VNS Therapy® System
Physician’s Manual

Pulse™ Generator—Model 102
Pulse Duo™ Generator—Model 102R
Demipulse® Generator—Model 103
Demipulse Duo® Generator—Model 104
AspireHC® Generator—Model 105
AspireSR® Generator—Model 106

Lead—Model 302
PerenniaFLEX® Lead—Model 304
PerenniaDURA® Lead—Model 303

For Healthcare Professionals

May 2015

Rx Only
www.VNSTherapy.com

Cyberonics®

U.S. Version
MRI with the VNS Therapy® System
13. MRI with the VNS Therapy System

13.1. Introduction

13.1.1. 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”.

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)

In vitro tests have been performed with a variety of VNS Therapy Systems in a variety of MRI facilities. Numerical simulations of multiple patient sizes, and the VNS device in worst case and clinical configurations have been conducted. These tests have shown that VNS Therapy System patients may be safely exposed to certain MR environments if the guidelines described herein are followed. However, a risk of injury related to heating of the lead electrodes has been shown in other scenarios. Direct exposure of any part of the VNS System to an MR system RF transmit coil (local or body) can cause the lead electrodes to heat to temperatures that may cause pain, temporary injury, necrosis, or permanent tissue damage. In the case of a broken lead, the exposed lead wire is the point at which these injuries may take place.

Worst case testing in an MR scanner has been performed on VNS System leads and generators. Due to similarity in construction and observed similarity in test results, VNS Therapy Systems that consist of Model 100C, 101, 102, 102R, 103, 104, 105, or 106 pulse generators and Model 300, 302, 303, or 304 leads are considered equivalent for MRI safety purposes.

Specific programmable configurations of the VNS Therapy System device are also required before an MRI is performed.
13.2. 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
- For 106 only, delivery of AutoStim may occur if the feature is programmed on and a rapid increase in heart rate occurs
- 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

13.2.1. 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 and numerical simulations for specific types of MRI conditions (see “Conditional MR Environments for VNS”).
13.2.2. 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.

13.2.3. 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.

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.

13.2.4. 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 (as well as AutoStim Mode for Model 106) output currents should be programmed to 0 mA before patient entry into the MR system room.
13.2.5. 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.

13.2.6. 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 “Adverse Events” in the indication-specific information chapters). 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.

13.2.7. VNS AutoStim Mode (Tachycardia Detection - Activation) - Model 106 Only

If Tachycardia Detection remains “ON” during the MRI, the MRI may contribute to false detections. If the AutoStim Mode output has not been programmed to 0 mA, the VNS Therapy System AutoStim Mode may be activated during the imaging, which may result in undesired stimulation.

Specific testing of this mode in the MRI environment has not been performed. However, if this feature is deactivated prior to MRI, the Model 106 device is expected to behave in the same way as the other VNS pulse generators. The VNS Therapy System Normal Mode, AutoStim, and Magnet Mode output currents should be programmed to 0 mA, and Tachycardia Detection should be programmed “OFF” prior to patient entry into the MR system room.

13.3. MRI Guidelines

*MRI with the VNS Therapy System* recommendations are based on phantom¹ tests and numerical simulations of worst-case and
recommended implant configurations of standard 43-cm bipolar VNS leads. The following guidelines pertain to full VNS Therapy Systems (generator and lead implanted). For guidance on performing scans on patients with abandoned leads or lead segments see “Special cases and considerations”.

13.3.1. 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.

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Device SN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantation Date</td>
<td></td>
</tr>
<tr>
<td>Output Current</td>
<td></td>
</tr>
<tr>
<td>Signal Frequency</td>
<td></td>
</tr>
<tr>
<td>Pulse Width</td>
<td></td>
</tr>
<tr>
<td>Signal On Time</td>
<td></td>
</tr>
<tr>
<td>Signal Off Time</td>
<td></td>
</tr>
<tr>
<td>Mag. Current</td>
<td></td>
</tr>
<tr>
<td>Mag. On Time</td>
<td></td>
</tr>
<tr>
<td>Mag. Pulse Width</td>
<td></td>
</tr>
<tr>
<td>Model 106 AutoStim Output Current</td>
<td></td>
</tr>
<tr>
<td>Model 106 AutoStim Pulse Width</td>
<td></td>
</tr>
<tr>
<td>Model 106 AutoStim On Time</td>
<td></td>
</tr>
<tr>
<td>Model 106 Tachycardia Detection</td>
<td></td>
</tr>
<tr>
<td>Model 106 Threshold for AutoStim</td>
<td></td>
</tr>
<tr>
<td>Model 106 Heartbeat Detection</td>
<td></td>
</tr>
</tbody>
</table>

2. Perform System Diagnostics to ensure proper operation of the device.

Caution: All VNS patients must have their VNS Therapy System assessed and programmed before an MRI procedure.

