Urgent Medical Device Correction

Merlin™ Patient Care System (PCS)
Software Model 3330 v25.0.X – v25.3.X
GTIN 05414734509725
When used with Gallant™, Entrant™ devices

March 2022

Dear Physician or Healthcare Professional:

Abbott is notifying physicians of a programmer software anomaly that may be encountered in a very specific circumstance when executing a pacing capture Decrement Test in-clinic on a Gallant™, or Entrant™ device using a Merlin™ Patient Care System (PCS) programmer. If a user presses the "Hold to Test" button and decides to stop testing by releasing the button prior to the first voltage decrement (within a narrow time window approximately 2.5 seconds after test initiation), the programmer may continue to execute the Decrement Test instead of terminating the test and restoring the permanent programmed pacing parameters. Under this scenario, the Decrement Test will continue running until an output of 0.25V is reached or until telemetry communication is broken. For pacemaker dependent patients, there is a potential for this scenario to cause a transient asystole until permanent parameters are restored if the voltage is below the patient's capture threshold.

Twenty-one (21) complaints have been received for this issue out of approximately 38,000 implanted devices globally. Sixteen (16) of the complaints occurred during an LV Capture Test where there is an increased likelihood of testing a vector with an elevated capture threshold.

There have been no reports of serious harm to patients resulting from this issue.

You are receiving this letter because Abbott records indicate that you currently utilize a Merlin™ PCS programmer with software versions supporting Gallant™ and Entrant™ devices.

Patient Management Recommendations:
Abbott has developed updated Merlin™ PCS software (v25.4.X rev 1 or higher) which corrects this issue. Your Abbott Representative will upgrade your programmer software beginning in March 2022.

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 www.fda.gov/MedWatch/getforms.htm 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, please contact Abbott Technical Support at 1-800-722-3774 (U.S.). 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