



URGENT FIELD SAFETY NOTICE

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

February 2012

GEHC Ref# 72285

To: Hospital Administrators /Risk Manager
Biomedical Engineering
Head of General Imaging Ultrasound Department

RE: **Wrong patient image when reviewing the images on LOGIQ S8**

GE Healthcare has recently become aware of a potential safety issue due to patient data mix up associated with the software of your LOGIQ S8 system. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

User may notice an image from a different patient, or an image from the current patient with title information from a different patient. As a result imaging may need to be repeated due to the confusion in the image information. The reported issue occurs only if both PRINT button is assigned to save data in DICOM format AND the PRINT button is pressed during LOGIQView pre-mode (between start and stop).

Safety Instructions

In order to avoid seeing the reported issue, do NOT press PRINT key during pre-mode of LOGIQView.

Affected Product Details

LOGIQ S8 R1.1.0 Software. Build date on the rating plate indicates August 2011 through October 2011.

Product Correction

GE will resolve the issue by providing a software update, at no cost, to remove the malfunction in the software level that is currently installed on your system.

Contact Information

If you have any questions or concerns contact your local GEHC service representative.

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 per the contact information above.

Sincerely,

