

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 25504

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

RE: **Potential for fluid leak onto floor on certain Revolution CT and Revolution Apex series CT systems.**

Safety Issue

GE HealthCare has become aware of a potential issue on certain Revolution CT and Revolution Apex series CT systems (please see affected product details and the Appendix) that can result in coolant fluid (glycol) leaking onto the floor near the base of the gantry. The fluid is visible as it has a blue color. It is not corrosive and is not at a harmful temperature. However, there is a potential for injury if the fluid is not noticed and a person slips and/or falls.

There have been no injuries reported as a result of this issue.

Actions to be taken by Customer/ User

You can continue to use your system.

Please monitor the floor near the base of the gantry for any accumulation of blue fluid. If blue fluid is observed, wear nitrile or rubber gloves, clean up the fluid by absorbing it with a noncombustible absorbent material, and dispose of the absorbent material in a suitable container for disposal.

Please contact your local GE HealthCare service representative if any blue fluid is observed.

Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please complete and return the attached acknowledgement form to recall.25504@gehealthcare.com.

Affected Product Details

The following CT system types are potentially affected. See Appendix for list of all affected serial numbers.

System Type	GTIN
Revolution CT	00840682118552 00840682146319
Revolution CT ES	00840682123471 00195278563149
Revolution Apex	00840682146616
Revolution Apex Elite	00195278460271
Revolution Apex Plus	00195278502179
Revolution Apex Select	00195278469700
Revolution Apex Expert	00195278633149

Intended Use:

The systems are intended for head, whole body, cardiac, and vascular X-ray Computed Tomography applications

Product GE HealthCare will correct all affected products at no cost to you.
Correction A GE HealthCare representative will contact you to arrange for the correction.

Contact If you have any questions or concerns regarding this notification, please contact GE
Information 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 Officer
GE Healthcare

Appendix – Affected Serial Numbers

00000438756CN9	CBFCG2400003HM	CBGMG2400008HM	REV2A2200029CN	REV2X2300018CN
00000440315CN0	CBFCG2400004HM	CBGMG2400013HM	REV2A2200036CN	REV2X2300019CN
00000440478CN6	CBFCG2400005HM	KITLL2400001CN	REV2A2200041CN	REV2X2300020CN
00000441066CN8	CBFCG2400006HM	KITLL2400003CN	REV2A2200046CN	REV2X2300021CN
00000441459CN5	CBFCG2400007HM	REGGL1900003YC	REV2A2200050CN	REV2X2300022CN
00000441716CN8	CBFCG2400008HM	REGGL1900004YC	REV2A2200053CN	REV2X2300023CN
00000442334CN9	CBFCG2400009HM	REGGL2000003YC	REV2A2200065CN	REV2X2300024CN
00000442412CN3	CBFCG2400011HM	REV242200002CN	REV2A2200070CN	REV2X2300025CN
00000442592CN2	CBFCG2400012HM	REV242200002CN	REV2A2200072CN	REV2X2300026CN
00000443327CN2	CBFCG2400013HM	REV242200004CN	REV2A2200081CN	REV2X2300027CN
00000443379CN3	CBFCG2400014HM	REV282300003CN	REV2A2200086CN	REV2X2300028CN
00000443409CN8	CBFCG2400015HM	REV282300029CN	REV2A2200101CN	REV2X2300032CN
00000445059CN9	CBFCG2400016HM	REV282400043CN	REV2A2200101CN	REV2X2300034CN
00000445119CN1	CBFCG2400017HM	REV282400047CN	REV2A2200105CN	REV2X2300036CN
436942CN7	CBFCG2400018HM	REV2A2000001CN	REV2A2200111CN	REV2X2300037CN
438438CN4	CBFCG2400019HM	REV2A2000007CN	REV2A2200119CN	REV2X2300040CN
439799CN8	CBFCG2400020HM	REV2A2000009CN	REV2A2200120CN	REV2X2300041CN
441578CN2	CBFCG2400021HM	REV2A2000010CN	REV2A2200122CN	REV2X2300042CN
441839CN8	CBFCG2400022HM	REV2A2000015CN	REV2A2200126CN	REV2X2300043CN
442378CN6	CBFCG2400023HM	REV2A2000017CN	REV2A2300023CN	REV2X2300044CN
444016CN0	CBFCG2400024HM	REV2A2000026CN	REV2A2300024CN	REV2X2300045CN
444913CN8	CBFCG2400025HM	REV2A2000030CN	REV2A2300042CN	REV2X2300046CN
AEGGL2300001YC	CBFCG2400026HM	REV2A2000032CN	REV2A2300043CN	REV2X2300047CN
AEGGL2300002YC	CBFCG2400027HM	REV2A2100002CN	REV2X2200001CN	REV2X2300048CN
AEGGL2300003YC	CBFCG2400028HM	REV2A2100003CN	REV2X2200002CN	REV2X2300049CN
AEGGL2300004YC	CBFCG2400029HM	REV2A2100004CN	REV2X2200003CN	REV2X2300050CN
AEGGL2300006YC	CBFCG2400030HM	REV2A2100005CN	REV2X2300001CN	REV2X2300051CN
AEGGL2300007YC	CBFCG2400031HM	REV2A2100006CN	REV2X23000029CN	REV2X2300052CN
AEGGL2400002YC	CBFCG2400032HM	REV2A2100011CN	REV2X2300002CN	REV2X2300053CN
AEGGL2400003YC	CBFCG2400033HM	REV2A2100018CN	REV2X23000030CN	REV2X2300054CN
AEGGL2400004YC	CBFCG2400034HM	REV2A2100019CN	REV2X2300003CN	REV2X2300055CN
AEGGL2400005YC	CBFCG2400035HM	REV2A2100029CN	REV2X2300004CN	REV2X2300056CN
AEGGL2400007YC	CBFCG2400036HM	REV2A2100033CN	REV2X2300005CN	REV2X2300057CN
AEGGL2400008YC	CBFCG2400037HM	REV2A2100034CN	REV2X2300006CN	REV2X2300058CN
AEGGL2400009YC	CBFCG2400039HM	REV2A2100036CN	REV2X2300008CN	REV2X2300059CN
AEGGL2400010YC	CBFCG2400041HM	REV2A2100042CN	REV2X2300009CN	REV2X2300060CN
AEGGL2400013YC	CBFHG2400015HM	REV2A2100053CN	REV2X2300010CN	REV2X2300061CN
AEGGL2400014YC	CBGLG2400001HM	REV2A2200002CN	REV2X2300011CN	REV2X2300062CN
CBFCG2300002HM	CBGMG2400001HM	REV2A2200003CN	REV2X2300012CN	REV2X2300063CN
CBFCG2300002HM	CBGMG2400003HM	REV2A2200006CN	REV2X2300013CN	REV2X2300064CN
CBFCG2400001HM	CBGMG2400004HM	REV2A2200007CN	REV2X2300016CN	REV2X2300068CN
CBFCG2400002HM	CBGMG2400005HM	REV2A2200013CN	REV2X2300017CN	REV2X2300069CN

