Important Medical Device Advisory Update

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Performance Update – February 2022: Enhanced Battery Depletion (BD) alert for earlier detection of hydrogen-induced accelerated battery depletion in Model A209 or A219 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs).[1]

In December 2020, Boston Scientific committed to developing a software enhancement that detects and alerts healthcare professionals (HCPs) if an EMBLEM S-ICD exhibits hydrogen-induced accelerated battery depletion. *This enhanced software is now available and sales professionals are upgrading programmers.*

When an EMBLEM S-ICD is first interrogated by an upgraded programmer, the user will be notified via the programmer screen of the initiation of the update and a progress bar will be displayed indicating the progress of the update. This software update enhances the current BD alert to detect hydrogen-induced accelerated depletion. If depletion conditions are met, a BD alert is initiated, and the device emits 16 beeping tones every 9 hours (if beeping tones are enabled). For devices enrolled/active on LATITUDE™, HCPs will be notified of a BD alert after a successful transmission from the patient's in-home LATITUDE communicator.

Current Status. Since the December 2020 communication, the malfunction rates for the approximately 29,300 active devices that compose the combined August 2019 and December 2020 advisory populations have converged to approximately 11.6% at 5 years. This behavior continues to be highly detectable. 99.4% of the 2,776 S-ICDs that have exhibited this behavior were replaced before the battery reached a depleted state. Based on the malfunction rate and detectability of hydrogen-induced accelerated battery depletion, the theoretical, potential for life-threatening harm is projected at 1 in 200,000 at 5 years. The most common associated clinical outcome is early replacement and there have been no deaths associated with this behavior.

In August 2018, Boston Scientific transitioned EMBLEM S-ICDs to an alternative low voltage capacitor. EMBLEM S-ICDs built with this contemporary low voltage capacitor have NOT exhibited this depletion behavior.

Recommendations. The December 2020 ongoing follow-up recommendations for managing devices with the potential for hydrogen-induced accelerated depletion are unchanged. Specific to this software update, Boston Scientific recommends:

- Programmer Software Upgrade. Confirm programmers at your center have been upgraded.
  - Model 3300 LATITUDE Programmers are supported with Model 3877 v1.03 application
  - Model 3200 EMBLEM Programmers are supported with Model 2877 v4.09 application
- Next Follow-up. Boston Scientific continues to recommend 3-month follow-ups per labeling. Bearing in mind the risk versus benefits of in-person visits in the setting of the global COVID-19 pandemic, consider an in-person visit at the next scheduled follow-up, so the enhanced BD alert can be enabled in each affected device.

[1]Boston Scientific originally communicated in August 2019 and expanded the population in December 2020. Boston Scientific's Product Performance Report (PPR) includes advisory information at www.BostonScientific.com/ppr

  - When an EMBLEM S-ICD is first interrogated by an upgraded programmer, an S-ICD software update will be performed. Per labeling, monitor the patient and have external defibrillation equipment available as tachycardia therapy is suspended during a S-ICD software update.
  - If a BD alert occurs, follow screen prompts and contact Technical Services. Using device data, Technical Services can provide a replacement interval.
- Update Records. For each patient with an affected EMBLEM S-ICD, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.
- Distribute This Letter. Please distribute this update to all other physicians and healthcare professionals within or outside your organization who need to be aware of this topic.

Enclosed is a list of affected devices. As this enhanced software becomes available in other countries, Boston Scientific will distribute this update. Adverse reactions or quality problems experienced with the use of these or any devices should be reported to Boston Scientific and your local regulatory authority, as applicable. Up-to-date product performance information about this topic, including a device lookup tool[2], is available within our Product Performance Resource Center at www.bostonscientific.com/ppr. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

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[2]Available at www.BostonScientific.com/lookup

Appendix A: Affected Product Model/Part Numbers

Affected product models/GTIN numbers that compose the subset of hydrogen-induced accelerated battery depletion advisory populations: August 2019 and December 2020 advisory populations composed of approximately 29,300 active EMBLEM S-ICDs.

Product Name	Model	GTIN	Product Name	Model	GTIN
EMBLEM S-ICD	A209	00802526544101	EMBLEM S-ICD	A209	00802526575204
EMBLEM S-ICD	A209	00802526548406	EMBLEM S-ICD	A209	00802526575211
EMBLEM S-ICD	A209	00802526575105	EMBLEM S-ICD	A209	00802526575228
EMBLEM S-ICD	A209	00802526575112	EMBLEM S-ICD	A209	00802526599002
EMBLEM S-ICD	A209	00802526575129			
EMBLEM S-ICD	A209	00802526575136	EMBLEM MRI S-ICD	A219	00802526581519
EMBLEM S-ICD	A209	00802526575143	EMBLEM MRI S-ICD	A219	00802526584404
EMBLEM S-ICD	A209	00802526575167	EMBLEM MRI S-ICD	A219	00802526584411
EMBLEM S-ICD	A209	00802526575174	EMBLEM MRI S-ICD	A219	00802526590429
EMBLEM S-ICD	A209	00802526575181	EMBLEM MRI S-ICD	A219	00802526590436