



INSPIRE SLEEP REMOTE™

Inspire Sleep Remote Model 2500

Rx Only

The following is a registered trademark of Inspire Medical Systems, Inc.:
Inspire®

The following is a trademark of Inspire Medical Systems, Inc.: Inspire
Sleep Remote™

Explanation of Symbols on Product or Package

Sleep Remote Symbols



Turn therapy on, or if therapy is already on, then push to pause therapy



Turn therapy off



Decrease stimulation strength



Increase stimulation strength



Replace sleep remote batteries



If the light is on but not flashing, your generator battery may be low



If the light is on and flashing, communication with your generator has been interrupted



Audio tones on



Audio tones off

Package Symbols



Consult instructions for use



For USA audiences only



Serial number



IEC 60601-1/EN60601-1, Type BF Equipment

This symbol means that the device comes into contact with the patient



Keep dry, use caution to prevent spilling or splashing liquids on the sleep remote



Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Directives



European authorized representative

IP22

IEC 60529, Protection from ingress by fingers or similar objects and moderate amounts of dripping water

Note: The sleep remote meets the water ingress rating of IP22, maintaining safe operation. Exposure to water or liquids could result in a loss of performance. Keep the sleep remote dry. Refer to “Battery and Sleep Remote Disposal” on page 39 for more detailed information.

Inspire Sleep Remote™ Quick Guide

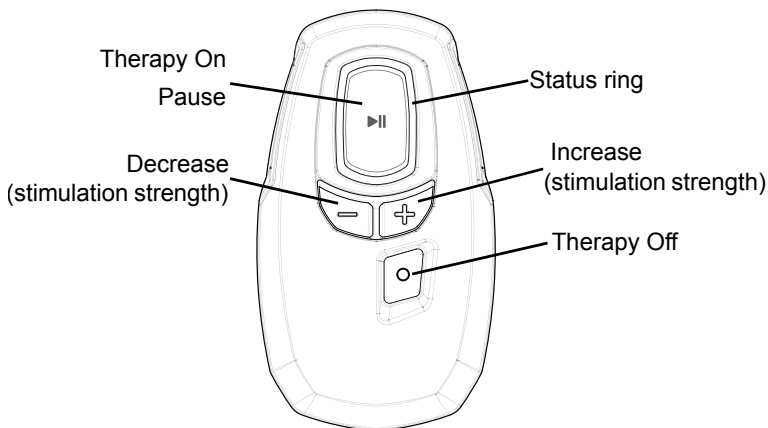


Figure 1. Sleep remote front view

Status Ring

White	Therapy is off
Green – Solid	Therapy is on and stimulation is on
Green – Dimming and brightening	Therapy is on, stimulation is paused

Turning Therapy On

- Press the Therapy On (▶||) button and hold the sleep remote over your generator for 10 seconds or until the sleep remote produces an audio tone.
- When therapy is turned on, the generator will produce a brief stimulation pulse.

Turning Therapy Off

- Press the Therapy Off button (○) and hold the sleep remote over your generator for 10 seconds or until the sleep remote produces an audio tone.

Decreasing Stimulation Strength

- Press the Decrease button (—) and hold the sleep remote over your generator for 10 seconds or until the sleep remote produces an audio tone.
- If the sleep remote produces three beeps immediately when you press the Decrease button (—), stimulation strength is at the lower limit.

Increasing Stimulation Strength

- Press the Increase button (+) and hold the sleep remote over your generator for 10 seconds or until the sleep remote produces an audio tone.
- If the sleep remote produces three beeps immediately when you press the Increase button (+), stimulation strength is at the upper limit.

Pausing Therapy

- While therapy is on, press the Therapy On button (▶||) and hold the sleep remote over your generator for 10 seconds or until the sleep remote produces an audio tone.

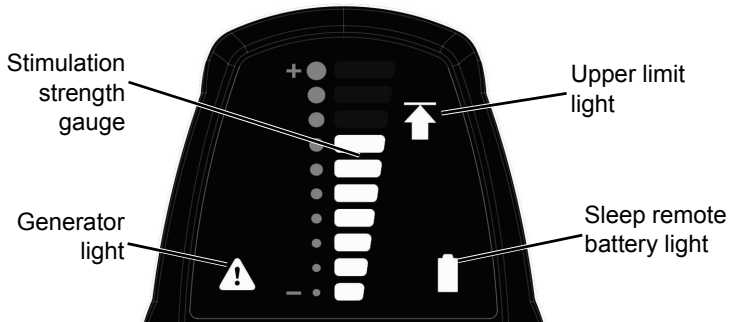


Figure 2. Sleep remote back view

Status Indicators



Replace sleep remote batteries



If the light is on and not flashing, your generator battery may be low, call your doctor



If the light is on and flashing, communication with your generator has been interrupted. Refer to “Interference” on page 9.



Stimulation strength is at the upper limit



Stimulation strength gauge

Finding the Generator

- Press the Therapy Off button (○) and move the sleep remote near your generator. When the sleep remote produces two beeps, with the second beep at a higher tone than the first, you have found the generator location.
- If the sleep remote produces three rapid beeps, you have not found the generator location. Try again.

Audio Tones

Two beeps with the second beep at a higher tone than the first



- Communication with the generator was successful

Three rapid beeps



- Communication with the generator was not successful, try again
 - Stimulation is at the upper or lower limit
-

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Glossary

Apnea — A temporary absence of breathing.

Caution — A statement describing actions that could result in minor or moderate injury to the patient, device damage, or improper functioning of a device.

Contraindication — A condition or circumstance when a person should not have an Inspire system.

Generator — The implanted component of the Inspire system that contains the battery and electronics that control stimulation.

Hypoglossal Nerve — The nerve that controls tongue movement.

Implantable Pulse Generator (IPG) — See Generator. Your doctor may refer to your generator as an IPG or implantable pulse generator.

Lead — A thin, implanted wire with protective coating that connects to the generator. The Inspire system has a respiratory sensing lead and a stimulation lead.

