Important
Medical Device Information

Cardiac Rhythm Management
4100 Hamline Avenue North
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www.bostonscientific.com

June, 2017

Dear Doctor,

Boston Scientific is committed to prompt and transparent communication about matters of patient safety. We want to inform you, as a physician who manages the care of patients with an S-ICD system, of a single, isolated S-ICD event that resulted in a device-related patient death in May of this year. We are providing the following information to you in order to address questions and concerns you or your patients may have about this event.

Boston Scientific engineers have determined that this patient's S-ICD repeatedly delivered an atypical amount of energy (similar to the arrhythmia induction function) because a specific memory location was corrupted by radiation[1] within the environment. This repeated atypical energy delivery prevented S-ICD arrhythmia detection/treatment and ultimately contributed to the patient death.

This device behavior has been simulated in a laboratory setting by corrupting two specific adjacent bits of device memory on similar model S-ICDs. Testing results correlated with information available from this event. Although this device behavior is highly unlikely to reoccur, Boston Scientific is actively developing an S-ICD software update to mitigate the effects of memory corruption by preventing atypical energy delivery. We expect software to be completed in July with submissions to Regulatory Authorities shortly thereafter[2]. You will receive additional communication when software is available in your country.

Root Cause Investigation
In the three weeks following notification of this event, Boston Scientific conducted an immediate investigation of the clinical data, performed a detailed analysis of the returned S-ICD system, assessed the system's software, and initiated work on an update to the software. Based on the information available, we have concluded that the memory corruption was due to a transient change of the S-ICD operating state caused by what engineers refer to as a single event upset (SEU). An SEU is a change of state in the device memory induced by environmental radiation interacting with a specific memory location.

Based on information received during the investigation, it does not appear that the patient was subjected to any readily identifiable external source of ionized particles (e.g., ionizing radiation therapy) prior to the event. All electronic devices utilizing integrated circuits are susceptible to SEUs. Cardiac implantable electronic devices include mechanisms to detect and correct memory corruption in order to reduce the occurrence of potentially adverse malfunctions. However, device memory corruption is not always detectable. This is especially true if corruption impacts multiple bits in an area of memory that is expected to change as software performs device operations, as was the case in this event.

Root cause investigation of this event identified a single scenario that could lead to this behavior in an S-ICD. Boston Scientific engineers simulated this scenario by corrupting two specific adjacent bits of memory on representative S-ICDs within a laboratory setting. Testing demonstrated energy output similar to the arrhythmia induction function, correlating with information available from this event. Additional simulations were performed in attempts to produce this behavior and no other scenarios were identified. Boston Scientific has concluded that the corruption of the two adjacent memory locations in this event was due to an SEU.

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[1] Ionized subatomic particle such as an alpha particle, neutron, or high energy proton
[2] The S-ICD software that addresses this device behavior will be v4.04 or higher

Observed Rate
This experience represents one (1) observed event in approximately 37,000 S-ICDs distributed worldwide. Given the rarity of this single event observed to date, a precise projection of occurrence cannot be derived with confidence. Engineering analysis of S-ICD device memory design and recorded instances of SEUs in fielded devices was conducted during our root cause investigation of this event. Based on this analysis, the probability of corruption of the specific location in memory that produces this device behavior within an S-ICD was determined to be approximately 1 in 300,000 over five years. Although reoccurrence of this device behavior is highly unlikely, Boston Scientific is developing software mitigations for EMBLEM™ S-ICDs (Model A209 and A219) and SQ-RX™ S-ICDs (Model 1010) to prevent this from occurring in the future. It is important to note that this particular device behavior cannot occur with any Boston Scientific transvenous defibrillators or pacemakers due to differences in hardware and software.

Recommendations
In consultation with our Patient Safety Advisory Board, Boston Scientific recommends NO changes to clinical follow-up due to this single event. Specifically, for patients with S-ICD systems:

- Continue using the S-ICD system to detect and treat life-threatening ventricular tachyarrhythmias;
- Keep scheduled LATITUDE™ and/or in clinic follow-ups; and
- Follow the precautions identified in the S-ICD user's manual when radiation therapy is prescribed.

