URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 85486

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 association following migration to Enterprise Archive (EA) in True PACS**

Safety Issue

GE HealthCare has identified that imaging studies or images within a study may be associated with an incorrect patient following migration of historical studies to the Enterprise Archive (EA) in True PACS. If this occurs, it could potentially result in misdiagnosis or a delay in care.

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

Actions to be taken by Customer/ User

You can continue to use your system by following the instructions below.

When reviewing or exporting imaging studies after migration to EA, verify that the study and images within the study are associated with the correct patient by:

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 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 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 to:
recall.85486@gehealthcare.com

Affected Product Details

The following product versions of Enterprise Archive, when in the True PACS, are affected:

EA Version	UDI Label
Enterprise Archive 8 SP 0.1.0	(01)00195278409287(10)8P0105865732
Enterprise Archive 8 SP0.2.0	(01)00195278409287(10)8P0205865732
Enterprise Archive 8 SP0.3.0	(01)00195278409287(10)8P0305865732
Enterprise Archive 8 SP0.3.1	(01)00195278409287(10)8P0315865732
Enterprise Archive 8 SP0.3.2	(01)00195278409287(10)8P0325865732
Enterprise Archive 8 SP0.4.0	(01)00195278409287(10)8P0405865732
Enterprise Archive 8 SP0.4.1	(01)00195278409287(10)80P0415865732
Enterprise Archive 8 SP1.0.0	(01)00195278409287(10)8P1005865732
Enterprise Archive 8 SP1.1.0	(01)00195278409287(10)80P1105865732

Intended Use:
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).

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 us 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. # 85486

FIELD SAFETY 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 Field Safety 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 Field Safety 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): _____

Please return by scanning or taking a photo of the completed form and email to recall.85486@gehealthcare.com or submitting an online Customer Response Form.

Email Link

Customer Response Form