URGENT FIELD SAFETY NOTICE

GE HealthCare

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

RE: **Infinia Series and VG Series Nuclear Medicine systems**

Safety Issue

GE HealthCare has become aware of a potential safety issue related to possible unintended radial detector motion, which can occur during patient setup or during a patient scan. This can occur if the system does not have the correct version of the gantry software installed (See Table 1). In addition to the incorrect software, several other mechanical failures would also have to be present in order for this issue to arise, including radial gear malfunctions, gear oil leaks, and brake pad misalignment. In the unlikely event that the above failures are all present at the same time and the unintended detector motion is not noticed by the technologist, the detector can slowly descend and contact the patient. If the unintended detector motion is not resolved it can ultimately result in life-threatening injury.

Table 1: Correct Gantry Software Versions

Product and Operating System	Infinia Running on Windows2000 (Win2K)	Infinia Running on Windows XP	VG (all operating systems)
Gantry Software (SW) Version	V.25BK	C.15BK or C.1523	V.60BK

Actions to be taken by Customer /User

Check the gantry software version by following the instructions in Appendix A.

If the system has the correct gantry software version installed as indicated in Table 1, you can continue to use your system.

If the software version is not one of the versions in Table 1, GE HealthCare recommends that you discontinue use of your system and contact GE HealthCare Service or your local Service Representative. If however, you decide to continue using your system, please take precautions by following the instructions below:

Monitor the patient and the system during the entire setup and scan procedure to ensure that there is enough clearance between the patient and the detectors.

If you hear the audible alarm or if you observe unintended detector motion, take the following actions, in the order below:
1. If not already in the room, immediately enter the patient room

2. **For the Infinia Systems:** Press the Detector '**OUT**' key together with the '**ENABLE**' lever on the Remote Control Unit (RCU) to move the detector(s) away from the patient (refer to Figure A).

For the VG Systems: Press the Detector '**RADIAL OUT**' key together with the '**ENABLE**' lever on the Remote Control Unit (RCU) to move the detector away from the patient (refer to Figure A).

3. Pull the 'Patient Release Handle' to remove the patient as directed in the User Manual.

Important: <u>Do not press the 'Emergency OFF' buttons (Infinia) / 'Emergency' buttons (VG) in this situation.</u> 'Emergency OFF' buttons (Infinia)/'Emergency' buttons (VG) will not stop the detector unintended motion and may prevent the ability to execute the steps above. In addition, the Pressure Sensitive Devices on the detectors may not stop the unintended motion.
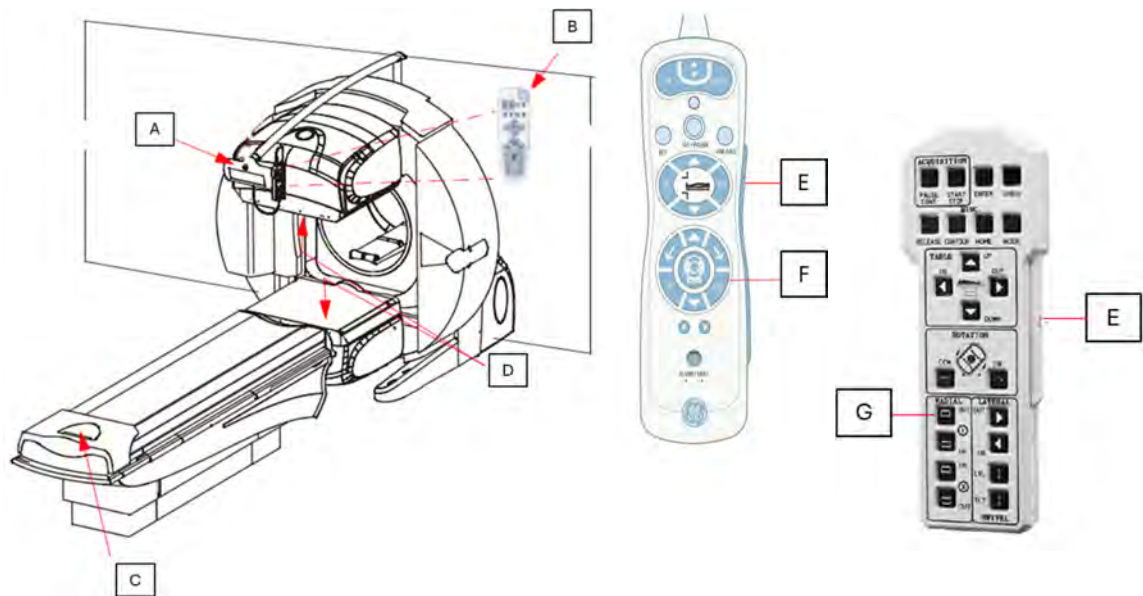
A	Gantry Display Unit (GDU)	E	'**ENABLE**' Lever
B	Remote Control Unit (RCU)	F	Detector '**OUT**' key (Infinia)
C	Patient Release Handle	G	Detector '**RADIAL OUT**' key (VG)
D	Pressure Sensitive Devices (PSD)		

