StimRouter®
neuromodulation system

MRI Guidelines

bioventus®
Innovations For Active Healing

Indications for Use

The StimRouter Neuromodulation System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.

Do not use the StimRouter Neuromodulation System in users who have an implanted demand cardiac pacemaker, implanted cardioverter defibrillator (ICD), or other implanted active device, or who have bleeding disorders that cannot be stopped in advance of the StimRouter implantation procedure. Do not use the system where a metallic implant or a cancerous lesion is present in the immediate implant area. Effects of stimulation during pregnancy are not known. StimRouter is capable of producing skin irritation and muscle ache in the area of stimulation.

Full prescribing information can be found in the Clinician Guide or https://stimrouter.com/safety-information.

Patients implanted with a StimRouter lead may need to undergo magnetic resonance imaging (MRI) after implant. The following guidelines should be followed for those patients to ensure that patient safety and device function are preserved. Any additional MRI-related questions should be directed to Bioventus at 800-211-9136.

MRI Safety Information

MRI Conditional

Nonclinical testing demonstrated that the StimRouter lead is **MR Conditional**. A patient with an implanted StimRouter lead 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)
- Specific conditions (see below) must be followed to ensure patient safety relative to the prevention of excessive heating of the StimRouter lead
- If the entire StimRouter lead is at least 50 cm away from the center of the bore of the MR system and the center of the transmit-RF body coil, the reported, whole-body-averaged (WBA) specific absorbtion rate (SAR) must not exceed 2 W/kg at 1.5 T/64 MHz or a whole-body-averaged SAR of 2 W/kg at 3 T/128 MHz in the normal operating mode of operation for the MR system
- Limit B1+rms and SAR to values in Table 3.1 if the entire StimRouter is not at least 50 cm from the center of the MRI bore (this is the reduced RF Zone)
- 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
- Skin above StimRouter must not be in direct contact with the wall of the MRI bore. Use insulating padding of at least 1 cm thickness between the skin above StimRouter and the wall of the bore
- Legs of patient do not touch each other
- Arms of patient are not in contact with each other or the side of the body
- MR system is in normal operating mode for gradient magnetic fields

Note: The precise anatomical position of the implanted StimRouter lead 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 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.

Position	WBA SAR 1.5 T	WBA SAR 3 T	B1+rms 1.5 T	B1+rms 3 T
Upper Arm	0.4	0.6	1.2	0.7
Intercostal	0.4	0.6	1.2	0.7
Lower Leg	0.2	0.6	1.2	0.7
Upper Leg	0.4	0.6	1.2	0.7

Table 3.1. Whole body SAR and B1+rms limits for StimRouter inside the reduced radio frequency (RF) zone, i.e., within 50 cm of center of the RF body coil.

⚠ **WARNING:** If the StimRouter lead is at least 50 cm from the center of the bore of the MR system and the center of the transmit/receive-RF body coil, DO NOT perform an MRI exam on the patient above a whole-body-averaged SAR of 2 W/kg in the normal operating mode for a 1.5 T/64 MHz or a 3 T/128 MHz MR system. For a StimRouter lead implant located inside the reduced RF zone (see Figures and Tables in this guide) a reduced value of the whole-body-averaged SAR or, alternatively, the value of the B1+rms must be utilized in order to ensure acceptable tissue temperature increases based on the MRI conditions that are used for the MRI exam.

The **reduced RF zone** is defined as the anatomic area of the patient that will receive the RF power deposition during an MRI exam. When all or part of the StimRouter lead is within a 50 cm distance from the center of the bore of the MR system and the center of the transmit-RF body coil, this is referred to as the reduced RF zone. Reduced values of the whole-body-averaged SAR and B1+rms must be utilized in order to ensure acceptable tissue temperature increases based on the MRI conditions that are used for the MRI exam. See Table 3.1 for the acceptable whole-body-averaged SAR and B1+rms values.

To ensure safety for a patient with an implanted StimRouter lead, MRI healthcare professionals must adhere to the following conditions:

Using the Transmit-RF Body Coil

When the entire StimRouter lead is outside of the reduced RF zone and a receive-only RF coil is being used (note, any type of receive-only RF coil is permitted for use under these circumstances), the reported whole-body-averaged SAR must not exceed 2 W/kg at 1.5 T/64 MHz and 2 W/kg at 3 T/128 MHz (Figure 3-1). 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.

