



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226,
USA

GE Healthcare Ref: FMI 10850

2011-10-25

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **VMX and VMX Plus Mobile X-ray Systems: Articulated Arm Base potential Casting Damage**

GE Healthcare has become aware of an issue associated with the base casting for the articulated arm of your VMX and VMX Plus Mobile X-ray systems that may impact Operator or Patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue The casting which retains the articulated arm to the base of the VMX may develop fatigue cracks through long term use of the product. If the casting develops cracks of significant size, the articulated arm may no longer be properly secured to the base of the VMX. The loss of retention may permit the articulated arm, X-ray tube, and collimator to fall in an uncontrolled manner. The fall of this object may create a hazard to Operators and Patients during transport or use of the equipment.

Safety Instructions If there is any problem with the normal operation of your unit, discontinue use and contact your local GE Healthcare Service Representative.

Affected Product Details All VMX and VMX Plus Mobile X-ray systems.

Product Correction GE Healthcare will replace the base casting on all affected units with a new version that has an increased margin of safety to prevent this type of failure from occurring. This update will be provided at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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