

### **URGENT FIELD SAFETY NOTICE**

**GE** Healthcare

3000 N. Grandview Blvd. - W440 Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 40874

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

RE: Collimator unlocked warning failure on Millennium VG, Discovery VH and VariCam Nuclear Medicine systems

Please ensure that all potential users 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 locking handle is not properly placed in the lock position and the warning circuit does not detect that the collimator is unlocked because of the patient proximity to the collimator during a clinical scan. There have been no injuries reported as a result of this issue.

#### Safety Instructions

- Ensure the collimator locking handles are in the locked position at all times. Pay special attention after collimators exchange procedure and verify that the collimator locking handles move from OPEN to CLOSE position without applying excessive force.
- 2. Confirm the collimator locking handles are properly placed in the locked position before beginning patient care.
- 3. 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.
- 4. 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.
- 5. 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: <a href="http://apps.gehealthcare.com/servlet/ClientServlet?REQ=Enter+Documentation+Library">http://apps.gehealthcare.com/servlet/ClientServlet?REQ=Enter+Documentation+Library</a>

## Affected Product Details

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

## Product Correction

GE Healthcare will inspect and if necessary 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 or concerns regarding this notification, please contact your local Service Representative.

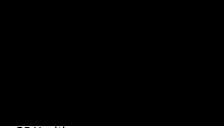
Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

GE Healthcare confirms that this notification has been sent to the relevant competent authorities.

## Sincerely,







GE Healthcare