URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 17144

To: Hospital Administrator / Risk Manager
Service Providers

RE: **Proteus XR/a Product De-installation**

Safety Issue

GE HealthCare has become aware that the XR system, Proteus XR/a, does not have a de-installation manual describing process steps for de-installing the devices. De-installation instruction process steps must be followed when de-installing these devices to avoid personnel injury during de-install.

Actions to be taken by Customer /User

You may continue to use the Proteus XR/a as intended for clinical use. This issue has no effect on clinical use of the equipment.

If you intend to de-install your Proteus XR/a system or contract a 3rd party to de-install the system:

1. Ensure all instructions and guidance in the De-Installation Manual are followed.
2. Access the De-installation Manual from the product documentation portal: https://www.gehealthcare.com/support/manuals
   In the search bar, type either: “Proteus XR/a De-Installation Manual” or “5273026-8EN”
3. If the table dolly service tool (Part Number: 611-3700) that is used during the original system installation has been retained, ensure the bolts specified in Section 1.4.1 the De-installation Manual are used with the table dolly during de-installation and the instruction for use in Section 1.4.2 of the De-installation Manual is followed.
4. If you do not have this table dolly, follow Section 1.4.3 of the De-installation Manual for de-installation of the table without the dolly.

Please ensure all potential service users in your facility or those contracted by your facility are made aware of this notification and the recommended actions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to RECALL-FMI-17144@ge.com.

Affected Product Details

All Proteus XR/a Systems (GTIN: 00840682120777)

Intended Use:

The Proteus XR/a System is intended for use in generating radiographic images of human anatomy in all general-purpose diagnostic procedures. This device is not intended for mammographic applications.

Product Correction

GE HealthCare has provided Proteus XR/a De-installation Manual including proper use of the table dolly via the website link in this letter.

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,

Chief Quality & Regulatory Officer
GE HealthCare

Chief Medical & Safety Officer
GE HealthCare

GE HealthCare Ref. # 17144

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: _____

☐ 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.

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: (e.g., RECALL-FMI-17144@ge.com)