URGENT MEDICAL DEVICE CORRECTION

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

Date of Letter Deployment

GEHC Ref# 25500

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 the accumulated dose is incorrectly displayed in certain situations. This occurs during an interventional exam using the SmartStep option if the table height is adjusted after the exam starts. In this situation, the SmartStep display will show a value that is higher (up to 100 times) than the actual dose delivered.

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 the use the system. The system will accurately deliver the prescribed dose even if the table is moved following exam initiation. If the table needs to be adjusted after initiating the exam, please be aware that the SmartStep reported dose display will be inaccurate but the delivered dose will be as prescribed.

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 at 1-800-437-1171 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

GE Healthcare

GEHC Ref# 25500

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.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, 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	REV2A2000017CN	REV2A2000013CN
REV2A2000007CN	REVVX1800110CN	REVV82000013CN
REVV81900020CN	REVVX1900040CN	REVV81900029CN
REV2A2000004CN	DUMFMI25490005	REVVX1900102CN
REVVX1900106CN	REVVX1900112CN	REVVX1800115CN
REVVX1900045CN	REVVX1900047CN	REVVX1800100CN
CBDJG2000002HM	REVVX1900041CN	REVVX1900034CN
REVVX1900098CN	REVV81900017CN	REVVX1900033CN
00000445060CN7	REVV82000032CN	REVVX1700106CN
REVVX1800009CN	00000442868CN6	00000443342CN1
REVVX1600054CN	REVVX1700084CN	REVVX1800024CN
REVV81700004CN	00000441716CN8	00000441839CN8
00000440051CN1	REVVX1800027CN	REVVX1800052CN
REVVX1800070CN	REVV81800008CN	REVVX1600049CN
REVVX1800075CN	00000445134CN0	REVVX1700071CN
REVVX1700006CN	REVVX1700082CN	REVVX1700074CN
REVVX1700008CN	REVVX1600046CN	REVVX1700085CN
REVVX1600044CN	00000441990CN9	REVVX1600043CN
REVVX1700075CN	REVVX1600009CN	REVVX1600041CN
00000443400CN7	00000443380CN1	REVVX1700104CN
REVVX1700116CN	00000442256CN4	REVVX1700027CN
REVVX1600021CN	REVV81700008CN	REVVX1800101CN
REV2A1900002CN	REVVX2000067CN	REVV82000036CN
REVV81900035CN	REV2A2000023CN	REV2A2000026CN
REVVX2000041CN	REVV82000027CN	REV2A2000030CN
REVV82000025CN	REV2A2100009CN	REV2A2000019CN
REVV82100003CN	REV2A2000029CN	REVV82000038CN
REV2A2100003CN	REVV82100004CN	REVV82000040CN
REGGL1900010YC	REGGL1900003YC	REVVX1900021CN
REGGL1900004YC	REVVX1700126CN	REGGL2000021YC
REGGL2000018YC	REVVX2100008CN	REGGL2100017YC
REGGL2100008YC	REGGL2100002YC	REGGL2100016YC
REGGL2100007YC	REV2A2100010CN	REVVX1800010CN
REVVX1700117CN	REVVX2100007CN	REVVX1900049CN
REVVX2100018CN	REV2A2100007CN	REVV82100017CN