

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 85471

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

RE: Universal Viewer Workflow Manager and Centricity Universal Viewer Workflow Manager

Safety Issue

GE HealthCare has become aware of an issue when using Universal Viewer or Centricity Universal Viewer with Workflow Manager (WFM). In that circumstance, if a third-party reporting application is used to launch exams, it could display information on a different patient than WFM and the Viewer.

The situation can occur during the following workflow:

- 1) Radiologist opens Study A from a third-party reporting application which in turn opens Study A in WFM and Study A's images in the Viewer.
- 2) Radiologist saves report for Study A in the third-party reporting application, and Study A's report closes in the third-party reporting application. If, at this point, the browser hosting WFM has timed-out due to inactivity in WFM, then WFM and the Viewer will not close Study A.
- 3) Radiologist opens Study B from the third-party reporting application. The third-party reporting application shows Study B, but WFM and the Viewer still show Study A with demographics for Study A displayed.

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

Actions to be taken by Customer/User

Pending a software update by GE HealthCare, you can continue to use your device and minimize the potential for this issue to occur by doing the following:

Option 1: Update Browser Settings

If using Microsoft Edge, add WFM homepage as a site to "Never put these sites to sleep"

- 1) Open a Microsoft Edge browser window, select "Settings" then "System and performance".
- 2) Under "Optimize Performance", make sure "Save resources with sleeping tabs" is set to "On".
- 3) Next to "Never put these sites to sleep", select "Add", type in your site's WFM homepage full URL, and then select "Add".

If using Google Chrome, add WFM homepage as a site you to "Keep these sites active"

- 1) Open a Google Chrome browser window, select to “Settings” then “Performance” .
- 2) In the “Keep these sites active” section, click “Add” and type in your site’s WFM homepage full URL.

And / Or

Option 2: Discontinue use of bi-directional reporting (bi-directional workflow refers to the ability to select an exam from the reporting application and put WFM into context for that exam). Follow instructions in the User Manual (available within the application Help option), for your affected product to discontinue use of bi-directional reporting. Reference to the applicable section of the User Manual is included in the impacted product list in the following section.

After applying either of the above options, continue to confirm the reporting text is associated with the correct patient in the viewer prior to saving the text.

Complete the attached Medical Device Acknowledgement Response form and send to Recall.85471@ge.com

Affected Product Details

The following systems with the software versions below are impacted:

Device sold under	Product	Impacted software versions	User Manual Section to Discontinue Bi-Directional Reporting
Centricity Universal Viewer	Centricity Universal Viewer with Workflow Manager	7.0 SP1.1	Section 8.3.11 Desktop Integrations
Centricity Universal Viewer	Centricity Universal Viewer with Workflow Manager	7.0 SP1	Section 8.3.12 Desktop Integrations
Centricity Universal Viewer	Centricity Universal Viewer with Workflow Manager	7.0 SP0.0.5	Section 8.4.14 Desktop Integrations
Centricity Universal Viewer	Centricity Universal Viewer with Workflow Manager	7.0 SP0.1.0	use v7 sp0.0.5 User Manual section 8.4.14 Desktop Integrations
Universal Viewer	Universal Viewer Workflow Manager	v8 SP1	Section 8.3.10 Desktop Integrations
Universal Viewer	Universal Viewer Workflow Manager	v8 SP0.1	Use v8 sp0 User Manual section 8.3.11 Desktop Integrations
Universal Viewer	Universal Viewer Workflow Manager	v8 SP0	Section 8.3.11 Desktop Integrations

Intended Use:

Universal Viewer is a software application that displays medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

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 Services or your local Service Representative.

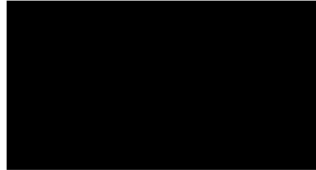
GE HealthCare confirms that this notice has been notified to the appropriate Regulatory Agency.

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



Chief Quality & Regulatory Officer
GE Healthcare



Chief Medical Officer
GE Healthcare

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

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.

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/18446744073710783936>



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.85471@ge.com

You can obtain this e-mail address through the QR code below:

