



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 60901

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: Discovery MR750w heating of the patient bore.

GE Healthcare has recently become aware of a potential safety issue with the patient bore heating on the Discovery MR750w. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

A small area on the bore surface, which is normally accessible to the patient, can get warm enough to cause a serious burn in the event the patient touches the bore and proper padding is not used.

No injury has been reported to GE as a result of this issue. This issue has been observed only in the rare situation in which a user has routinely used the system for off center imaging with large patients (for example, off center wrist or shoulder exams) with transmit gain set near maximum levels.

Safety Instructions

You can continue to use the system by following the existing Operator Manual Safety Information for proper patient padding and observation during scanning. This safety information includes:

- **WARNING:** Place appropriate non-conductive padding between the patient and the bore wherever a portion of the body may come into contact with the magnet opening.
- **CAUTION:** Continuous patient observation and contact are required in all modes of operation.
- **CAUTION:** Extra attention should be utilized when scanning patients who are unconscious, sedated, or may have loss of feeling in any body part or are physically or mentally impaired and unable to alert the personnel.

If a brown discoloration is seen on the inner surface of the patient bore, or if a burning smell is noticed, discontinue scanning.

Affected Product Details

Discovery MR750w

Product Correction

GE Healthcare will inspect all affected products, and make any corrections if necessary, at no cost to you. A GE Healthcare representative will contact you to arrange for the inspection.

**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