



MEDICAL DEVICE CORRECTION

Merlin™ Patient Care System (PCS) Software Model 3330 v26.0.1 rev 1 or earlier
and Merlin.net™ MN5000 v11.7 Remote Monitoring Application
when used with Accent™/Anthem™ and Endurity™/Assurity™/Allure™ family of pacemakers¹

June 2022

Dear Physician or Healthcare Professional:

Abbott is notifying customers of the potential for programmer software (Merlin™ PCS) and remote monitoring software applications (Merlin.net) to display overestimated predicted battery longevity for certain pacemakers¹. **Pacemaker/battery functionality, therapy delivery, and longevity remain normal** and within specifications. Voltage measurements and ERI (elective replacement indicator), which is based on direct voltage measurement, remain accurate.

As of May 2022, there have been 585 complaints reported for this issue, and 30 devices were prematurely explanted prior to ERI. **No patient harm or adverse events were reported as a result.**

At interrogation, the programmer software uses an algorithm to estimate remaining device battery longevity based on measured battery voltage and projected battery performance. The algorithm may overestimate pacemaker battery longevity, particularly during mid- to late-stage device life. Nearing ERI, the longevity estimate improves, reducing overestimation. However, as this occurs, users may observe a larger than expected drop in the remaining battery longevity estimate compared to the prior estimate, which may cause the appearance of a rapid change in battery performance. An example is provided in Appendix A.

Abbott has developed a software update to improve accuracy of predicted battery longevity. Remote monitoring (Merlin.net) and programmer software updates are targeted to begin June 2022 based on geography.

Patient Management Recommendations

Abbott provides the following guidance:

- **Prophylactic device replacement is not recommended**, as device functionality, actual longevity, and ERI indicator are not impacted (device functionality remains normal and within specifications).
- **Routine follow-up should remain as per local standard of care and clinical protocol**, and ERI should continue to serve as an indicator of the need for device replacement scheduling.
- **Please direct any questions about device longevity to Abbott Technical Support** at 1-800-722-3774 (U.S.).

Upon programmer software / remote monitoring software update, the improved longevity estimate will be displayed at the patient's next interrogation. Please note that until programmers are updated, a difference in longevity estimates between programmers and remote monitoring (Merlin.net) may be observed.

Abbott has notified all 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 address on 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 or work with your Abbott Representative.

Abbott is committed to providing the highest quality products and support. We apologize for any inconvenience this action may cause, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Thank you for your continued support.

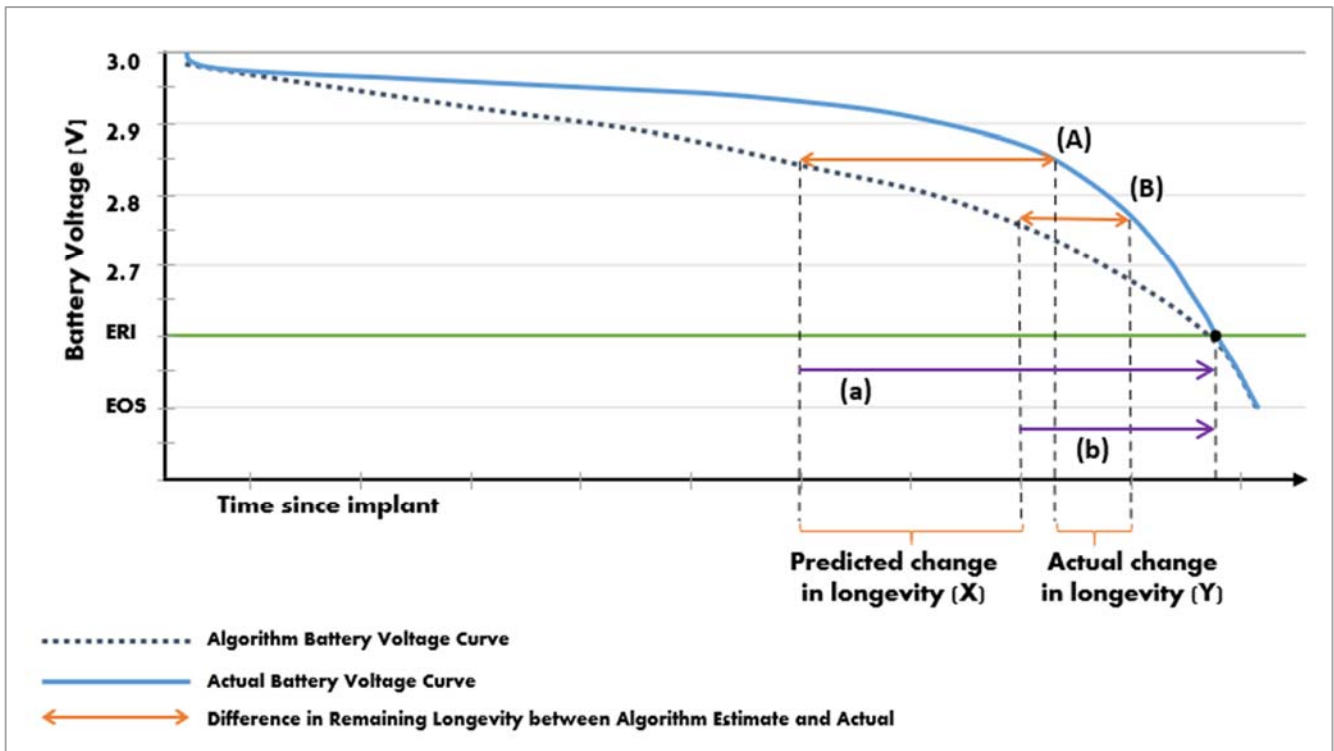
Sincerely,

Robert Blunt
Divisional Vice President, Quality
Abbott Cardiac Rhythm Management

¹ This programmer software pertains to the following devices:

Accent™/Accent MRI™/Assurity™/Assurity MRI™/Endurity™/Endurity MRI™/Nuance™/Zenex MRI™/Zenex MRI™ IPGs,
Allure™/Allure Quadra™/Quadra Allure™/Anthem™/Relieve™/Relieve Quadra™/Quadra Relieve™ CRT-Ps

Appendix A



Representative graphic not drawn to scale; for illustration purposes only

Example:

During the mid- to late-stage of device life, battery voltage (**A**) yields a predicted remaining longevity of ~ **5.0 years** [purple arrow **(a)**]. A year later, at battery voltage (**B**) the algorithm predicts a remaining longevity of ~ **3.0 years** [purple arrow **(b)**]. This could be interpreted as the device “aging” two years (**X**) in only one year of real time despite battery performance being normal throughout; the true change in longevity is much smaller (**Y**). The difference between the actual and predicted change in longevity decreases as the device approaches ERI. Hence, the longevity estimate improves, and overestimation of remaining longevity is reduced.