1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for the SENZA®, SENZA II®, SENZA Omnia™ Systems (IPG1000, IPG1500, IPG2000, and IPG2500)
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CE Mark effective on 4 May 2010

Nevro hereby declares that the Senza®, SENZA II®, SENZA Omnia™ 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.

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Description</th>
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<tbody>
<tr>
<td><img src="image1" alt="MR Conditional" /></td>
<td>MR Conditional</td>
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<td><img src="image2" alt="For USA audiences only" /></td>
<td>For USA audiences only</td>
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<tr>
<td><img src="image3" alt="MR Unsafe" /></td>
<td>MR Unsafe</td>
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<tr>
<td><img src="image4" alt="Manufacturer" /></td>
<td>Manufacturer</td>
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1. Introduction

Nevro® SENZA®, SENZA II®, and SENZA Omnia™ 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®, SENZA II®, and SENZA Omnia™ 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 cylindrical (closed 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. Additional information about Nevro products can be found at Nevro’s website (www.nevro.com/manuals).

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Model Number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nevro IPG(s)</td>
<td>NIPG1000, NIPG1500, NIPG2000, NIPG2500</td>
</tr>
<tr>
<td>Nevro Percutaneous Leads</td>
<td>LEAD10x8-x(B): LEAD1058-50(B), LEAD1058-70(B),</td>
</tr>
<tr>
<td></td>
<td>LEAD1058-90(B)</td>
</tr>
<tr>
<td>Surpass™ Surgical Lead</td>
<td>LEAD3005-xx(B): LEAD3005-50(B), LEAD3005-70(B),</td>
</tr>
<tr>
<td></td>
<td>LEAD3005-90(B)</td>
</tr>
<tr>
<td>Lead Anchors</td>
<td>All models (ACCK5000, ACCK5101, ACCK5200, ACCK5300)</td>
</tr>
<tr>
<td>IPG Port Plug</td>
<td>All models (ACCK7000)</td>
</tr>
<tr>
<td>x = Electrode spacing in mm</td>
<td></td>
</tr>
<tr>
<td>xx = Lead length in cm</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Model Number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Extensions</td>
<td>LEAD2008-xx(B): LEAD2008-25(B), LEAD2008-35(B),</td>
</tr>
<tr>
<td></td>
<td>LEAD2008-60(B)</td>
</tr>
<tr>
<td>xx = Extension length in cm</td>
<td></td>
</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Model Number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Stimulator</td>
<td>EXTS1000</td>
</tr>
<tr>
<td>Patient Remote</td>
<td>PTRC1000, PTRC2500</td>
</tr>
<tr>
<td>Charger</td>
<td>CHGR1000</td>
</tr>
<tr>
<td>Programmer Wand</td>
<td>CLPW1000</td>
</tr>
<tr>
<td>Clinician Programmer</td>
<td>CLPG2000/CLPG2500</td>
</tr>
<tr>
<td>S8 lead adaptors</td>
<td>SADP2008-xx(B)</td>
</tr>
<tr>
<td>M8 lead adaptors</td>
<td>MADP2008-xx(B)</td>
</tr>
</tbody>
</table>
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 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. 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 Conditional**: 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)**: Radiofrequency power absorbed per unit of mass (W/kg).
- **Tesla (T)**: The SI unit of magnetic induction equal to 10^4 gauss (G).
- **Transmit/Receive RF head coil**: 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.

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1 ASTM F2503-13, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”
11096 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 vertical field (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 required. See Section 7 for percutaneous leads or Section 8 for surgical leads 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, surgical 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.
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.
- 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. Contact Nevro technical services for additional information about the expected extent and appearance of the image artifact under various scan conditions.
- Turn stimulation off. This can be done using either the programmer, patient remote, or patient charger by the patient’s pain management physician, referring medical facility, implanting physician, a Nevro representative, or the patient. For instructions on how to turn stimulation, refer to the Patient Manual located at www.nevro.com/manuals.

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 kΩ.
7. Coil Positioning Restriction Zone with Percutaneous Leads (LEAD10x8-xx(B))
(1.5T Full Body Coil only)

Adherence to SAR limitations in ‘coil positioning restriction’ zone for the transmit only and transmit/receive full body MRI coil is required.

**NOTE:**
- The use of a transmit only and transmit/receive 3T full body coil is contraindicated on patients implanted with the SENZA system.
- The ‘coil positioning restriction’ zone must be observed when using a transmit only or transmit/receive full body 1.5T coil. This zone is not applicable to head or local transmit/receive coils if the SENZA system is outside the transmit coil.

*If the isocenter is positioned within the ‘coil positioning restriction’ zone as demonstrated by Zone A in Figure 1,*
- The whole body average SAR shall be limited to 0.4 W/Kg, and the head average SAR shall be limited to 0.6 W/kg.

*If the isocenter is positioned in outside ‘coil positioning restriction’ zone as demonstrated by Zone B in Figure 1,*
- The whole body 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 for percutaneous leads. 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 ‘coil 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.

**Zone A: ‘Coil positioning restriction’ zone**
If the RF coil is centered in this area, then the following SAR restrictions apply:

- Whole body average SAR ≤ 0.4 W/kg
- Head average SAR ≤ 0.6 W/kg.

*Scanning of a patient with percutaneous leads and lead extensions is contraindicated when the patient is positioned within Zone A.

**Zone B: Outside ‘Coil positioning restriction’ zone**
If the RF coil is centered in this area, normal operating mode (whole body average SAR ≤ 2 W/kg and head average SAR ≤ 3.2 W/kg) can be used for scanning.

Zone B: Outside ‘Coil positioning restriction’ zone
If the RF coil is centered in this area, normal operating mode (whole body average SAR ≤ 2 W/kg and head average SAR ≤ 3.2 W/kg) can be used for scanning.
8. Coil Positioning Restriction Zone with Surgical Leads (LEAD3005-xx(B))
(1.5T Full Body Coil only)

Adherence to SAR limitations in the ‘coil positioning restriction’ zone for the transmit only and transmit/receive full body MRI coil is required.

**NOTE:**

- The use of transmit only and transmit/receive 3T full body coil is contraindicated on patients implanted with SENZA system.
- The ‘coil positioning restriction’ zone must be observed when using a transmit only or transmit/receive full body 1.5T coil. This zone is not applicable to head or local transmit/receive coils if the SENZA system is outside the transmit coil.

*SAR restrictions for surgical leads extend over the entire body of the patient. If the isocenter is positioned within the ‘coil positioning restriction’ zone as demonstrated by Zone A in Figure 2,*

- The whole body average SAR shall be limited to 0.24 W/kg, and the head average SAR shall be limited to 0.40 W/kg.

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**Zone A: ‘Coil positioning restriction’ zone**

If isocenter is positioned in this area, then the following SAR restrictions apply:

- The whole body average SAR for Surgical leads is $\leq 0.24$ W/kg.
- The head average SAR for Surgical leads is $\leq 0.40$ W/kg.

*Scanning of a patient with surgical leads and lead extensions is contraindicated when the patient is positioned within Zone A.*

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*Figure 2: Coil positioning restriction zone for Surgical Leads (LEAD3005-xx(B))*
9. Conditions for Use of MRI with SENZA System

The MRI examinations described below 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.

9.1. 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 or Table 2 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 kΩ.
  - 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 vertical field (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 > 3.0T). 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.
  - For scanning at reduced SAR levels, only 1.5 T scanners capable of controlling SAR exposure to fractional limits less than 2 W/kg whole body average SAR or 3.2 W/kg head average SAR are allowed.
• Allowed coils for Head & Neck Scans:
  o For 1.5T scanners:
    ▪ Receive-only head coils, transmit/receive head coils, or transmit/receive body coils are allowed for patients implanted with any of the components listed in Table 1.
    ▪ If a receive-only head coil or transmit/receive body coil is used, then the SAR limitation associated with the ‘coil positioning restriction’ zone specified for full body coils applies (Refer to Figure 1 for percutaneous leads or to Figure 2 for surgical leads).
  o For 3T scanners: Only transmit/receive head coils are allowed.

