VNS Therapy™

PHYSICIAN'S MANUAL

MRI Guidance for the VNS Therapy™ System

October 2023

NOTE: The information contained in this document is one part of the full labeling for the implanted portions of the VNS Therapy system. It is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all VNS Therapy physician manuals, nor does this represent full disclosure of all pertinent information concerning use of this product, potential safety complications, or efficacy outcomes.

℞

CE 0344

26-0011-0700/2 (CE)

The year of authorization to affix the CE mark:

Model 102	2003
Model 102R	2003
Model 103	2005
Model 104	2005
Model 105	2011
Model 106	2014
Model 1000	2017
Model 1000-D	2020
Model 8103	2019
Model 302	2003
Model 303	2006
Model 304	2009

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Chapter 1

Introduction

NOTE: For a definition of VNS Therapy and MRI terms, see the glossary posted at www.livanova.com.

1.1. Warnings

Magnetic Resonance Imaging (MRI)

Patients with the VNS Therapy system, or any part of the system, implanted should have MRI procedures performed **only as described herein**. In some cases, surgery will be required to remove the VNS Therapy system if a scan using a transmit RF body coil is needed.

MR Unsafe Devices

The Wand, Programmer, and patient magnet are MR Unsafe devices. These devices are projectile hazards and must not be brought into the MR scanner room.

1.2. Precautions

Magnetic Resonance Imaging (MRI)

An MRI should not be performed using a transmit RF body coil for certain VNS Therapy device configurations or under certain specific conditions. In some cases, heating of the lead caused by the transmit RF body coil during MRI may result in serious injury. Static, gradient, and radio frequency (RF) electromagnetic fields associated with MRI may change the generator settings (i.e., reset parameters) or activate the VNS Therapy device if the Magnet Mode (epilepsy) or Normal Mode (depression) output remains "ON".

Receive RF Coils

Certain magnetic resonance (MR) system head coils operate in receive-only mode and require use of the transmit RF body coil. Other MR systems use a transmit/receive RF head coil. Local or surface coils may also be receive-only RF coils that require the transmit RF body coil for MRI. **The use of a receive RF coil does not alter hazards of the transmit RF body coil**.

Transmit RF Coils

Exposure of the VNS Therapy system to any transmit RF coil must be avoided. Do not perform MRI scans using any transmit RF coil in the defined exclusion zones.

1.3. MR Conditional Device

The implanted VNS Therapy system is an **MR Conditional** device that has demonstrated safety in the MR environment within defined conditions. For specific conditions for use, see "Conditional MR Environments" on page 9.

Conditions that define an MRI environment include the following:

- Transmit RF coil used
- Field strength of the static magnetic field (Tesla)
- Spatial gradient of the static magnetic field (Gauss/cm)
- Gradient slew rate (T/m/s)
- Radio frequency (RF) fields
- Specific absorption rate (SAR)
- Exposure time
- Scanner type (e.g., horizontal field, cylindrical closed bore)
- RF Transmission (e.g., RF shimming)
- Mode of operation (e.g., normal operating mode)

Many tests have been conducted with different VNS Therapy system device configurations. These include the following:

- In vitro tests in a variety of MRI facilities.
- Numerical simulations of multiple patient sizes and devices in numerous clinically relevant scenarios and configurations.

NOTE: Specific programmable configurations of the VNS Therapy system device are also required before an MRI is performed. For details, see "Pre-MRI Considerations and Preparation" on page 8.

The results have shown that VNS Therapy system patients may be safely exposed to certain MR environments if the guidelines described herein are followed. However, there is a risk of injury if the guidelines described herein are not followed. In particular, there is a risk of injury due to heating of the lead electrodes. Adverse effects from lead electrode heating may include 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.

NOTE: For additional information, see "Potential Risks and Effects of MRI with VNS Therapy" on page 20.

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.

Chapter 1

1.4. MRI Guidance Applicability

MRI guidance is specific to unique VNS Therapy device configurations.

