Inspire®
Sleep Apnea Innovation

MRI GUIDELINES FOR GENERATORS AND LEADS

[#] 3024, 3028, 3150, 4323, 4340, 4063

Rx 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 16.

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	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 7000-2497
	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

Commonly used acronyms in this manual

Head SAR = hdSAR	Whole body SAR = wbSAR	Transmit/receive = T/R	Radiofrequency = RF

Models and Implant Locations for MR Conditional Neurostimulation Systems

Table 1 lists all Inspire generator model numbers and identifies those that can comprise an MR conditional neurostimulation system. Since the leads are part of the Inspire Systems, they are also included in the chart.

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 and Lead Scan Eligibility*

Model*	**X-ray ID****	**Serial Number Prefix**	**Eligibility Details**
3024	NCR	NCRXXXXXXX	**Not eligible for MRI**
3028	IMS1	AIR######C	MR conditional per scan conditions 1-6 at 1.5T
3150	IMSV	TML######L	MR conditional per scan conditions 1-6 at 1.5T
4323; 4340 Sensing Lead	---	S##### (Polyurethane) T##### (Silicone) U##### (Silicone)	MR conditional per scan conditions 1-6 at 1.5T
4063 Stimulation Lead	---	C##### (Polyurethane) D##### (Silicone) E##### (Silicone)	MR conditional per scan conditions 1-6 at 1.5T

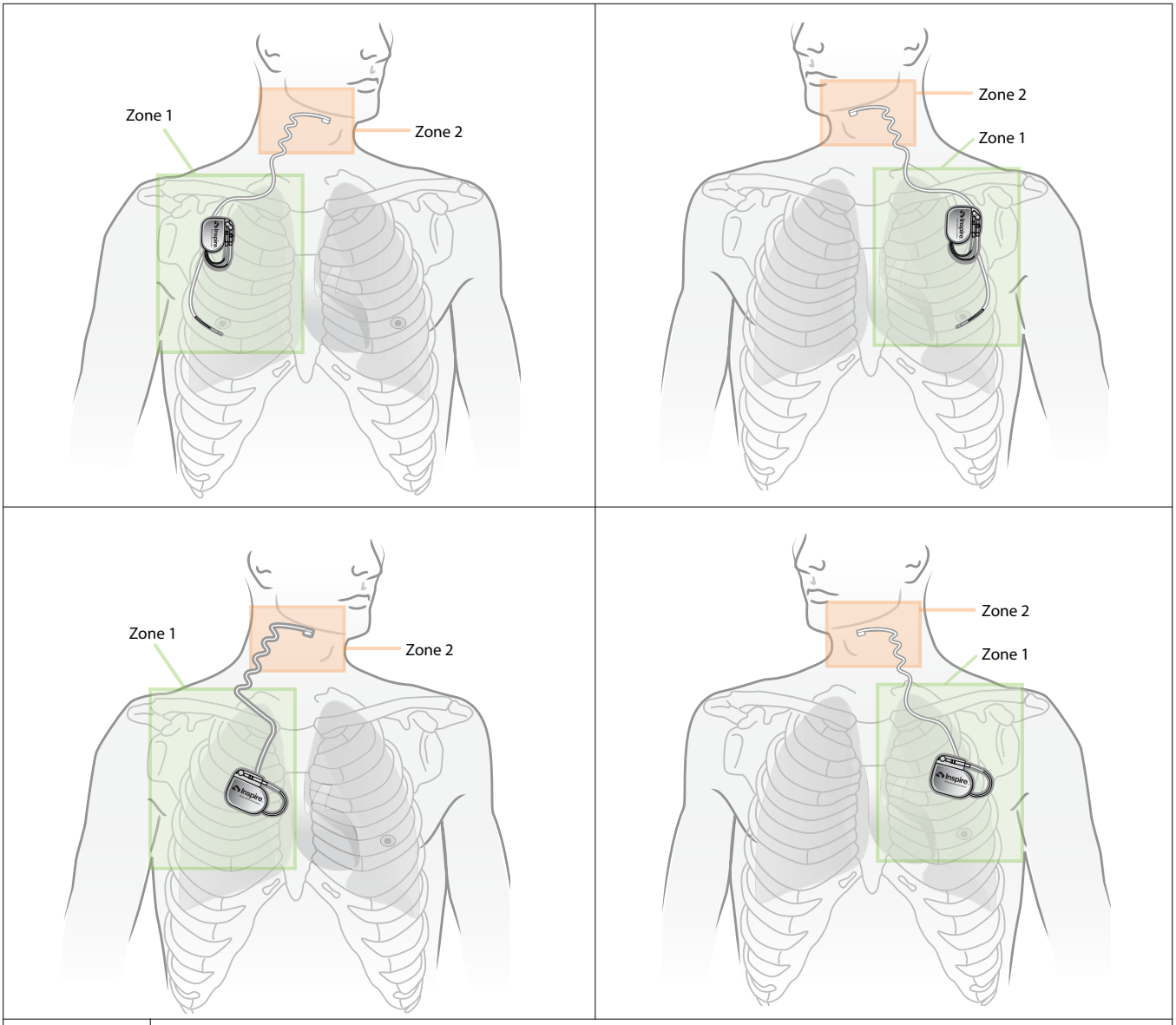
* All Inspire lead model numbers are MR conditional when connected to a working generator and are eligible for the scan conditions defined in this manual