Pause — A delay in therapy that allows the patient to temporarily stop stimulation without turning the therapy off. The pause time allows the patient to fall asleep before stimulation begins again.

Precaution — See Caution.

Remote — See Sleep Remote.

Sleep Remote — Device the patient uses to turn therapy on and off, and to change stimulation strength within limits set by a doctor.

Start Delay — A delay between when the therapy is turned on and when the stimulation begins. Start Delay allows the patient to fall asleep before stimulation begins.

Stimulation — The delivery of electrical pulses to the nerve that controls tongue movement (see Hypoglossal Nerve).

Stimulation Strength — The stimulation level (amplitude) measured in volts.

Therapy — Treatment of a disease or condition. The Inspire system uses stimulation to provide therapy.

Therapy Settings — The settings, stored in the generator, that define the therapy you receive.

Upper Airway — The breathing path from the mouth and nostrils to the larynx (voice box).

Warning — A statement describing an action or situation that could seriously harm the patient.

1. Introduction

You have received an Inspire system to deliver Inspire® Upper Airway Stimulation (UAS) therapy (Figure 3a). Your doctor has given you an Inspire Sleep Remote™ (Figure 3b). Use your sleep remote to turn your therapy on and off and adjust the strength of stimulation.

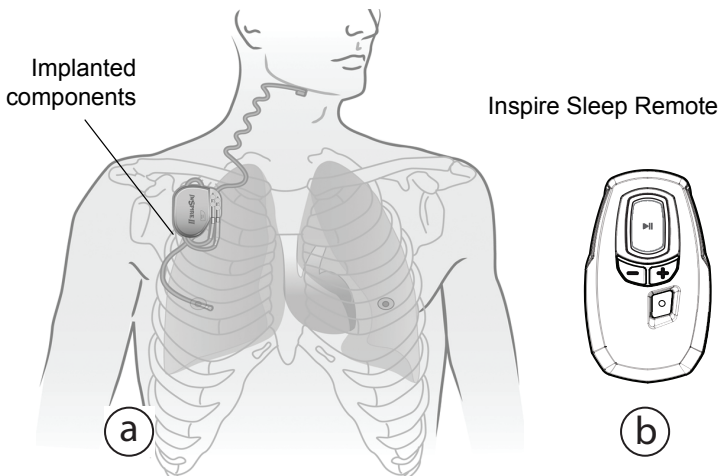


Figure 3. Inspire system

About This Manual

This manual provides information on using and maintaining your Inspire Sleep Remote. The sleep remote should only be used according to the instructions in this manual and the instructions provided by your doctor.

This manual also contains information about Inspire therapy. This includes answers to common questions about living with an Inspire system. For additional information about your implanted Inspire System, refer to the Patient Manual you received after your implant surgery.

Information is provided about what to do if you encounter problems with your Inspire system and when you should call your doctor. If you have questions that are not answered in this manual, or if any unusual situations or problems occur, talk to your doctor. For more information about Inspire therapy and the Inspire system, refer to “Inspire Therapy” on page 3 and your Inspire Patient Manual.

Package Contents

The sleep remote package contains the following:

- One Inspire Sleep Remote
- Two AAA or LR03 alkaline batteries
- Sleep Remote Manual and Quick Guide

2. Inspire Therapy

You have received an Inspire system to deliver Inspire Upper Airway Stimulation (UAS) therapy. Your doctor prescribed UAS therapy to treat your sleep apnea.

For more information about your Inspire system, refer to your Inspire Patient Manual.

Your Inspire System

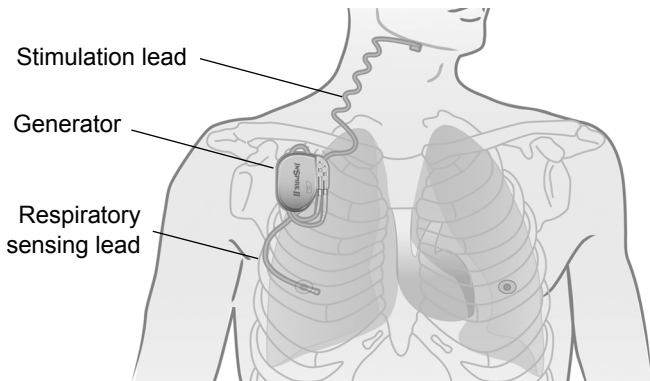


Figure 4. *Implanted components of the Inspire system*

The implanted components of the Inspire system (Figure 4) are a generator, a stimulation lead, and a respiratory sensing lead. For more detailed information about each component, refer to your Inspire Patient Manual or contact your doctor.

- **Generator** — Contains the battery and electronics that provide stimulation.
- **Respiratory sensing lead** — When therapy is on, this lead monitors your breathing.
- **Stimulation lead** — When therapy is on, this lead delivers stimulation to activate the muscles in your upper airway.

The external components of the Inspire system are:

- **Sleep remote** — That you use to control your implanted system.
- **Physician programmer** — That your doctor uses to program your therapy settings.

Therapy Summary

Inspire therapy is only used when you are sleeping. You will turn your therapy off during the day.

When you are preparing to go to sleep, you will use your sleep remote to turn your therapy on. You will feel a brief stimulation confirming that therapy has been turned on. After the confirmation, stimulation is delayed so you have time to fall asleep.

When the delay time has passed, the Inspire system delivers mild stimulation to the nerve that controls your tongue movement (the hypoglossal nerve) as it senses breathing. The stimulation causes the upper airway muscles to stiffen, preventing airway blockages. The therapy does not wait for an apnea to occur before delivering stimulation. Stimulation is delivered throughout the night to prevent apneas.

Additional Therapy Information

For additional information, such as therapy indications, contraindications, risks, benefits, and surgical procedure description, refer to your Inspire Patient Manual.

Frequently Asked Therapy Questions

What does stimulation feel like?

Most patients report that stimulation is a mild sensation. Stimulation results in an involuntary movement of the upper airway muscles and/or tongue. If the stimulation strength is too high, the upper airway may have a strong response that may be uncomfortable. Stimulation strength can be adjusted so that therapy is comfortable and effective.

