1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for the SENZA® Neuromodulation Systems

Effective February 2024
For United States of America Only

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CE Mark effective on 4 May 2010

Nevro hereby declares that the SENZA®, SENZA II®, SENZA OMNIA™, and SENZA Bluetooth® 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

Table of Contents

1 Introduction

Nevro SENZA®, SENZA II® and SENZA OMNIA™ Spinal Cord Stimulation (SCS) implantable pulse generators (IPG) 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. SENZA®, SENZA II® and SENZA OMNIA™ will be collectively referenced in this guideline as the Senza system unless otherwise stated. A description of the Senza system components and associated MR classification can be found in Section 2.

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.

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/physicianmanuals).

Contact Nevro Technical Services at +1.650.251.0005 if you have any questions.

An appendix is included at the end of this guideline to determine a patient's eligibility and scan restrictions.

2 Senza System MR Conditional Description

The following tables list model numbers of components that may comprise the Senza system. Additional information about Nevro products can be found at Nevro's website (www.nevro.com/physicianmanuals).

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

MR Conditional

Component	Model Number(s)
Nevro IPG(s)	NIPG1000, NIPG1500, NIPG2000, NIPG2500
Nevro Percutaneous Leads	LEAD10x8-xxB: LEAD1058-50B, LEAD1058-70B, LEAD1058-90B
Surpass® Surgical Lead	LEAD3005-xxB: LEAD3005-50B, LEAD3005-70B, LEAD3005-90B
Surpass-C™ Surgical Lead	LEAD2005-xxB: LEAD2005-50B, LEAD2005-70B, LEAD2005-90B
Lead Anchors	All models (ACCK5000, ACCK5101, ACCK5200, ACCK5300)
IPG Port Plug	All models (ACCK7000)
x = Electrode spacing in mm xx = Lead length in cm	

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

MR Conditional

Component	Model Number(s)
Lead Extensions	LEAD2008-xxB: LEAD2008-25B, LEAD2008-35B, LEAD2008-60B
xx = Extension 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:**

MR Unsafe

Component	Model Number(s)
Trial Stimulator	EXTS1000, EXTS3000
Patient Remote	PTRC1000, PTRC2300, PTRC2500, PTRC3000T
Charger	CHGR1000, CHGR2500
Programmer Wand	CLPW1000
Clinician Programmer	CLPG2000/CLPG2500
S8 lead adaptors	SADP2008-xxB
M8 lead adaptors	MADP2008-xxB
xx = Lead length in cm	

2.1 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.

3 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.

4 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).
- ***B_{1+RMS}*:** Time averaged B_{1+} field measured in micro-Tesla (µT).
- ***Tesla (T)*** [1]: The SI unit of magnetic induction equal to 10^4 gauss (G).
- ***Integrated Body Coil***: The coil built-in to the MRI system that functions both as transmit and received coil and can be used as transmit-only integrated body coil in conjunction with receive-only local coils.
- ***Transmit/Receive head coil***: A coil used to transmit and receive RF energy that is limited to the head only.
- ***Transmit/Receive 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 Stimulator***: In neuromodulation, a portable and external device that allows the patient to test the therapy prior to an IPG (Implantable Pulse Generator) being implanted.
- ***Patient Remote***: The Patient Remote is a handheld device that can turn the stimulation on or off, allows for adjustment of some therapy settings, and allows for impedance checks.

[1] ASTM F2503-20, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"

5 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

6 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 3T MR Scanner

- **Do not** use the integrated body coil for 3T imaging. Only 3T transmit/receive head or local coils may be used under specified conditions.
- Many 3T head and 3T local 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.
- Under no circumstances should the 3T transmit/receive head or local coil be placed over the implanted Senza system (IPG, lead(s), lead extensions, lead anchors or IPG port plugs). Because of this restriction, scanning of the area where the Senza system is implanted is not possible in 3T scanners.

7 Instructions for the MRI Center Prior to MRI Examination

7.1 Scheduling a Patient for an MRI Scan

The following steps shall be performed by the MRI center when scheduling the scan with the patient. Contact Nevro Technical Services if you have any questions.

Step 1: Confirm that the patient's implanted Senza System components are MR Conditional (Table 1 and Table 2).

Step 2: Check 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.

Step 3: Device preparation.

Inform the patient to charge their IPG prior to the MRI examination.

Step 4: What to bring the day of the MRI scan.

Inform the patient to bring their patient ID card and Patient Remote (MR Unsafe) to the MRI scan.

7.2 Preparing a Patient for an MRI Scan

Before conducting an MRI scan, the following steps must be performed. A checklist is included in the appendix to determine a patient's eligibility and scan requirements for an MRI scan. **If there are questions about these instructions, do NOT scan the patient and contact Nevro Technical Services.**

Step 1: Confirm that the patient has brought their patient ID card and Patient Remote (MR Unsafe).

Step 2: Confirm that the patient's implanted Senza System components are MR Conditional (Table 1 and Table 2).

Step 3: Check 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.

Step 4: Confirm that all implanted leads or lead extensions are connected to the IPG.

Do NOT conduct an MRI scan if the implanted lead(s) or lead extension(s) are not connected to the IPG.

Step 5: Document the patient's current program number and stimulation level.

The patient's current therapy information can be found on the Patient Remote or Clinician programmer. This information may be used for restoring the patient's therapy following an MRI scan.

Step 6: Perform an impedance check using the Patient Remote. Refer to Section 8 for instructions.

Do NOT perform an MRI scan if the impedance check on the Patient Remote does not pass or if any impedance is greater than or equal to 10kΩ.

Note: The impedance check cannot be performed using the Patient Remote if a patient is implanted with a single percutaneous lead (LEAD10x8-xxB) or Surpass-C Surgical Lead (LEAD2005-xxB).

Note: If the patient did not bring the Patient Remote, a Clinician Programmer can be used to perform the impedance check by a Nevro representative, the patient's pain management physician, referring medical facility or implanting physician.

Step 7: Turn stimulation off.

Stimulation can be turned off using either the Patient Remote or Clinician Programmer by the patient, Nevro representative, the patient's pain management physician, referring medical facility or implanting physician. For instructions on how to turn stimulation off, refer to the Patient Manual located at http://www.nevro.com/physicianmanuals.

Step 8: Perform the MRI scan per the requirements in the following sections.

- For Head Scans or Neck Scans (**1.5T & 3T**): Section 11.1.
- For Torso Scans (**1.5T only**): Section 11.2.
- For Extremity Scans (**1.5T & 3T**): Section 11.3.

