



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226,
USA

GE Healthcare Ref: FMI 10866

August 2012

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: Optima XR220amx, Optima XR200amx, Brivo XR285amx Maintenance Service Procedure – Wheel Replacement

GE Healthcare has become aware of a service procedure/documentation issue associated with wheel replacement on your Mobile X-ray systems that may impact service personnel safety, should service be required.

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

Safety Issue The service procedure for wheel and caster replacement in the service documentation does not contain sufficient warnings to ensure the service representative has placed the tube into locked position to ensure it does not swing out and change the center of gravity of the unit, thus resulting in the unit tipping over. It is also recommended to clear the work area of unnecessary personnel prior to performing this repair. The fall of the system may create a hazard to Service personnel.

Safety Instructions If there is any need for service on the wheels and casters on the unit, please ensure that the tube is parked and locked into position prior to lifting the unit for repair.

Affected Product Details Optima XR220amx, Optima XR200amx, Brivo XR285amx Mobile X-ray systems (Part numbers; 5555000, 5555000-2, 5555000-3, 5555000-4, 5555000-5, 5555000-6).

Product Correction GE Healthcare has included the new version service procedure on the electronic media with this letter that will replace the service documentation which was shipped with all affected units to prevent this type of safety concern from potentially occurring. This update is provided at no cost to you.

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,

Vice President QARA
GE Healthcare Systems

Chief Medical Officer
GE Healthcare