URGENT MEDICAL DEVICE CORRECTION

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

Date of Letter Deployment

GEHC Ref# 85465

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 and Universal Viewer: Inaccurate Distance and Area measurements with use of Global Stack viewport.

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

Distance and Area measurements can display inaccurate measurement values that are overestimated (measurement size is larger than true size) when a study is launched in Global Stack viewport on Centricity Universal Viewer and Universal Viewer.

True size printing on film/paper and images exported to storage medium (i.e. CD) will also reflect these inaccurate measurement values if the measurements were done in Global Stack viewport.

This issue impacts the following modality generated image series:
Computed Radiography (CR), Digital X-Ray Radiography (DX), X-Ray Angiography (XA), X-Ray Radio Fluoroscopy (XRF), Radio Fluoroscopy (RF) and Mammography (MG).

In the unlikely situation where this issue is not identified, 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

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

It is recommended that you do not rely on measurements displayed in the Global Stack viewport in the Viewer. Users can perform the measurement activity by;

1. Using Overview or Series Viewport to perform the measurement.
   or
2. If using Global Stack viewport, manually calibrate the image to create a measurement calibration reference and then perform necessary measurements (*Calibrate* section in the user manual.)

Please complete and return the attached acknowledgement form to **Recall.85465@ge.com**

Affected Product Details

The following Centricity Universal Viewer and Universal Viewer products are affected:

Product	GTIN
Centricity Universal Viewer Software Versions: 6.0 SP9 6.0 SP9.0.1 through 6.0 SP9.0.1.11 6.0 SP9.0.2 6.0 SP10 through 6.0 SP10.4	00840682103800
Centricity Universal Viewer Software Versions: 7.0 through 7.0 SP0.0.4.9 7.0 SP0.0.5 7.0 SP0.1.0 7.0 SP1	00840682145794
Universal Viewer Software Versions: 8.0 8.0 SP0.1.0 8.0 SP0.1.1	00195278379610

Device Clinical 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. Centricity Universal Viewer and Universal Viewer are intended for the diagnostic interpretation of medical images conducted 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 arrange for the correction.

After the software has been corrected, destroy all previous versions of the locally stored application installation package(s) immediately.

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

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

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.

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. We acknowledge that the affected software media has been destroyed.

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.85465@ge.com

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