

**URGENT MEDICAL DEVICE CORRECTION**

GE Healthcare

9900 Innovation Drive  
Wauwatosa, WI 53226  
USA

&lt;Date of Letter Deployment&gt;

GEHC Ref# 60888

To: Hospital Administrators / Risk Managers  
Radiology Department Managers  
Radiologists

RE: De-rating of 3.0T 6 Channel Flex Coil when used on Discovery MR750 running DV24, DV25, or DV25.1 Application Software.

GE Healthcare has recently become aware of a potential safety issue with the 3.0T 6 Channel Flex Coil used with the 3T MR750 Scanners. Based on information we have available, your site is not currently using this 6 Channel Flex Coil and, as a result, does not have a potential safety issue related to this coil at this time. However, GE will be updating your MR750 software to prevent any potential issue should your site add this coil in the future.

**Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

**Safety  
Issue**

The current versions of MR750 DV24, DV25, and DV25.1 software could allow for 3.0T 6 Channel Flex Coil overheating when the device is used in Mode 2 setup. This could lead to a serious patient thermal injury. There have been no injuries reported as a result of this issue.

**Safety  
Instructions**

No action Required. You may continue to use your Discovery 3.0T MR750 systems.

**Affected  
Product  
Details**

Discovery 3.0T MR750 systems running Application software versions DV24 R01, DV25 R02, or DV25.1 M3, when used with the 3.0T 6 Channel Flex Coil.

**Product  
Correction**

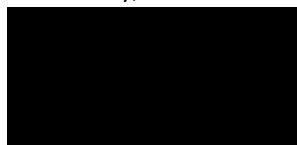
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

**Contact  
Information**

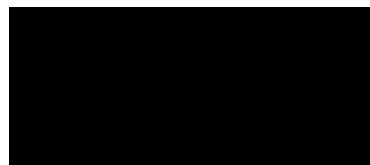
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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