FDA Patient Engagement Advisory Committee Meeting Medical Device Recalls

October 6, 2021

Gretchen Riccardi

Boston Scientific issues 3 S-ICD advisories on December 3, 2020

1. Elevated Likelihood of a Low Voltage Capacitor Causing Accelerated Battery Depletion.
2. Events of Electrical Overstress (i.e. damage to the device caused by electrical shorting) During Delivery of High Voltage Therapy.
3. Electrode Body Fractures at a Location Just Distal to the Proximal Sense Ring.

The Heart Rhythm Society's Recommendations Common to All Three Advisories:

1. Monitor patients through LATITUDE patient management system per the 2015 HRS Consensus Statement on remote monitoring.
2. Demonstrate and assess the patient's ability to hear the beeping alert in clinic.
   Repeat beeper demonstration in patients not followed by LATITUDE after an MRI which can affect the beeper volume.
   Remind patients to promptly call if they hear beeping tones.
3. Perform a device follow-up every 3 months either remotely or in person.

https://www.hrsonline.org/guidance/safety-alerts/safety-advisories-boston-scientific-emblem-s-icd

FDA Class I recall Boston Scientific EMBLEM S-ICD Subcutaneous Electrode (Model 3501) Due to Risk of Fractures

(content current as of 2/10/2021, Devices Recalled in the U.S.: 19,919)

What to Do

- On December 2, 2020, Boston Scientific sent an Important Medical Device Advisory letter to all affected customers with recommendations for prompt identification of devices at risk for electrode body fracture. Recommendations were offered to help physicians and patients evaluate the risks of using affected devices compared to replacing them. Care for recalled devices at risk for failure were provided:
- **Enroll and monitor patients through LATITUDE remote monitoring to detect any alerts or artifacts on the devices in between office device checks.**
  - **Ask patients to do weekly remote checks**
- Perform a system follow-up every three months by remote or in-office checks.

https://www.fda.gov/medical-devices/medical-device-recalls/boston-scientific-recalls-emblem-s-icd-subcutaneous-electrode-model-3501-due-risk-fractures

FDA Class I recall: Boston Scientific Corporation Recalls EMBLEM S-ICD (Subcutaneous Implantable Cardioverter Defibrillator) System Due to Risk of Short-Circuit

(content current as of 2/19/2021, Devices Recalled in the U.S.: 2825)

What to Do

- In December 2020, Boston Scientific sent an Urgent Medical Device Advisory to all affected customers. The notice instructed customers to:
- Follow-up in the next 6 weeks and discuss this advisory with patients to ensure awareness, to review their individual clinical status and perspective, and to determine their individual risk status.
  - Perform a system follow-up every 3 months per labeling thereafter via remote or in-office interrogation.
- **Enroll and monitor patients through LATITUDE remote monitoring to detect any alerts or artifacts on the devices in between office device checks.**

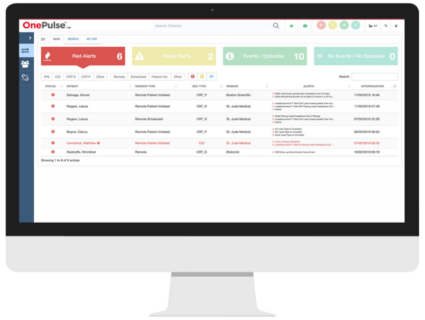
https://www.fda.gov/medical-devices/medical-device-recalls/boston-scientific-corporation-recalls-emblem-s-icd-subcutaneous-implantable-cardioverter

Remote Monitoring (RM) Network

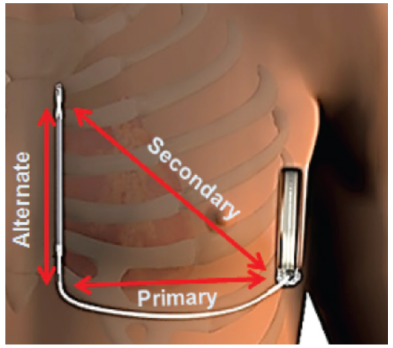
Entire RM network operates outside of HIPAA Privacy Law

SICD RM paradigm - 13 week cycle consists of:
-- 12 consecutive, weekly “Alert” checks which only produce reports if an alert is flagged
-- 1 full device interrogation test which results in a quarterly medical report

RM service providers



.PDF files and IDCO formatted data



Telemetry

Internet
Cellular
Network

Internet
SMS
Fax
Phone

Patient

Home Transmitter

Manufacturer Server
(unregulated, unlicensed laboratory?)

