Safety Communication

accelerated battery depletion cause elevated likelihood for early replacement

<table>
<thead>
<tr>
<th>Device/ Product Description:</th>
<th>Subcutaneous Implantable Cardioverter Defibrillators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name:</td>
<td>EMBLEM MRI S-ICDs</td>
</tr>
<tr>
<td>Lot numbers/Serials:</td>
<td>213750, 213773, 213831, 213852, 213925, 213954, 213960, 213971, 214034, 214037, 214051, 214072</td>
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<tr>
<td>Manufacturer:</td>
<td>Boston Scientific</td>
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<tr>
<td>Problem:</td>
<td>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.</td>
</tr>
</tbody>
</table>

Recommendation/Actions:
- monitor patients via LATITUDE to facilitate prompt detection of ERI/EOL
- Perform a device follow-up every 3 months via remote or in-office 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/VF
  - who are unable to be reliably followed every 3 months (via LATITUDE and/or in-clinic interrogation).
  - who are not monitored via LATITUDE and are unable to hear beeping tones.
- Replace As Needed

You can find more information and recommendations from [HERE].
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 **report any adverse events** 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
Fax: +966 (11) 2757245
Or
**Saudi Vigilance**

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Sincerely,

NCMDR Team