Inspire
Sleep Apnea Innovation

MRI GUIDELINES FOR INSPIRE THERAPY

Clinician's Manual

℞ ONLY

Introduction

Read the information in this manual prior to conducting an MRI scan on a patient with an implanted Inspire Medical Systems upper airway stimulation device. This manual contains information about the components that comprise the MRI Conditional system, applicable warnings and precautions related to the MR Conditional system, and the requirements that you must follow in order for the implanted Inspire system to be conditionally safe for MRI scans.

Refer to the System Implant Manual for non-MRI related information. If you have any questions, contact Patient Services. See “Patient Services” on page 14.

Note: Before conducting an MRI scan, always ensure that you are using the most recent version of these MRI procedures. Contact Patient Services or get the most recent version online at manuals.inspiresleep.com.

Symbols and Definitions

The following symbols may be used in the document and on some of the products and packaging:

Symbol	Description
	Caution, Consult Accompanying Documents
	Magnetic Resonance (MR) Conditional.
	Magnetic Resonance (MR) Unsafe.
	Manufacturer

Models and Implant Locations for MR Conditional Neurostimulation Systems

The following table lists all Inspire generator model numbers and identifies those that can comprise an MR Conditional neurostimulation system.

Warning: For an implanted system to be an MR Conditional system, the generator must be an approved MR Conditional model and must be connected to Inspire Medical System leads. The system components must also be implanted in the approved location; otherwise, the implanted system is considered untested.

Table 1. Generator Scan Eligibility

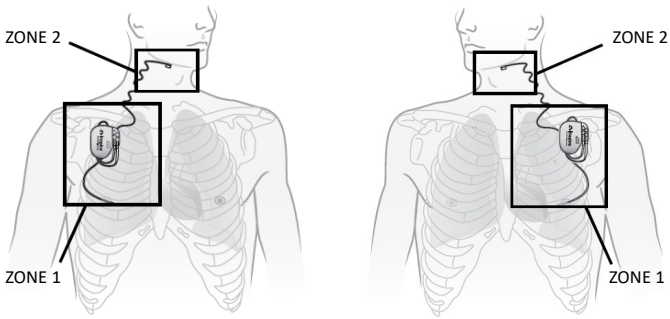
Model*	X-ray ID**	Serial Number Prefix	Eligibility Details
3028	IMS1	AIRXXXXXXX	MR Conditional at 1.5T
3024	NCR	NCRXXXXXXX	**Not eligible for MRI**

* All Inspire lead model numbers are MR conditional and are eligible for the scan conditions defined in this manual

** Reference “Appendix B: X-ray ID Tag” on page 18 for location and examples of the X-ray ID tag

The following table lists the approved locations for implanted components. Sensor location does not impact MR eligibility. Generator and stimulation lead can be implanted on either the right or left side of the body.

Table 2. Approved Locations for Implanted Components



Zone 1: Implant location for the generator should be within Zone 1. Implant location for the respiratory sensing lead may be within Zone 1 (e.g. within the generator pocket) or outside of Zone 1 as shown in the figure above.

Zone 2: Implant location for the tip of the stimulation lead should be within Zone 2.

See Patient Checklist in “Appendix A: Patient Checklist for MRI” on page 15.

MRI Safety Information

Testing has demonstrated that the Inspire Model 3028 System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

