Date: June 21, 2022

Canadian Heart Rhythm Society
Device Committee

RE: Battery Longevity Overestimates with The Merlin Patient Care System And Merlin.Net Remote Monitoring When Used With Accent/Anthem And Endurity/Assurity/Allure Family Of Pacemakers

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Nature of the Advisory: Abbott has identified the potential for the programmer software (Merlin PCS) and remote monitoring software applications (Merlin.net) to display overestimated predicted battery longevity for certain pacemakers. Specifically, during an in-person or remote interrogation, the programmer software uses an algorithm to estimate device battery longevity based on the measured battery voltage and projected battery performance. During the mid- to late-stage device life, this algorithm employed by the programmer may overestimate battery longevity. However, nearing ERI the accuracy of the longevity estimate improves (e.g., reducing overestimation), resulting in a larger than expected drop in the battery longevity estimate. While this suggests an apparent rapid change in battery performance, the observed change in the longevity estimate is a function of improved agreement between the actual and predicted change in longevity.

Abbott has developed a software update to improve accuracy of predicted battery longevity. Upon programmer software / remote monitoring software update, the improved longevity estimate will be displayed at the patient's next interrogation. Remote monitoring (Merlin.net) software was updated Globally as of June 18, 2022. Programmer updates are likely to follow in the fall, based on software availability in Canada. Until programmers are updated, a difference in longevity estimates between programmers and remote monitoring (Merlin.net) may be observed.

Scope of the problem: No patient harm or adverse events were reported as a result.

Response of the CHRS Device Committee:

- Prophylactic device replacement is not recommended, as device functionality remains normal, and the actual longevity and ERI indicator are not impacted.
- Routine follow-up should remain as per local standard of care and clinical protocol
- ERI should continue to serve as an indicator of the need for device replacement scheduling.

CHRS Device Committee
Jason Andrade, MD, (Chair, Device Committee)
François Philippon, MD, (Past chair, Device Committee)
Derek Exner, MD, Clarence Khoo, MD, Ratika Parkash, MD,
Calum Redpath, MBChB, Larry Sterns, MD, Raymond Yee, MD