



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 40860

<Date>

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

RE: **GE Healthcare nuclear medicine preventive 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.

<p>Select all desired NM Products</p> <ul style="list-style-type: none">AllApexApex F1Apex SPApex SP-XBrivo NM 615CamStarCamStar 2000CamStar 3000CamStar 3200CamStar 3200iCamStar 4000	<p>Select all desired Manual Types</p> <ul style="list-style-type: none">Option/Peripheral DocumentPlanned Maintenance ManualPre-InstallationProduct Data SheetProtocol ManualReference ManualRenewal PartsService Introduction PlannerService ManualSite Planning ManualSoftwareSystem Service ManualTechnical Publications	<p>Select all desired Classifications</p> <ul style="list-style-type: none">General (Class A)	<p>Select all desired Status</p> <ul style="list-style-type: none">NewUpdatedCDObsolete
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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.

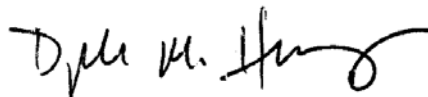
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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