



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 60913

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: MR Body Coil heating of the patient bore.

GE Healthcare has recently become aware of a potential safety issue with the patient bore heating on the Discovery MR450 narrow bore 1.5T MRI. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

In the event of a RF component failure, typically happening after extended system use, a small area on the bore surface may become warmer than normal. If this happens in an area where there is patient contact with the bore, and proper padding is not used, it may cause a serious burn.

No injury has been reported to GE as a result of this issue.

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 and contact your field service representative.

Affected Product Details

Discovery MR450, narrow bore 1.5T non-GEM.
Distribution dates: June 2009 through July 2016.

Product Correction

GE Healthcare will correct all affected products, at no cost to you. 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 or your local Service Representative.

Toll Free number: 8001243002

SaudiArabiaServiceCenter@ge.com.

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,

