

SIEMENS**Medical Solutions****To all users of a Tx/Rx Head MR Coil**

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Advisory Letter**Re: MR Scans of Patients with Deep Brain Stimulation (DBS) Implants****Dear customer,**

it has come to our attention, that you may have purchased a transmit/receive head coil specifically to scan patients with DBS implants. According to the DBS implant manufacturers (e.g. Medtronic), the examination of those patients requires the use of a transmit/receive head coil in combination with special MR parameter settings regarding SAR and dB/dt. According to Medtronic, the head SAR shall be limited to 0.4 W/kg and the gradient field slew rate (dB/dt) to 20 T/s.

Please be aware that

- the transmit/receive head coil was designed to support spectroscopy applications. We have not yet tested this coil configuration for DBS imaging with MRI.
- our MAGNETOM systems are currently not set up to guarantee a limitation of SAR and dB/dt to levels other than the limits for the normal and 1st level controlled operating mode according to FDA requirements and requirements from the international MR safety standard IEC 60601-2-33. Especially there is no possibility to guarantee limits which are required by implant manufacturers as a prerequisite for safe MR scanning and operation of their devices.

This standard (IEC 60601-2-33) and various scientific literature as well as a recent warning letter issued by the FDA provides strong indications that the examination of patients with active implants including DBS implants is contraindicated. **The contraindications of MRI examinations of patients with active and / or conductive implants are already stipulated in the MAGNETOM System Manual.**

We are aware of statements from some implant manufacturers claiming MR compatibility under certain circumstances. At this point in time we cannot comment on such statements, as we have not yet fully investigated the interaction of DBS implants and MRI.

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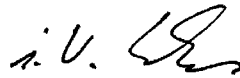
As we understand the importance of this application to our customers, we are looking into this issue more closely and are trying to develop methodologies to safely scan DBS implants with MRI.

Please be aware that if and to the extent you are scanning patients with DBS implants we assume no responsibility whatsoever but rather point again towards our contraindication hereto.

Sincerely,
Siemens Medical Solution



Dr. Kolem
President Magnetic Resonance



Dr. Bachus
VP, Quality and Process Management

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