Johnson & Johnson MEDICAL

FIELD NOTIFICATION

CARTO® 3 EP Navigation System

Catalog Number: FG540000 and FG540000U
Serial Numbers: All

January 13, 2017

Dear Valued Customer,

Biosense Webster, a division of Johnson & Johnson Medical NV/SA ("Biosense Webster"), has initiated a field notification for CARTO® 3 EP Navigation Systems (FG540000 and FG540000U) ("the CARTO® 3 System") as we have recently become aware of workflow scenarios that may lead to current leakage. Current leakage has the potential to induce a ventricular arrhythmia.

The CARTO® 3 System provides information about the electrical activity of the heart and catheter location during electrophysiology (EP) procedures. Despite the extremely low probability (0.000086%) of a patient experiencing a ventricular arrhythmia from current leakage, we would like to reinforce important information regarding factors that may contribute to current leakage from the Instructions For Use (IFU) for the CARTO® 3 System, the SMARTABLATE® RF Generator, and the nMARQ® Multi-Channel RF Generator[1].

1. **Do not ignore system indicators such as significant noise during ablation or an Error 7 message (a current leakage error available on some CARTO® 3 System configurations). Follow the IFU and stop using the system if current leakage is suspected.**
2. **Do not perform ablation while impedance readings from the ablation catheter are at extreme values beyond 250 Ω (or 300 Ω for the nMARQ® Multi-Channel RF Generator[1]). Monitor the impedance during the procedure and avoid switching off the Impedance Cut-Off Setting on the radio frequency (RF) generator. [NOTE: If you are conducting a procedure for an investigational device in a clinical study, follow the approved protocol requirements.]**
3. **Additionally, avoid ablation while pacing from the same electrode of the ablation catheter.**

See the Appendix for references to sections of the IFUs detailing these recommendations.

Please continue to be vigilant in ensuring the safe use of these devices by adhering to the directions in the IFU in regards to all ablation parameters. Ablation parameters are continuously available during a procedure on the EP recording system screen, the RF generator screen, and the CARTO® 3 System screen.

Actions Requested on Your Part:

1. Maintain awareness of this notice and pass it on to anyone in your facility that needs to be informed.
2. Complete, sign, and ***return the Customer Acknowledgement Form.***

Available Assistance:
For questions related to this issue, please contact your Biosense Webster sales representative.

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Head, Regulatory Affairs

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Appendix: References to Existing Warnings and Instructions Described in this Letter

NOTE: Review the complete IFUs for all warnings and precautions

Recommendation #1: Do not ignore system indicators such as significant noise during abalation or an Error 7 message (a current leakage error available on some CARTO® 3 System configurations). Follow the IFU and stop using the system if current leakage is suspected.

See the following IFU section:

- **CARTO® 3 System IFU: Chapter 20, or 22 depending on your IFU version[2,3], System-Related Messages**

Recommendation #2: Do not perform ablation while impedance readings from the ablation catheter are at extreme values beyond 250 Ω (or 300 Ω if using the nMARQ® Multi-Channel RF Generator[1]). Monitor the impedance during the procedure and avoid switching off the Impedance Cut-Off Setting on the radio frequency (RF) generator. [NOTE: If you are conducting a procedure for an investigational device in a clinical study, follow the approved protocol requirements.]

See the following IFU sections:

- **SMARTABLATE® RF Generator IFU: Section 3.3 Warnings and Precautions: During an Ablation Procedure[4]**
- **SMARTABLATE® RF Generator IFU: Section 6.3.3 Editing a Preset[4]**
- **nMARQ® RF Generator IFU: Section 4.3, Impedance Monitoring[1,5]**

Recommendation #3: Avoid ablation while pacing from the same electrode of the ablation catheter.

See the following IFU sections:

- **CARTO® 3 System IFU: Chapter 3, Pacing Stimulator Connectivity pages 40-42[2,3]**
- **CARTO® 3 System IFU: Chapter 4, Pacing and RF Energy Delivery page 58 or 61 depending on your IFU version[2,3]**

[1] nMARQ® Catheters and Generator are approved for investigational use only and are not for sale in the United States. nMARQ® Catheters and Generator are approved for sale only in countries-members of the European Union.
[2] CARTO® 3 System Software Version 3.2.3 Instructions for Use. Irvine, CA: Biosense Webster, Inc; March 2014
[3] CARTO® 3 System Software Version 4.3 Instructions for Use. Irvine, CA: Biosense Webster, Inc; November 2015
[4] SMARTABLATE® RF Generator Instructions for Use. Irvine, CA: Biosense Webster, Inc; December 2015
[5] nMARQ® RF Generator Instructions for Use. Irvine, CA: Biosense Webster, Inc; July 2015

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