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Voluntary Field Corrective Action Issued for GE Healthcare's MR Systems

February 4, 2015



WAUKESHA, WI - February 4, 2015 - GE Healthcare has initiated a voluntary field corrective action for all GE MR systems with superconducting magnets that were manufactured from 1985 through today.

GE Healthcare has found that some MR systems in India have been modified by service personnel or by equipment users to disable the Magnet Rundown Unit. The Magnet Rundown Unit is one of the methods that may be used to shut off the magnetic field of the MR system in response to an emergency situation in or around the MR system. In emergency situations, a disconnected Magnet Rundown Unit could delay removal of a ferrous object from the magnet, potentially resulting in life-threatening injuries. The Magnet Rundown Unit must be connected to the magnet at all times.

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Media Contacts

Amanda Gintoft

GE Healthcare

+1 414 721 3303

Mobile: 1-414-412-7062

[Email Amanda](#) →

Find a list of GE Media contacts here.

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(2,914)

GE Healthcare has begun notifying customers with superconducting magnets through an Urgent Medical Device Correction letter. This letter:

- Alerts the users of the possible concern.
- Advises users that the red Rundown button should be pressed only in an emergency situation.
- Instructs the users to perform a short test that confirms if the Magnet Rundown Unit is functioning properly and has not been disabled. This test is an action that operator manuals currently advise users to do on a regular basis.
- Informs the users that a GE Healthcare service representative will be visiting their site to inspect the Magnet Rundown Unit and make any corrections if needed.

GE Healthcare is following up with all customers and will correct affected systems at no cost to customers. For additional information regarding this field action, please contact GE Healthcare's Customer Service line (24 hours a day, 7 days a week) at 800-437-1171.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or email), or
- Call FDA 1-800-FDA-1088.

Tags

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日本GE、積水ハウス東北工場の「防災未来工場化計画」実現のため、大容量蓄電池、コジェネ用ガスエンジン、LED照明機器によるエネルギーソリューションを提供



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