URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 40906

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator
Director of Biomedical Engineering

RE: **MyoSPECT and MyoSPECT ES Systems: Potential for lead cover (Pb) service handles to fail**

Safety Issue

GE HealthCare has become aware of a potential issue regarding the service handles for the internal lead (Pb) covers (hereinafter "covers") on MyoSPECT and MyoSPECT ES systems. During service operations involving these covers, the handles could loosen or release which could cause a cover to drop, potentially resulting in injury to service personnel as the covers weigh up to 37.5 pounds (17 kg).

The system functions normally during clinical operation. This issue can only occur during specific servicing activities on the system.

There have been no injuries reported as a result of this potential issue.

Actions to be taken by Customer/ User

You can continue to the use the system.

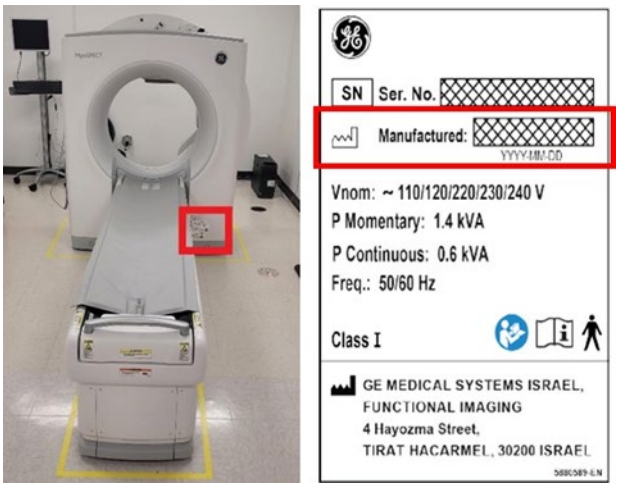
Until GE HealthCare implements the correction for this potential issue on your device, before conducting any servicing activities that involve movement of the covers, please contact GE HealthCare Service for guidance.

Please complete and return the attached acknowledgement form to recall.40906@gehealthcare.com

Affected Product Details

System	GTIN
MyoSPECT manufactured on or before 2024-02-13	00195278421586 00195278488619
MyoSPECT ES manufactured on or before 2024-02-15	00195278421579 00195278488626

The manufactured date is located on the label which can be found on the front of the gantry on the lower right-hand side as pictured below.



Intended Use:
The MyoSPECT and MyoSPECT ES systems are intended for Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body. MyoSPECT and MyoSPECT ES include a Nuclear Medicine system using tomographic scanning mode supported by various acquisition types.

Product Correction
GE HealthCare will correct all affected products at no cost to you.
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.

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 & Safety Officer
GE HealthCare

GE HealthCare

GE HealthCare Ref. # 40906

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.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to recall.40906@gehealthcare.com