7.3 Additional Information

- 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.
- 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.
- 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 contain image artifacts. Contact Nevro technical services for additional information about the expected extent and appearance of the image artifact under various scan conditions.

8 Conducting an Impedance Check using the Patient Remote

NOTE: The impedance check cannot be performed using the Patient Remote if a patient is implanted with a single percutaneous lead (LEAD10x8-xxB) or Surpass-C Surgical Lead (LEAD2005-xxB). Lead information can be located on the patient ID card or by contacting Nevro Technical Services.

IMPORTANT!

There are 6 steps in the impedance check. All 6 steps must be completed in the order specified prior to the MRI scan. Use the checklist to document that each step is performed.

Contact Nevro Technical Services at +1.650.251.0005 for any Impedance Check questions or if the Patient Remote does not operate as shown below.

8.1 Identify Model Number of Patient Remote

Model number can be determined by visual identification of the Patient Remote or by looking at the label on the back of the Patient Remote (MR Unsafe):

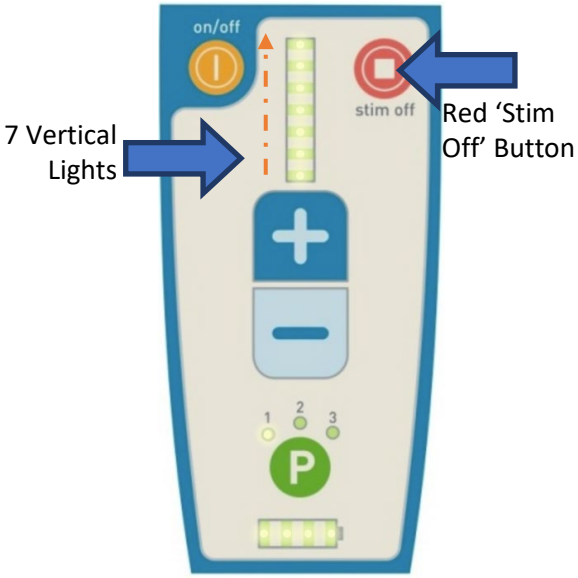
Patient Remote 1000 (PTRC1000)	**Patient Remote 2300 (PTRC2300) or Patient Remote 2500 (PTRC2500)**
Go to Section 8.2.	Go to Section 8.3.
	 
PTRC1000	**PTRC2300** **PTRC2500**

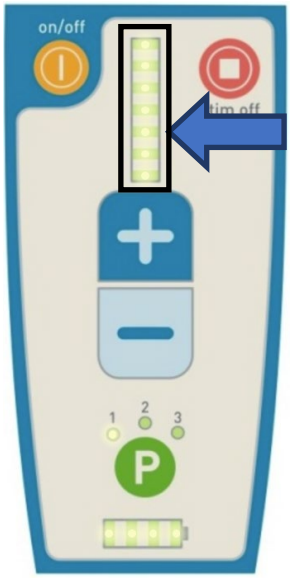
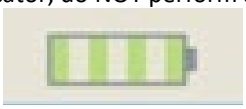
8.2 Conducting an Impedance Check using the Patient Remote 1000 (PTRC1000)

IMPORTANT!

There are 6 steps in the impedance check. All 6 steps must be completed in the order specified prior to the MRI scan. Use the checklist to document that each step is performed.

Contact Nevro Technical Services at +1.650.251.0005 for any Impedance Check questions or if the remote does not operate as shown below.

Step	Result	Checklist
1) Power on the Patient Remote Hold the Patient Remote near the patient. Press the yellow 'ON/OFF' button for up to five seconds until the Patient Remote beeps and turns on. 	**The Patient Remote will beep and turn on.**	☐Pass/Continue to Step 2
2) Press and hold the red 'Stim Off' button until you hear beeping. This should take 10 seconds. 	**After holding the red 'Stim Off' button for 10 seconds, the Patient Remote will beep and the vertical lights will light upwards to display the results of the impedance check.** **PASS:** If you hear a **single long beep**, move forward to Step 3. **FAIL:** If you hear **4 short beeps**, **do NOT perform an MRI.** **If after 10 seconds, no beeps were heard, the impedance check was not performed.** Hold the red 'Stim Off' button until a long beep or 4 short beeps are heard.	☐Pass/Continue to Step 3

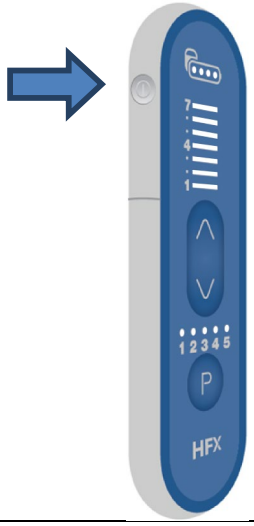
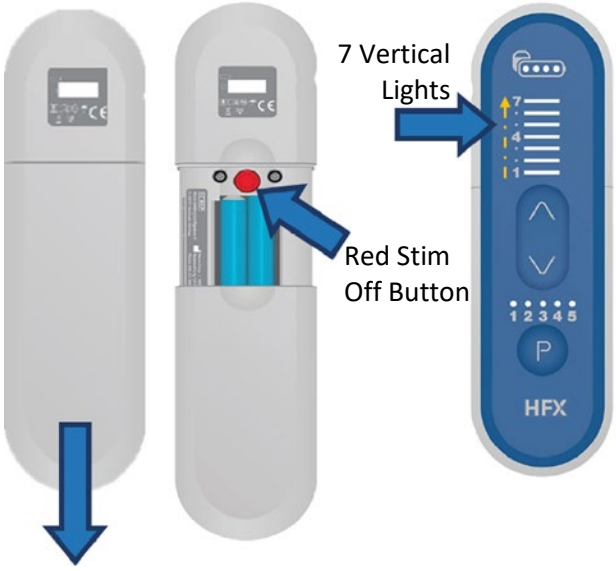
Step	Result	Checklist
3) Interpret Results – Vertical Lights  7 Vertical Lights	**PASS:** If all 7 vertical lights above the '+' button are **lit and not blinking,** move forward to Step 4. **FAIL:** If ANY of the 7 vertical lights above the '+' button are **blinking or not lit, do NOT perform an MRI scan.** **If any of the vertical lights are NOT lit an impedance check was not performed. Call Nevro Technical Services for assistance.**	☐Pass/Continue to Step 4
4) Interpret Results – Battery Lights  4 Battery Lights	**PASS:** All 4 of the battery lights below the 'P' button are **lit and not blinking.** **FAIL:** If any of the battery lights below the 'P' button are **blinking or not lit, do NOT perform an MRI scan.** **If Steps 2, 3 and 4 all had passing results,** the impedance check has passed. Return to Section 7.2 and continue with the MRI preparation. Note: If any light is blinking, including the battery indicator, do NOT perform an MRI scan.  **If unsure of the impedance check results, call Nevro Technical Services for assistance.**	☐Pass/Continue to Step 5
5) (Optional) To repeat the impedance check, press the '+' button.	**The Patient Remote repeats the impedance check.** **Return to Step 3.**	
6) (Optional) Power off the Remote Press the yellow 'ON/OFF' button for up to five seconds.	**The Patient Remote is turned off.**	Return to Section 7.2 and continue with MRI preparation.

