22 MRI SAFETY INFORMATION

22.1 Introduction

MR Conditional

The Vivistim® System is designated through non-clinical testing as an MR Conditional device that has been demonstrated to present no known hazards when exposed to a specific magnetic resonance (MR) environment that meets specific conditions of use as described in this manual. The Vivistim® System will not be functionally degraded under these conditions of use.

The clinician or radiologist must adhere to the guidelines, cautions, and warnings contained herein in order to perform an MRI on a patient implanted with the Vivistim® System using a 1.5T or 3T MRI closed bore scanner.

This information should be read and understood completely prior to conducting or ordering an MRI examination on a patient with the Vivistim® System. These instructions apply only to the Vivistim® System, and do not apply to other products of any type. If you have any questions, please contact MicroTransponder per the **Information and Support** section of this manual.

22.2 MTI Models and Components Approved for MR Conditional Use

Component	Model/Part Number	Note
Vivistim® Implantable Pulse Generator	1001	Vivistim® System
Lead, 43 cm length, 2 mm cuff diameter	3000	Vivistim® System
Lead, 43 cm length, 3 mm cuff diameter	3000	Vivistim® System

Table 22.1: MTI Models and Components Approved for MR Conditional Use

CAUTION: *No other component of the Vivistim® System is MR Conditional. Do not bring the following Vivistim® System components into the MR room; they are prohibited from MR scanning:*

- *Model 2000 Wireless Transmitter*
- *Model 4001 SAPS software*
- *All non-implantable surgical accessories*

MRI Unsafe: *Do not carry metal (for example magnets, jewelry, etc.) into the MR scanner room. Metal objects can become dangerous flying objects if attracted by the strong magnetic field of the MRI scanner.*

22.3 Risks of MRI With the Vivistim® System

Potential risks of performing MRI outside of the guidance provided in this manual on patients implanted with the Vivistim® System include:

- Lead electrode or IPG can heating, resulting in patient discomfort, tissue damage, or serious injury
- Functional impairment of the IPG, sustained beyond the end of an MRI-scanning session
- Movement, vibration, or rotation of the IPG, resulting in discomfort during MRI scan
- Unintended stimulation during MRI scan
- Image distortion and artifacts of IPG and Lead/electrodes over regions where diagnostic information required

22.4 Contraindications of MRI With the Vivistim® System

The contraindications associated with performing MRI on patients with an implanted Vivistim® System include:

- 3T MRI scans of the C7 to T12 area using a transmit RF body coil require surgical removal of the Vivistim® System unless the whole body averaged SAR is restricted to levels less than or equal to 1.5 W/kg. For details, see the **3T MRI Restricted Zones Overview** section of this manual**.**

- 1.5T MRI scans of the area from the top of the head to L5 using a transmit RF body coil require surgical removal of the Vivistim® System unless the whole body averaged SAR is restricted to levels less than or equal to 0.5 W/kg. For details, see the **1.5T MRI Restricted Zones Overview** section of this manual.
- No part of the implanted Vivistim® System (implantable pulse generator [IPG], Leads, Lead tie-downs) may be within a transmit/receive RF head coil or transmit/receive RF peripheral coil. Scanning of the area where the Vivistim® System is implanted with these types of transmit RF coils is strictly prohibited.
- Do not use open-sided MRI systems or systems operating at higher or lower Tesla values (for example, 0.5, 1.0, 4.0T). The risks of using MRI systems operating at other Tesla values have not been evaluated and could be significant.
- The Model 2000 Wireless Transmitter, Model 4001 SAPS software, all non-implantable surgical accessories, and all off-the-shelf accessories such as the magnet are considered MR Unsafe. These devices may be projectile hazards and should not be allowed into the MRI scan (magnet) room.
- The hazards of scanning patients that are implanted with other medical devices, together with the Vivistim® System, are not known and therefore MR scans on these patients are prohibited until safety has been demonstrated.
- Do not perform an MRI if the patient has a device or device component (Lead, extension, etc.) from a different manufacturer connected to the Vivistim® System IPG. The risks of performing MRI scans with a Vivistim® System IPG connected to a component manufactured by a different company have not been evaluated and could be significant.

22.5 Conditional MRI With the Vivistim® System

MRI examinations of the torso, head, and extremities can be safely conducted in patients with the Vivistim® System when all of the instructions in this manual are strictly followed. Non-clinical testing has shown that the Vivistim® System is MR Conditional when exposed to the MRI environment under the following specific conditions (reference the information found in Table 22.2 and Table 22.3 of this manual):

- A patient with this device can be scanned safely in an MR system meeting the following conditions (Please consult the MR scanner manufacturer for these specifications):
  - Static magnetic field of 1.5 Tesla (1.5T) or 3 Tesla (3T) only
  - Maximum spatial static magnetic field gradient of 5,000 gauss/cm (50 T/m)
  - Gradient magnetic field having a maximum slew rate of 200 T/m/s and amplitude of 40 mT/m
  - For transmit RF head coils in 1.5T and 3T scanners: whole head averaged SAR for the transmit RF coil must be < 3.2 W/kg (Normal Operating Mode).
    - No part of the implanted Vivistim® System (implantable pulse generator [IPG], Leads, or Lead tie-downs) may be within the transmit RF head coil or transmit RF peripheral coil.
    - The location of the implanted Vivistim® System components shall be confirmed prior to the MR scan to ensure compliance with this condition.
  - For transmit RF body coils in 3T scanners centered in the C7 – T12 area: whole body averaged SAR for the transmit RF body coil must be limited as detailed in the **3T MRI Restricted Zones Overview** section of this manual. Adherence to SAR limitations as detailed in Figure 22.1 is absolutely necessary.
  - For transmit RF body coils in 3T scanners centered outside of the C7 – T12 area: whole body averaged SAR for the transmit RF body coil must be < 2 W/kg (Normal Operating Mode).
  - For transmit RF body coils in 1.5T scanners centered in the area from the top of the head to L5: whole body averaged SAR for the transmit RF body coil must be limited as detailed in the **1.5T MRI Restricted Zones Overview** section of this manual. Adherence to SAR limitations as detailed in Figure 22.2 is absolutely necessary.
  - For transmit RF body coils in 1.5T scanners centered outside of the area from the top of the head to L5: whole body averaged SAR for the transmit RF body coil must be < 2 W/kg (Normal Operating Mode).
- Do not conduct an MRI if the implanted Model 3000 Lead is intact but not connected to the IPG.

- Reference the **Consideration for a Partially Explanted Vivistim® System (Remnant Leads)** section of this manual for MR scans of patients with remnant Leads that are less than 5 cm in length.
- The IPG Stimulation and Magnet Mode must be turned off.
- Limit MR scan time to 15 minutes.

Under these defined scan conditions, MicroTransponder's Vivistim® System is expected to produce a maximum temperature rise of less than 6.0 ºC after 15 minutes of continuous scanning.

CAUTION: *Receive RF Coils - Certain MR system head and peripheral RF coils operate in receive-only mode and require the use of a transmit RF body coil. The use of a head or peripheral receive RF coil does not alter hazards of the transmit RF body coil.*

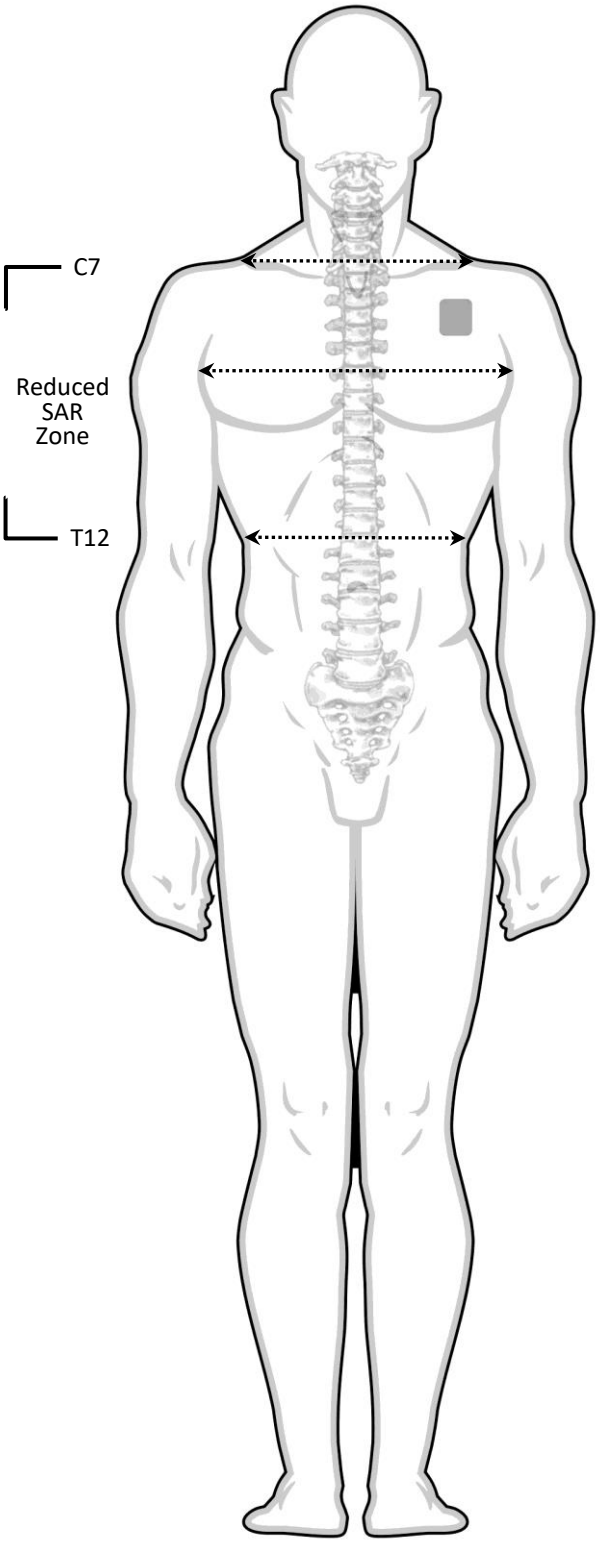
CAUTION: *The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.*

In non-clinical testing, the image artifact caused by the Vivistim® System extends approximately 10.4 cm from the IPG and 1.9 cm from the Lead when imaged with a spin-echo pulse sequence in a 3T MRI system and is less in a 1.5T MRI system.

22.6 3T MRI Restricted Zones Overview

Prior to scanning, verify the IPG is programmed to 0.0 mA output and Magnet Mode is programmed OFF.

No part of the Paired VNS™ System can be inside the Transmit RF head coil or Transmit RF peripheral coil.



Zone A: "Normal Operating Mode SAR Limit" zone

When the transmit RF coil is centered in this area, normal operating mode for 3T scans can be performed with the following SAR limitations:

≤ 2 W/kg whole body averaged SAR (Transmit RF body coil)

≤ 3.2 W/kg head average SAR (Transmit RF head coil)

Zone B: "Reduced whole body averaged SAR" zone

Further SAR reductions apply when the transmit RF body coil is centered in this area (C7 – T12):

≤ 1.5 W/kg whole body averaged SAR (Transmit RF body coil)

NOTE: Reduced SAR zone does not apply to transmit RF peripheral coils used on extremities.

Zone A: "Normal Operating Mode SAR Limit" zone

When the transmit RF coil is centered in this area, normal operating mode for 3T scans can be performed with the following SAR limitations:

≤ 2 W/kg whole body averaged SAR (Transmit RF body coil)

Figure 22.1: 3T MRI Restricted Zones Overview

22.7 3T MRI Scan Conditions for the Vivistim® System

MRI Conditions for Use		Zone A: NOM SAR Limit Conditions	Zone B: Reduced SAR Conditions
Scanner Type		Horizontal field, cylindrical closed-bore, clinical system for hydrogen proton imaging	
Scanner Characteristics	**Static magnetic field Strength**	3T	
	Spatial field gradient	< 5,000 G/cm (50.0 T/m)	
	Maximum slew rate	200 T/m/s and amplitude of 40 mT/m	
Scanner Operation	**Operating mode**	Normal Operating Mode (NOM)	Reduced SAR
	Maximum Specific Absorption Rate (SAR)	**Transmit RF head coil**: 3.2W/kg head averaged SAR **Transmit RF peripheral coil:** normal operating mode **Transmit RF body coil:** 2.0 W/kg whole body averaged SAR	**Transmit RF head coils**: N/A ***Transmit RF peripheral coil:** normal operating mode *NOTE: Reduced SAR zone does not apply to transmit RF peripheral coils used on extremities. **Transmit RF body coil:** ≤ 1.5 W/kg whole body averaged SAR
	Transmit RF coil	**Transmit RF head or peripheral coils**: Scan (placement of entire Transmit RF coil) must be outside of C7 - T12. **Transmit RF body Coil:** The iso-center of the scan (center of the MRI bore) must be outside C7 – T12. This may be accomplished by landmarking above C7 or below T12.	**Transmit RF head or peripheral coils**: N/A **Transmit RF body Coil:** The iso-center of the scan (center of the MRI bore) is permitted in this area: C7 – T12. Scans in this zone REQUIRE REDUCED SAR as specified in this column.
	Exposure time	**Transmit RF head or peripheral coils:** No restriction **Transmit RF body coil:** ≤ 15 minutes of active scan time within a 30-minute window	**Transmit RF head or peripheral coils:** N/A **Transmit RF body coil:** ≤ 15 minutes of active scan time within a 30-minute window
	Additional Restriction(s)	**Transmit RF head or peripheral coil:** None **Transmit RF body coil:** Circularly Polarized (CP) mode only (i.e., no shimming)	**Transmit RF head or peripheral coil:** N/A **Transmit RF body coil:** Circularly Polarized (CP) mode only (i.e., no shimming)

Table 22.2: Summary of 3T MR Scan Conditions

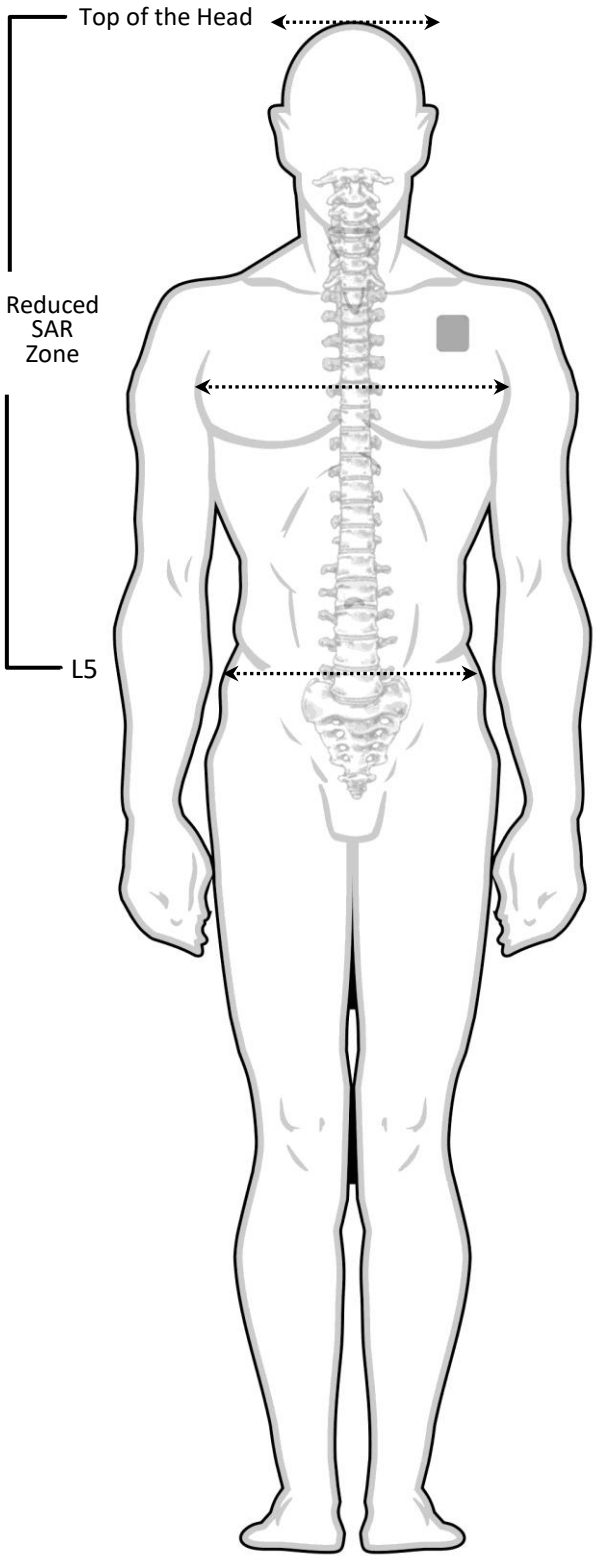
CAUTION: *No part of the Vivistim® System can be inside the Transmit RF head coil or Transmit RF peripheral coil.*

Specific absorption rate (SAR), expressed in watts per kilogram (W/kg), is a measure of RF power deposition in the patient. In MR systems, higher SAR limits lead to greater heating. Typically, SAR values are maximum head averaged when using the transmit RF head coil and whole body averaged when using the transmit RF body coil as reported by the MRI equipment.

22.8 1.5T MRI Restricted Zones Overview

Prior to scanning, verify the IPG is programmed to 0.0 mA output and Magnet Mode is programmed OFF.

No part of the Vivistim® System can be inside the Transmit RF head coil or Transmit RF peripheral coil.



Zone B: "Reduced whole body averaged SAR" zone

Further SAR reductions apply when the transmit RF body coil is centered in this area (Top of Head – L5):

1.5T: ≤ 0.5 W/kg whole body averaged SAR (Transmit RF body coil)

Scans of the head can be performed in normal operating mode for 1.5T scans using the transmit RF head coil with the following SAR limitations:

≤ 3.2 W/kg head average SAR (Transmit RF head coil)

NOTE: Reduced SAR zone does not apply to transmit RF peripheral coils used on extremities.

Zone A: "Normal Operating Mode SAR Limit" zone

When the transmit RF coil is centered in this area, normal operating mode for 1.5T scans can be performed with the following SAR limitations:

≤ 2 W/kg whole body averaged SAR (Transmit RF body coil)

Figure 22.2: 1.5T Restricted Zones Overview

22.9 1.5T MRI Scan Conditions for the Vivistim® System

MRI Conditions for Use		Zone A: NOM SAR Limit Conditions	Zone B: Reduced SAR Conditions
Scanner Type		Horizontal field, cylindrical closed-bore, clinical system for hydrogen proton imaging	
Scanner Characteristics	**Static magnetic field Strength**	1.5T	
	Spatial field gradient	< 5,000 G/cm (50.0 T/m)	
	Maximum slew rate	200 T/m/s and amplitude of 40 mT/m	
Scanner Operation	**Operating mode**	Normal Operating Mode (NOM)	Reduced SAR
	Maximum Specific Absorption Rate (SAR)	**Transmit RF head coil**: N/A **Transmit RF peripheral coil:** normal operating mode **Transmit RF body coil:** 2.0 W/kg whole body averaged SAR	***Transmit RF head coil**: 3.2 W/kg head averaged SAR **–** normal operating mode ***Transmit RF peripheral coil:** normal operating mode *NOTE: Reduced SAR zone does not apply to transmit RF head and peripheral coils used on the head and extremities. **Transmit RF body coil:** ≤ 0.5 W/kg whole body averaged SAR
	Transmit RF coil	**Transmit RF head coil**: N/A **Transmit RF peripheral coil**: Scan (placement of entire coil) must be outside of the Top of Head – L5 area. **Transmit RF body coil:** The iso-center of the scan (center of the MRI bore) must be outside of the Top of Head – L5 area. This may be accomplished by landmarking below L5.	**Transmit RF head coil**: No part of the Vivistim® System can be inside the transmit RF head coil **Transmit RF peripheral coil:** Scan (placement of entire coil) must be outside of the Top of Head – L5 area. **Transmit RF body coil:** The iso-center of the scan (center of the MRI bore) is permitted in this area: Top of Head – L5. Scans in this zone REQUIRE REDUCED SAR as specified in this column.
	Exposure time	**Transmit RF head coil:** N/A **Transmit RF peripheral coil:** No restriction **Transmit RF body coil:** ≤ 15 minutes of active scan time within a 30-minute window	**Transmit RF head coil:** No restriction **Transmit RF peripheral coil:** No restriction **Transmit RF body coil:** ≤ 15 minutes of active scan time within a 30-minute window
	Additional Restriction(s)	**Transmit RF head or peripheral coil:** None **Transmit RF body coil:** Circularly Polarized (CP) mode only (i.e., no shimming)	**Transmit RF head or peripheral coil:** None **Transmit RF body coil:** Circularly Polarized (CP) mode only (i.e., no shimming)

Table 22.3: Summary of 1.5T MR Scan Conditions

Specific absorption rate (SAR), expressed in watts per kilogram (W/kg), is a measure of RF power deposition in the patient. In MR systems, higher SAR limits lead to greater heating. Typically, SAR values are maximum head averaged when using the transmit RF head coil and whole body averaged when using the transmit RF body coil as reported by the MRI equipment.

