URGENT MEDICAL DEVICE CORRECTION

GE HealthCare

14 August 2026

GE HealthCare Ref. # 85492

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:

At the Study level:

- Compare name, date of birth, and patient identifiers only if burned-in or embedded in the image. **Do not rely on patient information in the image overlays that can be toggled on and off.**
- If burned-in or embedded patient identifiers are not available, compare with prior studies based on patient anatomy, implants, or unique anatomical features.

At the Image level:

- Confirm that the images within the study do not belong to different patients based on acquisition date and time or other patient identifiers.

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.

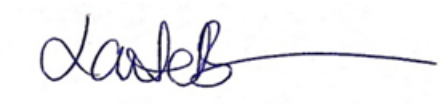
Workflow Core: is intended to provide set of services for storage and retrieval of patient data, exams and performs system Administration, common configuration management for consuming applications. Workflow Core does not use the stored data for clinical use and will be used by consuming applications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

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

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.

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 Medical Device Notification, 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**