



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

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GEHC Ref# 60876

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: MRU Connection; all GE Healthcare MRI systems with superconducting magnets

GE Healthcare has become aware of a potential safety issue due to a disconnected MRU (Magnet Rundown Unit) on some MRI systems in India. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The MRU (Magnet Rundown Unit) is a critical safety component of the MR system that quenches the magnet (i.e., makes it non-magnetic) in emergency situations, such as those that can occur when a ferrous (metal) object is brought into the magnetic field.

At certain sites, the MRU may not be connected to the magnet. If the MRU is disconnected, the MRU will not function as expected and will not quench the magnet when the button is pressed. In emergency situations, a disconnected MRU could delay removal of a ferrous object from the magnet, potentially resulting in life-threatening injuries. **The MRU must be connected to the magnet at all times.**

Safety Instructions

As a preventative measure, please confirm that MRU is connected to the magnet by performing the following four step test on the MRU.

1. Verify the green CHARGER POWER LED is lit.
2. Depress and hold the TEST BATTERY switch for 15 seconds. The green BATTERY TEST LED should light and remain lit while the TEST BATTERY switch is depressed.
3. Place the TEST HEATER toggle switch in the A position. The green HEATER TEST LED should light. If it does not light, depress TEST HEATER LED switch to verify that the LED is functioning.
4. Place the TEST HEATER toggle switch in the B position. Green HEATER TEST LED should light. If it does not light, depress TEST HEATER LED switch to verify that the LED is functioning.

If the MRU test does not perform as described in each of the 4 steps above, GEHC strongly recommends that you stop using the system, and immediately call your GEHC representative.

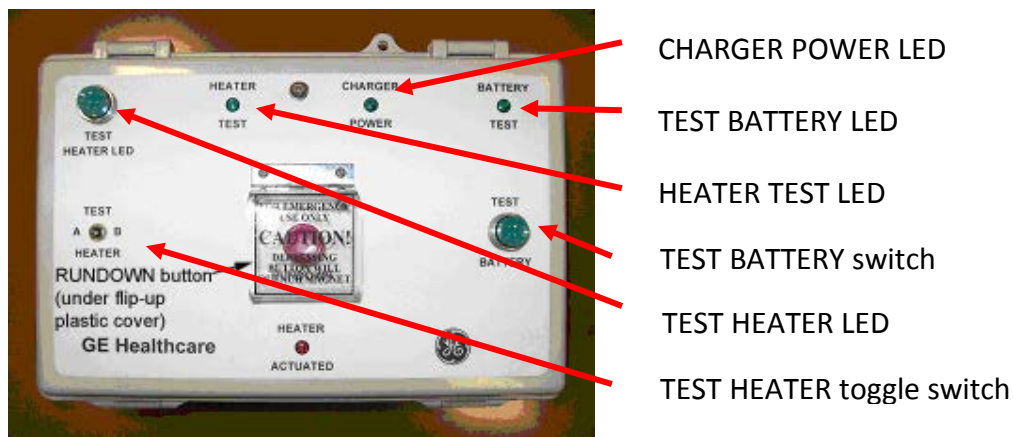


Illustration of the MRU and Its Features

Please refer to your Safety Manual for precautions regarding handling ferrous material around high magnetic fields. Not following these precautions can potentially result in life threatening injuries. Ensure that you are familiar with the routine inspection and maintenance of the system's safety features, and with the multiple methods that can be used if an emergency quench of the magnetic field is required. All of these are documented in the Safety Manual provided with your MRI system.

Affected Product Details

This correction applies to all GE Healthcare MRI systems with superconducting magnets: Discovery MR450, Discovery MR750, Signa HDx, Signa HDxt, Signa HDi, GE 1.5T Signa HDe, Optima MR360, Brivo MR355, Signa Excite-HD 1.5T & 3T, Signa Excite 1.5T HD Twinspeed, Signa Excite 1.5T HD Echospeed, Signa Excite 1.5T HD Highspeed, 1.5T Signa Infinity TwinSpeed , 1.5T Signa Infinity EchoSpeed Plus, 1.5T Signa Infinity HiSpeed Plus, 1.0T Signa Infinity HiSpeed Plus. 1.0T Signa Infinity SmartSpeed, Signa EXCITE 3.0T, Signa EXCITE 3.0T HD, Signa Excite 1.5T TwinSpeed, Signa Excite 1.5T EchoSpeed, Signa Excite 1.5T HiSpeed, Signa Excite 1.5T SmartSpeed, Signa Excite 1.5T, Signa Excite 3.0T, Signa Contour/I, Signa OpenSpeed, Vectra, MR Max, Optima MR450w GEM, Discovery MR750W GEM, Optima MR450w.

Product Correction

GE Healthcare will inspect all affected systems and ensure the MRU is properly connected to the magnet. This will be performed at no cost to you. A GE Healthcare service representative will contact you to arrange for this inspection and correction if needed.

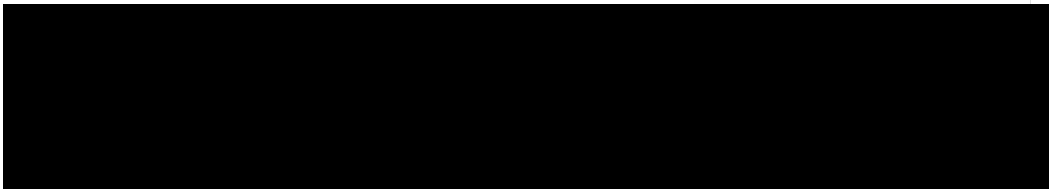
Contact Information

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 per the contact information above.

Sincerely,



Vice President QARA
GE Healthcare Systems

Acting Chief Medical Officer
GE Healthcare