1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for Senza® HFX iQ™ System

Effective July 2024

For United States of America only

℞ ONLY

All questions or concerns about Nevro Corp. products, including any serious incident that has occurred in relation to the device, should be forwarded to:

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Nevro hereby declares that the Senza® HFX iQ™ System is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive (2014/53/EU) and U.S. FCC CFR 47 Part 15.

IMPORTANT: Do not change or modify any component of the Senza® HFX iQ™ System, unless expressly approved by Nevro Corp.

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

CONTENTS

1 EXPLANATION OF SYMBOLS ON THE PRODUCT OR LABELING

SYMBOLS	DESCRIPTION
 MR Conditional	MR Conditional
 MR Unsafe	MR Unsafe

2 DEVICE AND PRODUCT DESCRIPTION

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.

The Nevro Senza® HFX iQ™ Implantable Pulse Generator (IPG) is an MR Conditional device that has been demonstrated to present no known hazards in a specified MR environment when following specific guidelines as described in this document. Senza® HFX iQ™ System will be 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 2.2.

This document is a supplement to the Senza ® HFX iQ™ Physician Implant, Patient, and Patient Application 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® HFX iQ™ IPG.

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 +1.888.895.8105 if you have any questions.

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

2.1 Definitions 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.
- **MR Unsafe**[1]: An item which poses unacceptable risks within the MR environment.
- **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 receive coil and can be used as transmit-only integrated body coil in conjunction with receive-only head or 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) stimulation 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 stimulation prior to an Implantable Pulse Generator (IPG) being implanted.
- **Implantable Pulse Generator (IPG)**: A small, battery-powered electronic device that is implanted inside the body to deliver stimulation.
- **MRI Mode**: MRI Mode is a function of the IPG that allows patients to safely receive an MRI scan. The IPG can be placed into and taken out of MRI Mode by using the HFX Patient Application. A Clinician Programmer can also be used to take the IPG out of MRI Mode.
- **HFX Patient Application (HFX App)**: The HFX Patient Application is an application on a mobile device that can turn the stimulation on or off, allows for adjustment of some stimulation settings, enables/disables MRI Mode, and allows for impedance checks.
- **Remote Control**: The Remote Control is a handheld device that can turn the stimulation on or off, allows for adjustment of some stimulation 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”

2.2 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.

	Component	Model Number(s)
	Implantable Pulse Generator	NIPG3000
	Percutaneous Leads	LEAD10x8-xx(B): LEAD1058-50(B), LEAD1058-70(B), LEAD1058-90(B)
	Surpass® Surgical Leads	LEAD3005-xx(B): LEAD3005-50(B), LEAD3005-70(B), LEAD3005-90(B)
	Surpass-C™ Surgical Leads	LEAD2005-xxB: LEAD2005-50B, LEAD2005-70B, LEAD2005-90B
	Lead Anchors	All models (ACCK5000, ACCK5101, ACCK5200, ACCK5300)
	IPG Port Plug	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:

	Component	Model Number(s)
	Lead Extensions	LEAD2008-xx(B): LEAD2008-25(B), LEAD2008-35(B), LEAD2008-60(B)
	xx = Extension length in cm	

Table 3: Senza System components that are **MR Unsafe**. **DO NOT bring these components into the MR scanner room.**

	Component	Model Number(s)
	S8 Lead Adaptors	SADP2008-xx(B): SADP2008-25(B)
	M8 Lead Adaptors	MADP2008-xx(B): MADP2008-25(B)
	Trial Stimulator	EXTS3000, EXTS3500
	Remote Control	PTRC3000T, PTRC3000
	Charger	CHGR1000, CHGR2500
	Clinician Programmer	CLPG2000, CLPG2500
	xx = Lead length in cm	

2.3 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 and to confirm the model number(s) of the implanted system.

3 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

4 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.

4.1 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.

DO NOT place the 3T transmit/receive head or local coil over the implanted Senza System (IPG, leads, lead extensions, lead anchors or IPG port plugs).

5 INSTRUCTIONS FOR THE MRI CENTER PRIOR TO MRI EXAMINATION

5.1 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 implanted Senza System is 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 either their mobile device with HFX App or their Remote Control (MR Unsafe) to the MRI scan. Note: Their mobile device and their Remote Control cannot be taken into the MRI room.

5.2 Preparation Prior to MRI Examination

Before conducting an MRI scan, the following 7 steps must be performed. All 7 steps must be completed prior to the MRI scan. A checklist is included in the appendix of this manual to assist in determining a patient's eligibility and scan requirements. **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 either their mobile device with HFX App or their Remote Control (MR Unsafe).

Step 2: Confirm that the implanted Senza System is 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 and that there are no lead fragments with the patient's pain management physician, referring medical facility or implanting physician.

