



**1.5 Tesla and 3 Tesla Magnetic Resonance
Imaging (MRI) Guidelines for the SENZA[®] and the
SENZA II[®] Systems
(IPG1000, IPG1500, and IPG2000)**

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CE Mark effective on 4 May 2010

Nevro hereby declares that the SENZA® System and SENZA II® System are 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



MR Conditional



MR Unsafe



Manufacturer

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1. Introduction

Nevro® SENZA® and SENZA II® Spinal Cord Stimulation (SCS) systems are MR Conditional devices that have been demonstrated to present no known hazards in a specified MR environment when following specific guidelines as described in this document. The SENZA® and SENZA II® systems will be collectively referenced in this guideline as the SENZA system unless otherwise stated.



This document is a supplement to the SENZA system Physician Implant and Patient Manuals and is related only to the use of a 1.5T or 3T horizontal bore MRI system for patients implanted with the SENZA system.

The following tables list model numbers of components that may comprise an MR Conditional SENZA System.

Table 1: SENZA System components that are eligible for full body MRI scans (1.5T only), and head and extremity MRI scans (1.5T and 3T) under specified conditions:



Component	Model Number(s)
Nevro IPG(s)	NIPG1000, NIPG1500, NIPG2000
Nevro Percutaneous Leads	LEAD10x8-xx(B)
Lead Extensions	LEAD2008-xx(B)
Lead Anchors	All models (ACCK5000, ACCK5101, ACCK5200, ACCK5300)
IPG Port Plug	All models (ACCK7000)
xx = Lead / Extension length in cm	

Table 2: SENZA System components that are eligible for head and extremity MRI scans only (1.5T and 3T) with transmit-receive head or transmit-receive local coils under specified conditions:



Component	Model Number(s)
Surpass™ Surgical Lead	LEAD3005-xx(B)
xx = Lead length in cm	

The following table lists components of the SENZA system that are **MR Unsafe****. **Do not bring these components into the MR scanner room.**

Table 3. Components of the SENZA System that are **MR Unsafe**:



Component	Model Number(s)
Trial Stimulator	EXTS1000
Patient Remote	PTRC1000
Charger	CHGR1000
Programmer Wand	CLPW1000
Clinician Programmer	CLPG2000/CLPG2500
S8 lead adaptors	SADP2008-xx(B)
M8 lead adaptors	MADP2008-xx(B)

**Additional information about Nevro products can be found at Nevro's website (www.nevro.com/manuals).

Patient ID card

Advise the patient to bring the most up-to-date patient ID card to all MRI appointments. MRI personnel can then use the patient ID card to identify Nevro Corp as the manufacturer of the patient's spinal cord stimulator system.

It is important to read this entire 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. The current version of these instructions can be found at Nevro's website (www.nevro.com/manuals). If you have any questions, please contact Nevro at the address or phone number at the end of this document.

2. 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 system 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.

3. Definition of Terms

- **MR Conditional¹:** 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 coil¹:** 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 (Spinal Cord Stimulator) 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.
- **Trial Simulator:** In neuromodulation, a portable and external device that allows the patient to test the therapy prior to an IPG (Implantable Pulse Generator) being implanted.

¹ ASTM F2503-13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"
11095-ENG Rev F

4. 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
- Uncomfortable sensation
- Image artifact

5. Contraindications

Do not use MRI systems that are open bore, or are operating at static magnetic field strengths other than 1.5T or 3T. The risks of using MRI systems operating at static magnetic field strengths other than 1.5T or 3T have not been determined and could be significant.

Contraindications specific to the 1.5T MR scanner

- Adherence to SAR limitations in 'coil positioning restriction' zone for the full body MRI coil is absolutely necessary. Please look at the section 'coil positioning restriction zone' for further details.

Contraindications specific to the 3T MR scanner

- **Do not** use the transmit RF body coil for 3T imaging. Only transmit / receive 3T head or local coils may be used under specified conditions.
- Many 3T head and 3T local RF coils are receive only. **Do not** use a receive only 3T head or 3T 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 leads, lead anchors or IPG port plugs) may be within the transmit/receive 3T RF Head coil.
- Under no circumstances should the 3T 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 in 3T scanners.