22.10 1.5T and 3T MRI Scan Scenarios for the Vivistim® System

22.10.1 Brain Scans

Head MRI scans are permissible using 1.5T or 3T scanners using transmit/receive RF head coils. Scan conditions specified in Table 22.2 and Table 22.3 of this manual must be met.

For transmit RF head coils in 1.5T and 3T scanners: whole head averaged SAR must be < 3.2 W/kg (Normal Operating Mode).

- No part of the implanted Vivistim® System (implantable pulse generator [IPG], Leads, or Lead tie-downs) may be within the transmit RF head coil.
- The location of the implanted Vivistim® System components shall be confirmed prior to the MR scan to ensure compliance with this condition.

CAUTION: *Direct exposure of the Vivistim® System to the transmit RF head coil must be avoided. Brain scans that are performed using a transmit/receive RF head coil result in minimal or no exposure of the Vivistim® System to RF energy.*

CAUTION: *Certain MR system head RF coils operate in receive-only mode and require the use of a transmit RF body coil. The use of a receive RF head coil does not alter hazards of the transmit RF body coil.*

22.10.2 Body Scans

Body (torso) scans are permissible using 1.5T or 3T transmit RF body coils. Scan conditions specified in Table 22.2 and Table 22.3 of this manual must be met. Adherence to SAR limitations within these tables and reiterated as detailed in Figure 22.1 and Figure 22.2 is absolutely necessary.

For transmit RF body coils in 3T scanners centered in the C7 – T12 area: whole body averaged SAR must be limited to ≤ 1.5 W/kg.

For transmit RF body coils in 3T scanners centered outside of the C7 – T12 area: whole body averaged SAR must be < 2 W/kg (Normal Operating Mode).

For transmit RF body coils in 1.5T scanners centered in the area from the top of the head to L5: whole body averaged SAR must be limited to ≤ 0.5 W/kg.

For transmit RF body coils in 1.5T scanners centered outside of the area from the top of the head to L5: whole body averaged SAR must be < 2 W/kg (Normal Operating Mode).

CAUTION: *Direct exposure of the Vivistim® System to the transmit RF peripheral coil must be avoided. Scans of the body (torso) performed using a transmit RF peripheral coil are strictly prohibited.*

CAUTION: *Scans performed with the RF coil centered in the C7 – T12 area must have the whole body averaged SAR limited to ≤ 1.5 W/kg for 3T scans and ≤ 0.5 W/kg whole body averaged SAR for 1.5T scans. Scans in this area at SAR levels higher than this are strictly prohibited.*

22.10.3 Extremity Scans

MRI scans of extremities are permissible using 1.5T or 3T transmit/receive RF peripheral coils. Scan conditions specified in Table 22.2 and Table 22.3 of this manual must be met.

For transmit RF peripheral coils in 1.5T and 3T scanners: scans shall be performed in Normal Operating Mode which limits the SAR appropriately.

CAUTION: *Direct exposure of the Vivistim® System to the transmit RF peripheral coil must be avoided. Scans of extremities performed using a transmit/receive RF peripheral coil results in minimal or no exposure of the Vivistim® System to RF energy.*

CAUTION: *Certain MR system peripheral RF coils operate in receive-only mode and require the use of a transmit RF body coil. The use of a receive RF peripheral coil does not alter hazards of the transmit RF body coil.*

22.11 Consideration for a Partially Explanted Vivistim® System (Remnant Leads)

22.11.1 MRI Safety Information

Non-clinical testing has demonstrated that remnants of MicroTransponder's Model 3000 Leads less than 5cm are MR Conditional. A patient with this remnant can be safely scanned in an MR system using a transmit RF body coil and meeting the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3 Tesla (3T)
- Maximum spatial static magnetic field gradient of 5,000 G/cm (50.0 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Level Operating Mode) for 1.5T and 3T scanners
- Maximum length of remnant Lead cannot exceed 5 cm. MRI should not be performed if the IPG has been removed and the remaining lead length is any length of 5cm or greater (up to and including a fully intact lead with no IPG connected).