Furthermore, Boston Scientific does NOT recommend the following:

- Early or off-cycle follow-ups are not recommended. This type of memory corruption cannot be detected, thus additional S-ICD checks do not reduce the potential for this device behavior.
- Prophylactic S-ICD replacement or explant is not recommended. The risks associated with such an additional surgical procedure significantly outweigh the risk of reoccurrence of this device behavior.

Until the software mitigation update is available, this S-ICD behavior represents an additional, small risk that should be considered when evaluating the relative risks associated with all available ICD therapy options.

Additional Information
Patient safety is our highest priority. As stated above, we have provided this communication to address questions or concerns that may arise from this event. If you require additional information regarding this communication or would like to report any clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,

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June 2017

Dear Patient,

Boston Scientific recently sent important information to your heart doctor about a problem that happened with another patient's Boston Scientific subcutaneous implantable cardioverter defibrillator (S-ICD) system, which resulted in the patient's death.

Our review showed that this was a rare event caused by interference from environmental radiation. Although Boston Scientific has found that this is very unlikely to happen ever again, we will prevent this in the future with a software change[1]. We are working to have the software available in the US, Europe, and most other countries by the end of the year. When it is available, your doctor will be able to update your S-ICD in the office.

What should you do?
We are sending this letter to you because we want you to have the most accurate information. There is nothing new that you need to do at this time. Please continue to follow your doctor's instructions. As always, if you hear beeping from your defibrillator, please contact your doctor.

Patient safety is our highest priority. We recommend that you discuss this letter with your doctor, who knows best how this new information may affect you.

Sincerely,

[1]The S-ICD software that addresses this will be v4.04 or higher

Important Medical Device Information

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May 2017

Dear Doctor,

Earlier this year 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. This behavior can ***only*** occur during an active, in-clinic interrogation/programming session with the Model 3200 S-ICD programmer. Boston Scientific is now releasing programmer software version 4.03 to address this behavior for EMBLEM™ S-ICDs[2] and your local Boston Scientific representative will arrange to update your programmer soon. Programmer software for SQ-RX S-ICD[3] is being developed and until available, the recommendations for programmer interrogations of SQ-RX S-ICDs are unchanged.

Once the S-ICD Programmer model 3200 has been upgraded with the new software by a Boston Scientific representative, the potential for RF interference to cause an unintended therapy command will be resolved for all the EMBLEM S-ICD devices. The software model and version number can be confirmed by following the directions in Appendix A. In clinic EMBLEM S-ICD device checks may resume at normal frequency when the programmer software is upgraded to v4.03 software. Also, there is no need to perform a second interrogation after the programmer software has been upgraded.

Boston Scientific is also developing software to mitigate this behavior for SQ-RX S-ICDs and anticipates software will be available in most countries in late 2017 or early 2018. A communication will be distributed when the software is available. Until a programmer software update is available for SQ-RX S-ICDs, Boston Scientific recommends the following:

- Consider reducing the frequency of in-clinic checks while following medical society guidelines.[4] The SQ-RX S-ICD is not compatible with the LATITUDE Patient Management System.
- When performing a programming change or device check of an SQ-RX using a Model 3200 S-ICD Programmer:
  - ensure external defibrillation equipment and medical personnel skilled in CPR[5] are available during in-office follow-up testing and do not leave the patient unattended
  - place the telemetry wand directly over the S-ICD at all times and increase the distance between any source of interference and the programmer and S-ICD as much as possible
  - minimize the duration of programmer communications and end the programmer telemetry session promptly after completion
- When the programmer is communicating with an SQ-RX S-ICD, it is possible that this behavior may alter temporary parameters without the user's knowledge. Altering of temporary parameters may result in an inability for the SQ-RX S-ICD to detect a tachyarrhythmia or an inappropriate detection of a heart rhythm.
  - To initiate a defibrillation therapy, press the Rescue Shock icon and follow screen prompts.
  - To abort an inappropriate shock, press the Abort button while the S-ICD is charging
- When the programming change or device check is complete, confirm SQ-RX S-ICD settings by performing the following steps:
  - end the original telemetry session
  - initiate a new telemetry session
  - print a device Summary Report (see Appendix B)

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[1] Subcutaneous Implantable Defibrillator
[2] EMBLEM S-ICD Model A209 and EMBLEM MRI S-ICD Model A219
[3] SQ-RX S-ICD Pulse Generator Model 1010
[4] 2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. Heart Rhythm, Vol 9, No 10, October 2012, page 1746, Table 3. In person checks for S-ICD's without evidence of battery depletion 3-6 months and with battery depletion 1-3 months. http://dx.doi.org/10.1016/j.hrthm.2012.08.021
[5] Cardiopulmonary Resuscitation

- end the telemetry session
- confirm device settings: if any settings have been altered from intended programming, contact Technical Services.
- instruct the patient to contact their physician if the device emits beeping tones

Description and Clinical Implications
The Model 3200 S-ICD programmer is a non-implantable, tablet computer that communicates wirelessly (telemetry) with an implanted S-ICD in order to adjust programmable settings and to collect patient data. Programmer User's Manual includes a warning that the presence of other equipment operating in the same frequency bands as the programmer may interfere with telemetry. RF interference can be reduced or eliminated by moving away from the source of interference and ensuring the wand is placed directly over the S-ICD.

Both the programmer and the S-ICD check the validity of telemetry commands using an algorithm intended to detect whether these commands have been altered. In nearly all instances, invalid commands are rejected. In rare instances, interference may go undetected and alter communications from the programmer. This can potentially result in the S-ICD performing an induction, utilizing temporary parameters that impair the S-ICD from detecting or treating a tachyarrhythmia during the active telemetry session, or disabling therapy in the permanent programming mode such that therapy will be unavailable after the telemetry session is ended.

Because the programmer display may not match device programming when this behavior occurs, ending the session and re-interrogating the S-ICD is an effective means to check the permanently programmed device parameters. The potential for this behavior to occur during this brief re-interrogation is extremely remote.

All communications between the programmer and S-ICD remain secure. This behavior is not related to a cybersecurity vulnerability. For SQ-RX patients, physicians should continue to use the Model 3200 S-ICD programmer using the recommendations provided. There have been no reports of permanent injury or death associated with this behavior.

Rate of Occurrence
There have been no additional observations of unintended programming commands or data changes in the SQ-RX™ S-ICD beyond the three original observations disclosed previously. One of the three was associated with a restoration of factory nominal parameters. None of the three were associated with permanent injury or death. Since there have not been any additional events beyond the three previously disclosed, the probability of serious adverse consequences for SQ-RX S-ICD has not changed from the estimated 1 in 200,000 at 5 years cited in the original Field Safety Notice.

Affected Programmer
Model 3200 S-ICD programmers. This programmer is the only means to program implanted S-ICDs and should remain in service at the institution.

