



URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 85446

To: Director/Manager of Radiology
Hospital Administrator
Head of Radiology Department
PACS Administrator
Director of IT Department
Chairman Medical Board
Relevant Head of Departments for hospital

RE: Image orientation markers may be displayed incorrectly in certain scenarios when images are flipped within Centricity Universal Viewer Zero Footprint (ZFP).

Please ensure that all users of Centricity Universal Viewer Zero Footprint are made aware of this safety notification and the recommended actions until GE Healthcare can correct this situation.

Safety Issue #1

Issue #1 affects Software Versions 6.0 SP7, SP7.0.1, SP7.0.2, SP7.0.3, SP8, SP8.0.1, SP8.0.a and SP8.0.2.

When an image is flipped horizontally and vertically, the orientation markers appear correctly on the image to which they were applied. However, once new image rendering happens on this image or series (with scrolling; playing ciné; maximizing or changing viewports/layouts; or synchronizing viewports and resizing the browser), the new image orientation is correctly maintained but the display of orientation markers can become incorrect.

This issue occurs when at least one vertical and one horizontal flip are both performed. The sequence of how images are flipped does not matter.

This issue persists for the duration of review session, but when the study is saved and reopened in any viewer, including ZFP, the issues correct themselves as the source data is not impacted (including presentation states), and remains correct.

This situation is independent of the type of medical imaging.

Safety Instructions for Issue #1

Until a product modification is available to correct this issue, the following actions are recommended.

- Use the Rotate tool (the toolbar icon shown below) to achieve the same orientation as a combination of flip horizontal and flip vertical i.e. rotate the image by 90 degrees twice.



Rotate an Image to the Right Icon

- Do not use isolated or extracted images from ZFP through screenshots or similar.

Apply the correct patient (prone) positioning registration at the medical imaging equipment prior to sending the images to PACS-archive to reduce the need for image manipulation (flipping an image) in ZFP.

Safety Issue #2

Issue #2 affects Software Versions 6.0 SP7, SP7.0.1, SP7.0.2, SP7.0.3, SP8, SP8.0.1, SP8.0.a, SP8.0.2, SP9 and SP9.0.1.

When an image in a series is flipped and then rotated in Zero Footprint Viewer (ZFP), the orientation markers appear correctly on the image to which they were applied. However, once you navigate to another image in the series and the image you navigated to has a different orientation than the prior image from which you navigated, the new image orientation is correctly maintained but the display of orientation markers can become incorrect.

This issue occurs when at least one flip followed by at least one rotate is performed.

When the study is saved and reopened in any viewer, including ZFP, the problem corrects itself as the source data is not impacted (including presentation states), and remains correct.

This situation is independent of the type of medical imaging.

**Safety
Instructions
for Issue #2**

Until a product modification is available to correct this issue, the following actions are recommended.

- Do not use the following combination of actions on an image (the toolbar icons shown below) if you intend to scroll through the rest of the series and the same orientation markers are not shared across all the images in the series:



Flip an image horizontally

OR



Flip an image vertically

AND Followed by



Rotate an image to the right

- Do not use isolated or extracted images from ZFP through screenshots or similar.
- Apply the correct patient (prone) positioning registration at the medical imaging equipment prior to sending the images to PACS-archive to reduce the need for image manipulation (flipping an image) in ZFP.

**Affected
Product
Details**

Centricity Universal Viewer Zero Footprint Client GTIN 00840682102988
Software Versions 6.0 SP7, SP7.0.1, SP7.0.2, SP7.0.3, SP8, SP8.0.1, SP8.0.a, SP8.0.2, SP9 and SP9.0.1

**Product
Correction**

A GE Healthcare representative will contact you to arrange for the correction. GE Healthcare will correct all affected products at no cost to you

**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,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare