



URGENT MEDICAL DEVICE CORRECTION

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

Date of Letter Deployment

GEHC Ref# 85464

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 inaccurate measurements on images in Centricity Universal Viewer Zero
Footprint Client (ZFP)

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 #1

GE Healthcare has become aware of an issue where Distance and Area measurement values can display inaccurately on images that are scaled down from their original resolution.

In the unlikely situation where this issue is not recognized by the user, it can potentially result in improper medical treatment.

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

Actions to be taken by Customer / User for Issue #1

You can continue to use your device in accordance with the User Manual and the actions below:

Do not utilize any measurements when the "Lossy" overlay is displayed in the lower left of the viewport and, when you hover over the word "Lossy", it displays the tooltip box with the phrase "Image scaled down from its original resolution".

Safety Issue #2

When the image contains non-squared pixels including DICOM Gray Scale Presentation State (GSPS), such as some ultrasound and legacy MR images, all measurements displayed in the viewer as well as the scale marker are inaccurate.

In the unlikely situation where this issue is not recognized by the user, it can potentially result in improper medical treatment.

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

Actions to be taken by Customer / User for Issue #2

You can continue to use your device in accordance with the User Manuals and the actions below:

Do not perform any measurement on non-squared pixel images. Always confirm critical diagnostic measurements by other means (i.e using a fiducial marker of known size).

Please complete and return the attached acknowledgement form to
Recall.85464@ge.com

**Affected
Product
Details**

Centricity Universal Viewer Zero Footprint Client Versions 6.0 SP6 through SP11.4

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 at 1-800-437-1171 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# 85464

**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.85464@ge.com

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

