

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. #85470

To: Director/Manager of Cardiology/Radiology
Hospital Administrator
Head of Cardiology/Radiology Department
PACS Administrator
Director of IT Department
Head, Biomedical Engineering

RE: Centricity PACS-IW V3.7.x, Centricity PACS-IW with Universal Viewer V5.0 and Centricity Universal Viewer V6.0 with PACS-IW foundation – **Images from two different patients may be contained in a single study.**

Safety Issue

GE HealthCare has become aware of an issue where images from two different patients may be contained in a single study, when stored in Centricity PACS-IW V3.7.x, Centricity PACS-IW with Universal Viewer V5.0 and Centricity Universal Viewer V6.0 with PACS-IW foundation. This issue could contribute to an adverse patient outcome.

This situation can occur during the following workflow:

1. The acquisition device (such as a DX scanner) obtains the information about the scheduled procedures (also known as orders) including patient demographics, accession number, procedure code, and Study Instance UID from a DICOM Modality Worklist provided by a Radiology Information System (RIS), an EMR, or an interface engine.
2. The technologist incorrectly selects Patient A at the acquisition device when performing a study on Patient B.
3. The technologist identifies this error and tries to address the issue by correcting the Patient Demographics of the study to Patient B, but this action does not change the Study Instance UID.
4. When Patient A arrives, the technologist selects the order for Patient A at the acquisition device and stores the study in PACS. Because the Study Instance UID is the same, the studies for Patients A and B will be merged (ie. both patient A and patient B images will be included) with Patient A's demographics.

In the rare event that this issue is not identified, it is possible that the images from Patient B will be used to diagnose Patient A, which can result in misdiagnosis for Patient A.

There have been no injuries reported because of this issue.

**Actions
to be
taken by
Customer
/User**

You can continue to use your device by following the instructions below:

The healthcare professional can use one of the two following options to correct when the wrong patient's (Patient A) order was selected when performing a study on Patient B.

Option 1: Correct the Study on Modality

1. Open Centricity Universal Viewer / Centricity PACS-IW and log into the application.
2. From the Worklist, select the exam needing correction.
3. Delete the series of Patient B from the Patient A's study in PACS using Centricity Universal Viewer Worklist / PACS-IW Worklist.
4. Associate the Images of Patient B with Order for Patient B on the Modality.
5. Store the study for Patient B into PACS.

or

Option 2: Correct the Study by using Centricity Universal Viewer Worklist (V5.0 / V6.0) / Centricity PACS-IW Worklist (V3.7.x)

1. Open Centricity Universal Viewer / Centricity PACS-IW and log into the application.
2. From the Worklist, select the exam needing correction, select the "Split Study" function.
3. The Split Study dialog displays list of series.
4. Select all series associated for Patient B, keep the "Change Patient/Study Info for New Study" checkbox checked, then select the "Split" button,
5. Update the demographic data with Patient B's data in the Change Patient/Study Information dialog.
6. Click "Change" - The study will now be split into two.
7. Save the study. A new Study is created with Patient B demographics, and a new Study Instance UID.

Complete the attached Medical Device Notification Acknowledgement Response form and send to Recall.85470@ge.com

**Affected
Product
Details**

Centricity PACS-IW software versions V3.7.x through 3.7.3.9 SP3.

Centricity PACS-IW with Universal Viewer software versions 5.0 SPx with PACS-IW foundation.

Centricity Universal Viewer with PACS-IW foundation software versions 6.0 SP0 through 6.0 SP7.1

These issues do not impact customers using Centricity Universal Viewer with a Centricity PACS foundation.

Intended Use

The affected products are devices that display medical images, data from various imaging sources, and other healthcare information sources. Medical images and data can be viewed, communicated, processed, and displayed. The devices can be used to provide images for diagnostic purposes by trained professionals.

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.

After the software has been corrected, please destroy all previous versions of the locally stored application installation package(s) immediately.

Contact Information If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local 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 per the contact information above.

Sincerely,



**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE HealthCare promptly upon receipt of this letter and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

There are two options for your convenience:

- 1) Electronic response form (this page)

OR

- 2) Manual filled and scanned response form (next page)

Please scan the QR code or follow the link below to complete the workflow

<https://app.sc.ge.com/esurveys/takesurvey/18446744073710815816>



Alternatively, if the workflow on the previous page is not possible, please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

*Customer/Consignee
Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: Recall.85470@ge.com