When all or part of the StimRouter lead is inside the reduced RF zone (Figure 3-1), reduced values of the WBA SAR or the B1+rms value must be used to result in acceptable tissue temperature increases. See Table 3.1 for the WBA SAR and the B1+rms recommended for use when all or part of the StimRouter lead is within the reduced RF zone during the MRI exam.

Using the Transmit-RF Body Coil and the Receive-Only RF Head Coil

When all or part of the StimRouter lead is inside of the reduced RF zone and a receive-only RF head coil is being used (Figure 3-2), reduced values of the whole-body-averaged (WBA) SAR and the B1+rms value must be used to result in acceptable tissue temperature increases. See Table 3.1 for the WBA SAR and the B1+rms recommended for use when all or part of the StimRouter lead is within the reduced RF zone during the MRI exam. Do not use the transmit-RF body coil with a receive-only RF head coil if the StimRouter lead is implanted above the shoulder.

Using the Transmit/Receive RF Head Coil

MRI scans with the transmit/receive-RF head coil may be performed provided that StimRouter lead is at or below the shoulder. Limit the head SAR to 3.2 W/kg using the normal operating mode of operation for the MR system (Figure 3-3).

As previously mentioned in the contraindication section, do not use the transmit/receive-RF head coil if the StimRouter lead is implanted above the shoulder. Please refer to Chapter 3 for a complete list of contraindications.

Using the Transmit/Receive-RF Knee Coil

MRI scans with the transmit/receive-RF knee coil (Figure 3-4) may be performed provided that StimRouter lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Using the Transmit/Receive-RF Hand/Wrist Coil

MRI scans with the transmit/receive-RF hand/wrist coil (Figure 3-5) may be performed provided that StimRouter lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Using the Transmit/Receive-RF Foot/Ankle Coil

MRI scans with the transmit/receive-RF foot/ankle coil (Figure 3-6) may be performed provided that StimRouter lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Note: The StimRouter lead is considered to be outside of the reduced RF zone if the entire lead is located outside of the transmit-RF body coil, as shown in Figures 3-1 and 3-2, StimRouter lead (A).

Note: The bore dimensions of clinical MR systems and associated transmit/receive-RF coils will vary according to the type of MR system used on the patient with the StimRouter lead.

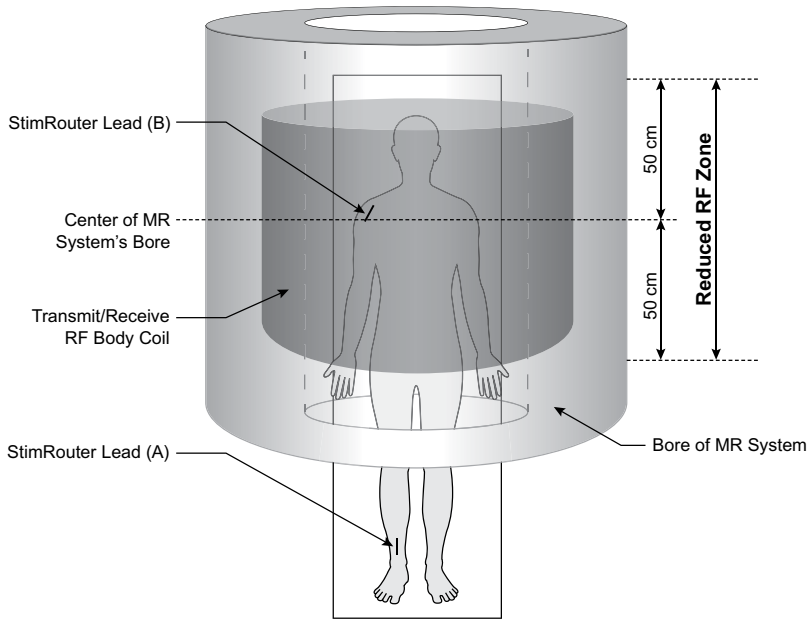

Figure 3-1: The StimRouter lead (A) is located outside of the reduced RF zone and is more than 50 cm away from the center of the MR system's bore and the transmit/receive-RF body coil. In this case, a whole-body-averaged SAR must not exceed 2 W/kg at 1.5 T/64 MHz or a whole-body-averaged SAR of 2 W/kg at 3 T/128 MHz in the normal operating mode of operation for the MR system. The StimRouter lead (B) is located inside of the reduced RF zone. The use of reduced WBA SAR and B1+rms values are required.

