

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 23015

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

RE: **Potential security vulnerability impacting AW Server deployed via Edison Health Link (EHL) based CT Smart Subscription on certain Revolution series CT systems**

Safety Issue

GE HealthCare has become aware of a potential security vulnerability impacting AW Server deployed via Edison Health Link (EHL) based CT Smart Subscription used in conjunction with certain Revolution Apex, Revolution Ascend, and Revolution CT systems with the serial numbers listed in Appendix A. A malicious actor with access to the hospital network can gain unauthorized access to the AW Server on EHL and could potentially compromise post-processed patient data and images such as secondary captures and save states.

There have been no injuries or unauthorized access to patient data reported to GE HealthCare as a result of this issue.

NOTE: This issue does not compromise access to the CT system itself, nor does it compromise the original scan data acquired by the CT system.

NOTE: Standalone AW Servers (not on EHL) and AW Enterprise products are not impacted.

Actions to be taken by Customer/User

Pending corrections by GE HealthCare, you can continue to use your system by following security and cybersecurity best practices. Before the interim solution (see Product Correction section below) is applied, please follow the instructions below as identified in the respective CT system User Manuals:

CAUTION: 3D or slab reconstructions provide additional supplemental information, complementing diagnosis that should be based on classical techniques.

WARNING: Do not use 3D or slab views only to perform any measurements (distance, angle, region of interest, report cursor, area, volume, etc.). Always check measurement points' position and refer to 2D baseline views (acquisition images or reformatted images of minimal thickness) to confirm measurements.

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 (<https://gehealthcare-svc.my.site.com/publicForm/s/?formId=aGjUr000002jnD7>) or print, fill out manually, scan and email to recall.23015@gehealthcare.com

Affected Product Details

Refer to Appendix A for the serial numbers of the CT systems in Table 1 that are affected.

Table 1: GTINs of Impacted CT System Types

System Types	GTIN
Revolution Apex	00840682146616
Revolution Apex Elite	00195278460271
Revolution Apex Plus	00195278502179
Revolution Apex Select	00195278469700
Revolution Ascend	00840682146173
Revolution CT	00840682118552, 00840682146319
Revolution CT ES	00840682123471

Intended Use:

Revolution Ascend is intended to be used for head, whole body Computed Tomography applications. Revolution Apex and Revolution CT series system are intended for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

Product Correction

GE HealthCare will correct all affected products at no cost to you in two steps. A GE HealthCare representative will contact you to arrange for an interim solution to deactivate AW Server authentication through the CT system on the EHL-based Smart Subscription, and later, to install a CT software update.

Note: With the interim solution, all alternative authentication mechanisms (direct application launch from CT console user interface, login using users defined in AW Server user database, federation with hospital user directory through LDAP) will remain available.

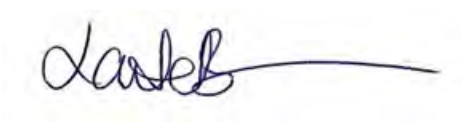
Contact Information

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,

Handwritten signature of Laila Gurney in blue ink, featuring a long horizontal stroke extending to the right.

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Handwritten signature of Scott Kelley in blue ink, consisting of a few stylized, connected letters.

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

Appendix A – Impacted CT System Serial Numbers

00000440713CN6	REV242400004CN	REV2X2300011CN	REVV82200047CN
438369CN1	REV282300006CN	REV2X2300020CN	REVV82200058CN
438902CN9	REV282300013CN	REV2X2300042CN	REVV82400005CN
441716CN8	REV282300022CN	REV2X2300047CN	REVV82400010CN
441839CN8	REV282400003CN	REV2X2300050CN	REVVX1600013CN
442792CN8	REV282400006CN	REV2X2300068CN	REVVX1600034CN
443327CN2	REV282400011CN	REV2X2300083CN	REVVX1600052CN
AS10G2100008YC	REV282400012CN	REV2X2300084CN	REVVX1700067CN
AS10G2200035YC	REV282400013CN	REV2X2300090CN	REVVX1700071CN
AS10G2200068YC	REV282400021CN	REV2X2300091CN	REVVX1700082CN
AS10G2200085YC	REV282400035CN	REV2X2300097CN	REVVX1700101CN
AS10G2200101YC	REV282400038CN	REV2X2400014CN	REVVX1700104CN
AS10G2200136YC	REV2A2000006CN	REV2X2400021CN	REVVX1800007CN
AS10G2300041YC	REV2A2000007CN	REV2X2400026CN	REVVX1800043CN
AS10G2300057YC	REV2A2000032CN	REV2X2400027CN	REVVX1800046CN
AS10G2300093YC	REV2A2100011CN	REV2X2400028CN	REVVX1800048CN
AS10G2400056YC	REV2A2100016CN	REV2X2400046CN	REVVX1800105CN
AS10G2400079YC	REV2A2100019CN	REV2X2400048CN	REVVX1900018CN
AS10G2400081YC	REV2A2100038CN	REV2X2400050CN	REVVX1900069CN
AS10G2400087YC	REV2A2100048CN	REV2X2400055CN	REVVX1900086CN
AS10G2400094YC	REV2A2200007CN	REV2X2400059CN	REVVX1900107CN
AS10G2500002YC	REV2A2200011CN	REV2X2400063CN	REVVX1900123CN
CBDWG2300041HM	REV2A2200014CN	REV2X2400065CN	REVVX2000005CN
CBDWG2300056HM	REV2A2200015CN	REV2X2400067CN	REVVX2000056CN
CBDWG2300081HM	REV2A2200018CN	REV2X2400068CN	REVVX2100014CN
CBDWG2400019HM	REV2A2200034CN	REV2X2400069CN	REVVX2100020CN
CBDWG2400085HM	REV2A2200037CN	REV2X2400078CN	REVVX2100028CN
CBDWG2400117HM	REV2A2200041CN	REV2X2400093CN	REVVX2100050CN
CBDWG2400126HM	REV2A2200067CN	REV2X2400095CN	REVVX2200007CN
CBDWG2400140HM	REV2A2200068CN	REV2X2400098CN	REVVX2200009CN
CBDWG2500003HM	REV2A2200072CN	REV2X2400107CN	REVVX2200025CN
CBDWG2500011HM	REV2A2200105CN	REVV82100016CN	REVVX2200039CN
REV242200002CN	REV2A2200116CN	REVV82100027CN	REVVX2200047CN
REV242300004CN	REV2A2200120CN	REVV82100031CN	REVVX2300007CN
REV242300006CN	REV2A2300016CN	REVV82200014CN	REVVX2400004CN
REV242400001CN	REV2X2300002CN	REVV82200017CN	
REV242400002CN	REV2X2300003CN	REVV82200046CN	

**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:

<https://gehealthcare-svc.my.site.com/publicForm/s/?formId=aGjUr00002jnD7>



To complete this form via email, scan or take a photo of the completed form and email to:

recall.23015@gehealthcare.com

