Urgent Field Safety Notice

23 June 2017

SUBJECT: Urgent Field Safety Notice- Ref. 100000038388-FA – Revision C - Model 3200 S-ICD Programmer follow-up letter

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)
  - end the telemetry session

[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

- 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.

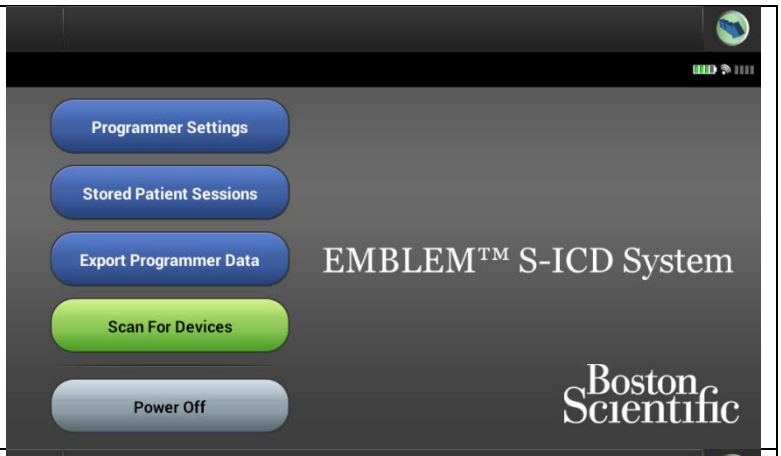
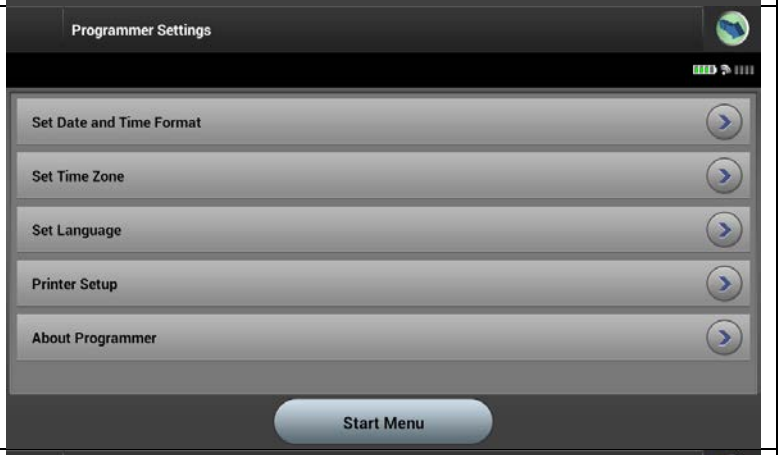
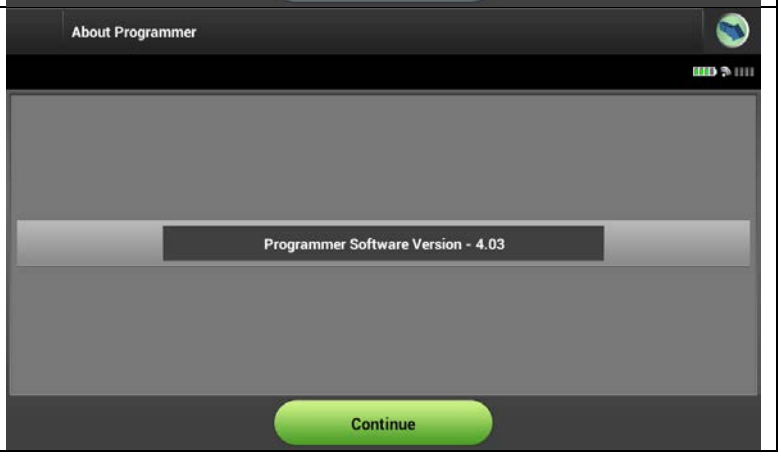
Sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

[1]Subcutaneous Implantable Defibrillator
[2]Magnetic Resonance Imaging

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	

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

Report Printed: 03/06/2017 8:32 AM
Programmer Software Version: 4.03
Device Software Version: 3.1.536

Patient Name: Test 1037-010
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#: 183125
Electrode Model#: 3010
Electrode Serial#: a123456

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

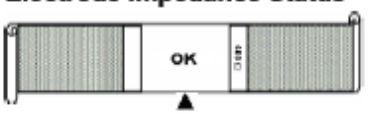
Since Last Follow-Up
Untreated Episodes: 0
Treated Episodes: 0
# of Shocks Delivered: 0

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

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: 05/01/2017
Implant Date: 08/04/2016

Device Model#: 1010 SQ-RX
Device Serial#: 20092
Electrode Model#: 3010
Electrode Serial#: a123456

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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