StimRouter®
Neuromodulation System

UPDATED STIMROUTER MRI INSTRUCTIONS

StimRouter and Bioness have updated the guidance for patients who have been implanted with StimRouter and are planning or need to undergo Magnetic Resonance Imaging (MRI). These changes are designed to simplify the previous StimRouter MRI guidelines for patients, physicians, and MR technicians. Please refer to the guidelines in this insert rather than the MRI section in Chapter 2 of the StimRouter User's Guide. Please contact Bioness at 800.211.9136 with any questions.

StimRouter MRI Information

Non-clinical testing has demonstrated that the StimRouter Lead is MR Conditional. Patients with an Implanted StimRouter Lead can be scanned safely, immediately after implantation, on MRI cylindrical bore systems that meet the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3 T.
- Highest spatial magnetic gradient of 2500 gauss/cm or less.
- MR system reported whole-body averaged SAR does not exceed 2 W/kg at 1.5T and 2 W/kg at 3T.
- Do not scan patients with a SAR level exceeding 2 W/kg. A scan above 2 W/kg may increase the risk of MRI-related heating.
- The entire StimRouter lead must be at least 50 cm (19.7 in.) from the center of the MR system's bore (the iso-center of the bore) and at least 16 cm (6.3 in.) outside of the MR coil measured from the edge of the MR coil, to ensure patient safety relative to MRI related heating.
- Communication is maintained with the patient so that the scan can be promptly terminated in the event of painful nerve stimulation or other adverse event.

Information regarding the position of the StimRouter Lead is necessary for routine MRI procedures. Review of the patient's Medical Device Identification card, direct communication with the implanting physician or obtaining an x-ray is recommended to determine the location of the implanted lead.

Patients must be screened for previously implanted (active or abandoned) medical devices, leads, lead extenders, or lead adapters.

Warnings

- Do not place a local RF transmit coil directly over the implanted StimRouter Lead.
- The entire StimRouter Lead must always be outside the MR coil and must not be exposed to any radio frequency field.
- Do not scan patients with a SAR level exceeding 2 W/kg. A scan above 2 W/kg may increase the risk of MRI-related heating.

StimRouter External Component Restrictions

All external components of the StimRouter system are contraindicated for the MRI environment. The StimRouter Gel Electrode, External Pulse Transmitter, and Patient Programmer must be removed before the patient is allowed into the MRI environment.

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MRI-Related Heating: Supplemental Information

1.5T/64 MHz

Temperature changes of the electrodes of the StimRouter Lead were measured at 1.5T/64 MHz according to ASTM F2182 (GE Signa, 46-258170G1, whole body transmit radio frequency (RF) coil). With the lead in an orientation and a position in the phantom to produce worst-case heating, the greatest measured temperature rise scaled to a background local SAR of 1 W/Kg was 3.9°C after six minutes of RF power application. This temperature change was with the lead in an elongated, "straight" configuration (i.e., no curves), which produced the highest temperature change. With the lead in curved or loped configurations, temperature changes were less.

A computer simulation that incorporated the worst-case measured rise and a whole-body-averaged SAR of 2 W/kg predicts a worst case in the patient during MRI of less than 2°C provided that the entire StimRouter Lead is at least 50 cm from the encter of the bore of the MR system and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

3 T/128 MHz

Temperature changes of the electrodes of the StimRouter Lead were measured at 3 T/128 MHz according to ASTM F2182 (GE Signa, 3T HDx, Software Version 15/LX/MR, 15.0.M4.0910a). With the lead in an orientation and a position in the phantom to produce worst-case heating, the greatest measured temperature rise scaled to a local background SAR of 2 W/kg was 2.9°C after six minutes of RF power application. This temperature change was with the lead in an elongated, "straight" configuration (i.e., no curves), which produced the highest temperature change. With the lead in curved or loped configurations, temperature changes were less.

A computer simulation that incorporated the worst-case measured rise and a whole-body-averaged SAR of 2 W/kg predicts a worst case in the patient during MRI of less than 1°C provided that the entire StimRouter Lead is at least 50 cm from the encter of the bore of the MR system and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

Image Artifacts

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the StimRouter Lead. Optimization of MR imaging parameters to compensate for the presence of the StimRouter Lead may be necessary.

Induce Currents

The electric fields induced in the patient with the StimRouter Lead by the pulsed gradient fields were calculated. The induced current will be less than the stimulation threshold if the StimRouter Lead is at least 50 cm from the center of the bore and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

Caution: Electrical current induced in the StimRouter Lead during MR procedures may cause stimulation of the nerves proximal to the lead, causing sensation, motor response, or nerve blocking.

Individual results vary. Patients are advised to consult with a qualified physician to determine if this product is right for them.
Important Safety Information and Risks: For Indications for Use, Contraindications, Warnings, Adverse Reactions, Precautions and other safety information please refer to www.stimrouter.com/risks (also available in the StimRouter Clinician's Guide).

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