Figure A: Emergency mechanisms on Infinia Series and VG Series systems

Please ensure that all potential users and service personnel in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to **recall.40908@gehealthcare.com**.

Affected Product Details

Infinia Nuclear Medicine Series Systems potentially affected:
- Infinia
- Infinia Hawkeye
- Infinia II
- Infinia II Hawkeye 4

<u>VG Nuclear Medicine Series Systems potentially affected:</u>
- Varicam
- Millennium VG
- Millennium VG Hawkeye
- Discovery VH

Intended Use:
For all the abovementioned configurations, the system is intended to be used to perform general Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and optional imaging features designed to enhance image quality in Oncology, Cardiology, Neurology and other clinical diagnostic imaging applications.

Product Correction	GE HealthCare will correct all systems at no cost to you. This correction will include a hardware update and, if necessary, a software update. 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 GE HealthCare Service or your local Service Representative.

You can contact our Customer Service Centre using the details below:
- Republic of Ireland: 08457 333 999
- Northern Ireland: 0800 0720 248
- Email: healthcareserviceireland@gehealthcare.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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

Appendix A: Instructions to be followed by the system administrator or Chief Technologist to check the software version on your gantry. See Section I for Infinia Series Systems and Section II for VG Series Systems

Section I: Infinia Series Systems

1. Log into the system using User Name: InfiniaAdmin, and the associated password

