



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 40860

November 4, 2014

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

RE: **GE Healthcare nuclear medicine preventative maintenance procedure and schedule update notice.**

GE Healthcare has recently performed a field action on your GE Healthcare Nuclear Medicine system due to a potential safety issue related to a portion of the system falling onto the patient during a scan due to fasteners being loose that secured the camera to the gantry. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

As part of this field action, GE Healthcare updated the preventative maintenance procedure and schedule and added an additional Preventative Maintenance check for loose fasteners on the Nuclear Medicine systems.

Safety Instructions

Please ensure that the organization that services your equipment uses the latest version of the service manual and the preventative maintenance procedure.

Affected Product Details

All VG and VG Hawkeye nuclear medicine systems, manufactured from 1996 - 2003:

- Millennium VG
- Millennium VG and Hawkeye
- Discovery VH
- Varicam

All Infinia nuclear medicine systems, manufactured from 2003 – 2014:

- Infinia
- Infinia and Hawkeye
- Infinia and Hawkeye 4

All Brivo NM615, Discovery NM630, Optima NM/CT640 and Discovery NM/CT670 systems.

You are being contacted because you have been identified as an owner of one or more of these systems.

Product Correction

The latest versions of the Service Manual and Preventative Maintenance procedure are available on the Internet at: <http://apps.gehealthcare.com/servlet/ClientServlet?REQ=Enter+Documentation+Library>

See details on the next page.

On the home page, click on [NM] to launch the search:

Common Documentation Library

Locate documents in the Common Documentation Library via

Search criteria:

CT MR NM PET US XR Radiopharmacy Cardiology CIS Clinical Systems
IIS OEC Sub-Acute Pre-Clinical Common Life Support Multi-Vendor PM AW
Interventional Mammo Lunar DXA **FAQ**

OR

Search Direction Number or Document Name:

[Search Help](#)

Note: This search method is **case insensitive** (you may enter upper or lower case). If multiple words are entered, the input is considered to be an exact phrase search.

Select your Nuclear Medicine Product from the list and choose [Service Manual] from the [Manual Type] and click on [Search] to launch the search to bring up the proper service manual:

Multiple selections can be made by holding <ctrl> and clicking on the desired entries.

Select all desired **NM Products**

- All
- Apex
- Apex F1
- Apex SP
- Apex SP-X
- Brivo NM 615
- CamStar
- CamStar 2000
- CamStar 3000
- CamStar 3200
- CamStar 3200i
- CamStar 4000

Select all desired **Manual Types**

- Option/Peripheral Document
- Planned Maintenance Manual
- Pre-Installation
- Product Data Sheet
- Protocol Manual
- Reference Manual
- Renewal Parts
- Service Introduction Planner
- Service Manual**
- Site Planning Manual
- Software
- System Service Manual

Select all desired **Classifications**

- General (Class A)

Select all desired **Status**

- New
- Updated
- CD
- Obsolete

AND
(additional search term)

Search Direction Number or Document Name:

[Search Help](#)

Note: This search method is **case insensitive** (you may enter upper or lower case). If multiple words are entered, the input is considered to be an exact phrase search.

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 289520
e-mail: paul.mardle@ge.com

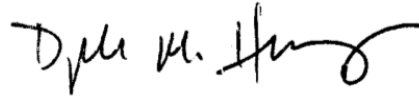
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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