• Implant location restriction:
  o For 1.5T scanners: If a transmit/receive head coil is used, then no part of the 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. If a receive-only head coil is used requirements specified in ‘coil positioning restriction’ zone shall be met. Refer to Figure 1 for percutaneous leads or to Figure 2 for surgical leads.
  o For 3T scanners: No part of the 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:
  o For transmit/receive head coils in 1.5T and 3T scanners: Head average specific absorption rate (SAR) must be < 3.2 W/kg (Normal Operating Mode).
  o If a receive-only head coil or body transmit/receive coil is used (1.5T only), then the SAR limitation associated with the ‘coil positioning restriction’ zone specified for full body coils applies (Refer to Figure 1 for percutaneous leads or to Figure 2 for surgical leads).

• Scan time:
  o 1.5T scanner: Total active scan time allowed is 30 minutes per study.
  o 3T scanner: Total active scan time allowed is 30 minutes per study.
9.2. Torso Scans using 1.5T

Torso scans (chest, cardiac, spine, pelvis etc) can be safely conducted in patients implanted with the 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 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 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 vertical field (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 > 3.0T). 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.
  - For scanning at reduced SAR levels, only 1.5 T scanners capable of controlling SAR exposure to fractional limits less than 2 W/kg whole body average SAR or 3.2 W/kg head average SAR are allowed.

- **Allowed coils for Torso Scans:**
  - For 1.5T scanners:
    - Use of a full body coil transmit/receive (built-in) or transmit (built-in) with any type of receive-only coil is allowed if the ‘coil positioning restriction’ zone requirements in Section 7 for percutaneous leads or Section 8 for surgical leads are met, for patients implanted with any of the components listed in Table 1.
  - For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.
• Implant location restriction:
  o For 1.5T scanners: Refer to the ‘coil positioning restriction’ zone – Section 7 for percutaneous leads
    Section 8 for surgical leads.
  o For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.

• MRI scan parameters:
  o For 1.5T scanners:
    ▪ Percutaneous Leads: Refer to Section 7 “Coil Positioning Restriction Zone with Percutaneous
      Leads (LEAD10x8-xx(B)).”
    ▪ Surgical Leads: Refer to Section 8 “Coil Positioning Restriction Zone with Surgical Leads
      (LEAD3005-xx(B)).”
  o For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.

• Scan time:
  o 1.5T scanner: Total active scan time allowed is 30 minutes per study.
  o 3T scanner: There are NO allowed coils with 3T scanners for torso scans.
9.3. 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 or Table 2 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 kΩ.
  - 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 vertical field (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 > 3.0T). 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.
  - For scanning at reduced SAR levels, only 1.5 T scanners capable of controlling SAR exposure to fractional limits less than 2 W/kg whole body average SAR or 3.2 W/kg head average SAR are allowed.
• Allowed coils for Extremity Scans:
  o For 1.5T scanners:
    ▪ Use of receive-only local coils, transmit/receive local coils or body transmit/receive coils is allowed for patients implanted with any of the components listed in Table 1.
    ▪ If a receive-only local coil is used, then the SAR limitation associated with the ‘coil positioning restriction’ zone specified for full body coils applies (Refer to Figure 1 for percutaneous leads or to Figure 2 for surgical leads).
  o For 3T scanners: Use of only transmit/receive local coils is allowed.

• Implant location restriction:
  o For 1.5T scanners:
    ▪ If a transmit/receive body coil or a receive-only local coil is used (with full body coil in the transmit mode): Refer to Figure 1 for percutaneous leads or to Figure 2 for surgical leads.
    ▪ If a transmit/receive local coil is used: 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.
  o 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:
  o For transmit/receive local coils in 1.5T and 3T scanners: SAR limit must be per Normal Operating Mode.
  o If a receive-only local coil or transmit/receive body coil is used (1.5T only), then the SAR limitation/positioning restriction zone specified for full body coils applies (Refer to Figure 1 for percutaneous leads or to Figure 2 for surgical leads).

• Scan time:
  o 1.5T scanner: Total active scan time allowed is 30 minutes per study.
  o 3T scanner: Total active scan time allowed is 30 minutes per study.
10. 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.

11. Considerations after the MRI Examination

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

- Turn the IPG on and restore the IPG to pre-MRI settings.

Inform the patient that s/he can contact Nevro to confirm that the IPG has been restored to pre-MRI settings.
## 12. Appendix: SENZA System MRI Scan Checklist

This checklist is provided as an optional resource to support MR centers in conducting and MRI of a patient implanted with the Nevro SENZA system. It is important to read the entire SENZA System MRI Guidelines manual (11096) prior to conducting an MRI scan.

