



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 10883

December 2013

To: Hospital Administrators - Risk Managers
Radiology Department Managers
Radiologists

RE: **Optima XR220amx, Optima XR200amx with Digital Upgrade - Incorrect patient selection concern.**

GE Healthcare has recently become aware of a software issue associated with patient selection from the worklist on your mobile X-Ray systems that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue Intermittently when a large number of patient exams are retrieved from the HIS/RIS system (Hospital Information System/Radiology Information System), the exams when displayed on the mobile X-Ray system are not properly displayed. If the user continues to attempt to select one of the exams when this issue has occurred, the system will update the screen and in doing so, potentially select a different exam/patient. If the user does not notice this change and continues to perform the exam, the images will be placed in an incorrect patient file.

Safety Instructions When using the mobile X-Ray system for exams, the user should pay close attention to the patient exam/entry selected from the worklist prior to selecting the Start Exam button to ensure that the system did not update and select an incorrect exam. The user may also confirm during the exam that the appropriate patient information was selected via the display on the upper left portion of the screen.

Affected Product Details Optima XR220amx, Optima XR200amx with Digital Upgrade mobile X-ray systems (Model numbers: 5555000-5, 5555000-6 and 5421698).

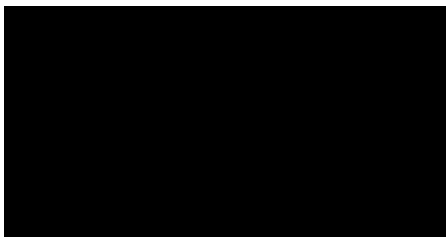
Product Correction GE Healthcare will, without charge, resolve the issue with a software release installed by your GE Field Service Representative.

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.

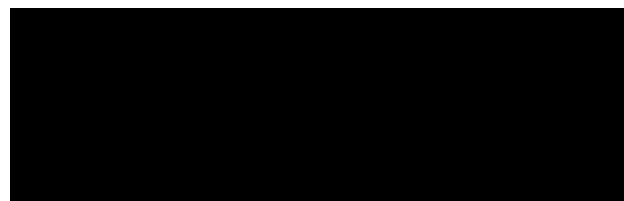
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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