MRI Guidelines for VNS Therapy®

MRI can be safely performed on patients with VNS Therapy provided that specified guidelines are followed.

VNS Therapy System
The VNS Therapy system (generator and lead), usually located between C7 and T8 vertebrae, must not be exposed to the radio frequency (RF) field.

Safe Zone

MR Exclusion Zone

Note: imaging techniques such as x-ray, computed tomography, and ultrasound are safe to perform in the MR exclusion zone.
**Safe MRI conditions**

**Performing MRI is safe when the guidelines below are followed**

<table>
<thead>
<tr>
<th>Allowable imaging zones</th>
<th>See graphic on front cover</th>
<th>Full body</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF coil type</td>
<td>Head or local ONLY</td>
<td>Any</td>
</tr>
<tr>
<td>RF coil mode</td>
<td>Transmit/receive ONLY</td>
<td>Any</td>
</tr>
<tr>
<td>Static magnetic field</td>
<td>3T or 1.5T</td>
<td>3T or 1.5T</td>
</tr>
<tr>
<td>MRI configuration</td>
<td>Closed-bore</td>
<td>Closed-bore</td>
</tr>
<tr>
<td>MRI operating mode</td>
<td>Normal</td>
<td>Normal</td>
</tr>
<tr>
<td>Spatial gradient field</td>
<td>≤720 gauss/cm</td>
<td>≤720 gauss/cm</td>
</tr>
<tr>
<td>Head-averaged SAR</td>
<td>≤3.2 W/kg</td>
<td>≤3.2 W/kg</td>
</tr>
</tbody>
</table>

*Equivalent to clipping the lead at the anchor tether.*
Pre- and Post-MRI instructions

Pre-MRI instructions

An appropriate healthcare professional with access to a VNS Therapy programming system must prepare the VNS Therapy generator before the patient enters an MR system room.

- Interrogate the VNS Therapy generator* and record the generator settings
- Perform System Diagnostics to ensure proper operation of the generator
- Reprogram the Output Current parameter settings for Normal Mode, Magnet Mode, and AutoStim Mode† as follows:
  - Output Current (mA): 0.0
  - Mag. Current (mA): 0.0
  - AutoStim Current (mA): 0.0 and Seizure Detection “OFF”
- Interrogate the generator* to verify that programming was successful
- Verify that placement of the VNS Therapy system is located between the C7 and T8 vertebrae
- Instruct the patient to notify the MR system operator of pain, discomfort, heating, or other unusual sensations so the operator can terminate the procedure, if needed

Post-MRI instructions

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:
  - Interrogate the VNS Therapy generator
  - If the generator was reset during the scan, reprogram the serial number, patient ID, and implant date, as needed
  - Program the patient’s therapeutic parameters as they were before the MRI procedure
  - Perform System Diagnostics. Results should indicate Impedance=OK
  - Interrogate the generator again to confirm that reprogramming was successful

*When an interrogation is performed by the programming software, the generator serial number, implant date, stimulation parameters, and generator operating time are automatically logged in the programmer database. This information may be retrieved from the database at any time after interrogation.
†Available on select generator models only.
VNS Therapy—foundational treatment with the potential to change the course of drug-resistant epilepsy

- Seizure reduction that improves and is maintained over time\(^1,2\)
- Proven improvement in mood and quality of life, independent of seizure control\(^3\)
- Nonpharmacological side effects typically decrease over time\(^2,4\)
- Nondrug adjunctive therapy that complements other treatment options

Additional MRI considerations

- Only the implanted VNS Therapy system components are safe for MRI. All other VNS Therapy components (eg, programming wand, programming computer, patient magnet) are MR unsafe and must not be brought into the MRI scanner room.
- A transmit RF body coil can only be used if the VNS Therapy system has been removed and \(\leq 2\) cm of lead remains in the body. Surgical removal of the VNS Therapy system will be required if it is necessary to perform MRI using a transmit RF body coil.

For more information about performing MRI on patients with VNS Therapy, please consult the VNS Therapy System Physician’s Manual, available at: www.cyberonics.com/manuals

Please see important safety information provided by your Cyberonics Representative or visit www.cyberonics.com