



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

December 18, 2015

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.**

Safety Issue

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.

Safety Instructions

You may continue to use the system.

Affected Product Details

All Optima XR200amx, Optima XR220amx and Brivo XR285amx X-ray imaging systems.

Product Correction

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 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