

URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

540 West Northwest Hwy
Barrington, IL 60010
USA

GE Ref: 85128, 1

<Date Of Mailing to be entered>

To: Director/Manager of Radiology
Hospital Administrator
Radiology Department

RE: GE Centricity PACS RA1000 Workstation; Software Versions: ALL

GE Healthcare Integrated IT Solutions (IITS) has become aware of a potential safety issue (described below) associated with Centricity PACS RA1000 Workstation Software.

Safety Issue There is a potential patient safety issue involving Default Display Protocols (DDPs). DDP's are hanging protocols used to layout images when displaying a study.

If the user/site DDP was configured to place the current and historical studies in different regions, the user may believe that the old study is the new one and vice versa. If the user does not check the Study Date Time of the exam on the image title bar, then they may interpret the current exam as a historical and vice versa.

Affected Product Details GE Centricity PACS RA1000 Workstation - All Software Versions.

Safety Instructions When displaying images, the user should check to determine if there are historical comparison exams, and in which image regions they are loaded. The study date/time is displayed in the image title bars of every image region.

The user could also check the name of the applied DDP, as it appears on the Display Functions combo button, to see if the applied DDP is a user/site DDP or a system default DDP.

Product Improvement A software enhancement will be provided to you to address this issue.

Contact Information Contact your Remote Online Center (ROC), Field Engineer (FE) or the GE Customer Care Center at 800-437-1171.

Customer Reply Form

GE Centricity PACS RA1000 Workstation Software.

PLEASE COMPLETE and FAX to GE Healthcare

CUSTOMER CONTACT INFORMATION

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

All Centricity PACS RA1000 Workstation software versions are affected.

Until an updated software release is applied, please refer to safety instructions above.

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

To access the Software Version or Build Number, click on the Utilities icon at the bottom of any monitor to open Utilities menu. Click on the "About" tab. This contains the software name, version, and build number.

Name	Date
Signature	Workstation Software or Build Number

Please FAX to 847-939-1479, Attention: Regulatory Affairs GE Healthcare Integrated IT Solutions 540 W. Northwest Highway Barrington, IL 60010 RE: Default Display Protocol Issue-(DDP's)

Please be assured that we are constantly making every effort to maintain a high level of safety and quality in our systems. If you have any questions, please contact us immediately.

Please fill out the attached **Customer Reply Form** and Email/Fax to us as indicated in the form.

Thank you,

A large black rectangular redaction box covering the signature area.A black horizontal redaction bar covering the name of the sender.

GM, Quality Assurance and Regulatory Affairs
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