

September 2017

**SUBJECT: Urgent Field Safety Notice. S-ICD programmer software version 4.04 addresses two previous Field Safety Notices (ref. 10000038388 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<sup>1</sup> 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,



Renold Russie  
Vice President, Quality Assurance

<sup>1</sup> EMBLEM Model A209/A219 and SQ-RX Model 1010

**EMNE: Haster - Vigtig produktinformation. S-ICD-programmerens softwareversion 4.04  
vedrører to tidligere vigtige produktinformationer (ref. 100000038388 og ref. 92127890)**

Kære læge,

Boston Scientific har tidligere sendt meddelelser til lægerne om de to former for adfærd, der beskrives herunder, som er forbundet med S-ICD-systemet. Boston Scientific udgiver nu softwareversion 4.04 til programmeren, der retter disse problemer, og den lokale Boston Scientific-repræsentant vil arrangere, at jeres programmer bliver opdateret snarest.

**S-ICD-adfærd, der rettes af softwareversion 4.04**

Version 4.04 S-ICD-programmerens software retter begge nedenstående former for adfærd ved at eliminere muligheden for RF-interferens, der forårsager en utilsigtet behandlingskommando, og forhindre en gentagen levering af atypisk energi, der skyldes hukommelsesbeskadigelse.

1. S-ICD-programmerens utilsigtede kommandoadfærd

I januar 2017 sendte Boston Scientific en meddelelse til lægerne om mulig radiofrekvent (RF) interferens, der kan ændre trådløs kommunikation fra en programmer, hvilket i sjældne tilfælde kan forårsage, at en S-ICD<sup>2</sup> udfører en utilsigtet kommando. Boston Scientific har for nyligt udgivet software i Nordamerika, Europa og flere andre lande, der retter programmerens kommandoadfærd for EMBLEM™ S-ICD'er. Med udgivelsen af softwareversion 4.04 er denne adfærd rettet for **alle** Boston Scientific S-ICD'er, inkl. SQ-RX™.

2. S-ICD-adfærd vedr. hukommelsesbeskadigelse

I juni 2017 sendte Boston Scientific en meddelelse til lægerne vedrørende en enkelt, isoleret S-ICD-hændelse, der resulterede i et enhedsrelateret patientdødsfald. Den var forårsaget af en gentagen atypisk energilevering der skyldes, at et bestemt sted i hukommelsen var blevet beskadiget af stråling i omgivelserne.

**Anbefalinger vedrørende S-ICD og programmere**

- Kontroller, at alle S-ICD-programmere model 3200 er opgraderet med softwareversion 4.04.
- Når jeres ICD-programmer model 3200 er opgraderet, skal der så tidligt som muligt udføres en standard S-ICD-opfølgning på klinikken af alle patienter med en implanteret S-ICD. Anbefalingen fra januar 2017 om at udføre endnu en interrogation er ikke længere nødvendig.  
Bemærk: Programmeren vil opdatere hver S-ICDs software, hvilket tager mindre end 5 minutter.
- Herefter kan opfølgende standard S-ICD-kontroller genoptages med normal frekvens med programmere, der er opdateret med softwareversion 4.04.  
Bemærk: Når en S-ICDs software er opgraderet, kan den kun interrogeres med programmere med softwareversion 4.04 eller højere. Tillæg A viser, hvorledes softwarens model- og versionsnummer kan identificeres ved hjælp af programmeren eller en S-ICD-oversigtsrapport.

**Yderligere oplysninger**

Boston Scientific erkender virkningen af disse meddelelser både for Dem og Deres patienter, og vi ønsker at forsikre Dem om, at vores højeste prioritet altid er patientens sikkerhed. Kontakt venligst Boston Scientifics repræsentant eller tekniske service, hvis der er yderligere spørgsmål vedrørende disse oplysninger, eller hvis De ønsker at rapportere kliniske hændelser.