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

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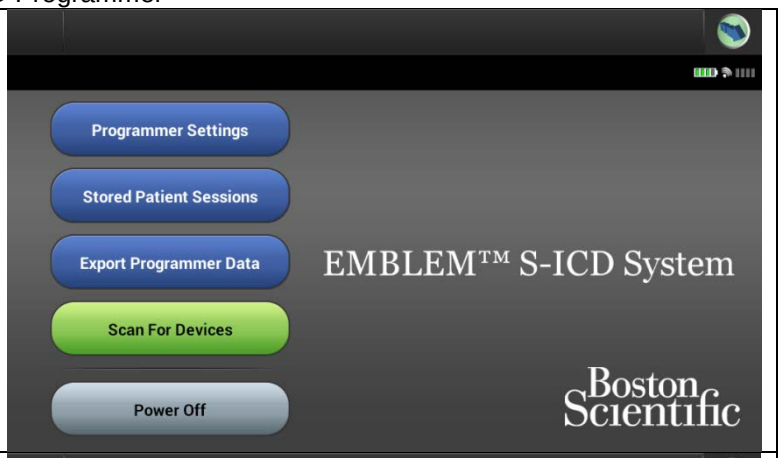
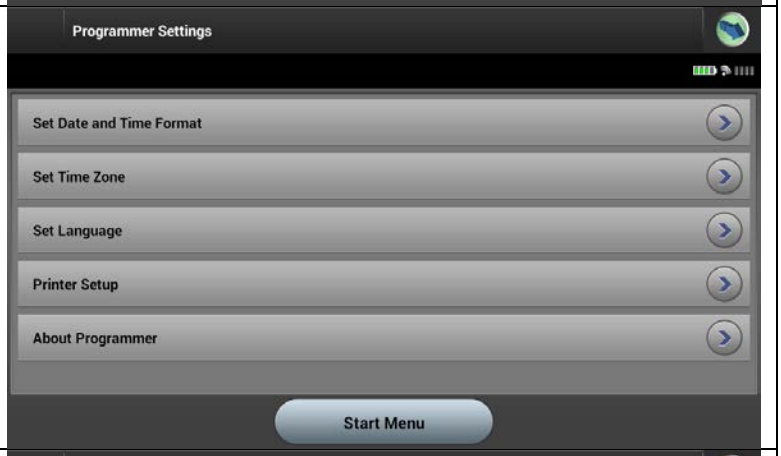
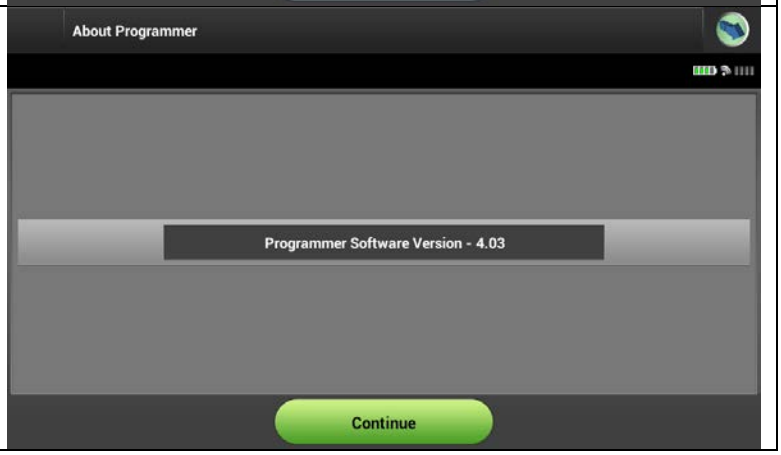
Appendix A – Identification of Programmer Software

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 4.03 or higher addresses this behavior for EMBLEM S-ICDs	

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Appendix A – Identification of Programmer Software (Continued)
The programmer software version used for each S-ICD in clinic follow-up is documented on the top of the Summary Report.

SUMMARY REPORT

Boston Scientific

Report Printed: 03/06/2017 8:32 AM
Programmer Software Version: 4.03

Patient Name:
Last Follow-up Date: 03/06/2017
Follow-up Date: 03/06/2017
Implant Date: 03/06/2017

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: ON
Days with measured AF: N/R
Estimate of measured AF: N/R

Lifetime MRI Protection Mode Count: 2
Last MRI Protection Mode: 03/06/2017

Episode Summary

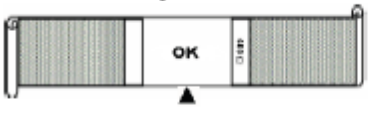
Since Last Follow-Up
Untreated Episodes: 0
Treated Episodes: 0
# of Shocks Delivered: 0

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

Battery Status

Remaining Battery Life to ERI: 100%

Electrode Impedance Status



Appendix B – Sample S-ICD Summary Reports

SUMMARY REPORT

Boston Scientific

Report Printed: 05/01/2017 8:05 AM
Programmer Software Version: 4.01
Device Software Version: 2.7.422

Patient Name: Sample Patient
Last Follow-up Date: 05/01/2017
Follow-up Date:
Implant Date: 08/04/2016

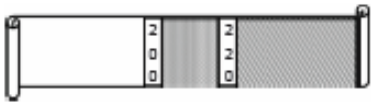
Device Model#: 1010 SQ-RX
Device Serial#:
Electrode Model#:
Electrode Serial#:

Programmable Parameters

Current Device Settings

Therapy: ON
Shock Zone: 220 bpm
Conditional Shock Zone: 200 bpm
Post Shock Pacing: 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

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

Parameter changes this session: NO

Episode Summary

Since Last Follow-Up

Untreated Episodes: 0
Treated Episodes: 0
# of Shocks Delivered: 0

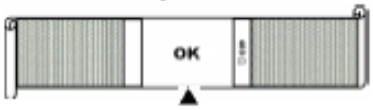
Since Implant

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

Battery Status

Remaining Battery Life to ERI: 79%

Electrode Impedance Status



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