Urgent Field Safety Notice

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

GE Healthcare Ref: FMI 25496

January 8, 2021

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

RE: **A potential for laceration due to sharp edge from exposed table screw on Revolution Apex, Revolution CT with Apex Edition, Revolution CT, and Revolution CT ES 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 a potential issue on Revolution Apex, Revolution CT with Apex Edition, Revolution CT, and Revolution CT ES systems where the table pinch protector could be damaged or missing leading to exposed table screws which could cause a laceration due to a sharp edge.

Safety Instructions

You can continue to use your Revolution Apex, Revolution CT with Apex Edition, Revolution CT, or Revolution CT ES system. To avoid this potential issue please ensure that the table pinch protector is properly attached to the gantry end of the system table (as shown in Figure 1).

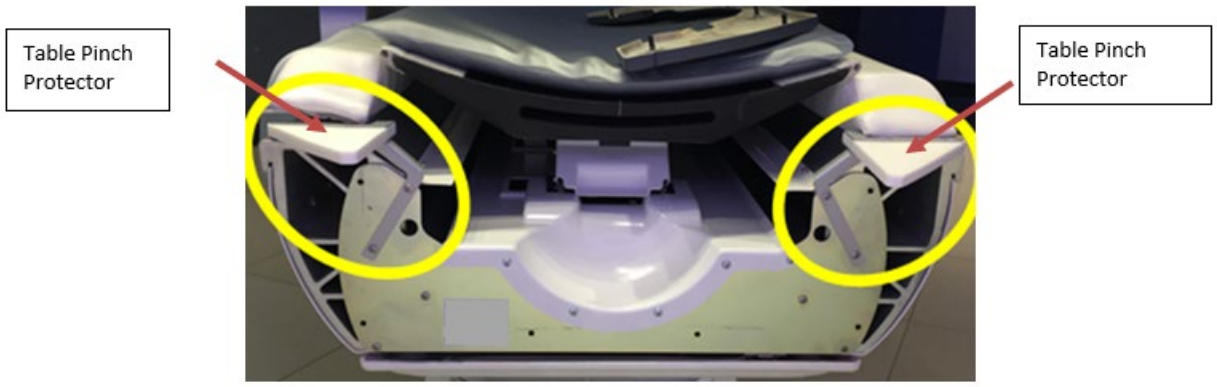

Figure 1 (Note: Table end cover is removed for demonstration purposes)

If the pinch protector is damaged or no longer attached, please contact your GE field engineer for replacement.

Affected Product Details

The following CT systems are potentially affected:
Revolution Apex
Revolution CT with Apex Edition
Revolution CT
Revolution CT ES

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 regarding this Field Safety Notice or the identification of affected items please contact your local Sales/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 immediately.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

GEHC Ref# 25496

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: FMI25496.mailbox@ge.com