



Urgent Field Safety Notice

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188 USA

Date of Letter Deployment

GEHC Ref# 25500-2

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

RE: **Potential SmartStep Dose display error on Revolution CT, Revolution CT ES, Revolution Apex, and Revolution CT with Apex Edition Systems**

This document contains important information for your product. 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.

Safety Issue

GE Healthcare has become aware of an issue on the products listed below where, in certain situations, the accumulated dose is incorrectly displayed during an interventional exam using the SmartStep option.

There are two situations that will result in the SmartStep displayed dose being inaccurately high (up to 100 times higher than actual delivered dose):

- 1) If the *table height* is adjusted after an exam starts (while in the *Ready to Scan* state),
- 2) If the *Revisit Settings* button is clicked within 1 second of pausing a scan

In these situations, there is no issue with the actual dose delivered to the patient; it is only an issue with the displayed value in SmartStep.

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 the system. The system will accurately deliver the prescribed dose even if one of the scenarios above occurs. To avoid these issues with the displayed dose, do not change the table height in the *Ready to Scan* state, and allow the system to complete the *Pause* operation before pressing any other buttons or changing settings.

Please complete and return the attached response form.

Affected Product Details

The following CT systems are affected:

Revolution CT
Revolution CT ES
Revolution Apex
Revolution CT with Apex edition

See attached Appendix for a list of serial numbers.

Intended Use: The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

*SmartStep is a mode of scanning designed to be used by the clinician during interventional procedures. SmartStep uses the hand-held controller and foot switch to assist the Radiologist or Physician with real-time CT fluoroscopy acquisitions for tracking, controlling, and orienting of an indwelling patient needle or patient catheter.

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 us immediately per the contact information above.

Sincerely,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical 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.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Field Safety Notice, and that we have informed appropriate staff 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: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: RecallFMI25500.mailbox@ge.com



Appendix – Affected Serial Numbers

REVVX2000057CN	REVV82000036CN	REVVX1700041CN	REVVX1900019CN
REV2A2000017CN	REVV81900035CN	REVVX1700060CN	REVVX1900030CN
REV2A2000013CN	REV2A2000023CN	REVVX1700080CN	REVVX1800103CN
REV2A2000007CN	REV2A2000026CN	REVVX1700054CN	REVVX1900052CN
REVVX1800110CN	REVVX2000041CN	REVVX1700095CN	REVVX1900048CN
REVV82000013CN	REVV82000027CN	REVV81700007CN	REVVX1900070CN
REVV81900020CN	REV2A2000030CN	REVV81700006CN	REVVX1900066CN
REVVX1900040CN	REVV82000025CN	REVVX1700109CN	REVVX1700063CN
REVV81900029CN	REV2A2100009CN	REVVX1700048CN	REVVX1900064CN
REV2A2000004CN	REV2A2000019CN	REVVX1800084CN	REVVX1900084CN
REV2A2000005CN	REVV82100003CN	REVV81800022CN	REVVX1900077CN
REVVX1900102CN	REV2A2000029CN	REVVX1800038CN	REVVX1900074CN
REVVX1900106CN	REVV82000038CN	REVVX1600050CN	REVV81900021CN
REVVX1900112CN	REV2A2100003CN	REVVX1700114CN	REVVX1900086CN
REVVX1800115CN	REVV82100004CN	REVV81800002CN	REVVX1900032CN
REVVX1900045CN	REVV82000040CN	REVV81700015CN	REVVX1900091CN
REVVX1900047CN	REGGL1900010YC	REVVX1800019CN	REVVX1900097CN
REVVX1800100CN	REGGL1900003YC	REVVX1700110CN	REVVX1900016CN
CBDJG2000002HM	REVVX1900021CN	REVVX1700069CN	REVVX1900073CN
REVVX1900041CN	REGGL1900004YC	REVVX1800017CN	REVVX1900121CN
REVVX1900034CN	REVVX1700126CN	REVVX1800020CN	REVV82000003CN
REVVX1900098CN	REGGL2000021YC	REVVX1800032CN	REVVX2000007CN
REVV81900017CN	REGGL2000018YC	REVVX1700118CN	REVV82000002CN
REVVX1900033CN	REVVX2100008CN	REVVX1800006CN	REVVX2000012CN
00000445060CN7	REGGL2100017YC	REVVX1800035CN	REGGL2000001YC
REVV82000032CN	REGGL2100008YC	REVVX1700122CN	REVV81900033CN
REVVX1700106CN	REGGL2100002YC	REVVX1700108CN	REVVX1900113CN
REVVX1800009CN	REGGL2100016YC	REVVX1800039CN	REVVX1900116CN
00000442868CN6	REGGL2100007YC	REVVX1800028CN	REVV82000010CN
00000443342CN1	REV2A2100010CN	REVVX1800002CN	REVVX1900079CN
REVVX1600054CN	REVVX1800010CN	REVVX1800034CN	REVCV1900021CN
REVVX1700084CN	REVVX1700117CN	REVVX1900044CN	REVVX2000014CN
REVVX1800024CN	REVVX2100007CN	REVVX1800050CN	REGGL1900009YC
REVV81700004CN	REVVX1900049CN	REVVX1800051CN	REVVX1900087CN
00000441716CN8	REVVX2100018CN	REVVX1800033CN	REVV81800023CN
00000441839CN8	REV2A2100007CN	REVV81800006CN	REVVX2000017CN
00000440051CN1	REVV82100017CN	REVVX1700124CN	REVVX1900095CN
REVVX1800027CN	REV2A2100034CN	REVVX1800057CN	REVVX1900127CN
REVVX1800052CN	REV2A2100027CN	REVVX1700053CN	REVVX1900103CN
REVVX1800070CN	REV2A2100028CN	REVVX1800064CN	REVVX2000025CN
REVV81800008CN	REV2A2100015CN	REVVX1800068CN	REVVX2000043CN
REVVX1600049CN	REV2A2100038CN	REVV81800009CN	REVVX1900122CN
REVVX1800075CN	REVVX2100032CN	REVVX1800072CN	REVV82000017CN
00000445134CN0	REV2A2100040CN	REVVX1800074CN	00000441648CN3
REVVX1700071CN	REVVX2100036CN	REVV81800016CN	REVVX2000020CN

