



MRI Guidelines for Generators and Leads

3024, 3028, 3150, 4323, 4340, 4063

Rx
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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 provides details on the MR conditional system components, related warnings and precautions, and the necessary requirements to ensure the implanted Inspire System is conditional 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 17.

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.

Acronyms

Circularly Polarized: CP	Radiofrequency: RF	Whole body SAR: wbSAR
Head SAR: hdSAR	Thoracic Vertebra 12: T12	
Multichannel-2: MC-2	Transmit/receive: T/R	

Definitions

Abandoned Generator	An abandoned generator is one that is not connected to any lead(s). An abandoned Inspire generator is MR Unsafe.
Abandoned Lead	An abandoned stimulation or sensing lead is one that is not connected to a generator. Determine MR eligibility for an abandoned lead using “Step 4: Assess the Lead(s)” on page 14.
Distal End	The lead distal end is the end furthest from the generator connection point. The distal end of the stimulation lead is the end with the electrode cuff. The distal end of the sensing lead is the end with the sensor capsule.
Functional Inspire System	A generator that has power, and is delivering therapy as programmed; the lead(s) are whole, properly connected, and show normal electrical function. A whole lead and functional system is confirmed per “Step 6: Confirm normal operation of the Inspire System” on page 15.
Lead Fragment	Any portion of the stimulation lead or sensing lead. Determine MR eligibility for an abandoned lead fragment using “Step 4: Assess the Lead(s)” on page 14
RF Coil	May be classified into transmit coils, receive coils, and transmit/receive coils.
Sensor Capsule	The distal end of the sensing lead detached from the lead body and terminal.
Whole-Body Transmit RF Coil	A coil used in MRI to transmit and receive RF energy that encompasses the entire body region within the MR scanner bore. It is often a separate component that can be used in conjunction with various receive coils to optimize image quality for different body parts.
Whole Lead	<p>A whole stimulation lead is an unbroken lead which includes the electrode cuff (distal end), lead body, and terminal and measures 45 cm.</p> <p>A whole sensing lead is an unbroken lead which includes the sensor capsule (distal end), lead body, and terminal which measures 25 or 45 cm.</p> <p>A patient may have whole lead(s) that are connected to a generator or abandoned. A whole lead connected to a functional generator is confirmed per “Step 6: Confirm normal operation of the Inspire System” on page 15.</p>

Symbols Glossary

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

Symbol	Title	Description	Standard Reference
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1; ISO 7000-0434A
	Consult instructions for use or electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1; ISO 7000-1641
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1; ISO 7000-3082
	Medical device	Indicates the item is a medical device	ISO 15223-1
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1; ISO 7000-2498
	Model number	Indicates the model number or type number of a product	ISO 15223-1; IEC 60417-6050
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields	ASTM F2503
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment	ASTM F2503
	Patient information website	Indicates a website where a patient can obtain additional information on the medical product	ISO 15223-1; ISO 7000-3705
	Date	Indicates the date that information was entered or a medical procedure took place	ISO 15223-1; ISO 7000-5662
	Patient identification	Indicates the identification data of the patient	ISO 15223-1; IEC 60417-5664
	Health care center or doctor	Indicates the address of the health care center or doctor where medical information about the patient may be found	ISO 15223-1; ISO 7001

Warnings and Precautions

Read this section for warnings and precautions related to an Inspire MR conditional system.

Warnings

Abandoned lead(s)/lead fragments: Do not perform an MRI scan on patients with abandoned lead(s)/fragments that don't meet the requirements in "Step 4: Assess the Lead(s)" on page 14.

Acceptable MR Scanners: Scanning a patient with an MR system other than a cylindrical bore 1.5T or 3.0T scanner has not been tested and may result in serious patient injury. 3.0T MRI scanners that use more than two transmit channels have not been studied but may be operated in CP or MC-2 modes if available.

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

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

Nonfunctional system: Do not perform an MRI scan on patients who cannot confirm a functioning system. MRI scans of patients with a nonfunctional system may result in higher than normal heating.

Other implanted medical devices: Scanning patients with other MR conditional devices is acceptable as long as all the MR conditional requirements for each implanted device 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.

Receive-only coil: Receive-only coils utilize the whole-body transmit RF coil for RF transmission and, therefore, must follow the scan conditions for the whole-body transmit RF coil.

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.

Scan time: Exceeding the 30-minute active scan time limit within any 90-minute period may cause unsafe heating resulting in nerve damage. If additional sequences are required, a minimum waiting period of 60 minutes should be observed.

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 system heating, which could result in serious patient injury.

Therapy off: Inspire therapy is intended for use during sleep only. Inspire therapy must be OFF during an MRI. Failure to turn therapy off during an MRI may result in stimulation of the tongue. If the patient experiences any pain or discomfort, they should immediately notify staff and stop the scan. If any of these symptoms persist, the patient should seek follow-up evaluation. Post-scan changes to stimulation or loss of function may also result from failure to turn therapy OFF during the scan. The patient should confirm the proper function of the Inspire System by using their sleep remote after an MRI. If the Inspire System does not seem to be functioning normally the patient should discontinue use and be seen by their sleep physician. If normal system function cannot be restored, a revision surgery may be needed to regain therapy.

Unapproved components: Do not perform an MRI scan on patients with any unapproved Inspire System components for use in an MR environment.

Precautions

B_{1+rms}: If the MR scanner does not display the B_{1+rms} value, then limit RF exposure based on the wbSAR and hdSAR listed for each scan condition. B_{1+rms} is the preferred method of limiting RF exposure.

External devices: Do not allow external devices into the scanner magnet room (MR facility Zone IV), 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 affected system component, and try performing the operation again.

