1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for the Senza System

CE
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NEVRO CORP.

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Nevro hereby declares that the Senza® System is in compliance with the essential requirements and other relevant provisions of the R&TTE Directive (1999/5/EC).

IMPORTANT: Do not change or modify any component of the Senza Spinal Cord Stimulation system, unless expressly approved by Nevro Corp.

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

Symbols	Description
	MR Conditional
	CE Marking of Conformity
	Manufacturer

Contents

Introduction

Nevro's Senza Spinal Cord Stimulation (SCS) system is an MR Conditional device that has been demonstrated to present negligible 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 and patient manuals and is related only to the use of a transmit / receive radio frequency (RF) head or other transmit/receive RF volume coil (wrist coil, knee / foot coil etc.) of a 1.5T or 3T cylindrical bore MRI system for patients implanted with the Senza system.

The implanted components of the Senza system may include Nevro® percutaneous leads (Model No: LEAD10x8-xxB), Surgical Lead (LEAD3005-xx(B), LEAD3015-xx(B), LEAD3025-xx(B)), lead extensions (Model No: LEAD2008-xxB), lead anchors (Model No: ACCK5xxx), IPG Port plug (ACCK7000), and the Senza implantable pulse generator (Model Nos: NIPG1000 or NIPG1500).

Please note that MR Conditional components of the Senza system **do not** include

- The trial stimulator (TSM), patient remote, charger, surgical accessories, programmer wand, and clinician programmer. Do not bring these components into the MR scan room.
- S8 lead adaptors (Model No.: SADP2008-xxB) and M8 lead adaptors (Model No.: MADP2008-xxB).
- Surgical lead (LEAD3005-xx(B), LEAD3015-xx(B), LEAD3025-xx(B))

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/ous/mri).

This manual is applicable only for patients implanted with the Senza system who are undergoing MR scans. This manual is not applicable for Healthcare professionals implanted with Senza system who are involved in conducting MR scans.

Overview

Magnetic Resonance Imaging (MRI) is a tool used to diagnose various diseases and conditions. MRI uses 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 Senza system can be safely exposed to MR environments specified in this guideline.

However, MR scans performed outside the 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 10^4 gauss (G).
- *Transmit / Receive RF head coil*[1]: A coil used to transmit and receive RF energy that is limited to the head only.
- *Other Transmit / Receive RF volume coil*: RF coil producing a homogeneous RF field over the volume encompassed by the coil. The homogenous RF field is limited to a section of body only (e.g. Knee, Wrist etc.). The coil both transmits and receives RF energy.
- *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 Associated with MRI with Senza System

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 other transmit / receive RF volume coils (e.g. wrist coil, knee coil etc.) are receive only. Do not use a receive only head, or a receive only RF volume coil (e.g. wrist coil, knee coil etc.) 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, leads, lead anchors or IPG port plugs) may be within the transmit / receive RF head coil.
- Under no circumstances should the transmit / receive RF volume 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.
- The trial stimulator (TSM), patient remote, charger, surgical accessories, programmer wand, and clinician programmer are MR Unsafe. These devices may be projectile hazards and should not be allowed into the MRI scan (magnet) room.

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 to be MR conditional when exposed to the MRI environment under the specific conditions listed below:

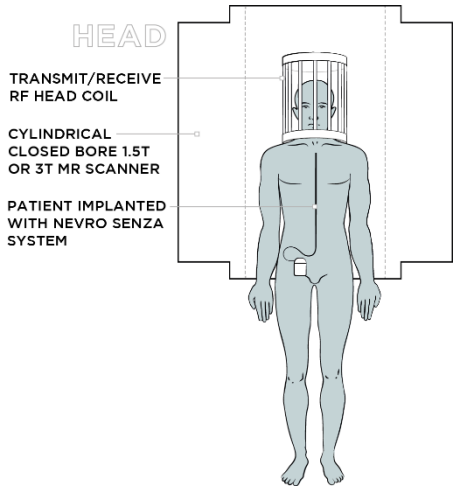
- Conditions for all scans
    - Do not perform an MRI if the patient has a device or device component (lead, extension, etc) from a different manufacturer attached to the Nevro IPG. The risks of performing MRI scan with a Nevro IPG connected to a lead manufactured by a different company have not been evaluated.
    - Use only a transmit / receive RF head coil or other transmit / receive RF volume coil (e.g. Wrist coil, Knee coil etc.). The risk of using other types of RF coils has not been evaluated.