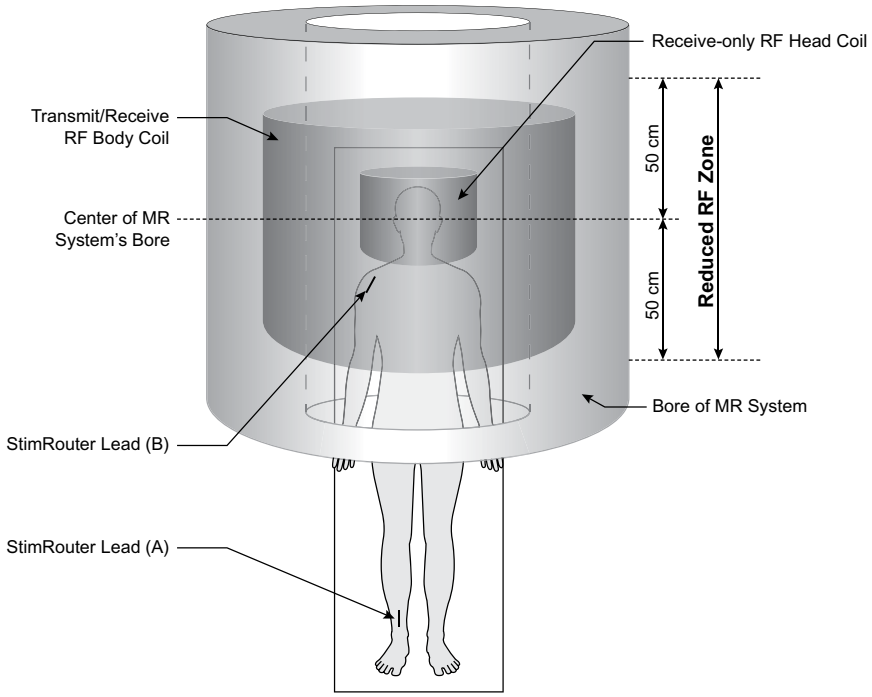

Figure 3-2: The transmit-RF body coil and the receive-only RF head coil are being used with the StimRouter lead (B) inside of the reduced RF zone, while StimRouter lead (A) is outside the reduced RF zone. The use of reduced WBA SAR and B1+rms values are required.

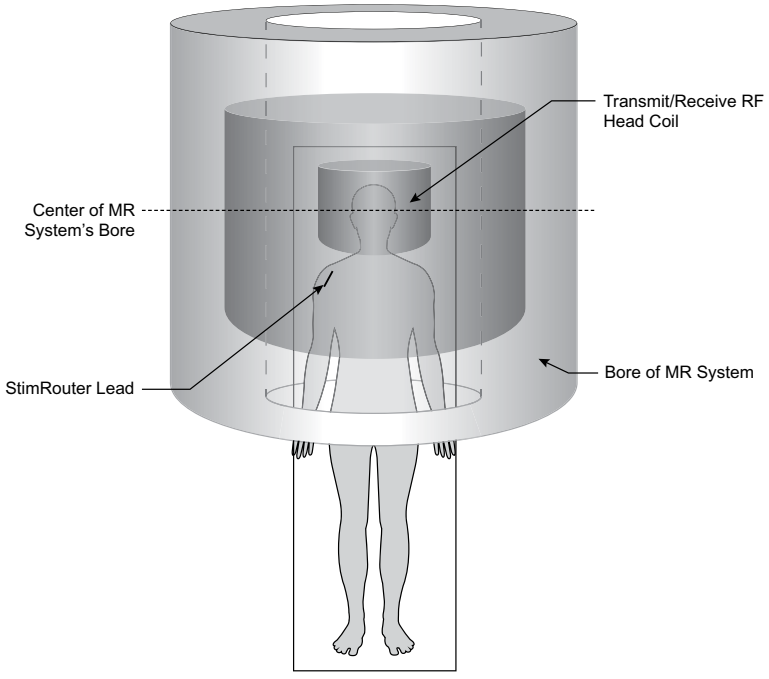

Figure 3-3: MRI scans with the transmit/receive-RF head coil may be performed provided that StimRouter lead is at or below the shoulder. Limit the head SAR to 3.2 W/kg using the normal operating mode of operation forthe MR system.