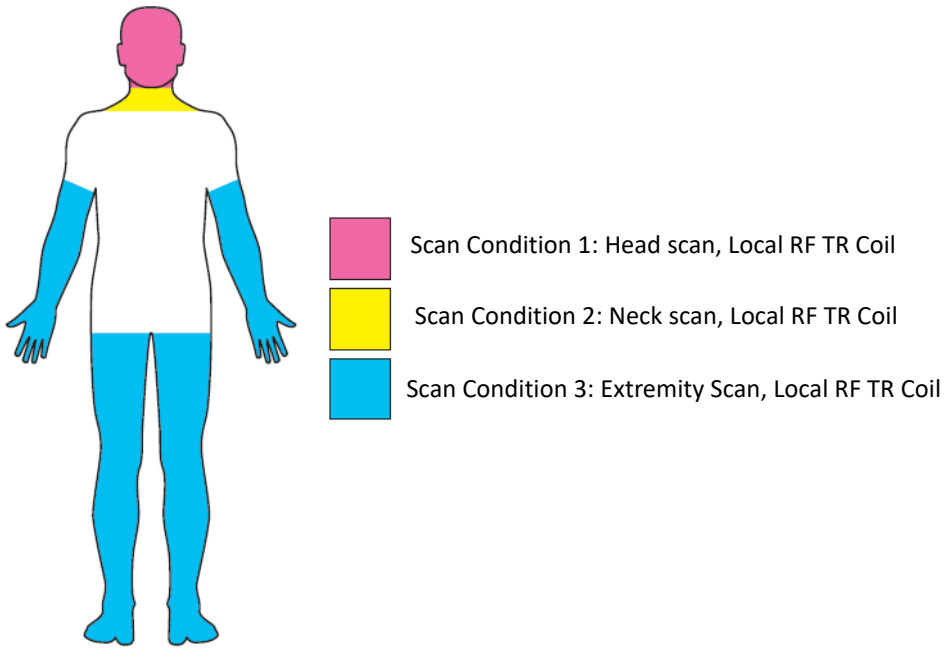


Figure 1. Scan Conditions Head RF Transmit/receive and Local Extremity RF transmit/receive coils

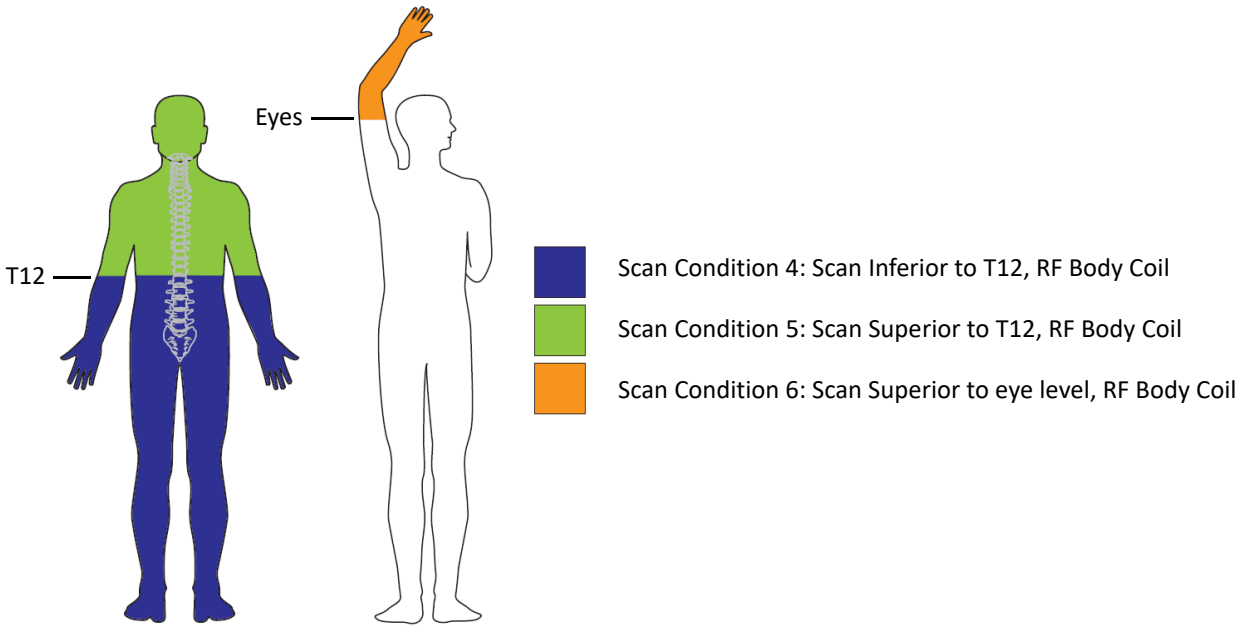


Figure 2. Scan conditions for Whole body RF transmit coil

MRI Safety Information, Scan Condition 1

For Head RF transmit-receive coil arranged so as not to extend below the chin. A person implanted with the Inspire Model 3028 System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Model 3028 Generator. All Inspire lead model numbers are MR conditional.
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B_0)	1.5T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Transmit Coil Type	Head RF transmit-receive coil
RF Receive Coil Type	Head RF transmit-receive coil
RF Conditions	B_{1+}rms ≤ 6 µT
Scan Duration	Scan for up to 30 minutes within any 90 minute period
Scan Regions	Head RF transmit-receive coil arranged so as not to extend below the chin
Image Artifact	The presence of the stimulation lead may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

MRI Safety Information, Scan Condition 2

For Head RF transmit-receive coil arranged so as to extend below the chin. A person implanted with the Inspire Model 3028 System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Model 3028 Generator. All Inspire lead model numbers are MR conditional.
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B_0)	1.5T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Transmit Coil Type	Head RF transmit-receive coil
RF Receive Coil Type	Head RF transmit-receive coil
RF Conditions	B_{1+}rms ≤ 4 µT
Scan Duration	Scan for up to 30 minutes within any 90 minute period
Scan Regions	Head RF transmit-receive coil arranged so as to extend below the chin
Image Artifact	The presence of the stimulation lead may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

MRI Safety Information, Scan Condition 3

For Local Extremity RF transmit-receive coil covering no component of the Inspire system. A person implanted with the Inspire Model 3028 System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Model 3028 Generator. All Inspire lead model numbers are MR conditional.
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B_0)	1.5T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Transmit Coil Type	Local Extremity RF transmit-receive coil
RF Receive Coil Type	Local Extremity RF transmit-receive coil
Operating Mode	Normal Operating Mode
RF Conditions	n/a. Normal Operating Mode
Scan Duration	Scan for up to 30 minutes within any 90 minute period
Scan Regions	Extremities
Image Artifact	The Inspire Model 3028 System is not implanted in the extremities. No image artifact should be seen in extremity scans.

MRI Safety Information, Scan Condition 4

For Whole Body MR Examinations with iso-center of the scan at or inferior to vertebra T12. A person implanted with the Inspire Model 3028 System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Model 3028 Generator. All Inspire lead model numbers are MR conditional.
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B_0)	1.5T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Transmit Coil Type	Integrated Whole Body transmit coil
RF Receive Coil Type	Any
RF Conditions	B_{1+}rms ≤ 3.2 µT
Scan Duration	Scan for up to 30 minutes within any 90 minute period
Scan Regions	Iso-center of the scan at or inferior to vertebra T12
Image Artifact	The Inspire Model 3028 System is not implanted in inferior to vertebra T12. No image artifact should be seen in scans.

MRI Safety Information, Scan Condition 5

For Whole Body MR Examinations with iso-center of the scan superior to vertebra T12. A person implanted with the Inspire Model 3028 System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Model 3028 Generator. All Inspire lead model numbers are MR conditional.
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B_0)	1.5T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
RF Receive Coil Type	Any
RF Conditions	B_{1+}rms ≤ 1.9 µT
Scan Duration	Scan for up to 30 minutes within any 90 minute period
Scan Regions	Iso-center of the scan superior to vertebra T12
Image Artifact	The presence of the Inspire Model 3028 System may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

MRI Safety Information, Scan Condition 6

For Whole Body MR Examinations with iso-center of the scan superior to eye level. Patient positioned with arm over their head laying supine or prone. A person implanted with the Inspire Model 3028 System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Model 3028 Generator. All Inspire lead model numbers are MR conditional.
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B_0)	1.5T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Transmit Coil Type	Integrated Whole Body transmit coil
RF Receive Coil Type	Any
RF Conditions	B_{1+}rms ≤ 2.3 µT
Scan Duration	Scan for up to 30 minutes within any 90 minute period
Scan Regions	Iso-center of the scan superior to eye level. Patient positioned with arm over their head laying supine or prone.
Image Artifact	The Inspire Model 3028 System is not implanted in the arm. No image artifact should be seen in arm scans.

Warnings and Precautions

Read this section for warnings and precautions related to an MR Conditional neurostimulation system.

Warnings

Incorrect RF Transmit Coil. Follow the different scan conditions for the whole body RF transmit coil and local/head RF Transmit-Receive coil. Use of incorrect coil and scan conditions will result in unsafe heating and may cause nerve damage.

Receive-only head or extremity coil. Receive-only head or extremity coil must follow scan conditions for the whole body RF transmit coil. A receive-only head or extremity coil utilizes the whole body RF transmit coil for RF transmit.

RF coil position. Incorrect RF coil positioning may result in unsafe heating resulting in nerve damage.

- For scan conditions 1 and 2 performing a head or neck scan, ensure the RF field strength (B_{1+}rms) is correct for the coil position.
- For scan condition 3 performing an extremity scan, do not include any implanted components in the RF field. Implant locations can be confirmed with X-ray images.
- For scan conditions 4 and 5, ensure the RF field strength (B_{1+}rms) is correct for the iso-center location relative to vertebra T12.
- For scan condition 6, ensure the iso-center location is superior to eye level.

RF field strength. Do not conduct MRI scans in first or second level controlled operating mode. These modes allow higher levels of RF energy that may cause unsafe heating resulting in nerve damage.

B_{1+}rms: Do not perform a scan unless the B_{1+}rms value is visible on the MRI console and meets the RF field strength limits for the Inspire system. Contact the MRI manufacturer if you cannot identify the B_{1+}rms on the MRI console prior to the scan.

Hydrogen only. Imaging atoms other than hydrogen has not been tested and could result in serious patient injury.

Scan time. Exceeding the 30 minute active scan time limit within any 90 minute period may cause unsafe heating resulting in nerve damage. If the required scans can not be completed within these time constraints, additional scanning sessions should be scheduled for a later time such that these limits are not exceeded.

Cylindrical bore 1.5T only. Scanning a patient with an MR system other than a cylindrical bore 1.5T scanner has not been tested and may result in serious patient injury.

Unapproved components. Do not perform an MRI scan on patients who have any components of a neurostimulation that are unapproved for use in an MR environment.

Abandoned devices. Do not perform an MRI scan on patients who have an abandoned generator or lead >2cm in length. Abandoned lead segments <2cm in total length are eligible for MR scans (for example, an abandoned cuff on nerve, reference “Appendix C: Stimulation Cuff Dimensions” on page 19).

Nonfunctional leads. Do not perform an MRI scan on patients with broken or nonfunctional leads. MRI scans of patients with nonfunctional leads may result in higher than normal heating occurring at the location of the implanted lead electrodes.

Skin erosion. Do not perform an MRI scan on patients who have any portion of their implanted system exposed due to skin erosion. The MRI scan may cause heating of the system, which could result in serious patient injury.

Other implanted medical devices. Scanning patients who have other MR Conditional devices is acceptable as long as all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it. If you are unclear what implants are present, perform an X-ray to determine the implant type and location.

Precautions

Therapy off. Inspire therapy is intended for use during sleep only. Inspire therapy must be off during the MRI scan. Failure to turn therapy off during an MRI may result in unintended changes to stimulation.

External devices. Do not allow external devices into the scanner magnet room (zone 4), such as the sleep remote and Inspire programmer. Because these devices contain ferromagnetic material, they can be affected by the MRI magnet, may present a projectile hazard, and are considered MR Unsafe.

Electromagnetic interference (EMI). Some electrical equipment, such as an MRI machine, may generate enough EMI to interfere with the operation of the internal or external electronic components of the Inspire system. To mitigate the effects of possible EMI, increase the distance between the electrical equipment and the system component that is affected, and try performing the operation again.

Potential Adverse Events

The Inspire Medical System MR Conditional system has been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events that may occur in the MRI environment:

- Lead electrode heating resulting in tissue damage or serious patient injury
- Generator heating resulting in tissue damage in the implant pocket or patient discomfort or both
- Induced currents on leads resulting in over stimulation or unintended stimulation
- Damage to the generator or leads causing the system to fail to deliver stimulation or causing the system to deliver over stimulation
- Damage to the functionality or mechanical integrity of the generator resulting in the inability to communicate with the generator
- Movement or vibration of the generator or leads

Preparing a Patient for an MRI Scan

Before conducting an MRI scan, you must perform the following steps:

1. Confirm that the implanted Inspire generator is MR Conditional and is connected to Inspire leads.
2. Confirm that no adverse conditions to MR scanning are present.
3. Select the MRI parameters according to the scanning requirements.
4. Notify the patient of potential interactions.

The following sections provide more information about each of these steps. You can also use the form in the appendix of this manual as a quick-reference checklist to help you determine a patient's eligibility for an MRI scan.

Note: Before the day of the MRI procedure, inform patients to bring their patient ID card and their sleep remote with them. The patient receives their sleep remote at activation, approximately 30 days after their implant surgery. If the patient does not have a sleep remote, coordinate with a local Inspire representative or contact Inspire Patient Services for access to a patient remote or programmer.

Step 1: Confirm the Implanted System Contains Only MR Conditional Components

To confirm that the patient's implanted Inspire System is MR Conditional, review the patient's identification card for his or her system. When an Inspire system is implanted, a patient receives an identification card that identifies the model numbers of the implanted components to help you identify them as MR Conditional.

1. Request the identification card from the patient.
2. Cross-reference the model numbers on the card with the model numbers of the MR Conditional components identified in Table 1.

   Note: If a patient does not have his or her system identification card, consider other means of confirming the MR Conditional system, such as referencing the patient's medical history, X-ray, or contacting Inspire Patient Services.

   Caution: Do not bring the sleep remote or Inspire programmer into the scanner magnet room (Zone 4). These devices contain ferromagnetic material that can be affected by the MRI magnet and may present a projectile hazard. The sleep remote and programmer are MR Unsafe.

Step 2: Confirm No Adverse Conditions to Scanning Are Present

If any conditions exist that could make an MRI scan unsafe, do not scan the patient. Such conditions include:

- The presence of implanted neurostimulation components that are not listed as MR Conditional as outlined in Table 1.
- The location of MR Conditional components in an area other than what is noted in Table 2.
- The presence of broken or non-functional MR Conditional leads.
- The presence of abandoned devices >2cm, such as a generator or lead.
- Any exposed portions of MR Conditional neurostimulation system components due to skin erosion.
- The presence of any other implanted devices (active or passive implanted devices) that prohibit safe scanning.
- The presence of a fever in the patient the day of the scan.

Using the Sleep Remote or Inspire Programmer to Confirm Normal Operation

Within 30 minutes prior to each scan, use the patient's sleep remote or Inspire Programmer to confirm normal system operation. If using an Inspire Programmer, the local Inspire representative can confirm tongue motion and normal system operation. To confirm the patient's Inspire system is operating normally with the sleep remote, follow these steps.

1. Using the patient's sleep remote, find the Therapy On/Pause button as shown in Figure 3.

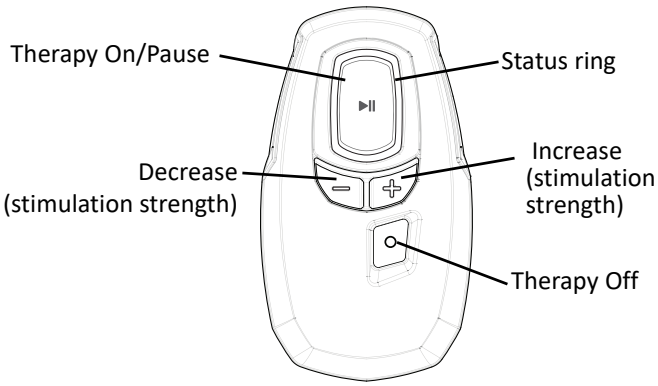


Figure 3. Sleep remote front view

2. Activate therapy by pressing the Therapy On/Pause button and holding the remote over the Inspire generator as shown in Figure 4.

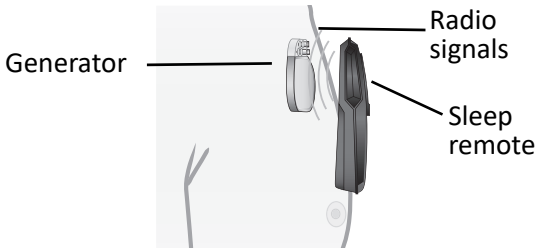


Figure 4. Communication between sleep remote and generator

3. Confirm that stimulation occurs and clearly moves the patient's tongue.
4. Turn the patient's therapy off by pressing the Therapy Off button as shown in Figure 3 and holding the remote over the Inspire generator as shown in Figure 4.
5. Turn the remote over and confirm the generator light as shown in Figure 5 is NOT illuminated. If the generator light is illuminated, DO NOT scan the patient. Refer the patient to their sleep physician to resolve the issue with their implant.
6. Confirm therapy has been turned off by confirming that the remote therapy status ring and stimulation strength gauge lights are illuminated white and are not flashing.

