URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188 USA

Date of Letter Deployment

GEHC Ref# 85459

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: Potential to display incomplete patient imaging study in Centricity Universal Viewer Zero Footprint configured with a Centricity PACS back end.

This document contains important information for your product. Please ensure all potential Users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

GE Healthcare has become aware of a potential safety issue associated with the viewing of incomplete studies with Centricity Universal Viewer Zero Footprint (ZFP).

When an Image Volume (image storage device) is newly added or modified with the Centricity PACS Short-term Storage (STS), this image storage device will not be recognized by Centricity Universal Viewer Zero Footprint until the ZFP System is restarted.

As a result, parts of a patient's study (a series or individual images) that may reside on this newly added or modified Image Volume are not displayed in Zero Footprint.

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 below instructions, until a GE Service Representative can restart your ZFP system.

1) Check the completeness of a patient's study based on clinical procedure type, intended reason for exam, and/or other indications on the worklist.

A) For current studies, viewed with ZFP on a desktop or tablet, the worklist provides a complete count of DICOM series objects and images present in the study. Upon launching of a study, verify that the count of DICOM series objects and images in the navigator are consistent with the count in the worklist. The worklist can be accessed by logging into the ZFP server or by using the study search icon, if configured, on the ZFP viewer page toolbar.

B) For an already dictated study, if the study contains a report/clinical document, the report may reference pathology that is not present in the images being viewed on ZFP, indicating that images are missing from the study.

If you encounter potentially affected studies, please contact a GE Healthcare Service Representative.

2) For inquires related to historical data, please contact a GE Healthcare Service Representative for assistance.

3) Complete and return the attached response form to Recall.85459@ge.com

Affected Product Details

Centricity Universal Viewer Zero Footprint Client Versions 6.0 SP9, SP9.0.1, SP9.0.1.1, SP9.0.1.2, SP9.0.1.3, SP9.0.1.4, SP9.0.1.5, SP10, SP10.1, SP10.2, SP10.2.1, SP10.2.1.1, SP10.2.2, SP10.2.2.1 configured with a Centricity PACS back end.

GTIN 00840682102988

This does not impact systems where Centricity Universal Viewer Zero Footprint Client is configured to retrieve patient studies only from Centricity Enterprise Archive.

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.

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 immediately per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

GEHC Ref# 85459

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.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

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): _____

Please return completed form by scanning or taking a photo of the completed form and email to:
Recall.85459@ge.com

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