



Safety Communication

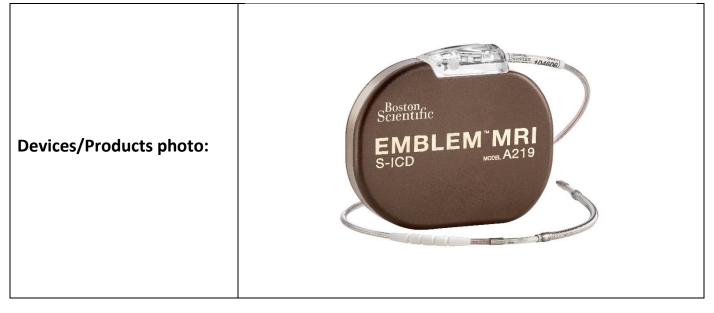
accelerated battery depletion cause elevated likelihood for early replacement

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Device/ Product Description:	Subcutaneous Implantable Cardioverter Defibrillators
Brand Name:	EMBLEM MRI S-ICDs
Lot numbers/Serials:	213750, 213773, 213831, 213852, 213925, 213954, 213960, 213971, 214034, 214037, 214051, 214072
Manufacturer:	Boston Scientific
Problem:	performance of EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) may result in a need for device replacement (ERI/EOL) earlier than expected due to compromised performance of an electrical component causing accelerated battery depletion.
Recommendation/Actions:	 monitor patients via LATITUDE to facilitate prompt detection of ERI/EOL Perform a device follow-up every 3 months via remote or inoffice interrogation. Promptly investigate any suspected indication of accelerated depletion Evaluate Risk for patients: with a history of life-threatening ventricular arrhythmias such as a secondary prevention indication or previous appropriate shock for VT/VF2. 2who are unable to be reliably followed every 3 months (via LATITUDE and/or in-clinic interrogation). 2who are not monitored via LATITUDE and are unable to hear beeping tones. Replace As Needed
	You can find more information and recommendations from (HERE).

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You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should <u>report any adverse events</u> suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector

Saudi Food and Drug Authority

Postal Address: Saudi Arabia - Saudi Food and Drug Authority

4904 northern ring branch rd - Hitteen Dist.

RIYADH 13513 - 7148

Tel: +966 (11) 2038222 Ext: 2995, 2952

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Or

Saudi Vigilance

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely, NCMDR Team



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