Note: This is one part of a multi-part physician’s manual. The information contained herein is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all of the physician’s manual sections for the VNS Therapy System and its component parts, nor does this represent full disclosure of all pertinent information concerning use of this product, potential safety complications, or efficacy outcomes.
MRI with the VNS Therapy® System
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MRI with the VNS Therapy® System
1. INTRODUCTION _________________________

1.1. MR Conditional Device

The VNS Therapy® System is an **MR Conditional** device that has been shown to pose no known hazards in a specified magnetic resonance (MR) environment with specified conditions for use. For specific conditions refer to “Conditional MR Environments for VNS” on page 10.

Conditions that define an MRI environment include:

- Transmit RF coil used
- Field strength of the static magnetic field (Tesla)
- Spatial gradient of the static magnetic field (Gauss/cm)
- Time varying magnetic fields (dB/dt)
- Radio frequency (RF) fields
- Specific absorption rate (SAR)

**Caution:** The VNS Therapy System Lead can focus strong RF energy fields, such as those used during MRI, and cause excessive heating and possible injury if used outside of instructions provided herein.

**Note:** See “Pre-MRI Preparation” on page 9 for details.
2. **Potential Risks and Effects of MRI with VNS**

The potential risks of performing MRI on patients with an implanted VNS Therapy System include:

- Heating effects around the VNS Therapy System, especially electrodes, from RF energy
- Non-significant levels of current induced through the VNS Lead wire by the time-varying gradient level
- Inadvertent device reset, which erases historical information stored on the device (possibly including device serial number)
- Inadvertent Magnet Mode activation (i.e., brief Magnet application and removal, which initiates a stimulation) from magnetic fields
- Image distortion and artifacts
- Magnetic field interactions
- Device malfunction or damage
- Hazards from Cyberonics® Magnets (not implanted) in the vicinity of the MRI scan room

2.1. MRI-related Heating Effects

If the specific MRI conditions are not followed, tissue damage may result from excessive temperature increases at the electrode end of the Lead during MRI scans. Damage to the vagus nerve and/or surrounding structures in the carotid sheath is of particular concern due to the location of VNS Therapy System stimulation electrodes.

*In vitro* tests have shown clinically significant heating of the VNS Therapy System stimulation electrodes of up to a 30°C increase and higher during MRI scans of the head and/or body when the transmit RF body coil was used to apply RF energy. The degree of MRI-related heating observed is primarily influenced by location of the patient in the MR system and by Lead wire configuration and length. Acceptable levels of heating, consistently less than a 2°C increase, were shown during *in vitro* tests for specific types of MRI conditions (see “Conditional MR Environments for VNS” on page 10).

2.1.1. Special Cases and Considerations

2.1.1.1. Partially Explanted VNS Therapy Systems

The primary risk of MRI to VNS patients is MRI-related heating of the Lead. Because heating effects have not been characterized nor safety
demonstrated on Leads without Pulse Generators or partial Leads, MRI should not be performed on patients who have Leads without the Pulse Generators or partial Leads.

2.1.1.2. Broken Leads

**Warning**: MRI procedures should not be performed on patients with VNS Therapy Systems who have a Lead break. A broken Lead should be removed prior to MRI. Suspected Lead breaks should be confirmed by performing appropriate diagnostic procedures and consultation with Cyberonics. Broken Lead wires present increased risk of thermal injury to patients during MRI procedures. The point of the Lead break may heat to temperatures which may cause injury to tissue. In rare cases, the Lead wire may break at a length that may cause injurious heating at the electrodes on the vagus nerve.

2.1.1.3. Other Implanted Medical Devices

Safety has not been demonstrated in patients with implanted devices in addition to VNS Therapy. MRI should not be performed in these patients until safety has been demonstrated.

2.2. Gradient Induced Current

There is a potential risk that the device may reset due to the MRI environment. There is no safety risk to the patient from MRI gradient induced currents through the device’s Lead wire. By design, the VNS System delivers levels of current within a specified range on a scheduled duty cycle throughout the day.

The currents induced by the MRI were measured, modeled, and demonstrated to be less than the lowest programmable VNS output. Any current induced in the Lead by MRI time-varying magnetic fields may result in slight tingling sensation.

2.3. Device Reset

There is no safety risk to the patient from a device reset. Some information (including serial number, implant date, stimulation parameters, and device operating time) may be lost from the VNS Therapy System Pulse Generator during a device reset. Most erased data can be reprogrammed, but device operating time cannot.
MRI with the VNS Therapy® System

Strong magnetic field gradients and RF energy, similar to that used to reset the Pulse Generator by design, are present in the MR environment. Pulse Generator reset has not been observed during in vitro tests. A few cases of Pulse Generator reset have been reported by VNS patients in association with MRI procedures. Clinically, nothing can be done to prevent this rare occurrence. In the event of a device reset and loss of data, the VNS Therapy Programming System should be used to reprogram the device serial number, implant date, and stimulation parameters to their pre-MRI scan values.

