

URGENT – Field Safety Notice

CARTO® 3 System Version V7.1.80, CARTO VISITAG® Module

Catalog Number	Description
KT5400222	CARTO PRIME™
KT5400222G	CARTO PRIME™ (JPN)
KT5400222U	CARTO PRIME™ (OBL)
KT5400221	CARTO® 3 V7
KT5400221U	CARTO® 3 V7 (OBL)

Date

Dear Valued Customer,

At Biosense Webster, Inc. we continuously monitor the performance of our products to help ensure patient safety and compliance. Recently, an issue was detected in the released CARTO® 3 System Version V7.1.80, CARTO VISITAG® Module. None of the other CARTO® 3 Software released versions or modules of the CARTO® 3 Software are affected.

You are receiving this letter because this version of the CARTO® 3 Software is currently installed in your Electrophysiology (EP) lab.

Please be aware of the following

- This product is not being removed from the market and does not need to be returned.
- Use of already installed CARTO® 3 Software V7.1.80 and the CARTO PRIME™ Module can be continued.
- No complaints or adverse events have been reported related to this issue.

Description of the Issue:

The CARTO VISITAG® Module provides accurate location and ablation parameters during the procedure. However, every recalculation of the CARTO VISITAG tag may result in unexpected disappearance of some CARTO VISITAG sites if Tag Index calculations are not a part of the CARTO VISITAG preset. Recalculation typically occurs when a CARTO VISITAG preset settings changes, during review of a previous case, or after restart of the study. Loss of CARTO VISITAG tags may lead to additional ablation sites. This may lead to prolongation of the procedure and, in extremely rare circumstances, cardiac perforation.

No complaints or adverse events have been reported related to this issue.

A software service pack will be provided by Biosense Webster at no cost. Your Biosense Webster representative will notify you when it is available and will arrange for installation of the service pack.

In the meantime, we have identified certain mitigations preventing the issue from occurring:

If your system is equipped with a VISITAG SURPOINT™ Module License:

- Always work with VISITAG SURPOINT™ Module and enable the Tag Index calculation at all VISITAG presets.

- When working in review mode, please review all the presets and ensure they all include the Tag Index check box selected.
- When VISITAG recalculation was applied with the Tag Index option unselected, recalculate again with SURPOINT by enabling the Tag Index calculation at the preset and apply it to the study.

If your system is not equipped with a VISITAG SURPOINT™ Module License:

- Avoid triggering CARTO VISITAG recalculations as much as possible.
- During the procedure consider applying a manual tag for each ablation location by acquiring an ablation point in addition to the CARTO VISITAG® Module marking the ablation locations.
- If a CARTO VISITAG tag disappears, the CARTO 3 system will still provide an indication of ablation at this location for the manually acquired points.
- During offline review of a previous study, be aware that some CARTO VISITAG tags may have disappeared.

Next Steps

1. Please review this letter carefully and share it with anyone in your facility that needs to be informed.
2. Please complete, sign, and **return the Business Reply Form** to the following email Address: **to be updated per local information & process.**

We have communicated this information to the applicable regulatory authorities.

Sincerely,



Helit Dovrin
Director, Quality & Regulatory