URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. #85467

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

RE: Centricity PACS-IW, (PACS-IW) Centricity PACS-IW with Universal Viewer (UV-IW) and Centricity Universal Viewer with PACS-IW foundation (UV-IW) - **Incorrect patient identification and/or patient demographic errors.** Potential patient mismatch in certain clinical scenarios.

Safety Issue

GE HealthCare has become aware of an issue where information from two different patients can be mismatched when correcting patient or study information.

The issue occurs when the following sequence of events happens:

1. The user incorrectly selects Patient A at the acquisition device (such as a CT scanner) when they are performing a study on Patient B.

2. The user recognizes they selected the wrong patient at the acquisition device and tries to address the issue by using a combination of Cancel Order and Delete Study workflows. However, this action does not permanently detach the study for Patient B from Patient A's record.

3. When any new order for Patient A is received, the study for Patient B will revert to association with Patient A's record and will no longer be associated with Patient B's record.

In the rare event that this mismatch is not noticed, it may result in misdiagnosis for Patient A.

There have been no injuries reported as a result of this issue.

Actions to be taken by Customer /User

You can continue to use your device.

GE HealthCare will contact you to review your historic studies to determine if any existing studies on your system are affected.

To prevent the occurrence of the issue, the user can select either of the two following options when updating or correcting data for a patient or study.

Option 1: Detach Workflow

1. Detach patient A order from the study.
2. Update patient information to the corrected study from Study List by using a study management function so that patient demographics and images match.
3. Match the correct patient order from Study List.

OR

Option 2: Delete Study Workflow

1. Delete Patient A Study from PACS-IW or UV-IW worklist by selecting the "Delete study" menu.
2. Correct the patient information at the acquisition device console for the study.
3. Resend corrected study from acquisition device to PACS-IW or UV-IW.

Complete the attached Medical Device Notification Acknowledgement Response form and send to Recall.85467@ge.com

Affected Product Details

Centricity PACS-IW Software versions 3.6.x through 3.7.3.9 SP3.

Centricity PACS-IW with Universal Viewer with PACS-IW foundation Software versions 5.0.x.

Centricity Universal Viewer with PACS-IW foundation Software versions 6.0 through 6.0 SP7.1; GTIN 00840682103800.

NOTE: These issues do not impact customers using Centricity Universal Viewer with a Centricity PACS foundation or Centricity Universal Viewer Cardiology.

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 plan execution for the correction.

After a GE HealthCare representative has updated your system, please destroy the installation media for affected software at your site.

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 & Safety Officer
GE HealthCare

GE HealthCare Ref. # 85467

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://supportcentral.ge.com/esurvey/GE_survey/takeSurvey.html?form_id=18446744073710487948

In case of issues with the link, please contact GE Healthcare at 1-800-437-1171

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.85467@ge.com