2.4. VNS Magnet Mode Activation

Failure to program the Magnet Mode output to 0 mA may cause Magnet Mode activation by the MRI magnets leading to undesired stimulation.

Magnet Mode activation is a frequent occurrence near MR systems. For this reason, the VNS Therapy System Normal Mode and Magnet Mode output currents should both be programmed to 0 mA before patient entry into the MR system room.

2.5. Magnetic Field Interactions

Patients may feel a tugging sensation at the site of the Pulse Generator. The VNS Therapy System may experience magnetic field interactions associated with the static magnetic field of the MR system due to small amounts of material in the Pulse Generator sensitive to magnetic fields. This may cause the Pulse Generator to shift or move slightly within the implant pocket and/or may place mechanical stress on tissues and/or the Lead. The VNS Therapy System Lead does not directly experience magnetic field interactions, since it is made from nonferromagnetic materials.

2.6. Device Malfunction or Damage

Tests in various MR systems have not shown damage to, or malfunction of, any VNS Therapy System. If device malfunction or damage were to occur, it could cause painful stimulation or direct current stimulation. Either event may cause nerve damage and other associated problems (See the “Adverse Events” section in the indication-specific parts of the Generator physician’s manuals). If patients suspect a malfunction, they should be instructed to exit the MR system room and hold their Magnet over their device to stop stimulation, and then contact their physician immediately for further evaluation. Prompt surgical intervention may be required if a malfunction occurs.

Note: See “Pre-MRI Preparation” on page 9 for details on proper procedures to ensure data is not lost due to device reset.

Note: Patients in whom the implant has had time to heal should not experience problems from magnetic field interactions.

Caution: Lower static magnetic field strength does not imply greater safety. Because the primary hazard of MRI to VNS patients is MRI-related heating, a lower static magnetic field strength and transmit frequency may present a greater hazard.
3. MRI GUIDELINES

*MRI with the VNS Therapy System* recommendations are based on phantom\(^1\) tests and numerical simulations of worst-case and recommended implant configurations of standard 43-cm bipolar VNS Leads.

3.1. Pre-MRI Preparation

Because of the need to perform diagnostics and change programming parameters, an appropriate healthcare professional with access to a VNS Therapy Programming System must prepare the VNS device before the patient enters an MR system room.

To prepare the VNS device:

1. Perform an interrogation and record the following information in the patient record or on a copy of the table below. This information is used to restore the device settings in case of a reset.

|------------|-----------|-------------------|----------------|------------------|-------------|----------------|----------------|--------------|--------------|-----------------|

2. Perform System Diagnostics to ensure proper operation of the device. High or low impedance may indicate a potential Lead break.

3. Reprogram the Output Current (OC) parameter settings for both Normal Mode and Magnet Mode as follows:

- **Output Current (mA): 0.0**

\(^1\) Phantom—A patient-equivalent form filled with gelled saline, used for *in vitro* tests of MRI-related heating.
4. Perform a Device Interrogation to verify programming was successful.
5. Verify that placement of the VNS Therapy System is located between C7-T8.

Immediately before starting the MRI procedure, the patient should be instructed to notify the MR system operator of pain, discomfort, heating, or other unusual sensations so the operator can terminate the procedure, if needed.

3.2. Conditional MR Environments for VNS

Non-clinical testing has demonstrated the VNS Therapy System is MR Conditional.

3.2.1. Precautions

- Do not use the transmit RF body coil for 3T or 1.5T imaging. Surgical removal of the entire VNS Therapy System will be required if MRI using a transmit RF body coil is needed.
- Not all head RF coils are transmit and receive type. Many are receive only. The use of any local receive coil with the body coil in RF transmit mode presents the same RF heating hazards as the body coil alone with no local coils.
- Exposure of the VNS Therapy System to any RF transmit coil must be avoided. An exclusion zone has been defined in Figure 3 on page 13. Surgical removal of the entire VNS Therapy System will be required if an MRI of the exclusion zone is needed.

3.2.2. 1.5 and 3.0 Tesla (T) Conditions

The VNS Therapy System can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 1.5T or 3T only
- Spatial gradient field of 720 Gauss/cm or less

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1 When an interrogation is performed by the Programming Software, the device serial number, implant date, stimulation parameters, and device operating time are automatically logged in the programmer database. This information may be retrieved from the database at any time after interrogation. (See the Programming Software physician’s manual for further information.)
Note: Specific absorption rate (SAR) is a measure of RF power deposition in the patient, usually expressed in watts per kilogram (W/kg). For a given MR system, higher SAR leads to greater heating. For imaging VNS patients, SAR values are maximum head-averaged when using the transmit/receive head coil.

