Johnson & Johnson MEDICAL

Important Customer Notification

The FTI Feature in the CARTO VISITAG™ Module of the CARTO® 3 System

Please distribute this information to appropriate personnel at your facility.

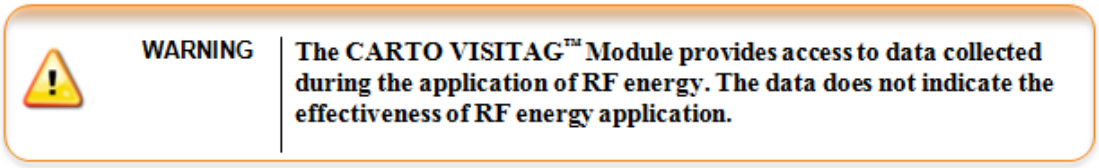
Dear Valued Customers,

The purpose of this communication is to reinforce the importance of proper use of the Force Time Interval (FTI) setting in the CARTO VISITAG™ Module of the CARTO® 3 System. As part of our commitment to you as a user of this product, we at Biosense Webster, Inc. want to share practical examples for better understanding of the FTI feature in the CARTO VISITAG™ Module during ablation procedures.

The intended use of the CARTO® 3 System is catheter-based cardiac electrophysiological (EP) procedures. The CARTO® 3 System provides information about the electrical activity of the heart and about catheter location during the procedure. The CARTO VISITAG™ Module provides the ability to continuously store, track, and quantify ablation catheter positions along with the electrophysiological parameters acquired during RF applications, according to user preferences.

When the CARTO VISITAG™ Module is in use, ablation catheter positions that meet the user-defined thresholds for filters such as temperature, impedance drop and force data are grouped into areas according to their spatial stability. Visual indication of this data can be presented as CARTO VISITAG™ Module Locations, which appear as elements similar to Ablation Tags in a standard CARTO® 3 System Study.

We would like to reinforce the following warning, which appears in the CARTO® 3 System Instructions for Use:



Lesion formation depends on many factors that include but are not limited to catheter stability, power, time, and applied force. The CARTO VISITAG™ Module provides visual display for tracking these parameters. The CARTO VISITAG™ Module Locations can be colored according to FTI, a calculation of force and time. However, it is important to note that the FTI value is not a lesion predictor.

The same FTI value (with different combinations of forces and time) can yield different lesions when applying different power settings as shown in the image below.

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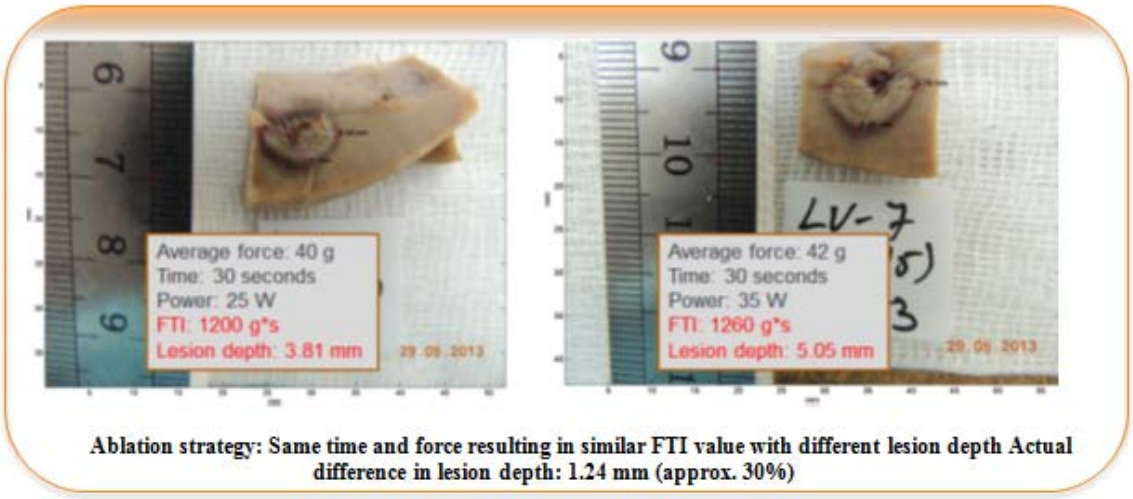

Ablation strategy: Same time and force resulting in similar FTI value with different lesion depth Actual difference in lesion depth: 1.24 mm (approx. 30%)

Biosense Webster does not issue any recommendation for targeting specific FTI values.

Biosense Webster is presenting this information to you as part of our commitment to the optimal outcome for your patients. Please share this information with any of your staff who uses the CARTO VISITAG™ Module while performing ablation procedures. In addition, please refer to the Instructions for Use provided with your CARTO® 3 System and the CARTO VISITAG™ Module, as well as for the catheters that you use during procedures for recommendations on the ablation parameters. Biosense Webster will be deploying additional training on the CARTO VISITAG™ Module in the upcoming months.

Like you, Biosense Webster, remains dedicated to advancing the standard of care in ablation procedures.

For questions related to the information provided in this Customer Notification, please contact your Biosense Webster sales representative.

ACTIONS REQUIRED FROM YOU

1. Complete the **Customer Acknowledgement Form** and pass it to your BW Representative or fax it to **6720 0750 within 2 business days.**

2. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

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Thank you for your cooperation and patience.

Yours sincerely,

Lee Ching Hwee
Senior Regulatory Affairs Specialist

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