

# TECHNICAL GUIDANCE



TG-00021 | Version 1.0

October 22, 2018

**Title:** Medical Procedures and Electromagnetic Interactions

**Audience:** This document is intended for Inspire patients.

## Overview

This document provides information for Inspire patients regarding medical procedures, diagnostic procedures, and sources of electromagnetic disturbances. This supplements the information available in the Inspire manuals, which are available at [manuals.inspiresleep.com](http://manuals.inspiresleep.com).

Surgical procedures are not covered in this document.

## Potential Effects

Medical procedures, diagnostic procedures, and electromagnetic disturbance can have the following effects:

| Potential Effect   | Estimated Frequency |
|--|---------------------|
| Interference preventing communication between the sleep remote or programmer and the Inspire implant | Common              |
| Temporary loss of therapy due to generator reset requiring an office visit and reprogramming         | Uncommon            |
| Unintended Stimulation   | Uncommon            |
| Patient injury or permanent device damage  | Rare                |

## General Recommendations

The Inspire system includes features that provide protection from common sources of electromagnetic disturbance. Most electrical devices encountered in a normal day are unlikely to affect the operation of an Inspire system. However, extremely strong sources of electromagnetic disturbance could interfere with normal system operation. As a general precaution, other medical equipment and devices should be set to the lowest power setting available. Do not use medical equipment or undergo a procedure that is contraindicated for patients with implantable neurostimulation devices.

## Avoid Sources

In most cases, turning off or moving away from the source of the electromagnetic disturbance will return the system to normal operation. If you suspect a medical procedure is interacting or interfering with an Inspire system, discontinue the procedure immediately and contact Inspire therapy support before continuing.

For Questions Contact INSPIRE THERAPY SUPPORT at: 1.844.OSA.HELP (1.844.672.4357, option 3)

### Only Use When Sleeping

To reduce the likelihood of interaction between the Inspire system and other equipment, only use Inspire therapy when sleeping and turn off therapy after waking up.

### Test After Exposure

Following a medical procedure or exposure to a strong electromagnetic disturbance, the Inspire system should be tested by turning therapy on.

- When therapy is turned on, the patient should feel stimulation at their therapeutic level for several seconds.
- If the patient cannot feel stimulation when therapy is turned on or if the stimulation level has changed, then the patient should discontinue therapy use until the Inspire system can be evaluated by their physician.

Contact Inspire if additional information is required at 1-844-OSA-HELP (press 3 for therapy support).

## Potential Effects Matrix

| Medical Procedure/Interference Source   | Potential Effects |                        |               |                 |                            | Additional Information |
|---|-------------------|------------------------|---------------|-----------------|----------------------------|------------------------|
|   | Patient Injury    | Unintended Stimulation | Device Damage | Generator Reset | Communication Interference |                        |
| Arc Welding   |                   | X                      | X             | X               | X                          | Page 5                 |
| Bioelectrical Impedance Analysis (BMI calculation)  |                   |                        |               |                 | X                          |                        |
| Bone Growth Stimulators   |                   | X                      | X             | X               | X                          | Page 6                 |
| Cardiac Implantable Electronic Devices (Pacemaker, ICD, CRT)                                | X                 | X                      | X             | X               | X                          | Page 6                 |
| Communication Devices (Cellular Phones, Wireless Access Points, Qi Wireless Chargers, etc.) |                   |                        |               |                 | X                          | Page 8                 |
| Cryoablation and Cryotherapy  |                   |                        | X             |                 |                            | Page 7                 |
| Defibrillation/Cardioversion  |                   | X                      | X             | X               | X                          | Page 7                 |
| Dental Drill and Ultrasonic Probes  |                   | X                      |               |                 | X                          | Page 7                 |
| Diagnostic X-Rays, CT, and Fluoroscopy  |                   |                        |               |                 |                            | Page 7                 |
| Diathermy   | X                 | X                      | X             | X               | X                          | Page 5                 |
| Diesel-Electric Locomotives   |                   | X                      |               | X               | X                          | Page 8                 |
| Electrocautery  | X                 | X                      | X             | X               | X                          | Page 5                 |
| Electroconvulsive Therapy (ECT)   |                   | X                      | X             | X               | X                          | Page 7                 |
| Electrolysis  |                   |                        |               | X               | X                          |                        |
| Electromagnetic Therapy (BEMER, OMI)  |                   | X                      |               |                 | X                          | Page 7                 |
| High-Power Transmission Lines   | X                 | X                      | X             | X               | X                          | Page 9                 |
| High-Power Electromagnetic Field Devices  | X                 | X                      | X             | X               | X                          | Page 8                 |
| Household Items   |                   |                        |               |                 | X                          | Page 8                 |
| Implanted Device External Accessories   |                   |                        |               |                 | X                          |                        |

