



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 60937

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator
Director of Biomedical Engineering

RE: Discovery MR750w heating of the patient bore.

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.

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, please contact your local Service Representative.

Affected Product Details

Discovery MR750w

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

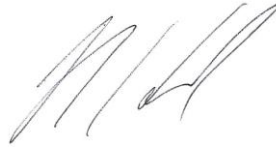
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

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,

A handwritten signature in black ink, appearing to read "JDennison".

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

A handwritten signature in black ink, appearing to read "JHersh".

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare