MRI Guidelines

The latest VNS Therapy technology* provides expanded access to high quality 1.5T and 3T MRI

Patients now have access to:

7,000 MRI centers
100% of brain MRI
90% of ALL MRI scans performed on people with epilepsy
An MRI center within 4 miles of their neurologist’s office, on average

Scan Conditions - Latest VNS Therapy technology
*AspireHC® Model 105, AspireSR® Model 106, SenTiva™ Model 1000

No special MRI equipment/coils required

<table>
<thead>
<tr>
<th>Group A</th>
<th>Permissible Scan Area</th>
<th>MRI Exclusion Zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>C7</td>
<td>Generator in upper left chest, at or above armpit (above rib 4)†</td>
<td></td>
</tr>
<tr>
<td>L3</td>
<td>Note: The scan iso-center must be outside the exclusion zone</td>
<td></td>
</tr>
</tbody>
</table>

† Patients with implants in other locations must follow Group B scan conditions

MR Conditional: Yes

<table>
<thead>
<tr>
<th>Static Magnet Strength</th>
<th>1.5T or 3T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanner Type</td>
<td>Horizontal field, cylindrical closed-bone 1.5T or 3T scanner</td>
</tr>
<tr>
<td>Operating Mode</td>
<td>Normal Operating Mode</td>
</tr>
<tr>
<td>Exclusion Zone</td>
<td>Body coil: C7-L3 Transmit-receive head or extremity coil: C7-T8</td>
</tr>
<tr>
<td>Max Spatial Gradient</td>
<td>≤3000 Gauss/cm</td>
</tr>
<tr>
<td>Max Slew Rate</td>
<td>200 T/m/s</td>
</tr>
<tr>
<td>RF Coil</td>
<td>Transmit: Body coil or Transmit-receive head or extremity coils Receive: No Restrictions</td>
</tr>
<tr>
<td>Max SAR</td>
<td>Transmit head coil: 3.2 W/kg Transmit body coil: 2.0 W/kg</td>
</tr>
<tr>
<td>System Programming</td>
<td>Stimulation OFF Sensing OFF*</td>
</tr>
<tr>
<td></td>
<td>*for select models with AutoStim mode Optional device features OFF (Model 1000 only)</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>Transmit head or extremity coil: No restrictions Transmit body coil: ≤ 15 minutes of active scan time within a 30 minute window</td>
</tr>
<tr>
<td>Additional Restrictions</td>
<td>Transmit head or extremity coil: none Transmit body coil: Circularized Polarized mode only</td>
</tr>
</tbody>
</table>

Imaging techniques such as computed tomography, x-ray, and ultrasound are safe to perform in the MRI exclusion zone.

Review the most current labeling prior to performing an MRI scan. For full MRI safety information, refer to MRI Instructions for Use at www.easy-mri.com

7,000 MRI centers
100% of brain MRI
90% of ALL MRI scans performed on people with epilepsy
An MRI center within 4 miles of their neurologist’s office, on average
1.5T and 3T MRI scans are safe with ALL VNS Therapy models provided specific guidelines are followed.

**MRI Guidelines**

**100% access to brain MRI**

**Access to extremity scans including knee, ankle, and wrist**

**Requires special MRI equipment/coils**

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**Scan Conditions**

Applies to all Pulse™ Model 102, Pulse Duo™ Model 102R, DemiPulse™ Model 103, DemiPulse Duo™ Model 104 and AspireHC® Model 105, AspireSR® Model 106, SenTiva™ Model 1000 implanted lower than rib 4 (below armpit level)

<table>
<thead>
<tr>
<th>GROUP B</th>
<th>Requires local transmit-receive coil</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI Exclusion Zone</td>
<td>Availability may vary</td>
</tr>
</tbody>
</table>

**C7**

**T8**

Permissible scans include head, knee, ankle, and wrist

**MR Conditional**

- Yes

**Static Magnet Strength**

- 1.5T or 3T

**Scanner Type**

- Horizontal field, cylindrical closed-bore 1.5T or 3T scanner

**Operating Mode**

- Normal Operating Mode

**Exclusion Zone**

- C7-T8

**Max Spatial Gradient**

- ≤3000 Gauss/cm

**Max Slew Rate**

- 200 T/m/s

**RF Coil**

- Transmit-receive head or extremity coils

**Max SAR**

- Transmit-receive head coil: 5.2 W/kg

**System Programming**

- Stimulation OFF Sensing OFF*
  - *for select models with AutoStim mode
  - Optional device features OFF (Model 1000 only)

**Exposure Time**

- Transmit-receive head or extremity coil: No restrictions

**Additional Restrictions**

- None

Imaging techniques such as computed tomography, x-ray, and ultrasound are safe to perform in the MRI exclusion zone.