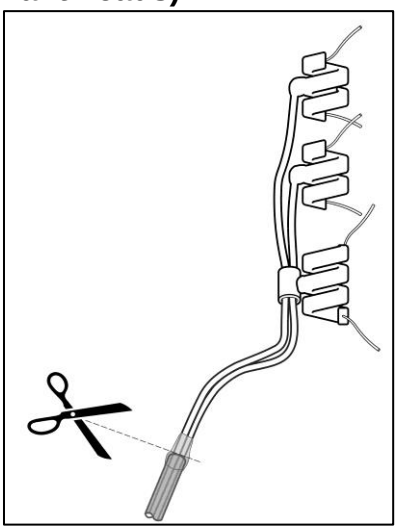


Figure 22.3: Example of a Remnant Lead

- If a remnant portion remains in a patient needing an MRI then a safe length of lead segment remaining (i.e., ≤ 5 cm) can be assessed by taking an x-ray.

Under the defined scan conditions, MicroTransponder's Model 3000 Lead remnants are expected to produce a maximum temperature rise of less than 6.0 ºC after 15 minutes of continuous scanning.

CAUTION: *The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.*

In non-clinical testing, the image artifact caused by MicroTransponder's Model 3000 Lead remnant extends approximately 1.9 cm from the Lead when imaged with a spin-echo pulse sequence in a 3T MRI system and is less in a 1.5T MRI system.

22.12 Preparation Prior to MRI Examination

- No transmit RF head or transmit RF peripheral coil can be placed over any component of the implanted Vivistim® System. Inform the patient of all the risks associated with undergoing an MRI examination as stated in this manual.
- A trained professional with the proper knowledge of MRI equipment such as an MRI-trained radiologist must ensure the MRI examination will be conducted according to the information outlined in this manual.
- If the patient has other active medical device implants, the patient must be made aware that additional risks may occur, as potential interaction with the Vivistim® System has not been evaluated.
- Patient must see their physician prior to undergoing an MRI examination to perform the following:
  - Perform a Lead Impedance Check. Do not perform an MRI if the Lead impedance is greater than 10 kΩ.
  - Program Magnet Mode OFF
  - Document the patient's programmed parameters.
  - Program the Amplitude (mA) to 0.0 mA
- Do not conduct an MRI if the implanted Lead is not connected to the IPG (a Lead surgically cut no farther than 5 cm from the most distal tip of the electrodes may be safely MRI-scanned per the conditions of this manual).

- Do not conduct an MRI with any non-implantable component of the Vivistim® System in the MRI scan room, including the Wireless Transmitter, SAPS software, and surgical accessories. Off-the-shelf accessories such as the magnet are considered MR Unsafe and are also to be left outside of the MRI scan room. These could become dangerous flying objects if attracted by the strong magnetic field of the MRI scanner.
- If possible, do not sedate the patient so the patient can inform the MRI operator of any problems during the examination.
- Instruct the patient to immediately inform the MRI operator if any discomfort, stimulation, shocking, or heating is experienced during the subsequent scan.

22.13 Considerations During the MRI Examination

Carefully monitor the patient throughout the MRI examination both visually and audibly. Discontinue the MRI examination immediately if the patient cannot respond to questions or reports any problems.

22.14 Considerations After the MRI Examination

- Turn the device on and restore the IPG to pre-MRI settings.
- Confirm that the IPG has been restored to pre-MRI settings.
- Confirm the IPG communicates and reports a Lead impedance <10 kΩ.

23 Information and Support

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info@microtransponder.com

24 Glossary

AE (adverse event)—Any symptom, sign, illness, or experience that develops or worsens in severity and/or frequency during the course of the study (i.e., any changes from baseline).

BOL (beginning of life)—This the state of the battery when the first therapy session is initiated that is used to project the lifetime of the battery.

