GE Healthcare

Urgent Field Safety Notice

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>   GEHC Ref# 60891-2

To: Hospital Administrators / Risk Managers
     Radiology Department Managers
     Radiologists

RE: 3.0T GEMflex Coil Potential Overheating

This is a correction to previous notification you may have received to remove that the system is indicated for adult use only which was incorrect.

GE Healthcare has recently become aware of a potential safety issue with the 3.0T GEMflex Coil manufactured by NeoCoil used with GE Healthcare 3.0T Scanners. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

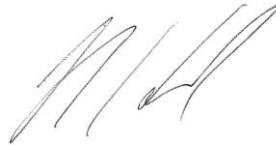|	
Safety Issue	Part of the cable assembly may overheat when the device is used. Rarely this could result in minor burn injury in case of prolonged direct skin contact with the overheating part. There have been no injuries reported as a result of this issue.
Safety Instructions	The issue is observed in various situations of coil setup and port connections. To prevent this issue: Follow the user instructions on using proper padding to avoid all direct contact of the patient with the cable. You may continue to use the device. Ensure that you use the following precautions as described in the 3.0T GEM Flex System Instructions for Use. • Place the foam cover over the Interface. • Do not allow the cable to touch the patient. Use a pad to keep the cable from touching the patient. • Keep the length of the cable in the bore to a minimum.
Affected Product Details	3.0T GEM Flex Coil 16-L Array 5430008-2 3.0T GEM Flex Coil 16-M Array 5430008-3 3.0T GEM Flex Coil 16-S Array 5430008-4 3.0T GEM Flex Interface 5430008-5
Product Correction	GE Healthcare will collaborate with NeoCoil to correct all affected products at no cost to you. You will be contacted 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

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,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare