



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 17099-2

<Date>

To: Hospital Administrators - Risk Managers
Managers of Radiology - Cardiology
Radiologists - Cardiologists

RE: Service Procedure Update Notice for Proteus XR/a and Revolution XR/d systems.

GE Healthcare is in the process of performing device updates to your GE Healthcare Proteus XR/a and/or Revolution XR/d X-ray systems related to collimator re-installation errors. The purpose of this second communication is to supply you with the Internet access link to the updated service procedures.

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

Safety Issue

The Proteus XR/a and/or Revolution XR/d X-ray service manuals at your site may not contain the latest collimator servicing instructions. These servicing instructions have been updated to further ensure proper re-installation. Reinstallation errors may result in a fall of a collimator while the system is in use, resulting in an injury to a patient or operator. There was a reported incident of a collimator fall which caused a serious patient injury.

Safety Instructions

Please ensure that the organization that services your equipment uses the latest version of the Service procedures as listed below.

Preventive Maintenance Manual:

- Proteus XR/a: 2273022-100 Rev 30 or greater: PM 012
- Revolution XRD: 2296990-100 Rev9 or greater: Section 2-5-2

Installation Manual:

- Proteus XR/a: 2273022-100 Rev 30 or greater: IST 014, IST 015
- Revolution XRD: 2357602-100 Rev 10 or greater: Section 7-7, Section 7-9

Affected Product Details

1. Proteus XR/a X-ray systems installed with collimator P.N.'s: 2261763, 2261765.
2. All Revolution XR/d X-ray 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 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 select and click on [XR] 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 X Ray Imaging 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.

Select all desired XR Products
All
Advantage Windows
Advantx
Advantx & Innova
Advantx-E
Advantx-E Positioners
All Interventional Systems
All RAD and R&F Products
AMX 110
AMX 3
AMX 4
AMX 4+

Select all desired Manual Types
Pre-Installation
Product Data Sheet
Proprietary Service Manual
Quality Control Manual
Quick Guide
Release Notes
Renewal Parts
Schematic Diagrams
Service Information Letter
Service Manual
Specification
System Service Manual

Select all desired Classifications
General (Class A)

Select all desired Status
New
Updated
CD
Obsolete

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

Werner Van den Eynde, M.D.
Acting Chief Medical Officer
GE Healthcare