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| Medical Procedure/Interference Source              | Potential Effects |                        |               |                 |                            | Additional Information |
|--|-------------------|------------------------|---------------|-----------------|----------------------------|------------------------|
|  | Patient Injury    | Unintended Stimulation | Device Damage | Generator Reset | Communication Interference |                        |
| Laser Procedures (LASIK, PRK, LASEK, Nd:YAG)       |                   |                        |               |                 | X                          |                        |
| Linear Induction Motors                            |                   | X                      | X             | X               | X                          | Page 9                 |
| Magnetic Resonance Imaging (MRI)                   | X                 | X                      | X             | X               | X                          | Page 6                 |
| Radiation Therapy                                  |                   |                        | X             | X               |                            | Page 6                 |
| Radiofrequency (RF) or Microwave Ablation          | X                 | X                      | X             | X               | X                          | Page 6                 |
| Taser  |                   |                        |               | X               | X                          |                        |
| Theft Detectors and Security Screening Devices     |                   | X                      |               | X               | X                          | Page 9                 |
| Therapeutic Magnets                                |                   |                        |               |                 | X                          | Page 8                 |
| Transcranial Magnetic Stimulation (TCMS)           | X                 | X                      | X             | X               | X                          | Page 6                 |
| Transcutaneous Electrical Nerve Stimulation (TENS) |                   |                        |               |                 | X                          | Page 7                 |
| Ultrasound - Diagnostic                            |                   |                        |               |                 |                            | Page 8                 |
| Ultrasound – Therapeutic (Lithotripsy, etc.)       |                   |                        | X             |                 | X                          | Page 8                 |

*Table 1: Potential Effects of Medical Procedures and Interference Sources*

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## Warnings and Precautions

Refer to manuals at [manuals.inspiresleep.com](http://manuals.inspiresleep.com) for additional information.

### Warnings

Exposure to certain medical procedures and interference sources may damage the patient or implanted devices. Please consider the following:

- **Arc Welding (AC/DC, MIG, EIG, Plasma)** — Inspire patients should not go near arc welding equipment until they have discussed the risks with their physician. Inspire recommends the use of non-electric welding techniques and keeping the implanted system as far away from the welding equipment as possible. Patients should follow the same employer or workplace guidelines for patients with implanted cardiac or neurostimulation devices. If an Inspire patient will be near arc welding equipment, the following precautions apply:
  - Ensure welding equipment is properly maintained and grounded.
  - Wear non-conductive gloves and dry shoes.
  - Do not work in a damp area.
  - Do not use current settings higher than necessary.
  - Keep cables close by twisting them together.
  - Keep cables as far from the implanted system as possible.
  - If you feel stimulation while welding, stop immediately.
  - Do not work alone.
- **Diathermy** — Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with the Inspire system. Energy from diathermy can be transferred through the implanted system causing tissue damage at the location of the implanted electrodes, resulting in severe injury or death. Diathermy can also damage the implanted system components, resulting in loss of therapy and requiring additional surgery for system explantation and replacement.