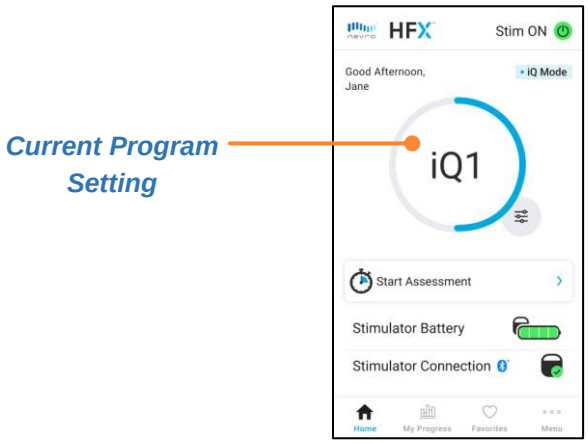
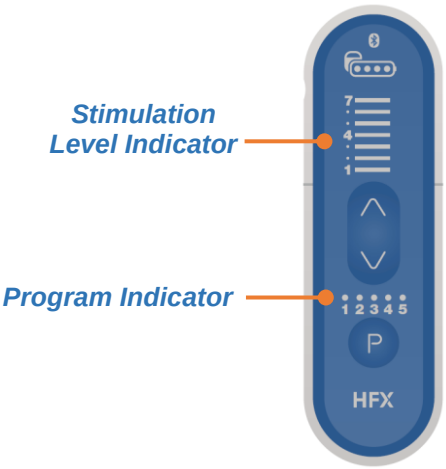
WARNING!

DO NOT conduct an MRI scan if the implanted lead(s) are not connected to the IPG or if there are any lead fragments. Scanning patients with lead(s) that are not connected to the IPG or who have lead fragments may cause excessive heating of or around the implanted components.

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

The patient's current stimulation information can be found on the HFX App or Remote Control. This information may be used for restoring the patient's stimulation following the MRI scan.

Note: If the stimulation information cannot be recorded using the HFX App or Remote Control, the HFX Care Team, the patient's pain management physician, referring medical facility or implanting physician can use the Clinician Programmer to document the patient's current stimulation information.

Using the HFX App	**Using the Remote Control**
 Note: The patient's current program setting in the HFX App may appear as their initials followed by a number.	

Step 6: Depending on the type of MRI coil used for the scan, prepare the IPG using either the HFX App or Remote Control (Table 4 and Table 5).

Table 4: Instructions to Prepare the IPG for Scanning with Integrated Body Coil

Integrated Body Coil with or without Receive-only Coils (1.5T Only)	
If the IPG cannot enter MRI Mode using the HFX App or if the impedance check on the Remote Control does not pass, **DO NOT** perform the MRI scan and contact Nevro Technical Services.	
Using the HFX App	**Using the Remote Control**
1. Place the IPG into MRI Mode using the HFX App (refer to Section 6 for instructions). MRI Mode is a function of the IPG that allows patients to safely receive an MRI scan. This function will check impedances and turn stimulation off.	1. Perform an impedance check using the Remote Control (refer to Section 7 for instructions). The impedance check will check impedances and turn stimulation off.

Table 5: Instructions to Prepare the IPG for Scanning with Transmit/Receive Head or Local Coil

Transmit/Receive Head or Local Coil (1.5T & 3T)	
Using the HFX App	**Using the Remote Control**
1. Turn stimulation off. For instructions on how to turn stimulation off, refer to the HFX App Manual (10001171 for software version 1.0 or 10002273 for software version 2.0) located at http://www.nevro.com/physicianmanuals.	1. Turn stimulation off. For instructions on how to turn stimulation off, refer to the Patient Manual (10001170) located at http://www.nevro.com/physicianmanuals.

Step 7: Perform the MRI scan per the requirements in:

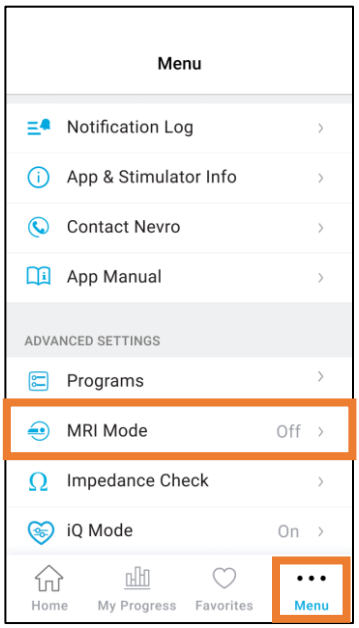
- For Head / Neck or Extremity Scans
  - Section 10 if using Transmit/Receive Head or Local Coil (**1.5T & 3T**)
  - Section 11 if using Integrated Body Coil (**1.5T only**) with or without receive-only coils
- For Torso Scans
  - Section 11 if using Integrated Body Coil (**1.5T only**) with or without receive-only coils

5.3 Additional Information

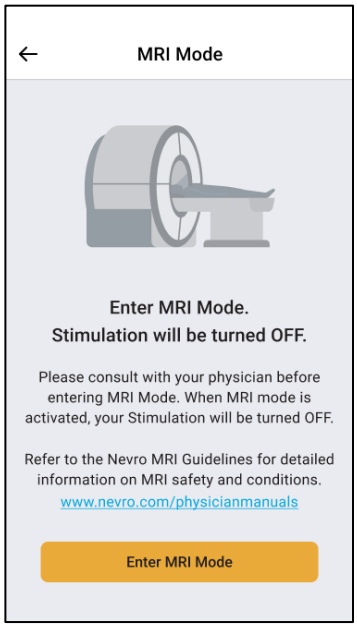
- A trained professional with the proper knowledge of MRI equipment such as an MRI technologist, MRI-trained radiologist or MRI physicist must ensure the MRI examination will be conducted according to the information outlined in this document.
- Inform the patients of all the risks associated with undergoing an MRI examination as stated in this document.
- Always consult with the physician responsible for managing the patient's SCS system for any questions related to use of MRI and implanted SCS system.
- **DO NOT** sedate the patient, so the patient can inform the MRI technologist of any problems during the examination.
- Instruct the patient to immediately inform the MRI technologist 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.

