

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 80192

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

RE: **AW Server – Potential Security Vulnerability**

Safety Issue

GE HealthCare has become aware of a security vulnerability in AW Server products. If a complex password has not been configured for the AW Server and a malicious actor gains access to the network the AW Server is installed on, the vulnerability could be exploited. If this occurs, the malicious actor could potentially compromise the confidentiality, integrity, and availability of patient data.

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 device by following the instructions below.

1. Ensure the AW Server is installed on a facility internal network, that is **not** accessible from any public network. If access to AW Server from outside the facility network is desired, this connectivity must be configured to be usable exclusively through the facility's Virtual Private Network (VPN) or equivalent network security solution as described in your AW Server's Pre-Installation Manual that is available in the Customer documentation portal.

NOTE: Access management to the facility's internal network on which the AW Server is installed on, and management of the network security solution is under the strict responsibility of the facility.

2. Ensure strong, secure passwords are configured for the AW Server.
3. GE HealthCare recommends that organizations follow security and cybersecurity best practices, including securing the network where AW Server is connected.

Please ensure all potential users in your facility are made aware of this notification.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.80192@gehealthcare.com

**Affected
Product
Details**

The following products with the software versions listed below are impacted

Product	UDI reference
AW Server 2.0 Ext. X	N/A
AW Server 3.0 Ext. X	N/A
AW Server 3.1 Ext. X	N/A
AW Server 3.2 Ext. X	(01)00840682102384(10)AWS XXXXX

NOTE: The above products, when installed directly on GE HealthCare CT or PET/CT scanners to provide 3D application functionality on scanner console are not impacted.

**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

**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): _____

Please return completed form by scanning or taking a photo of the completed form and email to: recall.80192@gehealthcare.com or complete the online response form.



QR Code for email



QR Code for online response form