



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Ref: FMI # 60802

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To: Hospital Administrators / Risk Managers
Radiology Managers
Radiologists

RE: **MRU Fuse Replacement**

GE Healthcare has become aware that in the event of a significant power surge, such as one that might be caused by a lightning strike or a utility equipment failure; there is a possibility that the fuse in the MRU (Magnet Run-down Unit) circuit could be affected. This situation could indirectly lead to a potential hazard if an emergency magnet quench is required.

Safety Issue

The MRU (Magnet Run-down Unit) is a critical safety device of the MR System. It is used, by the responder, to quench the magnet (i.e., make it non-magnetic) if required when responding to an emergency situation.

If a significant power surge occurs, the fuse in the MRU circuit could be affected. In this event, the MRU will continue to function as expected for a period of 10 days. However, if the fuse has not been replaced in that time the MRU will not function as expected and will not quench the magnet when the button is pressed. This issue may indirectly impact safety. Please ensure that all users in your facility are made aware of this safety notification and the recommended actions. Instructions for performing a safety check are provided in the MR Safety Manual and MRU User Manual (5265188).

No injury has been reported related to this issue.

Affected Product Details

Optima MR450w, Discovery MR450, Discovery MR750, Signa HDx, Signa HDxt, Signa HFO, GE 1.5T Signa HDe, GE 1.5T Signa HDsv, Signa Excite 1.5T & 3T

All MRU units (5196918) shipped to the field between October/01/2009 – December/10/2010 will be included in the fix.

Safety Instructions

As a preventative measure, the effectiveness of the fuse can be checked by following the procedures from section 5.0 1 of the MRU User Manual (5265188).

5.0 USER WEEKLY TESTING

The charger check should be performed weekly.

5.01 Verify CHARGER POWER LED is illuminated. If this LED is illuminated the MRU fuse is functioning properly. If the CHARGER POWER LED is not illuminated immediately contact your GE Field Service representative.

Illustration 1

Charger Power LED

Verify that the Charger Power LED is illuminated.



Please note that this same Charger Power check is required to be done weekly as described in the MRU User Manual (5265188).

Product Correction

GE Healthcare will correct all affected systems by providing a hardware resolution 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 the appropriate Regulatory Agencies have been notified.

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,



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