Physician Office
Login access to Mfr website
and/or RM service provider

RM configuration settings

RM configuration settings

Phone contact between Patient and Physician

Note: Each CIED manufacturer has a similar remote monitoring service /network design.

Remote Monitoring (RM) Network
What goes into patient's medical record?

HIPAA Privacy Law guarantees patients have right of access to data held by Covered Entities.

Physician Office
Login access to Mfr website and/or RM service provider (outside of HIPAA Privacy Law).

Physician decides which interrogation reports to copy into patient's medical record.

Covered Entity Health Record warehouse

Patient Access
Patients can access Interrogation reports via Patient Portals or medical record requests.

S-ICD Medical Device Recall Issues:

- The FDA's S-ICD Class 1 recalls stipulates that physicians should enroll and monitor patients through Boston Scientific's Latitude RM system.

  BUT – Per OCR's decisions of my HIPAA complaint and HIPAA reconsideration request, the Latitude Remote Monitoring system operates outside of HIPAA Privacy Law.

- Boston Scientific's Latitude RM system weekly "Alert checks" do not generate benign report results.

  Patients submit weekly device "Alert" medical tests to check for device malfunctions, however there are no corresponding reports for benign test results. The Latitude system works on a "no news is good news" notification methodology. If an Alert is triggered, a full device interrogation report is generated.

- Physicians don't have the ability to conduct in-person S-ICD "Alert" checks.

  Only RM home communicators can perform Alert checks. Hand-held, in-person S-ICD programmers can only perform full device interrogations. There is no option within S-ICD programmers to just check S-ICDs for triggered alerts.

- Latitude Remote Monitoring system does not have a patient report detailing the alert conditions (e.g. device battery is depleted, high electrode impedence etc) being monitored. These settings can be configured and disabled remotely without patient notification.

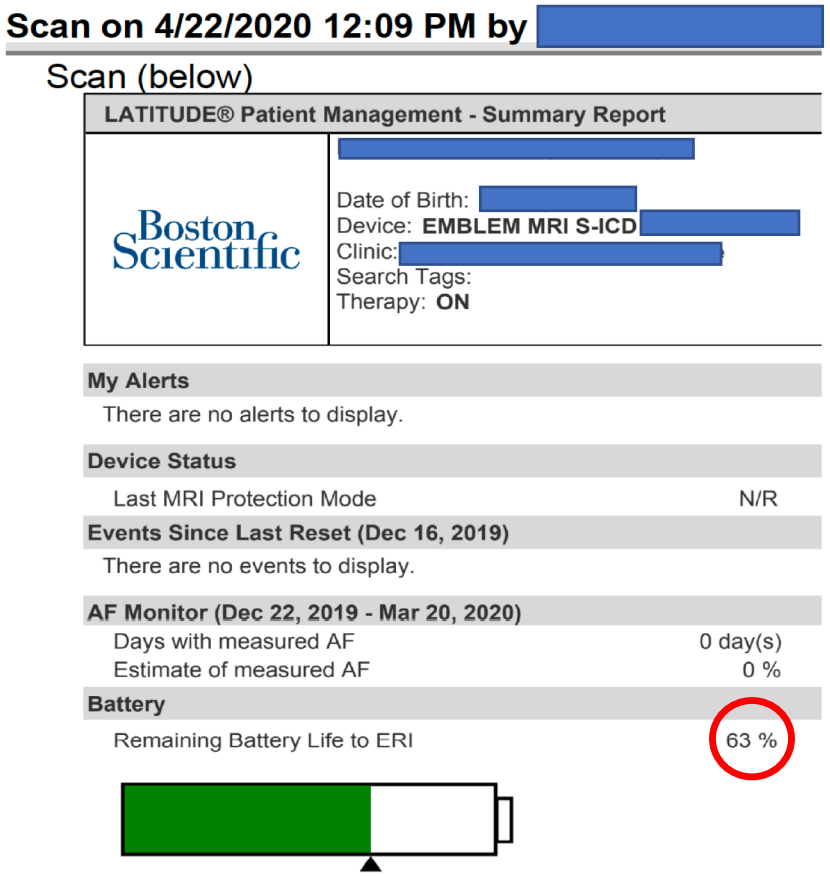
  Latitude downloads RM configuration changes automatically to patient home communicators. There is no patient notification system for RM setting changes currently in place. Patients can't confirm if RM Alerts are ON or OFF. See Appendix II detailing Remote Monitoring Alerts.

Appendix I – My S-ICD Early Battery Depletion (Model A219) issue:

My physician informed me on June 30, 2020 (6 days after the Interrogation report date) that I had a malfunctioning S-ICD.

On December 3, 2020, Boston Scientific issued a product advisory detailing early battery depletion issues. The large decrease in my remaining battery life over a 3-month period was due to a switchover from a calculated battery percentage to actual battery percentage.

March 20, 2020 Interrogation Report



Scan on 4/22/2020 12:09 PM by [redacted]

Scan (below)

LATITUDE® Patient Management - Summary Report

[redacted]

Boston Scientific

Date of Birth: [redacted]
Device: **EMBLEM MRI S-ICD** [redacted]
Clinic: [redacted]
Search Tags:
Therapy: **ON**

My Alerts

There are no alerts to display.

Device Status

Last MRI Protection Mode	N/R

Events Since Last Reset (Dec 16, 2019)

There are no events to display.

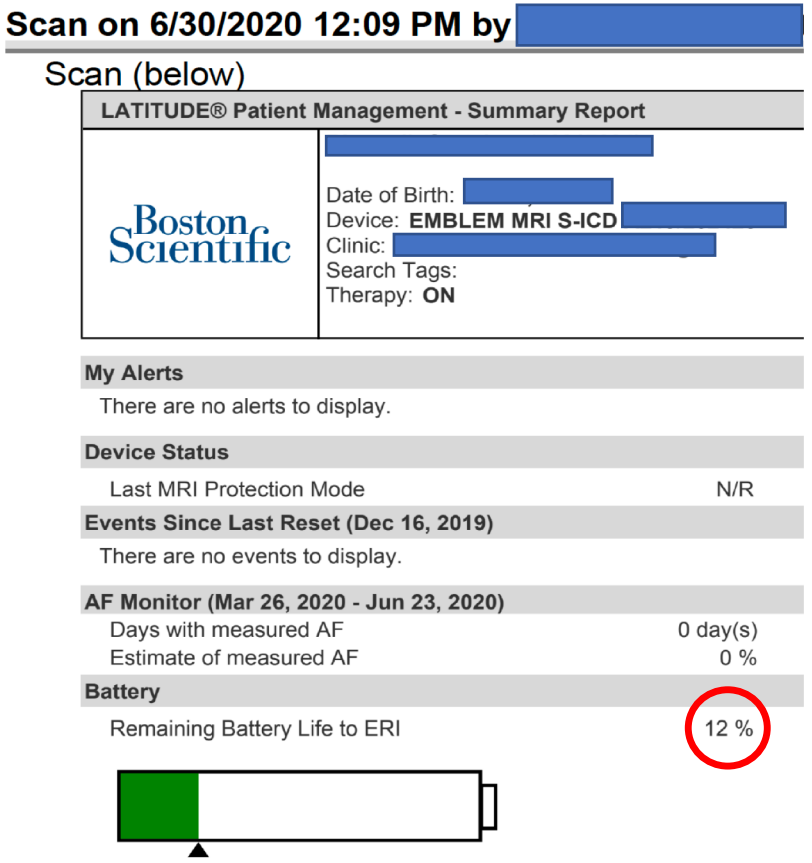
AF Monitor (Dec 22, 2019 - Mar 20, 2020)

Days with measured AF	0 day(s)
Estimate of measured AF	0 %

Battery

Remaining Battery Life to ERI	63 %

June 24, 2020 Interrogation Report



Scan on 6/30/2020 12:09 PM by [redacted]

Scan (below)

LATITUDE® Patient Management - Summary Report

[redacted]

Boston Scientific

Date of Birth: [redacted]
Device: **EMBLEM MRI S-ICD** [redacted]
Clinic: [redacted]
Search Tags:
Therapy: **ON**

My Alerts

There are no alerts to display.