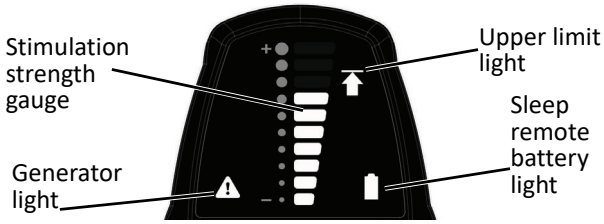


Figure 5. Sleep remote back view

Step 3: Select the MRI Parameters According to the Scanning Requirements

Set up the MRI equipment per “MRI Safety Information” on page 3. Confirm that the RF field strength (B_{1+}rms) does not exceed the limits for the coil labeling. Confirm correct scan condition based on use of head RF transmit-receive coil, local extremity RF transmit-receive coil, or whole body RF transmit coil. A gradient echo localizer sequence can be used to determine vertebra location relative to the planned scan area.

Step 4: Notify the Patient of Potential Interactions

Notify the patient that they may notice the following interactions with their implanted system during the scan:

- Vibration of the generator.
- Generator or stimulation electrode heating.
- Mild stimulation of the tongue, similar to therapy.

Instruct the patient to notify the scan operator if either condition becomes uncomfortable.

Performing the Scan and Monitoring the Patient

While performing the scan, follow these guidelines:

- Leave any external control devices, such as a programmer or sleep remote, out of the scanner magnet room (Zone 4).
- During the MRI scan, visually and audibly monitor the patient, including verbal communication.
- When selecting the field of view and imaging parameters, consider that minimal image distortion may occur around an implanted lead or generator. Consider these factors also when interpreting the MRI images.
- Stop the scan if the patient feels uncomfortable stimulation or heating.

Patient Services

For technical questions and support please contact Inspire Patient Services at 1-844-OSA-HELP (844-672-4357).

For additional assistance, call your local Inspire Medical Systems representative.

Appendix A: Patient Checklist for MRI

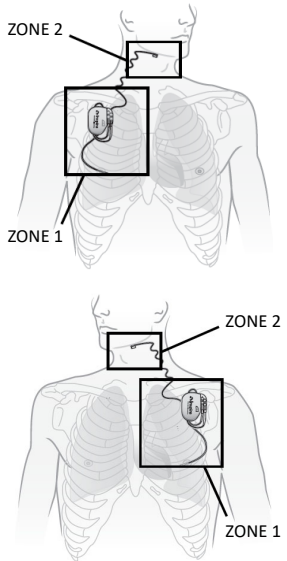
Complete this form to help you determine the eligibility of a patient with an implanted Inspire neurostimulation system for an MRI scan.

If the answers to all of the following questions are “Yes,” consult the MRI procedures in this manual for complete information on conducting an MRI scan. If the answer to any of the questions is “No,” do not perform the scan. If the answer to any of the questions is “Unsure,” contact the patient's physician or Inspire Patient Services for help.

Warning: Scanning patients who have other MR Conditional devices is acceptable as long as all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it. If you are unclear what implants are present, perform an X-ray to determine the implant type and location.

Note: Before conducting an MRI scan, always ensure that you using the most recent version of these MRI procedures. Contact Inspire Patient Services or retrieve the most recent version online at manuals.inspiresleep.com