Will I feel anything when I turn therapy on?

Yes. When therapy is turned on you should feel a brief stimulation for a few seconds. Then stimulation is delayed for a period of time while you fall asleep. After this Start Delay, stimulation resumes.

3. Safety Information

The following warnings and precautions are in regard to the sleep remote. For additional warnings and precautions regarding Inspire therapy overall, refer to your Inspire Patient Manual. The Inspire Patient Manual includes safety information about medical procedures, equipment, devices, and activities that could interfere with the function of your Inspire system. If you need another Inspire Patient Manual, please contact your doctor or Inspire Medical Systems Inc. to request a replacement.

Warnings

Choking hazard. The sleep remote batteries may pose a choking hazard. Keep the sleep remote and batteries away from children and pets.

Flammable environment. Avoid using the sleep remote in the presence of flammable gases and/or fumes. An interaction between the flammable environment and the batteries in the sleep remote could occur. The consequences of using a battery-powered device near flammable environments are unknown.

Precautions

System and Therapy

Using a programmer or a sleep remote with other medical devices. Do not use the sleep remote on another medical device, such as a cardiac pacemaker. The sleep remote is not compatible with other medical devices. Using the sleep remote with other devices will not make the desired (or any) adjustment. Therefore, that medical device may not perform its function in the desired manner and could lead to improperly treated symptoms. For the same reasons, do not use a sleep remote or programmer from another medical device with your Inspire generator.

Keep the sleep remote dry. Keep the sleep remote away from sources of water and condensation such as sinks and humidifiers. Failure to keep the sleep remote dry could damage the sleep remote.

Sleep remote connection to other equipment. Do not connect the sleep remote to other equipment, cables, or devices. The sleep remote is only for use with the Inspire system. Connection to other equipment could damage the sleep remote.

Sleep remote modification. Do not modify (change) the sleep remote. Modification of the sleep remote can result in damage to the sleep remote, causing it to not work properly.


Patient Activities

Children and pets. Keep the sleep remote away from children and pets. Children or pets may damage the sleep remote.

Interference

Any electric device could be a potential source of interference with the communication between your remote and your generator.

- *Home wireless products such as walkie-talkies, Bluetooth, or WiFi networking devices.* Stay 30 cm (1 ft) away from such devices when using your sleep remote.
- *Mobile phones.* Note that mobile phones may interfere with sleep remote communications if operated at the same time and within 70 cm (2.3 ft).

A flashing , as shown on page 17, indicates there is interference with the communication between your remote and your generator.

If you suspect that equipment is causing unwanted stimulation or interfering with your Inspire system, do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. Use the sleep remote to turn your therapy off.
4. If the above actions do not resolve the effects of the interference, or you suspect that your therapy is not the same after exposure to interference, contact your doctor.

4. Using Your Sleep Remote

Your sleep remote allows you to turn your therapy on before you go to sleep, off during waking hours, and pause therapy if you wake and need time to fall back to sleep. It also allows you to adjust the stimulation strength within a range determined by your doctor. You also use your sleep remote to check the status of your generator battery.

The sleep remote communicates with your generator by sending and receiving short range radio signals to and from your generator. To communicate with your generator, the sleep remote Therapy On button (▶||) must be directly over your generator and facing away from you as shown below (Figure 5).

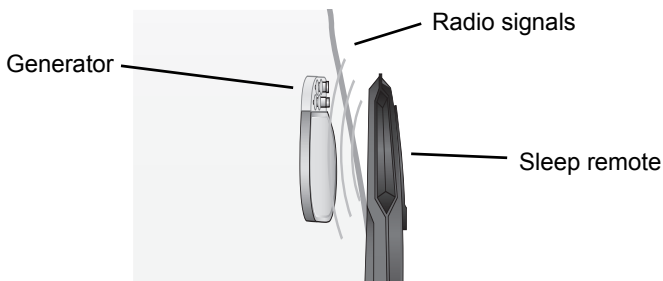


Figure 5. Communication between sleep remote and generator

Sleep Remote Buttons

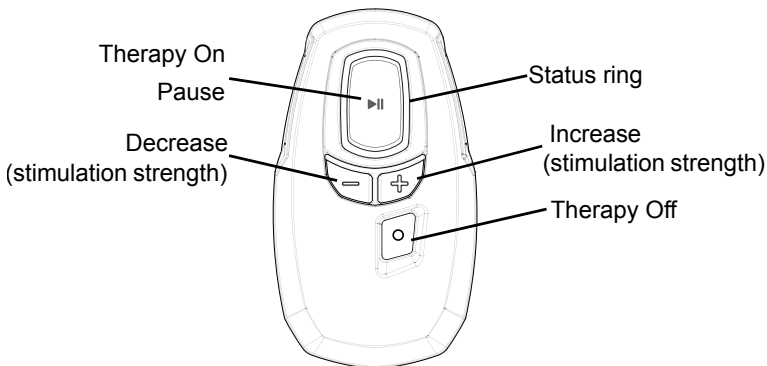


Figure 6. Sleep remote buttons

The sleep remote buttons (Figure 6) allow you to turn your therapy on and off, and to pause therapy. Also, you can increase or decrease your stimulation strength within a range selected by your doctor.

Select:	To:
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Turn therapy on. If therapy is on, pause therapy.



Turn therapy off



Decrease the stimulation strength



Increase the stimulation strength

Status Ring

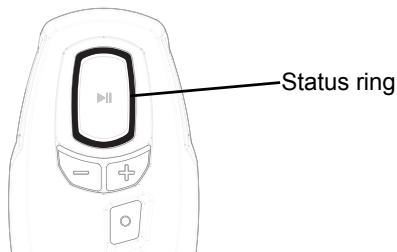


Figure 7. Status ring

The sleep remote has a status ring (Figure 7) around the Therapy On button (▶||). The status ring lights up and indicates if therapy is on, off, or paused.

To check your therapy status:

- Pick up or gently shake the sleep remote. The status ring lights up to indicate your therapy status.

