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# MRI GUIDELINES FOR INSPIRE THERAPY

Clinician's Manual



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## 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 Therapy Support. See “Therapy Support” on page 8.

**NOTE:** Before conducting an MRI scan, always ensure that you are using the most recent version of these MRI procedures. Contact Therapy Support or get the most recent version online at [manuals.inspiresleep.com](http://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
	For USA audiences only

## Models and Implant Locations for MR Conditional Neurostimulation Systems

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

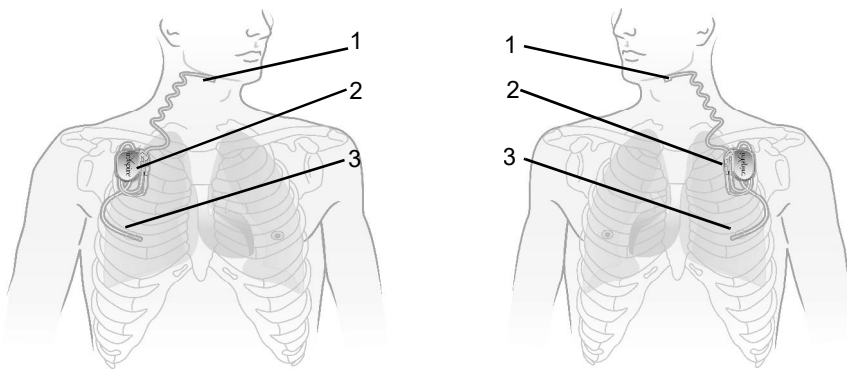
**WARNING:** For an implanted system to be an MR Conditional system, the generator must be an approved MR Conditional model and must be connected to Inspire Medical System leads. The system components must also be implanted in the approved location; otherwise, the implanted system is considered untested.

**Table 1. Generator Scan Eligibility**

Model	X-Ray ID	Eligibility Details
3028	IMS1	Head and extremity scans only
3024	NCR	<b>Not eligible for MRI</b>

The following table lists the approved locations for implanted components.

**Table 2. Approved Locations for Implanted Components**



1. Implant location for the tip of the stimulation lead
2. Implant location for the generator
3. Implant location for the respiratory sensing lead



## MRI Safety Information

Non-clinical testing has demonstrated that the Model 3028 generator system is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Transmit/receive birdcage head coil (circularly polarized only) arranged so as to not extend below the chin; no RF transmit body coil
- Maximum MR system reported, B1+rms of 6 $\mu$ T
- Static magnetic field of 1.5T
- Cylindrical bore MR system
- Maximum spatial field gradient of 1900 gauss/cm (19T/m)
- Maximum gradient slew rate of 200 T/m/s per axis
- Maximum active RF scan time of 30 minutes out of any 90-minute period

**OR:**

- Transmit/receive birdcage head coil (circularly polarized only); no RF transmit body coil
- Maximum MR system reported B1+rms of 4 $\mu$ T
- Static magnetic field of 1.5T
- Cylindrical bore MR system
- Maximum spatial field gradient of 1900 gauss/cm (19T/m)
- Maximum gradient slew rate of 200 T/m/s per axis
- Maximum active RF scan time of 30 minutes out of any 90-minute period

**OR:**

- Transmit/receive extremity coil covering no component of the Inspire system; no RF transmit body coil
- Normal mode
- Static magnetic field of 1.5T
- Cylindrical bore MR system
- Maximum spatial field gradient of 1900 gauss/cm (19T/m)
- Maximum gradient slew rate of 200 T/m/s per axis
- Maximum active RF scan time of 30 minutes out of any 90-minute period

Under the scan conditions defined above, the Model 3028 generator system is expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 3.6mm from the stimulation lead when imaged with a gradient echo pulse sequence and a 1.5T MRI system.

## Warnings and Precautions

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

### Warnings

**No body coil.** Do not use the body coil to perform an MRI scan. Do not use a receive-only head or extremity coil with an RF transmit body coil. It will result in unsafe heating and may cause nerve damage.

**No receive-only head or extremity coil.** Do not use a receive-only head or extremity coil. A receive-only head or extremity coil utilizes the body coil for RF transmit. Use of the body coil for RF transmit will result in unsafe heating and may cause nerve damage.

**RF coil position.** When performing a head scan, ensure the RF field strength (B1+rms) is correct for the coil position. When performing an extremity scan do not include any implanted components in the RF field. Implant locations can be confirmed with x-ray images. Incorrect RF coil positioning may result in unsafe heating resulting in nerve damage.