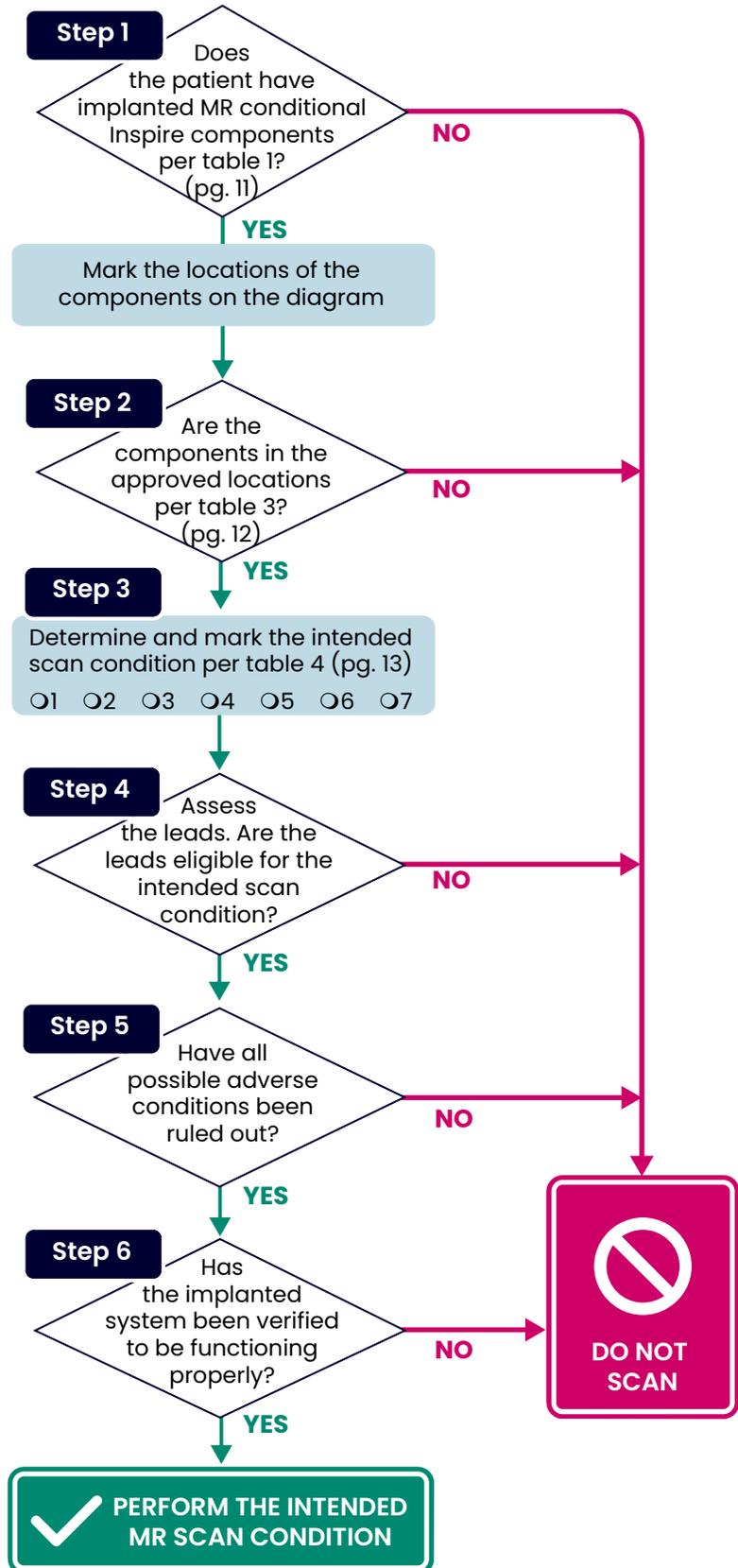
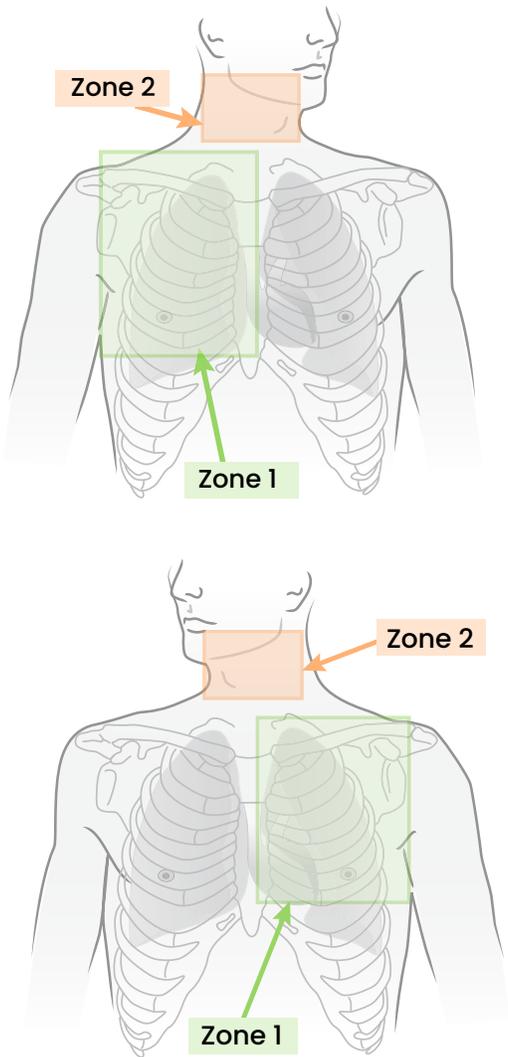
Potential Adverse Events

The Inspire 3028 and 3150 Systems have been designed to minimize the potential adverse events that may cause patient harm. Inspire has evaluated the following potential adverse events but have determined MRI to be safe utilizing the conditions noted within this guidance.

- Heating of the electrodes on the lead 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 overstimulation or unintended stimulation
- Damage to the generator or leads causing the system to fail to deliver stimulation or causing the system to deliver overstimulation
- 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

At a Glance Patient MRI Eligibility Flow Chart

This flow chart provides an overview of the steps that must be completed prior to performing an MRI scan. Please ensure that all steps listed after the chart are followed in full.



Determine Patient Eligibility for an MRI Scan

Before conducting an MRI scan, you must perform the following six steps on pages 10–15. See Patient Checklist in “Appendix A: Patient Checklist for MRI” on page 25 to aid in determining MRI eligibility.

Notes:

- ▶ Before the day of the MRI procedure, inform patients to bring their patient implant card and their sleep remote with them.
- ▶ When an Inspire System is implanted, a patient receives an implant card that identifies the model and serial numbers of the implanted components to help you identify their MR status.
- ▶ Patients should receive their sleep remote when their Inspire therapy is activated, which typically occurs around 30 days after implant surgery. If the therapy is not yet activated, consider rescheduling the patient’s MRI appointment until after activation. If rescheduling is not feasible, contact Patient Services to check if a local Inspire representative can verify device functionality using an Inspire programmer.

 **WARNING:** 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.

Step 1: Confirm that the implanted Inspire System is MR conditional

To confirm that the patient’s implanted Inspire System is MR conditional, review the patient’s implant card.

- a. Request the implant card from the patient.

Note: If a patient does not have their system implant card, consider other means of confirming MR compatibility, such as referencing the patient’s medical history, x-ray (see “Appendix B: X-ray ID Tag” on page 27), or contacting Inspire Patient Services.

- b. Cross-reference the model numbers on the card with the model numbers identified in Table 1 on page 11. If the model number is not listed on the patient implant card, use Table 1 and the serial number format to determine model number. Table 1 lists all Inspire generator model numbers and identifies those that can comprise an MR conditional system. Since the leads are part of the Inspire System, they are also included in the table.
- c. If the patient does not have an implanted generator, this step may be skipped.

