



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 80150

February 2013

To: Hospital Administrators
Radiology Managers
Risk Managers

RE: **GenIQ software application on Advantage Workstation (AW) or AW Server may lead to incorrect parametric values calculation when 3T datasets are invoked while using an MR system.**

GE Healthcare has recently become aware of a potential safety issue with respect to T1 value correction applied in the GenIQ application software on AW or AW Server. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue All processing performed in GenIQ uses preset T1 values specific to 1.5T. Results generated by GenIQ correspond to 1.5T settings even if 3T datasets are loaded. T1 preset values are applied to convert the arbitrary signal intensity units in the dynamic series, into units of contrast agent concentration. Consequently, 1.5T T1 preset values applied on 3T datasets generate incorrect parametric values, resulting in potential misdiagnosis.

Safety Instructions With patient follow up, ensure datasets are acquired using an MR system with the same field strength.

If they are not, please refer to the instructions below:

- Launch GenIQ application and then select "General Protocol"
- Define 3D VOI (volume of interest) as usual and select Semi-Auto Vascular Input Function (VIF) mode
- Select the 3rd review step (Review Permeability Maps)
- Go to "Advanced Settings" and modify both T1 Correction value inside the "T1 Correction" tab and T1 Blood value inside the "Physiological Parameters" tab
- Select the 1st review step and define a Region of Interest (ROI) on vessel area and click on "Search"
- Select the 2nd review step (Review All Maps) to trigger the computation.

Refer to section "T1 tissue correction" in the "Advanced settings" chapter of the GenIQ User manual for T1 values of Blood and Tissue.

A retrospective analysis should be considered for prior cases acquired for the purpose of a patient follow up if data examinations were acquired at different field strength.

Affected Product Details

The following versions of the AW and AW Server are affected if the GenIQ application software is installed:

AW 4.6, Volume Share 6 – vxtl.11.3 or vxtl.11.3 ext1
AW Server 2.0, Volume Share 6 – vxtl.11.3 or vxtl.11.3 ext1

To identify which version of AW you are using, select "Admin" and "Display Config." Buttons. The version number is displayed along with the GenIQ software key.

To identify which version of AW Server you are using, launch the AW Server client and verify the version in the top left corner of the log in screen (shown below with version highlighted in the red box).



Product Correction

GE Healthcare will correct all affected systems at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

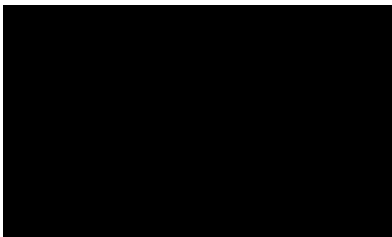
Contact Information

If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

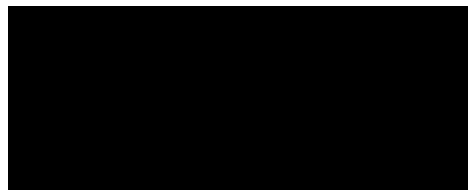
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,



Vice President QARA
GE Healthcare Systems



Chief Medical Officer
GE Healthcare