



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 25468

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: Revolution CT table elevation

GE Healthcare has recently become aware of a potential safety issue with the table elevation of Revolution CT systems. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue GEHC has become aware of a potential safety issue in the Revolution CT Patient Table that can result in unintended motion in cases involving large patients. The Revolution CT cradle can descend on its own after activation by the user. This can put the patient at risk for harm. The harm can involve the impinging or crushing of a hand if caught between the cradle and CT inner gantry bore. No injuries have been reported to date related to this issue.

Safety Instructions You can continue to use your Revolution CT product. Be sure to follow the Patient Positioning warning outlined in the Revolution CT User Manual. The information and warnings can be found in your Revolution CT User Manual (5480385-1XX) Mechanical Safety – Patient Positioning (Safety Chapter 3, Section 9.2). *To prevent pinching or crushing of the patient's extremities, keep the patient's hands and feet away from the edge of the moving table top/cradle and its surrounding equipment, or between table base and side panels of the table. Take special care when positioning physically large patients.*

Affected Product Details Revolution CT

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.

8001243002 SaudiArabiaServiceCenter@ge.com

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

Jeff Hersh, M.D.
Chief Medical Officer

