Boston Scientific

Urgent Field Safety Notice

SUBJECT: Urgent Field Safety Notice. S-ICD programmer software version 4.04 addresses two previous Field Safety Notices (ref. 100000038388 and ref. 92127890)

Dear Doctor,

Boston Scientific has previously advised physicians about two behaviors described below that are associated with the S-ICD system. Boston Scientific is now releasing programmer software version 4.04 to address these behaviors and your local Boston Scientific representative will arrange to update your programmer soon.
S-ICD Behaviors Addressed By Version 4.04 Software.

The version 4.04 S-ICD Programmer software addresses both behaviors below, by eliminating the potential for RF interference to cause an unintended therapy command and preventing repeated atypical energy delivery due to memory corruption.

1. S-ICD Unintended Programmer Command Behavior
   In January 2017, Boston Scientific advised physicians about the potential for radio frequency (RF) interference to alter wireless communication from a programmer, which in rare instances may cause an S-ICD[1] to perform an unintended command. Recently Boston Scientific released software in North America, Europe, and several other countries to address the programmer command behavior for EMBLEM™ S-ICDs. Now with the release of version 4.04 software, this behavior is addressed for **all** Boston Scientific S-ICDs, including SQ-RX™.

2. S-ICD Memory Corruption Behavior
   In June 2017, Boston Scientific advised physicians about a single, isolated S-ICD event that resulted in a device-related patient death. This was caused by repeated atypical energy delivery due to corruption of a specific memory location from radiation within the environment.

Recommendations for S-ICD and Programmers
- Confirm all Model 3200 S-ICD programmers are upgraded with version 4.04 software.
- Once your Model 3200 S-ICD programmers are upgraded, perform a standard in-clinic S-ICD follow-up for all patients implanted with an S-ICD at their earliest convenience. The January 2017 recommendation to perform a second interrogation is no longer required.
  Note: The programmer will upgrade each S-ICD's software which takes less than 5 minutes.
- Thereafter, standard in-clinic S-ICD follow-up checks may resume at normal frequency with programmers upgraded with version 4.04 software.
  Note: When an S-ICD's software has been upgraded, it can only be interrogated with programmers installed with version 4.04 or greater software. Appendix A shows how the software model and version number can be identified through the programmer or an S-ICD summary report.

Additional Information
Boston Scientific recognizes the impact of communications on both you and your patients, and wants to reassure you that patient safety remains our highest priority. If you have additional questions regarding this information or would like to report clinical events, please contact your Boston Scientific representative or Technical Services.

Sincerely,

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[1] EMBLEM Model A209/A219 and SQ-RX Model 1010

Appendix A – Identification of S-ICD Programmer Software
To identify the version of software on a Model 3200 S-ICD Programmer

1. Select Programmer Settings	
2. Select About Programmer	
3. Software that is version 4.04 or higher addresses this behavior for S-ICDs	

Appendix A – Identification of S-ICD Programmer Software (Continued)

The programmer software version used for each in clinic follow-up is documented on the top of the Summary Report.

SUMMARY REPORT

Boston Scientific

Report Printed: 07/25/2017 7:17 AM
Programmer Software Version: 4.04
Device Software Version: 3.1.539

Patient Name:
Last Follow-up Date: 07/25/2017
Follow-up Date: 07/25/2017
Implant Date: 07/17/2017

Device Model#: A219 EMBLEM™ MRI S-ICD
Device Serial#:
Electrode Model#: 3010
Electrode Serial#:

Programmable Parameters

Current Device Settings
Therapy: ON
Shock Zone: 220 bpm
Conditional Shock Zone: 200 bpm
Post Shock Pacing: ON
SMART Pass: ON

Gain Setting: 1X
Sensing Configuration: Alternate
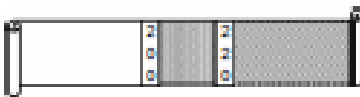
Initial Device Settings
Therapy: ON
Shock Zone: 220 bpm
Conditional Shock Zone: 200 bpm
Post Shock Pacing: ON
SMART Pass: ON

Gain Setting: 1X
Sensing Configuration: Alternate
Shock Polarity: STD

Parameter changes this session: NO

Device Status

AF Monitor 07/18/2017 - 07/24/2017
Days with measured AF: 0 Days
Estimate of measured AF: 0%

Lifetime MRI Protection Mode Count: 1
Last MRI Protection Mode: 07/25/2017

Episode Summary

Since Last Follow-Up
Untreated Episodes: 0
Treated Episodes: 0
# of Shocks Delivered: 0

Since Implant
Untreated Episodes: 0
Treated Episodes: 0
# of Shocks Delivered: 1

Battery Status

Remaining Battery Life to ERI: 95%

Electrode Impedance Status

OK

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