



## Urgent Field Safety Notice

GE Healthcare

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

GE Healthcare Ref: FMI 85260

January 2013

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

RE: **Improper labeling of exams when using hanging protocols that label exams as Current/Prior/Baseline**

GE Healthcare has recently become aware of a potential safety issue due to the possible improper application of a chronological label used in the hanging protocols - Current, Prior or Baseline labels, which are used for review or interpretation from your Centricity PACS Web Diagnostic (DX) system. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

### Safety Issue

Web-Dx allows the user to be able to label their exams as Current, Prior and Baseline within hanging protocols. It has been found that in certain workflows involving the display of a set of comparison exams where the system labels them, an issue can occur. There are two circumstances in which this can occur.

- A) This can occur when the clinician double clicks additional exams from within the patient folder for review and selecting the appropriate (Current, Prior, Baseline) hanging protocol manually to load the three studies. In some of these instances the prior and baseline studies are reversed and labeled incorrectly (the prior exam is labeled as baseline exam and the baseline exam is labeled as prior exam). This can cause exams to be given the wrong label. This may result in the user being misled as to the true chronological order of the exams displayed.
- B) This can also occur when a user chooses to display comparison studies from the patient folder by right clicking on an exam and selecting "Display as Prior" or "Display as Baseline". This may result in an incorrect study interpretation.

### Safety Instructions

It is recommended that the user be aware of the possibility of the mismatch in labeling of the Baseline and Prior studies:

1. The users should be instructed to look at the date on each exam displayed rather than just the labels assigned to the exam by the system
2. If this problem is detected in your specific workflows, a system administrator can remove the study category labels (Current/Prior/Baseline) from all overlays on the images/exams.

**Affected  
Product  
Details**

GE Centricity PACS Web Diagnostic Software Versions: 1.0, 1.1, 2.0 and 2.1

**Product  
Correction**

A permanent product correction will be provided to address the above issue.

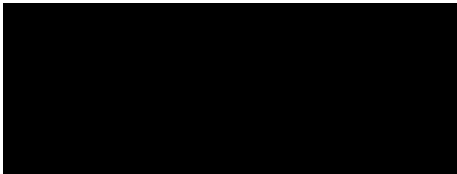
**Contact  
Information**

Please contact your local GEHC-IT service representative with any questions regarding this issue.

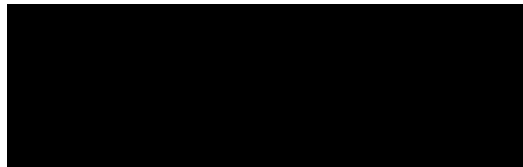
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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.

Sincerely,



Vice President QARA  
GE Healthcare IT



Chief Medical Officer  
GE Healthcare