REV2X2300070CN	REV2X2400020CN	REV2X2400071CN	REV2X2400123CN	REVV81900021CN
REV2X2300071CN	REV2X2400021CN	REV2X2400073CN	REV2X2400124CN	REVV81900026CN
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REV2X2300074CN	REV2X2400023CN	REV2X2400076CN	REV2X2400126CN	REVV82000020CN
REV2X2300075CN	REV2X2400024CN	REV2X2400078CN	REV2X2400127CN	REVV82100002CN
REV2X2300076CN	REV2X2400025CN	REV2X2400080CN	REV2X2400128CN	REVV82100006CN
REV2X2300077CN	REV2X2400026CN	REV2X2400081CN	REV2X2400129CN	REVV82100013CN
REV2X2300078CN	REV2X2400027CN	REV2X2400082CN	REV2X2400130CN	REVV82100024CN
REV2X2300079CN	REV2X2400028CN	REV2X2400083CN	REV2X2400131CN	REVV82100041CN
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REV2X2300082CN	REV2X2400031CN	REV2X2400087CN	REV2X2400134CN	REVV82200025CN
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REV2X2400009CN	REV2X2400058CN	REV2X2400113CN	REV2X2400166CN	REVVX1700071CN
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REV2X2400018CN	REV2X2400069CN	REV2X2400121CN	REVV81900011CN	REVVX1800009CN
REV2X2400019CN	REV2X2400070CN	REV2X2400122CN	REVV81900012CN	REVVX1800010CN

REVVX1800013CN	REVVX2200025CN
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REVVX1800070CN	SID 082421091287
REVVX1800083CN	SID 082421140968
REVVX1800093CN	SID 12128152
REVVX1800101CN	SID 13043139
REVVX1800108CN	SID 169766CT01
REVVX1800110CN	SID 4427492A
REVVX1800120CN	SID AUCTX24814311
REVVX1800133CN	SID AUCTX25000302
REVVX1900008CN	SID CT00639
REVVX1900016CN	SID KRCT54893311
REVVX1900020CN	SID KRCT54972221
REVVX1900027CN	SID M001CT06
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REVVX1900036CN	
REVVX1900040CN	
REVVX1900046CN	
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REVVX2100014CN	
REVVX2100043CN	
REVVX2100047CN	
REVVX2200004CN	

**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): _____

Please return completed form by scanning or taking a photo of the completed form and email to: (e.g., recall.25504@gehealthcare.com)