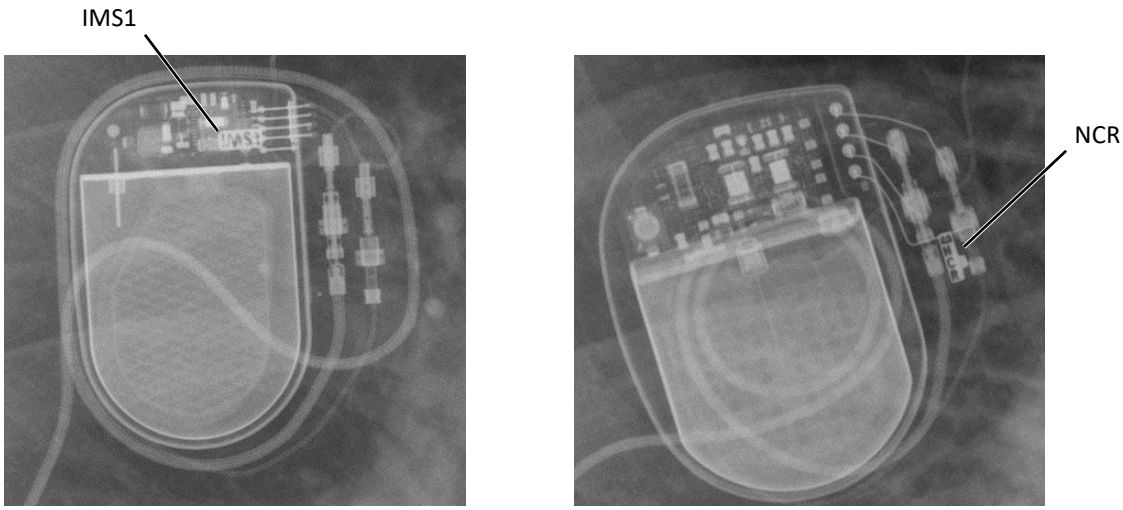
Patient's Name	
Physician's name and contact information (office name, address, phone number)	
Date of eligibility assessment	
Generator Model:	Generator Location:
Stimulation Lead Model:	Stimulation Lead Location:
Sense Lead Model:	Sense Lead Location:

Eligibility Question	Yes	No	Unsure	Approved Implant Locations
1. Does the patient have a generator model that is MR Conditional? (See the patient's ID card for generator model)				 Zone 1, Generator location: sub-clavicle region Zone 2, Stimulation lead tip location: tongue base.
2. Are the MR Conditional components the only Inspire components implanted?				
3. Identify the location of the implanted components and mark them on the diagram to the right. Is the generator within zone 1? Is the stimulation lead tip within zone 2? Symmetrical left sided implants are MR eligible.				
4. RF coil: a. If the head transmit-receive coil is being used, is B_{1+}rms limited to 6µT if not extending below the chin or 4µT if extending below the chin (scan condition 1 or 2)? b. Is the RF coil to be used a local extremity transmit-receive coil (scan condition 3)? c. If the whole body RF transmit coil is being used (this includes scans with a local receive only coil) or a receive only head / extremity coil, is the B_{1+}rms value correct for iso-center location (scan condition 4 <3.2µT, scan condition 5 <1.9µT, scan condition 6 <2.3µT)?				

5. Do the static and gradient fields meet the following conditions? ▪ Static magnetic field of 1.5T ▪ Cylindrical bore MR system ▪ Maximum spatial field gradient of 3000 gauss/cm (30T/m) ▪ Maximum gradient slew rate of 200 T/m/s per axis				
6. Is the patient free of broken or abandoned devices >2cm in length?				
7. Is the MRI for an approved scan region?				

Appendix B: X-ray ID Tag

The X-ray images below show Generator Models 3028 and 3024, with specific reference to the location of the X-ray identification tag.



Model 3028: X-ray ID is “IMS1” and generator is MR Conditional

Model 3024: X-ray ID is “NCR” and generator is not eligible for an MRI

Figure 6. X-ray ID Tag Locations

Appendix C: Stimulation Cuff Dimensions

The following image shows a stimulation cuff with dimensions. Abandoned lead segments <2cm in total length are eligible for MR scans.

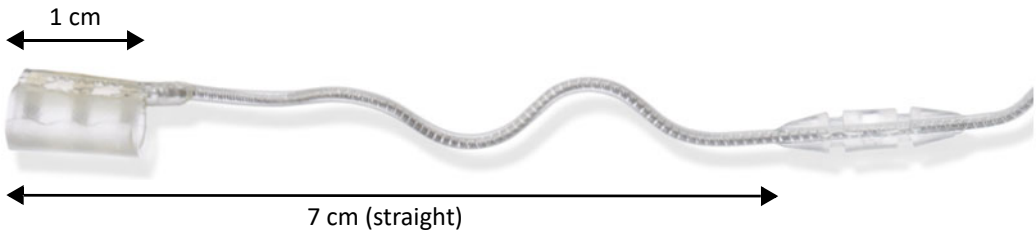


Figure 7. Stimulation Cuff Dimensions

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