



## URGENT FIELD SAFETY NOTICE

### GE Healthcare

Healthcare Systems  
9900 Innovation Drive  
Wauwatosa, WI 53226  
USA

<Date>

GEHC Ref# 70209

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

RE: **Patient Image mismatch and incorrect measurements/calculations on GE LOGIQ E9 system.**

GE Healthcare has recently become aware of a potential safety issue associated with the data of your LOGIQ E9 system 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

- 1 - User may notice an image from a different patient, or an image from the current patient with title information from a different patient.
- 2 - Incorrect measurements/calculations on images, when viewed on the off-line review station.

As a result imaging may need to be repeated due to the confusion in the image information.

#### Safety Instructions

**Issue 1: If you use the LOGIQView option, you may notice that a wrong patient image/name is displayed on the title of the image.**

##### Actions To Take:

- a. This issue may occur only if your system is enabled to perform LOGIQView functionality.
- b. Avoid using any of the print buttons when in live scanning while system is acquiring LOGIQView
- c. Push the Freeze button to finish LOGIQView acquisition. You may use the print button at this time to archive the image

**Issue 2: On the scanner or on a PACS review station, when performing measurements on a cine clip image received from LOGIQ E9 system, you may notice that the measured value is not correct.**

##### Actions to Take:

Please view table below and avoid using the configurations marked as "Do Not Use" to work around this issue. The best solution is to set the 'Format' to 'RawDicom', and the 'Image Frames' to 'Single'. Please check each print button configuration (P1, P2, etc.) since each button can be configured differently.

| Image Resolution Settings   | Print Button Configurations Mode (P1, P2 ...)                                  |             |   |             |   |
|---|--|-------------|---|-------------|---|
|   | On the scanner go to Utility > Connectivity > Button                           |             |   |             |   |
| On the scanner go to:<br>Utility > Connectivity ><br>Miscellaneous ><br>DICOM Multi-frame image<br>resolution | If 'Format' is set to<br>'Dicom' and<br>'Image Frames' is set to<br>'Multiple' |             | If 'Format' is set to<br>'RawDicom' and<br>'Image Frames' is set to<br>'Multiple' |             | If 'Format' is set to<br>'RawDicom' and<br>'Image Frames' is set to<br>'Single' |
|   | On scanner   | Off Scanner | On Scanner  | Off Scanner | On or Off Scanner   |
| Default   | Do not use   | Do not use  | OK  | Do not use  | OK  |
| Medium  | Do not use   | Do not use  | OK  | Do not use  | OK  |
| Large   | OK   | OK          | OK  | OK          | OK  |

**Affected  
Product  
Details**

GE LOGIQ E9 DIAGNOSTIC ULTRASOUND SYSTEM with R3.1.0 and R3.1.1 software.

**Product  
Correction**

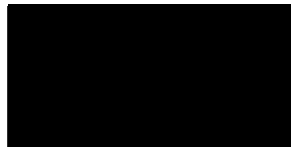
GE will resolve these issues by providing a software update, at no cost, to remove the malfunction in the software level that is currently installed on your system.

**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,



Vice President QARA  
GE Healthcare Systems



Chief Medical Officer  
GE Healthcare