URGENT FIELD SAFETY NOTICE

April 4, 2008

To: [redacted]

RE: **Advantage Workstation - Possible mismatches of vessel labels**

GE Healthcare has recently become aware of a possible mismatch between the label of the tracked vessel and the underlying image associated with the cardio-vascular applications of your Advantage Workstation that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

When using the vessel analysis software with multiple branches, the software can incorrectly reload a Save State / Save Tracking and display an incorrect vessel name over the restored images. This happens whenever a branch name has a leading or trailing space in the name, either predefined or user defined. In particular, the predefined branches "Right Popliteal Artery" and "Left Popliteal Artery", included in the "Lower Extremity Detailed Analysis" factory protocol, are impacted.

On Volume Viewer 3.x only, a mismatch of vessel labels can occur if the Show Tracking button is not immediately pressed after depositing a bifurcation point, and that a branch is added, removed or renamed after having deposited the bifurcation. Subsequently the Saved State will be incorrectly relooaded.

A mismatch of vessel labels can also happen when removing the last extremity points of a branch that has been defined using several intermediate points. The curved image is not correctly refreshed.

With a multiple phase cardiac dataset, the mismatch will occur if a vessel branch is deleted from any cardiac phase other than the one on which the vessel has been defined.

No patient injury has been reported to date resulting from this issue. The mismatch between the vessel name and the displayed image could possibly lead to the diagnosis of vessel disease on an incorrect site.

Affected Product

Advantage Workstations AW Volume Share 2 (version AW4.4_04).
ONLY IF THE ONE OF FOLLOWING APPLICATIONS IS INSTALLED:

- *VesselIQ Xpress or AVA Xpress*
- *CardIQ Xpress Pro or Plus*
- *CardEP*
- *CardIQ Fusion PET or SPECT*

*provided with **Volume Viewer 3** and **3.1** version from 7.0 to 7.5 and version 8.1.*

Advantage Workstations AW Volume Share (version AW4.3) and AW4.2 (version 4.2_05 and above).
ONLY IF THE FOLLOWING APPLICATION IS INSTALLED:

- *CardIQ Xpress Pro or Plus*
- *CardEP*

provided with ***Volume Viewer 2*** version from 6.0 to 6.11.

To verify the version installed on your system: Select the "Admin" menu from the "Patient list" page. Then select "Display Configuration". You will find the version of your system in "Installed Application(s)".

Product Correction

GEHC will install a new version of the software on your system. The installation will be performed at no charge.

Safety Instructions

Users are recommended to follow the instructions below until new software is installed.

- *Do not make any clinical decisions based on a Save State that can contain either the predefined branches "Right Popliteal Artery" or "Left Popliteal Artery", or the possibly customer defined branches that could contain leading or trailing blank spaces in the branch name.*
- *Always select "show tracking" (centerline) after adding a "bifurcation point".*
- *After clearing the last point of a branch, switch to at least two other vessels.*
- *When processing cardiac images with multiple phases do not delete a branch point from any cardiac phase other than the one on which the points were deposited.*
- *Always crosscheck the tracked vessel location with the surrounding anatomy and the orientation annotations.*

Contact Information

Call Centers phone number:
800 437 1171 (United States)
0120 - 055 - 919 (Japan)
0800.15.25.25. (France)
For other countries, please contact your local GE Healthcare sales or field service representative.

Please be assured that we are constantly making every effort to maintain a high level of safety and quality in our systems. If you have any questions, please contact us immediately.

Sincerely,

[redacted]

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