Prior to performing a scan, verify all information with the patient’s pain management physician, the referring medical facility, the implanting physician or a Nevro representative.

### Table 4: SENZA system components eligible for MR conditional full body scans (1.5T only) and Head/Neck & Extremity Scans (1.5T and 3T):

<table>
<thead>
<tr>
<th>Full Body Eligible (1.5T only)</th>
<th>Head/Neck &amp; Extremity Eligible (1.5T and 3T)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ IPG1000</td>
<td>☐ LEAD10x8-xx(B): LEAD1058-50(B), LEAD1058-70(B), LEAD1058-90(B)</td>
</tr>
<tr>
<td>☐ IPG1500</td>
<td>☐ LEAD3005-xx(B): LEAD3005-50(B), LEAD3005-70(B), LEAD3005-90(B)</td>
</tr>
<tr>
<td>☐ IPG2000</td>
<td>☐ IPG2500</td>
</tr>
<tr>
<td>☐ IPG2500</td>
<td></td>
</tr>
</tbody>
</table>

'’-xx’ = Lead length

### Table 5: SENZA system components ONLY eligible for MR conditional Head/Neck & Extremity Scans (1.5T and 3T):

<table>
<thead>
<tr>
<th>Head/Neck &amp; Extremity Scans Only (1.5T and 3T)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ LEAD2008-xx(B): LEAD2008-25(B), LEAD2008-35(B), LEAD2008-60(B)</td>
</tr>
</tbody>
</table>

'’-xx’ = Lead/Extension length

### 12.1. Verify model numbers of implanted SCS system components:

### 12.2. Ensure the following:

- ☐ No abandoned leads: leads or extensions not connected to the IPG
- ☐ No lead electrode impedance is greater than or equal to 10 kΩ
- ☐ Using a horizontal cylindrical (closed bore) MRI
- ☐ Maximum spatial field gradient 1900 gauss/cm (19 T/m) or less
- ☐ Maximum gradient slew rate limited to 200T/m/sec per axis or less
- ☐ Stimulation is turned off

### 12.3. Perform scans per conditions listed below. If conducting an image of the:

<table>
<thead>
<tr>
<th>Percutaneous Leads</th>
<th>Surgical Leads</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEAD10x8-xx(B)</td>
<td>LEAD3005-xx(B)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Head and/or Neck</th>
<th>Section 12.4</th>
<th>Section 12.7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torso</td>
<td>Section 12.5</td>
<td>Section 12.8</td>
</tr>
<tr>
<td>Extremities</td>
<td>Section 12.6</td>
<td>Section 12.9</td>
</tr>
</tbody>
</table>
Head / Neck Scans for Percutaneous Leads (LEAD10x8-xx(B))

1.5T Scanner

Coil Types
- Body Transmit/Receive Coil
- Body Transmit with Receive-only Head Coil

Verify all implanted components are listed in Table 1

Patient’s body temperature ≤ 37°C (no fever)

Isocenter within Zone A*?

Yes

Whole body average SAR ≤ 0.4 W/kg**
Head average SAR ≤ 0.6 W/kg**

No

Whole body average SAR ≤ 2 W/kg
Head average SAR ≤ 3.2 W/kg (Per Normal Operating Mode)

Total active scan time ≤ 30 minutes per study

1.5T or 3T Scanner - Transmit/Receive Head Coil

Coil Types
- Transmit/Receive Head Coil

Verify all implanted components are listed in Table 1 or Table 2

Ensure no part of implanted system is within RF coil

Max. SAR per Normal Operating Mode

Total active scan time ≤ 30 minutes per study

*Zone A = Coil positioning Restriction Zone of Figure 1

** A patient cannot be scanned in the “Coil Positioning Restriction” Zone (Zone A) unless the MR system provides the ability for the operator to control or modify SAR levels to the values stated in the conditions of use.
12.5. Torso Scans for Percutaneous Leads (LEAD10x8-xx(B))

Torso Scans for Percutaneous Leads (LEAD10x8-xx(B))

1.5T Scanner Only

Coil Types
- Body Transmit/Receive Coil
- Body Transmit with Receive-only Local Coil

Verify all implanted components are listed in Table 1

Patient’s body temperature ≤ 37°C (no fever)

Isocenter within Zone A?

