URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 40909

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

RE: **GE HealthCare Stop Use Notice for Certain Nuclear Medicine Systems that are past the End of Guaranteed Service (systems that have not been manufactured for many years and for which GE HealthCare has previously communicated End of Guaranteed Service)**

Safety Issue

GE HealthCare has become aware that certain Nuclear Medicine systems that are past the End of Guaranteed Service (herein referred to as "Impacted Systems" and listed in the Affected Product Details section of this letter) could have been transported or relocated without adequate detector support. This could result in excessive stress being applied to the detector mounting mechanisms, compromising their integrity. If this occurs, it can potentially result in a detector fall and lead to life-threatening bodily injury.

There have been no reports of detector falls or injuries as a result of this potential issue.

The Impacted Systems affected by this notice are those that have not been manufactured for several years. GE HealthCare has previously communicated End of Guaranteed Service for these Impacted Systems.

Actions to be taken by Customer /User

You have previously been formally notified that these Impacted Systems have reached their End of Guaranteed Service life, and that GE HealthCare can no longer correct the devices. GE HealthCare requests you to immediately **STOP USING** your Impacted System(s). As these devices are no longer supported and are no longer serviceable, continued use may compromise patient or user safety, negatively impact product performance, or introduce other risks to patients, users, and facilities.

This is the **final communication from GE HealthCare** regarding these devices.

Please ensure all potential users in your facility are made aware of this Stop Use safety notification.

If you require assistance in removal and disposal of your system, please contact your local GE HealthCare representative.

If you would like to discuss your replacement options, please contact your GE HealthCare account representative.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.40909@gehealthcare.com.

Affected Product Details

Elscint Cardial
Elscint Model 4XX
Elscint SPX4
Elscint SPX6
Elscint Varicam
Elscint Helix
Maxicam
Millenium MG/MC
Millenium VG
Millenium Myosight
Millenium MPR
Millenium MPS
Optima NX
Sopha Medical Vision (SMV) DSXi/DST-XLi,/ DST-XL/ DSTi
Starcam/Camstar

Intended Use:
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.

Product Correction

GE HealthCare has previously communicated these Impacted Systems have reached their End of Guaranteed Service. GE HealthCare cannot correct these devices and requests that you immediately stop using the Impacted System(s).

Contact Information

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or 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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

GE HealthCare Ref. # 40909

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 Medical Device Correction Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

Additionally, **if your device is in your possession but not in clinical use**, please confirm:

We have taken the device(s) out of service **OR** we attest that the device(s) will be taken out of service.
We will no longer use the device(s) with the following serial number(s): _____

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.40909@gehealthcare.com)