



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 85444

To: Director/Manager of Radiology
Hospital Administrator
Head of Radiology Department
PACS Administrator
Chairman Medical Board and relevant Head of Departments

RE: **Centricity Universal Viewer with Cross Enterprise Display.**

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

**Safety
Issue**

GE Healthcare has recently become aware of an issue with Universal Viewer when Cross Enterprise Display is enabled to view remote exams from 3rd Party DICOM Providers.

Remote comparison studies displayed in Centricity Universal Viewer may be associated with the wrong patient, without a caution icon present.

This issue occurs when Cross Enterprise Display is configured to match remote studies using patient demographics matching (at the full or partial level) and the Remote DICOM Providers are 3rd party (Non-GE). This does not impact the Primary Exam or comparisons from the local PACS. There have been no injuries reported as a result of this issue.

**Safety
Instructions**

Until a product modification is available to correct this issue, the site should configure Image Overlays to display Patient Demographic information associated with the image including Name, Date of Birth and Gender. Instructions for doing so are contained within the Centricity Universal Viewer User Manual under the section titled *Configuring Image Overlays*.

**Affected
Product
Details**

Centricity Universal Viewer with Cross Enterprise Display connected to a 3rd Party DICOM Provider using Demographic Matching. This impacts product versions 6.0 SP1 and higher.

**Product
Correction**

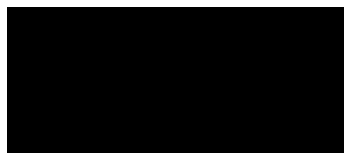
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

**Contact
Information**

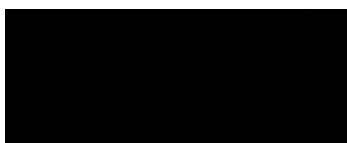
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare