URGENT MEDICAL DEVICE CORRECTION

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
Chairman Medical Board and relevant Head of Departments

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

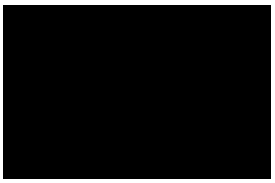
Users should discontinue use of the UV study management functionality for study split / study info updates until a correction is available.

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

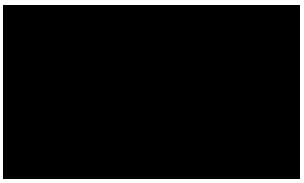
Affected Product Details	Centricity Universal Viewer with Centricity PACS foundation 6.0 SP9 or higher used in combination with Centricity PACS 6.0 SP9 or higher Universal Viewer 6.0 SP9 – (01)00840682103800(10)6.0SP92094097001D Universal Viewer 6.0SP9.0.0.1 – (01)00840682103800(10)60SP90012094097001F 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,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
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

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