** Reference “Appendix B: X-ray ID Tag” on page 19 for location and examples of the x-ray ID tag

“Scan Conditions 1-6” on page 4 show the generator and lead scan conditions for an MRI. See “MRI Safety Information, Abandoned Leads and Lead Fragments, Scan Condition 7” on page 11 to determine MRI eligibility for abandoned leads and lead fragments.

Table 2 lists the approved MRI 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. Generator orientation can vary.

Table 2. *Approved locations for implanted components*



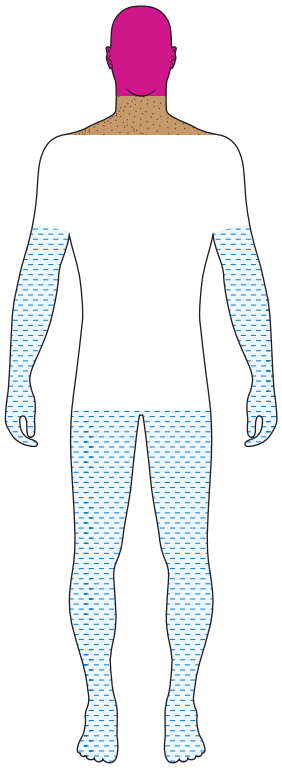
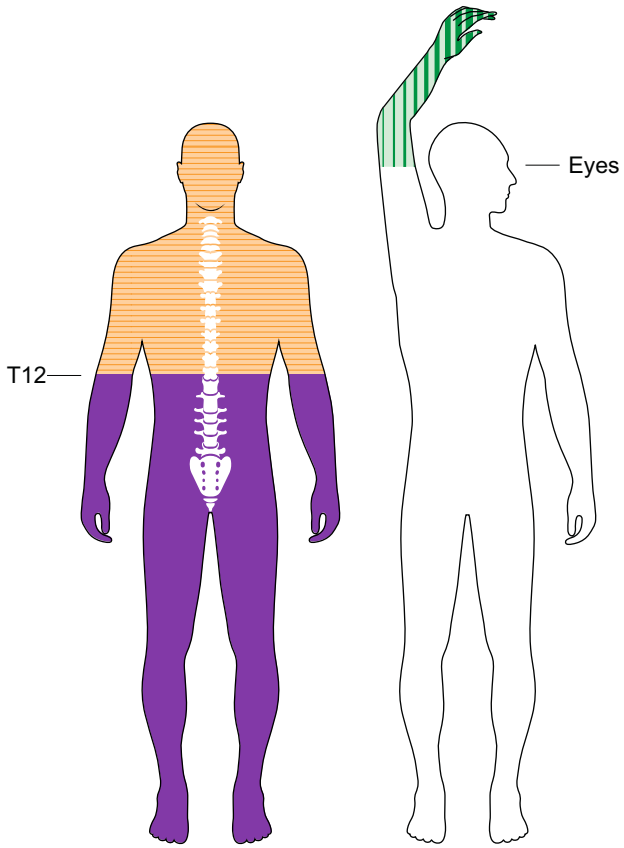
	Zone 1: Implant location for the generator should be within Zone 1.
	Zone 2: Implant location for the tip of the stimulation lead should be within Zone 2.

See Patient Checklist in “Appendix A: Patient Checklist for MRI” on page 17.

MRI Safety Information

Testing has demonstrated that the Inspire 3028 and 3150 Systems are MR conditional at 1.5T. A patient with these devices can be safely scanned with a whole body or local coil in an MR system meeting the conditions in Table 3.

Table 3. *Scan Conditions 1-6*

Transmit/receive (T/R) RF local coils	**Whole-body transmit RF coil (any receive coil may be used)**
	

	Scan Condition 1: Head scan, local transmit/receive RF coil		**Scan Condition 4:** Scan inferior to T12, whole-body transmit RF coil (any receive coil)
	Scan Condition 2: Neck scan, local transmit/receive RF coil		**Scan Condition 5:** Scan superior to T12, whole-body transmit RF coil (any receive coil)
	Scan Condition 3: Extremity scan, local transmit/receive RF coil		**Scan Condition 6:** Scan superior to eye level, whole-body transmit RF coil (any receive coil)

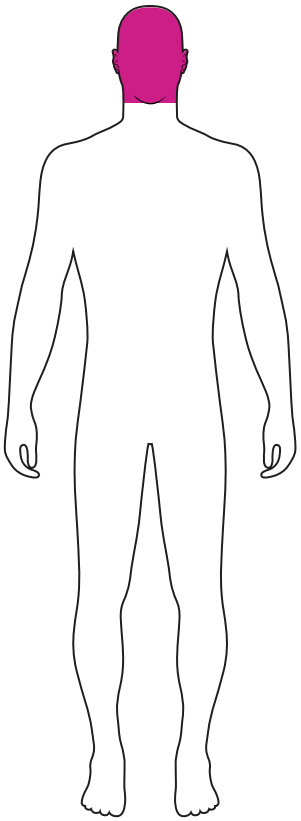
Note: If you are unsure which scan condition to use for abdominal scans, Scan Condition 5 is more conservative than Scan Condition 4.

Note: The scan condition choice is predicated on the body part being scanned as well as the transmit RF coil.

MRI Safety Information, Scan Condition 1

For a head scan with transmit/receive RF coil, position 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 under the following conditions. Failure to follow these conditions may result in injury.

Additional MR safety information may be found by calling “Patient Services” on page 17.

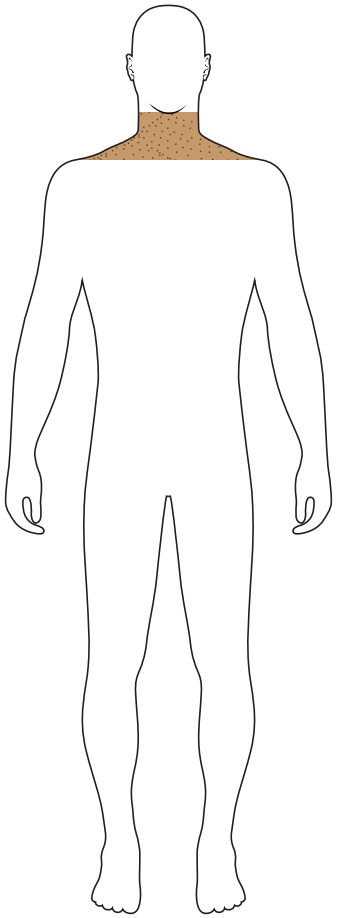
Area	Parameter	Condition
	Device Name	Inspire 3028 Generator, Inspire 3150 Generator and all Inspire lead models are MR conditional. This condition also applies if an abandoned sensor lead (4340; 4323) is present.
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B_0)	1.5T
	MR Scanner 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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Detachable head transmit/receive RF coil
	RF Receive Coil Type	Detachable head transmit/receive RF coil
	Operating Mode	Normal operating mode
	RF Conditions	B_{1+}rms ≤ 6 µT **Note:** The B_{1+}rms limit shown is the value before scanning. For 1.5T MRI scanners that do not report B_{1+}rms, limit hdSAR ≤ 2.9 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	Position the head transmit/receive RF coil so that it does not 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.

Caution: When using this scan condition, ensure the RF conditions are correct for the coil position. Incorrect RF coil positioning may result in unsafe heating resulting in nerve damage. In the event that the T/R coil extends below the chin, use “MRI Safety Information, Scan Condition 2” on page 6.

MRI Safety Information, Scan Condition 2

Use scan condition 2 for a neck scan with 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 under the following conditions. Failure to follow these conditions may result in injury.

Additional MR safety information may be found by calling “Patient Services” on page 17.

Area	Parameter	Condition
	Device Name	Inspire 3028 Generator, Inspire 3150 Generator and all Inspire lead models are MR conditional. This condition also applies if an abandoned sensor lead (4340; 4323) is present.
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Head RF transmit-receive coil
	RF Receive Coil Type	Head RF transmit-receive coil
	Operating Mode	Normal operating mode
	RF Conditions	B_{1+}rms ≤ 4 µT **Note:** The B_{1+}rms limit shown is the value before scanning. For 1.5-T MRI scanners that do not report B_{1+}rms, limit the hdSAR ≤ 2.1 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	Arrange the head RF transmit-receive coil 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.

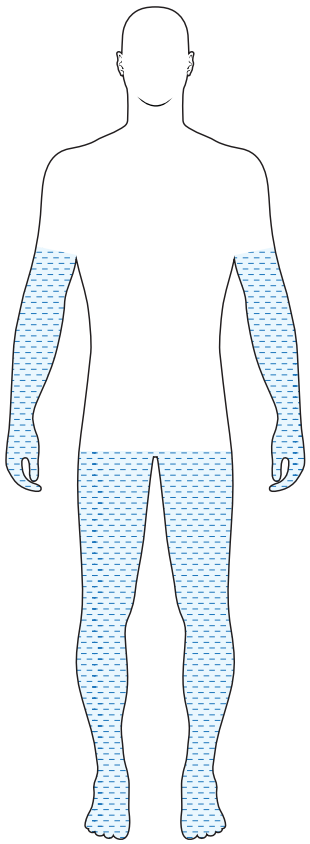
Caution: When using this scan conditions, ensure the RF conditions are correct for the coil position. Incorrect RF coil positioning may result in unsafe heating resulting in nerve damage.

Note: For scanning this area you may also consider, “MRI Safety Information, Scan Condition 5” on page 9.

MRI Safety Information, Scan Condition 3

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 under the following conditions. Failure to follow these conditions may result in injury.

Additional MR safety information may be found by calling “Patient Services” on page 17.

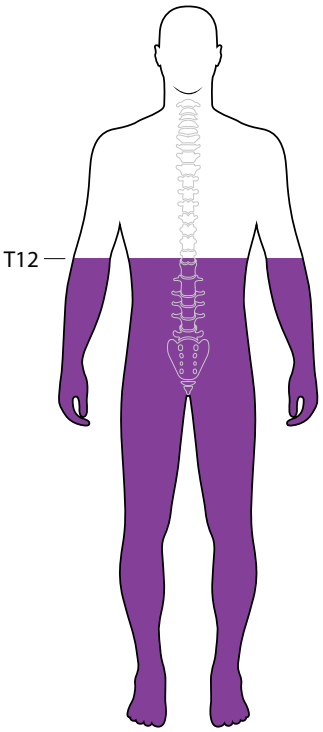
Area	Parameter	Condition
	Device Name	Inspire 3028 Generator, Inspire 3150 Generator and all Inspire lead models are MR conditional. This condition also applies if an abandoned sensor lead (4340; 4323) is present.
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B_0)	1.5T
	MR Scanner 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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Local extremity transmit/receive RF coil
	RF Receive Coil Type	Local extremity transmit/receive RF coil
	Operating Mode	Normal operating mode
	RF Conditions	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 arm over their head lying supine or prone.
	Image Artifact	The Inspire systems are not implanted in the extremities. No image artifact should be seen in extremity scans.

Caution: When using this scan condition 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

Use scan condition 4 with a integrated whole-body transmit 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 under the following conditions. Failure to follow these conditions may result in injury.

Additional MR safety information may be found by calling “Patient Services” on page 17.

Area	Parameter	Condition
	Device Name	Inspire 3028 Generator, Inspire 3150 Generator and all Inspire lead models are MR conditional. This condition also applies if an abandoned sensor lead (4340, 4323) is present.
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Integrated whole-body transmit coil
	RF Receive Coil Type	Any
	Operating Mode	Normal operating mode
	RF Conditions	B_{1+}rms ≤ 3.2 µT **Note:** The B_{1+}rms limit shown is the value before scanning. For 1.5-T MRI scanners that do not report B_{1+}rms, limit wbSAR ≤ 2 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
	Image Artifact	The Inspire systems are not implanted in inferior to T12. No image artifact should be seen in scans.

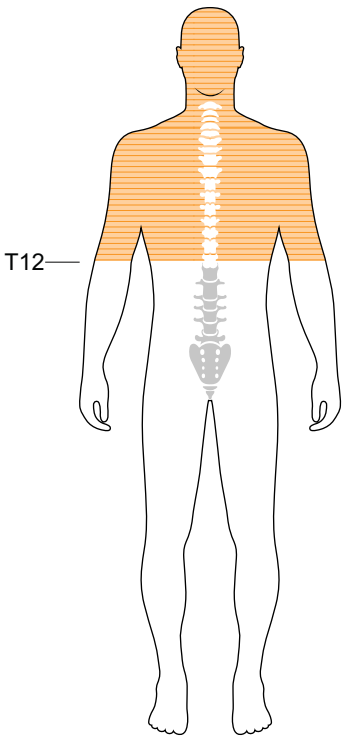
Caution: When using this scan condition ensure the iso-center is at or inferior to T12 and the RF conditions are correct. Incorrect positioning of the iso-center or incorrect RF conditions may result in unsafe heating resulting in nerve damage.

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

MRI Safety Information, Scan Condition 5

Use scan condition 5 with a integrated whole-body transmit 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.

Additional MR safety information may be found by calling “Patient Services” on page 17.

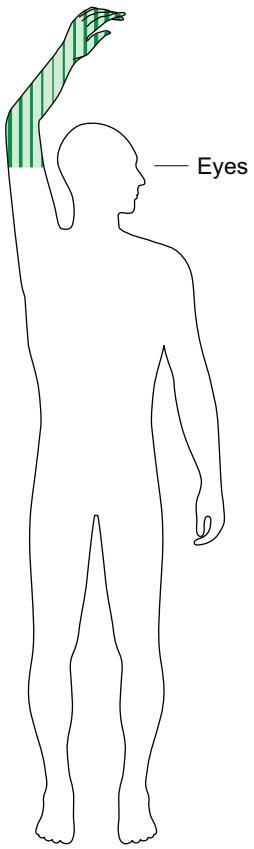
Area	Parameter	Condition
	Device Name	Inspire 3028 Generator, Inspire 3150 Generator and all Inspire lead models are MR conditional. This condition also applies if an abandoned sensor lead (4340, 4323) is present.
	Device Configuration	Stimulation OFF
	Static Magnetic Field Strength (B_0)	1.5T
	MR Scanner 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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Integrated whole-body transmit coil
	RF Receive Coil Type	Any
	Operating Mode	Normal operating mode
	RF Conditions	B_{1+}rms ≤ 1.9 µT **Note:** The B_{1+}rms limit shown is the value before scanning. For 1.5-T MRI scanners that do not report B_{1+}rms, limit wbSAR ≤ 0.3 W/kg and hdSAR ≤ 0.5 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 superior to T12
	Image Artifact	The presence of an Inspire system may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

Caution: When using this scan condition, 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

Use scan condition 6 with a integrated whole-body transmit 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.

Additional MR safety information may be found by calling “Patient Services” on page 17.

Area	Parameter	Condition
	Device Name	Inspire 3028 Generator, Inspire 3150 Generator and all Inspire lead models are MR conditional. This condition also applies if an abandoned sensor lead (4340; 4323) is present.
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Integrated whole-body transmit coil
	RF Receive Coil Type	Any
	Operating Mode	Normal operating mode
	RF Conditions	B_{1+}rms ≤ 2.3 µT **Note:** The B_{1+}rms limit shown is the value before scanning. For 1.5-T MRI scanners that do not report B_{1+}rms, limit wbSAR ≤ 2 W/kg and hdSAR ≤ 0.7 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 superior to eye level. Patient positioned with arm over their head lying supine or prone.
	Image Artifact	The Inspire systems are not implanted in the arm. No image artifact should be seen in arm scans.

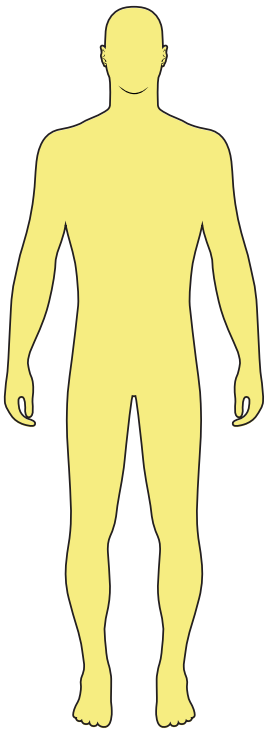
Caution: When performing this scan ensure the iso-center location is superior to eye level. Incorrect positioning may result in unsafe heating resulting in nerve damage.

Note: This condition only applies to the highlighted extremities. Also, consider using a T/R coil; “MRI Safety Information, Scan Condition 3” on page 7.

MRI Safety Information, Abandoned Leads and Lead Fragments, Scan Condition 7

Use scan condition 7 in cases where the patient does not have an implanted generator but has lead(s) or lead fragments. Failure to follow these conditions may result in injury.

Additional MR safety information may be found by calling “Patient Services” on page 17.

Area	Parameter	Condition
	Device Name	Detached sensor lead capsule from 4340 or 4323 and/or abandoned stimulation lead (4063) ≤ 9 cm. See “Appendix C: Abandoned Leads and Lead Fragments” on page 20.
	Device Configuration	No generator should be present for this scan
	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 Polarization	Circularly Polarized (CP)
	RF Transmit Coil Type	Integrated whole-body transmit coil
	RF Receive Coil Type	Any
	Operating Mode	Normal operating mode
	RF Conditions	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	The presence of an Inspire components may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

Warnings and Precautions

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

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 additional sequences are required, a minimum waiting period of 60 minutes should be observed.

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 with any unapproved neurostimulation components for use in an MR environment.

Abandoned stimulation lead: Do not perform an MRI scan on patients with an abandoned stimulation lead > 9 cm long.

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.

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.

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.

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 to 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.

Precautions

B_{1+}rms: If the MR scanner does not display the B1+rms value, then limit RF exposure based on the wbSAR and hdSAR listed for each scan condition. B1+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 MR conditional 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

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.
2. Assess the lead(s).
3. Confirm that no adverse conditions to MR scanning are present.
4. Confirm normal operation of the generator.
5. Select the MRI parameters according to the scanning requirements.
6. 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 A: Patient Checklist for MRI” on page 17 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 implant card and their sleep remote with them. The patient receives their sleep remote when their Inspire therapy is activated, 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 implant card. 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.

1. 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 19), or contacting Inspire Patient Services.

2. Cross-reference the model numbers on the card with the model numbers identified in Table 1. If the model number is not listed on the patient implant card, use Table 1 and the serial number format to determine model number.
3. Reference Table 1 to determine if the implanted components are within the approved areas.

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

Step 2: Assess the Leads

All Inspire stimulation and/or sense leads that are attached to a functional Inspire generator, per Table 1, are MR conditional. Check for lead fragments or abandoned leads. See "MRI Safety Information, Abandoned Leads and Lead Fragments, Scan Condition 7" on page 11.

- The distal end of a stimulation lead less than 9 cm is MR conditional (see "Appendix C: Abandoned Leads and Lead Fragments" on page 20).
- An intact sense lead of any length is MR conditional (see "Appendix C: Abandoned Leads and Lead Fragments" on page 20).
- A broken sensor lead distal tip (lead body and terminal are explanted) is MR conditional (see "Appendix C: Abandoned Leads and Lead Fragments" on page 20).
- Any other broken lead circumstance is MR unsafe.

Step 3: 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 other than what is described in "Step 2: Assess the Leads".
- The presence of an abandoned generator.
- The presence of an abandoned stimulation lead > 9 cm.
- 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. 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 4: Use the Sleep Remote or Inspire Programmer to Confirm Normal Operation

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 using their Inspire Sleep

Remote. If the patient does not have their sleep remote, the local Inspire representative can confirm tongue motion and normal system operation with the Inspire Programmer.

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

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

1. 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 while holding the remote over the Inspire generator as shown in Figure 2. This will trigger a single stimulation pulse which should cause the patient's tongue to move forward. You may hear 2 beeps to confirm the device has turned on and the status ring will change to pulsating green.

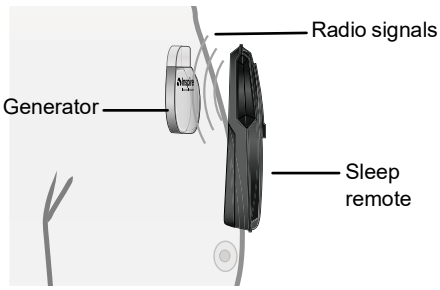


Figure 2. *Communication between sleep remote and generator*

3. Confirm that stimulation occurs and clearly moves the patient's tongue or feels normal to the patient.

⚠ **Caution:** If it does not feel normal to the patient or fails to move the patient's tongue, do not continue with the scan.

4. Turn the therapy off by pressing the Therapy Off button as shown in Figure 1 while holding the remote over the Inspire generator as shown in Figure 2.
   - Confirm therapy has been turned off by confirming that the remote therapy status ring and stimulation strength gauge lights are solid white and are not flashing.
   - 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.

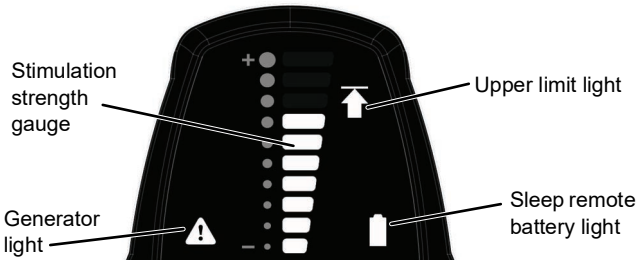


Figure 3. *Sleep remote back view*

Step 5: Select the MRI Parameters According to the Scanning Requirements

1. Set up the MRI equipment per “MRI Safety Information” on page 4.
2. Confirm that the RF field strength (B_{1+}rms, hdSAR, and wbSAR) does not exceed the limits for the coil labeling.
3. 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.
4. A gradient echo localizer sequence can be used to determine vertebra location relative to the planned scan area.

Performing the Scan and Monitoring the Patient

While performing the scan, follow these guidelines:

- Leave any external control devices, such as the programmer or the sleep remote, out of the scanner magnet room (MR facility zone IV).
- Notify the patient of potential interactions and instruct them to communicate to you if they experience any of the following:
  - 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. It is best practice to monitor the patient audibly 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. These factors should be considered 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) option 3, or direct at 844-672-6720.

