URGENT MEDICAL DEVICE CORRECTION

1 August 2024

GE HealthCare Ref. # 85476

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

RE: Centricity Universal Viewer Zero Footprint Client - Latest clinical addended report is not showing by default in certain situations.

Safety Issue

GE HealthCare has become aware of an issue in Centricity Universal Viewer Zero Footprint Client (ZFP) versions v6.0 SP9.x and SP10.x where the latest addended report is not shown by default to the user. The issue occurs when the addendum is created on the same day as the original report but at a different time, and only when launched on the following browsers.

- Internet Explorer 10 (IE10)
- Internet Explorer 11 (IE11)
- Firefox

Users continue to have access to all reports via in the Series Selector. However, since the latest addendum may not be shown by default in the ZFP Viewer, this could lead to potential misdiagnosis if a user relies only on the information in the original report and does not review the addended report.

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. Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions below.

Follow one of the below recommendations to ensure the latest addendum is being reviewed:

1. Use Microsoft Edge or Google Chrome browsers when launching ZFP Viewer.

   OR

2. If you cannot use the browsers listed in #1, to find the addendum / latest report, review all the reports available for the study in the Series Selector. Navigation to the series selection can be found in the User Manual under Section 2.3.3 of The Series Selector, with subheading as “Open a report/document using series selector”.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.85476@gehealthcare.com.

Affected Product Details

Centricity Universal Viewer Zero Footprint Client Versions 6.0 SP 9.x and 10.x
GTIN 00840682102988

INTENDED USE:

Centricity Universal Viewer Zero Footprint Client is a device that displays medical images, data from various imaging sources, and other healthcare information sources. Medical images and data can be viewed, communicated, processed, and displayed within a computer network or on a workstation. The device may be used to provide images for diagnostic purposes by trained professionals.
Typical users of this system are authorized individuals and trained healthcare professionals who view medical images and data.
Mammographic images may only be interpreted using a monitor compliant with requirements of local regulations and must meet other technical specifications reviewed and accepted by the local regulatory agencies.

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, be sure to 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.

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,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

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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.

Facility 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 all potential users 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: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: recall.85476@gehealthcare.com