Status ring light:	Means:
Solid white	Therapy is off
Solid green	Therapy is on and stimulation is active
Slowly dimming and brightening green	Therapy is on and stimulation is paused
Flashing yellow bars	A yellow status light on the back of the sleep remote is on. Turn the sleep remote over and review the status lights.

Note: Your sleep remote may not respond to a gentle shake if it has been excessively bounced during the previous 30 minutes, such as when it has been in a car. If your remote

does not respond to a gentle shake, press the Therapy Off button (○) and wait for 10 seconds.

Stimulation Strength Gauge

Your doctor may have provided a range of stimulation strength values for you to use. If you have a range of stimulation strengths available, the increase (+) and decrease (-) stimulation strength buttons allow you to change the stimulation strength.

The stimulation strength gauge on the back of the sleep remote indicates the current stimulation strength, and if the stimulation strength has reached the upper or lower limit (Figure 8). The stimulation strength gauge color also indicates if therapy is on, off, or paused.

Note: If your doctor did not program a range of stimulation strengths for you to use, the Increase (+) and Decrease (-) buttons do not change your stimulation strength.

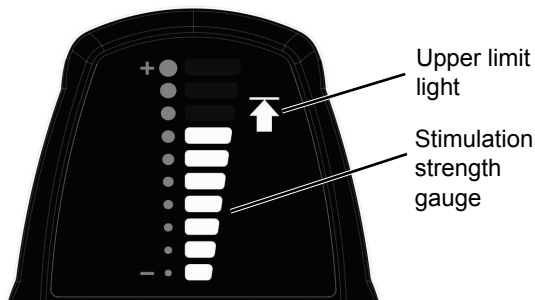



Figure 8. Stimulation strength gauge

To check your stimulation strength:

- Pick up or gently shake the sleep remote. The stimulation strength gauge indicates your current stimulation strength.

Note: Your sleep remote may not respond to a gentle shake if it has been excessively bounced during the previous 30 minutes, such as when it has been in a car. If your remote does not respond to a gentle shake, press the Therapy Off button (○) and wait for 10 seconds.

Stimulation strength gauge:		Means:
One bar lit		Stimulation strength is at minimum and may not be decreased
Upper limit light on		Stimulation strength is at maximum and may not be increased
Solid white		Therapy is off
Solid green		Therapy is on and stimulation is active
Slowly dimming and brightening green		Therapy is on and stimulation is paused

Status Lights

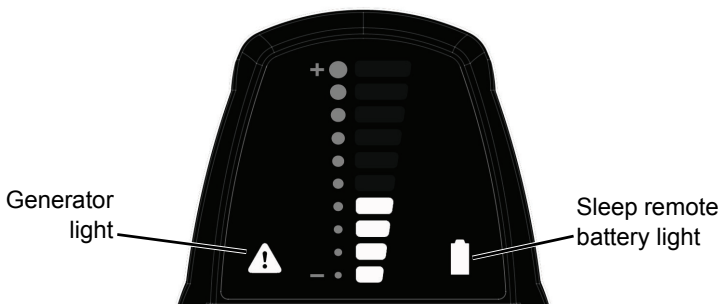


Figure 9. Status lights

The generator light and the sleep remote battery light on the back of your sleep remote indicate the status of your generator and sleep remote batteries (Figure 9).

Note: When either status light turns on, yellow bars on the status ring flash. The status ring is on the front of the sleep remote. The bars flash for several seconds to notify you to check the status lights on the back of the sleep remote.

Status light:	Means:
Both status lights off	Sleep remote and generator are operating normally
Sleep remote battery light on	Sleep remote batteries are low and need to be changed
Generator light on	Contact your doctor
Both status lights on	<p data-bbox="453 425 964 517">Replace sleep remote batteries, because low batteries may be preventing normal sleep remote operation.</p> <p data-bbox="453 530 954 626">If condition persists, contact your doctor. Your sleep remote may not be working properly.</p>
Generator light flashing	<p data-bbox="453 646 948 804">Communication with your generator has been interrupted by electromagnetic interference. Move away from potential sources of interference, and try again. Refer to “Interference” on page 9.</p>

Audio Tones

When audio tones are turned on, the sleep remote beeps when a change to the therapy settings is successfully completed.

Audio tone: Means:



Two beeps with the second beep at a higher tone than the first

- Your change was successful.



Three rapid beeps

- Your change was not successful, because the sleep remote was unable to communicate with your generator. Try the change again. (For instructions on positioning your sleep remote, refer to page 20.)
- You tried to increase the stimulation strength outside the range set by your doctor, and you have reached the upper limit. (For instructions on increasing your stimulation strength, refer to page 28.)
- You tried to decrease the stimulation strength outside the range set by your doctor, and you have reached the lower limit. (For instructions on decreasing your stimulation strength, refer to page 29.)



Six rapid beeps

- Communication with your generator was interrupted by electromagnetic interference. Move away from potential sources of interference, and try again.
-

Turning Audio Tones On or Off

Your sleep remote audio tones can be turned on or off. Inspire recommends that you keep audio tones on.

Turning audio tones on or off:

1. Remove the battery compartment cover. (For instructions, refer to page 37.)
2. Push the audio tones switch up to turn the audio tones on (🔊) and down to turn the audio tones off (🔇) (Figure 10).

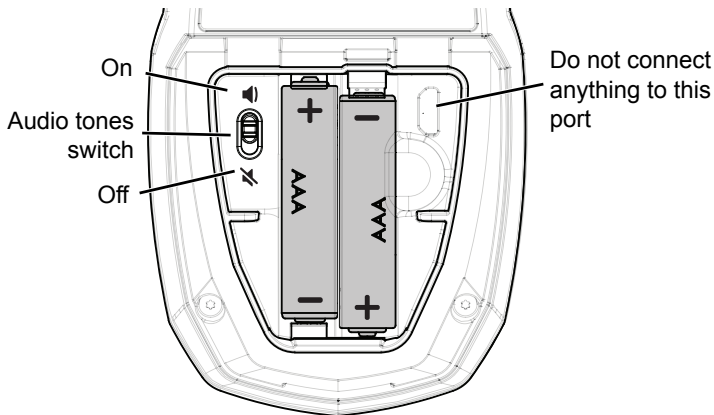


Figure 10. Turning audio tones on or off

3. Replace the battery compartment cover. (For instructions, refer to page 38.)

Using Your Inspire Sleep Remote

Positioning Your Sleep Remote

The sleep remote communicates with your generator by sending and receiving short range radio signals.

