GE Healthcare

URGENT FIELD SAFETY NOTICE

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<Date of Letter Deployment>   GEHC Ref# 85446

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

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 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,

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare