



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226,
USA

GE Healthcare Ref: FMI 10855

2011-11-29

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Revolution XR/d X-ray Systems: Table Hand grip may dislodge**

GE Healthcare has become aware of a potential issue associated with the hand grip that is clamped to the table top of your Revolution XR/d X-ray systems 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 The hand grip accessory that is clamped to the table top may not be properly adjusted and can dislodge during use. Should this happen during patient loading or unloading, patient injury could occur.

Safety Instructions The hand grip accessory should be removed from use until the product is corrected. Take extra precautions when loading or unloading patients from the table while the hand grips are not in use.

Affected Product Details All Revolution XR/d X-ray systems.

Product Correction GE Healthcare will adjust the hand grip accessory on all affected units to ensure effective clamping of hand grip to table top. This activity will be performed at no cost to you. A GE Healthcare service representative will contact you to arrange for this 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,

James Dennison
Vice President QARA
GE Healthcare Systems

William Denman, M.D., FRCA
Chief Medical Officer
GE Healthcare