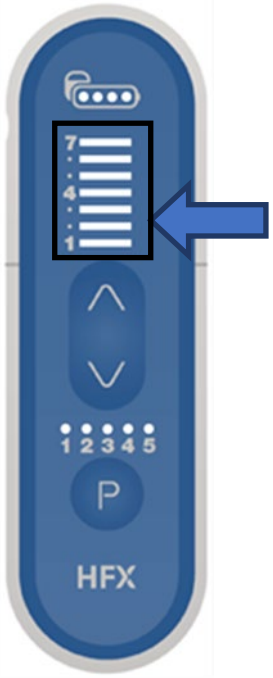
8.3 Conducting an Impedance Check using the Patient Remote model PTRC2300 or PTRC2500

IMPORTANT!

There are 6 steps in the impedance check. All 6 steps must be completed in the order specified prior to the MRI scan. Use the checklist to document that each step is performed.

Contact Nevro Technical Services at +1.650.251.0005 for any Impedance Check questions or if the remote does not operate as shown below.

Step	Result	Checklist
1) Power on the Patient Remote Hold the Patient Remote near the patient. Press the 'ON/OFF' button for up to five seconds until the Patient Remote beeps and turns on. 	**The Patient Remote will beep and turn on.**	☐Pass/Continue to Step 2
2) Turn the Patient Remote over and slide open the battery door. Press and hold the red 'Stim Off' button until you hear beeping. This should take 10 seconds. 	**The red 'Stim Off' button will be accessible.** **After holding the red 'Stim Off' button for 10 seconds, the Patient Remote will beep and the vertical lights will light upwards to display the results of the impedance check.** **PASS:** If you hear a **single long beep**, move forward to Step 3. **FAIL:** If you hear **4 short beeps**, **do NOT perform an MRI scan.** If after 10 seconds, no beeps are heard, the impedance check was not performed. Hold the red 'Stim Off' button until a long beep or 4 short beeps are heard.	☐Pass/Continue to Step 3

Step	Result	Checklist
3) Interpret Results – Vertical Lights  7 Vertical Lights	**PASS:** If all 7 vertical lights above the 'Up' button are **lit and not blinking,** move forward to Step 4. **FAIL:** If ANY of the 7 vertical lights above the 'Up' button are **blinking or not lit, do not perform an MRI.** **If any of the vertical lights are NOT lit, an impedance check was not performed. Call Nevro Technical Services for assistance.**	☐Pass/Continue to Step 4
4) Interpret Results – Battery Lights  4 Battery Lights	**PASS:** All 4 of the battery lights at the top of the remote are **lit and not blinking.** **FAIL:** If any of the battery lights at the top of the Patient Remote are **blinking or not lit, do NOT perform an MRI scan.** **If Steps 2, 3 and 4 all had passing results,** the impedance check has passed. Return to Section 7.2 and continue with MRI preparation. Note: If any light is blinking, including the battery lights, do NOT perform an MRI scan.  **If unsure of the impedance check results, call Nevro Technical Service for assistance.**	
5) (Optional) To repeat the impedance check, press the 'Up' button.	**The Patient Remote repeats the impedance check.** **Return to Step 3.**	
6) (Optional) Power off the Patient Remote Press the 'ON/OFF' button for up to five seconds.	**The Patient Remote is turned off.**	Return to Section 7.2 and continue with MRI preparation.

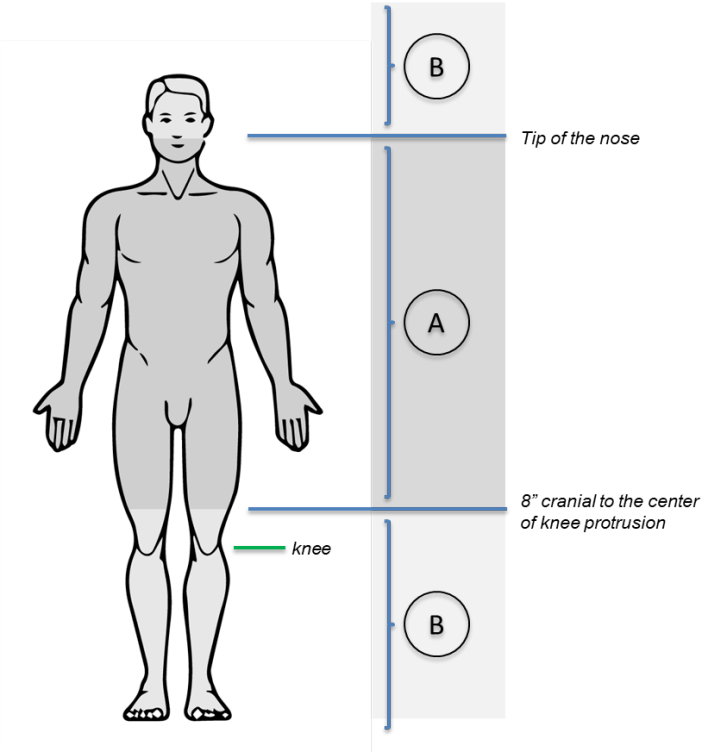
9 Coil Positioning Restriction Zone with Percutaneous Leads
(1.5T Integrated Body Coil Only)

Adherence to B_{1+RMS} or SAR limitations in the 'coil positioning restriction' zone for the *transmit only* and *transmit/receive* integrated body coil is required.

NOTE:

- The use of an integrated transmit only and transmit/receive integrated body coil in 3T scanners is contraindicated on patients implanted with the Senza system.
- The 'coil positioning restriction' zone must be observed when using an integrated transmit only or transmit/receive integrated body coil in 1.5T scanners. This zone is not applicable to head or local transmit/receive coils if the Senza system is outside the transmit coil.

Figure 1: Coil positioning restriction zone for Percutaneous Leads (LEAD10x8-xxB)



If the marker 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 the 'coil positioning restriction' zone (Zone A).

