MRI with the VNS TherapyTM System

For Healthcare Professionals

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Worldwide Version

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.



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. Copies of all VNS Therapy manuals are posted at www.VNSTherapy.com/manuals.

MRI with the VNS Therapy[™] System

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The VNS TherapyTM Pulse Generator system (including components thereof) and use of the system for treatment of epilepsy and/or depression is protected under one or more of United States patent nos. 4,867,164, 4,979,511, 5,154,172, 5,179,950, 5,186,170, 5,222,494, 5,235,980, and 5,299,569, as well as corresponding international patents. Other patents are pending.

MAGNETIC RESONANCE IMAGING (MRI)

Caution: Magnetic resonance imaging (MRI) should not be performed with a magnetic resonance body coil in the transmit mode. The heat induced in the Lead by an MRI body scan can cause injury.

If an MRI should be done, use only a transmit and receive type of head coil. Magnetic and RF fields produced by MRI may change the Pulse Generator settings (change to reset parameters) or activate the device. Stimulation has been shown to cause the adverse events reported in the "Adverse Events" section in the indication-specific parts of the multi-part physician manuals. MRI compatibility was demonstrated using a 1.5T General Electric Signa Imager with a Model 100 only. The Model 102 and Model 102R are functionally equivalent to the Model 100. Testing on this imager as performed on a phantom¹ indicated that the following Pulse Generator and MRI procedures can be used safely without adverse events:

- Pulse Generator output programmed to 0 mA for the MRI procedure, and afterward, retested by performing the System Diagnostics (Lead Test) and reprogrammed to the original settings
- Head coil type: transmit and receive only
- Static magnetic field strength: ≤2.0 tesla
- Specific absorption rate (SAR): <1.3 W/kg for a 154.5-lb (70-kg) patient
- Time-varying intensity: <10 tesla/sec

Use caution when other MRI systems are used, since adverse events may occur because of different magnetic field distributions. Consider other imaging modalities when appropriate.



Caution: Procedures in which the RF is transmitted by a body coil should not be done on a patient who has the VNS TherapyTM System. Thus, protocols must not be used that utilize local coils that are RF-receive only, with RF-transmit performed by the body coil. Note that some RF head coils are receive-only, and that most other local coils, such as knee and spinal coils, are also RF receive-only. **These coils must not be used in patients with the VNS Therapy System.**

¹ A phantom is a material resembling a body in mass, composition, and dimensions that is used to measure absorption of radiation.