



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 68002

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: Missing ferrous warning label on the SIGNA Pioneer Table Control Box

GE Healthcare has recently become aware of a potential safety issue with a missing ferrous warning label on your SIGNA Pioneer Table Control Box (TCB). **Please ensure that all personnel servicing your MR system are made aware of this safety notification and the recommended actions. Clinical scanning of patients is NOT affected by this safety notification.**

Safety Issue Ferrous material in the TCB could cause unexpected attraction to the MR system's high-strength magnetic field during servicing activities. This could create a potential risk of serious injury to service personnel who attempt to inappropriately remove the TCB from the magnetic field. There have been no events reported as a result of this issue. Clinical scanning of patients is NOT affected by this safety notification.

Safety Instructions

- Service personnel must consciously plan a clear path to be taken when moving ferrous objects in order to stay as far from the magnet as possible.
- Never put yourself between the magnet and the ferrous object at any time.
- In the event a ferrous object becomes attached to the magnet, contact your MR Service Representative before attempting any removal.

Affected Product Details SIGNA Pioneer MR systems

Product Correction GE Healthcare will correct all affected products at no cost to you by applying the ferrous warning label to the TCB. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare



Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare