



## URGENT FIELD SAFETY NOTICE

GE Healthcare

Healthcare Digital  
500 W. Monroe St.  
Chicago, IL 60661 USA

<Date of Letter Deployment>

GEHC Ref# FMI 85452

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

RE: Centricity Universal Viewer Study Management for Systems with CPACS Foundations potential to view studies with incorrect patient images.

***This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.***

### **Safety Issue**

The study management feature in Centricity Universal Viewer supports use cases of splitting and merging series and studies. A software anomaly exists in which the series and/or study changes are properly updated in the Universal Viewer with the Centricity PACS database, however the finalized series or study changes are not propagated, should the study or series be already archived, to either the Enterprise Archive or other Vendor Neutral Archives (VNA).

There is the possibility of viewing studies directly from the Enterprise Archive or VNA with incorrect patient images because the updated series or study is not present in the archive.

This issue does not impact viewing of studies from Universal Viewer.

There have been no injuries reported because of this issue.

### **Safety Instructions**

Users should discontinue use of the UV study management functionality for study split / study info updates until a correction is available.

Users can utilize Centricity PACS Exam Manager or Centricity RA600 for study management.

**Affected  
Product  
Details**

Centricity Universal Viewer with Centricity PACS foundation 6.0 SP9 or higher used in combination with Centricity PACS 6.0 SP9 or higher

Universal Viewer 6.0 SP9 – (01)00840682103800(10)6.0SP92094097001D  
Universal Viewer 6.0SP9.0.0.1 – (01)00840682103800(10)60SP90012094097001F  
Universal Viewer 6.0SP9.0.0.2 – (01)00840682103800(10)60SP90022094097001F  
Universal Viewer 6.0SP9.0.1 – (01)00840682103800(10)6.0SP9012094097001F  
Universal Viewer 6.0SP9.0.1.1 – (01)00840682103800(10)60SP90112094097001F  
Universal Viewer 6.0SP9.0.1.2 – (01)00840682103800(10)60SP90122094097001G  
Universal Viewer 6.0SP9.0.1.3 – (01)00840682103800(10)60SP90132094097001G  
Universal Viewer 6.0SP9.0.1.4 – (01)00840682103800(10)60SP90142094097001G  
Universal Viewer 6.0SP9.0.1.5 – (01)00840682103800(10)60SP90152094097001G  
Universal Viewer 6.0SP9.0.1.6 – (01)00840682103800(10)60SP90162094097001G  
Universal Viewer 6.0SP10 – (01)00840682104807(10)6.0SP102094610001C

**Product  
Correction**

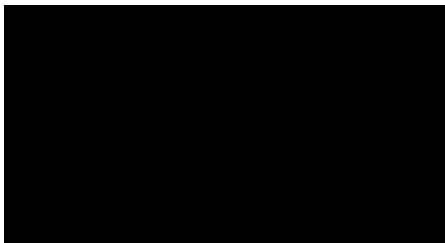
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

**Contact  
Information**

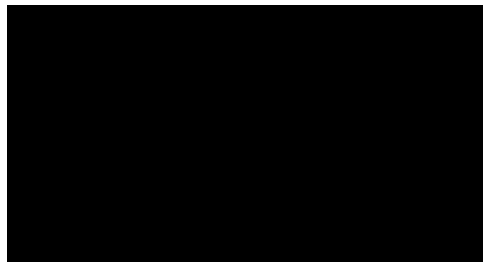
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

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,



GE Healthcare



GE Healthcare



GE Healthcare

GEHC Ref# 85452

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT  
RESPONSE REQUIRED**

**Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice Ref# 85452.**

Customer/Consignee Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP/Country: \_\_\_\_\_

Email Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

**Please provide the name of the individual with responsibility who has completed this form.**

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

**Please return completed form scanning or taking a photo of the completed form e-mailing to:**

[Recall85452@ge.com](mailto:Recall85452@ge.com)

**You may obtain this e-mail address through the QR code below:**