- Normal operating mode only.
- Use only head or local transmit/receive coils.
- The VNS Therapy System should not migrate in this MRI environment. Non-clinical testing at field strengths other than 1.5 and 3.0 Tesla has not been performed to evaluate migration or heating.
- In non-clinical testing using a head transmit coil, the VNS Therapy System produced a maximum temperature rise of less than 2°C at a maximum head-averaged specific absorption rate (SAR) of 3.2 W/kg, which was determined by a validated calculation for 15 minutes of MRI scanning in a 1.5T or 3T scanner.
- Imaging the head with the transmit/receive RF head coil will not result in distortion of the image of the brain due to the presence of the electrodes, Leads, or Generator.
- If the specific MRI conditions are not followed (i.e., body coil is used, exclusion zone (see Figure 3 on page 13) is not adhered to) the presence of the VNS Therapy System components may contribute to artifacts and distortion in the area of interest. The artifacts and distortion may extend up to 1 cm from the Leads and up to 10 cm from the Generator.

3.2.2.1. 1.5 and 3.0 MR Imaging Scenarios

Figure 1. Head MR Imaging

Area of Interest: Brain
Transmit RF Coil: Head

Brain scans are performed using a transmit/receive RF head coil, which results in minimal or no exposure of VNS to RF energy.
Figure 2. Lower Extremity MR Imaging

Area of Interest: Knee, Ankle
Transmit RF Coil: Local

Scans of extremities are performed using an appropriate transmit/receive local coil, which results in minimal or no exposure of VNS to RF energy. Although not illustrated, MRI scans of the wrist are also possible using an appropriate transmit/receive local coil.

3.2.3. Unsafe MR Conditions

*In vitro* MRI-related heating tests with the transmit RF body coil have shown potentially injurious temperature increases; therefore, scans *should not* be performed on patients with VNS under the following conditions:

- Magnetic resonance imaging (MRI) should not be performed with a magnetic resonance body coil in the transmit mode.
- Under no circumstances should the local transmit coil be placed over the VNS System. Because of this restriction, scanning of the area where the VNS System is implanted is not possible. See Figure 4 for details.
- Open MRI scanners should not be used for scanning VNS patients.
- Systems other than 1.5T and 3T should not be used for scanning VNS patients.

**Caution:** Exposure of the VNS Therapy System to any RF transmit coil must be avoided.

**Note:** Testing was only performed using closed (i.e., cylindrical) MRI scanners.
3.2.3.1. Unsafe MR Imaging Scenarios

**Caution:** This exclusion zone is dependent upon the typical placement of the VNS Therapy System and cannot be scanned under any circumstances.

Surgical removal of the entire VNS Therapy System will be required if an MRI of the exclusion zone is needed.

**Figure 3. Unsafe MR - Exclusion Zone**

**Area of Interest:** C7-T8 Exclusion Zone  
**Transmit RF Coil:** All types

The VNS Therapy System, usually located between C7 and T8, must not be exposed to any RF field from a RF transmit coil.

**Note:** The crosshairs indicate the iso-center of the MR system’s bore.

**Figure 4. Unsafe MR Imaging**

**Area of Interest:** Any  
**Transmit RF Coil:** Body

3.2.4. **MR Unsafe Devices**

The VNS Therapy Programming system, including the Programming Wand and the Programming Computer are MR Unsafe. The Patient Magnet is also MR Unsafe. These devices must not be brought into the MR scanner room.

Many VNS patients or caregivers carry Magnets to activate and inhibit the VNS Therapy System. A small Magnet, which can attach to a wristband or belt clip, is included in the kit given to all VNS patients. The Magnet may
be accidentally carried into an MR scan room, where it could cause damage or injury if it becomes a projectile.

Figure 5. MR Unsafe Devices

3.3. Post-MRI Assessment

After the MRI procedure, an appropriate healthcare professional with access to a VNS Therapy Programming System should assess the condition of the VNS Therapy System.

To assess the VNS Therapy System:
1. Interrogate the VNS device.
2. If the Pulse Generator was reset during the scan, reprogram the serial number, patient ID, and implant date, as needed.
3. Program the patient’s therapeutic parameters as they were before the MRI procedure.
4. Perform System Diagnostics. Results should indicate Impedance = OK.
5. Interrogate the device again to confirm that reprogramming was successful.

Note: For a complete list of information needed to restore the device settings, see “Pre-MRI Preparation” on page 9.