TALISMANN®
neuromodulation system

MRI Guidelines

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Innovations For Active Healing

Patients implanted with a StimRouter Lead and TalisMann Pulse Generator/Receiver may need to undergo Magnetic Resonance Imaging (MRI) after implantation. The following guidelines should be followed for those patients to ensure that patient safety and device function are preserved. Additional MRI-related information can be found at www.stimrouter.com. MRI-related questions should be directed to Bioventus at 800-211-9136.

MRI Resonance Imaging (MRI) Warnings and Precautions

- An MRI examination performed on a patient with a StimRouter Lead and TalisMann Pulse Generator/Receiver should only be done if there is a valid indication as determined by the supervising physician and if all guidelines are carefully followed to ensure patient safety.
- Depending on the type of MRI examination to be performed in the patient, consideration must be given to the scan region and the location of the StimRouter Lead and TalisMann Pulse Generator/Receiver to ensure patient safety.
- Do not perform MRI in patients using a whole-body-averaged SAR level that exceeds 2 W/kg. An MRI exam scan performed using a whole-body-averaged SAR level above 2 W/kg may increase the risk of unacceptable MRI-related heating of the implanted StimRouter Lead and TalisMann Pulse Generator/Receiver.
- When any part of the StimRouter Lead and TalisMann Pulse Generator/Receiver is located 50 cm or less from the center of the transmit RF body coil, this is the **Reduced RF Zone**. In this zone reduced values of the WBA SAR and B1+rms must be utilized in order to ensure acceptable tissue temperature increases during the MRI exam.
- The precise anatomical position of the implanted StimRouter Lead and TalisMann Pulse Generator/Receiver is necessary to know prior to the MRI exam. Therefore, before initiating an MRI exam, the supervising clinician (e.g., the radiologist) should review the patient's Medical Device Identification Card, communicate directly with the implanting physician, and/or obtain an X-ray to determine the precise anatomic location of the implanted StimRouter Lead and TalisMann Pulse Generator/Receiver in the patient's body. Additionally, the patient must undergo a proper MRI screening procedure to determine the presence of a previously implanted (active or abandoned) medical device, including leads, lead extenders, lead adapters, and passive implants.
- All external components of the TalisMann Pulse Generator/Receiver System are contraindicated for the MR system room. Therefore, the StimRouter Electrode and External Electric Field Conductor must be removed before the patient is allowed into the MR system room.

Do not conduct an MRI examination on a patient with a StimRouter Lead and TalisMann Pulse Generator/Receiver until you read and fully understand the information in this document. Failure to follow all warning and guidelines related to MRI can result in a **SERIOUS INJURY** to the patient.

MRI Safety Information

MRI Conditional

The StimRouter Lead and TalisMann Pulse Generator/Receiver is **MR Conditional**. A patient with an implanted StimRouter Lead and TalisMann Pulse Generator/Receiver can be scanned safely, immediately after implantation, under the following conditions:

- Static magnetic field of 1.5 T or 3 T, only
- Maximum spatial field gradient magnetic field of 2,500 gauss/cm (25 T/m)
- MR system is in Normal Operating Mode for gradient magnetic fields.
- Do not use the transmit/receive RF head coil if the StimRouter Lead and TalisMann Pulse Generator/Receiver is implanted above the shoulder.
- Do not place a local RF transmit coil directly over the implanted StimRouter Lead or TalisMann Pulse Generator and Receiver.
- The patient must be conscious. Maintain communication with the patient so that the MRI examination can be terminated in the event of painful nerve stimulation or other adverse or unusual event.
- Specific conditions (see below) must be followed to ensure patient safety relative to the prevention of excessive heating of the StimRouter Lead and TalisMann Pulse Generator/Receiver.

Outside of the **Reduced RF Zone** (> 50 cm away from the center of the transmit RF body coil)	Inside of the **Reduced RF Zone** (≤ 50 cm away from the center of the transmit RF body coil)
WBA SAR must not exceed 2 W/ kg at 1.5 T/64 MHz or 3 T/128 MHz in the Normal Operating Mode of operation for the MR system.	Reduced values of the WBA SAR and B1+rms must be utilized. See Table 1 for the acceptable WBA SAR and B1+rms values.

Table 1: WBA SAR and B1+rms limits inside the Reduced RF Zone. **NOTE:** Limits for both WBA SAR and B1+rms must be observed.