6 MRI MODE USING HFX PATIENT APPLICATION

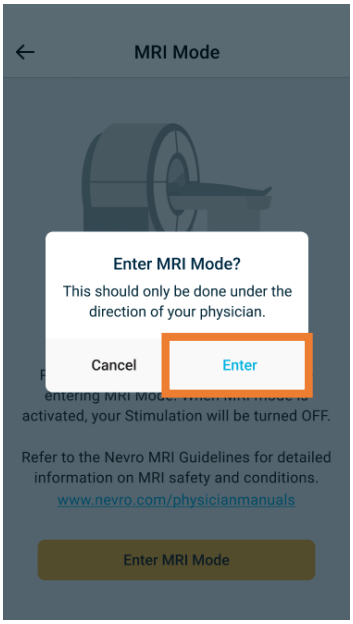
6.1 To Enter MRI Mode



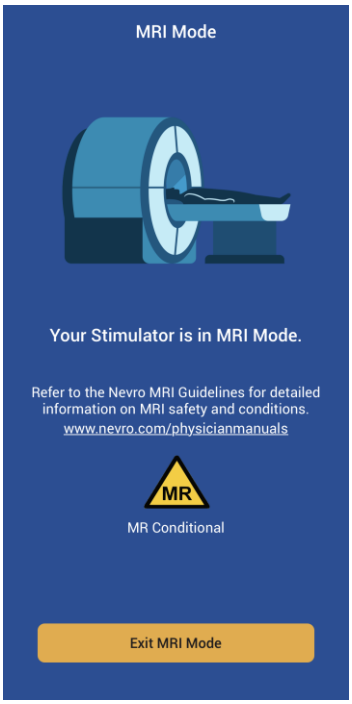
1. At the bottom of the Home Screen, tap **Menu.**
2. Under Advanced Settings, tap **MRI Mode**.



3. Click on the **Enter MRI Mode** button.



4. The following popup will appear. Tap **Enter** to enter MRI Mode. This will turn off stimulation.

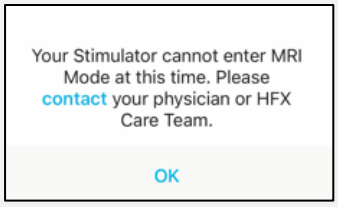


5. If the IPG successfully entered MRI Mode, the MRI Mode ON screen will appear. Once you enter MRI Mode, your stimulator will be turned off. You will not be able to use your HFX App while you are in MRI Mode.

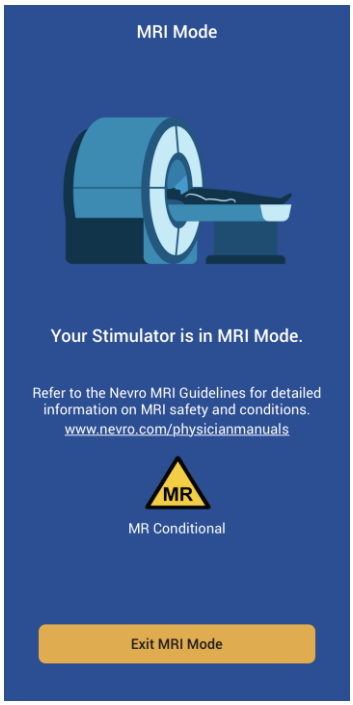
   Continue with Step 7 of Section 5.2.

WARNING!

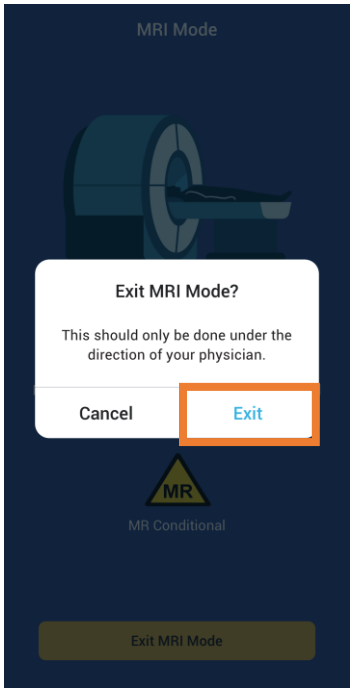
If the IPG fails to enter MRI Mode, **DO NOT** proceed with the MRI scan and contact the patient's physician or HFX Care Team for assistance.



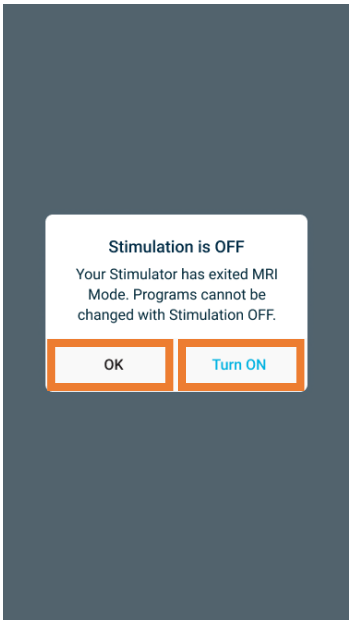
6.2 To Exit MRI Mode



1. From the MRI Mode screen, tap on the **Exit MRI Mode** button.



2. Tap **Exit** to exit MRI Mode. This will not turn on stimulation.



3. After successfully exiting MRI Mode, tap **Turn ON** to resume stimulation.

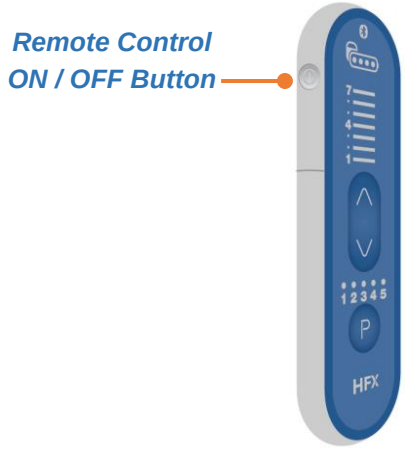
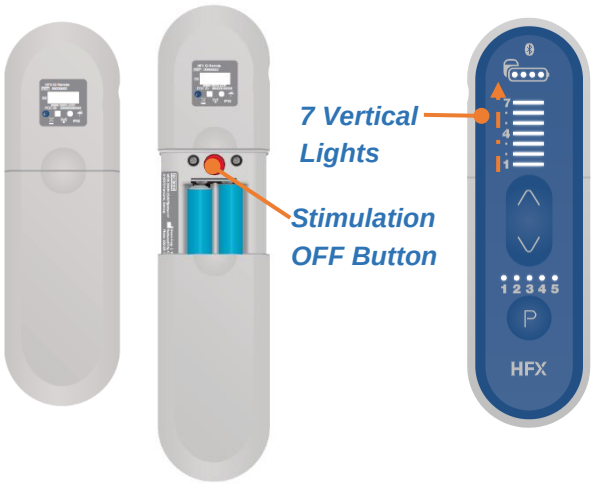
   If you do not wish to resume stimulation at this time, tap **OK**.

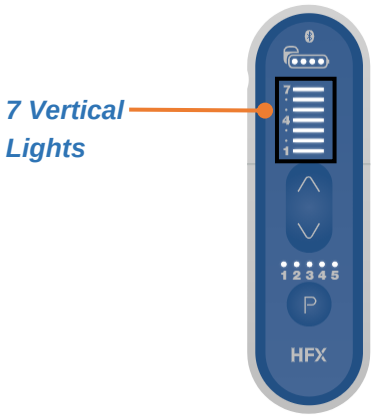
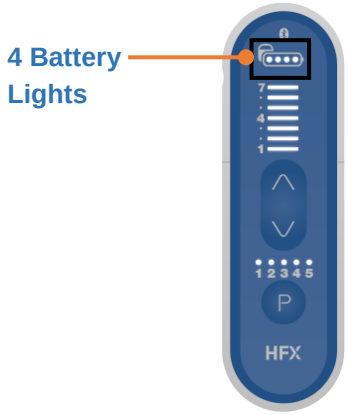
7 CONDUCTING AN IMPEDANCE CHECK USING THE HFX IQ REMOTE

Contact Nevro Technical Services at +1.888.895.8105 for any Impedance Check questions or if the Remote Control does not operate as shown below.

WARNING!

There are 4 steps in the impedance check. All 4 steps must be completed in the order specified prior to the MRI scan. Use the checklist to document that each step is performed.

Step	Result	Checklist
1. Power on the Remote Control (MR Unsafe). Hold the Remote Control near the patient. Press the 'ON/OFF' button for up to five seconds until the Remote Control beeps and turns on. 	The Remote Control will beep and turn on.	☐ Pass/Continue to Step 2
2. Turn the Remote Control over and slide open the battery compartment. Press and hold the red 'Stimulation OFF' button until you hear beeping. This should take 10 seconds. 	The red 'Stimulation Off' button will be accessible. After holding the red 'Stimulation OFF' button for 10 seconds, the Remote Control will beep and 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 'Stimulation OFF' button until a long beep or 4 short beeps are heard.	☐ Pass/Continue to Step 3

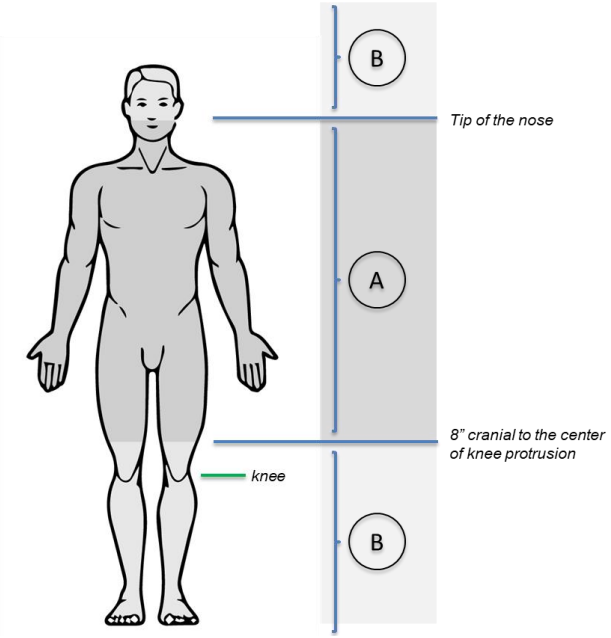
Step	Result	Checklist
3. Interpret Results – Vertical Lights  	**PASS**: If all 7 stimulation level indicator lights above the 'Up' button are not blinking, move forward to Step 4. **FAIL**: If ANY of the 7 stimulation level indicator lights above the 'Up' button are blinking, **DO NOT** perform an MRI. Call Nevro Technical Services for assistance. If any of the stimulation level indicator 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  	**PASS**: All 4 of the battery level indicator lights at the top of the Remote Control are not blinking. **FAIL**: If any of the battery level indicator lights at the top of the Remote Control are blinking, **DO NOT** perform an MRI scan. Call Nevro Technical Services for assistance. **If Steps 2, 3 and 4 all had passing results,** the impedance check has passed. Continue with Step 7 of Section 5.2. 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 Services for assistance.**	Return to Section 5.2 and continue with MRI preparations.

8 COIL POSITIONING RESTRICTION ZONE WITH PERCUTANEOUS LEADS (1.5T INTEGRATED BODY COIL ONLY)

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.

NOTE: When the isocenter is within the 'coil positioning restriction zone,' adherence to B_{1+RMS} or SAR limitations 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 transmit/receive head or transmit/receive local coils if the Senza System is outside the transmit coil.

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



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).

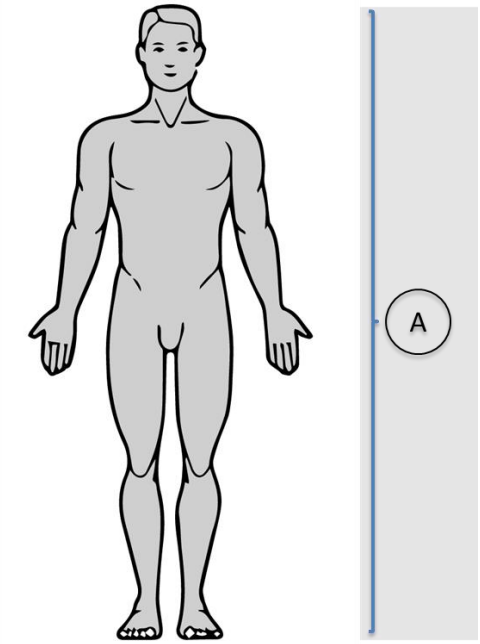
Zone	RF Restriction by Zone
A	B_{1+RMS} < 2.0 µT Whole Body Average SAR ≤ 0.4 W/kg or Head Average SAR ≤ 0.6 W/kg For scanners that do not display both B_{1+RMS} and Whole-Body Average SAR values, we recommend using only Whole-Body Average or Head Average SAR.
B	Normal Operating Mode Whole Body Average SAR ≤ 2.0 W/kg or Head Average SAR ≤ 3.2 W/kg limited by scanner per normal operating mode. No additional limitation on B_{1+RMS} or SAR.

9 COIL POSITIONING RESTRICTION ZONE WITH SURPASS SURGICAL LEADS (LEAD3005-XX(B)) OR SURPASS-C SURGICAL LEADS (LEAD2005-XXB) (1.5T INTEGRATED BODY COIL ONLY)

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.

NOTE: When the isocenter is within the 'coil positioning restriction zone,' adherence to B_{1+RMS} or SAR limitations 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 transmit/receive head or transmit/receive local coils if the Senza System is outside the transmit coil.

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



B_{1+RMS} or SAR limitations for the Surpass Surgical Leads or Surpass-C Surgical Leads are applicable only when scanning with 1.5T integrated 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	RF Restriction by Zone
A	B_{1+RMS} < 1.6 µT Whole Body Average SAR ≤ 0.24 W/kg or Head Average SAR ≤ 0.40 W/kg For scanners that do not display both B_{1+RMS} and Whole-Body Average SAR values, we recommend using only Whole-Body Average or Head Average SAR.

10 HEAD / NECK AND EXTREMITY SCANS WITH TRANSMIT/RECEIVE HEAD OR LOCAL COIL (1.5T OR 3T)

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

10.1 General Requirements

Verify with the patients' pain management physician, referring medical facility, implanting physician or Nevro Technical Services.

- **DO NOT** perform an MRI if the patient has a device or device component (leads, lead extension, etc) from a different manufacturer attached to the Nevro IPG. The risks of performing MRI scan with a Nevro IPG connected to leads manufactured by a different company have not been evaluated.

