URGENT FIELD SAFETY NOTICE

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 60888-SW

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 or your local Service Representative. You can also contact: Sean Cunningham Modality Leader - MR NE Phone +44 (0) 7789757144 e-mail: sean.cunningham@ge.com Paul Mardle UKI Regulatory Affairs Manager T: +44 (0) 1494 498169 M: +44 (0) 7775 817269 E: paul.mardle@ge.com

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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,

GE Healthcare

GE Healthcare

Customer Reply Form

PLEASE COMPLETE and FAX to GE Healthcare

CUSTOMER CONTACT INFORMATION

Note: please list all site locations and names if you are responsible for more than one site or if your site is known by other names. Thank you.

Site Name		Site Contact			
Other site					
Street Address		City			
State		Postal Code		Country	
Phone		Email			

By signing below, I acknowledge receipt of the letter and I accept to follow and to apply the safety instructions. Please record below the date on which your facility received this information.

Name and Title	Date
Signature	

Please FAX back to:

+44 (0) 1 75 341 7098

Or Email to:

SafetyNotice@ge.com

Attention:

GE Healthcare
EMEA Customer Safety letters Specialist
283, rue de la Minière
78530 Buc - France