Review the most current labeling prior to performing an MRI scan. For full MRI safety information, refer to MRI Instructions for Use at [www.easy-mri.com](http://www.easy-mri.com)
### Special Cases

<table>
<thead>
<tr>
<th>Exclusion Zone</th>
<th>C7-T8</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR Conditional</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Static Magnet Strength</td>
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<td>Transmit: Body or transmit-receive head or extremity coils&lt;br&gt;Receive: No Restrictions</td>
</tr>
<tr>
<td>Max SAR</td>
<td>Transmit/receive head coil: 3.2 W/kg</td>
<td>Transmit head coil: 3.2 W/kg&lt;br&gt;Transmit body coil: 2.0 W/kg</td>
</tr>
</tbody>
</table>

* Equivalent to clipping the lead at the anchor tether

### Special populations:

For patients with tuberous sclerosis (TS), VNS Therapy allows:

- 100% access to brain MRI (follow safety instructions per device type and implant location)
- No restrictions to other typical TS imaging techniques like computed tomography

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**Imaging techniques such as computed tomography, x-ray, and ultrasound are safe to perform on patients with all VNS Therapy systems.**
MRI Guidelines

To ensure effective communication with the MRI center, complete the Patient MRI Form. Send with the patient to their MRI appointment. Download from easy-mri.com

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
  - Magnet Current (mA): 0.0
  - AutoStim Current (mA): 0.0 and Tachycardia Detection “OFF”
- Turn off any other optional device features (Model 1000 only)
- 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.

† for select models with AutoStim mode

For full MRI safety information, the VNS Therapy System Physician’s Manual can be found at www.easy-mri.com
For technical product questions, contact LivaNova Technical Services at 1-866-882-8804

Brief summary attached
INTENDED USE / INDICATIONS

**Epilepsy (USA)** — The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications.

**CONTRAINDICATIONS**

**Vagotomy** — The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy.

**Depolarization** — Do not use short-wave diathermy, microwave diathermy, or ultrasonic ultrasound diathermy on patients implanted with a VNS Therapy System. Diagnostic ultrasound is not included in this contraindication.

**WARNINGS — GENERAL**

Physicians should inform patients about all potential risks and adverse events discussed in the physician's manuals. This document is not intended to serve as a substitute for the complete physician's manuals. The safety and efficacy of the VNS Therapy System has not been established for uses outside the intended uses/indications section of the physician's manuals. It is important to follow infection control procedures. Infections related to any implanted device are difficult to treat and may require that the device be explanted. The patient should be given antibiotics prophylactically. This is particularly recommended for procedures that increase the risk of surgical site infection. Certain procedures (e.g., tonsillectomy) have been associated with an increased risk of complications.

It is important that the electrodes are attached to the left vagus nerve in the correct orientation. It is also important that the electrodes remain in place for as long as possible. The electrode cuff will be replaced if it becomes loose or if the outer insulation begins to fray. Patients should remove the electrode cuff as soon as possible if it becomes dislodged or if the outer insulation begins to fray. Patients should consult their physician if they notice any changes in the position of the electrode cuff or if they notice any changes in their symptoms.

The VNS Therapy System may affect the operation of other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include sensing problems and inappropriate device responses. The physician should be aware of the potential for these effects and be prepared to follow guidelines consistent with Advanced Cardiac Life Support (ACLS). If the patient requires concurrent implantable pacemaker, defibrillator therapy or other types of stimulators, careful programming of each system may be necessary to optimize the patient's benefit and avoid any adverse effects. The patient can use a neck brace for the first 2 weeks to help ensure proper lead placement. Do not program the VNS Therapy System to an "ON" or periodic stimulation program for at least 14 days after the initial or replacement implantation.

For Models 100, 101, 102 and 102R do not use frequencies of 5 Hz or below for long-term stimulation. For Models 103, 104, and 104R, the device is capable of operating in the transmit mode with a transmit power level of less than 0.1 mW. For Model 100, 101, 102 and 102R, resetting the generator will result in device history loss. Patients who smoke may have an increased risk of laryngeal irritation.

**Contraindications** — The VNS Therapy System is not curative. Physicians should warn patients that the VNS Therapy System is not a substitute for a complete and thorough understanding of the material presented in all of the physician's manuals. It is important to follow infection control procedures. Infections related to any implanted device are difficult to treat and may require that the device be explanted. The patient should be given antibiotics prophylactically. This is particularly recommended for procedures that increase the risk of surgical site infection. Certain procedures (e.g., tonsillectomy) have been associated with an increased risk of complications.

**USE / INDICATIONS**

- **Epilepsy**
- **Depolarization**
- **Vagotomy**
- **Depolarization**
- **WARNINGS — GENERAL**
- **CONTRAINDICATIONS**
- **USE / INDICATIONS**

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1 The information contained in this Brief Summary for Physicians represents partial excerpts of important prescribing information taken from the physician's manuals. (Copies of VNS Therapy physician's and patient's manuals are posted at www.livanova.com.) The information is not intended to serve as a substitute for a comprehensive and detailed patient's manual. Readers are encouraged to read the physician's manuals for the VNS Therapy System and its component parts nor does this information represent full disclosure of all pertinent information concerning the use of this product, potential safety complications, or efficacy. © 2015-2017 LivaNova, PLC, London, UK. All rights reserved.

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