1 Phantom—A patient-equivalent form filled with gelled saline, used for in vitro tests of MRI-related heating.
3. Reprogram the Output Current (OC) parameter settings for Normal Mode, Magnet Mode and AutoStim Mode as follows:
   - Output Current (mA): 0
   - Mag. Current (mA): 0
   - AutoStim current (mA): 0 and Tachycardia Detection “OFF”
   (Model 106 only)

4. Perform a Device Interrogation¹ to verify programming was successful.

5. Verify that placement of the VNS Therapy System is located between C7-T8.

   **Caution:** Scanning of a patient with a VNS Therapy System located outside the C7-T8 exclusion zone has not been evaluated in pre-clinical testing and therefore necessitates further evaluation by the MR System operator to verify that the device will not be exposed to the RF Field.

   **Note:** See the Revision / Replacement / Removal chapter for instructions.

13.3.2. **Conditional MR Environments for VNS**

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

13.3.2.1. **Precautions**

- Do not use the transmit RF body coil for 3 T or 1.5 T imaging. Surgical removal of the 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 88. Surgical removal of the VNS Therapy System will be required if an MRI of the exclusion zone is needed.

13.3.2.2. **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 1.5 T or 3 T only

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.)
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- Spatial gradient field of 720 Gauss/cm or less
- Normal operating mode only
- Use only head or local transmit/receive coils.
- 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 1.5 T or 3 T 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.
- 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.

**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.

**Caution:** 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.

**Caution:** Exposure of the VNS Therapy System to any RF transmit coil must be avoided.
13.3.2.3. Special cases and considerations

13.3.2.3.1. Partially explanted VNS Therapy systems

The primary risk of MRI to VNS patients is MRI-related heating of the lead. Testing and computer modeling have shown, however, that MRI can be performed safely under the following conditions:

- 1.5 T or 3 T with T/R Head Coil or T/R Extremity Coil
  - If there is a suspected lead break (IPG is still connected)
  - If any length (43 cm or less) remains (no IPG)
- 1.5 T or 3 T with transmission of RF with the Body Coil (any landmark)
  - If there is ≤ 2 cm of lead (i.e., electrodes remain implanted)

13.3.2.3.2. Assessing lead segment length

If an MR image is needed and must be obtained using the body coil, a safe length of lead segment remaining (i.e., ≤ 2 cm) implanted can be assessed by taking an x-ray. The length of 2 cm can be approximated by visualizing the distance between the positive and negative electrode (~1 cm). By design, there is approximately 1 cm between the positive electrode and the anchor tether, which is also likely remaining. Surgeons are instructed to remove as much of the lead as possible if explanting a system.

Figure 84 illustrates the relationship of the electrodes to each other and the positive electrode to the anchor tether. An MRI using the Body coil for transmission of RF, or MRI of the head or extremities with a Head coil or Local (Extremity) coil (respectively) for transmission of RF is allowed if the lead is transected as seen in Figure 84.

**Figure 84. Transected Lead (≤ 2 cm)**
If the lead is transected as seen in Figure 85, only a T/R head MRI or T/R extremity MRI is recommended. A full body MRI is not allowed.

**Figure 85. Transected Lead (> 2 cm)**

**Warning:** If it appears that more than 2 cm of lead remains, then the patient cannot have an MRI with the body coil, but can still have an MRI using a local T/R or head T/R coil as instructed in this chapter. Abandoned lead wires present increased risk of thermal injury to patients during MRI procedures based on their length and their exposure to RF.

**13.3.2.3.3. 1.5 and 3.0 MR imaging scenarios**

**Figure 86. 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.
Caution: Exposure of the VNS Therapy System to any RF transmit coil must be avoided.

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.

13.3.2.4. 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 89 for details.
- Open MRI scanners should not be used for scanning VNS patients.
- Systems other than 1.5 T and 3 T should not be used for scanning VNS patients.

Note: Testing was only performed using closed (i.e., cylindrical) MRI scanners.
13.3.2.4.1. Unsafe MR imaging scenarios

**Figure 88. Unsafe MR - Exclusion Zone**

![Image of 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.

**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 VNS Therapy System will be required if an MRI of the exclusion zone is needed. See the Revision / Replacement / Removal chapter for instructions.

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

**Figure 89. Unsafe MR Imaging**

![Image of unsafe MR imaging]

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

13.3.2.5. **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 90.  MR Unsafe Devices**

![Picture of MR Unsafe Devices]

13.3.3. 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.
14. INFORMATION AND SUPPORT ____________________________

If there are questions regarding use of the VNS Therapy System or any of its accessories, contact Cyberonics:

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