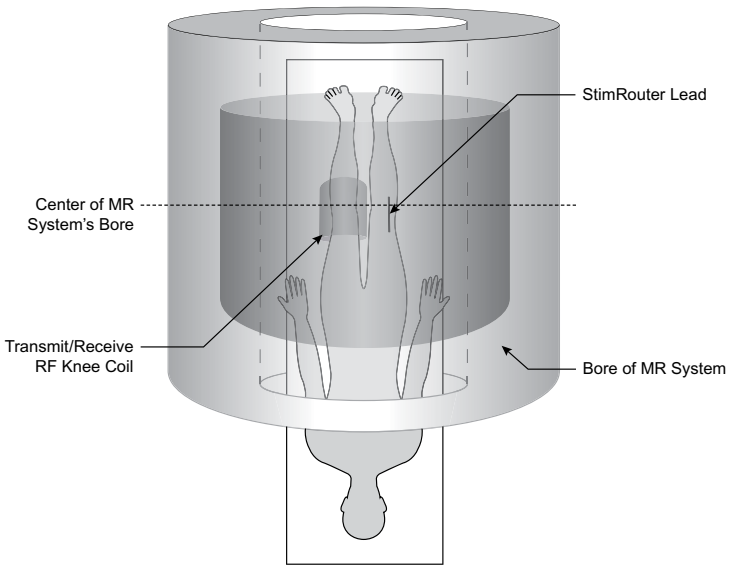

Figure 3-4: MRI scans with the transmit/receive-RF knee coil may be performed provided that StimRouter lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter lead is inside the coil or less than a coil radius away from the edge.

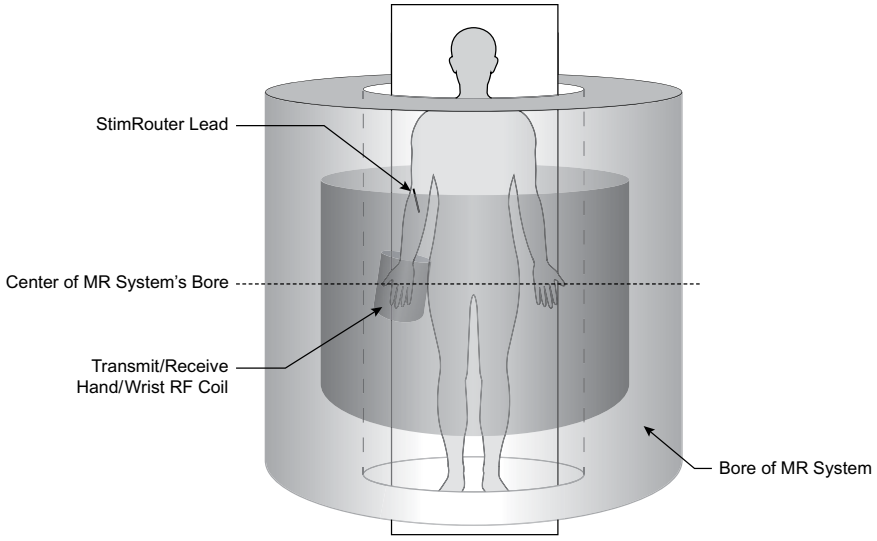

Figure 3-5: MRI scans with the transmit/receive-RF hand/wrist coil may be performed provided that StimRouter lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter lead is inside the coil or less than a coil radius away from the edge.

