

**URGENT FIELD
SAFETY NOTICE
UPDATE**



Date of Letter Deployment

GE HealthCare Ref. # 85492-2

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

RE: **Potential for Incorrect Patient and Study Association Following Historical Data Migration from a Legacy System to Enterprise Archive with Core Services Hub/ Workflow Core Services or to Centricity PACS or to standalone Enterprise Archive**

Safety Issue

GE HealthCare has become aware that, under certain conditions, historical imaging data migrated from a legacy system may become incorrectly associated with a different patient. If this occurs, studies or images may be displayed under the wrong patient record, which could lead to misdiagnosis or a delay in patient care.

This issue may occur in certain historical data migration scenarios, including duplicate accession numbers, duplicate Study Instance UIDs, orderless migration scenarios, and customized data migration use conditions.

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

Actions to be taken by Customer/User

Pending corrections from GE HealthCare, you can continue to use your systems by following the instructions below.

1. Do not perform any new inbound data (DICOM) migration projects. Please contact GE HealthCare before starting any new migration projects.
2. If using Enterprise Archive with Core Services Hub/Workflow Core Services, when reviewing or exporting prior imaging studies after migration to Enterprise Archive, verify that the study and images within the study are associated with the correct patient as follows:
 - Confirm the patient's name, date of birth, and other patient identifiers (e.g., Patient Identification Number / Medical Record Number) only if permanently embedded in the

image. **Do not rely on patient information in image overlays that can be toggled on and off.**

- After patient identity has been verified as described above, anatomy, implants, or similar features may be used as a secondary check for inconsistencies that may indicate a possible image mismatch.
- Confirm that the acquisition date/time is consistent with the expected study timing.
- If patient identity cannot be reliably confirmed using the identifiers and checks described above, treat the affected study or image(s) as **patient identity unverified**. Do not use the affected content for image/study interpretation or reporting. Follow local procedures for potential patient misidentification (e.g., notify PACS administrator, imaging informatics team, radiology management).

Please maintain any previous source systems or migration servers pending correction of this issue by GE HealthCare.

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions above.

Please retain this document for your records.

Please complete and return the attached acknowledgement form electronically via [FMI 85492 Digital Response Form](#) or print, fill out manually, scan, and email to recall.85492@gehealthcare.com.

Affected Product Details

The following product versions of Centricity Enterprise Archive, Enterprise Archive, Centricity PACS, and Centricity PACS Server are affected:

Table 1: List of Affected Products and their versions

Product	GTIN Number
All versions of Centricity Enterprise Archive V2	Not available
All versions of Centricity Enterprise Archive V3	Not available
All versions of Centricity Enterprise Archive V4	00840682102766
All versions of Enterprise Archive V8	00195278409287
All versions of Centricity PACS V2	Not available
All versions of Centricity PACS V3	Not available
All versions of Centricity PACS V4	00840682124430
All versions of Centricity PACS V6	00840682104807
All versions of Centricity PACS V7	00840682145572
All versions of Centricity PACS Server V7	00195278882585
All versions of Workflow Core Services V8	Not available
All versions of Core Services Hub V8	Not available

Intended Use:

Enterprise Archive: Enterprise Archive (EA) is a software product for receiving, archiving, and sending electronic medical data. Qualified system administrators install, monitor, and maintain the system. DICOM devices (e.g. modalities, workstations) communicate with the archive using the DICOM protocol (published by ACR-NEMA) or the HL7 protocol (published by Health Level Seven International). XDS enabled systems communicate with the archive using the XDS and XDS-I profiles (published by IHE).

Centricity PACS: Centricity PACS software product is intended for the storage, reading, diagnostic review, analysis, annotation, distribution, printing, editing, and processing of digital images and data acquired from diagnostic imaging devices.

Centricity PACS Server: Centricity PACS Server is intended for managing digital medical images and associated data. It enables storage, retrieval, and distribution of medical data. Centricity PACS Server allows healthcare professionals to access and work with medical images and reports via clinical viewer applications based on their intended use.

Core Services Hub: Core Services Hub product is a set of backend services including Cross Enterprise (XE) and Workflow Core (WFC) services that enables enterprise imaging workflows.

Workflow Core: is intended to provide set of services for storage and retrieval of patient data, exams and performs system Administration, common configuration management for consuming applications. Workflow Core does not use the stored data for clinical use and will be used by consuming applications based on their intended use.

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.

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 GE HealthCare per the contact information above.

Sincerely,



Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare



Scott Kelley
Chief Medical & Safety Officer
GE HealthCare



GE HealthCare Ref. # 85492-2

**FIELD SAFETY NOTICE 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 Field Safety Notice.

Facility Name: _____
Street Address: _____
City/State/ZIP/Country: _____
Customer Email Address: _____
Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Field Safety Notice, and that we have informed all potential users 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: _____
Position/Job Title: _____
Date (DD/MM/YYYY): _____

To complete this form electronically, please scan the QR Code below or [click this link](#):



To complete this form via email, scan or take a photo of the completed form and email to: recall.85492@gehealthcare.com