Zone	B_{1+RMS} or SAR Restriction by Zone		
A	B_{1+RMS} < 2.0 µT	OR	Whole Body Average SAR ≤ 0.4 W/kg Head Average SAR ≤ 0.6 W/kg
B	Normal Operating Mode No Restriction on B_{1+RMS}	OR	Normal Operating Mode Whole Body Average SAR ≤ 2.0 W/kg Head Average SAR ≤ 3.2 W/kg

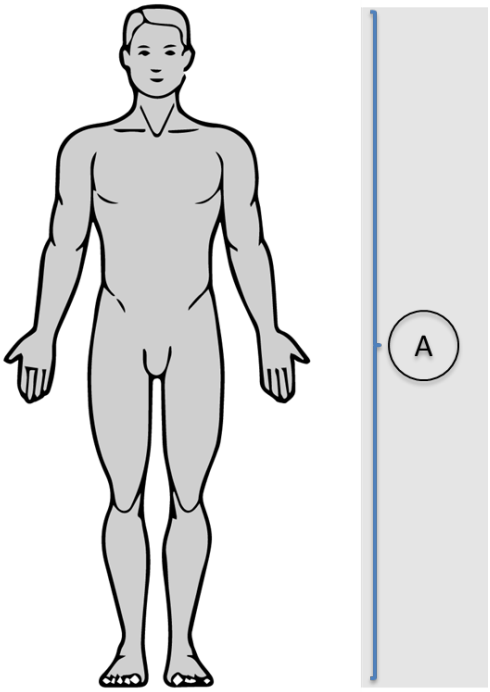
10 Coil Positioning Restriction Zone with Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB) (1.5T Integrated Body Coil Only)

Adherence to B_{1+RMS} or SAR limitations in the 'coil positioning restriction' zone for the integrated *transmit only* and *transmit/receive* integrated body coil is required.

NOTE:

- The use of an integrated transmit only and transmit/receive integrated body coil in 3T MR scanners is contraindicated on patients implanted with Senza system.
- The 'coil positioning restriction' zone must be observed when using an integrated transmit only or transmit/receive integrated body coil in 1.5T scanners. This zone is not applicable to head or local transmit/receive coils if the Senza system is outside the transmit coil.

Figure 2: Coil positioning restriction zone for Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB)



B_{1+RMS} or SAR limitations for the Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB) are applicable only when scanning with 1.5T full body coil (either body transmit/receive coil or body transmit only with receive-only head or local coil) and extend over the entire body of the patient.

Zone	B_{1+RMS} or SAR Restriction by Zone		
A	B_{1+RMS} < 1.6 µT	OR	Whole Body Average SAR ≤ 0.24 W/kg Head Average SAR ≤ 0.40 W/kg

11 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 system can be safely scanned in an MR system meeting the following conditions.

11.1 Head Scans and Neck Scans

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

- General Requirements (Verify with the patients' 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.
  - Do not conduct an MRI if the implanted lead(s) or lead extension(s) are not connected to the IPG.
  - Do not perform an MRI if the impedance check on the Patient Remote does not pass or if impedance on any of the conductor path on the lead is greater than or equal to 10kΩ.
  - Body Temperature – If an integrated 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:
  Note: Do not use vertical field (open bore) MRI systems or systems operating at other static magnetic field strengths. The risk of using MRI systems operating at other static magnetic field strengths has not been evaluated.
  - Only use static magnetic field strengths of 1.5T or 3T.
  - Only use horizontal cylindrical (closed bore) MR scanners.
  - Only use circular polarized (CP) mode coils to transmit (ie quadrature birdcage coils).
  - Only use MR scanners with maximum spatial field gradient of up to 2000 gauss/cm (20 T/m).
  - Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.
  - For scanning at reduced B_{1+RMS} levels, only use 1.5T scanners capable of controlling B_{1+RMS} exposure.
  - For scanning at reduced SAR levels, only use 1.5T 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:
  - For 1.5T scanners:
    - Use of transmit/receive head coils are allowed for patients implanted with any of the components listed in Table 1 and Table 2.
    - Use of integrated body coils (transmit/receive) or receive-only head coils with integrated body coils (transmit-only) are allowed for patients implanted with any of the components listed in Table 1.
    - If an integrated body coil (transmit/receive) or a receive-only head coil is used, then the B_{1+RMS} or SAR limitation associated with the 'coil positioning restriction' zone specified for integrated body coils applies:
      - Percutaneous Leads: Refer to Figure 1 in Section 9.
      - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.
  - For 3T scanners: Only transmit/receive head coils are allowed.

- Implant location restriction:
  - For 1.5T scanners:
    - If a transmit/receive head coil is used, then no part of the Senza system (IPG, lead(s), lead extensions, lead anchors or IPG port plugs) may be within the transmit/receive head coil.
    - If a receive-only head coil is used, the Senza system may be within the head coil, and requirements specified in 'coil positioning restriction' zone shall be met.
      - Percutaneous Leads: Refer to Figure 1 in Section 9.
      - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.
  - For 3T scanners: No part of the implanted Senza system (IPG, leads), lead extensions, lead anchors or IPG port plugs) may be within the transmit/receive head coil.

- MRI scan parameters:
  - 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).
  - If a receive-only head coil or integrated body coil (transmit/receive) is used (1.5T only), then the B_{1+RMS} or SAR limitation associated with the 'coil positioning restriction' zone specified for integrated body coils applies:
    - Percutaneous Leads: Refer to Figure 1 in Section 9.
    - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.

- Scan time:
  - 1.5T scanner: Total active scan time allowed is 30 minutes per study followed by a minimum cooling period of 60 minutes between studies.
  - 3T scanner: Total active scan time allowed is 30 minutes per study followed by a minimum cooling period of 60 minutes between studies.

11.2 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.
  - Do not conduct an MRI if the implanted lead(s) or lead extension(s) are not connected to the IPG.
  - Do not perform an MRI if the impedance check on the Patient Remote does not pass or if impedance on any of the conductor path on the lead is greater than or equal to 10kΩ.
  - 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:
  Note: Do not use vertical field (open bore) MRI systems or systems operating at other static magnetic field strengths. The risk of using MRI systems operating at other static magnetic field strengths has not been evaluated.
  - Only use static magnetic field strengths of 1.5T for torso scans.
  - Only use horizontal cylindrical (closed bore) MR scanners.
  - Only use circular polarized (CP) mode coils to transmit (ie quadrature birdcage coils).
  - Only use MR scanners with maximum spatial field gradient of up to 2000 gauss/cm (20 T/m).
  - Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.
  - For scanning at reduced B_{1+RMS} levels, only use 1.5T scanners capable of controlling B_{1+RMS} exposure.
  - For scanning at reduced SAR levels, only 1.5T 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 scanner:
    - Use of the integrated body coil (transmit/receive) or any type of receive-only coil with integrated body coil (transmit-only) is allowed if the 'coil positioning restriction' zone requirements are met, for patients implanted with any of the components listed in Table 1.
      - Percutaneous Leads: Refer to Figure 1 in Section 9.
      - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.
  - For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.

