URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
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USA

<Date of Letter Deployment>

GEHC Ref# 60884

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: **Potential safety issue with Head Specific Absorption Rate (SAR) and recommendations for scanning patients with medical implants using GE Healthcare 3.0T MR Scanners**

GE Healthcare has recently become aware of a potential safety issue with performing head or neck scans on the Discovery MR750w 3.0T, Discovery MR750 3.0T, SIGNA PET/MR 3.0T, SIGNA HDxt 3.0T, SIGNA HDx 3.0T, SIGNA HD 3.0T, SIGNA Excite 3.0T, SIGNA 3.0T MR scanners. The currently displayed SAR values could be lower than the actual SAR in the head as predicted by SAR modeling. The predicted HEAD SAR value from the modeling suggests the actual SAR in the head could exceed IEC60601-2-33 limit of 3.2 W/kg for some scans. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The predicted Head SAR value from the modeling, when using GE Healthcare 3.0T MR scanners with the whole body RF transmit coil and receive-only surface coils for head and/or neck imaging, suggests that actual SAR delivered to the head could potentially exceed the 3.2 W/kg SAR limit defined in IEC60601-2-33. This issue does not affect MR scans performed outside the head and neck areas.

When the system transmits RF power using the whole body RF transmit coil, the SAR value displayed on the system user interface (UI), will be shown as equal to the Whole Body SAR; therefore the SAR delivered to the head could be higher than the displayed SAR value. This issue was identified through computer modeling, and has not been linked to patient injury.

If patients receive higher than expected radio-frequency (RF) energy absorbed during MR imaging procedures, specifically for patients with MR Conditional implants, then localized deep-tissue heating or thermal injury in the vicinity of implants could occur. There have been no injuries identified as a result of this issue.

Safety Instructions

When considering or conducting head or neck imaging, please ensure the following.

For patients with MR Conditional head and neck implants, use only the transmit/receive (T/R) HEAD coil for conducting head and neck imaging/scans. Follow the implant's labeling and instructions strictly.

Note: do not scan patients with implants that have been labeled as MR Conditional with HEAD SAR requirements other than the IEC limit for 3.2 W/kg, as stated in the MR operator manual.

> *"WARNING: Scanners are not designed to regulate SAR and dB/dt for levels other than the IEC NORMAL MODE (WB SAR <= 2 W/kg, head SAR <= 3.2 W/kg and dB/dt <= 80% of the mean nerve stimulation limit) and IEC FIRST*

CONTROLLED MODE (WB SAR <= 4 W/kg, head SAR <= 3.2 W/kg and dB/dt <= 100% of the mean nerve stimulation limit). No other limits are enforced."

For all patients, limit the length of scan protocols; specifically, do not scan any patient continuously without any break for longer than 100 minutes.

As is the case for all MR imaging, follow Good Clinical Practices:

- Continuous patient observation and contact are required. All patients should be monitored for increased temperature during the scan acquisition. If the patient reports discomfort due to excessive warming, stop the scan.
- Extra attention should be utilized when scanning patients who are unconscious, sedated, or may have loss of feeling in any body part (temporary or permanent paralysis). They may not be able to alert the operator to RF heating.
- Give patient breaks to cool down, provide light clothing, limit room temperature to 18 ± 3 °C, and maximize air flow.

Affected Product Details

The following GE Healthcare 3.0T MR systems: Discovery MR750w 3.0T, Discovery MR750 3.0T, SIGNA PET/MR 3.0T, SIGNA HDxt 3.0T, SIGNA HDx 3.0T, SIGNA HD 3.0T, SIGNA Excite 3.0T, SIGNA 3.0T.

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 – Medical Solutions
GE Healthcare