GE Healthcare

Urgent Field Safety Notice

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.

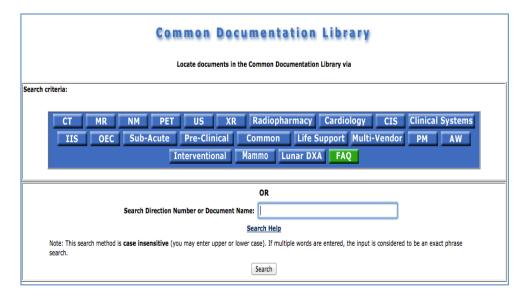|	
Safety Issue	The Proteus XR/a and/or Revolution XR/d X-ray service manuals at your site may not contain the latest collimator servicing instructions. These servicing instructions have been updated to further ensure proper re-installation. Reinstallation errors may result in a fall of a collimator 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:

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.

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