To communicate with your generator, you must place the sleep remote Therapy On button (▶||) directly over your generator immediately after you press a button with the button facing away from you as shown below (Figure 11).

The sleep remote attempts to communicate with your generator for 10 seconds. If communication is not successful after 10 seconds the sleep remote beeps rapidly three times and the sleep remote light indicate the therapy status for several seconds.

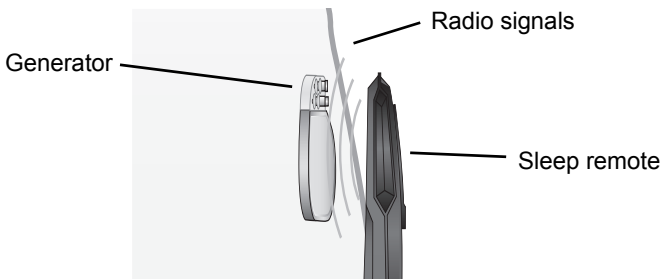


Figure 11. Communication between sleep remote and generator

To position your sleep remote for communication with your generator:

1. Press a button. The therapy status light flashes to indicate the change is in progress.
2. Position the sleep remote over your generator and against your body. The buttons should face away from your body (Figure 12).



Figure 12. Correct positioning of sleep remote over generator

3. Adjust the sleep remote position until the Therapy On button (▶||) is directly over your generator.
4. Slowly adjust the sleep remote position until the sleep remote produces a tone or 10 seconds pass.
5. Remove the sleep remote from your body and review the sleep remote lights to confirm that the change was communicated to your generator.

Note: If the sleep remote produces three rapid beeps, or the change you want is not indicated by the sleep remote lights, then try communicating with your generator again.

If you are having trouble positioning the sleep remote:

Note: These steps turn therapy off.

1. Make sure the audio tones are on. (For instructions on turning audio tones on and off, refer to page 19.)
2. Press the Therapy Off button (○).
3. Position the sleep remote directly over your generator and against your body. The buttons should face away from your body (Figure 12).
4. Adjust the sleep remote position until the rear surface of the remote, opposite the Therapy On button (▶||), is directly over your generator (Figure 5).
5. Wait until the sleep remote produces a tone or 10 seconds pass.
6. Remove the sleep remote from your body and review the sleep remote lights to confirm that the change was communicated to your generator.

Notes:

- If the sleep remote produces three rapid beeps, or the change you want is not indicated by the sleep remote lights, then try communicating with your generator again.
- The sleep remote communicates one change at a time. If you press an incorrect button, wait for 10 seconds until the sleep remote stops attempting to communicate with the generator, and then press the correct button.

- Pressing the Therapy Off button (○) cancels communication in progress. The sleep remote then attempts to turn your generator off.

Communicating with your Generator

When the sleep remote is communicating with your generator, the status ring and stimulation strength gauge blink on and off.

The blinking lights indicate the change the sleep remote is attempting to make to your generator.

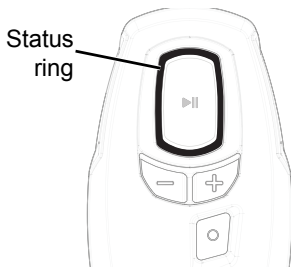


Figure 13. Status ring

Status ring:	Means:
Whole ring blinking white	Turning therapy off
Whole ring blinking green	Turning therapy on or pausing therapy
Top of ring blinking	Increasing stimulation strength
Bottom of ring blinking	Decreasing stimulation strength

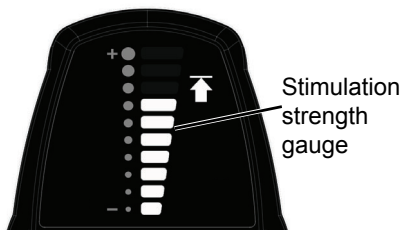


Figure 14. Stimulation strength gauge

Stimulation strength gauge: Means:

Whole gauge blinking white	Turning therapy off
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Whole gauge blinking green	Turning therapy on or pausing therapy
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One step on the gauge is blinking	Increasing or decreasing stimulation strength. The newly selected stimulation strength step is blinking.
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Turning Therapy On

It is recommended that you turn therapy on as part of your bedtime routine. Immediately after turning therapy on, the generator will produce a brief stimulation pulse. After that initial stimulation, therapy is delayed so you have time to fall asleep.

To turn your therapy on:

1. Press the Therapy On button (▶||).
2. Position the sleep remote over your generator and against your body with the buttons facing away from your body (Figure 15).



Figure 15. Correct positioning of sleep remote over generator

3. Wait until the sleep remote produces a tone or 10 seconds pass.
4. Check the status ring.
 - If the status ring is solid green or is slowly dimming and brightening green, therapy is on. The sleep remote

lights stay on for several seconds after communicating with the generator.

- If the sleep remote lights are off, gently shake the remote and the lights turn on.

Note: When you turn stimulation on, the generator will produce a brief stimulation pulse, and then your generator will delay further stimulation while you fall asleep. Your doctor sets the length of this Start Delay time for your generator.

Turning Therapy Off

Always turn therapy off when you are not sleeping. Leaving therapy on reduces generator battery life and increases the likelihood of unwanted stimulation.

To turn your therapy off:

1. Press the Therapy Off button (○).
2. Position the sleep remote over your generator and against your body with the buttons facing away from your body (Figure 15).
3. Wait until the sleep remote produces a tone or 10 seconds pass.
4. Check the status ring.
 - If the status ring is a solid white, therapy is off. The light stays on for several seconds after communicating with the generator.
 - If the sleep remote lights are off, gently shake the remote and the lights will turn on.