Static Magnetic Field	**1.5 T**		**3.0 T**	
Position	**WBA SAR (W/kg)**	**B1 +rms (uT)**	**WB SAR (W/kg)**	**B1 +rms (uT)**
Upper Arm	0.4	1.2	1.0	0.9
Intercostal	0.4	1.2	1.0	0.9
Lower Leg	0.2	1.2	1.0	0.9
Upper Leg	0.4	1.2	1.0	0.9

To ensure safety for a patient with an implanted StimRouter Lead and TalisMann Pulse Generator/ Receiver, MRI healthcare professionals must adhere to the following conditions:

Using the Transmit Body RF Coil

Outside the Reduced RF Zone: When the entire StimRouter Lead and TalisMann Pulse Generator/Receiver is outside of the **Reduced RF Zone** (as illustrated in "A" of Figure 2-1) the reported WBA SAR must not exceed 2 W/kg at 1.5 T/64 MHz and 2 W/kg at 3 T/128 MHz. Note, any type of receive-only RF coil, for example Receive-Only RF Head Coil, is permitted for use under these circumstances.

Inside the Reduced RF Zone: When all or part of the StimRouter Lead and TalisMann Pulse Generator/ Receiver is inside the **Reduced RF Zone** (as illustrated in "B" of Figure 2-1), reduced values of the WBA SAR and B1+rms must be used to result in acceptable tissue temperature increases (See Table 1).

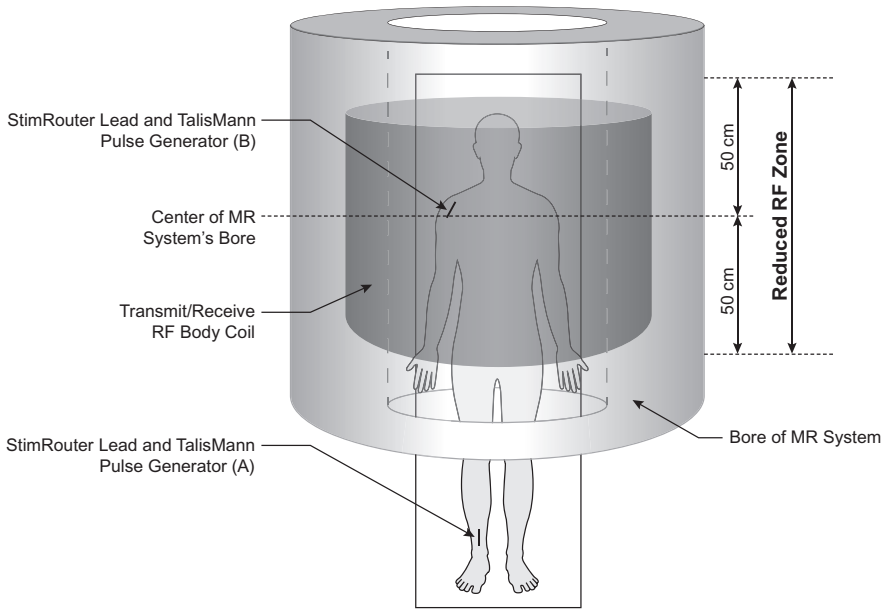

Figure 2-1: MRI examination performed on a patient using the transmit RF body coil and any receive-only RF coil.

Using the Transmit/Receive RF Head Coil

When using Transmit/Receive RF Head Coil, and TalisMann Pulse Generator/Receiver is located in the patient's shoulder or a lower anatomic position (Figure 2-2), limit the head SAR to 3.2 W/kg using the Normal Operating Mode of operation for the MR system if the StimRouter Lead.

As previously mentioned in the MRI Safety Information section, do not use the transmit/receive RF head coil if the StimRouter Lead and TalisMann Pulse Generator/Receiver is implanted above the shoulder.