10.2 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 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) or less.
- Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.

10.3 Allowed coils for Head / Neck & Extremity Scans:

- For 1.5T scanners:
  - Use of transmit/receive head or local coils are allowed for patients implanted with the components listed in Table 1 and Table 2.
- For 3T scanners: Only transmit/receive head or local coils are allowed.

10.4 Implant location restriction:

- No part of the Senza System (IPG, leads, lead extensions, lead anchors or IPG port plugs) may be within the transmit/receive head or local coil.

10.5 MRI scan parameters:

- For transmit/receive head coils in 1.5T and 3T scanners: Head average SAR must be ≤ 3.2 W/kg (Normal Operating Mode).
- For transmit/receive local coils in 1.5T and 3T scanners: Whole body average SAR must be ≤ 2.0 W/kg (Normal Operating Mode).

10.6 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 MRI SCANS USING INTEGRATED BODY COIL (1.5T ONLY)

Head / Neck, Torso (chest, cardiac, spine, pelvis etc), and Extremity scans can be safely conducted in patients implanted with the Senza System using 1.5T integrated body coil with or without receive-only coils if the following conditions are met.

11.1 General requirements

Verify with the patient's pain management physician, referring medical facility, implanting physician or Nevro Technical Services Team

- **DO NOT** perform an MRI if the patient has a device or device component (leads, lead extension, etc) from a different manufacturer attached to the Nevro IPG. The risks of performing MRI scan with a Nevro IPG connected to leads manufactured by a different company have not been evaluated.
- 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.

11.2 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 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) or less.
- Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.
- For scanners that do not display both B_{1+RMS} and Whole-Body Average SAR values, we recommend using only Whole-Body Average or Head Average SAR.
- 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.

11.3 Allowed coils for Integrated Body Coil 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 in Section 8 for percutaneous leads or Section 9 for Surpass Surgical Leads (LEAD3005-xx(B)) or Surpass-C Surgical Leads (LEAD2005-xxB) are met for patients implanted with any of the components listed in Table 1.
- For 3T scanners: **DO NOT** use a 3T integrated body coil for scanning.

11.4 Implant location restriction:

- For 1.5T scanners:
  - Percutaneous Leads: Refer to Section 8.
  - Surpass Surgical Leads (LEAD3005-xx(B)) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Section 9.
- For 3T scanners: **DO NOT** use a 3T integrated body coil for scanning.

11.5 MRI scan parameters:

- For 1.5T scanners:
  - Percutaneous Leads: Refer to Section 8.
  - Surpass Surgical Leads (LEAD3005-xx(B)) or Surpass-C Surgical Leads (LEAD2005-xxB): Refer to Section 9.
- For 3T scanners: **DO NOT** use a 3T integrated body coil for scanning.

11.6 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: **DO NOT** use a 3T integrated body coil for scanning.

12 CONSIDERATIONS AFTER THE MRI EXAMINATION

The patient's pain management physician, referring medical facility, implanting physician, the HFX Care Team, or the patient should perform the following instructions and restore the IPG to pre-MRI settings.

- For patients with the HFX App, depending on the MRI scan type and preparation steps, stimulation can be turned ON by either exiting MRI Mode (Section 6.2) or turning stimulation on as if during normal use. For instructions on how to turn stimulation ON, refer to the HFX App Manual (10001171 for software version 1.0 or 10002273 for software version 2.0) located at http://www.nevro.com/physicianmanuals.
- For patients with only the Remote Control, turn stimulation back ON by powering the Remote Control ON and then pressing the '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.

13 APPENDIX: SENZA HFX IQ SYSTEM MRI SCAN CHECKLIST

This checklist is provided as an optional resource to support MR centers in conducting an MRI of a patient implanted with the Nevro Senza® HFX iQ system. It is important to read this entire Senza System MRI Guidelines manual (10001162) 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, the HFX Care Team or Nevro Technical Services.

Patient Name:	

☐ **Step 1: Confirm that the patient has brought their Patient ID card and either their mobile device with HFX App or their Remote Control (MR Unsafe).** Note: Their mobile device and their Remote Control cannot be taken into the MRI room.

Step 2: Verify model number(s) of implanted Senza System components.

Component	**Model Number**	**Full Body Eligible (1.5T only)**	**Head/Neck & Extremity Eligible (1.5T and 3T)**
Implantable Pulse Generator	NIPG3000	☐	☐
Percutaneous Leads	LEAD10x8-xx(B): LEAD1058-50(B), LEAD1058-70(B), LEAD1058-90(B)	☐	☐
Surpass Surgical Leads	LEAD3005-xx(B): LEAD3005-50(B), LEAD3005-70(B), LEAD3005-90(B)	☐	☐
Surpass-C Surgical Leads	LEAD2005-xxB: LEAD2005-50B, LEAD2005-70B, LEAD2005-90B	☐	☐
Lead Extensions	LEAD2008-xx(B): LEAD2008-25(B), LEAD2008-35(B), LEAD2008-60(B)	NOT Eligible	☐
Lead Anchors	All models (ACCK5000, ACCK5101, ACCK5200, ACCK5300)	☐	☐
IPG Port Plug	All models (ACCK7000)	☐	☐
S8 Lead Adaptors	SADP2008-xx(B): SADP2008-25(B)	MR Unsafe	MR Unsafe
M8 Lead Adaptors	MADP2008-xx(B): MADP2008-25(B)	MR Unsafe	MR Unsafe
x = Electrode spacing in mm xx = Lead/Extension 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 and that there are no lead fragments.**