Med venlig hilsen



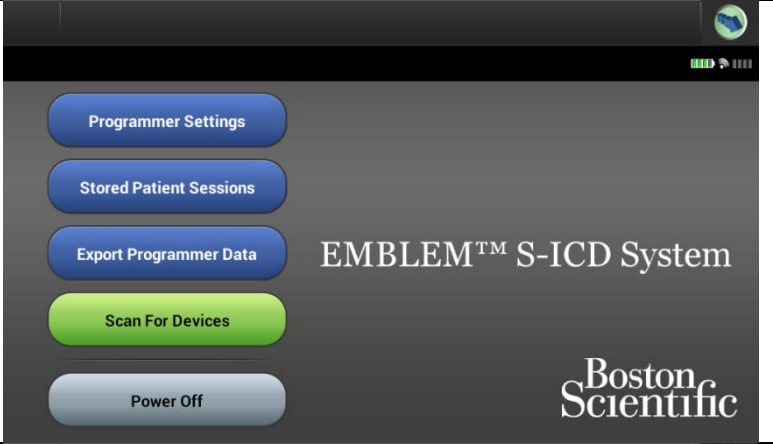
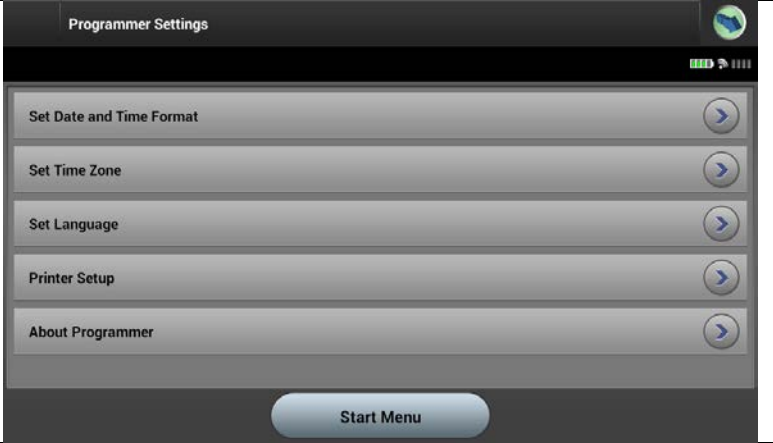
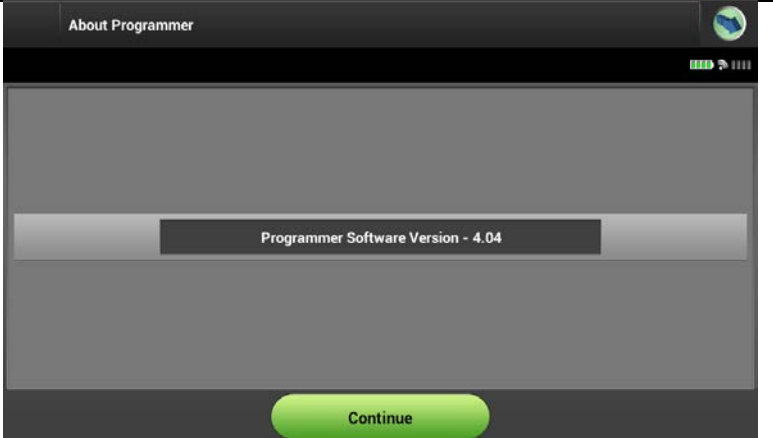
Renold Russie

Vicepræsident, Kvalitetssikring

<sup>2</sup> EMBLEM model A209/A219 og SQ-RX model 1010

**Tillæg A – Identifikation af S-ICD-programmerens software**

Sådan identificeres softwareversionen på en S-ICD programmer model 3200

<p>1. Vælg "Programmer Settings"</p>	
<p>2. Vælg "About Programmer"</p>	
<p>3. Software, der er version 4.04 eller højere, afhjælper dette problem for S-ICD'er</p>	

### Tillæg A – Identifikation af S-ICD-programmerens software (fortsat)

Den programmersoftwareversion, der anvendes i den kliniske opfølgning, er angivet øverst på oversigtsrapporten.

## SUMMARY REPORT



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

Patient Name:	Device Model#: A219 EMBLEM™ MRI S-ICD
Last Follow-up Date: 07/25/2017	Device Serial#:
Follow-up Date: 07/25/2017	Electrode Model#: 3010
Implant Date: 07/17/2017	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