Note: Pressing the Therapy Off button (○) cancels communication in progress. The sleep remote then attempts to turn your generator off.

Pausing Therapy

If you wake with your therapy on, and you intend to go back to sleep, you can pause therapy instead of turning therapy off. The length of time that the therapy pauses is set by your doctor.

Therapy Pause and Start Delay are different. Start Delay begins automatically when you turn therapy on. When therapy is on, Therapy Pause begins when you press the Therapy On button (▶||).

To pause therapy:

1. Press the Therapy On button (▶||).
2. Position the sleep remote directly over your generator and against your body with the buttons facing away from your body (Figure 15).
3. Wait until the sleep remote produces a tone or 10 seconds pass.
4. Check the status ring.
 - If the status ring is slowly dimming and brightening green, therapy is paused. The status ring stays lit for several seconds after communication with the generator.
 - If the sleep remote lights are off, gently shake the remote and the lights will turn on.

Increasing Stimulation Strength

The sleep remote allows you to increase stimulation strength within a range set by your doctor. If you feel little or no stimulation, you can **increase** (**+**) the stimulation. Stimulation can be increased when therapy is on or off.

The stimulation strength gauge on the back of the sleep remote indicates the current stimulation strength and the upper limit light (**↑**) indicates when you have reached the highest stimulation strength allowed by your doctor. (For information on the stimulation strength gauge and upper limit, refer to page 14.)


Contact your doctor if you can't achieve the desired stimulation strength.

To test the current stimulation strength:

1. Turn therapy off by pressing the Therapy Off button (**○**) and positioning the sleep remote over your generator.
2. Wait until the sleep remote produces a tone or 10 seconds pass.
3. Turn therapy on by pressing the Therapy On button (**▶||**) and positioning the sleep remote over your generator.
4. Wait until the sleep remote produces a tone or 10 seconds pass.
5. You will receive one short stimulation immediately when therapy is turned on.

To increase stimulation strength:

1. Press the Increase button (+).

Note: If the sleep remote beeps rapidly three times, and the upper limit light () on the back of the remote is on, you have reached the upper limit.

2. Position the sleep remote directly over your generator and against your body with the buttons facing away from your body (Figure 15).
3. Wait until the sleep remote produces a tone or 10 seconds pass.
4. To test the new stimulation strength:
 - a. Turn therapy off.
 - b. Turn therapy on. You will receive one short stimulation immediately when therapy is turned on.

Decreasing Stimulation Strength

The sleep remote allows you to decrease the stimulation strength within a range set by your doctor. If stimulation feels too strong, you may want to **decrease** (—) the stimulation strength. Stimulation strength can be decreased with therapy on or off.

The stimulation strength gauge on the back of the sleep remote indicates the current stimulation strength. If only one bar on the gauge is lit, then stimulation strength is at the lowest allowed setting. (For information on the stimulation strength gauge, refer to page 14.)

Contact your doctor if you can't achieve the desired stimulation strength.

To test the current stimulation strength:

1. Turn therapy off by pressing the Therapy Off button (○) and positioning the sleep remote over your generator.
2. Wait until the sleep remote produces a tone or 10 seconds pass.
3. Turn therapy on by pressing the Therapy On button (▶||) and positioning the sleep remote over your generator.
4. Wait until the sleep remote produces a tone or 10 seconds pass.
5. You will receive one short stimulation immediately when therapy is turned on.

To decrease stimulation strength:

1. Press the Decrease button (—) to adjust your stimulation strength.

Note: If the sleep remote beeps rapidly three times, and only one bar on the stimulation strength gauge is on, you have reached the lower limit.

2. Position the sleep remote directly over your generator and against your body with the buttons facing away from your body (Figure 15).
3. Wait until the sleep remote produces a tone or 10 seconds pass.
4. To test the new stimulation strength:
 - a. Turn therapy off.

b. Turn therapy on. You will receive one short stimulation immediately when therapy is turned on.

5. Living with Your Inspire System

Travel Information

As you travel, your sleep remote will allow you to operate your generator at any travel destination while you sleep.

It is possible that airport security devices may affect the operation of your generator and detect the metal in your generator. Always tell security staff that you have an implanted generator and carry your Inspire Identification Card for verification. This also applies if you encounter similar security devices in other situations.

When to Call Your Doctor

Call your doctor if:

- You experience anything unusual, such as new, unexplained symptoms.
- You notice signs of infection such as redness and swelling near an implant site.

- You notice that the stimulation begins to feel different or becomes uncomfortable. Turn the therapy off first, then call.
- You are not getting adequate stimulation.
- The location of your stimulation has dramatically changed. This could result from movement of the stimulation lead.
- The generator light on the back of your sleep remote is on.

If you are unable to reach your doctor immediately, try again at a later time. Meanwhile, discontinue therapy and contact the doctor who implanted your system.

Manufacturer's Information

Your primary resource for all questions and requests is your doctor. As an additional resource, you may contact Inspire Medical Systems, Inc:

Address: 5500 Wayzata Blvd, Suite 1600
Golden Valley, MN 55416

Phone: 763-205-7970 or 1-844-672-4357 Toll Free

Website: www.inspiresleep.com

6. Maintaining Your Inspire Sleep Remote

You will need to replace your sleep remote batteries and clean the sleep remote as needed. Although your doctor will monitor your generator battery status during your follow-up appointments, you can also use your sleep remote to check your generator battery status.

Sleep Remote Batteries

Warning: The sleep remote batteries may pose a choking hazard. Keep the sleep remote and batteries away from children and pets.

The sleep remote uses two AAA or LR03 alkaline batteries. Replace the batteries when the sleep remote battery light is on or after 4 months of use.

Cautions:


- **Do not use rechargeable batteries in the sleep remote. Rechargeable batteries may cause the sleep remote to not function properly.**

- **Do not leave batteries in the sleep remote if it will not be used for more than 4 weeks. Batteries left in the sleep remote may corrode and damage the sleep remote.**

Checking the Sleep Remote Battery Status

Develop a routine where you check your sleep remote battery status regularly. Inspire recommends checking the sleep remote batteries each morning after you turn therapy off.

