes may appear to have been successfully programmed but the device could remain at previously programmed settings. All other device therapeutics and other functionalities are unaffected. Abbott records indicate you are following one or more patients who have been interrogated by a programmer with V24.6.1.

This issue can occur only if changes to tachycardia therapy Tilt or Waveform (monophasic/biphasic) settings are made and therapy energy value is modified from nominal using the new programmer software. Changes to any other device parameter are not impacted. Re-interrogation in a new session will correctly display the currently programmed values stored in the device for all parameters. Abbott has proactively reviewed all session records for devices that have been interrogated by programmer software V24.6.1 and determined there is no impact to patients.

Patient Management Recommendations

Abbott has developed an updated Merlin™ PCS programmer software V24.6.1 rev1 which corrects this issue. This solution does not present additional risk to patients and no intervention is needed for patients. Abbott will update programmer software in the coming days.

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

Abbott is committed to providing the highest quality products and support. We apologize for any inconvenience this may cause you and your patients, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction. If you have any questions about this communication or the patient management recommendations, please contact your Abbott representative or Abbott Technical Support at **1-800-722-3774 (U.S.)**.

Sincerely,

A handwritten signature in black ink that reads 'B. Blunt'.

Robert Blunt
Divisional Vice President, Quality
Cardiac Rhythm Management