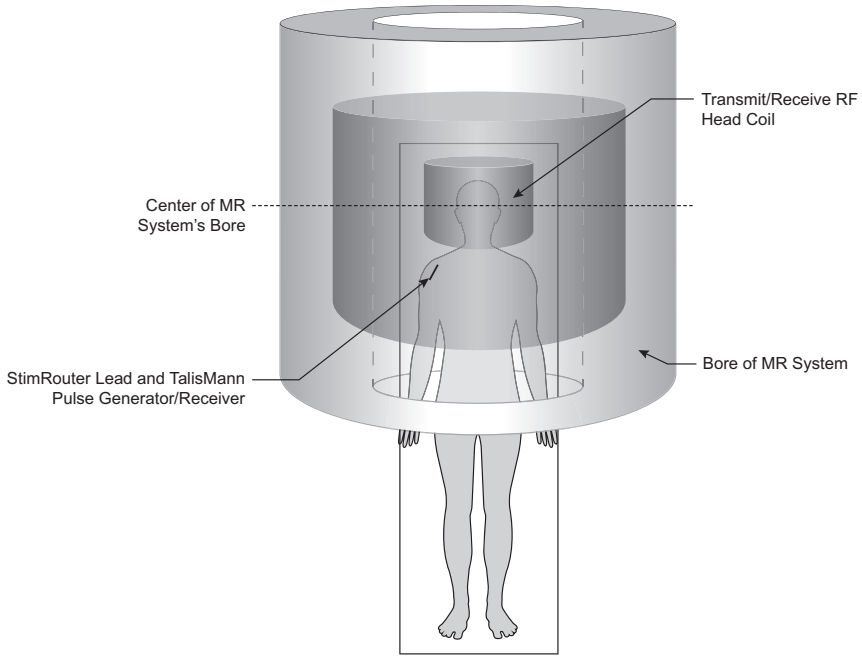

Figure 2-2: MRI examination performed on a patient using the transmit/receive RF head coil.

Using the Transmit/Receive RF Knee Coil

MRI scans with the Transmit/Receive RF Knee Coil (Figure 2-3) may be performed provided that StimRouter Lead and TalisMann Pulse Generator/Receiver is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if the StimRouter Lead and TalisMann Pulse Generator/Receiver is inside the coil or less than a coil radius away from the edge.

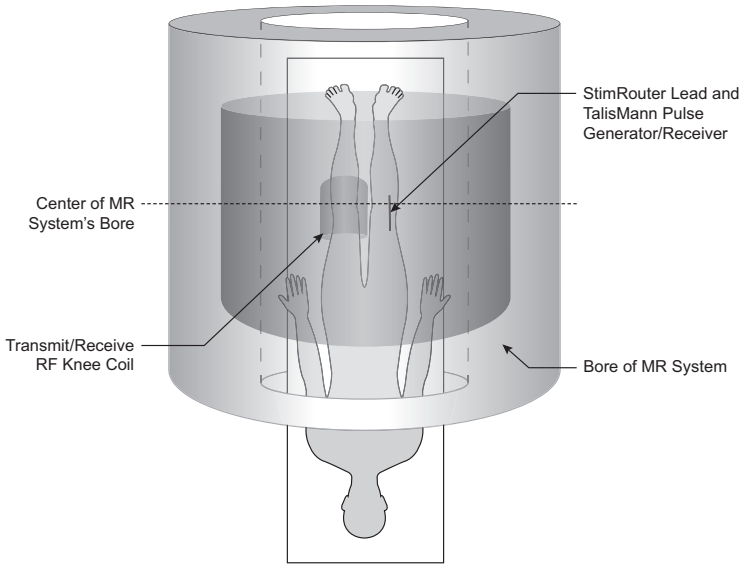

Figure 2-3: MRI examination performed on a patient using the transmit/receive RF knee coil.

Using the Transmit/Receive RF Hand/Wrist Coil

MRI scans with the Transmit/Receive RF hand/wrist Coil (Figure 2-4) may be performed provided that StimRouter Lead and TalisMann Pulse Generator/Receiver is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if the StimRouter Lead and TalisMann Pulse Generator/Receiver is inside the coil or less than a coil radius away from the edge.