Patient injury or device damage can occur during diathermy treatment when:

  - The generator is turned on or off.
  - Diathermy is used anywhere on the body—not just at the location of the implanted Inspire system.
  - Diathermy delivers heat or no heat.
  - Any component of the Inspire system (leads or generator) remains in the body.
- **Electrocautery** — Electrocautery tools used near or in contact with the generator or leads can cause tissue damage, uncomfortable stimulation, or damage to the generator. Unipolar electrocautery should be avoided as it can be transmitted along the lead body and could cause nerve damage. Bipolar electrocautery should be used

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if alternatives are not available. If electrocautery must be used, therapy should be turned off prior to the procedure and the return electrode should be located such that the current path through the body is located away from the implanted Inspire components.

- **Magnetic Resonance Imaging (MRI)** — Do not utilize MRI on patients implanted with the Model 3024. If certain criteria are met, patients with the MR Conditional Model 3028 may undergo an MRI scan. For details, refer to the “MRI Guidelines for Inspire Therapy” manual at [manuals.inspiresleep.com](http://manuals.inspiresleep.com). Do not bring the sleep remote or Inspire programmer into the scanner magnet room (Zone 4).
- **Radiation Therapy** — The generator should not be directly irradiated by therapeutic levels of ionizing radiation (such as produced by cobalt machines or linear accelerators used for cancer treatment) because of the risk of permanent damage to the generator circuitry. If such therapy is required in the vicinity of the generator, shield the device.
- **Radiofrequency (RF) or Microwave Ablation** — Radiofrequency (RF) or microwave ablation should not be used directly over the implant sites. Induced currents may result in heating or damage to the patient’s tissue, uncomfortable stimulation, or damage to the implanted components.
- **Transcranial Magnetic Stimulation (TCMS)** — Do not use TCMS on patients implanted with the Inspire system.

## Precautions

Exposure to the medical procedures and interference sources below are unlikely to affect the performance of the Inspire system if the recommended guidelines are followed.

## Medical Environment and Devices

- **Bone Growth Stimulators** — Both ultrasonic and electromagnetic bone growth stimulators are commercially available. Exposure to *ultrasonic* bone growth stimulators may result in device damage or communication interference. Patients should avoid use within 6 inches of the generator.  
Exposure to *electromagnetic* bone growth stimulators may result in unintended stimulation, generator reset, or communication interference. Patients should avoid use of these devices within 18 inches from all implanted components.
- **Cardiac Implantable Electronic Devices (Pacemaker, ICD, CRT)** — Refer to Technical Guide TG-00004 for recommendations on the use of Inspire Therapy with other implanted devices.

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- **Cryoablation and Cryotherapy** — Cryoablation and cryotherapy may result in device damage if the cryoprobe comes into direct contact with implanted components. If cryoprobes are kept at least 6 inches from implanted components, risks are minimal.
- **Defibrillation/Cardioversion** — The Model 3028 generator incorporates enhanced protection against defibrillation/cardioversion, however, device damage or generator reset may occur. Inspire recommends the following for patients undergoing defibrillation/cardioversion:
  - Utilize biphasic waveforms and minimize the energy delivered.
  - Position paddles as far as possible from implanted Inspire components.
  - Following defibrillation, confirm normal system operation.
- **Dental Drills and Ultrasonic Probes** — All precautions taken with other implantable devices, such as pacemakers, should be taken and the dentist should keep all electrical devices and cables as far as possible from the implanted system. Stop immediately if stimulation is felt.
- **Diagnostic X-Rays, Computed Tomography (CT), and Fluoroscopy** — Exposure to diagnostic X-rays (including mammograms and PET), CT, or fluoroscopic radiation should not affect the generator or leads. Patients should inform their technician they have an implantable device and show them where the components are located.
- **Electroconvulsive Therapy (ECT)** — The following steps should be taken to reduce the likelihood of unintended interactions between ECT and the Inspire system:
  - The ECT electrodes should be placed as far from the Inspire stimulation lead as possible.
  - The ECT wires should be routed as far from the implanted Inspire components as possible and should never run directly over any implanted component.
  - Inspire therapy should be off.
- **Electromagnetic Therapy (BEMER, OMI)** — It is possible for electromagnetic therapy devices to interact with the Inspire system, however the risk is low if the following precautions are taken:
  - Turn off the electromagnetic therapy device when using the Inspire sleep remote to avoid communication interference.
  - Discontinue use of electromagnetic therapy if stimulation is felt.
- **Transcutaneous Electrical Nerve Stimulation (TENS)** — External stimulation device should be kept as far as possible from the implanted Inspire components and at least 6 inches away. If separate stimulation and return electrodes are used, ensure that the implanted Inspire components are not between them. After activating the external stimulator, test for interference with sleep remote communication by using the sleep remote to turn

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therapy on and off. If the sleep remote does not report successful communication, move the external stimulator further away from the implanted Inspire system.

- **Therapeutic Magnets** — Magnetic blankets, wrist wraps, belts, etc., should be kept 10 inches away from the generator.
- **Ultrasound - Diagnostic** — There no known effects from exposure to diagnostic levels of ultrasound.
- **Ultrasound - Therapeutic (lithotripsy, etc.)** — Exposure to high ultrasonic power/frequencies may result in damage to the generator or leads. Inspire patients should avoid the use of high-output ultrasonic devices such as electrohydraulic lithotripters within 6 inches of the generator.

## Home, Work, and Public Environments

- **Airport Travel** — See recommendations listed for Theft Detectors and Security Screening Devices.
- **Communication Devices (cellular phones, wireless access points, Qi wireless chargers, etc.)** — Maintain a separation of at least 6 inches between the generator and communication devices.
- **Diesel-Electric Locomotives** — The motors of diesel-electric locomotives may create strong magnetic fields that can interact with an implanted Inspire system. Patients should follow the recommendations listed for Linear Induction Motors.
- **High-Power Electromagnetic Field Devices** — Consult Inspire Medical Systems when the patient will be in an area where contact with current carrying conductors is possible or near high-powered electromagnetic fields radiated by power stations, induction furnaces, resistance welders, AM/FM/TV transmitters, etc.
- **Household Items** — The Inspire system should not be affected by most household electrical equipment such as appliances, computers, electric machine shop tools, microwave ovens, internal combustion engines, low-powered radio, and microwave frequency transmitters. All such equipment should be kept in good repair and properly grounded to avoid the possibility of electrical shock or interference with the proper operation of the generator. Therapy should be turned off before a patient operates potentially dangerous equipment such as power tools.  
Some devices, such as heating pads or induction stoves, may interfere with remote communication. If this occurs, patients may need to unplug the interfering device to control the implant.

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- **Linear Induction Motors** — Induction motors may create strong magnetic fields that can interact with an implanted Inspire system. The fields produced can potentially reset the generator or result in unintended stimulation. Inspire patients should follow employer or workplace guidelines for patients with implanted cardiac or neurostimulation devices.

If an Inspire patient will be near linear induction motors, the following precautions apply:

- Keep motors and associated cables as far from the implanted system as possible.
  - Ensure equipment is properly maintained and grounded.
  - Ensure stimulation is turned off.
  - If stimulation is felt while working, stop immediately.
  - Do not work alone.
- **High-Power Transmission Lines** — Inspire patients should follow employer or workplace guidelines for patients with implanted cardiac or neurostimulation devices.
- **Theft Detectors and Security Screening Devices (including millimeter wave scanners)** — Use care when approaching theft detectors and security devices (such as those found in airports, libraries, department stores, and government buildings). When approaching these devices, do the following:
  - Show the security personnel your Inspire identification card and notify them that you have an implanted medical device.
  - Make sure your therapy is off.
  - Proceed through the security device. Do not linger near or lean on the security device.

Note: Some theft detectors might not be visible.

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