Urgent Field Safety Notice

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 10902

July 9, 2015

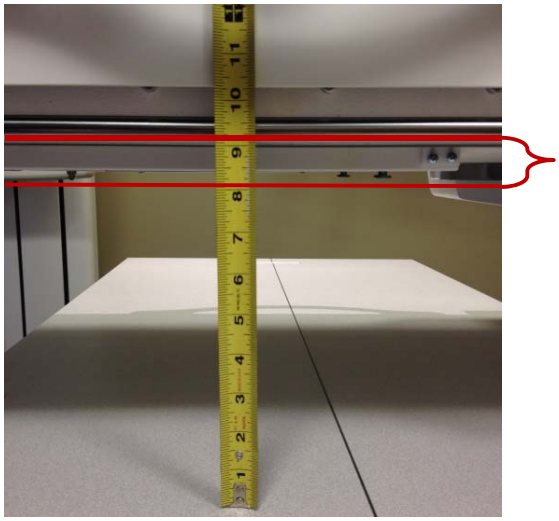
To: Hospital Administrators - Risk Managers
Managers of Radiology - Cardiology
Radiologists - Cardiologists

RE: **Potential fall of the Spot Film Device (SFD) or Intelligent Digital Device (IDD).**

GE Healthcare has recently become aware of a potential safety issue with Precision 500D and Advantx Legacy/Legacy-D Radiographic and Fluoroscopic Systems. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The SFD/IDD safety mechanism installed on your system may not engage properly at the lower range of SFD/IDD travel. This mechanism is installed to hold and prevent the SFD/IDD from falling due to a counterweight cable failure. The lower range of travel is 1.1" (28mm) from the lowest point of normal SFD/IDD vertical compression (see below picture for safety reference). A fall of the SFD/IDD could result in an injury to a patient or operator. There have been no reported injuries as a result of this issue.



Safety Instructions

You may continue to use the system.

- Perform preventative maintenance in accordance with your product labeling. This includes inspection of the counterweight cables and pulleys every 6 month, and replacement of the counterweight cables every four years.
- Set the manual Myelographic stop on the fluoroscopy carriage during exams.

Affected Product Details

All Precision 500D Radiographic and Fluoroscopic (R&F) Systems
Advantx Legacy/Legacy-D Radiographic and Fluoroscopic (R&F) Systems

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.

You can also contact:

Fredrik Brorson
Modality Leader - XRay
Phone: +44 7979293186
e-mail: fredrik.brorson@med.ge.com

Paul Mardle
RA Manager UK/Ireland
Phone: +44 1707 263570
e-mail: paul.mardle@ge.com

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 W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

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

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.

Site Name		Site Contact			
Other site					
Street Address		City			
State		Postal Code		Country	
Phone		Email			

By signing below, I acknowledge receipt of the letter and I accept to follow and to apply the safety instructions. Please record below the date on which your facility received this information.

Name and Title	Date
Signature	

Please FAX back to:

+44 (0) 1 75 341 7098

Or Email to:

SafetyNotice@ge.com

Attention:

GE Healthcare

EMEA Customer Safety letters Specialist
283, rue de la Minière
78530 Buc - France