

GE Healthcare

**URGENT MEDICAL DEVICE
CORRECTION**

GE Healthcare IT
540 West Northwest Hwy
Barrington, IL 60010
USA

<Date Of Mailing to be entered>

GE Ref: 85128, 2

To: Director/Manager of Radiology
Hospital Administrator
Head of Radiology Department
Head of Clinical Department

RE: GE Centricity PACS RA1000 Workstation; Software Versions: *PathSpeed 7.x, 8.x,*
Centricity 1.X, 2.0.X.

GE Healthcare IT has become aware of a potential issue associated with Centricity PACS RA1000 Workstation Software. **Please ensure that all potential users in your facility are made aware of this product notification and the recommended actions.**

Safety Issue Issue 1:

A potential patient safety issue has been identified related to image orientation. GE PACs RA1000 has the capability to modify image orientations per system and/or user preferences. Where an image has been modified from the original modality acquired state and is viewed on other DICOM viewer applications, the image orientation may not display with the modifications as expected. All image orientation markers, however, will be correctly displayed.

Safety Instructions:

Your Site System Administrator or GE Healthcare Field Service Engineer should determine the current settings for the following properties:

```
com.ge.med.platinum.work.MedImageDE.flipHorizontal=false  
com.ge.med.platinum.work.MedImageDE.flipVertical=false
```

If the above properties are already set to false, no further action needed. Setting the above properties to false will ensure that Centricity RA1000 will initially display images with the original modality acquired state as specified in the DICOM header. (Users can and will 'flip and save' to put into the desired orientation as recommend below.)

If the above properties are set to true, please work with the your Site System Administrator or GE Healthcare Field Service Engineer for the site and have it set to false. Changing these settings can impact workflow. The most commonly affected workflow would be related to prone scans such as CT Sinus, CT Renal Biopsy and MRI Breast. The recommend workflow for these types of studies is for the technologist to flip and save the images during the verification process. It is important that you determine any impacts to your workflow resulting from the re-set, and communicate them to all users appropriately.

Issue 2:

A potential safety issue has been identified related to use of the mouse wheel when used in the sheet mode to navigate between the pages of images. Images can

inadvertently be selected or unselected. If the user subsequently modifies the image orientation of one of these selected images, other selected images may be modified without the user being aware of images being unintentionally selected.

This may occur under the following condition:

- Image display in sheet layout mode only
 - The problem does not exist when the images are in stacked mode
- Page Images option for Sheet Layout under Wheel Mouse Options in the Cine Preferences tab is selected
 - To prevent this issue, set the wheel mouse in sheet mode to 'Show Next Image', then this problem does not happen

Safety Instructions:

- Do not use the wheel mouse in sheet mode to navigate page by page. Instead, choose another tool for navigating through images such as arrow navigation keys, hot keys, etc.
- Set user preference to select "Show Next Image" option for Wheel Mouse Options in the Cine Preferences tab.
- When a user is reviewing the images, it is important to check the image orientation marker to ensure the image is in the correct orientation.

Issue 3:

A potential safety issue has been identified when the image orientation is modified by the system or other users. The image orientation marker may not be visually apparent to the user and may result in misinterpretation with the orientation of the image.

Safety Instructions:

When a user is reviewing the images, it is important to check the image orientation marker to ensure image is in the correct orientation.

Issue 4:

A potential safety issue has been identified when a user modifies and saves presentation state in RA1000. Examples of modification include image orientation change, window leveling, pan, zoom, and annotations. When modified images are exported from the PACs system to a CD burner, the user may not be aware that the modified presentation state has not been saved with the DICOM images when sent to the CD burner.

Safety Instructions:

DICOM images sent out are not modified from the original acquired state when exported from GE PACS system.

For Centricity 3.0.x., to send saved presentation state, users must send GSPS (gray scale presentation state) with DICOM images to CD burner. GSPS functionality is supported only on 3.0.x versions of Centricity PACs RA1000 workstations.

Users need to ensure DICOM image display viewer used to display exported images has the capability of displaying images with GSPS objects.

For Centricity 1.x, 2.0.x, 2.1.x version, users need to be aware that exported DICOM images do not have presentation modification saved on PACS system since GSPS

objects are not supported in these versions.

Affected Product Details GE Centricity PACS RA1000 Workstation; Software Versions: PathSpeed 7.x, 8.x, Centricity 1.X, 2.0.X.

Product Correction Please follow the instructions described above for issue resolution.

Contact Information If you have questions regarding this notice, please contact your Remote Online Center (ROC), Field Engineer (FE), or GE Customer Care Center at:

Americas: 800-437-1171

EMEA: +33 1 30 83 13 00

Asia:

Singapore - 63880932

Malaysia - 1800883911

Australia - 1800659465

New Zealand - 0800659465

India - 1800114567

Korea - 15446119

Japan - 0120055919

Taiwan - 0800021770

China - 8008108188


Hong Kong - 852-21006288

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.

Please complete the attached **Customer Reply Form** and Email/Fax to us as indicated on the form.

Thank you,




GM, Quality Assurance and Regulatory Affairs
GE Healthcare Integrated IT Solutions
540 W. Northwest Highway
Barrington, IL 60010
USA

Customer Reply Form

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PLEASE COMPLETE and FAX to GE Healthcare

CUSTOMER CONTACT INFORMATION

Hospital Name		Hospital Contact	
Street Address		City	
State		Postal Code	Country
Phone		Email	

Affected versions: GE Centricity PACS RA1000 Workstation; Software Versions: PathSpeed 7.x, 8.x, Centricity 1.X, 2.0.X.

Please record the date on which your facility received this information as well as the Software version in your facility.

To access the Software Version, click on the HELP menu information where this will be displayed. Alternatively, when logging into the system a Splash Screen will appear which will show the Software Version.

Name, role/position (print/type)	Date
Signature	Software Version

Please FAX back to

+1-847-939-1479

Attention: Regulatory Affairs

GE Healthcare Integrated IT Solutions
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 Barrington, IL 60010

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