

Date: October 11, 2023

## Canadian Heart Rhythm Society Device Committee

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### Transient Sensing Behaviour, Boston Scientific S-ICD Models A209 and A219.

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#### Nature of the Advisory:

Boston Scientific has identified an issue with the sensing behaviour of the EMBLEM S-ICD. This issue is transient and only occurs when a LATITUDE telemetry communication occurs coincident with an EMBLEM S-ICD system impedance measurement.

The EMBLEM S-ICD performs a system impedance measurement every three days. During the system impedance measurement, the EMBLEM S-ICD uses low energy pulses to assess impedance. During this assessment the device temporarily disables sensing to prevent non-cardiac artifacts from being over-sensed by the device or displayed on the S-ECG.

If a LATITUDE communication is initiated coincident (within 700 msec) of an automatic impedance check then the device will abandon the impedance check and reschedule the impedance measurement 24 hours later. During that 24-hour interval, the device sensing function remains disabled, meaning an arrhythmic event will not be detected so shock therapy will be unavailable.

Since this problem was identified, Boston Scientific has been able to develop and issue a software update. This software update prevents postponement of the system impedance measurement so sensing resumes in approximately one cardiac cycle as intended.

#### Scope of the problem:

EMBLEM S-ICDs enrolled in LATITUDE have the rare potential for transient sensing behavior. As of 9 August 2023, Boston Scientific has received three (3) reports of this rare behavior and associated transient device operating state out of approximately 136,000 EMBLEM S-ICDs. In all instances, the S-ICDs remained in service with no reports of associated patient injury.

#### Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue and reassured that the risk of harm due to this malfunction is low.
- The next patient follow-up should occur *in-person* in order to update the device software.
  - Model 3300 LATITUDE programmer with Model 3877 v1.04 software
  - Model 3200 EMBLEM programmer with Model 2877 v4.10 software
- If you have any questions, please contact your local Boston Scientific representatives or Boston Scientific Technical Services (1-800-227-3422).
- The CHRS device committee may update these recommendations should more data become available or if there are delays in approval of the software update.

#### CHRS Device Committee

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