To check the sleep remote battery status:

1. Pick up or gently shake the sleep remote.
2. Check the sleep remote battery light () on the back of your sleep remote
 - If the light is on, replace the sleep remote batteries.
 - If the light is off, the batteries are good.

Replacing the Sleep Remote Batteries

The sleep remote batteries are located in a battery compartment on the bottom of the sleep remote.

To remove the battery compartment cover:

1. Hold the sleep remote with the battery compartment cover facing upwards as shown in Figure 16.

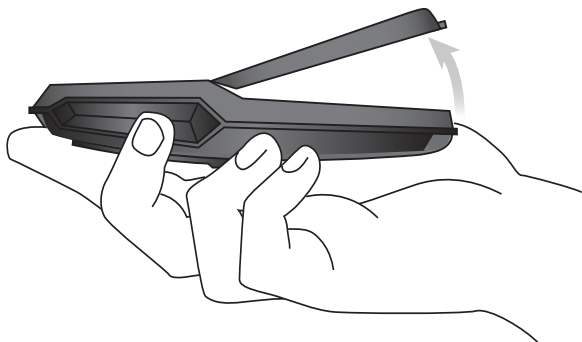


Figure 16. Removing the battery compartment cover

2. Push gently and firmly upward on the release tab at the end of the sleep remote.
3. Gently rotate the cover upwards.

To replace the sleep remote batteries:

1. Insert your finger in the finger hole to loosen the first battery, and then gently remove the batteries.
2. Position each battery to match the figure in the battery compartment (Figure 17).

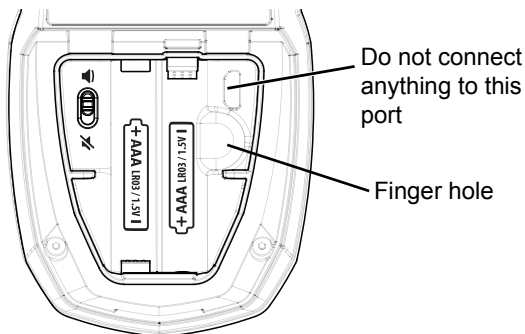


Figure 17. Battery compartment and battery placement

To close the battery compartment:

1. Insert the battery door tabs into the two slots located above the batteries.
2. Gently lower the battery compartment cover.
3. Gently press down on the end of the battery compartment cover to lock it in place.
4. Inspect the battery door to make sure it is properly closed.

Battery and Sleep Remote Disposal

Dispose of depleted batteries and a worn out sleep remote according to local requirements. If desired, remove the batteries and return the sleep remote to Inspire for disposal.

Cleaning Your Sleep Remote

Clean the outside of the sleep remote with a slightly damp cloth. The sleep remote is not sterile and is not intended to be sterilized. Diluted mild household detergents will not damage the sleep remote.

Cautions:

- Your sleep remote is water-resistant, not waterproof, and exposure to water or other liquids beyond a slightly damp cloth used for cleaning could damage the sleep remote.
- Do not use corrosive liquids to clean your sleep remote (eg, bleach, nail polish remover). Corrosive liquids could damage the external housing of the sleep remote.

Handling Your Sleep Remote

The sleep remote should be handled with care.



Caution:

Handle your sleep remote with care. Mishandling the sleep remote can damage the sleep remote.

- Do not drop the sleep remote. Protect the sleep remote against sharp blows and physical shocks.
- Do not disassemble or tamper with the internal components of the sleep remote. Accessing the internal components could affect the performance of the sleep remote and void the warranty.

Checking the Sleep Remote

Pick up or gently shake the sleep remote to display the status.

- If the status ring is illuminated on the front of the remote, and both the yellow status lights () and () on the back of the remote are off, you may resume use of your sleep remote.
- If both lights are not off, refer to page 17 of this manual to determine the meaning of the status lights, and if both lights are lit you may need to replace your remote batteries (refer to page 37).

Checking the Generator Battery Status

You can check your generator battery status. If your generator battery is low, your generator will need to be replaced.

To check the generator battery status:

1. Pick up or gently shake the sleep remote.
2. Check the generator light (⚠) on the back of your sleep remote. If the light is on, contact your doctor.

7. Troubleshooting Your Sleep Remote

The following table provides possible solutions to common questions that may arise when using your sleep remote. If you need further assistance in setting up, using, or maintaining your sleep remote, or to report problems with your sleep remote, contact your doctor or Inspire Medical Systems, Inc. For contact information, refer to “Manufacturer’s Information” on page 34.

If this happens: Possible causes:	Try these steps:
Yellow bars are flashing left and right on the front of your sleep remote.	<ul style="list-style-type: none">• A status light on the back of the sleep remote is on.• Turn the sleep remote over and view the status lights. For information on status lights, refer to page 16.
A yellow light (▲ or ■) on the back of your sleep remote is on.	<ul style="list-style-type: none">• For information on status lights, refer to page 16.

If this happens:	Possible causes:	Try these steps:
No lights turn on after you press a button.	<ul style="list-style-type: none"> • Sunlight may obscure your view of the sleep remote lights. • No batteries, depleted batteries, or a battery is placed backwards in the battery compartment. 	<ul style="list-style-type: none"> • If you are outdoors, move indoors or use your sleep remote in the shade. • Check the orientation of the batteries. If the batteries are oriented correctly, replace with new batteries (refer to page 35). • If the problem persists, call your doctor.
Both status lights (▲ ■) on the back of the sleep remote are on, and the sleep remote does not work.	<ul style="list-style-type: none"> • The sleep remote batteries may be very low and need to be replaced. • The sleep remote may not be operating properly. 	<ul style="list-style-type: none"> • Replace the sleep remote batteries with new batteries. Make sure that you are not pressing any buttons while inserting batteries. • For information on status lights, refer to page 16. If all the lights stay on, call your doctor.
You want to check your generator battery without making any other changes.		<ul style="list-style-type: none"> • Pick up or gently shake the sleep remote to display the battery status. If the generator status light (▲) is off, your generator battery is good (refer to page 41).

