School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

Department of Radiology

To: Department of Radiology and UW Health Practitioners with patients undergoing MRI exams

From: Scott B. Reeder, MD, PhD, Chief of Magnetic Resonance Imaging
Howard A. Rowley, MD, Chair of MRI Safety Committee

Re.: Potential safety issue for scanning patients with metal implants using GE Healthcare 3.0T MRI Scanners

The purpose of this memo is to describe a recent medical device correction communication issued by GE Healthcare on August 31, 2015. Specifically, GE Healthcare has recently become aware of a potential safety issue when performing head or neck scans on their 3.0T MRI scanners. One of the known risks of MRI is tissue heating due to absorption of radiofrequency energy. This can become more acute in the presence of metallic implants. GE has identified a theoretical risk of underestimating the amount of heating for head and neck MRI scans, only in patients with metallic implants in the head and/or neck that are safety rated as "MR Conditional". There are many patients with head and neck metallic implants, most of which are listed as conditional. *Scans acquired at 1.5T and in other body areas are not affected.*

It is important to stress this is only a theoretical risk and to date, despite millions of patient scans at 3.0T, no adverse events, injury or other adverse outcome has been reported on GE systems due to this theoretical safety issue.

In response to this notice, the MRI Safety Committee met on September 9, 2015, to discuss a course of action. Key members of the MRI Safety Committee, including representatives from neuroradiology, MRI safety nursing staff, and MRI physics support, are actively investigating the device correction notice from GE Healthcare. Recommendations from GE Healthcare are being reviewed and the course of action that is felt to be appropriate for the UW Health Practice is currently being assessed. At this time, given the outstanding safety record of GE 3.0T scanners in the community and within our practice, no change in our practice will be mandated. However, when recommendations from the team evaluating the device correction notice have been made, the MRI Safety Committee may make specific recommendations for those patients with conditional metallic implants in the head and/or neck who are scheduled for head and/or neck imaging at 3.0T. It is our general opinion that the GE recommendations are exercising ample caution, and, if adopted as specifically recommended, would result in significantly longer scans of lower quality, as well as other clinical limitations. However, we take all aspects of MRI safety seriously, and so additional information will follow.

Additional information from GE is anticipated in the coming weeks and will be taken into consideration as a plan for managing this device correction is formulated. Please see the following pages for further detail from GE Healthcare.

For further information, please do not hesitate to contact GE Healthcare Services at 1-800-437-1171.

Clinical Science Center
600 Highland Avenue
Madison, WI 53792-3252

Phone: 608-263-6042
Fax: 608-263-0876

URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

August 31, 2015

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