Contraindications specific to Surpass surgical leads LEAD3005-xx(B)

- **Do not** use the transmit RF body coil for imaging when Surpass surgical leads are part of the system. Only transmit / receive head or local coils may be used under specified conditions.
- Many head and local RF coils are receive only. **Do not** use a receive only head or 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, 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 with Surpass surgical leads. Because of this restriction, scanning of the area where the SENZA system with surgical leads is implanted is not possible in 1.5T or 3T scanners.

6. Preparation Prior to MRI Examination

- Inform the patients of all the risks associated with undergoing an MRI examination as stated in this document.
- Always consult with the physician responsible for managing the Patient's SCS System.
- 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.

The patient's pain management physician, referring medical facility, implanting physician or a Nevro representative shall perform the following:

- Document the patient's programming parameters.
- Perform an impedance check. Do not perform an MRI if any impedance is greater than or equal to 10 k Ω .
- Turn stimulation off. This can be done using either the programmer, patient remote, or patient charger.
- Do not conduct an MRI scan if the implanted percutaneous lead(s), surgical lead(s) or lead extension(s) are not connected to the IPG.
- 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.

7. Coil Positioning Restriction zone (applicable when using 1.5T full body coil)

- Adherence to SAR limitations in 'coil positioning restriction' zone for the *transmit only and transmit/receive* full body MRI coil is absolutely necessary.

NOTE:

- The use of transmit only and transmit/receive 3T full body coil is contraindicated on patients implanted with SENZA system.
- The use of transmit only and transmit/receive 1.5T and 3T full body coils is contraindicated on patients implanted with SENZA system with Surpass surgical leads (LEAD3005-XX(B)).
- The 'coil positioning restriction' zone only applies to transmit only and transmit/receive full body 1.5T coil, and the receive only 1.5T coils do not have any positioning restrictions

If the patient is positioned within the 'Positioning restriction zone' as demonstrated by zone A in Figure 1

- The average whole body SAR shall be limited to 0.4 W/Kg and the head average SAR shall be limited to 0.64 W/kg.

If the patient is positioned in 'Outside restriction' zone as demonstrated by zone B in Figure 1

- The average SAR shall be limited to 2 W/Kg (normal operating mode) and the head average SAR shall be limited to 3.2 W/kg (normal operating mode).

In practice this means that if the marker line of the laser light localizer, which is used for subsequent positioning of the patient within the MRI scanner, is between the tip of the nose and 8" cranial (superior) to the knee protrusion then the patient is in 'coil positioning restriction' zone.

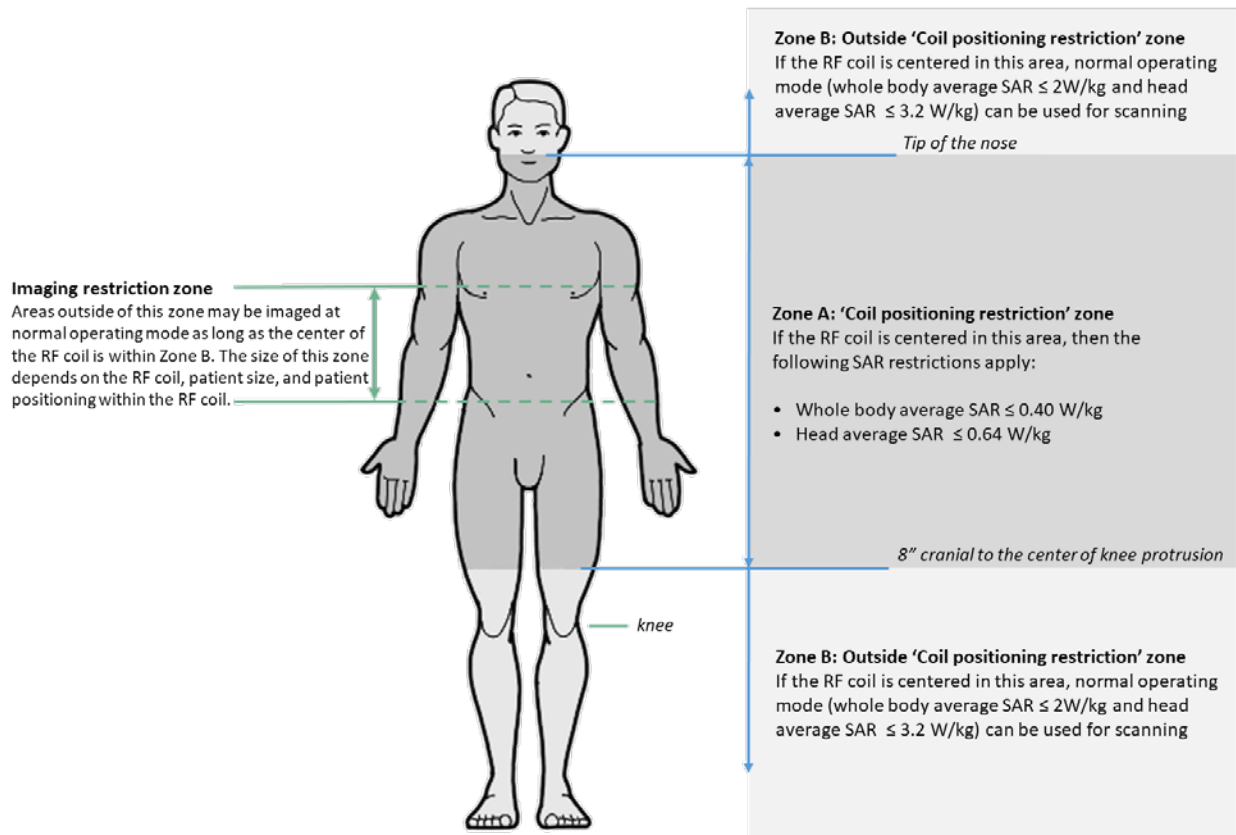


Figure 1: Coil positioning restriction zone. Starting from the foot end, the 'coil positioning restriction zone' starts at 8" cranial to the center of knee protrusion. Starting from the top of the skull, the 'positioning restriction' zone starts at the tip of the nose. In practice this means that if the marker line of the laser light localizer, which is used for subsequent positioning of the patient within the MRI scanner, is between the tip of the nose and 8" cranial to the knee protrusion then the patient is in 'coil positioning restriction' zone.

8. Conditions for Use of MRI with SENZA System

Head Scans and Neck Scans

MRI scans of head can be safely conducted in patients implanted with SENZA system using 1.5T and 3T MR scanners if the following conditions are met:

- General requirements (Verify with the patient's pain management physician, referring medical facility, implanting physician or a Nevro representative)
 - 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.
 - 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.
 - Do not perform MR scan if the patient is implanted with a SENZA System component not listed in Table 1 above.
 - Do not conduct an MRI if the implanted Nevro percutaneous lead(s), surgical lead(s) or lead extension(s) are not connected to the IPG.
 - Do not perform an MRI if impedance on any of the conductor path on the lead is greater than or equal to 10 k Ω .
 - Body Temperature – If a body coil is used (transmit only or transmit/receive), do not perform a scan if the patient's body temperature is greater than 37°C. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.
 - Do not cover the patient with blankets or heated blankets. Blankets raise the patient's body temperature and increase the risk of tissue heating, which could cause tissue damage.
- Scanner requirements:
 - Only use horizontal cylindrical (closed) bore MR scanners. Do not use open bore 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.
 - Only use MR scanners with maximum spatial field gradient of 1900 gauss/cm (19 T/m) or less.
 - Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.
- Allowed coils:
 - For 1.5T scanners:
 - Both receive-only head coil and transmit / receive head coils are allowed for patients implanted with any of the components listed in Table 1.
 - If receive-only head coil is used, then the SAR limitation associated with the 'coil positioning restriction zone' specified for full body coils applies (see Figure 1).

