



PRODUCT SAFETY NOTIFICATION

540 West Northwest Hwy
Barrington, IL 60010
USA

<Date Of Mailing to be entered>

To: Director/Manager of Radiology
Hospital Administrator
Cardiology Department

RE: Advantage Workstation Suite-Card IQ: Possible incorrect vessel labeling with the use of the custom label feature.

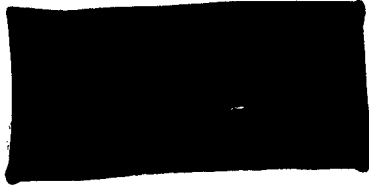
GE Healthcare has recently become aware of a possible mismatch between the label assigned to a tracked vessel and the underlying image when using the custom labeling feature in the cardio-vascular applications of your AW Suite software package, which has the potential to impact patient safety. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue	When using any vessel analysis protocol of the AW Suite Card IQ application, the software can reload saved tracking objects (Save State) incorrectly and display an incorrect vessel label over the restored images. This failure only occurs when users create a custom label in the vessel analysis protocol and include leading or trailing blank characters (space bar) in the custom label.
Affected Product Details	AW Suite 2.0 and AW Suite 2.0.1 ONLY IF THE ONE OF FOLLOWING APPLICATIONS IS INSTALLED: • Card IQ Xpress Pro or Plus <i>To verify the version installed on your system: go to the Windows Control Panel page and double-click on Add or Remove Programs, then select the AW Suite entry and click on the "Click here for support information" hyperlink. The version number displayed is 2.00.0000 for AW Suite 2.0, 2.01.0000 for AW Suite 2.0.1.</i>
Safety Instructions	Users are recommended to follow the instructions below until new software is installed. <ul style="list-style-type: none">• Do not make any clinical decisions based on a Card IQ Save State when a custom label has been entered.• Do not include leading or trailing blank spaces (space bar) in the new branch name when customizing a Card IQ vessel analysis protocol.
Product Correction	GEHC will install a new version of the software on your system. The installation will be performed at no charge.
Contact Information	Contact your Remote Online Center (ROC), Field Engineer (FE) or the GE Customer Care Center at 800-437-1171.

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.

Please fill out the attached **Customer Reply Form** and Email/Fax to us as indicated in the form.

Thank you,



GM, Quality Assurance/Regulatory Affairs
GE Healthcare Integrated IT Solutions
540 W. Northwest Highway
Barrington, IL 60010 - 3076
USA

Customer Reply Form

AW Suite 2.0 and AW Suite 2.0.1

ONLY IF THE ONE OF FOLLOWING APPLICATIONS IS INSTALLED:

Card IQ Xpress Pro or Plus

PLEASE COMPLETE and FAX to GE Healthcare

CUSTOMER CONTACT INFORMATION

Hospital Name		Hospital Contact	
Street Address		City	
State		Postal Code	Country
Phone		Email	

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

- Do not make any clinical decisions based on a Card IQ Save State when a custom label has been entered.
- Do not include leading or trailing blank spaces (space bar) in the new branch name when customizing a Card IQ vessel analysis protocol.

Please record the date on which your facility received this information as well as the Workstation Build Number/Software version in your facility.

To verify the version installed on your system: go to the Windows Control Panel page and double-click on Add or Remove Programs, then select the AW Suite entry and click on the "Click here for support information" hyperlink. The version number displayed is 2.00.0000 for AW Suite 2.0, 2.01.0000 for AW Suite 2.0.1.

Name	Date
Signature	Workstation Software or Build Number

Please FAX to 847-277-5240,

Attention: [REDACTED] - Manager, Product Quality Assurance. [REDACTED]