URGENT FIELD SAFETY NOTICE

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188 USA

Date of Letter Deployment

GEHC Ref# 85458

To: Director/Manager of Radiology
Director/Manager of Cardiology
Hospital Administrator
Head of Radiology Department
PACS Administrator
Director of IT Department
Head, Biomedical Engineering

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

This document contains important information for your product. Please ensure 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

A software anomaly exists in the Centricity Universal Viewer study management feature in which study changes are not propagated to either the Centricity Enterprise Archive (EA) or another Vendor Neutral Archive (VNA).

This results in the potential to view studies with incorrect patient images or patient information when these studies are directly viewed from the archive.

This issue occurs when 1) Centricity Universal Viewer is configured to synchronize between Centricity PACS backend and either the Centricity EA or another VNA AND also 2) when a diagnostic viewer (e.g. Centricity Universal Viewer Zero Footprint or a third-party viewer) is connected directly to the Archive to display images. Both 1 and 2 are necessary for the issue to occur.

Note: The series and/or study changes are properly updated in the Centricity Universal Viewer with the Centricity PACS database. This issue does not affect images being viewed from Centricity Universal Viewer, Centricity Universal Viewer Zero Footprint or the RA1000 workstation connected directly to the Centricity PACS foundation.

There have been no injuries reported as a result of this issue.

Actions to be taken by Customer / User

Users should discontinue use of the Centricity Universal Viewer study management functionality for study changes until a correction is available.

Users are advised to use Centricity PACS Exam Manager or Centricity RA600 Quality Control Module for study management.

Affected Product Details

Centricity Universal Viewer, Software Versions 7.0 SP0.0.4.5 and 7.0 SP0.0.5
GTIN 00840682145794

This issue does not impact Centricity Universal Viewer for Cardiology using an Enterprise Archive foundation.

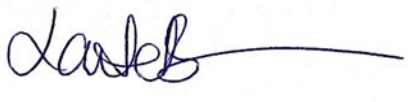
Intended Use

	Centricity Universal Viewer is an Internet based medical image display and interpretation software product that is part of a picture archiving and communications system that assists radiologists and cardiologists in their diagnostic workflows. It provides users with capabilities relating to the acceptance, transfer, display, storage, and to assist the healthcare provide to make a diagnostic interpretation of medical images (including digital mammograms).
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. After the GE Healthcare representative has updated your system, be sure to destroy the installation media for affected software at your site.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

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,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

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.

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 informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: Recall.85458@ge.com