GE Healthcare

Urgent Field Safety Notice

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226,
USA

GE Healthcare Ref: FMI 80135

December 2012

To: Hospital Administrators
Radiology Managers
Risk Managers

RE: **AW Server (AWS) May Display Incorrect Patient Name on Images (Volume Viewer) or Tabs (Results Viewer)**

GE Healthcare has become aware of two separate, unrelated safety issues on the AW Server product. These issues and associated safety instructions are discussed below. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issues   **Issue #1:**
On monitors with 2 megapixel (2MP) resolution and higher (i.e. higher than 1600×1200 resolution), for a certain sequence of user commands detailed in the Appendix for issue #1, switching between two Volume Viewer tabs with different patients, the topmost strip of the Volume Viewer display fails to update between patients. This causes the incorrect patient name to display in the topmost viewports. **See Appendix for more details.**

Issue #2:
When starting the Results Viewer application in the AWS client window for a particular patient exam, if a second patient exam is selected while the application is starting, the Results Viewer will display the second patient's image data and name in the viewports; however, the first patient name will display on the applications tab. **See Appendix for more details.**

Safety Instructions   **Issue #1:**
For monitors with resolutions between 2MP and 3MP, contact your field engineer to install the correct configuration file per the instructions in the GE service manual. **Please note that higher than 3MP resolutions are not supported with AW Server**

Note also that a GE Customer Release Note (5398897-199 Revision 1) recommended changes to the solo.ini file to improve paging performance for high resolution monitors. DO NOT apply these changes, as these recommended changes cause the safety issue to occur.

Issue #2:
When starting the Results Viewer application, wait until the application has fully initialized and has displayed images from the first patient exam selected before making another patient exam selection.

| **Affected Product Details** | Both issues affect AW Server Version 2.0 with release 2.0-4.0 only. To identify which version of AW Server software you are using, launch an AW Server client and verify the version in the top left corner of the log in screen (shown below with version highlighted in red box). Version 2.0 will display as "aws-2.0-4.0". |

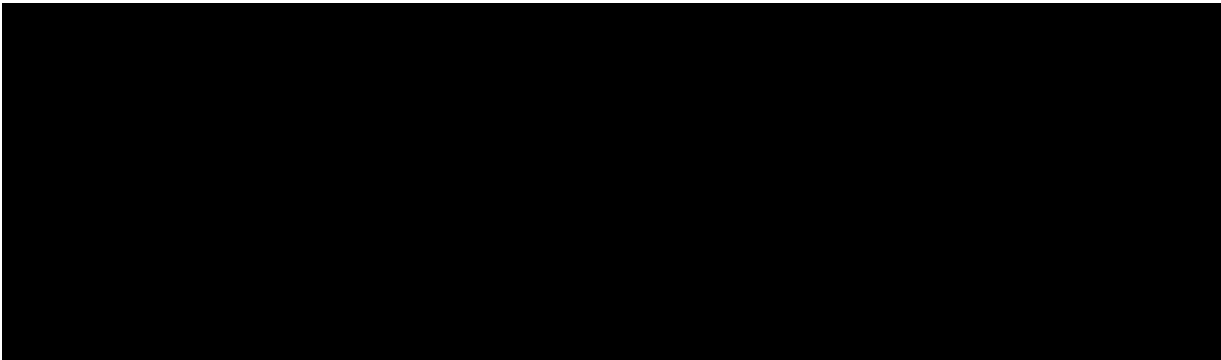| **Product Correction** | GE Healthcare will correct all affected AW server installations by providing a software upgrade at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction. |
| **Contact Information** | If you have any questions regarding this 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.
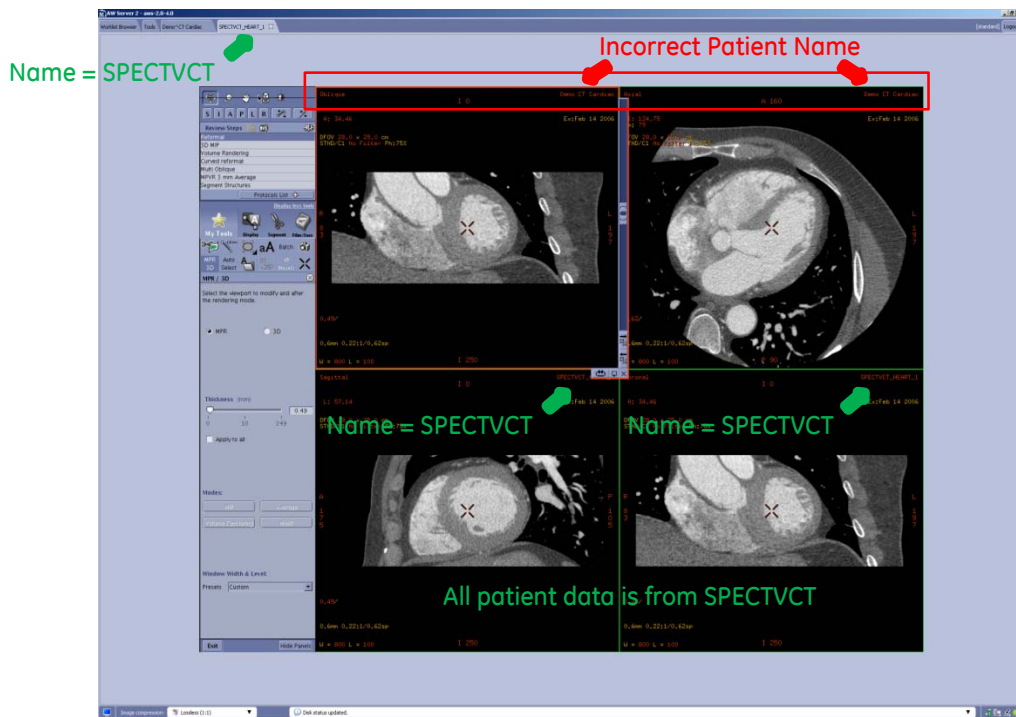
Sincerely,

Safety Issue #1

On AW Server, when using a client with a high resolution monitor, if a user opens a minimum of two Volume Viewer tabs with different patient's data, a certain sequence of user commands when switching between patient tabs can cause the topmost strip of a Volume Viewer display to fail to update to the new patient's data. This can cause the incorrect (i.e., first) patient name to be displayed in the topmost viewports when the second patient's image data is displayed. The lower viewports display the correct patient name, as does the patient name tab as shown below. This error occurs only on monitors having 2MP resolution and higher (i.e. higher than 1600×1200).

The sequence of commands leading to this issue includes: (1) maximizing the AW Server client window; (2) switching to full screen mode while viewing the first patient's data; (3) subsequently switching back from full screen mode while viewing the second patient's data; and (4) switching back to the first patient's data.

Safety Issue #2

On AW Server, the Results Viewer application may take 5-8 seconds to initialize and display a selected patient exam when first started. If a second patient exam is selected before this initialization has completed, the second patient's data will be displayed in the viewports with the corresponding patient name on the viewports. However, the first patient's name will be displayed on the applications tab as shown below.

1st patient selection:
Name = SPECTVCT

2nd patient selection:
Name = Demo CT Cardiac

All patient data is
from Demo CT Cardiac