- Only transmit/receive head coils are allowed for patients implanted with the Surpass surgical lead (LEAD3005-xx(B)).
 - For 3T scanners: Only transmit/receive head coil is allowed.
- Implant location restriction:
 - For 1.5T scanners: If transmit/receive head coil is used, then no part of (implantable pulse generator (IPG), extensions, percutaneous leads, surgical leads, lead anchors or IPG port plugs) may be within the transmit / receive RF head coil. If receive only head coil is used requirements specified in 'coil positioning restriction zone' shall be met.
 - For 3T scanners: No part of implanted SENZA system (implantable pulse generator (IPG), extensions, percutaneous leads, surgical leads, lead anchors or IPG port plugs) may be within the transmit/receive RF head coil.
- MRI scan parameters:
 - For transmit/receive head coils in 1.5T and 3T scanners: Whole head averaged specific absorption rate (SAR) must be < 3.2 W/kg (Normal Operating Mode).
 - If receive only head coil is used (1.5T only), then the SAR limitation associated with the 'coil positioning restriction zone' specified for full body coils applies (see Figure 1).
 - Whole body average SAR is limited to 0.4 W/Kg and head average SAR is limited to 0.64 W/kg in the 'coil positioning restriction' zone. Please refer to section 'coil positioning restriction zone'.
 - Whole body average SAR is limited to 2 W/Kg (normal operating mode) and the head average SAR is limited to 3.2 W/kg (normal operating mode) in the 'outside coil restriction' zone. Please refer to section 'coil positioning restriction zone'.
- Scan time:
 - 1.5T scanner: Maximum active scan time allowed is 30 minutes per study followed by a minimum wait period of 60 minutes between studies.
 - 3T scanner: Maximum active scan time allowed is 30 minutes per study followed by a minimum wait period of 60 minutes between studies.

Torso Scans

Torso scans (chest, cardiac, spine, pelvis etc) can be safely conducted in patients implanted with SENZA system using 1.5T scanners if the following conditions are met:

- General requirements (Verify with the patient's pain management physician, referring medical facility, implanting physician or a Nevro representative)
 - Do not perform an MRI using the transmit RF body coil if the patient has a Surpass surgical lead (LEAD3005-XX(B)) attached to the Nevro IPG, as this can cause significant heating at the lead tip resulting in serious patient injury and/or device damage. The risks of performing MRI scan with a Nevro IPG connected to a Surpass surgical lead have not been evaluated for transmit RF body coils.
 - 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.

- 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.
- Do not perform MR scan if the patient is implanted with a SENZA System component not listed in Table 1 above.
- Do not conduct an MRI if the implanted Nevro percutaneous lead(s) or lead extension(s) are not connected to the IPG.
- Do not perform an MRI if impedance on any of the conductor path on the lead is greater than or equal to 10 kΩ.
- Body Temperature – Do not perform a scan if the patient’s body temperature is greater than 37°C. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.
 - Do not cover the patient with blankets or heated blankets. Blankets raise the patient’s body temperature and increase the risk of tissue heating, which could cause tissue damage.
- Scanner requirements:
 - Only use horizontal cylindrical (closed) bore MR scanners. Do not use open- bore 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.
 - Only use MR scanners with maximum spatial field gradient of 1900 gauss/cm (19 T/m) or less.
 - Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.
- Allowed coils:
 - For 1.5T scanners:
 - Use of full body coil is allowed if the ‘coil positioning restriction zone’ requirements are met, for patients implanted with any of the components listed in Table 1.
 - Use of full body coil is NOT allowed for patients implanted with the Surpass surgical lead (LEAD3005-xx(B)).
 - For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.
- Implant location restriction:
 - For 1.5T scanners: Please refer to section ‘coil positioning restriction zone’.
 - For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.
- MRI scan parameters:
 - For 1.5T scanners:
 - Whole body average SAR is limited to 0.4 W/Kg and head average SAR is limited to 0.64 W/kg in the ‘coil positioning restriction’ zone. Please refer to section ‘coil positioning restriction zone’.
 - Whole body average SAR is limited to 2 W/Kg (normal operating mode) and the head average SAR is limited to 3.2 W/kg (normal operating mode) in the ‘outside coil restriction’ zone. Please refer to section ‘coil positioning restriction zone’.