**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.

**B1+rms:** Do not perform a scan unless the B1+rms 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 B1+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 active scan time limit may cause unsafe heating resulting in nerve damage.

**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.

**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 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 a neurostimulation system if the equipment and the system component is too close to the system component. 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 UAS 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.

### 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 Therapy Support.

**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:

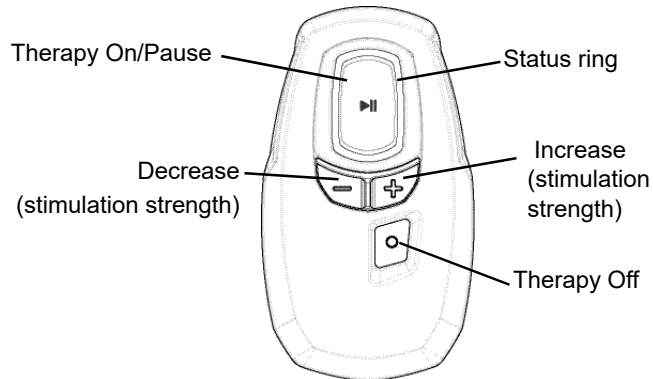
- The presence of implanted neurostimulation components that are not listed as MR Conditional as outlined in Table 1.
- The location of MR Conditional components in an area other than what is noted in Table 2.
- The presence of broken or non-functional MR Conditional leads.
- The presence of abandoned devices, such as an 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 to Confirm Normal Operation

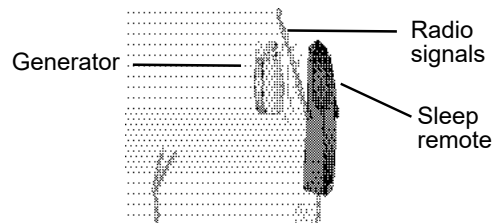
Within 30 minutes prior to each scan, use the patient's sleep remote to confirm normal system operation. To confirm the patient's Inspire system is operating normally, follow these steps.

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



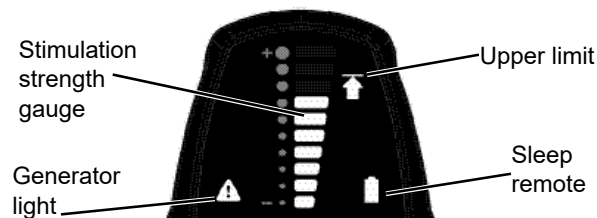
**Figure 1.** Sleep remote front view

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



**Figure 2.** 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 1 and holding the remote over the Inspire generator as shown in Figure 2.
5. Turn the remote over and confirm the generator light as shown in Figure 3 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 3.** 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. If a head coil is being used, confirm that the RF field strength does not exceed the limits for the coil labeling.

- If the head coil extends below the chin, B1+rms must be limited to 4 $\mu$ T.
- If the head coil does not extend below the chin, B1+rms must be limited to 6 $\mu$ T.

### **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).
- If not performing a head scan, ensure that the transmit-receive coil does not cover any part of the implanted MR Conditional system.
- Keep the duration of the total active scanning time to 30 minutes or less per session. Wait at least 60 minutes between scanning sessions.
- 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.

## **Therapy Support**

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

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

## Appendix A: Patient Eligibility Form for MRI Head or Extremity Scans

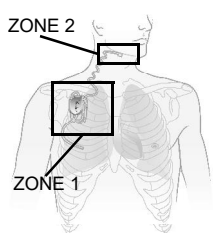
Complete this form to help you determine the eligibility of a patient with an implanted neurostimulation system for an MRI head or extremity scan using the RF transmit-receive coil only.

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 Therapy Support 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 Therapy Support or retrieve the most recent version online at [manuals.inspiresleep.com](http://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 an generator model that is MR Conditional? (See the patient's ID card for generator model)				
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, and is the stimulation lead tip within zone 2?				
4. Is the coil to be used a local transmit-receive coil?				Zone 1, Generator location: sub-clavicle region
5. If the head coil is being used, is B1+rms limited to 4μT if extending below the chin or 6μT if not extending below the chin?				Zone 2, Stimulation lead tip location: tongue base.
6. Is the patient free of broken or abandoned devices?				
7. Is the MRI for an approved scan region?				



**Manufacturer**

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