2. Enter the configuration menu (tools icon on the right, see Figure B):

Figure B: Tools Icon

3. Select the 'Utilities' tab, and the 'Gantry Configuration' tool (see Figure C):

Figure C: Gantry Configuration Tool

4. Check the SW version on the gantry (marked with a rectangle in Figure D):and write it on the reply attached customer reply form
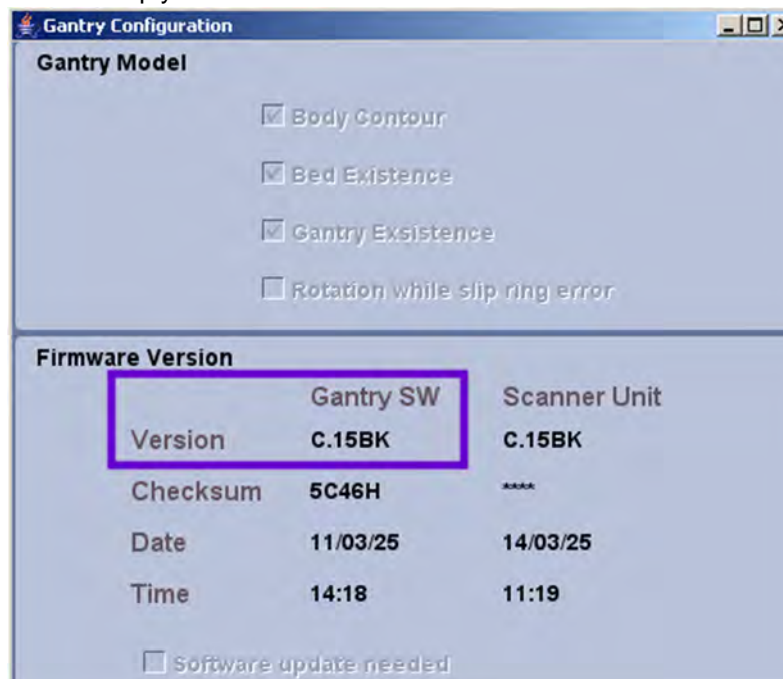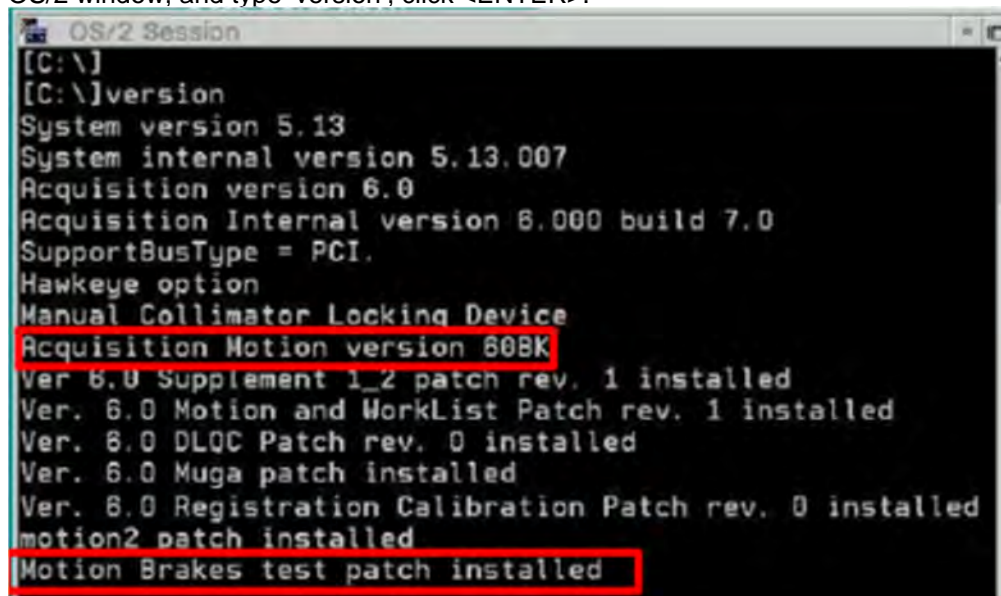
Figure D: Infinia Gantry software versions screen

Section II: For VG Series Systems

1. Open OS/2 window, and type 'version', click <ENTER>.

Figure E: VG Gantry software version screen

2. If the correct software version (60BK) is installed, you will see the two text strings highlighted in red boxes in Figure E. Please write the software version on the customer reply form.

   If the correct software version is NOT installed, you will see a different software version and the text string, "Motion Brakes test patch installed" will not appear on the screen. Please select "Other" on the customer reply form and provide the software version from the screen.

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Ref. # 40908 Correction Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

System Serial Number	Gantry Software version
	☐ V.25BK ☐ C.15BK ☐ C.1523 ☐ V.60BK ☐ Other:_____
	☐ V.25BK ☐ C.15BK ☐ C.1523 ☐ V.60BK ☐ Other:_____
	☐ V.25BK ☐ C.15BK ☐ C.1523 ☐ V.60BK ☐ Other:_____
	☐ V.25BK ☐ C.15BK ☐ C.1523 ☐ V.60BK ☐ Other:_____
	☐ V.25BK ☐ C.15BK ☐ C.1523 ☐ V.60BK ☐ Other:_____
	☐ V.25BK ☐ C.15BK ☐ C.1523 ☐ V.60BK ☐ Other:_____

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to recall.40908@gehealthcare.com

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