



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 40856

February 21, 2014

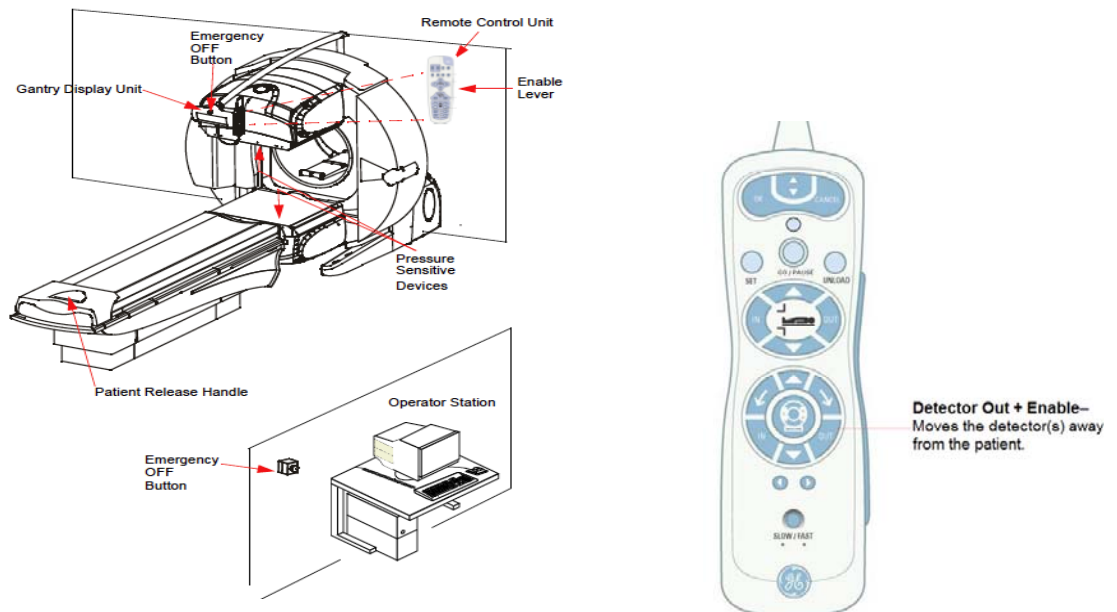
To: Managers of Nuclear Medicine
Hospital Administrators - Risk Managers
Managers of Radiology - Cardiology

RE: Unintended detector motion on Infinia and Infinia Hawkeye Nuclear Medicine systems, Millennium VG, VG Hawkeye and VariCam Nuclear Medicine systems.

GE Healthcare has recently become aware of a potential safety issue related to unintended radial detector motion, which may occur during patient setup or at the end of a patient scan. **Please ensure that all potential users and service personnel in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue A potential life-threatening hazardous situation may occur if there is unintended radial detector motion leading to patient contact. This failure mode has been observed on a single system for a Whole Body scan, in which the detector moved to the home position and then slowly started drifting inward toward the patient. This generated both a visual and audio alert condition on both the console and the gantry. No injuries have been reported to date. This potential detector slippage is due to a combination of gear box self-lock failure due to wear a malfunction in the brake electrical command circuit.

Safety Instructions Monitor the patient and the system during the entire scan procedure to ensure that there is enough clearance between the patient and the detectors. **In the case that the detector comes into contact with the patient, press the Detector Out button on the Remote Control Unit to reverse the motion of the detector. In the case that any unintended motion of the detector is identified, press the Emergency Off button either at the console or on the gantry (shown below) to halt this motion and pull the Patient Release Handle to extract the patient as directed in the user manual. Using the Pressure Sensitive Devices at the gantry may not stop the detector unintended motion.** If you see error # 147 in axis 1 please follow the user manual instructions and contact GE Service.



**Affected
Product
Details**

GE Healthcare Infinia and Infinia Hawkeye Nuclear Medicine systems, Millennium VG, VG Hawkeye and VariCam Nuclear Medicine systems, all configurations.

**Product
Correction**

A GE Healthcare Service representative will perform a software upgrade on each affected system. This activity will be performed at no cost to you.

**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:

Phil Walker
Regional Support Engineer - NM
Mobile: +44 (0) 7771 767106.
e-mail: philip.walker@med.ge.com

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

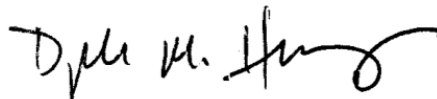
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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 Dennison
Vice President QARA
GE Healthcare Systems



Douglas M. Hansell, M.D., MPH
Chief Medical Officer
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.

<u>Name and Title</u>	<u>Date</u>
<u>Signature</u>	

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