



URGENT FIELD SAFETY NOTICE

GE Healthcare

GE Healthcare IT
540 W. Northwest Hwy
Barrington, IL 60010
USA

May 2014

GEHC Ref# 85324

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

RE: **Inadvertent Image Rejection and Deletion, Centricity PACS RA1000 Workstation versions 3.2 and higher**

GE Healthcare has recently become aware of a potential safety issue with Centricity PACS. **Please ensure that the facility PACS Administrators and all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

It has been identified that in a reject image workflow where multiple studies are simultaneously opened on the Centricity PACS RA1000 workstation and images are rejected from the active displayed study, images from the previously displayed study may also be rejected.

The issue can occur with a previously displayed study that remains open in the background.

- If one or more, but not all, images in the exam were inadvertently rejected, the image count in the work modes palette identifies fewer images; however, all of the images remain viewable.
- For newly acquired exams, if the entire exam was inadvertently rejected, the RA1000 will return a message stating "Unable to fetch this exam: No images in the exam". The images would then need to be resent to PACS from the modality.
- For historical exams, if the entire exam was inadvertently rejected, the RA1000 will return a message stating "Unable to fetch this exam: No images in the exam", and the exam is not available on the modality, a GE Healthcare Service representative would need to be contacted to restore the exam on the database.

There is a DelRejImg task in Centricity PACS versions 3.2 and higher, that if enabled and running, in conjunction with the inadvertently rejected image issue, poses a potential patient safety hazard due to data loss.

If the DelRejImg task runs, the inadvertently rejected images will be permanently deleted from PACS. If you do not have the DelRejImg task running, there is no potential hazard since the inadvertently rejected images remain on the system.

The deletion of the inadvertently rejected images could result in missed intervention or mis-diagnosis. No patient injuries have been reported. There are no risks to

patients associated with previous use of affected versions of this product

**Safety
Instructions**

Until the permanent fix for this issue is deployed, GE recommends that the following steps be taken:

1. Check to see if the DelRejImj task is active and running.
 - a) Log into CA Tool
 - b) From the Navigation menu, select System Monitor
 - c) From the pull down menu, select Dbase Maintenance
 - d) Scroll to the DelRejImj task (this list is alphabetical)
 - e) Review the Task Status. Possible statuses are "IDLE" or "SUSPEND"
 - f) If the task status is set to "SUSPEND" The task is not running
 - g) If the task is set to "IDLE", move to Step 2
2. Check the Minimum Rejected Image Deletion Time
 - a) From the Navigation menu, select Sys. Configuration
 - b) From the pull down menu, select Pacs Configuration
 - c) Scroll to Minimum Rejected Image Deletion Time (this list is alphabetical)
 - d) Review the Value field
 - e) If the value field is a negative integer (such as the default setting of -1), the Delete Rejected Image process is NOT running and there is no patient safety hazard. If the value field is a positive integer (such as 1 or higher), the Delete Rejected Image process IS running and there is a potential patient safety hazard.
3. A GE Healthcare Service Representative will remove the DelRejImj task from the task table in the Centricity PACS database. This will prevent the DelRejImj task from running, and prevent any rejected images from being deleted. This feature is being removed entirely from the 3.2 release family of Centricity PACS and will be reinstated in a future 4.X workstation release of Centricity PACS.
4. Perform the reject image workflow with only one patient study open at a time.

**Affected
Product
Details**

Centricity PACS versions: 3.2; 3.2.0.1; 3.2.0.2; 3.2.1; 3.2.2; 3.2.2.1; 3.2.2.2; 3.2.2.3; 3.2.6; 3.2 SP7; 3.2 SP8; 4.0; 4.0.1; 4.0 SP3

**Product
Correction**

A future release of Centricity PACS will address the unintentional rejected image issue.

Until a correction for the unintentional rejected image issue is available, A GE Healthcare service representative will remove the DelRejImj task from the task table in the Centricity PACS database. This will remove the rejected image deletion feature, and eliminate the hazard situation.

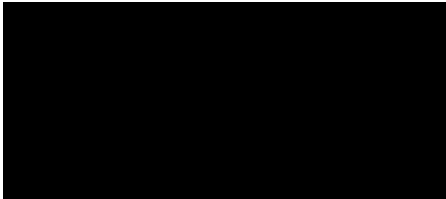
**Contact
Information**

Please contact your local GE Healthcare service representative with any questions regarding this issue.

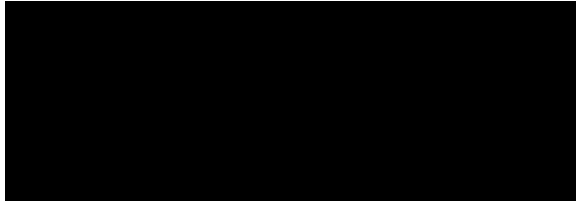
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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,



Vice President QARA
GE Healthcare IT



Chief Medical Officer
GE Healthcare