



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. W440
Waukesha, WI 53188 USA

<Date of Letter Deployment>

GEHC Ref# FMI 85454

To: Director/Manager of Radiology
Director/Manager of Cardiology
Hospital Administrator
Head of Radiology Department
PACS Administrator
Director of IT Department

RE: Centricity Universal Viewer measurements saved into a DICOM Grayscale Presentation State are incorrect in subsequent views for exams containing series with different pixel sizes.

This document contains important information for your product. Please ensure that 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 identified that Centricity Universal Viewer 6.0 SP10 or higher versions may save inaccurate point to point / area measurement values into DICOM Grayscale Presentation States (GSPS).

When exams containing series with differing pixel sizes (CT, MR, US or any modality generating series with differing pixel sizes) are opened and image measurements measured by point to point or area measurement tools in Centricity Universal Viewer 6.0 SP10 or higher version, and subsequently saved into the DICOM Grayscale Presentation State, the values will be magnified in the GSPS saved state.

Subsequent viewing of this study in Universal Viewer with the applied presentation state will display an incorrect measurement value. This may lead to a potential misdiagnosis.

Centricity Universal Viewer 6.0 SP10 or higher versions with either Centricity PACS (CPACS) or Enterprise Archive (EA) Foundations are affected by this issue.

There have been no injuries reported because of this issue.

The Presentation State and measurement values are displayed correctly when viewed in GEHC Centricity Universal Viewer Zero Footprint Client.

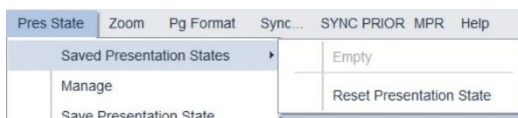
Safety Instructions

You may continue to use your system in accordance with the User Manual and the instructions below.

When viewing a primary or comparison study with a presentation state applied:

1. Reset the presentation state in order to view the images as acquired and complete any measurements in accordance with instructions below for completing measurements in a primary or comparison study without a

presentation state applied. To reset the presentation state, choose the “Reset Presentation State” option under “Saved Presentation States” in the “Pres States” menu:



2. Do not create or load any Presentation State for a study.
3. In Universal Viewer Done option, uncheck “Save Presentation State for primary” and “Save for local comparison also” option.
4. In Universal Viewer Done option, Uncheck “Load presentation state on startup” option.

When completing measurements in a primary or comparison study without a presentation state applied:

1. Measurements are saved correctly when a key image is created and are displayed as a standard DICOM image object. Key image function allows you to mark any images as key images, and it captures the display state of an image with presentation state (W/L, Zoom, Annotations, Measurements, etc.). Refer to the Centricity Universal Viewer User Manual Section *Key images* for more information about how to create key images.

As a System or PACS Administrator:

1. In order to prevent the creation of incorrect presentation state, it is recommended that the System administrator remove “PrState-Insert” and “QC mark” privileges from all user accounts. Refer to the Centricity Universal Viewer Administrator Manual Section *To Add or Edit Privileges for an Admin Group*.
2. Review the accuracy of measurements when viewing studies in non-GE viewers or applications, which had been saved with a presentation state created on Universal Viewer.

Affected Product Details

Centricity Universal Viewer 6.0 SP10 or higher

Universal Viewer 6.0SP10 – (01)00840682104807(10)6.0SP102094610001C
Universal Viewer 6.0SP10.1 – (01)00840682103800(10)60SP10.12094097001G
Universal Viewer 6.0SP10.1.1 – (01)00840682103800(10)60P1011.2094097001H

Product Correction

GE Healthcare will correct the described issue on all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction, which will be installed by a GE service engineer.

After the GE Healthcare representative has updated your system, be sure to delete the affected installation media 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,

A handwritten signature in dark blue ink, appearing to read "Laila", followed by a long horizontal flourish.

Laila Gurney
Senior Executive, Quality & Regulatory
GE Healthcare

A handwritten signature in dark blue ink, appearing to read "Jeff", followed by a long horizontal flourish.

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



GE Healthcare

GEHC Ref# 85454

**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 Ref# 85454.

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 taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:

Recall.85454@ge.com

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