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

Device Used	☐HFX App ☐Remote Control ☐Clinician Programmer
Current Program Number:	
Current Stimulation Level:	

☐ **Step 6: Depending on the type of MRI coil used for the scan, prepare the IPG using either a mobile device with the HFX App or Remote Control.**

<table>
<tr><th colspan="2"><u>Integrated Body Coil with or without Receive-only Coils
(1.5T Only)</u></th></tr>
<tr><td colspan="2">If the IPG cannot enter MRI Mode using the HFX App or if the impedance check on the Remote Control does not pass, DO NOT perform the MRI scan and contact Nevro Technical Services.</td></tr>
<tr><td><u>Using the HFX App</u>

1. Place the IPG into MRI Mode using the HFX App (refer to Section 6 for instructions). MRI Mode is a function of the IPG that allows patients to safely receive an MRI scan. This function will check impedances and turn stimulation off.</td><td><u>Using the Remote Control</u>

1. Perform an impedance check using the Remote Control (refer to Section 7 for instructions). The impedance check will check impedances and turn stimulation off.

Note: If the impedance check cannot be performed or does not pass, the HFX Care Team, the patient's pain management physician, referring medical facility or implanting physician can use the Clinician Programmer to determine a patient's eligibility.</td></tr>
</table>

<table>
<tr><th colspan="2"><u>Transmit/Receive Head or Local Coil
(1.5T & 3T)</u></th></tr>
<tr><td><u>Using the HFX App</u>

1. Turn stimulation off.

For instructions on how to turn stimulation off, refer to the HFX Patient Application Manual (10001171 for software version 1.0 or 10002273 for software version 2.0) located at http://www.nevro.com/physicianmanuals.</td><td><u>Using the Remote Control</u>

1. Turn stimulation off.

For instructions on how to turn stimulation off, refer to the Patient Manual (10001170) located at http://www.nevro.com/physicianmanuals.</td></tr>
</table>

Step 7: Verify the following MR scanner requirements and perform scans per checklists listed below.

☐ Use a horizontal cylindrical (closed bore) MRI
☐ Maximum spatial field gradient up to 2000 Gauss/cm (20 T/m) or less
☐ Maximum gradient slew rate limited to 200T/m/sec per axis or less

13.1 Head / Neck and Extremity Scans using Transmit/Receive Head or Local Coil (1.5T & 3T)

Head / Neck and Extremity Scans with Transmit/Receive Head or Local Coil

1.5T or 3T Scanner

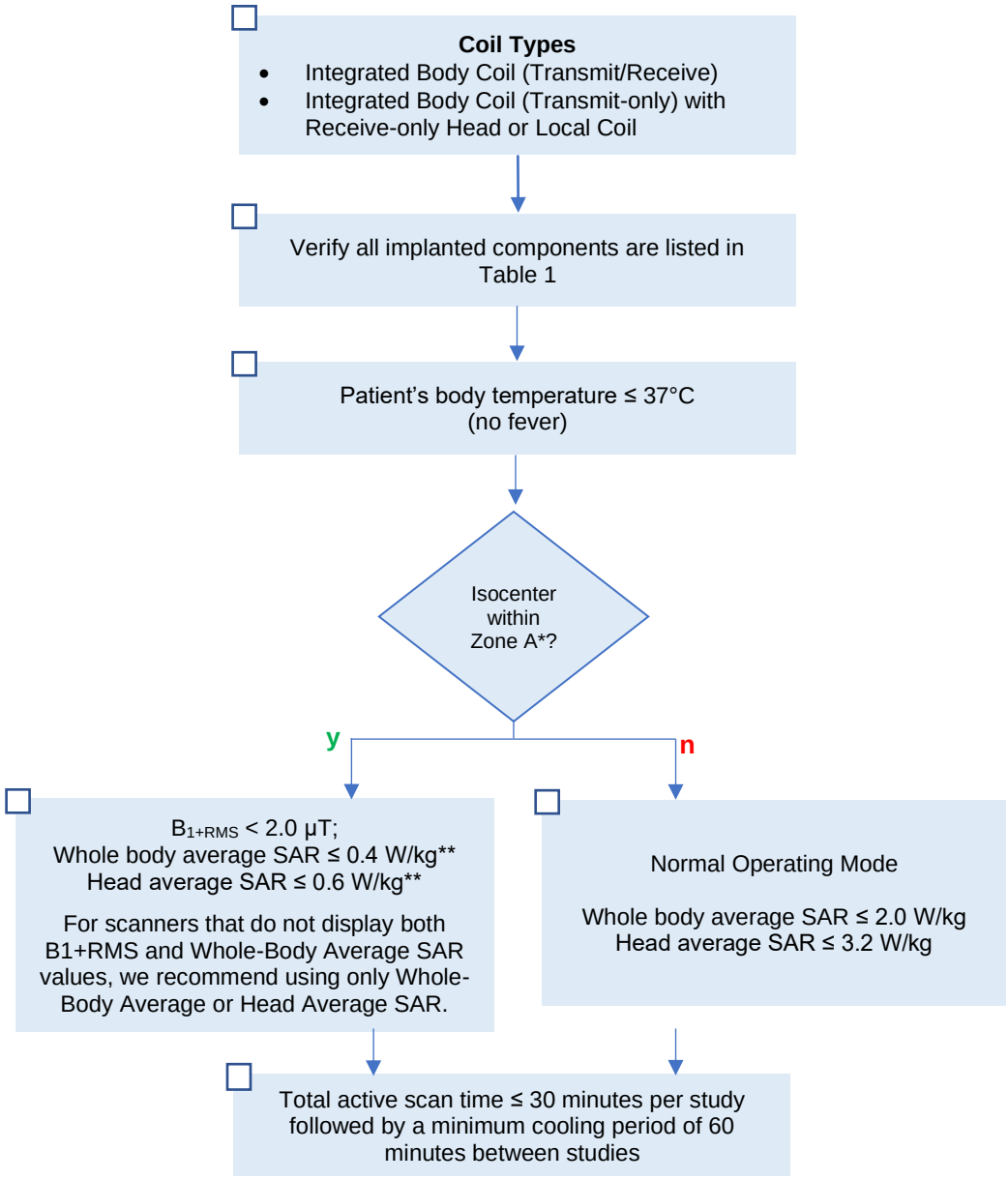
- **Coil Types**
  Transmit/Receive Head or Local Coil
- Verify all implanted components are listed in Table 1 or Table 2
- Ensure no part of the implanted system is within the RF Coil
- Normal Operating Mode
- Total active scan time ≤ 30 minutes per study followed by a minimum cooling period of 60 minutes between studies

