URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GEHC Ref# 85460

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 (ZFP), Centricity PACS RA1000 Workstation (RA1000), Centricity Radiology RA600 (RA600), Centricity Cardiology CA1000 (CA1000) and Centricity Enterprise Web (CWeb): Inaccurate Distance and Area measurements

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.

GE HealthCare has become aware of two potential issues where inaccurate Distance and Area measurements can be displayed.

Both issues impact 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) including saved DICOM Grayscale Presentation State (GSPS).

Safety Issue #1

Distance and Area measurements can display inaccurate measurement values when performed on magnified images.

True size printing on film/paper for images will also reflect these inaccurate measurement values.

Images exported from RA600 or CA1000 to a storage medium (e.g., CD) will also reflect these inaccurate measurement values.

The measurement value is always overestimated (measured size is larger than true size).

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 #1

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

It is recommended that you do not rely on measurements displayed in the Viewer. Manually calibrate the image to create a measurement calibration reference and then perform necessary measurements:

- Image Calibration with ZFP product
- Measure Calibration Tool with RA1000 product
- Calibrate Option with RA600 and CA1000 products by selecting (Image → Annotation → Create → Calibrate) from the main viewer tool bar.

- Note: Image Calibration is not applicable for CWeb product.

Please complete and return the attached acknowledgement form to **Recall.85460@ge.com**

Safety Issue #2

Specific to ZFP, Distance and Area measurements can display inaccurate measurement values when performed on lossy images that are scaled down from their original resolution.

The measurement value is always underestimated (measured size is smaller than true size).

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 #2

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

It is recommended that you do not perform measurements on lossy images.

Please complete and return the attached acknowledgement form to **Recall.85460@ge.com**

Affected Product Details

The following Centricity systems with the software versions listed below are impacted. The table also indicates the impacted modality images for each of the products:

Product	Impacted Software Version	Device Identification Number / GTIN	CR/DX Images	XA/XRF/RF Images	MG Images
Centricity Universal Viewer Zero Footprint Client	6.0 SP11 through 6.0 SP11.4	00840682102988	Impacted	Impacted by Safety Issue 2 only	Impacted by Safety Issue 2 only
Centricity PACS RA1000 Workstation	3.0 through 3.2 SP8 4.0 through 4.0 SP14 6.0 through 6.0 SP10.3 7.0 through 7.0 SP0.0.4.7	Not applicable 00840682124447 00840682104821 00840682145558	Impacted	Not impacted	Not Impacted
Centricity Radiology RA600	7.0 through 7.0 SP 8.0 through 8.0 SP14H	Not applicable 00840682125260	Impacted	Not impacted	Impacted
Centricity Cardiology CA1000	1.0 through 1.0 SP 2.0 through 2.0 SP14H	Not applicable 00840682125260	Impacted	Not impacted	Impacted
Centricity Enterprise Web	3.0 through 3.0 SP14d 4.0 through 4.0 Spa6c and 4.0 Spa7b	Not applicable Not applicable	Impacted	Impacted	Impacted

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. The devices can be used to provide images for diagnostic purposes by trained professionals, except in the following instances outlined in the product labeling:

- Warning: Centricity Universal Viewer Zero Footprint client for mobile devices is intended for non-diagnostic review.
- Warning: Centricity Universal Viewer Zero Footprint client is contraindicated for the use of lossy compressed mammographic images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.
- Warning: The ZFP DICOM Viewer is not intended for diagnostic use with Mammography images.
- Warning: Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations with Centricity RA600 and Centricity CA1000.
- Warning: The Centricity Enterprise Web is not intended for primary diagnosis.

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.

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

Scott Kelley
Chief Medical Officer
GE HealthCare

GE HealthCare

GEHC Ref# 85460

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.85460@ge.com

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