

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 80193

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator
Director of Biomedical Engineering
Director of IT Department

RE: AW Server 3.2 ext. 6.5 – Potential Patient Context Synchronization Issue

Safety Issue

GE HealthCare has become aware of a context synchronization issue in AW Server 3.2 ext. 6.5. When a user selects a patient or exam in the AW Server Web Client worklist and launches an interactive application (e.g. Volume Viewer), the application may open the previous patient’s exam instead of the intended one. When this issue occurs, there is no system warning or error notification. If the error is not recognized, a clinical user could review, interpret, or report images for the wrong patient which could lead to misdiagnosis, incorrect clinical decisions, resulting in delayed or incorrect treatment.

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 the device by following the instructions below:

- Ensure that users verify the correct patient identity (including name, patient ID, and date of birth) and confirm that the selected study matches the intended patient and clinical context prior to reviewing or interpreting imaging studies.

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.

Please complete and return the attached acknowledgement form electronically via this [FMI 80193 Digital CRE](#) or print, fill out manually, scan, and email to Recall.80193@gehealthcare.com.

Affected Product Details

- AW Server 3.2 ext. 6.5

Table 1:

Product	Ref#	GTIN Number
AW Server 3.2 ext.6.5	(01)00840682102384(10)AWS03D02E6D5	00840682102384

Intended Use:

AW Server is a medical software system that allows multiple users to remotely access AW applications from compatible computers on a network. The system allows networking, selection, processing and filming of multimodality DICOM images.

Both the client and server software are only for use with off the shelf hardware technology that meets defined minimum specifications.

The device is not intended for diagnosis of mammography images. The device is not intended for diagnosis of lossy compressed images. For other images, trained physicians may use the images as a basis for diagnosis upon ensuring that monitor quality, ambient light conditions and image compression ratios are consistent with clinical application.

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

**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 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): _____

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.80193@gehealthcare.com