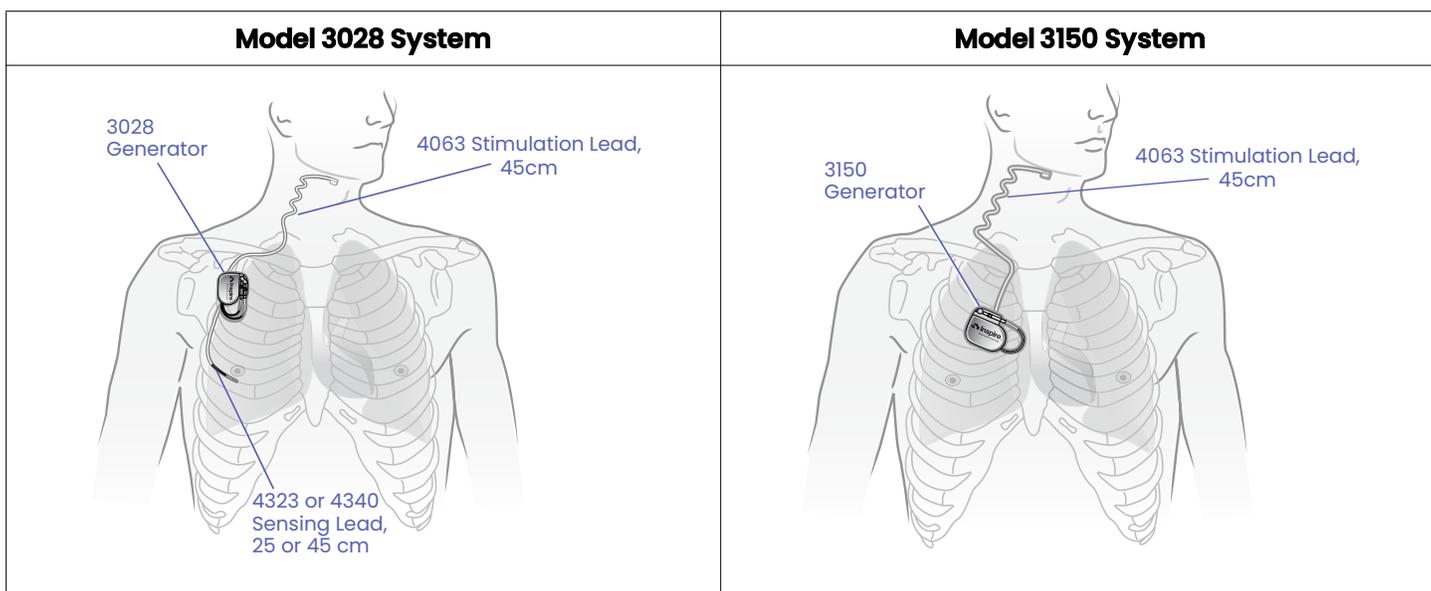
Table 1. Generator and Lead Scan Eligibility

Model*	X-ray ID**	Serial Number Format	Eligibility Details
3024 Generator	NCR	NCR#####	Not eligible for MRI 1.5T: MR conditional per Scan Conditions 1-6 3.0T: MR conditional per Scan Conditions 1-4
3028 Generator	IMSI	AIR#####	
3150 Generator	IMSV	TML#####	
4323; 4340 Sensing Lead	---	S##### T##### U#####	
4063 Stimulation Lead	---	C##### D##### E##### C#####	

* All Inspire lead model numbers are MR conditional when connected to a working generator (including those that are coiled or looped) and are eligible for the scan conditions defined in this manual.

**Reference "Appendix B: X-ray ID Tag" on page 27 for location and examples of the x-ray ID tag.

Table 2. Model 3028 and Model 3150 System Components



Note: System may be implanted on either the right (shown above) or left side of the body.

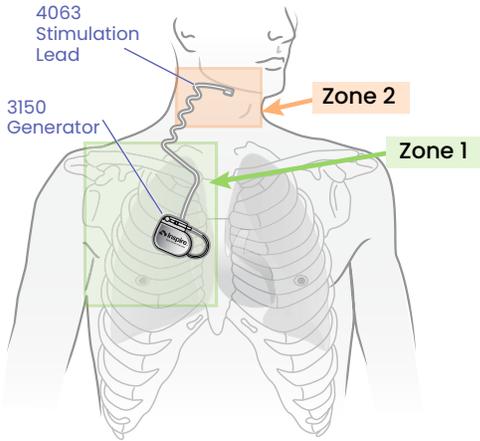
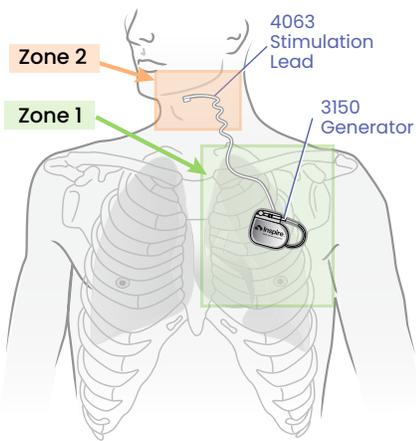
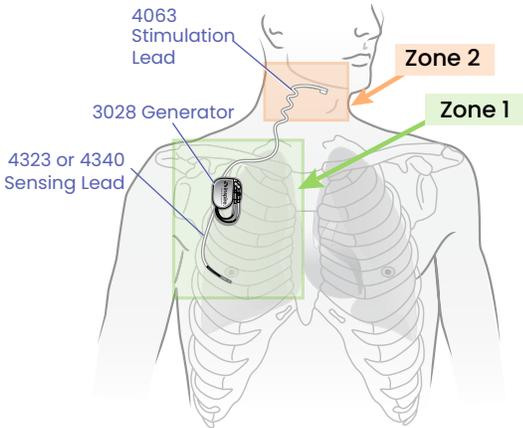
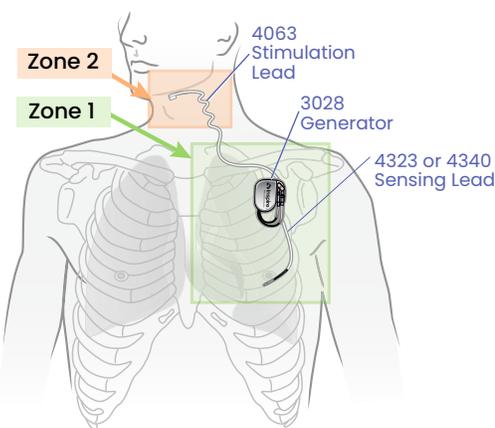
Step 2: Confirm the Implanted System is in an Approved Location

- If the patient does not have an implanted generator, this step may be skipped.
- Reference Table 3 to determine if the implanted components are within the approved areas.
- The implant zone and model numbers may be recorded in "Appendix A: Patient Checklist for MRI" on page 25, questions 1 and 2.

Table 3 lists the approved MRI locations for implanted components. Generator orientation can vary.

WARNING: Do not scan the patient if the system components are not implanted in the approved location.

Table 3. Approved locations for implanted components

Right sided implant	Left sided implant
 <p>4063 Stimulation Lead</p> <p>3150 Generator</p> <p>Zone 2</p> <p>Zone 1</p>	 <p>4063 Stimulation Lead</p> <p>3150 Generator</p> <p>Zone 2</p> <p>Zone 1</p>
 <p>4063 Stimulation Lead</p> <p>3028 Generator</p> <p>4323 or 4340 Sensing Lead</p> <p>Zone 2</p> <p>Zone 1</p>	 <p>4063 Stimulation Lead</p> <p>3028 Generator</p> <p>4323 or 4340 Sensing Lead</p> <p>Zone 2</p> <p>Zone 1</p>
<p>Zone 1: Implant location for the generator should be within Zone 1, below the clavicle and at or above anterior rib 5.</p> <p>Note: Sensing lead location does not impact MR eligibility.</p>	
<p>Zone 2: Implant location for the distal end of the stimulation lead should be within Zone 2.</p>	

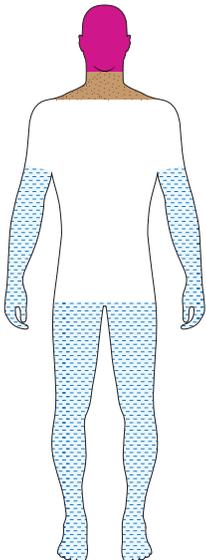
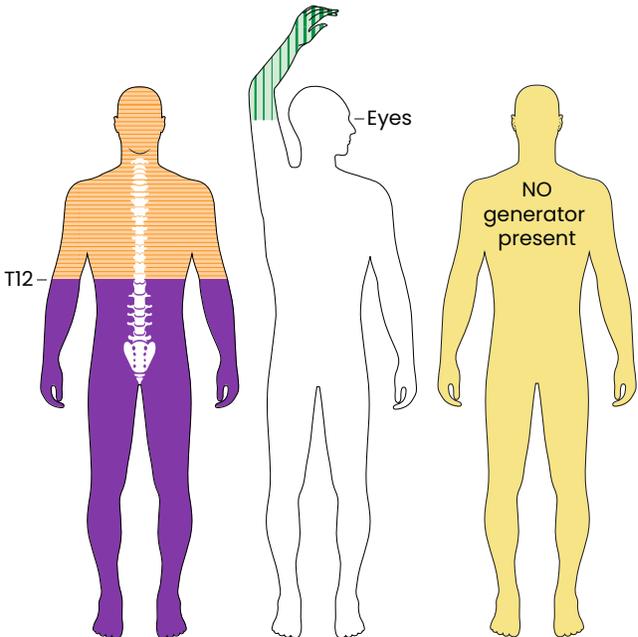
Step 3: Identify the Intended Scan Condition

Determine the scan condition based on the body part being scanned as well as the transmit RF coil and the type of MRI scanner. The intended scan condition may be recorded in “Appendix A: Patient Checklist for MRI” on page 25, question 3.

Patients with eligible Inspire Systems can be safely scanned with a whole-body or local coil in an MR system meeting the scan conditions in Table 4 on page 13.

When **NO generator** is present, scanning is also conditional at 1.5T and 3.0T by utilizing the parameters described in “MRI Safety Information, Scan Condition 7”, “Abandoned Leads and Lead Fragments when No Generator Present” on page 24 which uses a whole-body transmit RF coil (any receive coil) at Normal Operating Mode.

Table 4. Scan Conditions 1-7

Local transmit/receive (T/R) RF coils	Whole-body transmit RF coil (any receive coil may be used)
	
 Scan Condition 1 (page 18): “Head scan, local transmit/receive RF coil”	 Scan Condition 4 (page 21): “Scan at or inferior to T12, whole-body transmit RF coil (any receive coil)”
 Scan Condition 2 (page 19): “Neck scan, local transmit/receive RF coil”	 Scan Condition 5 (page 22): “Scan superior to T12, whole-body transmit RF coil (any receive coil)”  1.5T only—Scan Condition 5 cannot utilize 3.0T
 Scan Condition 3 (page 20): “Extremity scan, local transmit/receive RF coil”	 Scan Condition 6 (page 23): “Scan superior to eye level, whole-body transmit RF coil (any receive coil)”  1.5T only—Scan Condition 6 cannot utilize 3.0T
	 Scan Condition 7 (page 24): “Abandoned Leads and Lead Fragments when No Generator Present”, no generator present

Notes:

- ▶ For any scan condition, patients may be scanned in either the head-first or feet-first position and in the prone or supine position.
- ▶ If you are unsure which scan condition to use for abdominal scans, Scan Condition 5 is more conservative than Scan Condition 4.

Step 4: Assess the Lead(s)

All Inspire stimulation and/or sensing leads that are whole and connected to a functional Inspire generator are MR conditional (including those that are coiled or looped).

Note: A whole lead and functional system is confirmed per Step 6 on page 15.

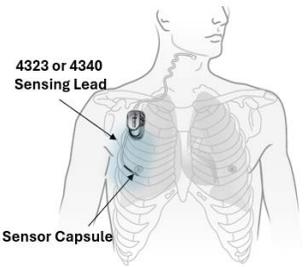
If the patient has any lead fragments greater than 2 cm or abandoned whole leads, assess the leads using Table 5 and Table 6 below.

Note: Any fragment less than 2 cm is MR conditional for any scan.

The lead assessment may be recorded in "Appendix A: Patient Checklist for MRI" on page 25, question 4.

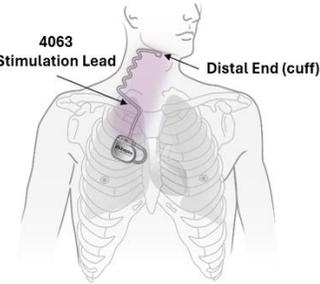
Abandoned Leads or Fragments

Table 5. Model 4323 or 4340 Abandoned **Sensing** Leads or Fragments (see Figure 4 on page 28)

 <p>4323 or 4340 Sensing Lead</p> <p>Sensor Capsule</p> <p>Note: System may be implanted on either the right (shown above) or left side of the body.</p>	Length of Lead or Fragment	 Generator Present	 No Generator
	Whole Sensing Lead (25cm or 45cm)	Scan Conditions 1 - 6 (1.5T) Scan Conditions 1 - 4 (3.0T)	Scan Conditions 1 - 6 (1.5T) Scan Conditions 1 - 4 (3.0T)
	Sensor Capsule ONLY	Scan Conditions 1 - 6 (1.5T) Scan Conditions 1 - 4 (3.0T)	Scan Condition 7
	Any other Fragment > 2cm	Do NOT Scan	Do NOT Scan

Note: "Generator present" indicates the patient has an implanted, functional MR-conditional Inspire Generator.

Table 6. Model 4063 Abandoned **Stimulation** Leads or Fragments (see Figure 5 on page 28)

 <p>4063 Stimulation Lead</p> <p>Distal End (cuff)</p> <p>Note: System may be implanted on either the right (shown above) or left side of the body.</p>	Length of Lead or Fragment	 Generator Present	 No Generator
	Whole Stimulation Lead (45cm)	Do NOT Scan	Do NOT Scan
	Distal Fragment < 9cm with Cuff	Scan Conditions 1 - 6 (1.5T) Scan Conditions 1 - 4 (3.0T)	Scan Condition 7
	Any Fragment > 2cm with NO Cuff	Do NOT Scan	Do NOT Scan

Note: "Generator present" indicates the patient has an implanted, functional MR-conditional Inspire Generator.

Step 5: Confirm No Adverse Conditions to Scanning Are Present

This assessment may be recorded in "Appendix A: Patient Checklist for MRI" on page 25, question 5.

- WARNING:** Do not scan the patient if they have any of the following:
- ▶ The presence of an Inspire abandoned generator.
 - ▶ Any exposed portions of the implanted system components due to skin erosion.
 - ▶ The presence of any other implanted devices (active or passive implanted devices) that prohibit safe scanning. Refer to the device manufacturer instructions for use for MR safety information.
 - ▶ The presence of a fever in the patient the day of the scan.

Step 6: Confirm normal operation of the Inspire System

The Inspire 3028 and 3150 Systems are designed to be MR conditional when functioning properly and off. The patient should confirm that their Inspire System is functioning properly prior to each scan by following the steps below using their Inspire Sleep Remote. They should confirm that stimulation occurs and clearly moves the patient's tongue or that the patient reports feeling stimulation.

Note: If the patient does not have their sleep remote, the local Inspire representative can confirm normal system operation with the Inspire Programmer.

- WARNING:** If the system isn't working properly, do not continue with the scan.

Note: If the patient does not have an implanted generator and the leads have been confirmed to be MR conditional, you may proceed with the scan.

The patient should follow these steps to confirm the Inspire System is operating normally with the sleep remote.

- a. Find the Therapy On/Pause button as shown in Figure 1 on page 15.



