



**URGENT MEDICAL DEVICE CORRECTION**

**GE Healthcare**  
 9900 Innovation Drive  
 Wauwatosa, WI 53226  
 USA

<Date of Letter Deployment>

GEHC Ref# 17108

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

RE: **Proteus XR/a X-ray imaging systems - Potential cable breakage of the wall stand steel cable.**

GE Healthcare has recently become aware of a potential safety issue involving the breakage of the steel cable which support the bucky device in certain wall stands of Proteus XR/a X-ray imaging systems. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

- Safety Issue** GE Healthcare has recently become aware of a bucky device having restricted vertical movement which results in a breakage of its supporting cable. A fall of a bucky while the system is in use could result in an injury to a patient or operator. There were no injuries reported as a result of this issue.
- Safety Instructions** If you observe any abnormal bucky movement or noises during the movement of your Proteus XR/a X-ray imaging system wall stand, immediately stop using your system and contact your local GE Healthcare Service Representative.
- Affected Product Details** Proteus XR/a X-ray imaging systems manufactured with wall stand model number 2260354. See attached addendum page 3 for instructions to locate the model number of your system.
- Product Correction** GE Healthcare will inspect, and repair as necessary, all affected systems at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

Additionally, the Service Procedure which defines the service interval for periodic cable maintenance and replacement is being updated to require a cable replacement every 15 years, and specify annual inspections of the counterweight guide rail bolt paint marking to confirm tightness of the bolt. This is to ensure the ongoing safe operation of this device. Please be sure to review and apply the updated Service Procedure maintenance instructions and ensure the Bucky wall stand steel cables of your Proteus XR/a X-ray imaging system are inspected and replaced as specified in the updated procedure.

Please see the updated Service Procedure (**2273022-100 Rev 33 or above**) which will be available at the link shown below by 31 March 2015.  
<http://apps.gehealthcare.com/servlet/ClientServlet?REQ=Enter+Documentation+Library>

See details on the next page.

**Released**

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.

<p>Select all desired <a href="#">XR Products</a></p> <ul style="list-style-type: none"> <li>Prestige SI</li> <li>Prestilix</li> <li>Processor</li> <li><b>Proteus XR/i</b></li> <li>Proteus XR/e XR/i BRX</li> <li>PS600</li> <li>R500</li> <li>RA0 - Generator</li> <li>RA0-TMX</li> <li>RapidScan</li> <li>Revolution XQ/i</li> <li>Revolution XR/d</li> </ul>	<p>Select all desired <a href="#">Manual Types</a></p> <ul style="list-style-type: none"> <li>Quality Control Manual</li> <li>Quick Guide</li> <li>Release Notes</li> <li>Renewal Parts</li> <li>Schematic Diagrams</li> <li>Service Information Letter</li> <li><b>Service Manual</b></li> <li>Specification</li> <li>System Service Manual</li> <li>Troubleshooting Manual</li> <li>Upgrade Document</li> <li>User Manual</li> </ul>	<p>Select all desired <a href="#">Classifications</a></p> <ul style="list-style-type: none"> <li><b>General (Class A)</b></li> </ul>	<p>Select all desired <a href="#">Status</a></p> <ul style="list-style-type: none"> <li>New</li> <li><b>Updated</b></li> <li>CD</li> <li>Obsolete</li> </ul>
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**AND**  
(additional search term)

Search Direction Number or Document Name:

[Search Help](#)

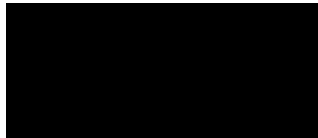
Note: This search method is **case insensitive** (you may enter upper or lower case). If multiple words are entered, the input is considered to be an exact phrase search.

### Contact Information

If you have any questions or concerns regarding this notification, please call the following phone number: United States: 800 437 1171. For other countries, please contact your local GE Healthcare 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 immediately per the contact information above.

Sincerely,



James W. Dennison  
Vice President Devices  
GE Healthcare



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

## Addendum

### Instructions for locating Wall stand Model number 2260354

1. Locate wallstand and stand on the Left-hand side of wall stand column. The label is located in the bottom of wallstand column (see Figure. 1), Model number is printed on the Label.



Figure 1