



URGENT MEDICAL DEVICE CORRECTION - UPDATE

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

Date of Letter Deployment

GEHC Ref# 85466

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

RE: **Centricity Universal Viewer with PACS-IW foundation 6.0 and Centricity PACS-IW with Universal Viewer version 5.0 utilizing the UV-IW Image Acquisition and Synchronization Tool (IAS) - Studies not available in the Study List.**

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

Your site has been identified as having received the UV-IW Image Acquisition and Synchronization (IAS) tool as part of GEHC Ref# 85456. When operating correctly, the IAS tool identifies and temporarily hides incomplete studies and makes them available for interpretation when the studies are complete without undue delay. GE Healthcare has become aware that after installation of the IAS tool, some studies can remain hidden without user notification. Access to those hidden studies requires GE Healthcare assistance, which can result in a delay in reading the study.

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

Actions to be taken by Customer / User

You can continue to use your Centricity Universal Viewer by following the instructions below:

- 1) When a study is not present on the Study List, contact a GE Healthcare Service Representative for assistance in recovering the study.
- 2) In situations where study interpretation is time sensitive, interpret the study at the scanning unit or plan for an alternate means of reading studies for emergent cases.

Please complete and return the attached acknowledgement form to Recall.85466@ge.com.

Affected Product Details

Centricity Universal Viewer with PACS-IW foundation software versions 6.0 through 6.0 SP7.1; GTIN 00840682103800.

Centricity PACS-IW with Universal Viewer software versions 5.0.x with PACS-IW 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 provider 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.

**Contact
Information**

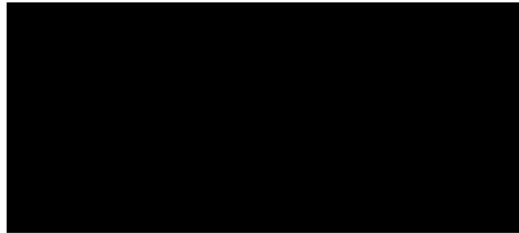
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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



**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.85466@ge.com

