



URGENT FIELD SAFETY NOTICE
MERLIN™ PATIENT CARE SYSTEM (PCS)
PROGRAMMER SOFTWARE VERSION 25.0.2 Rev 3
(MODEL: 3330)
WHEN USED WITH GALLANT™ ICDs
(MODELS: CDVRA500Q, CDDRA500Q, CDHFA500Q)

May 12, 2020

Dear Physician,

This letter is to inform you of an anomaly discovered within the Merlin™ Patient Care System (PCS) programmer software version 25.0.2 rev 3. When AutoCapture™ or Cap Confirm features are enabled, the software anomaly may result in automatic capture algorithms overestimating the right ventricular (RV) and left ventricular (LV) capture thresholds in Gallant™ Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Devices (CRT-Ds).

Background

Gallant™ ICDs have a programmable RV AutoCapture™ feature, and CRT-Ds have programmable RVCap™ Confirm and LVCap™ Confirm features. These features determine and trend capture thresholds and provide pacing at outputs above the determined capture threshold.

Safety Impact

As a result of this programmer software anomaly, in devices with these feature(s) enabled (ON or MONITOR) measured and reported capture thresholds may be falsely elevated and pacing outputs delivered may be greater than necessary. When this occurs, outputs will always be greater than required ensuring capture. This may result in device alerts and additional follow-up, reduced battery longevity, or extra-cardiac stimulation. There have been three (3) complaints as a result of this anomaly and no (0) reports of patient injury.

Patient Management Recommendations

For patients already implanted, the enabled RV AutoCapture™, RVCap™ Confirm, and LVCap™ Confirm feature(s) should be disabled at the next routine scheduled in-clinic follow-up.

During new implants, do not enable RV AutoCapture™, RVCap™ Confirm, and LVCap™ Confirm feature(s). Manual threshold assessment should be executed.

Abbott is working to make Merlin™ PCS Programmer software available to mitigate this issue and once the new software is available, these features can be enabled or re-enabled.

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 +46-8-474-4147 (for Customers in Africa, Europe, and the Middle East).

Sincerely,

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

Robert Blunt
Divisional Vice President, Quality
Cardiac Rhythm Management