- Use only a 1.5T or 3T cylindrical bore MRI system with a maximum static field spatial gradient of 1110 gauss/cm (11.1 T/m). Please consult the MR manufacturer for the maximum spatial gradient field in the MR scanner.
- Do not use open-sided MRI systems or systems operating at higher or lower Tesla value (0.5, 1.0 or 4.0T). The risks of using MRI systems operating at other Tesla values have not been evaluated.
- The trial stimulator (TSM), patient remote, charger, surgical accessories, programmer wand, and clinician programmer are MR Unsafe and should not be allowed into the MRI scan (magnet) room.
- Stimulation must be turned off.
- Do not perform MR scan if the patient is undergoing the trial phase. Please refer to the Nevro's patient manual about details on the trial phase.
- Do not conduct an MRI if the implanted Nevro lead(s) or lead extension(s) are not connected to the IPG.
- Do not conduct an MRI if the patient has implanted leads / extensions from another manufacturer which are not connected to a IPG.
- Only use MRI systems which limit slew rate to 200T/m/sec per axis or less. Please consult the MR scanner manufacturer for the maximum possible slew rate on the MR scanner.
- Limit total scan time to 15 minutes.

- Additional conditions for head MR scans
  - Only use transmit / receive RF head coil.
  - No part of the implanted Senza system (implantable pulse generator (IPG), extensions, leads, lead anchors, or IPG port plugs) may be within the transmit / receive RF head coil. The location of implanted Senza system components shall be confirmed prior to the MR scan to ensure compliance with this condition.
  - Use MRI scan parameters that limit the head Specific Absorption Rate (SAR) level lower than 3.2 W/kg.
- Additional conditions for extremity MR scans
  - Only use transmit / receive RF volume coils (e.g. Wrist coil, Knee coil etc.).
  - Under no circumstances should the transmit / receive RF volume coil be placed over the implantable Senza system (implantable pulse generator (IPG), extensions, leads, lead anchors, or IPG port plugs). The location of implanted Senza system components shall be confirmed prior to the MR scan to ensure compliance with this condition.

- Conduct wrist MR scans with wrist placed above the head to minimize RF interaction with the implanted Senza device. Risks associated with placing the wrist coil close to the torso during MR scan have not been evaluated.

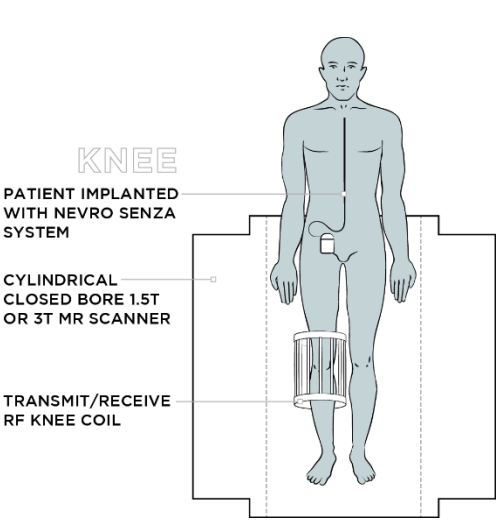
1.5T and 3T MR scan scenarios



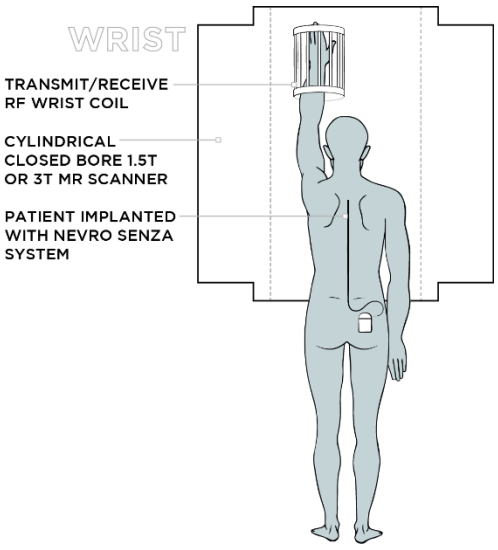
Head MR Imaging

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



(a)



(b)

Figure 2: Extremity scans are permissible using an appropriate transmit / receive RF volume coil, as long as the RF volume 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 wrist MR scan scenario. Although not illustrated, MRI scans of the ankle are also possible using an appropriate transmit / receive RF volume 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 using Nevro's Clinician Programmer. Do not perform an MRI if any impedance is greater than 10 kΩ. Details on how to conduct impedance check can be found in Nevro's Physician Implant manual.
- Turn stimulation off. This can be done using either the programmer, patient remote, or patient charger. Details on how to switch off the simulation can be found in Nevro's Patient manual.
- Do not conduct an MRI if the implanted 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.

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.
- Once the Nevro IPG has been turned off, the MRI will not turn on the IPG.

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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