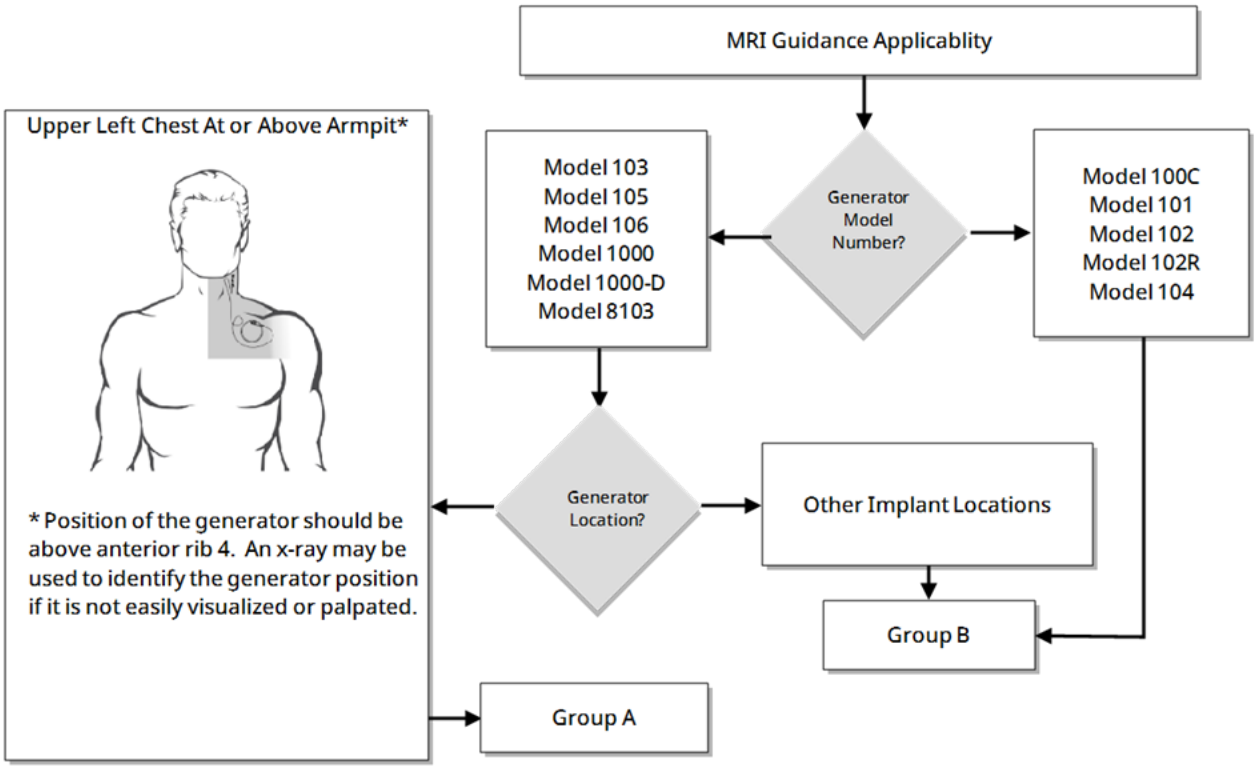
Applicable Generator Models	1000	1000-D	106	105	104	103	8103	102	102R	101	100C

Applicable Lead Models	304	303	302	300

Use the flowchart below to determine the applicable group (A or B) by device configuration.

NOTE: Contact "Technical Support" on page 24 for the most current MR information for VNS Therapy.

Figure 1. MRI Guidance Applicability Flowchart



Chapter 2

MRI Guidelines

2.1. Pre-MRI Considerations and Preparation

⚠ CAUTION: All patients *must have their VNS Therapy system assessed and programmed before* an MRI procedure.

