

01 February 2017

SUBJECT: Urgent Field Safety Notice- Ref. 10000038388-FA - Model 3200 S-ICD Programmer follow-up letter

Dear Doctor,

In conjunction with the Health Products Regulatory Authority (HPRA), Boston Scientific (BSC) is reissuing this Field Safety Notice (FSN) letter of 12 January 2017. BSC wants to provide you with Appendix B (enclosed) which provides additional guidance and clarification. No other changes have been made to this FSN.

This letter provides important product performance information regarding the potential for radio frequency (RF) interference to alter wireless communication from a programmer, which in rare instances may cause an S-ICD¹ 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. There is no risk of this behavior occurring when the LATITUDE Patient Management System communicates with an S-ICD in an ambulatory setting. Boston Scientific is developing software to mitigate this behavior. Until a software update is available, Boston Scientific recommends the additional precautions listed below.

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 labeling 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.

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. The LATITUDE Patient Management System (remote monitoring) is not subject to this behavior and is a reliable way to check S-ICD settings and performance. There have been no reports of permanent injury or death associated with this behavior.

Rate of Occurrence

Seven observations of unintended programming commands or data changes have been observed within the population of approximately 16,400 EMBLEM and EMBLEM MRI² S-ICDs. Four of the seven had the potential to impact health, but all were successfully detected and managed without patient harm. For the EMBLEM S-ICD, the probability of serious adverse consequence is estimated to be 1 in 25,000 at 5 years.

¹Subcutaneous Implantable Defibrillator

²Magnetic Resonance Imaging

Three observations of unintended programming commands or data changes have occurred with the SQ-RX™ S-ICD. One of the three was associated with a restoration of factory nominal parameters. None of the three were associated with permanent injury or death. For SQ-RX S-ICD, the probability of serious adverse consequences is estimated to be 1 in 200,000 at 5 years.

Recommendations

Boston Scientific is developing software to mitigate this behavior. Until updated software is available, the recommendations below mitigate the risks associated with this behavior:

- Using the LATITUDE Patient Management System for routine S-ICD assessments will minimize the number of programmer interactions with an S-ICD.
- If the LATITUDE Patient Management System is not available, consider reducing the frequency of in-clinic checks while following medical society guidelines.³
- When performing any S-ICD programming or check using a Model 3200 S-ICD Programmer:
 - ensure external defibrillation equipment and medical personnel skilled in CPR⁴ are available during implant and 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 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 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 S-ICD programming or check is complete, confirm S-ICD settings by performing the following steps:
 1. end the original telemetry session
 2. initiate a new telemetry session
 3. print a device Summary Report (see Appendix A)
 4. end the telemetry session
 5. confirm device settings: if any settings have been altered from intended programming, contact Technical Services.
 6. instruct the patient to contact their physician if the device emits beeping tones

See Appendix B for additional details and clarification.

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,

³2012 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>

⁴Cardiopulmonary Resuscitation

Appendix A – Sample S-ICD Summary Reports



SUMMARY REPORT

Report Printed: 11/17/2016 10:30 AM
GenE Software Version: 1.27.0
Device Software Version: 3.1.529

Patient Name:
Last Follow-up Date: 09/12/2016
Follow-up Date: 09/13/2016
Implant Date:

Device Model #: A209 EMBLEM™ S-ICD
Device Serial #:
Electrode Model #: 3401
Electrode Serial #:

Current Device Settings

Therapy: ON
Shock Zone: 250 bpm
Conditional Shock Zone: 200 bpm
Post Shock Pacing: ON
SMART Charge: 1.83 s (8 intervals)
SMART Pass: ON

Gain Setting: 1X
Sensing Configuration: Primary



Programmable Parameters

Initial Device Settings

Therapy: ON
Shock Zone: 250 bpm
Conditional Shock Zone: 200 bpm
Post Shock Pacing: ON
SMART Charge: 1.83 s (8 intervals)
SMART Pass: ON

Gain Setting: 1X
Sensing Configuration: Primary
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

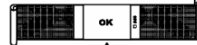
Untreated Episodes: 2
Treated Episodes: 2
of Shocks Delivered: 3

Battery Status



Remaining Battery Life to ERI: 93%

Electrode Impedance Status



SUMMARY REPORT

Report Printed: 10/05/2016 04:14 PM
GenE Software Version: 1.27.0
Device Software Version: 2.7.422

Patient Name:
Last Follow-up Date: 08/11/2016
Follow-up Date: 09/23/2016
Implant Date:

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

Current Device Settings

Therapy: ON
Shock Zone: 250 bpm
Conditional Shock Zone: 200 bpm
Post Shock Pacing: ON

Gain Setting: 1X
Sensing Configuration: Secondary



Programmable Parameters

Initial Device Settings

Therapy: ON
Shock Zone: 250 bpm
Conditional Shock Zone: 200 bpm
Post Shock Pacing: ON

Gain Setting: 1X
Sensing Configuration: Secondary
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

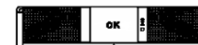
Untreated Episodes: 0
Treated Episodes: 0
of Shocks Delivered: 1

Battery Status



Remaining Battery Life to ERI: 75%

Electrode Impedance Status



Appendix B – Questions and guidance

- What are the recommendations in regards of LATITUDE?
 - BSC recommends that all patients with Emblem devices are followed with LATITUDE.

- What are the recommendations in regards to patients implanted with a SQ-RX?
 - The SQ-RX S-ICD is not compatible with LATITUDE. For SQ-RX patients, physicians should continue to use the Model 3200 S-ICD programmer and follow the specific recommendations contained within the Field Safety Notice dated 12th January 2017.

- If the telemetry wand is placed closer to the patient's PG, can this reduce the occurrence rate?
 - The occurrence rate will be minimized when the telemetry wand is placed directly over the PG. Therefore, 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.

- What are the recommendations during implantation of new devices and follow-up?
 - Implantation and in-clinic follow-up of S-ICDs may continue in accordance with instructions for use. The physician's ability to observe normal device operation through normal diagnostic programmer functions remains unchanged. In case of un-expected behavior the physician continues to have the ability to apply safety measures such as rescue shock and/or abort function. Until the software mitigations are available the recommendations in the letter mitigate the risks associated with this behavior.

- What are the residual risks if all recommendations are followed?
 - Boston Scientific is developing software to mitigate this behavior. Until updated software is available, the recommendations in the FSN mitigate the risks associated with this behavior by informing the physicians and providing a method of detecting the behavior.

- When will software mitigations be available to address this behavior?
 - Two software mitigations will be required: one for the Emblem S-ICD and a further upgrade for the SQ-RX S-ICD. The EMBLEM software is in development now and anticipated to be available in late Q2/2017. A subsequent SQ-RX software update is anticipated to be available at a later date; the date for this cannot be confirmed at this time.