- For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.
- Scan time:
 - 1.5T scanner: Maximum active scan time allowed is 30 minutes per study followed by a minimum wait period of 60 minutes between studies.
 - 3T scanner: There are NO allowed coils with 3T scanners for torso scans.

Extremity Scans

Extremity scans (knee, wrist, foot) can be safely conducted in patients implanted with SENZA system using 1.5T and 3T scanners if the following conditions are met:

- General requirements (Verify with the patient's pain management physician, referring medical facility, implanting physician or a Nevro representative)
 - 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.
 - 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.
 - Do not perform MR scan if the patient is implanted with a SENZA System component not listed in Table 1 above.
 - Do not conduct an MRI if the implanted Nevro percutaneous lead(s), surgical lead(s) or lead extension(s) are not connected to the IPG.
 - Do not perform an MRI if impedance on any of the conductor path on the lead is greater than or equal to 10 k Ω .
 - Body Temperature – If a body coil is used (transmit only or transmit/receive), do not perform a scan if the patient's body temperature is greater than 37°C. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.
 - Do not cover the patient with blankets or heated blankets. Blankets raise the patient's body temperature and increase the risk of tissue heating, which could cause tissue damage.
- Scanner requirements:
 - Only use horizontal cylindrical (closed) bore MR scanners. Do not use open bore 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.
 - Only use MR scanners with maximum spatial field gradient of 1900 gauss/cm (19 T/m) or less.
 - Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.
- Allowed coils:
 - For 1.5T scanners:

- Use of receive only, or transmit / receive local coils is allowed for patients implanted with any of the components listed in Table 1.
 - If receive only local coil is used, then the SAR limitation associated with the 'coil positioning restriction zone' specified for full body coils applies (see Figure 1).
 - Only transmit / receive local coils are allowed for patients implanted with the Surpass surgical lead (LEAD3005-xx(B)).
 - For 3T scanners: Use of only transmit / receive local coils is allowed.
- Implant location restriction:
 - For 1.5T scanners:
 - If a receive only local coil is used (with full body coil in the transmit mode): Please follow the requirements set in section 'coil positioning restriction zone'.
 - If a transmit / receive local coil is used: No part of implanted SENZA system (implantable pulse generator (IPG), extensions, percutaneous leads, lead anchors or IPG port plugs) may be within the transmit / receive RF head coil.
 - For 3T scanners: No part of implanted SENZA system (implantable pulse generator (IPG), extensions, percutaneous leads, surgical leads, lead anchors or IPG port plugs) may be within the transmit / receive RF local coil.
- MRI scan parameters:
 - For transmit/receive local coils in 1.5T and 3T scanners: SAR limit must be per Normal Operating Mode.
 - If receive only local coil is used (1.5T only), then the SAR limitation/positioning restriction zone specified for full body coils applies (see Figure 1).
 - Whole body average SAR is limited to 0.4 W/Kg and head average SAR is limited to 0.64 W/kg in the 'coil positioning restriction' zone. Please refer to section 'coil positioning restriction zone'.
 - Whole body average SAR is limited to 2 W/Kg (normal operating mode) and the head average SAR is limited to 3.2 W/kg (normal operating mode) in the 'outside coil restriction' zone. Please refer to section 'coil positioning restriction zone'.
- Scan time:
 - 1.5T scanner: Maximum active scan time allowed is 30 minutes per study followed by a minimum wait period of 60 minutes between studies.
 - 3T scanner: Maximum active scan time allowed is 30 minutes per study followed by a minimum wait period of 60 minutes between studies.

9. 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.

10. Considerations after the MRI Examination

The patient's pain management physician, referring medical facility, implanting physician or a Nevro representative shall perform the following:

- 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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