Patients should consult with the treating physician prior to MR imaging. The MRI should be performed at least 2 weeks after implantation or revision surgery of the VNS Therapy system. Safety has not been demonstrated in patients with the VNS Therapy system in combination with other implanted devices. Until safety has been demonstrated for patients implanted with the VNS Therapy system and another implanted device, MRI should not be performed.

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 Therapy device *before the patient enters an MR system room*.

To prepare the device, perform the following steps:

1. For Model 100C – Model 102R generators, 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 after the MRI scan in the rare case of a reset.

Table 1. Model 102 and Model 102R Generator Device Settings

Device Settings			
Patient ID		Pulse Width (µsec)	
Model ID		Signal On Time (sec)	
Device Serial Number		Signal Off Time (min)	
Implantation Date		Magnet Output Current (mA)	
Normal Output Current (mA)		Magnet On Time (sec)	
Signal Frequency (Hz)		Magnet Pulse Width (µsec)	

2. Program the parameter settings as shown below.

Parameter		Setting
Normal Output Current		0 mA
Magnet Current		0 mA
Detection	Model 106 Model 1000 Model 1000-D	OFF
AutoStim Output Current	Model 106 Model 1000 Model 1000-D	0 mA

3. Turn off any other optional device features (Model 1000 / Model 1000-D only).
4. Perform an interrogation to verify that programming was successful.
5. Verify that placement of the VNS Therapy system is located between C7–T8.

⚠ CAUTION: MRI scans of a patient with a VNS Therapy system implanted outside C7–T8 has not been evaluated in pre-clinical testing; therefore further evaluation by the MR system operator to verify that the device will not be exposed to the RF Field is required.

ⓘ NOTE: Magnet Mode and AutoStim Mode are *not available* for Model 8103.

The device has been evaluated for MRI induced risks, including heating, unintended stimulation, force, torque, device malfunction and device vibration and has been determined to be safe under the conditions specified in labeling; however, the patient may feel sensations of warmth or vibration at the implant site during the MRI scan.

2.2. Conditional MR Environments

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

. See sections below for MRI guidance for Group A and Group B devices.

2.2.1. Precautions for Group A Devices

If the patient requires a MRI scan of the C7–T8 area using a head / extremity coil or C7–L3 area using a body coil, surgical removal of the VNS Therapy system will be required.

ⓘ NOTE: See Revision, Replacement and Removal—Overview in the indication specific physician's manual.

2.2.2. Precautions for Group B Devices

Do not use the transmit RF body coil for 1.5 T or 3 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 transmit RF coil must be avoided. Surgical removal of the VNS Therapy system will be required if an MRI of the C7–T8 exclusion zone is needed.

2.2.3. MRI Conditions for Use

NOTE: These guidelines pertain to the full VNS Therapy system (generator and lead implanted). For guidance on performing scans on patients with abandoned leads or lead segments see "Special Cases and Considerations" on page 16.

The recommendations herein are based on phantom tests and numerous numerical simulations of clinically relevant scenarios and implant configurations of standard 43-cm bipolar leads. The results show that the VNS Therapy system can be scanned safely under the conditions listed in the table below with the patient in supine or prone positions.

Table 2. MRI Conditions for Use

Device	Group A	Group B
Scanner Type	Horizontal field, cylindrical closed-bore, clinical system for hydrogen proton imaging	

Table 2. MRI Conditions for Use (continued)

Device		Group A	Group B
Scanner Characteristics	Static magnetic field strength	1.5 or 3 T	
	Spatial field gradient Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103 Model 102 Model 102R	≤ 3000 Gauss/cm	
	Spatial field gradient Model 101 Model 100C	≤ 720 Gauss/cm	
	Maximum slew rate	200 T/m/s	

Table 2. MRI Conditions for Use (continued)

