

«Hospital_Name»

«Users_Name»- «Department»

«Customer_Address»

«Zip_Code» «City» - «Country_name»

Reference: 92178058-FA

«Date_notif_sent»

Urgent Field Safety Notice - Medical Device Correction Firmware update for Maestro 4000™ Cardiac Ablation System.

UPN: M00440000, M0044000D0, M0044000H0, M0044000R0, and M0044000Z0

Dear «Users_Name»,

This Field Safety Notice (FSN) contains important information about installation of a firmware update for the Maestro 4000 Cardiac Ablation System(s) in your facility.

Boston Scientific previously notified customers about the potential for unintended continuation of radiofrequency (RF) energy delivery from the Maestro 4000™ Cardiac Ablation System after releasing the foot switch. Only systems using the optional foot switch accessory are susceptible to this unintended RF delivery behaviour.

Unintended RF energy delivery can be detected if, after releasing the foot switch, RF parameters continue displaying on the control panel and the system continues emitting an audible tone. If this behaviour occurs after releasing the foot switch, follow instructions within the manual to stop RF delivery by pressing the RF Power Control Button on either the System Controller (Generator) or System Remote Control (Remote)¹ as illustrated in Appendix A of the attached June 2018 Field Safety Notice.

A firmware update related to this behaviour has recently been approved. Boston Scientific is beginning the process of upgrading the firmware of Maestro 4000 Cardiac Ablation Systems. Please be aware that the firmware update will eliminate one potential cause of this behavior. Residual risks for other potential causes of RF termination delay remain.

Cath/EP Lab Manager Updated Actions:

- 1- Distribute this FSN to Maestro 4000 Cardiac Ablation System operators within your facility.
- 2- Continue to post a copy of Appendix A - Maestro 4000 System recommendations from the June 2018 FSN on or in a visible location near each system at your facility.
- 3- Allow Boston Scientific representative(s) access to all Maestro 4000 Cardiac Ablation Systems within your facility when they schedule the firmware upgrade.
- 4- Complete and sign the enclosed Acknowledgement Form and return the form to your local Boston Scientific Office.

Maestro 4000 Cardiac Ablation System Operator Actions: As described in the June 2018 letter, continue to do the following:

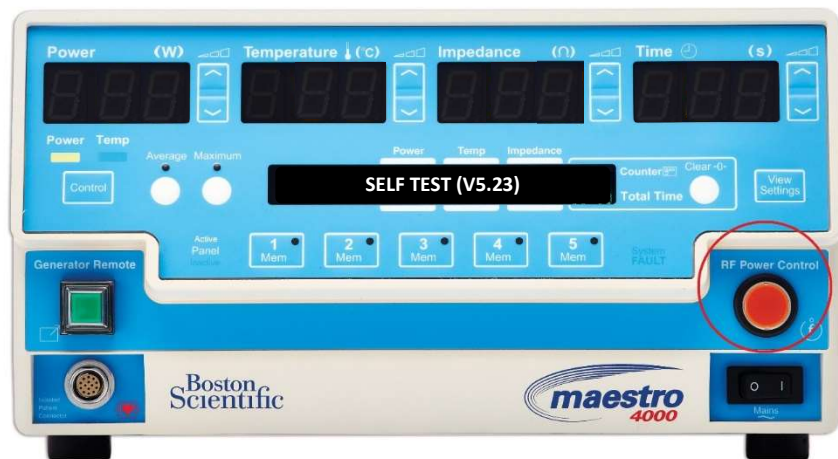
¹Reference the Maestro 4000 Cardiac Ablation System Manual: System Controls, Displays and Indicators section, RF Power Control Button, "Press to stop RF delivery while in DELIVER state."

- 1- If RF energy delivery continues after releasing the foot switch, follow instructions in the system manual to stop RF energy delivery by pressing the RF Power Control button on the Generator or Remote panel.
- 2- Report the occurrence and clinical outcome promptly to your local Boston Scientific representative.

Firmware Update for Maestro 4000 Cardiac Ablation System FSCA

Identifying System Firmware Version

When the Maestro 4000 Cardiac Ablation System is first powered up, the firmware version is displayed on the System Controller (Generator) or System Remote Control (Remote). After the firmware upgrade, the display will show 5.23.



Clinical Impact

The Maestro 4000 Cardiac Ablation System is intended for use with Boston Scientific cardiac ablation catheters in cardiac ablation procedures through the delivery of RF energy. Delivery of RF energy is controlled by either the foot switch or one of the RF Power Control Buttons located on the Generator and Remote Control. While energy is being delivered, the system displays RF delivery parameters and emits an audible tone. Since the June 2018 letter, no additional instances of patient harm have been reported.

Additional Information

Your Competent Authority is being notified of this Field Safety Notice.

