

**URGENT MEDICAL DEVICE CORRECTION**

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.

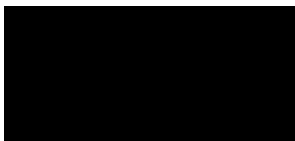
Affected Product Details Revolution CT Computed Tomography X-ray systems manufactured from July 2015 to March 2016.

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.

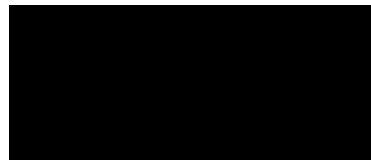
Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare



Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare