



1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for the Senza II™ Implantable Pulse Generator (IPG2000)

! USA

R_x ONLY

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CE Mark effective on 4 May 2010

Nevro hereby declares that the Senza® System is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive (2014/53/EU).

IMPORTANT: Changes or modification to any component of the Nevro® Spinal Cord Stimulation system, unless expressly approved by Nevro Corp., could void your authority to operate this product.

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

Explanation of symbols. Refer to the product for symbols that apply.

Symbols	Description
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MR Conditional



CE Marking of Conformity



For USA audiences only



Manufacturer

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Introduction

Nevro's Senza Spinal Cord Stimulation (SCS) system is an MR Conditional device that has been demonstrated to present no known hazards in a specified MR environment when following specific guidelines as described in this document.



MR Conditional

This document is a supplement to the Senza system Physician Implant and Patient Manuals and is related only to the use of a transmit/receive radio frequency (RF) head or transmit/receive local coils of a 1.5T or 3T horizontal bore MRI system for patients implanted with the Senza II™ Model IPG2000 device and associated components.

The implanted components of the Senza system may include Nevro® percutaneous leads (LEAD10x8-xx(B)), Surpass™ surgical leads (LEAD3005-xx(B)), lead extensions (LEAD2008-xx(B)), lead anchors (ACCK5xxx), IPG port plug (ACCK7000), and the Senza II™ implantable pulse generator (NIPG2000).

**xx is the lead or lead extension length in centimeters.*

***xxx refers to various anchor model numbers*

Please note that the following components of the Senza system are **MR Unsafe**. Do not bring these components into the MR scanner room.

- The trial stimulator (EXTS1000), patient remote (PTRC1000), charger (CHGR1000), surgical accessories, programmer wand (CLPW1000) and clinician programmer (CLPG2000, and CLPG2500).
- S8 lead adaptors (SADP2008-xx(B)) and M8 lead adaptors (MADP2008-xx(B)).

**xx is the lead or lead extension length in centimeters.*

It is important to read this full document prior to conducting or recommending an MRI examination on a patient with the Senza system. These instructions only apply to the Senza system, and do not apply to other products. If you have any questions, please contact Nevro at the address or phone number at the end of this document. These instructions can also be found at Nevro's website (www.nevro.com/manuals).

Overview

Magnetic Resonance Imaging (MRI) is a tool used to diagnose various diseases and conditions. MRI uses a powerful static magnetic field, gradient magnetic fields, and RF energy to construct an image of a section of the body.

Bench-top tests have shown that patients implanted with the Senza II™ Model IPG2000 device and associated components can be safely exposed to MR environments specified in this guideline.

However, MR scans performed outside these guidelines may result in the MRI field interacting with implanted devices, potentially injuring the patient and damaging the implanted device. Due to risks associated with using an MRI with an implanted device, it is important to read, understand, and comply with these instructions to prevent potential harm to the patient and/or damage to the device.

Definition of Terms

- *MR Conditional*¹: An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
- *Radio frequency (RF) magnetic field*: The magnetic field in MRI that is used to flip the magnetic moments.
- *Specific absorption rate (SAR)*¹: Radiofrequency power absorbed per unit of mass (W/kg).
- *Tesla (T)*¹: The SI unit of magnetic induction equal to 10⁴ gauss (G).
- *Transmit/Receive RF head coil*¹: A coil used to transmit and receive RF energy that is limited to the head only.
- *Transmit/Receive RF local coil*: A coil used to transmit and receive RF energy that is limited to a section of the body only (e.g. Knee coil).
- *Trial Phase*: A time during which a person with chronic pain tests SCS therapy to see if and how well it works. During the trial phase, the person will use a Trial Stimulator, which is not implanted in the body.