Device Status

Last MRI Protection Mode	N/R

Events Since Last Reset (Dec 16, 2019)

There are no events to display.

AF Monitor (Mar 26, 2020 - Jun 23, 2020)

Days with measured AF	0 day(s)
Estimate of measured AF	0 %

Battery

Remaining Battery Life to ERI	12 %

Appendix I (cont'd) – Excerpts from Boston Scientific's December 2020 S-ICD Advisory detailing Early Battery Depletion issues:

Boston Scientific is expanding an August 2019 advisory device population to a total of approximately **38,350 active EMBLEM S-ICDs** (Models A209 and A219) with an elevated likelihood of a low voltage capacitor causing accelerated battery depletion.

- In EMBLEM S-ICDs, battery capacity is determined with a **two-phase battery monitoring algorithm**. At the beginning of battery life, the algorithm determines battery capacity using both implant time and charging cycles and then transitions to using solely the battery's voltage to determine capacity later in life. Since the algorithm's early-life inputs are independent of battery voltage, the estimated percentage of Remaining Battery Life to ERI will decrease at the same rate whether the battery is depleting normally or in an accelerated fashion.
- **When the battery reaches the level at which the battery monitoring algorithm transitions to determining capacity solely using voltage, a device experiencing accelerated depleting battery will exhibit a relatively large decrease in Remaining Battery Life to ERI** (e.g., between follow-ups, a decrease from 60% at the preceding check to 18% at the check 3 months later). This notable decrease in Remaining Battery Life happens as part of the design of the S-ICD's two-phase battery monitoring algorithm. It is not indicative of an actual abrupt change in Remaining Battery Life. The algorithm reflects the accelerated battery depletion when it shifts to solely using battery voltage later in life. The battery status monitor functions as intended.

https://www.bostonscientific.com/content/dam/bostonscientific/quality/dlt/reg-code-228/2020Dec_BSC_EmblemPBD_PhysLtr_US_Final.pdf

Appendix II: Boston Scientific Remote Monitoring Alerts:

Table 2. LATITUDE™ NXT Alerts for the EMBLEM™ S-ICD

Grouping	Alert	Configurable via LATITUDE System (Nominal)
S-ICD	Device battery has reached End of Life (EOL)	ON
	High Electrode Impedance [5]	ON
	Therapy Off	ON
	Possible device malfunction [5]	ON
	Device battery has reached Elective Replacement Indicator (ERI)	ON, OFF (ON)
	Shock therapy delivered to convert arrhythmia	ON, OFF (ON)
	Untreated episode	ON, OFF (ON)
	Sensing not fully optimized	ON, OFF (ON)
	Measured AF of at least {> 0, 0.5, 1, 3, 6, or 12} hours in a 24 hour period (A219 only)	ON, OFF (ON) (If ON > 0 hours in a 24 hour period)
	Weight gain of at least {0.45, 0.911, 1.36, 1.81, 2.27, 2,72, 3.18, 3.63, 4.08, or 4.54} kg(s) or {1, 2, 3, 4, 5, 6, 7, 8, 9, or 10} lb(s) in {1-7} day(s)	ON, OFF (OFF) (If ON - 2.27 kgs /5 lbs, 7 days)

Note: On April 20, 2020, as part of the Latitude NXT 6.1.5 software release, Boston Scientific released a new Yellow Alert for the S-ICD called “SMART Pass Disabled” which will trigger if the S-ICD firmware automatically disables the SMART Pass filter.

https://www.bostonscientific.com/content/dam/bostonscientific/quality/education-resources/english-a4/EN_ACL_LATITUDE_NXT_Alerts_20200213.pdf