Device		Group A	Group B
Scanner Operations	Operating mode	Normal Operating mode	
	Transmit RF coil	**Head or extremity coils**: Scan (placement of entire coil) must be outside of C7–T8 **Body coil:** Iso-center of scan (center of the MRI bore) must be outside of C7–L3. This may be accomplished by landmarking above C7 or below L3.	**Transmit / receive head or extremity coils only**: Scan (placement of entire coil) must be outside of C7–T8
	Maximum Specific Absorption Rate (SAR)	**Transmit head coil**: 3.2 W/kg **Transmit body coil**: 2.0 W/kg	**Transmit / receive head coil**: 3.2 W/kg
	Exposure time	**Transmit head or extremity coil**: No restriction **Transmit body coil**: ≤ 15 minutes of active scan time within a 30 minute window	**Transmit / receive head or extremity coil**: No restriction
	Additional Restrictions	**Transmit head or extremity coil:** None **Transmit body coil**: Circularly Polarized (CP) mode only (i.e., no shimming)	None

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 patients, SAR values are maximum head-averaged when using the transmit / receive head coil and whole body averaged as reported by the MRI equipment when using the body coil.

⚠ CAUTION: (Group B only) Not all head RF coils are transmit and receive type. Many are receive only. The use of any extremity receive coil with the body coil in RF transmit mode presents the same RF heating hazards as the body coil alone with no extremity coils.

⚠ CAUTION: Exposure of the VNS Therapy system to any transmit RF coil must be avoided.

2.2.4. Acceptable MR Imaging Scenarios (1.5 and 3.0 T)

ⓘ NOTE: The cross-hairs in the images below indicate the iso-center of the MR system's bore (i.e., landmark placement).

Table 3. Acceptable Configurations for Brain Scans

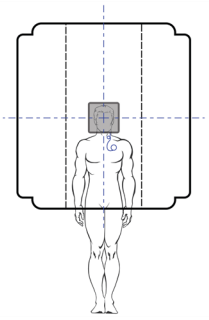
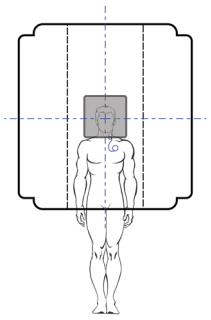
	Group A and Group B	Group A
	The shaded region in the images represents the field of view of the head, extremity, or body coil.	
	The transmit / receive head coil is placed outside of the C7–T8 exclusion zone, which results in minimal or no exposure of the VNS Therapy system to RF energy.	The brain may also be scanned using the transmit RF body coil. In this case, the iso-center (center of the MRI bore) must be above C7. This may be accomplished by landmarking above C7. With this configuration, either the body coil or head coil may be used as the receive coil.
		
Area of Interest	Brain	Brain
Transmit RF Coil	Head	Body
Receive Coil	Head	Body or Head

Table 4. Acceptable Configurations for Extremity Scans

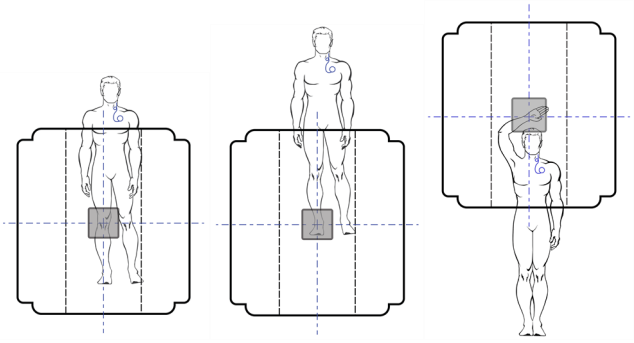
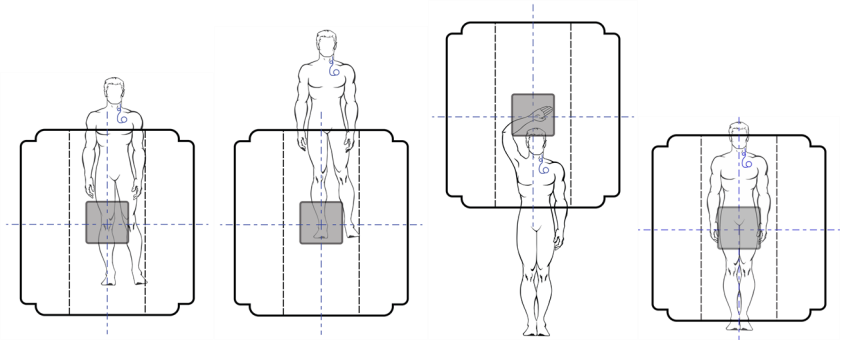
	Group A and Group B
	⚠ CAUTION: Do not perform scans using any transmit RF coil in the defined exclusion zones.
	The shaded region in the images represents the field of view of the head, extremity, or body coil.
	The appropriate transmit / receive extremity coil is used outside of the C7–T8 exclusion zone, which results in minimal or no exposure of the VNS Therapy system to RF energy.
	
Area of Interest	Knee, Ankle, Wrist
Transmit RF Coil	Extremity

Table 4. Acceptable Configurations for Extremity Scans (continued)

Receive Coil	Extremity
	Group A
	The shaded region in the images represents the field of view of the head, extremity, or body coil.
	The same areas of interest may be scanned using the transmit RF body coil. In these cases, the iso-center (center of the MRI bore) must be outside of the C7–L3 exclusion zone. This may be accomplished by landmarking above C7 or below L3. In these configurations, either the body coil or extremity coil may be used as the receive coil.
	
Area of Interest	Knee, Ankle, Wrist, Lower Back (Below L3)
Transmit RF Coil	Body
Receive Coil	Body or Extremity

2.2.5. Unsafe MR Conditions

NOTE: For instructions specific to scans on patients with abandoned leads where use of the body coil for transmission of RF may be permissible, see "Special Cases and Considerations" on page 16.

Patients may be safely scanned with MRI only under the conditions given herein. The safety of scans that use other conditions has not been evaluated and may result in severe patient injury. In vitro MRI-related heating tests with the transmit RF body coil have shown potentially injurious temperature increases in some cases. In particular, take care to ensure that scans are not performed on patients under the following conditions:

Group B

Magnetic resonance imaging (MRI) should not be performed with a magnetic resonance body coil in the transmit mode.

Group A and Group B

- Under no circumstances should the transmit RF coil be placed over the VNS Therapy system. Because of this restriction, scans of the area where the VNS Therapy system is implanted is not possible. See "Unsafe MR Imaging Scenarios" below for details.
- Open MRI scanners should not be used.

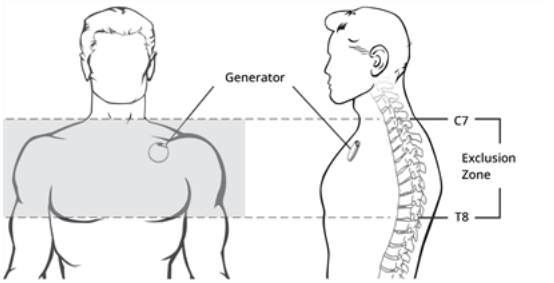
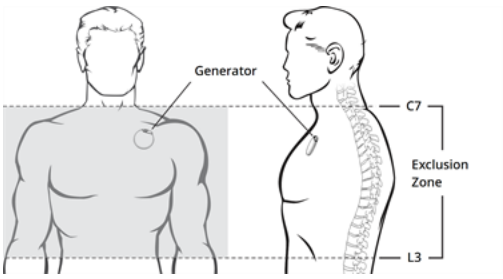
NOTE: Tests were only performed using closed (i.e., cylindrical) MRI scanners.

- Systems other than 1.5 T and 3 T should not be used.

2.2.6. Unsafe MR Imaging Scenarios

Under no circumstances should the transmit / receive head or extremity coil be placed over the shaded exclusion zone defined for Group A and Group B or the iso-center of the scan (center of the MRI bore) be inside the shaded exclusion zone for Group A .

Table 5. Unsafe MR — Exclusion Zone

	Group A and Group B	Group A
		
Exclusion Zone	C7–T8	C7–L3
Transmit RF Coil	Head, Extremity	Body

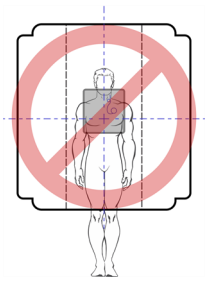
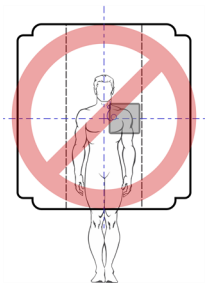
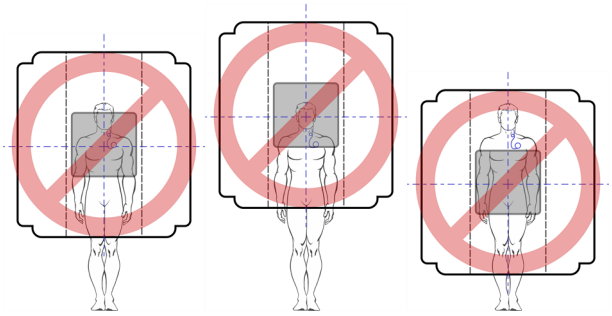
CAUTION: This exclusion zone is dependent upon the typical placement of the VNS Therapy system and placement of the extremity coil or positioning of the iso-center cannot be inside the exclusion zone under any circumstances.

CAUTION: Surgical removal of the VNS Therapy system will be required if an MRI of the exclusion zone is needed. See Revision, Replacement and Removal in the indication specific physician's manual.

The VNS Therapy system, usually located between C7 and T8, must not be exposed to any RF field from a transmit RF coil. The images below show examples of unsafe MR imaging.

NOTE: The cross-hairs in the images below indicate the iso-center of the MR system's bore (i.e., landmark placement).

Table 6. Unsafe MR Imaging

	Group A	
		
Area of Interest	Iso-center inside C7–L3	Iso-center inside C7–T8
Transmit RF Coil	Body	Extremity
	Group B	
		
Area of Interest	Any	
Transmit RF Coil	Body	

2.2.7. Special Cases and Considerations

2.2.7.1. Partially Explanted VNS Therapy System or Damaged Lead

The primary risk of MRI to patients is MRI-related heating of the lead. Tests and computer models have shown, however, that MRI can be performed safely under the conditions and configurations listed below.

Table 7. Scan Conditions for Partially Explanted VNS Therapy Systems or Damaged Leads

Implant Configuration	Scan Conditions	
	1.5 T or 3 T with transmit / receive Head Coil or transmit / receive Extremity Coil	1.5 T or 3 T with transmission of RF with the Body Coil

Table 7. Scan Conditions for Partially Explanted VNS Therapy Systems or Damaged Leads (continued)

Implant Configuration	Scan Conditions	
VNS Therapy system with a suspected lead break (generator is still connected)	 C7–T8 exclusion zone (i.e., Group B Scan Conditions	
Lead length > 2 cm remains (no generator)	 C7–T8 exclusion zone (i.e., Group B Scan Conditions	
≤ 2 cm of lead remains (i.e., electrodes remain implanted) and no generator	 No exclusion zones	 Any landmark, no exclusion zones

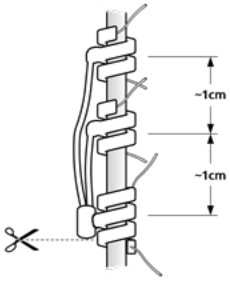
NOTE: See "MRI Conditions for Use" on page 10 for further guidelines.

2.2.7.2. Lead Segment Length Assessment

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.

