



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

GE Healthcare IT
 540 W. Northwest Hwy
 Barrington IL 60010
 USA

<Date to be added when letters are sent>

GEHC Ref# 85386

To: Director/Manager of Radiology
 Hospital Administrator
 Head of Radiology Department
 PACS Administrator
 Director of IT Department

RE: **Centricity PACS-IW with Universal Viewer versions 5.0 through 5.0 Sp5.1**

GE Healthcare has recently become aware of a potential safety issue with Centricity PACS-IW with Universal Viewer. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue A database deadlock could occur during the image acquisition process affecting the completeness of acquired images. While infrequent, database deadlocks do occur during normal database operations. There is the potential that one or more images may be missing from exams. No actual patient injuries have been reported.

Safety Instructions A software update is available to correct this issue. Until this software update is installed, the following actions are recommended:

1. Utilize the image count within the QC process to alert the user of a discrepancy in the number of transmitted images from the modality to the number of images available in the PACS IW viewer.
 - a. If a discrepancy is identified, attempt to retransmit the exam to PACS.
 - b. If retransmission is unsuccessful, a GE Healthcare Service representative will need to be contacted to assist with resolution of the impacted exam. Urgent cases impacted by this issue should be interpreted at the modality.
2. If DICOM storage commit is configured and in use, no commit notification is sent to the modality for images that were impacted by this issue.
3. Attention should be given to prior cases, acquired before the application of the safety instructions given in this communication as they may be affected by the safety issue. For historical data inquiries, please contact GE service for assistance in identifying any affected images.

Affected Product Details Centricity PACS-IW with Universal Viewer versions: 5.0 through 5.0 SP5.1

Product Correction This issue has been resolved via a software correction in version 5.0 Sp6 and higher. A GE service representative will contact you to install this or a newer version of the software at no cost to you.

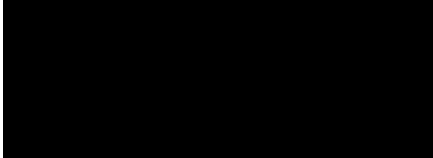
Released

**Contact
Information**

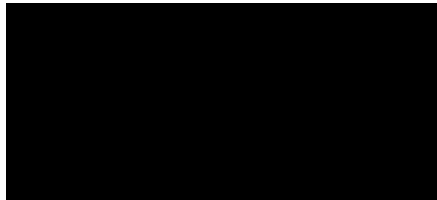
If you have any questions or concerns regarding this notification, please call the following phone number: United States: 1-800-437-1171. For other countries, please contact your local GE Healthcare Service Representative.

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,



Russell Roberson
Vice President QARA
GE Healthcare IT



Jeff Hersh, MD
Chief Medical Officer – Medical Solutions
GE Healthcare