

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. #85469

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

RE: Centricity™ Enterprise Archive V2.X, V3.X, V4.X and Enterprise Archive Version 8

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 Enterprise Archive (EA) and/or Enterprise Archive (EA). 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), Cardiovascular Information System (CVIS), 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 EA. 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.

Note: The issue does not occur when the EA is used in the following configurations:

- Centricity Universal Viewer with EA foundation when the configuration has Centricity Cardio Workflow (CCW)
- Centricity Universal Viewer with Centricity PACS foundation and the EA used as a long-term archive
- Universal Viewer V8 with EA foundation

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

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

If the site has Centricity Universal Viewer, 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. Delete the series of Patient B from the Patient A's study in EA using Centricity Universal Viewer Worklist.
2. Associate the Images of Patient B with Order for Patient B on the Modality.
3. Store the study for Patient B.

Option 2: Correct the Study by using Centricity Universal Viewer Worklist

1. Open Centricity Universal Viewer and log into the application.
2. From Centricity Universal Viewer 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.

If the site does not have Centricity Universal Viewer, the EA Administrator 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 or reuse of Study Instance UID workflows are detected:

Option 1: Correct the Study on Modality

1. Delete the impacted series from the study on EA Console.
2. Associate the Images with correct Order/Study Instance UID on the Modality.
3. Store the Correct study in EA.

Option 2: Correct the Study by Splitting Study using EA console

1. In the event the images from two patients are part of one study, please refer to EA reference guide *Splitting Study* section
2. Create a new study and move the impacted series from combined study to newly created study.

Complete the attached Medical Device Notification Acknowledgement Response form and send to Recall.85469@ge.com

**Affected
Product
Details**

Centricity Enterprise Archive V2.X, V3.X, V4.X and Enterprise Archive Version 8

Intended Use

The affected software products are devices that are used for receiving, archiving, and sending electronic medical data. Qualified system administrators install, monitor and maintain the system. DICOM devices communicate with the archive using the DICOM protocol. XDS-enabled systems communicate with the archive following the XDS and XDS-I profiles.

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 immediately per the contact information above.

Sincerely,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Scott Kelley
Chief Medical Officer
GE Healthcare

**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/18446744073710726636>



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.85469@ge.com