Appendix – Affected Serial Numbers

REVVX1700006CN	00000440906CN6	REVVX1800081CN	REVVX2000055CN
REVVX1700082CN	00000441322CN5	REVV81800014CN	REVVX2000049CN
REVVX1700074CN	00000438994CN6	REVVX1800083CN	REVVX2000056CN
REVVX1700008CN	00000441768CN9	REVVX1800029CN	REVV82000033CN
REVVX1600046CN	442124CN4	REVVX1800107CN	REVV82000004CN
REVVX1700085CN	00000442507CN0	REVVX1800094CN	REVVX2000063CN
REVVX1600044CN	00000443590CN5	REVVX1800106CN	REVVX2000019CN
00000441990CN9	00000444038CN4	REVV81800021CN	REVV82000009CN
REVVX1600043CN	00000444175CN4	00000526280HM3	REVVX2000061CN
REVVX1700075CN	444840CN3	REVV81800028CN	REVV82000028CN
REVVX1600009CN	REVVX1600003CN	REVVX1800112CN	REV2A2100002CN
REVVX1600041CN	REVVX1600011CN	REVVX1800079CN	REVVX2100003CN
00000443400CN7	REVVX1700003CN	REVVX1800060CN	REGGL2100020YC
00000443380CN1	REVVX1700007CN	REVVX1800099CN	REVVX2100012CN
REVVX1700104CN	REVVX1700022CN	REVVX1800131CN	REGGL1900013YC
REVVX1700116CN	REVVX1600059CN	REVV81900005CN	REGGL2100022YC
00000442256CN4	REVVX1700028CN	REVV81900003CN	REVVX2100026CN
REVVX1700027CN	REVVX1700037CN	REVV81900006CN	REVVX1800010CN
REVVX1600021CN	REVVX1600024CN	REVV81900007CN	00000439505CN9
REVV81700008CN	00000444253CN9	REVVX1900018CN	00000441210CN2
REVVX1800101CN	REVVX1600014CN	REVV81900013CN	REVV82100023CN
REV2A1900002CN	REVVX1700050CN	REVV81900014CN	REVVX1600012CN
REVVX2000067CN	REVVX1700035CN	REVVX1900054CN	REVV81900023CN
System ID 81627CT			