

«Hospital_Name»

«Users_Name»- «Department»

«Customer_Address»

«Zip_Code» «City» - «Country_name»

Reference: 92178058-FA

xx June 2018

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.

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."

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.

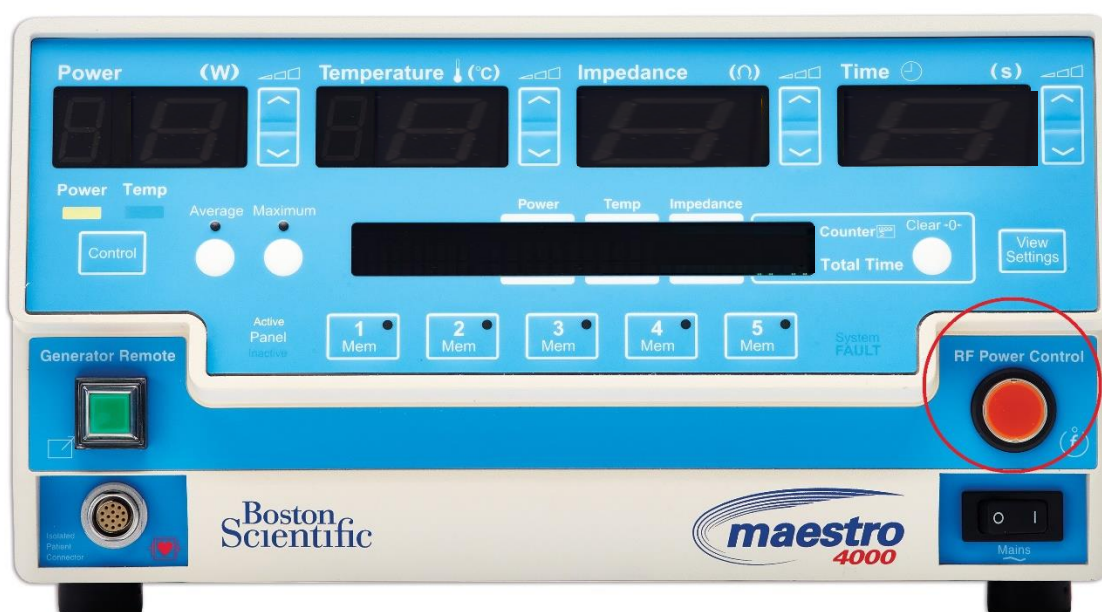
Yours sincerely,

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

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.