Chronic Stroke — According to agreed definitions for the timeline of stroke recovery developed by the Stroke Recovery and Rehabilitation Roundtable workforce (Agreed Definitions and a Shared Vision for New Standards in Stroke Recovery Research: The Stroke Recovery and Rehabilitation Roundtable Taskforce. Bernhardt J, et. al. Neurorehabil Neural Repair. 2017 Sep;31(9):793-799.) - ≥6 months post stroke is generally considered chronic.

D02 clinical study (depression study) and E01 through E05 (epilepsy studies)—Clinical trials conducted by Cyberonics. The D02 study used VNS Therapy® in patients with chronic or recurrent treatment-resistant depression. The E01 through E05 used VNS Therapy® in patients with refractory epilepsy. VNS Therapy® stimulates the vagus nerve at stimulation settings somewhat similar to Paired VNS™, except that there is no pairing with rehabilitation like is done with Paired VNS™. Also, Paired VNS™ typically only occurs for about 90 minutes in a session, while VNS Therapy® typically stimulates 24 hours a day.

Electrode—The mechanical and electrical interface of the Vivistim® System to the vagus nerve. The electrode is part of the Lead.

EMI—Electromagnetic interference

EOL (end of life)—The SAPS software displays an EOL indicator when there is less than 5% of the battery remaining. EOL indicates that the IPG will cease to function in the very near future.

ERI (Elective Replacement Indicator)—The SAPS software displays an ERI indicator when there is less than 15% of the battery remaining. This is a warning to the user that the IPG is quickly approaching EOL and may stop functioning in the near future.

High Lead Impedance—For the purposes of the Paired VNS™ IFUs, any impedance above 10,000 Ω is considered high. Resistance to the flow of output current produced by the IPG, caused by any of the following: possible fibrosis between the nerve and electrode, dry nerve (during surgery), Lead fracture, Lead disconnection from the IPG, or high battery impedance approaching end of life (EOL).

IPG (Implantable Pulse Generator) —The stimulator portion of the Vivistim® System, typically implanted in the chest below the clavicle. The IPG provides stimulation to the vagus nerve through a connected Lead and Lead electrodes.

Lead—An implantable part of the Vivistim® System; delivers electrical impulses from the IPG to the electrodes attached to the vagus nerve; contains flexible conductive wires within a bio-compatible insulating sheath.

Low Lead Impedance—Lower than expected resistance to the flow of output current produced by the IPG potentially caused by a short-circuit condition resulting from a break within the Lead body or connector boot.

MRI—Magnetic resonance imaging

MR Conditional—Item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

MR Unsafe—An item that poses hazards in all MRI environments.

Output current—Amount of electrical current delivered in a single pulse of stimulation, measured in mA.

Paired VNS™—VNS delivered by the Vivistim® System. The Vivistim® System pairs VNS with movements during standard rehabilitation therapy.

Pulse width—Duration of a single pulse within a train of stimulation, measured in µs.

Safe Mode—an IPG firmware mode initiated when the firmware determines an error that could affect proper delivery of therapy. Therapy is not possible while the IPG is in Safe Mode. A reset function must be performed to enable therapy.

SAE (serious adverse event)—Any adverse event that resulted in any of the following outcomes: death, a life threatening adverse experience, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, a congenital anomaly/birth defect, or any medical intervention that prevents one of the above.

SAPS (Stroke Application & Programming Software)—Software that allows the clinician or clinic personnel to set the VNS settings and initiate stimulations paired with rehabilitation.

Signal frequency—Repetition rate of pulses in a stimulation; measured in number of pulses per second (Hz).

Signal "off" time—Interval between stimulations when there is no stimulation; measured in minutes.

Signal "on" time—Length of time the programmed output current is delivered; measured in seconds.

Train—Duration (in seconds) that the signal frequency is output from the IPG.

Vagus nerve—Either of the pair of tenth cranial nerves arising from the medulla and supplying mainly the viscera, especially with autonomic sensory and motor fibers.

Vivistim®—Trade name of the Vivistim® System for upper extremity motor deficits associated with stroke.

VNS—Vagus Nerve Stimulation

VNS Therapy®—VNS delivered by Cyberonics' VNS Therapy® System. Paired VNS™ is delivered by the MicroTransponder's Vivistim® System.

WT (Wireless Transmitter)—An RF device that connects via a USB plug to the laptop's USB port and provides communication with the IPG, used in conjunction with SAPS.