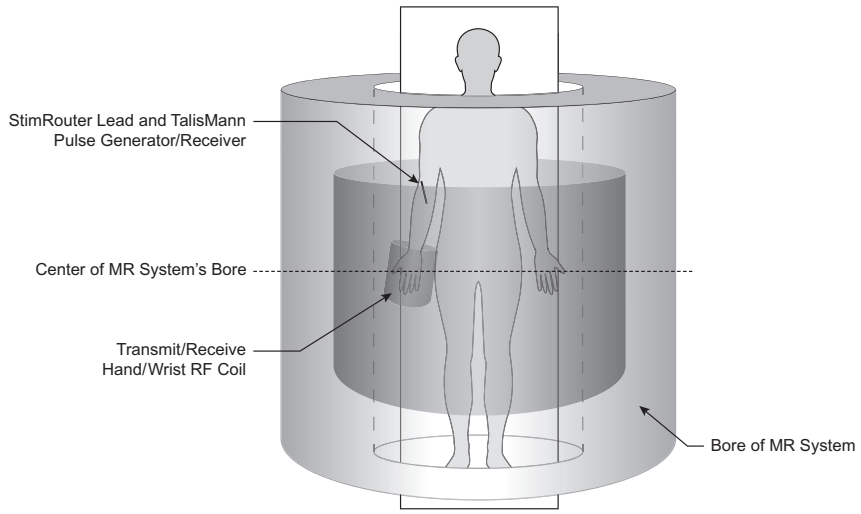

Figure 2-4: MRI examination performed on a patient using the transmit/receive hand and/wrist RF coil.

Using the Transmit/Receive RF Foot/Ankle Coil

MRI scans with the Transmit/Receive RF foot/ankle Coil (Figure 2-5) may be performed provided that the StimRouter Lead and TalisMann Pulse Generator/Receiver is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if the StimRouter Lead and TalisMann Pulse Generator/Receiver is inside the coil or less than a coil radius away from the edge.

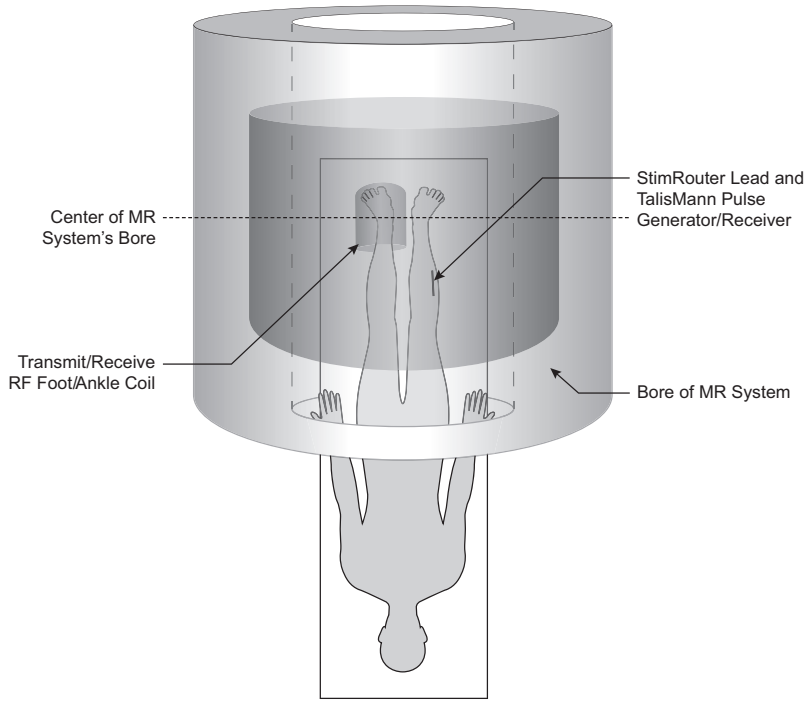

Figure 2-5: MRI examination performed on a patient using the transmit/receive RF foot/ankle coil.

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 and TalisMann Pulse Generator/Receiver. Therefore, optimization of MR imaging parameters to compensate for the presence of the StimRouter Lead and TalisMann Pulse Generator/Receiver may be necessary.

Induced Currents

The electric fields induced in the patient with the StimRouter Lead and TalisMann Pulse Generator/Receiver by the pulsed gradient fields were calculated. The induced current will be less than the stimulation threshold if the StimRouter Lead and TalisMann Pulse Generator/Receiver are more than 50 cm from the center of the transmit RF body coil.

Potential Adverse Events

Use of MRI could result in excessive heating of the StimRouter Lead and TalisMann Pulse Generator/Receiver if the MRI conditions of use are not followed. Induced voltages in the lead may occur, possibly causing uncomfortable levels of neurostimulation.

Note: The StimRouter Lead and TalisMann Pulse Generator/Receiver are not life-sustaining devices. They could be explanted prior to an MRI procedure.

Bioventus LLC
4721 Emperor Blvd Suite 100
Durham, NC 27703 USA
Telephone: (800) 211-9136 or (661) 362-4850
Website: StimRouter.com

Rx Only

LBL-000741 Rev. B 07/25