Canadian Heart Rhythm Society
Société canadienne de rythmologie

Date: July 8, 2022

Canadian Heart Rhythm Society
Device Committee

UPDATED ADVISORY: Premature Battery Depletion, Boston Scientific SICD Models A209 and A219.

NOTE: The CHRS device committee released a performance note in July 2020 followed by a response to the formal Advisory in December 2020. This letter is an update to those documents.

Nature of the Advisory: In August 2019 Boston Scientific reported that a subset of 400 worldwide S-ICD devices had an increased risk of accelerated battery depletion approaching 15% at 5 years. The premature battery depletion occurs when hydrogen ions within the device can affect a low voltage capacitor which increases its current drain. Because of unique battery management algorithm in these devices, that increased current drain is not reflected in the longevity estimates for the first 80% of battery life, as the midlife estimates are based on time since implant and number of charges rather than battery voltage. When the device battery voltage starts to fall in the last 15-20% of device life, the longevity estimates become accurate once again as they are now based on voltage, however at this point there may be very limited capacity left in the system if the current drain is rapid.

It was subsequently determined that this issue may affect a broader population of S-ICD devices produced with similar manufacturing techniques prior to a change made in mid 2018. The risk of premature battery depletion in this larger group was initially estimated at 0.08% at 3 years, which was revised to 2.3% at 5 years in July 2020, and 3.7% at 5 years in December 2020. Since the December 2020 communication, the malfunction rates for the approximately 28,000 active devices have stabilised at approximately **11.9% at 5 years**.

Importantly, the battery behavior continues to be highly detectable. Approximately 99.5% of the 3,611 S-ICDs that have exhibited this behavior were replaced before the battery reached a depleted state.

Note - The time to early replacement indicator (ERI) status could be as brief as 60 days. If the battery is depleting quickly, the subsequent time from ERI to end of service (EOS) could be as little as 21 days. Therefore, prompt generator replacement is recommended. Boston Scientific Technical Service can provide a device specific battery estimate for impacted devices.

In December 2020, Boston Scientific committed to developing a software enhancement that enables earlier identification of EMBLEM S-ICDs exhibiting hydrogen-induced accelerated battery depletion. This software is now approved and will be installed on the Model 3200 and 3300 programmers. When an EMBLEM S-ICD is first interrogated by an upgraded programmer, the programmer screen will notify the user that an update has been initiated. This update enhances the detection of hydrogen-induced accelerated depletion between in-office and/or remote interrogations. Devices with premature battery depletion can be identified by a moderate or sudden decrease in estimated longevity from middle of life to end of life in 3 consecutive daily measurements. If premature battery depletion is confirmed by the algorithm, or once the device reaches ERI, it will trigger an audible patient alert (16 beeping tones every 9 hours) and send an

alert via the Latitude remote monitoring system. The programmer will also display a red alert screen

Scope of the problem: Devices potentially at risk of this issue were manufactured prior to a change in the low voltage capacitor that occurred in the middle of 2018. Devices manufactured after that date have not been found to be impacted by this issue. Of the 28,000 active devices that include the low voltage capacitors potentially at risk of this issue worldwide, there are approximately 365 active devices in Canada.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue and reassured that with close follow-up the risk of harm due to this malfunction is low.
- Patients with S-ICDs should be followed according to manufacturer's guidelines every 3 months either in person or via remote monitoring.
    - *It is recommended that an in-person visit occur at the next scheduled follow-up, so the Enhanced Battery Depletion alert can be enabled in each affected device.*
- All patients with S-ICDs should be enrolled on the Latitude system where possible.
    - In contrast to transvenous devices, patients with an S-ICD are required to interact with the bedside Latitude Communicator to transmit the data. It is recommended that this interaction occur on a weekly basis in order to ensure no alerts are missed.
- The patient alert tones should be demonstrated to patients at each in-person follow-up to ensure they are able to hear them. Patients should be instructed to notify their follow-up device clinic as soon as possible if they hear the alert tone.
- If the device shows a sudden decrease in estimated longevity between routine follow-up visits, then more intensified follow-up (every 1 month or less) or plans for prompt generator replacement should be made. Note: Consultation with Boston technical services may be considered to better define the anticipated EOS time for a given device.
- <u>Prophylactic device generator replacement is not recommended</u> but may be considered in certain high-risk individuals (e.g., inability to use the Latitude system, secondary prevention indication with multiple arrhythmic events, those unable to hear device tones, with planned prolonged travel, or those living remote from medical facilities).

If you have any questions, please contact your local Boston Scientific representatives. Contact Boston Scientific Technical Services for assistance as needed 1-800-227-3422.

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