Risks Associated with MRI with Senza System

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

- Device movement
- Excessive heating of or around the implanted device components
- Tissue damage
- Damage to the device

¹ ASTM F 2503-13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"

- Uncomfortable sensation
- Image artifact

Contraindications

The contraindications associated with performing MRI on patients with an implanted Senza system include:

- Do not use the transmit RF body coil for 1.5T and 3T imaging.
- Many head and local RF coils are receive only. Do not use a transmit body coil with a receive-only head coil or a receive-only local RF coil as this can cause significant heating at the lead tip resulting in serious patient injury and/or device damage.
- No part of the implanted system (implantable pulse generator (IPG), extensions, percutaneous or surgical leads, lead anchors or IPG port plugs) may be within the transmit/receive RF head coil.
- Under no circumstances should the transmit/receive RF local coil be placed over the implanted Senza system. Because of this restriction, scanning of the area where the Senza system is implanted is not possible.

Conditions for Use of MRI with Senza System

1.5T and 3T MR scan conditions

MRI examinations of the head and extremities can be safely conducted in patients with the Senza system if all the instructions in this document are followed. Non-clinical testing has shown the Senza system is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole head averaged specific absorption rate (SAR) of < 3.2 W/kg (Normal Operating Mode), when a transmit / receive RF head coil is used.
- Limit the gradient field dB/dt slew rate to 200 T/m/sec per axis or less.
- Limit the total active scan time to 30 minutes.
- Stimulation must be turned off.
- For head MR scans, only use transmit / receive RF head coils. No part of implanted Senza system (implantable pulse generator (IPG), extensions, percutaneous or

surgical leads, lead anchors or IPG port plugs) may be within the transmit / receive RF head coil.

- For extremity MR scans, only use transmit / receive RF local coils. Under no circumstance should the transmit / receive RF local coil be placed over the implantable Senza system.

Additional conditions for all MR scans

- Do not perform an MRI if the patient has a device or device component (lead, extension, etc.) from a different manufacturer attached to the Nevro IPG. The risks of performing MRI scan with a Nevro IPG connected to a lead manufactured by a different company have not been evaluated.
- Use only a transmit/receive RF head coil or transmit/receive RF local coil. The risk of using other types of RF coils has not been evaluated.
- Do not use open-sided MRI systems or systems operating at other static magnetic field strengths. Do not use higher or lower static magnetic field strengths (0.5, 1.0 or 4.0T). The risk of using MRI systems operating at other static magnetic field strengths has not been evaluated.
- The trial stimulator, patient remote, charger, surgical accessories, programmer wand, and clinician programmer are MR Unsafe and should not be allowed into the MRI scan (magnet) room.
- Do not perform MR scan if the patient is undergoing the trial phase.
- Patients implanted with percutaneous or surgical lead(s) and lead extension(s) can undergo MR scans under specified conditions.
- Do not conduct an MRI if the implanted Nevro percutaneous or surgical lead(s) or lead extension(s) are not connected to the IPG.

1.5T and 3T MR scan scenarios

Head MR Imaging

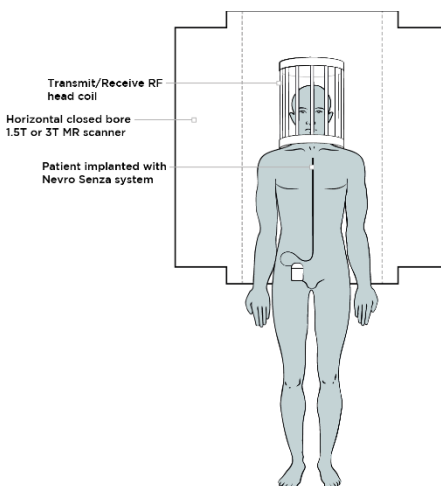


Figure 1: Head MRI scans are permissible using 1.5T or 3T transmit / receive RF head coil, as long as the implanted Nevro Senza system components are not within the transmit / receive head coil and other aforementioned scan conditions are met.