- Implant location restriction:
  - For 1.5T scanners:
    - Percutaneous Leads: Refer to Figure 1 in Section 9.
    - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.
  - For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.

- MRI scan parameters:
  - For 1.5T scanners:
    - Percutaneous Leads: Refer to Figure 1 in Section 9.
    - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.
  - For 3T scanners: There are NO allowed coils with 3T scanners for torso scans.

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

11.3 Extremity Scans

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

- General Requirements (Verify with the patients' 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 the MR scan if the patient is undergoing the trial phase.
  - Do not perform the MR scan if the patient is implanted with a Senza System component not listed in Table 1 or Table 2.
  - Do not conduct an MRI if the implanted lead(s) or lead extension(s) are not connected to the IPG.
  - Do not perform an MRI if the impedance check on the Patient Remote does not pass or if impedance on any of the conductor path on the lead is greater than or equal to 10kΩ.
  - Body Temperature – If an integrated 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:
  Note: Do not use vertical field (open bore) MRI systems or systems operating at other static magnetic field strengths. The risk of using MRI systems operating at other static magnetic field strengths has not been evaluated.
  - Only use static magnetic field strengths of 1.5T or 3T.
  - Only use horizontal cylindrical (closed bore) MR scanners.
  - Only use circular polarized (CP) mode coils to transmit (ie quadrature birdcage coils).
  - Only use MR scanners with maximum spatial field gradient of up to 2000 gauss/cm (20 T/m).
  - Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.
  - For scanning at reduced B_{1+RMS} levels, only use 1.5T scanners capable of controlling B_{1+RMS} exposure.
  - For scanning at reduced SAR levels, only 1.5T scanners capable of controlling SAR exposure to fractional limits less than or equal to 2 W/kg whole body average SAR or 3.2 W/kg head average SAR are allowed.

- Allowed coils for Extremity Scans:
  - For 1.5T scanners:
    - Use of transmit/receive local coils are allowed for patients implanted with any of the components listed in Table 1 and Table 2.
    - Use of integrated body coils (transmit/receive) or receive-only local coils with integrated body coil (transmit-only) are allowed for patients implanted with any of the components listed in Table 1.
    - If a receive-only head coil or integrated body coil (transmit/receive) is used, then the SAR limitation associated with the 'coil positioning restriction' zone specified for integrated body coils applies:
      - Percutaneous Leads: Refer to Figure 1 in Section 9.
      - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.
  - For 3T scanners: Only transmit/receive local coils are allowed.

- Implant location restriction:
  - For 1.5T scanners:
    - If a receive-only local coil is used, the Senza system may be within the local coil, and the requirements specified in 'coil positioning restriction' zone shall be met.
      - Percutaneous Leads: Refer to Figure 1 in Section 9.
      - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.
    - If a transmit/receive local coil is used: No part of the Senza system (IPG, leads, lead extensions, lead anchors or IPG port plugs) may be within the transmit/receive local coil.
  - For 3T scanners: No part of the implanted Senza system (IPG, leads, lead extensions, lead anchors or IPG port plugs) may be within the transmit/receive local coil.

- MRI scan parameters:
  - For transmit/receive local coils in 1.5T and 3T scanners: Whole body average specific absorption rate (SAR) must be ≤ 2.0 W/kg (Normal Operating Mode).
  - If a receive-only local coil or integrated body coil (transmit/receive) is used (1.5T only), then the B_{1+RMS} or SAR limitation associated with the 'coil positioning restriction' zone specified for integrated body coils applies:
    - Percutaneous Leads: Refer to Figure 1 in Section 9.
    - Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Figure 2 in Section 10.

- Scan time:
  - 1.5T scanner: Total active scan time allowed is 30 minutes per study followed by a minimum cooling period of 60 minutes between studies.
  - 3T scanner: Total active scan time allowed is 30 minutes per study followed by a minimum cooling period of 60 minutes between studies.

12 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.

13 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. This can be done using the Patient Remote (MR Unsafe).
- To turn stimulation back ON, power the Patient Remote ON and then press the '+' or 'Up' button to turn stimulation ON. You will hear a beep and see at least one vertical light to indicate stimulation is ON. Ensure the program number and stimulation level is correct.

Inform the patient that s/he can contact Nevro to confirm that the IPG has been restored to pre-MRI settings.

14 Appendix: Senza System MRI Scan Checklist

This checklist is provided as an optional resource to support MRI centers in conducting an 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.

Patient Name:	

☐ **Step 1: Confirm that the patient has brought their patient ID card and Patient Remote (MR Unsafe).**

☐ **Step 2: Verify model numbers of implanted Senza System components**

Component	**Model Number**	**Full Body Eligible (1.5T only)**	**Head/Neck & Extremity Eligible (1.5T and 3T)**
Nevro IPG(s)	NIPG1000, NIPG1500, NIPG2000, NIPG2500	☐	☐
Nevro Percutaneous Leads	LEAD10x8-xxB: LEAD1058-50B, LEAD1058-70B, LEAD1058-90B	☐	☐
Surpass® Surgical Leads	LEAD3005-xxB: LEAD3005-50B, LEAD3005-70B, LEAD3005-90B	☐	☐
Surpass-C™ Surgical Lead	LEAD2005-xxB: LEAD2005-50B, LEAD2005-70B, LEAD2005-90B	☐	☐
Lead Extensions	LEAD2008-xxB: LEAD2008-25B, LEAD2008-35B, LEAD2008-60B	NOT Eligible	☐
Lead Anchors	All models (ACCK5000, ACCK5101, ACCK5200, ACCK5300)	☐	☐
IPG Port Plug	All models (ACCK7000)	☐	☐
x = Electrode spacing in mm xx = Lead length in cm			

☐ **Step 3: Check 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.

☐ **Step 4: Confirm that all implanted leads or lead extensions are connected to the IPG.**

☐ **Step 5: Document the patient's current program number and stimulation level.**

Current Program Number:	
Current Stimulation level:	

☐ **Step 6: Perform an impedance check. Refer to Section 8 for detailed instructions.**
Do NOT perform an MRI scan if the impedance check on the Patient Remote does not pass or if any impedance is greater than or equal to 10kΩ.

☐ **Step 7: Stimulation is turned off.**

Step 8: Verify the following MR scanner requirements and perform scans per checklists listed below.
☐ Using a horizontal cylindrical (closed bore) MRI
☐ Maximum spatial field gradient of up to 2000 gauss/cm (20 T/m) or less
☐ Maximum gradient slew rate limited to 200T/m/sec per axis or less

	Percutaneous Leads (LEAD10x8-xxB)	**Surpass® Surgical Leads (LEAD3005-xxB) or Surpass™ Surgical Leads (LEAD2005-xxB)**
Head and Neck Scans (1.5T & 3T)	Section 14.1	Section 14.4
Torso Scans (1.5T)	Section 14.2	Section 14.5
Extremity Scans (1.5T & 3T)	Section 14.3	Section 14.6

14.1 Head/Neck Scans for Percutaneous Leads (LEAD10x8-xxB)

Head / Neck Scans for Percutaneous Leads (LEAD10x8-xxB)

1.5T Scanner

- **Coil Types**
  - Integrated Body Coil (Transmit/Receive)
  - Integrated Body Coil (Transmit-only) 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*?
  - y:
    - B_{1+RMS} < 2.0 µT** OR Whole body average SAR ≤ 0.4 W/kg** Head average SAR ≤ 0.6 W/kg**
  - n:
    - Whole body average SAR ≤ 2.0 W/kg Head average SAR ≤ 3.2 W/kg (Normal Operating Mode)
- Total active scan time ≤ 30 minutes per study followed by a minimum wait period of 60 minutes between studies

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 head coil
- Max. SAR per Normal Operating Mode
- Total active scan time ≤ 30 minutes per study followed by a minimum wait period of 60 minutes between studies

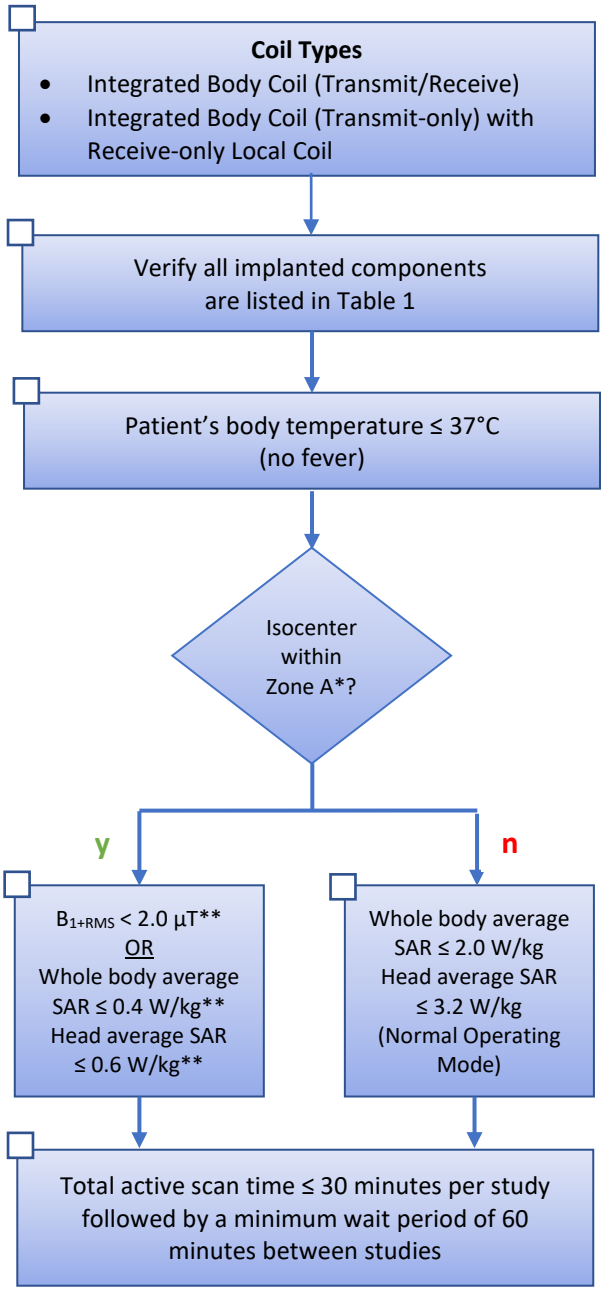
*Zone A = Coil positioning Restriction Zone of Figure 1

** 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 B_{1+RMS} or SAR levels to the values stated in the conditions of use.

14.2 Torso Scans for Percutaneous Leads (LEAD10x8-xxB)

Torso Scans for Percutaneous Leads (LEAD10x8-xxB)