Yes
- Whole body average SAR ≤ 0.4 W/kg
  Head average SAR ≤ 0.6 W/kg

No
- Whole body average SAR ≤ 2 W/kg
  Head average SAR ≤ 3.2 W/kg (Per Normal Operating Mode)

Total active scan time ≤ 30 minutes per study

*Zone A = Coil positioning Restriction Zone of Figure 1
** A patient cannot be scanned in the “Coil Positioning Restriction” Zone (Zone A) unless the MR system provides the ability for the operator to control or modify SAR levels to the values stated in the conditions of use.
12.6. Extremity Scans for Percutaneous Leads (LEAD10x8-xx(B))

**Extremity Scans for Percutaneous Leads (LEAD10x8-xx(B))**

**1.5T Scanner**

- **Coil Types**
  - Body Transmit/Receive Coil
  - Body Transmit with Receive-only Local Coil

- Verify all implanted components are listed in Table 1

- Patient’s body temperature ≤ 37°C (no fever)

- Isocenter within Zone A**?

  - Y: Whole body average SAR ≤ 0.4 W/kg**
    - Head average SAR ≤ 0.6 W/kg**
  
  - N: Whole body average SAR ≤ 2 W/kg
    - Head average SAR ≤ 3.2 W/kg (Per Normal Operating Mode)

- Total active scan time ≤ 30 minutes per study

**1.5T or 3T Scanner - Transmit/Receive Local Coil**

- **Coil Types**
  - Transmit/Receive Local Coil

- Verify all implanted components are listed in Table 1 or Table 2

- Ensure no part of implanted system is within RF coil

- Max. SAR per Normal Operating Mode

- Total active scan time ≤ 30 minutes per study

---

*Zone A = Coil positioning Restriction Zone of Figure 1*

** A patient cannot be scanned in the “Coil Positioning Restriction” Zone (Zone A) unless the MR system provides the ability for the operator to control or modify SAR levels to the values stated in the conditions of use.
12.7. Head / Neck Scans for Surgical Leads (LEAD3005-xx(B))

* A patient cannot be scanned in the “Coil Positioning Restriction” Zone (Zone A) unless the MR system provides the ability for the operator to control or modify SAR levels to the values stated in the conditions of use.
12.8. Torso Scans for Surgical Leads (LEAD3005-xx(B))

**Torso Scans for Surgical Leads (LEAD3005-xx(B))**

1.5T Scanner Only

- **Coil Types**
  - Body Transmit/Receive Coil
  - Body Transmit with Receive-only Local Coil

- **Verify all implanted components are listed in Table 1**

- **Patient’s body temperature ≤ 37°C (no fever)**

- **Whole body SAR ≤ 0.24 W/kg**
  - Head SAR ≤ 0.40 W/kg

- **Total active scan time ≤ 30 minutes per study**

* A patient cannot be scanned in the “Coil Positioning Restriction” Zone (Zone A) unless the MR system provides the ability for the operator to control or modify SAR levels to the values stated in the conditions of use.
12.9. Extremity Scans for Surgical Leads (LEAD3005-xx(B))

Extremity Scans for Surgical Leads (LEAD3005-xx(B))

1.5T Scanner

1.5T or 3T Scanner - Transmit/Receive Local Coil

Coil Types
- Body Transmit/Receive Coil
- Body Transmit with Receive-only Local Coil

Verify all implanted components are listed in Table 1

Patient’s body temperature ≤ 37°C (no fever)

Whole body SAR ≤ 0.24 W/kg*
Head SAR ≤ 0.40 W/kg*

Total active scan time ≤ 30 minutes per study

Coil Types
- Transmit/Receive Local Coil

Verify all implanted components are listed in Table 1 or Table 2

Ensure no part of implanted system is within RF coil

Max. SAR per Normal Operating Mode

Total active scan time ≤ 30 minutes per study

* A patient cannot be scanned in the “Coil Positioning Restriction” Zone (Zone A) unless the MR system provides the ability for the operator to control or modify SAR levels to the values stated in the conditions of use.