Extremity MR Imaging

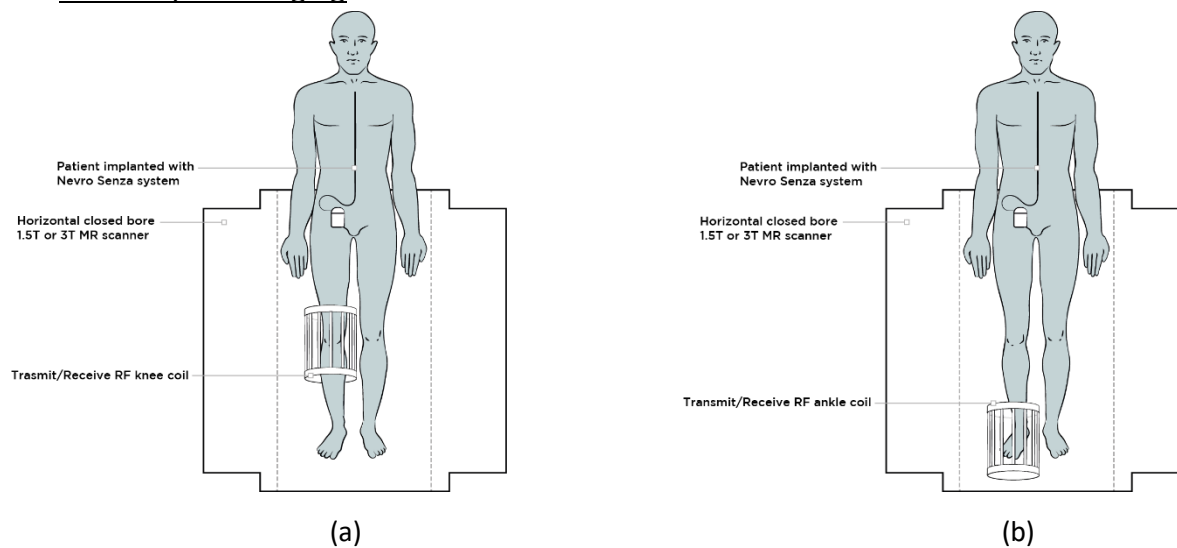


Figure 2: Extremity scans are permissible using an appropriate transmit / receive RF local coil, as long as the RF local coil is not placed over the implanted Nevro Senza system components and other aforementioned scan conditions are met. (a) represents a permissible knee scan scenario. (b) represents a permissible ankle MR scan scenario. Although not illustrated, MRI scans of the wrist are also possible using an appropriate transmit / receive RF local coil.

Preparation Prior to MRI Examination

- Inform the patients of all the risks associated with undergoing an MRI examination as stated in this document.
- A trained professional with the proper knowledge of MRI equipment such as an MRI-trained radiologist or MRI physicist must ensure the MRI examination will be conducted according to the information outlined in this document.
- Identify if the patient has any other medical device implants. The most restrictive MRI exposure requirements must be used if the patient has multiple medical device implants. Consult with the manufacturers of the devices.
- Document the patient's programming parameters.
- Perform an impedance check. Do not perform an MRI if any impedance is greater than 10 k Ω .
- Turn stimulation off. This can be done using either the programmer, patient remote, or patient charger.
- Do not conduct an MRI if the implanted percutaneous or surgical lead(s) or lead extension(s) are not connected to the IPG.
- Do not conduct an MRI with a trial stimulator (TSM), patient remote, charger, surgical accessories, programmer wand, and clinician programmer in the MRI scan room.
- Any part of the implanted Senza system (IPG, extensions, leads) should not be in the transmit / receive RF head coil. The transmit / receive RF volume coil should not be placed over any components of the implanted Senza system. Because of this restriction, scanning of the area where the Senza system is implanted is not possible.
- If possible, do not sedate the patient so the patient can inform the MRI operator of any problems during the examination.
- Instruct the patient to immediately inform the MRI operator if any discomfort, stimulation, shocking, or heating is experienced during the examination.
- MRI images near implanted devices may be distorted. Contact Nevro technical services for additional information about the expected extent and appearance of the image artifact under various scan conditions.

Considerations during the MRI Examination

- Carefully monitor the patient throughout the MRI examination both visually and audibly. Discontinue the MRI examination immediately if the patient cannot respond to questions or reports any problems.

Considerations after the MRI Examination

- Turn the device on and restore the IPG to pre-MRI settings.
- Confirm that the IPG has been restored to pre-MRI settings.

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