



URGENT MEDICAL DEVICE RECALL

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI
United States

**Infinia Nuclear Medicine Systems
VG and VG Hawkeye Nuclear Medicine Systems
Helix Nuclear Medicine Systems
Brivo NM615
Discovery NM630
Optima NM/CT640
Discovery NM/CT670**

July 3, 2013

GEHC Ref: 40849

To: Nuclear Medicine Department
Hospital Risk Manager
Hospital Administrator
Director of Radiology and Radiologists

The purpose of this letter is to advise you that GE Healthcare is voluntarily recalling the products listed above. Serious injuries or deaths could occur due to the failure mode associated with this recall. We have a report of 1 death. This letter provides important updates to the notice sent in June 2013 to users of certain types of systems listed above. Please review this notice carefully, and ensure that all potential users in your facility of the devices listed above are made aware of this recall and recommended actions.

Based on current investigation information, GE Healthcare recommends that your site cease use of your Nuclear Medicine system until GE Healthcare can complete an inspection of your system. Please see below for additional details.

Safety Issue

On Wednesday, June 5, 2013, GE Healthcare became aware of an incident at a VA Medical Center facility in the United States. According to information available to us, a patient died due to injuries sustained while being scanned on an Infinia Hawkeye 4 due to a portion of the system falling onto the patient during the scan.

GE Healthcare responded immediately upon being notified about this event and is working with the facility and all appropriate government agencies to complete a thorough investigation. GEHC was permitted access to the equipment on June 17, 2013. As a result, GEHC has been able to determine the cause of this incident. Bolts securing the camera to the gantry were loose, thereby stressing the support mechanism and resulting in the incident. The safety concern is related to a potential patient entrapment or crush hazard if the camera falls during a patient exam.

Because of the similarities in the design of support mechanisms across many products, we have included all types and manufacturing dates of Infinia and Infinia Hawkeye nuclear medicine systems; all types and manufacturing dates of VG and VG Hawkeye nuclear medicine systems; and all types and manufacturing dates of Helix nuclear medicine systems by Elscint Ltd. In this letter, we are adding the Brivo NM615, Discovery NM630, Optima NM/CT640, Discovery NM/CT670 to the notification due to similarities in basic mechanical concepts between these devices and the Infinia systems.

Safety Instructions

GE Healthcare recommends that your site cease use of your Nuclear Medicine system until an inspection of your system by GE Healthcare, as described in the product correction section below, can be completed.

**Affected
Product
Details**

Infinia nuclear medicine systems:

- Infinia 3/8
- Infinia-II 3/8
- Infinia VC
- Infinia II VC
- Infinia 3/8 Hawkeye
- Infinia VC Hawkeye
- Infinia II 3/8 Hawkeye
- Infinia II VC Hawkeye
- Infinia II 3/8 HE4
- Infinia II 5/8 HE4
- Infinia II VC HE4

VG and VG Hawkeye nuclear medicine systems:

- Varicam
- Millennium VG 3/8
- Millennium VG 5/8
- Millennium VG 3/8 Hawkeye
- Millennium VG 5/8 Hawkeye
- Discovery VH

Helix nuclear medicine systems (manufactured by Elscint Ltd).

Devices added as part of this notice:

- Brivo NM615
- Discovery NM630
- Optima NM/CT640
- Discovery NM/CT670

All manufacturing dates of the above products are included. You are being contacted because you have been identified as an owner of one or more of these systems.

**Product
Correction**

GE Healthcare will inspect all affected systems to verify that the support mechanism fasteners are secured properly. A GE Healthcare service representative will contact you to arrange for this inspection as soon as possible. If an issue with the support mechanism fasteners is found on your system, your GEHC Field Engineer will coordinate the replacement of impacted parts in your Gantry and ensure that your system is operating safely and meets all specifications. These activities will be performed at no cost to you.

**Contact
Information**

If you have any questions or concerns regarding this notification, please call the following phone number: United States: 1-800-437-1171. For other countries, please contact your local GE Healthcare Service Representative.

Problems experienced with these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax. 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.

Sincerely,



James Dennison
Vice President QARA
GE Healthcare Systems



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