Boston Scientific recognizes the impact of communications on you and your institution and wants to reassure you that patient safety is our highest priority. If you have additional questions regarding this information, please contact your Boston Scientific representative.

Yours sincerely,

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

Attachments: - June 2018 Maestro 4000 Cardiac Ablation System Field Safety Notice Letter
- Acknowledgement Form

Urgent Field Safety Notice - Important Medical Device Information Maestro 4000™ Cardiac Ablation System

Subject: Troubleshooting for Maestro 4000 Cardiac Ablation System Optional Footswitch accessory: UPNs M00440000, M0044000D0, M0044000H0, M0044000R0 and M0044000Z0.

Dear «Users_Name»,

Boston Scientific has received reports of unintended continuation of radiofrequency (RF) energy delivery from the Maestro 4000™ Cardiac Ablation System after the foot switch has been released. Boston Scientific has confirmed the Maestro 4000 is meeting performance expectations and that this rare behaviour can be resolved with existing instructions within the operator's manual.

Unintended RF energy delivery can be detected if, after releasing the foot switch, RF parameters continue displaying on the control panel and the system continues emitting an audible tone. If this behaviour occurs after releasing the foot switch, follow instructions within the manual to stop RF delivery by **pressing the RF Power Control Button** on either the System Controller (Generator) or System Remote Control (Remote)¹ as illustrated in Appendix A.

Affected Product: All Maestro 4000 Generators (M00440000, M0044000D0, M0044000H0, M0044000R0, and M0044000Z0) used with the optional foot switch. Systems that do not use the optional foot switch accessory are not susceptible to this unintended RF delivery behaviour.

Cath/EP Lab Manager Actions:

- 1- Distribute this letter to Maestro 4000 Cardiac Ablation System operators within your facility.
- 2- Immediately post a copy of Appendix A Maestro 4000 System Notice Recommendations on or in a visible location near each system at your facility.

Maestro 4000 Cardiac Ablation System Operator Actions:

1- If RF energy delivery continues after releasing the foot switch, follow instructions in the system manual to stop RF energy delivery by pressing the RF Power Control button on the Generator or Remote panel.

- 2- Report the occurrence and clinical outcome promptly to your local Boston Scientific representative.

Clinical Impact. The Maestro 4000 Cardiac Ablation System is intended for use with Boston Scientific cardiac ablation catheters in cardiac ablation procedures through the delivery of RF energy. Delivery of RF energy is controlled by either the foot switch or one of the RF Power Control Buttons located on the Generator and Remote Control. While energy is being delivered, the system displays RF delivery parameters and emits an audible tone.

Continuing display of RF delivery parameters and emission of audible tone after foot switch release are indications of unintended RF delivery and may result in life-threatening harm. There was one reported case of conductive pathway injury (heart block) during RF energy delivery which may be associated with this behaviour.

Your Competent Authority is being notified of this Field Safety Notice.

Additional Information

Boston Scientific recognizes the impact of communications on you and your institution and wants to reassure you that patient safety is our highest priority. If you have additional questions regarding this information, please contact your Boston Scientific representative.

Yours sincerely,



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

¹Reference the Maestro 4000 Cardiac Ablation System Manual: System Controls, Displays and Indicators section, RF Power Control Button, "Press to stop RF delivery while in DELIVER state."

Appendix A: Maestro 4000™ Cardiac Ablation System Notice Recommendations

Troubleshooting for Maestro 4000™ Cardiac Ablation System M00440000, M0044000D0, M0044000H0, M0044000R0, and M0044000Z0

Releasing the foot switch may not stop RF delivery. If RF delivery does not stop as intended, press and release the RF Power Control button.



Report any occurrence and clinical outcome of unintended RF delivery promptly to your local Boston Scientific representative. Contact your local Boston Scientific representative for additional information.

Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_name»

**Acknowledgement Form – Urgent Medical Device Correction
Firmware update for Maestro 4000™ Cardiac Ablation System.
92178058-FA**

**By signing this form, I confirm that I have read and understood
the Boston Scientific Field Safety Notice dated «Date_notif_sent» related to:
Firmware Update for Maestro 4000™ Cardiac Ablation System.**

Does your center have a Maestro 4000?

- No, my center does NOT have a Maestro 4000 system
 Yes, my center has a Maestro 4000

It is located: _____

Does your center use the footswitch for this system?

- No, my center does NOT use the footswitch for this system
 Yes, my center uses the footswitch for this system

Name of appropriate person to
arrange firmware upgrade: _____

Coordinator's Phone: _____

Coordinator's Email: _____

Customer Acknowledgement:

NAME* _____ **TITLE** _____

Telephone _____ Email _____

Customer' **SIGNATURE*** _____ **DATE*** _____
* Required field (dd/mm/yyyy)