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

Appendix A: Patient Checklist for MRI

Inspire provides this checklist to aid in determining MR eligibility and is for clinician use 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 Patient Services for help.

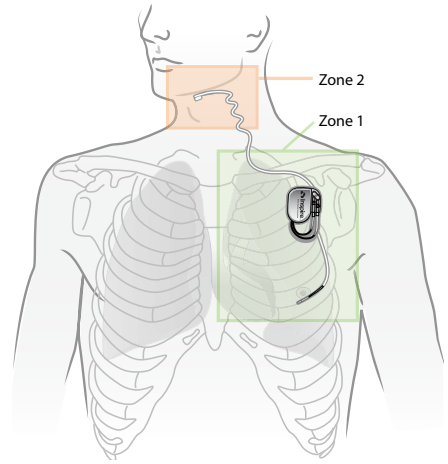
Scanning patients who have other MR conditional devices is acceptable as long as all the MR conditional requirements for each of the implanted devices are met.

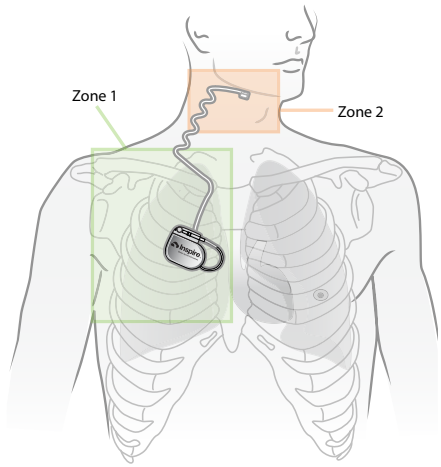
Warning: Do not conduct an MRI scan if any conditions or implants prohibit it. If you are unclear what implants are present, perform an x-ray to determine the implant type and location.

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:	
Sense Lead Model:	

Eligibility Questions	Yes	No
1. Does the patient have a generator model that is MR conditional? (See the patient's ID card for generator model) If it is MR conditional, mark the locations of the implant on the diagram to the right. Is the generator within zone 1? Is the stimulation lead tip within zone 2?		
2. Are the leads and any lead fragments MR conditional? (See "Appendix C: Abandoned Leads and Lead Fragments" on page 20).		
3. Have all possible adverse scan conditions been ruled out? (See "Step 3: Confirm No Adverse Conditions to Scanning Are Present" on page 14).		
4. Has the implanted system been verified to be working properly with the remote? (See "Step 4: Use the Sleep Remote or Inspire Programmer to Confirm Normal Operation" on page 14).		
5. Circle the intended scan condition here: 1 2 3 4 5 6 7 Do the scan conditions of the MR scanner match the scan conditions in this document?		
If all answers are YES, proceed with the scan.		





Zone 1, Generator location: sub-clavicle region

Zone 2, Stimulation lead tip location: tongue base.

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.

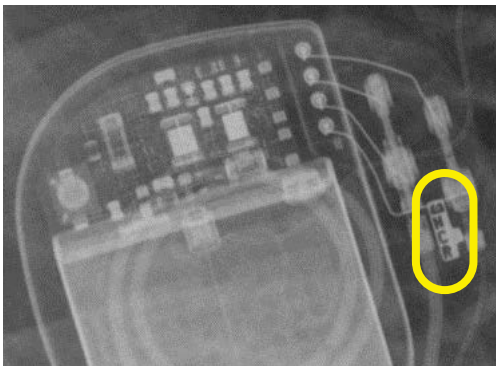
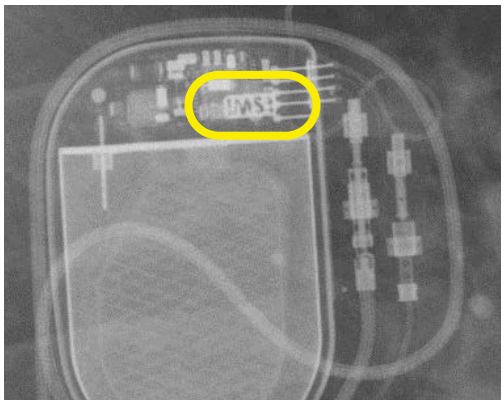
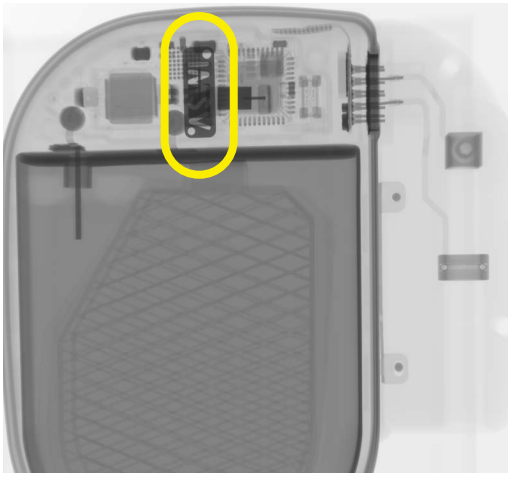
Generator	X-ray ID	MR Specifications
Model 3024 		**X-ray ID is "NCR" and generator is not eligible for an MRI**
Model 3028 		**X-ray ID is "IMS1" and generator is MR conditional**
Model 3150 		**X-ray ID is "IMSV" and generator is MR conditional**

