



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 40865

<Date>

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

RE: Collimator Fall on Millennium VG, Discovery VH and VariCam Nuclear Medicine systems.

GE Healthcare has recently become aware of a potential safety issue due to a collimator falling off a VG system during a Quality Control check, while the detectors were rotating. **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 hazardous situation may occur if the collimator falls during a clinical scan due to the collimator being in close patient proximity. No injuries have been reported to date.

Safety Instructions

1. Monitor the patient and the system during the entire scan procedure.
In case of collimator detachment, pull the Table Patient Release Handle to extract the patient as directed in the user manual.
2. If any difficulties or errors with the collimator exchange procedure are experienced at any time, please follow the user manual instructions and contact GE Service.
3. Ensure that the servicer of your equipment uses the latest version of the Service manual and the Preventative Maintenance procedure.

Before every service event, the servicer should check for the latest versions of the Service Manual and Preventative Maintenance procedure, available on the Internet at:

<http://apps.gehealthcare.com/servlet/ClientServlet?REQ=Enter+Documentation+Library>

Affected Product Details GE Healthcare Millennium VG, Discovery VH and VariCam Nuclear Medicine systems, all configurations.

Product Correction A GE Healthcare Service representative will inspect all affected systems to verify the collimator carts and collimator locking mechanisms are operating safely and meeting all specifications. 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.

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 Devices
GE Healthcare

Werner Van den Eynde, M.D.
Acting Chief Medical Officer
GE Healthcare