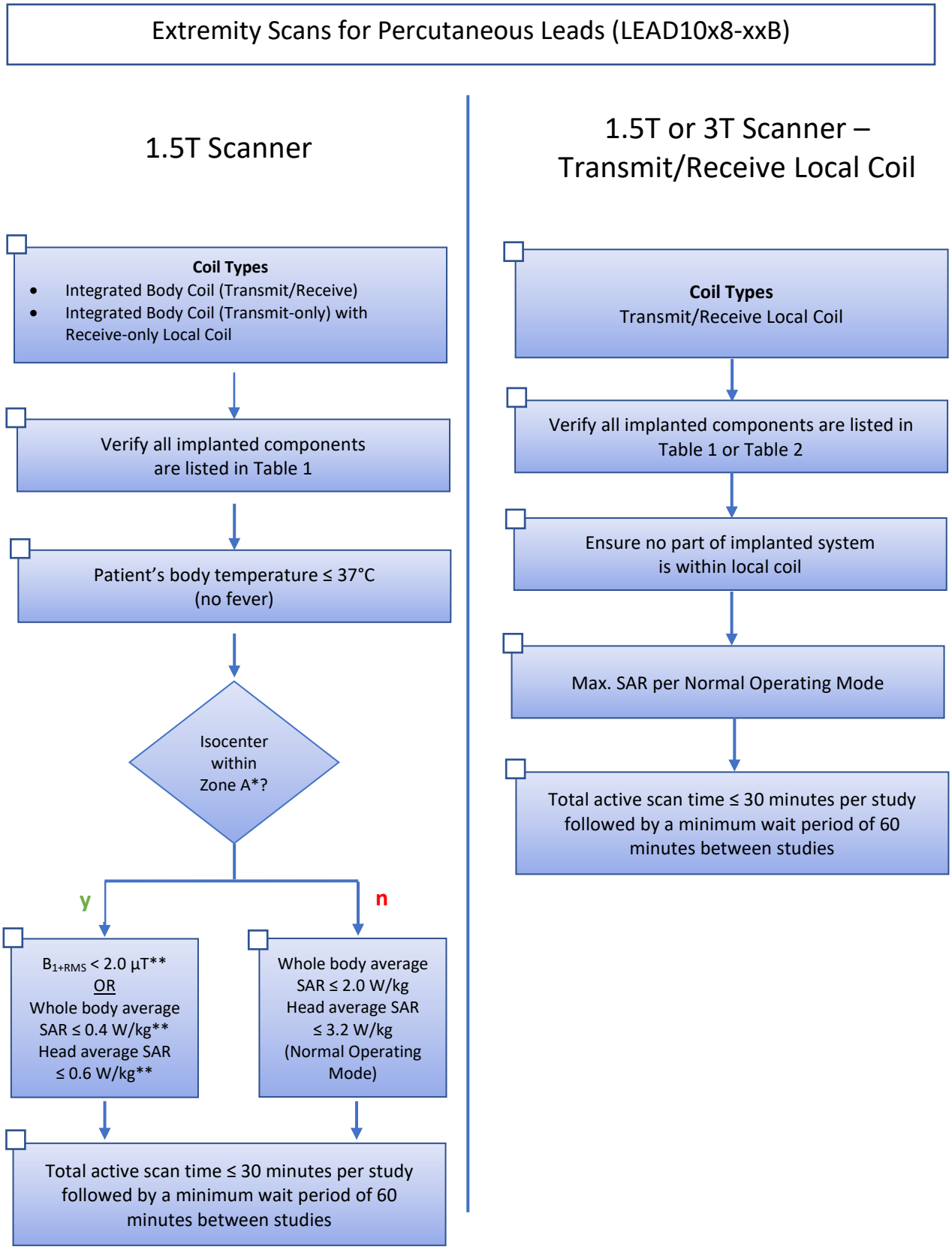
1.5T Scanner Only



*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 B_{1+RMS} or SAR levels to the values stated in the conditions of use.

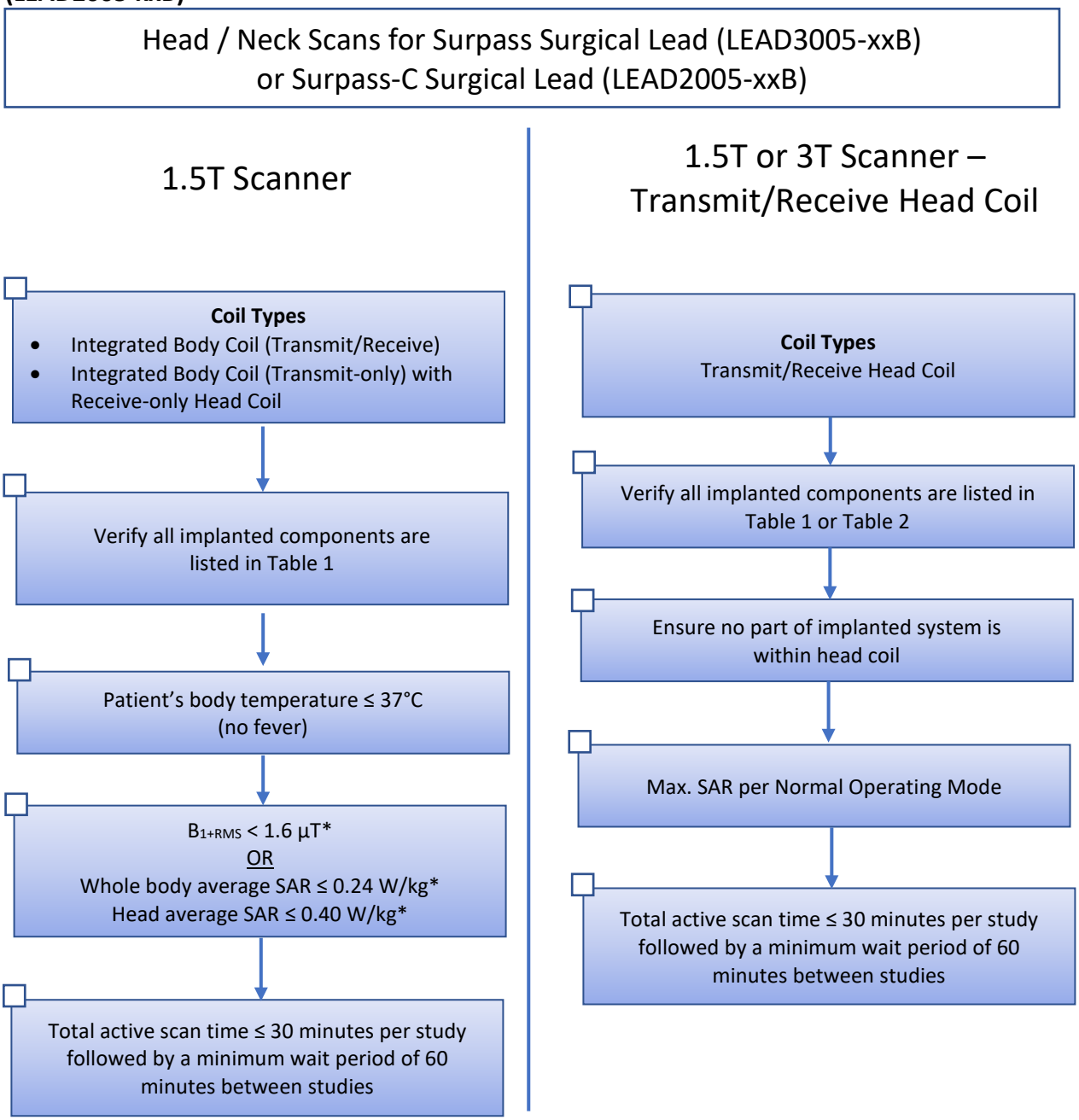
14.3 Extremity Scans for Percutaneous Leads (LEAD10x8-xxB)



*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 B_{1+RMS} or SAR levels to the values stated in the conditions of use.

