



## URGENT FIELD SAFETY NOTICE

GE Healthcare  
Healthcare Systems  
9900 Innovation Drive  
Wauwatosa, WI 53226  
USA

<Date of Letter Deployment>

GEHC Ref# 25469

To: Hospital Administrators / Risk Managers  
Managers of Radiology/Cardiology  
Radiologist/Cardiologist

RE: GE Healthcare Revolution CT Re-torque needed

GE Healthcare has recently become aware of a potential safety issue due to the use of an out of tolerance torque tool on three bolted joints of your Revolution CT scanner. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

**Safety Issue** GE Healthcare has become aware that an out of tolerance torque tool was used on three joints on your Revolution CT system during the manufacturing process. If the X-ray Tube becomes loose on the CT gantry during operation, this could result in beam tracking errors, potential scan aborts and/or a possible image artifact. There is a secondary safety mechanism to prevent components from being expelled from the gantry if the bolts fail. There have been no injuries reported as a result of this issue.

**Safety Instructions** The site can continue to use the GE Healthcare Revolution CT scanner. If the X-ray Tube joint loosens, the system would fail internal checks and cause the previous mentioned hazards of beam tracking errors, potential scan aborts and/or image artifacts, requiring immediate action by service to realign the system. Should this occur, stop using the system and call your service team to bring the system back into proper operational status.

**Affected Product Details** Revolution CT Computed Tomography X-ray systems manufactured from July 2015 to March 2016.

**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.

You can also contact:

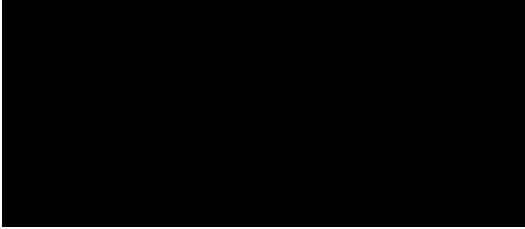
Francois Dubos  
NE CT Modality Leader  
T: +46 702661865  
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Paul Mardle  
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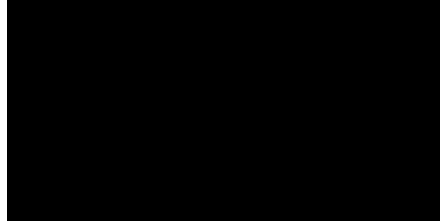
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



GE Healthcare



GE Healthcare

# Customer Reply Form

PLEASE COMPLETE and FAX to GE Healthcare

## CUSTOMER CONTACT INFORMATION

Note: please list all site locations and names if your responsible for more than one site or if your site is known by other names. Thank you.

Site Name		Site Contact		
Other site				
Street Address		City		
State		Postal Code	Country	
Phone		Email		

By signing below, I acknowledge receipt of the letter and I accept to follow and to apply the safety instructions. Please record below the date on which your facility received this information.

<u>Name and Title</u>	<u>Date</u>
<u>Signature</u>	

Please FAX back to:

**+44 (0) 1 75 341 7098**

Or Email to:

[SafetyNotice@ge.com](mailto:SafetyNotice@ge.com)

Attention:

**GE Healthcare**  
 EMEA Customer Safety letters Specialist  
 283, rue de la Minière  
 78530 Buc - France