



## URGENT MEDICAL DEVICE CORRECTION

## GE Healthcare

Healthcare Systems  
9900 Innovation Drive  
Wauwatosa, WI 53226  
USA

<Date of Letter Deployment>

GEHC Ref# 10906

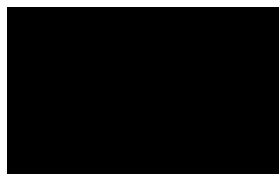
To: Director of Biomedical Engineering  
Director of Radiology  
Chief of Cardiology

RE: **Optima XR200amx, Optima XR220amx and Brivo XR285amx X-ray imaging systems - Potential safety latch mechanism failure.**  
GE Healthcare has recently become aware of a potential safety issue regarding the safety latch holding mechanism for the horizontal arm of the x-ray product. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

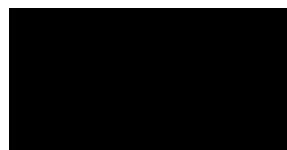
<b>Safety Issue</b>	GE Healthcare has recently become aware of an issue related to the operation of the safety latch within the column that supports the horizontal arm. This safety latch mechanism serves as a backup in the unlikely event the primary safety cable breaks. A fall of the arm assembly could result in bodily harm to a person. There have been no incidents or injuries reported as a result of this internally found issue.
<b>Safety Instructions</b>	You may continue to use the system.
<b>Affected Product Details</b>	All Optima XR200amx, Optima XR220amx and Brivo XR285amx X-ray imaging systems.
<b>Product Correction</b>	GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.
<b>Contact Information</b>	If you have any questions or concerns regarding this notification, please contact GE Healthcare Service India at: 18001027750 / 18004257255 / 18004258025, or your local 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 QARA - Devices  
GE Healthcare



Jeff Hersh, M.D.  
Chief Medical Officer – Medical Solutions  
GE Healthcare