14.4 Head/Neck Scans for Surpass Surgical Lead (LEAD3005-xxB) or Surpass-C Surgical Lead (LEAD2005-xxB)

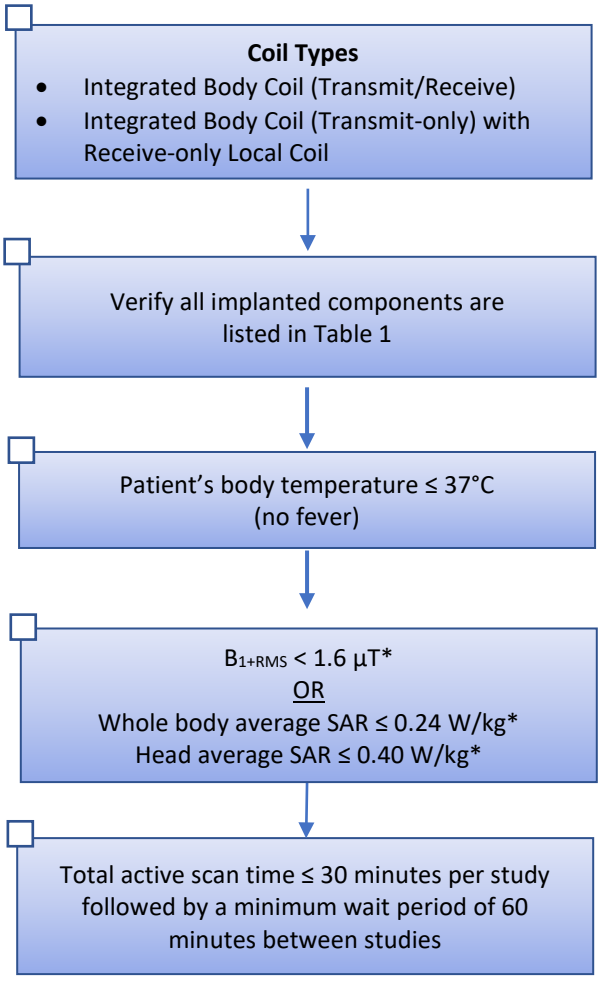


* A patient cannot be scanned in the "Coil positioning Restriction" Zone (Zone A) unless the MR system provides the ability for the operator to control or modify B_{1+RMS} or SAR levels to the values stated in the conditions of use.

14.5 Torso Scans for Surpass Surgical Lead (LEAD3005-xxB) or Surpass-C Surgical Lead (LEAD2005-xxB)

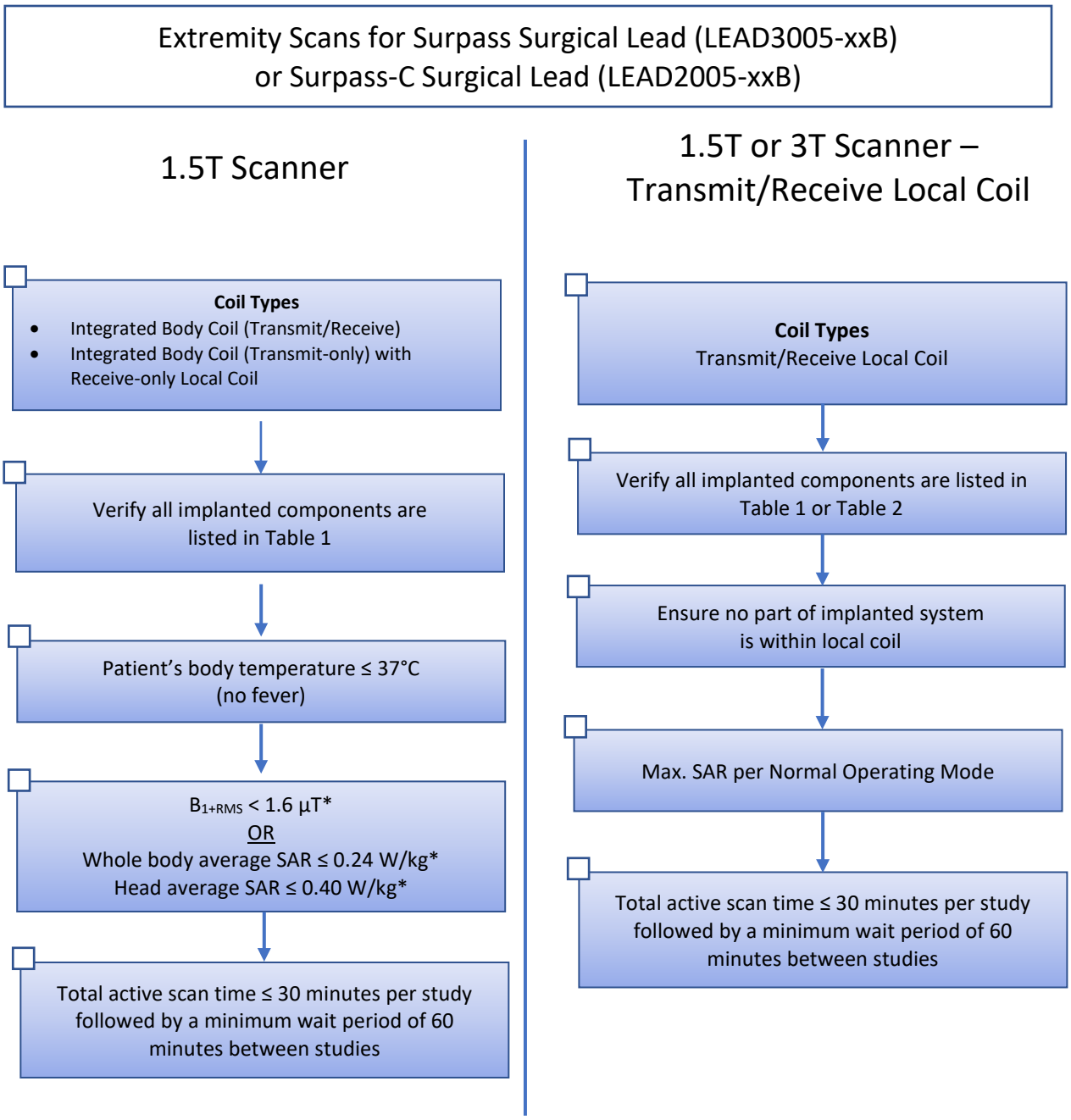
Torso Scans for Surpass Surgical Lead (LEAD3005-xxB)
or Surpass-C Surgical Lead (LEAD2005-xxB)

1.5T Scanner Only



* 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 B_{1+RMS} or SAR levels to the values stated in the conditions of use.

14.6 Extremity Scans for Surpass Surgical Lead (LEAD3005-xxB) or Surpass-C Surgical Lead (LEAD2005-xxB)



* 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 B_{1+RMS} or SAR levels to the values stated in the conditions of use.

NEVRO CORP.

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