Figure 1. Sleep remote front view

- b. Start therapy by pressing the Therapy On/Pause button and then hold the remote over the Inspire generator as shown in Figure 2 on page 16 for 10 seconds or until you hear 2 beeps to confirm the device has turned on and the status ring changes to pulsating green. This will trigger a single stimulation pulse which should cause the patient's tongue to move forward or the patient reports feeling stimulation.

Note: In certain circumstances, depending on a patient's programmed settings, therapy may start immediately after turning on therapy and the remote status ring will be solid green.

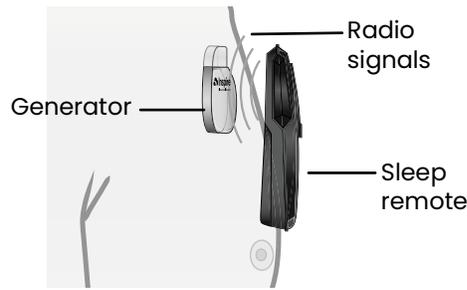


Figure 2. Communication between sleep remote and generator

- c. Confirm that the stimulation pulse occurs and clearly moves the patient's tongue or that the patient reports feeling stimulation. If unable to confirm normal functionality, do not scan the patient and contact Patient Services.

WARNING: If the Inspire System does not seem to be functioning normally, do not continue with the scan. The patient should discontinue use and be seen by their sleep physician.

- d. Turn the therapy OFF. Press the Therapy Off button as shown in Figure 1 on page 15 and then hold the remote over the Inspire generator as shown in Figure 2 on page 16 for 10 seconds or until you hear 2 beeps to confirm the device has turned off.
- Confirm therapy has been turned OFF by looking at the remote status ring and making sure that it is solid white and not flashing.
 - Turn the remote over and confirm the generator light as shown in Figure 3 on page 16 is NOT illuminated. If the generator light is illuminated, do not scan the patient and contact Patient Services. Refer the patient to their sleep physician to resolve the issue with their implant.
- e. Functionality check results may be recorded in "Appendix A: Patient Checklist for MRI" on page 25, question 6.



Figure 3. Sleep remote back view

WARNING: Inspire therapy must be OFF during an MRI. Failure to turn therapy off during an MRI may result in stimulation of the tongue. If the patient experiences any pain or discomfort, they should immediately notify staff and stop the scan.

Setting up, Performing the Scan, and Monitoring the Patient

- a. Set up the MRI equipment per MRI safety information starting on page 18.
- b. Confirm correct scan condition based on use of head transmit/receive RF coil, local extremity transmit/receive RF coil, or whole-body transmit RF coil.
- c. A gradient echo localizer sequence can be used to determine vertebra location relative to the planned scan area.
- d. Scan for 30 minutes with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 60 minutes before resuming scanning.
- e. When selecting the field of view and imaging parameters, consider that minimal image distortion may occur around an implanted lead or generator. These factors should be considered when interpreting the MRI images.

 **WARNING:** Exceeding the 30-minute active scan time limit within any 90-minute period may cause unsafe heating resulting in nerve damage. If additional sequences are required, a minimum waiting period of 60 minutes should be observed.

While performing the scan, follow these guidelines:

 **CAUTION:** Do not allow external devices into the scanner magnet room (MR facility Zone IV), 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.

- Notify the patient of potential interactions during the scan:
 - Vibration of the generator
 - Generator or stimulation electrode heating
 - Mild stimulation of the tongue, similar to therapy
- During the MRI scan, visually monitor the patient.
 - If possible, do not sedate the patient; this will allow for audible monitoring and communication with the patient. Stop the scan if the patient reports uncomfortable stimulation or heating.
 - If sedation is necessary or if the patient is in a non-responsive state, monitor the patient per facility guidelines and stop the scan when deemed necessary.

Patient Services

For technical questions and support please contact Inspire Patient Services at 1-844-OSA-HELP (844-672-4357) option 3, or direct at 844-672-6720.

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



MRI Safety Information, Scan Condition 1

Head scan, local transmit/receive RF coil

Use Scan Condition 1 for a head scan with a head transmit/receive RF coil, positioning the coil so that it does NOT extend below the chin. A person implanted with an Inspire 3028 or 3150 System may be safely scanned at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Patient eligibility can be determined by working through the steps in “Determine Patient Eligibility for an MRI Scan” on page 10.

Note: In the event that the T/R coil extends below the chin, use “MRI Safety Information, Scan Condition 2” on page 19.

Area	Parameter	Condition
	Device Name	Inspire Generator (Models 3028, 3150) connected to any whole Inspire lead model(s).
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B ₀)	1.5T or 3.0T
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Head transmit/receive RF coil
	RF Receive Coil Type	Head transmit/receive RF coil
	Operating Mode	Normal operating mode
	RF Conditions	<p>1.5T: B_{1+rms} ≤ 6 μT For 1.5T MRI scanners that do not report B_{1+rms}, limit hdSAR ≤ 2.9 W/kg.</p> <p>3.0T: B_{1+rms} ≤ 2.6 μT For 3.0T scanners that do not report B_{1+rms}, limit hdSAR ≤ 2.0 W/kg.</p>
	Scan Duration	Scan for 30 minutes with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 60 minutes before resuming scanning.
	Scan Regions	Position the head transmit/receive RF coil so that it does not extend below the chin.
Image Artifact	Presence of the stimulation lead may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.	



WARNING: When performing this scan, ensure the RF conditions are correct for the coil position. Incorrect RF coil positioning may result in unsafe heating resulting in nerve damage.



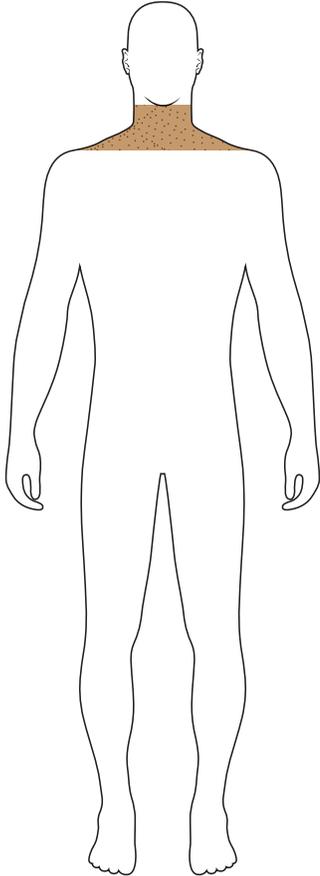
MRI Safety Information, Scan Condition 2

Neck scan, local transmit/receive RF coil

Use Scan Condition 2 for a neck scan with a head transmit/receive RF coil, positioning the coil so that it extends below the chin. A person implanted with an Inspire 3028 or 3150 System may be safely scanned at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Patient eligibility can be determined by working through the steps in "Determine Patient Eligibility for an MRI Scan" on page 10.

Note: For scanning this area you may also consider, "MRI Safety Information, Scan Condition 5" on page 22 which uses a whole-body transmit RF coil (any receive coil) to scan superior to T12.

Area	Parameter	Condition
	Device Name	Inspire Generator (Models 3028, 3150) connected to any whole Inspire lead model(s).
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B_0)	1.5T or 3.0T
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Head transmit/receive RF coil
	RF Receive Coil Type	Head transmit/receive RF coil
	Operating Mode	Normal operating mode
	RF Conditions	<p>1.5T: $B_{1+rms} \leq 4 \mu T$ For 1.5T MRI scanners that do not report B_{1+rms}, limit the hdsAR $\leq 2.1 W/kg$.</p> <p>Note: The B_{1+rms} limit shown is the value before scanning.</p> <p>3.0T: $B_{1+rms} \leq 2.6 \mu T$ For 3.0T MRI scanners that do not report B_{1+rms}, limit the hdsAR $\leq 2.0 W/kg$.</p>
	Scan Duration	Scan for 30 minutes with one or more MR imaging pulse sequences (scans or series), followed by a wait time of 60 minutes before resuming scanning.
	Scan Regions	Arrange the head transmit/receive RF coil to extend below the chin.
Image Artifact	Presence of the stimulation lead may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.	



WARNING: When performing this scan, ensure the RF conditions are correct for the coil position. Incorrect RF coil positioning may result in unsafe heating resulting in nerve damage.



MRI Safety Information, Scan Condition 3

Extremity scan, local transmit/receive RF coil

Use Scan Condition 3 for a local extremity transmit/receive RF coil, covering no component of the Inspire System. A person implanted with an Inspire 3028 or 3150 System may be safely scanned at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Patient eligibility can be determined by working through the steps in “Determine Patient Eligibility for an MRI Scan” on page 10.

Area	Parameter	Condition
	Device Name	Inspire Generator (Models 3028, 3150) connected to any whole Inspire lead model(s).
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B_0)	1.5T or 3.0T
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Volume or local extremity transmit/receive RF coil
	RF Receive Coil Type	Volume or local extremity transmit/receive RF coil
	Operating Mode	Normal operating mode
	RF Conditions	1.5T or 3.0T: Normal operating mode
	Scan Duration	Scan for 30 minutes with one or more MR imaging pulse sequences (scans or series), followed by a wait time of 60 minutes before resuming scanning.
Scan Regions	Extremities. Patient may be positioned with their arm at their side or above their head, in either the prone or supine position.	
Image Artifact	Inspire Systems are not implanted in the extremities. No image artifact should be seen in extremity scans.	

WARNING: When performing this scan, do not include any implanted components in the RF coil. Implant locations can be confirmed with x-ray images. Incorrect RF coil positioning may result in unsafe heating resulting in nerve damage.



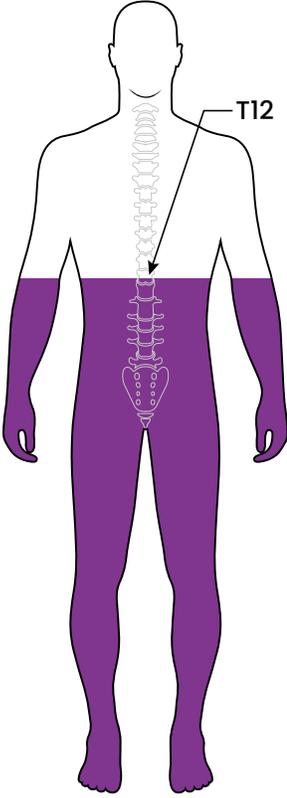
MRI Safety Information, Scan Condition 4

Scan at or inferior to T12, whole-body transmit RF coil (any receive coil)

Use Scan Condition 4 with a whole-body transmit RF coil with the iso-center of the scan at or inferior to T12. A person implanted with the Inspire 3028 or 3150 System may be safely scanned at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Patient eligibility can be determined by working through the steps in "Determine Patient Eligibility for an MRI Scan" on page 10.

Note: If you are unsure which scan condition to use for abdominal scans, Scan Condition 5 is more conservative than Scan Condition 4.

Area	Parameter	Condition
	Device Name	Inspire Generator (Models 3028, 3150) connected to any whole Inspire lead model(s).
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B_0)	1.5T or 3.0T
	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 Polarization	1.5T: Circularly Polarized (CP) 3.0T: Circularly Polarized (CP) or Multichannel-2 (MC-2)
	RF Transmit Coil Type	Whole-body transmit RF coil
	RF Receive Coil Type	Any
	Operating Mode	Normal operating mode
	RF Conditions	1.5T: $B_{1+rms} \leq 3.2 \mu T$ For 1.5T MRI scanners that do not report B_{1+rms} , limit $wbSAR \leq 2.0 W/kg$. 3.0T: $B_{1+rms} \leq 1.6 \mu T$ For 3.0T MRI scanners that do not report B_{1+rms} , limit $wbSAR \leq 2.0 W/kg$.
	Scan Duration	Scan for 30 minutes with one or more MR imaging pulse sequences (scans or series), followed by a wait time of 60 minutes before resuming scanning.
	Scan Regions	Iso-center of the scan at or inferior to T12. Patient may be positioned either prone or supine and can enter the scanner head-first or feet-first.
Image Artifact	Inspire Systems are not implanted inferior to T12. No image artifact should be seen in scans.	

WARNING: When performing this scan, ensure the iso-center is at or inferior to T12 and the RF conditions are correct. Incorrect positioning of the iso-center or incorrect RF conditions may result in unsafe heating resulting in nerve damage.



MRI Safety Information, Scan Condition 5

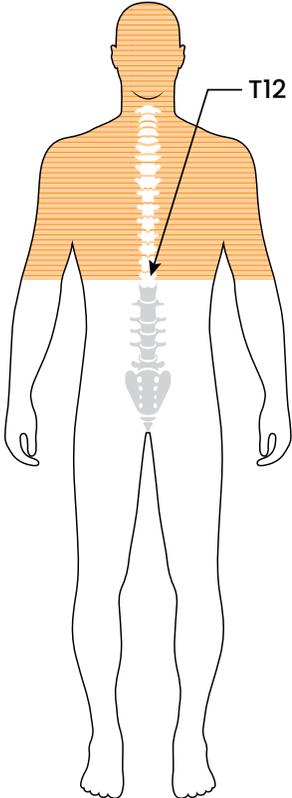
Scan superior to T12, whole-body transmit RF coil (any receive coil)

Use Scan Condition 5 with a whole-body transmit RF coil with the iso-center of the scan superior to T12. A person implanted with the Inspire 3028 or 3150 System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.

Patient eligibility can be determined by working through the steps in “Determine Patient Eligibility for an MRI Scan” on page 10.

WARNING: Do not use Scan Condition 5 with 3.0T MRI scanners. Use of 3.0T scanners may result in device damage, unsafe heating or nerve damage.

Note: For this scan condition, it is acceptable for the implanted components to be positioned within the coil.

Area	Parameter	Condition
	Device Name	Inspire Generator (Models 3028, 3150) connected to any whole Inspire lead model(s).
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B_0)	1.5T only
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Whole-body transmit RF coil
	RF Receive Coil Type	Any
	Operating Mode	Normal operating mode
	RF Conditions	1.5T: $B_{1+rms} \leq 1.9 \mu T$ For 1.5T MRI scanners that do not report B_{1+rms} , limit $wbSAR \leq 0.3 W/kg$ and $hdsAR \leq 0.5 W/kg$. Note: The B_{1+rms} limit shown is the value before scanning.
	Scan Duration	Scan for 30 minutes with one or more MR imaging pulse sequences (scans or series), followed by a wait time of 60 minutes before resuming scanning.
	Scan Regions	Iso-center of the scan superior to T12. Patient may be positioned either prone or supine and can enter the scanner head-first or feet-first.
Image Artifact	Presence of an Inspire System may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.	

WARNING: When performing this scan, ensure the RF conditions are correct when the iso-center is located superior to T12. Incorrect RF conditions may result in unsafe heating resulting in nerve damage.



MRI Safety Information, Scan Condition 6

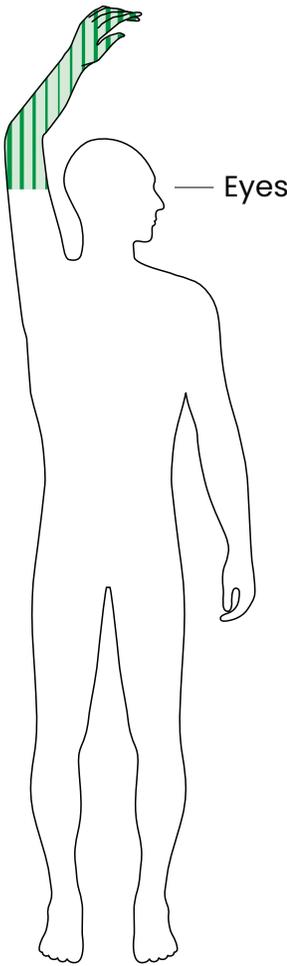
Scan superior to eye level, whole-body transmit RF coil (any receive coil)

Use Scan Condition 6 with a whole-body transmit RF coil with iso-center of the scan superior to eye level. Position the patient with their arm over their head, laying supine or prone. A person implanted with an Inspire 3028 or 3150 System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.

Patient eligibility can be determined by working through the steps in “Determine Patient Eligibility for an MRI Scan” on page 10.

WARNING: Do not use Scan Condition 6 with 3.0T MRI scanners. Use of 3.0T scanners may result in device damage, unsafe heating or nerve damage.

Note: This scan condition only applies to the highlighted extremities. Also, consider using a local extremity T/R coil; “MRI Safety Information, Scan Condition 3” on page 20.

Area	Parameter	Condition
	Device Name	Inspire Generator (Models 3028, 3150) connected to any whole Inspire lead model(s).
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B_0)	1.5T only
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Whole-body transmit RF coil
	RF Receive Coil Type	Any
	Operating Mode	Normal operating mode
	RF Conditions	1.5T: $B_{1+rms} \leq 2.3 \mu T$ For 1.5T MRI scanners that do not report B_{1+rms} , limit $wbSAR \leq 2 W/kg$ and $hdSAR \leq 0.7 W/kg$. Note: The B_{1+rms} limit shown is the value before scanning.
	Scan Duration	Scan for 30 minutes with one or more MR imaging pulse sequences (scans or series), followed by a wait time of 60 minutes before resuming scanning.
Scan Regions	Highlighted extremities. Iso-center of the scan superior to eye level. Patient positioned with arm over their head, in either the prone or supine position.	
Image Artifact	Inspire Systems are not implanted in the arm. No image artifact should be seen in arm scans.	

WARNING: When performing this scan, ensure the iso-center location is superior to eye level. Incorrect positioning may result in unsafe heating resulting in nerve damage.



MRI Safety Information, Scan Condition 7

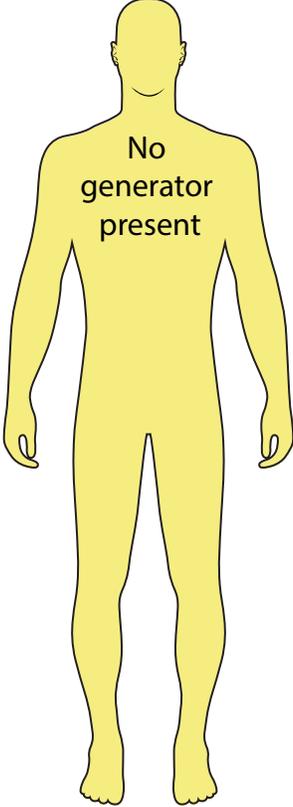
Abandoned Leads and Lead Fragments when No Generator Present

Use Scan Condition 7 in cases where **both** of the following are true:

- Patient **does NOT** have an implanted generator, and
- Patient has eligible **abandoned leads or lead fragments** per “Step 4: Assess the Lead(s)” on page 14.

Failure to follow these conditions may result in injury.

Patient eligibility can be determined by working through the steps in “Determine Patient Eligibility for an MRI Scan” on page 10.

Area	Parameter	Condition
 <p>No generator present</p>	Device Name	This condition applies to abandoned leads and lead fragments eligible per Step 4 when NO Generator is present.
	Device Configuration	Not applicable—no generator should be present for this scan
	Static Magnetic Field Strength (B_0)	1.5T or 3.0T
	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 Polarization	1.5T: Circularly Polarized (CP)
		3.0T: Circularly Polarized (CP) or Multichannel-2 (MC-2)
	RF Transmit Coil Type	Whole-body transmit RF coil
	RF Receive Coil Type	Any
	Operating Mode	Normal operating mode
	RF Conditions	1.5T or 3.0T: Normal operating mode
	Scan Duration	Scan for 30 minutes with one or more MR imaging pulse sequences (scans or series), followed by a wait time of 60 minutes before resuming scanning.
	Scan Regions	No restrictions
Image Artifact	Presence of Inspire components may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.	

Appendix A: Patient Checklist for MRI

Inspire provides this voluntary checklist to aid in determining MR eligibility.

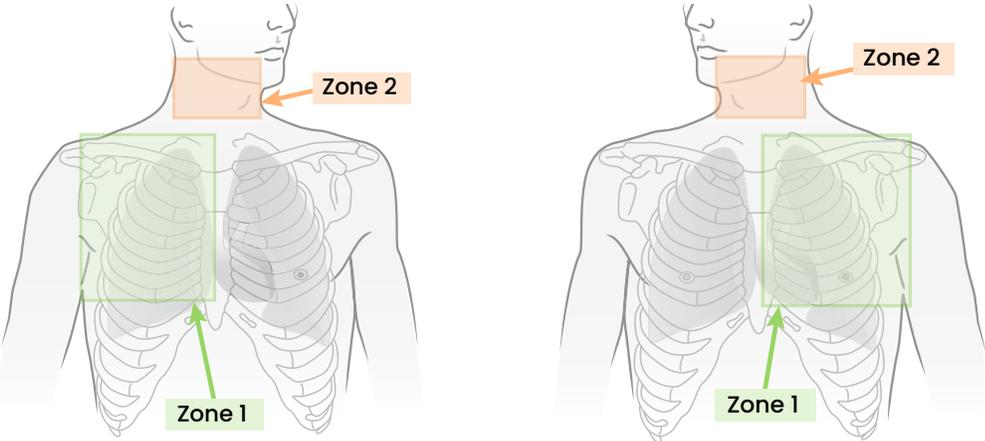
If you reach the end of the worksheet with “Yes, proceed with the scan”, you may proceed with the scan. If you answer any of the questions with “No, do not scan the patient”, do not proceed with the scan. If the answer to any question is “Unsure,” contact the patient’s physician or Inspire Patient Services for help.

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.

 **WARNING:** 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 are using the most recent version of these MRI procedures. Contact Inspire Patient Services or retrieve the most recent version online at manuals.inspiresleep.com.