13.2 MRI Scans using Integrated Body Coil for Percutaneous Leads (LEAD10x8-xx(B)) (1.5T Only)

MRI Scans using Integrated Body Coil
for Percutaneous Leads (LEAD10x8-xx(B))

Percutaneous Leads (LEAD10x8-xxB)

1.5T Scanner



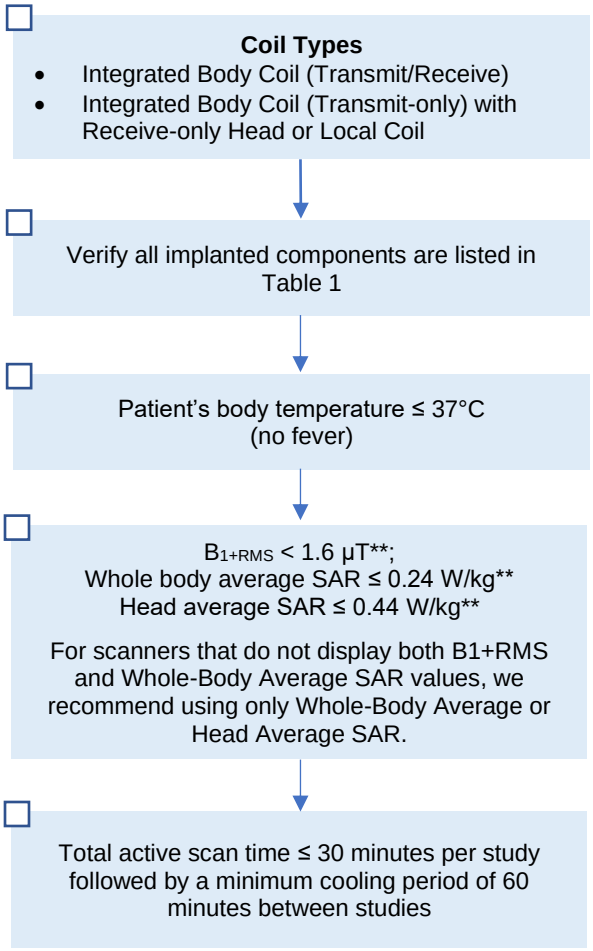
* Zone A = Coil Positioning Restriction Zone of Figure 1
** A patient cannot be scanned in the "Coil Positioning Restriction" Zone (Zone A) unless the MR system provides the ability for the operator to control or modify B_{1+RMS} or SAR levels to the values stated in the conditions of use.

13.3 MRI Scans using Integrated Body Coil for Surpass Surgical Leads (LEAD3005-xx(B)) or Surpass-C Surgical Leads (LEAD2005-xxB) (1.5T Only)

MRI Scans using Integrated Body Coil for Surpass Surgical Leads (LEAD3005-xx(B)) or Surpass-C Surgical Leads (LEAD2005-xxB)

Surpass Surgical Leads (LEAD3005-xxB) or Surpass-C Surgical Leads (LEAD2005-xxB)

1.5T Scanner



** A patient cannot be scanned in the "Coil Positioning Restriction" Zone (Zone A) of Figure 2 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.

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NEVRO CORP.

All questions or concerns about Nevro Corp. products, including any serious incident that has occurred in relation to the device, should be forwarded to:

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