



## URGENT FIELD SAFETY NOTICE

GE Healthcare

9900 Innovation Drive  
Mail Stop: RP2130  
Wauwatosa, WI 53226  
USA

18.09.2009

To: Hospital Administrators / Risk Managers  
Radiology Department Managers  
Radiologists

RE: **Compax 40E X-ray systems: Tabletop movement.**

GE Healthcare has recently become aware that table lock safety features, which are provided with Compax 40E X-ray systems, are not always being utilized and has resulted in unintended lateral tabletop movement that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

**Safety Issue** Compax 40E X-ray system is designed to allow tabletop movement to facilitate patient positioning. The table can be locked and stabilized using the movement inhibition button and the manual mechanical lock safety features. If these features are not being utilized during patient loading or unloading, unintended tabletop movement may occur and could result in patient injury.

<b>Affected Product Details</b>	GE Compax 40 E X-Ray systems manufactured between February 1996 and June 2004, with Model Numbers				
	2208203	2208205	2244282	2244284	2225863
	2225864	2225865	2225870	2225881	2225882

**Safety Instructions** Table manual mechanical lock is provided with the system and should be engaged when loading or unloading patients to ensure the tabletop is stabilized and not moving. When the power is ON, the tabletop can also be locked and stabilized using the available movement inhibition button. Take extra precautions when loading or unloading patients from the table.

**Product Correction** GE Healthcare will place labels on Compax 40E systems to remind operators to use the manual mechanical lock and the movement inhibition button safety features. This correction will be done through Field Modification Instruction (FMI) 10828 in the near future. A GE Healthcare service representative will contact you to arrange for this field modification. The modification will require less than a half-hour to perform and will be completed at no cost to you.

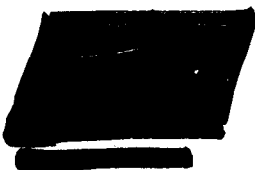
**Contact Information** If you have any questions or concerns regarding this notification, Please contact your local sales or service representative if you need additional information regarding this notification.

Nicholas Davies  
Modality Leader Xray  
+44 (0) 1753 874043  
352 Buckingham Avenue  
Slough SL1 4ER  
United Kingdom

This information has been communicated to the appropriate National Competent Authorities.

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,



Senior Executive QARA  
GE Healthcare Systems  
9900 Innovation Drive  
Mail Stop: RP2130, Wauwatosa, WI 53226, USA  
[Redacted]@ge.com

# 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.

<b>Site Name</b>		<b>Site Contact</b>	
<b>Other site</b>			
<b>Street Address</b>		<b>City</b>	
<b>State</b>		<b>Postal Code</b>	<b>Country</b>
<b>Phone</b>		<b>Email</b>	

By signing below, I acknowledge receipt of the letter and have an understanding of the necessary actions. Please record below the date on which your facility received this information.

<b><u>Name and Title (please print)</u></b> (Please provide the name of individual with responsibility for risk and compliance)	<b><u>Date</u></b>
<b><u>Signature</u></b> (Please provide the signature of individuals with responsibility for risk and compliance)	

**Please FAX back to**  
**+44 (0) 1753 417098**

**Or Email to**  
**██████████@ge.com**

**Or Call**  
**+44 (0) ██████████**

**Attention: ██████████**

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