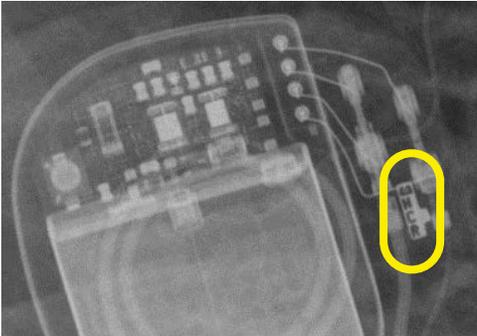
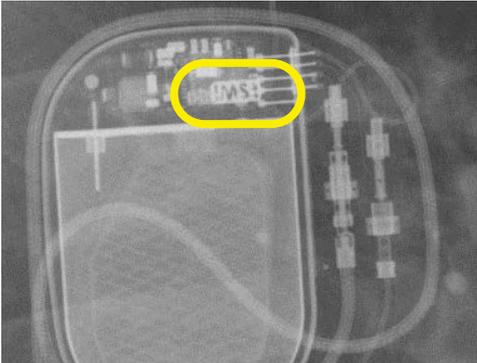
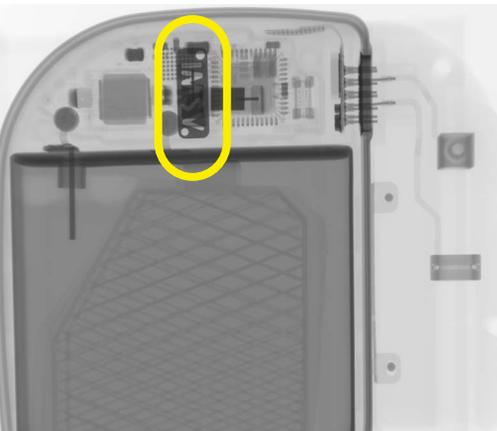
Patient's Name:	
Physician's name and contact information (office name, address, phone number):	
Date of eligibility assessment:	
Generator Model:	
Stimulation Lead Model:	
Sensing Lead Model:	

Eligibility Steps	Mark the response	
<p>1. Are the Inspire System components MR conditional per Table 1? See "Step 1: Confirm that the implanted Inspire System is MR conditional" on page 10.</p>	<input type="radio"/> Yes	<input type="radio"/> No, do not scan the patient
<p>2. Are the components in an approved location? See "Step 2: Confirm the Implanted System is in an Approved Location" on page 12.</p> <p>– Mark the location and model numbers of the implanted system components on the diagram below.</p> 	<input type="radio"/> Yes	<input type="radio"/> No, do not scan the patient
<p>3. Identify and mark the intended scan condition below. See "Step 3: Identify the Intended Scan Condition" on page 13</p> <p><input type="radio"/>1 <input type="radio"/>2 <input type="radio"/>3 <input type="radio"/>4 <input type="radio"/>5 <input type="radio"/>6 <input type="radio"/>7</p>	Continue to question 4.	
<p>4. Assess the lead(s). See "Step 4: Assess the Lead(s)" on page 14.</p> <p>– If the patient has no abandoned leads/lead fragments, mark "Yes" and move to step 5.</p> <p>– If the patient has abandoned leads or lead fragments, assess the leads per "Step 4: Assess the Lead(s)" on page 14 and record the eligible scan condition below.</p> <p>Abandoned Sensing Lead(s)/Fragments. See Table 5 on page 14: <input type="radio"/>1-6 (1.5T) <input type="radio"/>1-4 (3.0T) <input type="radio"/>7 <input type="radio"/>No eligible scan condition <input type="radio"/>Not present</p> <p>Abandoned Stimulation Lead(s)/Fragments. See Table 6 on page 14: <input type="radio"/>1-6 (1.5T) <input type="radio"/>1-4 (3.0T) <input type="radio"/>7 <input type="radio"/>No eligible scan condition <input type="radio"/>Not present</p> <p>– If the abandoned lead(s)/fragment(s) are eligible for the intended scan condition mark "Yes".</p> <p>– If there are no eligible scan conditions or the abandoned lead(s)/fragment(s) are not eligible for the intended scan condition, mark "No".</p>	<input type="radio"/> Yes	<input type="radio"/> No, do not scan the patient
<p>5. Have all possible adverse scan conditions been ruled out? See "Step 5: Confirm No Adverse Conditions to Scanning Are Present" on page 15.</p>	<input type="radio"/> Yes	<input type="radio"/> No, do not scan the patient
<p>6. If the patient has an Inspire System, is the system functioning properly and turned OFF? See "Step 6: Confirm normal operation of the Inspire System" on page 15.</p> <p>– If the patient does not have an implanted generator and the leads have been confirmed to be MR conditional, you may proceed with the scan.</p>	<input type="radio"/> Yes, proceed with the scan	<input type="radio"/> No, do not scan the patient

Appendix B: X-ray ID Tag

The x-ray images below show Inspire generators, with specific reference to the location of the x-ray identification tag.

Table 7. X-ray ID Tag Locations

Generator	X-ray ID	MR Specifications
<p>Model 3024</p> 		<p>X-ray ID is "NCR" and generator is NOT eligible for an MRI</p> <p> MR Unsafe</p>
<p>Model 3028</p> 		<p>X-ray ID is "IMS1" and generator is MR conditional</p>
<p>Model 3150</p> 		<p>X-ray ID is "IMSV" and generator is MR conditional</p>

Appendix C: Reference Images for Lead Fragments

Model 4323 or 4340 Sensing Lead(s)/Fragments

The whole sensing lead is 25cm or 45cm. Figure 4 shows the sensor capsule at the distal end of the sensing lead. A sensor capsule that is detached from the lead body at the line shown below is MR conditional per Table 5 on page 14.

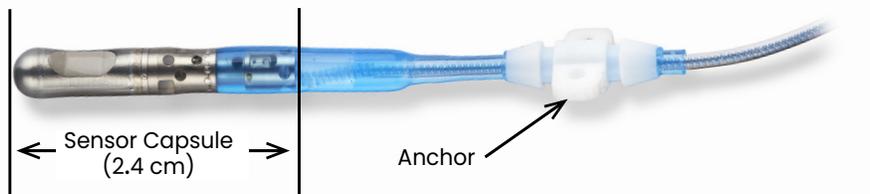


Figure 4. Sensor capsule on the distal end of the sensing lead

Model 4063 Stimulation Lead/Fragments

The whole stimulation lead is 45cm. Figure 5 shows the distal end of the stimulation lead to 0.5 cm beyond the proximal edge of the anchor, which is 9 cm in length. The distal end of a stimulation lead fragment with a cuff that is <9cm is MR conditional per Table 6 on page 14.

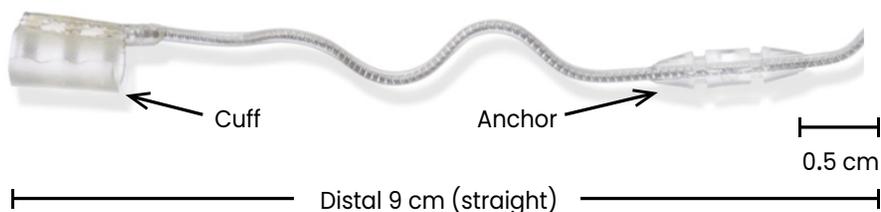


Figure 5. Distal end of a 9cm stimulation lead fragment with cuff

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