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GE Healthcare MRI Recall Update

February 20, 2015



In connection to the recent U.S. FDA recall notice regarding MRI devices, GE Healthcare would like to clarify:

- This U.S. FDA notice was not related to any manufacturing defect or product-related error. It was a case of human error on site, and is in response to a single safety incident in India. GE Healthcare wanted to ensure this human error was not occurring at other sites globally.
- The action instructs MRI customers to perform a five minute check to ensure no one on site post-installation has disconnected the magnetic rundown unit (MRU), which is effectively an “emergency off switch” for the magnet. It is a common industry practice to have an “emergency off switch” for the magnet, which should be checked regularly. GE Healthcare already recommends that this check be done weekly.
- Once the five minute check is confirmed, MRI operations can continue as normal.
- Maintaining a high level of safety and quality is a priority for GE Healthcare.

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