



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 60865

April 2014

To: Hospital Administrators - Risk Managers
Radiology Department Managers
Radiologists

RE: **Gradient coil connections in Magnetic Resonance Imaging products.**

GE Healthcare has recently become aware of a potential safety issue with gradient coil electromechanical connections associated with GE MRI products. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue Gradient coil electromechanical connections may loosen causing an increase in electrical resistance. The increased resistance can lead to increasing heat during scanning which, in turn, can cause material in the rear endbell enclosure to overheat, generate smoke in the scan room, and cause some localized melting of the endbell. This overheating has occurred only while units were being serviced by GE service engineers during repeated evaluation scanning. However, the issue could also occur in clinical mode.

Safety Instructions While in clinical mode, if the operator is notified via user interface message that there are multiple X, Y, or Z gradient distortion faults, they should monitor for smoke odors or evidence of overheating. If they detect either a smoke odor or evidence of overheating, they should stop scanning immediately, remove the patient and call their GE Healthcare Service Representative. Scanning should not resume until the GE Healthcare Service Representative has confirmed the MRI scanner is functioning normally.

Affected Product Details Discovery MR450, Discovery MR750, Optima MR450w, Optima MR 450w equipped with GEM option, Discovery MR750w and Discovery MR750w equipped with GEM option.

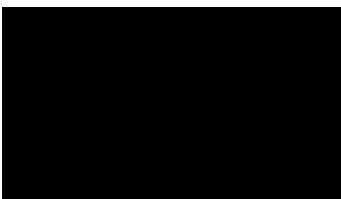
Product Correction GE Healthcare will correct all affected products at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

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.

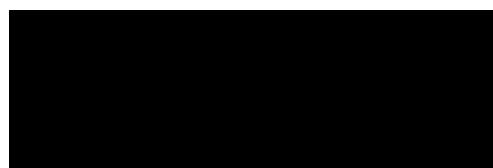
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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