



Maestro 4000™ Cardiac Ablation System Correction Notice

M00440000, M0044000D0, M0044000H0, M0044000R0, and M0044000Z0

13-Jan-2020

Dear Doctor,

Cc: Chairman Medical Board and relevant Head of Department

This letter 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 behavior.

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 Notification.

A firmware update related to this behavior 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 letter 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 letter on or in a visible location near each system at your facility. (Included below)
- 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:

- 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.
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Firmware Update for Maestro 4000 Cardiac Ablation System M00440000, M0044000D0, M0044000H0, M0044000R0, and M0044000Z0

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

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.

Sincerely,



Renold Russie
Vice President, Quality Assurance



CUSTOMER ACKNOWLEDGEMENT FORM
Maestro 4000™ Cardiac Ablation System

Instructions: This form must be completed and returned in all cases even if you do not have any affected product.

Immediately complete form and Scan/e-mail to: bscfieldactioncenter@bsci.com OR Fax to #: 1-866-213-1806

Account #:		Customer Name:	
Contact Name:			
Address:			
City:	State:	Postal Code:	
Country:			

PLEASE COMPLETE, SIGN AND RETURN THIS FORM AS A CONFIRMATION THAT YOU RECEIVED THIS NOTICE FROM BOSTON SCIENTIFIC (even if you do not have any of the referenced product on the enclosed product listing in your current inventory).

My signature below acknowledges receipt of the Boston Scientific Notice regarding Maestro 4000™ Cardiac Ablation System.

Section to be filled out by Customer:

<p>1. <u>Please Indicate:</u></p> <p>Does your center have a Maestro 4000 system?</p> <p><input type="checkbox"/> No, my center does NOT have a Maestro 4000 system. <input type="checkbox"/> Yes, my center does have a Maestro 4000 system.</p> <p>It is located: _____</p> <p>Does your center use the footswitch for this system?</p> <p><input type="checkbox"/> No, my center does NOT use the footswitch for this system. <input type="checkbox"/> Yes, my center does use the footswitch for this system.</p> <p>Name of appropriate person to arrange firmware upgrade: _____</p> <p>Coordinators Phone: _____ Coordinators email: _____</p> <p>Are you a Distributor?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, and we have notified all customers that have been shipped/sold affected product</p> <p>2. <u>Sign and Date to acknowledge this Field Action Notification (must be completed):</u></p> <p>Print Name: _____ Signature: _____ Date: _____</p> <p>Phone: _____ Fax: _____ E-mail: _____</p>

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