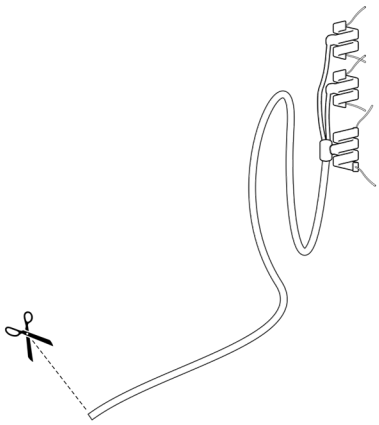
The image below illustrates the relationship of the electrodes to each other and the positive electrode to the anchor tether. An MRI using the Body coil for transmission of RF, or MRI of the head or extremities with a Head coil or Local (Extremity) coil (respectively) for transmission of RF is allowed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

Figure 2. Transected Lead (≤ 2 cm)



If the lead is transected as seen in the image below, only a transmit / receive head MRI or transmit / receive extremity MRI is recommended. A full body MRI is not allowed.

Figure 3. Transected Lead (> 2 cm)

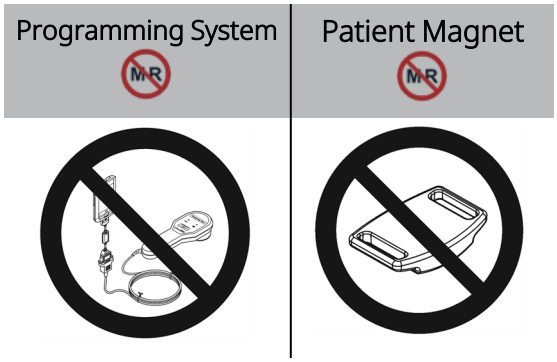


WARNING: If it appears that more than 2 cm of lead remains, then the patient cannot have an MRI with the body coil, but can still have an MRI using a extremity transmit / receive or head transmit / receive coil as instructed herein. Abandoned lead wires present increased risk of thermal injury to patients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

2.2.8. MR Unsafe Devices

The programming system, which includes the Wand and the Programmer, is MR Unsafe. The patient magnet is also MR Unsafe. These devices must not be brought into the MR scanner room.

Figure 4. MR Unsafe Devices



Many patients or caregivers carry magnets to activate and inhibit the VNS Therapy system. A magnet, which can attach to a wristband or belt clip, or carried, is included in the kit given to all patients. The magnet may be accidentally carried into an MR scan room, where it could cause damage or injury if it becomes a projectile. Screen all patients to make sure they do not carry their patient magnet into the MRI scan room.

2.3. Post-MRI Assessment

After the MRI procedure, an appropriate healthcare professional with access to a programming system must assess the condition of the VNS Therapy system.

To assess the VNS Therapy system, perform the following steps:

1. Interrogate the generator.
2. If the generator was reset during the scan, reprogram the serial number, patient ID, and implant date, as needed.

   NOTE: Model 102R and earlier devices – For a complete list of information needed to restore the device settings, see "Pre-MRI Considerations and Preparation" on page 8.

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.

Potential Risks and Effects of MRI with VNS Therapy

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

All Models	Heating effects around the system, especially electrodes, from RF energy
	Non-significant levels of current induced through the lead wire by time-varying gradient and RF fields
	Inadvertent Magnet Mode stimulation from magnetic fields if Magnet Mode was left on (epilepsy patients only)
	Vibration or movement of the device or lead
	Image artifacts and distortion
	Device malfunction or damage
Model 104 Model 103 Model 8103 Model 102 Model 102R Model 101 Model 100C	Inadvertent device reset
Model 1000 Model 1000-D Model 106	Delivery of AutoStim may occur if the feature is programmed on and a rapid increase in heart rate occurs

NOTE: For complete indications, contraindications, warnings, and precautions, see the indication specific physician's manual.

3.1. 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 the VNS Therapy system stimulation electrodes.

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.

Group A:

Safe levels of heating, typically less than a 2 °C increase, were shown during numerical simulations for acceptable imaging scenarios (see "Conditional MR Environments" on page 9). In some cases the heating was found to be higher than 2 °C, but these results have also been demonstrated to be safe.