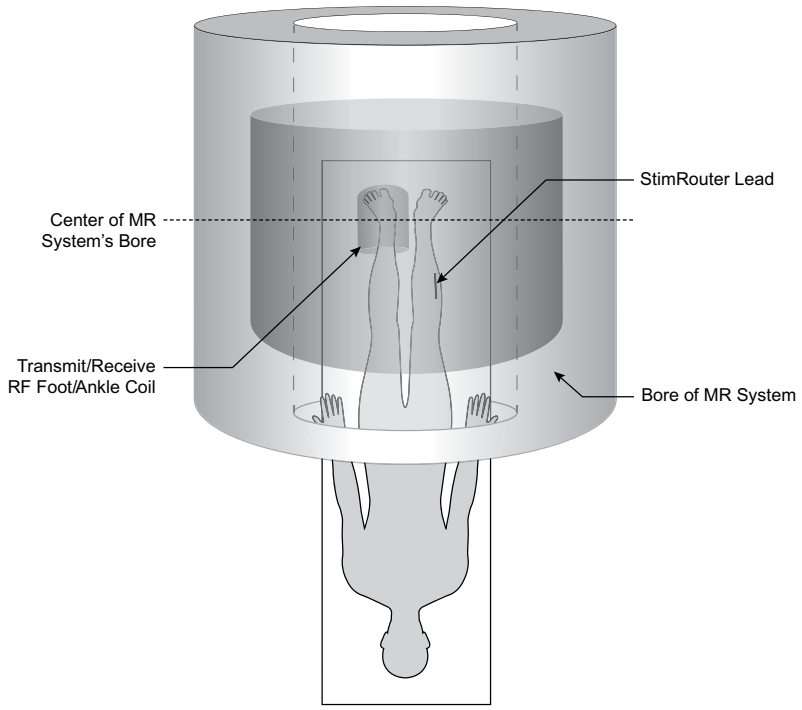

Figure 3-6: MRI scans with the transmit/receive-RF foot/ankle coil may be performed provided that StimRouter lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter lead is inside the coil or less than a coil radius away from the edge.

MRI-Related Heating of the StimRouter lead: Supplemental Information

1.5 T/64 MHz

For situations where the entire StimRouter lead is located **outside** of the reduced RF zone:

Temperature changes of the electrodes of the StimRouter lead were measured at 1.5 T/64 MHz according to American Society for Testing and Materials (ASTM) International F2182 (i.e., using a 64-MHz transmit-RF body coil). With the StimRouter 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 the application of RF power. This temperature change was with the StimRouter lead in an elongated, straight configuration (i.e., no curves), which produced the highest temperature rise. With the StimRouter lead in curved or looped configurations, temperature rises were less.

A computer simulation that incorporated the worst-case measured temperature rise at several anatomic locations and at a whole-body averaged SAR of 2 W/kg predicts a worst-case heating of an implanted StimRouter lead in the patient during an MRI exam of less than 2°C after 15 minutes of continuous scanning (i.e., per pulse sequence) provided that the entire StimRouter lead implant is outside of the reduced RF zone (see **Figures 3-1 to 3-6**).

For a StimRouter lead implant located inside of the reduced RF zone, the worst-case heating was calculated to be less than 6°C for the values of whole-body-averaged (WBA) SAR and B1+rms in Table 3.1.

3 T/128 MHz

For situations where the entire StimRouter lead is located **outside** of the reduced RF zone:

Temperature changes of the StimRouter lead electrodes were measured at 3 T/128 MHz according to ASTM International F2182 (i.e., using a 128-MHz transmit-RF body coil). With the StimRouter 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 application of RF power. The highest temperature rise occurred with the StimRouter lead in an elongated, straight configuration (i.e., no curves). Temperature rises were less when the StimRouter lead was in curved or looped configurations.

A computer simulation showed that there would be less than a 1°C heating of an implanted StimRouter lead in the patient during an MRI exam, provided the entire StimRouter lead implant was outside of the reduced RF zone (see Figures). The computer simulation incorporated the worst-case measured temperature rise at several anatomic locations and a whole-body-averaged (WBA) SAR of 2 W/kg.

For a StimRouter lead implant located inside of the reduced RF zone, the worst-case heating was calculated to be less than 6°C for the values of whole-body-averaged (WBA) SAR and B1+rms in Table 3.1.

Image Artifacts

MR imaging quality may be compromised if the area of interest is in the same area or relatively close to the position of the StimRouter lead. Therefore, optimization of MRI parameters to compensate for the presence of the StimRouter lead may be necessary.

Induced Currents

The electric fields induced in a patient with the StimRouter lead by the time-varying, gradient magnetic fields used during MRI were calculated.

If the StimRouter lead is at least 50 cm from the center of the bore of the MR system and outside the gradient coils of the MR system, the induced current will be less than
the stimulation threshold. However, the induced current may reach the stimulation threshold if the StimRouter lead is located less than 50 cm from the center of the bore of the MR system and the center of the transmit-RF body coil (i.e., the approximate area inside the reduced RF zone).

CAUTION: Electrical current induced in the StimRouter lead during an MRI procedure may cause stimulation of the nerves proximal to the lead, causing sensation, motor response, or nerve blocking.

Potential Adverse Events

The utilization of MRI could result in excessive heating of the StimRouter lead, if all MRI parameters and conditions of use are not carefully followed.

Induced voltages in the StimRouter lead may occur due to the time-varying, gradient magnetic fields of the MR system, possibly causing uncomfortable levels of neurostimulation.

Note: Since the StimRouter lead is not a life-sustaining device, it could be explanted from the patient prior to an MRI exam and re-implanted after the MRI exam.

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