Table 4. *X-ray ID Tag Locations*

Appendix C: Abandoned Leads and Lead Fragments

Abandoned leads and lead fragments may be MR conditional if the requirements in this section are met. Inspire has completed testing to confirm these scenarios are MR conditional using a 1.5T MR scanner if these requirements are met.

If a patient has an abandoned sensor lead (whole lead), then the sensor lead is MR conditional per the scan conditions described in scan conditions 1-6 on pages 5-10. These scan conditions apply if the patient does or does not have an Inspire neurostimulation generator.

Some patients may have their sensor lead explanted, but in some cases the sensor capsule on the distal end of the sensor lead (see Figure 4) cannot be removed. The lead terminal and body may be explanted and the sensor capsule may remain implanted. If an Inspire neurostimulation generator is not present, the sensor capsule is MR conditional per scan condition 7 on page 11. If an Inspire neurostimulation generator is present, the sensor capsule is MR conditional per scan conditions 1-6 on pages 5-10.

Some patients may have their stimulation lead explanted, but in most cases the nerve cuff cannot be removed. The lead body and terminal may be explanted and the distal end of the lead may remain implanted. If an Inspire neurostimulation generator is not present, the distal end of the stimulation lead is MR conditional per scan condition 7 if the stimulation lead segment is less than or equal to 9 cm in length. **Note:** It is 9 cm from the distal end of the stimulation lead to the proximal edge of the lead anchor, see Figure 4. If an Inspire neurostimulation generator is present, the distal end of the stimulation lead is MR conditional per scan conditions 1-6. Also note that any fragment less than 2 cm is MR conditional. Figure 4 shows a stimulation cuff with dimensions. Abandoned lead segments <9 cm in total length are eligible for MR scans.

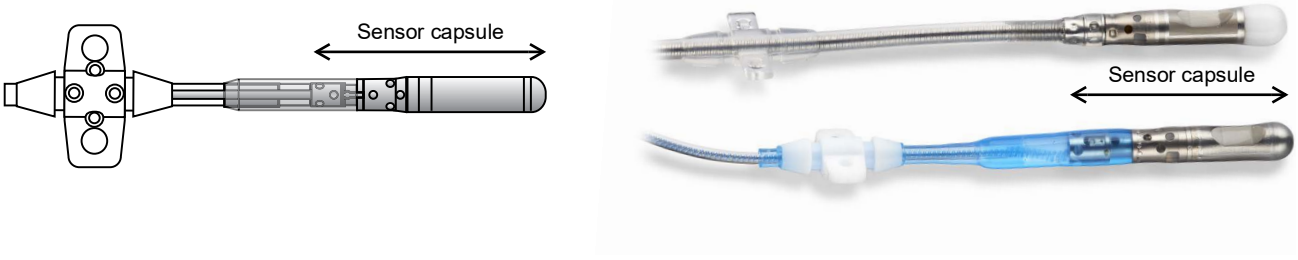


Figure 4. *Images of the sensor capsule on the distal end of the sensing lead*

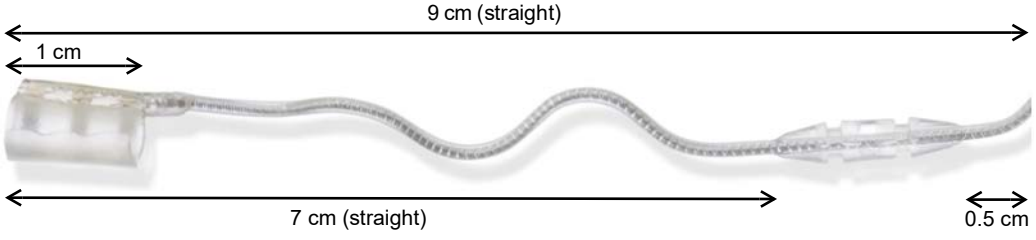


Figure 5. *Stimulation cuff dimensions*

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