Group B:

⚠ CAUTION: Surgical removal of the VNS Therapy system will be required if MRI using a transmit RF body coil is needed. See "System Removal" in the indication specific physician's manual.

For some Group B device configurations, 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. However, safe levels of heating, consistently less than a 2 °C increase, were shown during in vitro tests and numerical simulations for the acceptable imaging scenarios (see "Conditional MR Environments" on page 9).

3.2. Gradient Induced Current

There is no safety risk to the patient from MRI gradient induced currents through the device's lead wire. By design, the VNS Therapy 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 output required for nerve activation[1]. Any current induced in the lead by MRI time-varying magnetic fields may result in slight tingling sensation.

3.3. Generator Reset

Applicable Models:	104	103	8103	102	102R	101	100C

There is no safety risk to the patient from a generator reset. For Model 102R and earlier devices some information (e.g., serial number, implant date, stimulation parameters, device operating time) may be lost from the VNS Therapy system generator during a 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 generator by design, are present in the MR environment. A generator reset has not been observed during *in vitro* tests. A few cases of a reset have been reported by patients in association with MRI procedures. Clinically, nothing can be done to

[1]Smith CD, Geddes LA, Bourland JD. et al. Cardiovascular Engineering (2001) 1: 77

prevent this rare occurrence. In the event of a reset and loss of data, use the programming system to reprogram the device serial number, implant date, and stimulation parameters to their *pre-MRI* scan values..

NOTE: For details on proper procedures to ensure data is not lost due to a reset, see "Pre-MRI Considerations and Preparation" on page 8.

3.4. Magnet Mode Activation

NOTE: Magnet Mode is only intended for use in epilepsy patients.

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, Magnet Mode, and AutoStim Mode (For generators capable of AutoStim) output currents should be programmed to 0 mA *before patient entry into the MR system room*. Any other optional device features should also be disabled before patient entry into the MR system room.

3.5. AutoStim Mode

Applicable Models:	1000	1000-D	106

NOTE: AutoStim Mode is only intended for use in epilepsy patients.

If Heartbeat 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 detection is turned off prior to MRI (See "Pre-MRI Considerations and Preparation" on page 8), the device is expected to behave in the same way as VNS Therapy generators without the AutoStim feature. The VNS Therapy system Normal Mode, AutoStim Mode, and Magnet Mode output currents should be programmed to 0 mA, and detection should be programmed “OFF” prior to patient entry into the MR system room.

3.6. Vibration or Movement

Patients may feel a tug or vibration at the site of the generator. The VNS Therapy system may experience magnetic field interactions associated with the static and gradient magnetic field of the MR system due to small amounts of material in the generator sensitive to magnetic fields. This may cause the generator to shift or vibrate slightly within the implant pocket and/or may place mechanical stress on tissues and/or the lead.

The lead does not directly experience magnetic field interactions, since it is made from non-ferromagnetic materials.

⚠ CAUTION: Lower MRI static magnetic field strength does not imply greater safety. Only follow approved instructions in "Conditional MR Environments" on page 9.

3.7. Image Artifacts and Distortions

Image artifacts or distortions may be observed under certain conditions.

Table 8. Image Artifacts and Distortions

Type of Coil Used	Image Artifacts and Distortions
Head coil	None
Body coil	In non-clinical testing, the worst-case image artifact caused by the device extends approximately 100 mm from the generator when imaged with a gradient echo pulse sequence and a 3 T MRI system.

3.8. 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. 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.

Contacts and Resources

For information and support in use of the system or any of its accessories, contact LivaNova.

Contacts

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Technical Support

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Regulatory Authority Websites

Report all adverse events related to the device to LivaNova and to your local regulatory authority.

Australia	https://www.tga.gov.au/
Canada	https://www.canada.ca/en/health-canada.html
UK	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
EU	https://ec.europa.eu/growth/sectors/medical-devices/contacts_en