If this happens:	Possible causes:	Try these steps:
You do not hear audio tones, but the sleep remote is working.	<ul style="list-style-type: none"> • Audio tones are turned off. 	<ul style="list-style-type: none"> • Turn audio tones on (refer to page 19).
You hear three beeps after pressing the Increase (+) or Decrease button (-).	<ul style="list-style-type: none"> • The stimulation strength is at the upper or lower limit. 	<ul style="list-style-type: none"> • Confirm that the current stimulation strength does not work for you. Contact your doctor to change the stimulation strength limits.
You hear three beeps several seconds after pressing a button.	<ul style="list-style-type: none"> • A setting in your generator has changed. • Communication with your generator was not successful. 	<ul style="list-style-type: none"> • Review current therapy settings and try your change again.
Stimulation is uncomfortable.		<ol style="list-style-type: none"> 1. Press the Therapy Off button (O). 2. Reduce the stimulation strength by pressing the Decrease button (-), and then holding the sleep remote over your generator. 3. Press the Therapy On button (▶) to test the stimulation strength. Decrease stimulation further if necessary (refer to page 29).

If this happens: Possible causes:	Try these steps:
Stimulation is too strong.	<ul style="list-style-type: none"> • Decrease stimulation (refer to page 29).
Stimulation is not strong enough.	<ul style="list-style-type: none"> • Increase stimulation (refer to page 28).
You feel that a change took place after you pressed a button, but the sleep remote lights did not change.	<ul style="list-style-type: none"> • The sleep remote was too far from the generator. (The generator may have received the sleep remote signal, but the sleep remote did not receive the generator confirmation signal.) • An electronic device interfered with communication between your sleep remote and generator. • Hold the sleep remote closer to your generator. Review the positioning instructions on page 20. Try your change again. • Turn off or move away from other electronic devices. Try your change again.

If this happens: Possible causes:

Try these steps:

You do not feel stimulation immediately when turning therapy on.

- Therapy may not have turned on.
- Pick up or gently shake the sleep remote to check therapy status. If the status ring is white, therapy is off. Turn therapy on again.

- Your stimulation may be delayed or paused.
- Pick up or gently shake the sleep remote to check therapy status. If the status ring is slowly dimming and brightening green, therapy is on and stimulation is paused. Stimulation will automatically start after the Start Delay or pause time.

- The stimulation strength may be set too low.
- Pick up or gently shake the sleep remote to check therapy status. If the status ring is solid green, stimulation is on. You may want to increase the stimulation strength (refer to page 28). If you still do not feel stimulation, contact your doctor.

- Your generator may need attention from your doctor.
 - Pick up or gently shake the sleep remote. If the generator status light (▲) on the back of the sleep remote is on, contact your doctor.
-

If this happens:	Possible causes:	Try these steps:
Your sleep remote lights do not turn on when it is gently shaken.	Your sleep remote may have been excessively bounced during the previous 30 minutes and has temporarily disabled motion sensing to save battery life.	<ul style="list-style-type: none"> • Press the Therapy Off button (○) and wait 10 seconds. If the remote lights do not turn on, replace the remote batteries (refer to page 35).
Your sleep remote falls into water.		<ol style="list-style-type: none"> 1. Immediately remove the sleep remote from the water. 2. Dry the sleep remote with a towel. 3. Remove the batteries and dry the battery compartment if needed. 4. Allow the battery compartment to air dry at room temperature for at least 24 hours. 5. Insert new batteries.
Your sleep remote falls off a cabinet or table.		<ul style="list-style-type: none"> • The sleep remote is designed to withstand a short drop and still operate normally, even if the case is chipped or otherwise damaged.

8. Specifications

If the sleep remote may have been stored at high or low temperatures or at greater than 90% humidity, store the sleep remote at room temperature and at less than 90% humidity for one hour before use. This will allow the remote to return to normal operating temperature.

Inspire Sleep Remote

Power source	2 AAA or LR03 alkaline batteries
Operating temperature	5 – 40°C 41 – 104°F
Storage temperature (inside or outside of packaging)	-25 – 70°C -13 – 158°F
Operating humidity	15 – 90%
Storage humidity	up to 90%
Operating/storage atmospheric pressure	700 hPa – 1060 hPa (20.7 Hg – 31.3 Hg)
Protection against electric shock	Internally powered equipment
Battery life of sleep remote batteries	2 months (average)
Expected service life of sleep remote	5-year expected (minimum) life

Connections to Additional Equipment

Anybody connecting additional equipment to medical electrical equipment configures a medical system and is responsible that the system complies with the requirements for medical electrical systems.

Additional equipment connected to the sleep remote must comply with the respective IEC or ISO standards (for example IEC 60950 for data processing equipment such as personal computers). All configurations must comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively).

Local laws take priority over the requirements of this section. Contact your doctor or Inspire for additional information.

Do Not Modify

Do not modify the sleep remote. Changes or modifications could void the user's authority to operate the equipment.

FCC Statements

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Inspire Medical Systems Limited Warranty

Summary

Inspire provides a limited warranty against defects. The warranty period for implanted products is 3 years. All other products have a warranty period of 1 year.

The warranty information below is intended for doctors (referred to as physicians in the warranty), but is included here for reference. Ask your doctor if you have any questions. The information below takes precedence over the information contained in this Summary.

Inspire Medical Systems' products consist of Implantable Pulse Generators (IPG), tools to connect the IPG to implantable leads, leads, Inspire Sleep Remotes, and physician programmers.

- 1. EXCLUSION OF WARRANTIES, NO WARRANTIES FOR TOOLS.** The implied warranties of MERCHANTABILITY and fitness for a particular purpose and all other warranties, express or implied with regard to tools are EXCLUDED from any transaction and shall not apply. Inspire Medical Systems will not be liable for any damages, whether direct, consequential, or incidental caused by tool defects, failures, or malfunctions, whether such claims are based on warranty, contract, tort or otherwise. No person has any authority to bind Inspire Medical Systems to any representation or warranty with respect to tools. You may have other rights, which vary from state to state. If one or more of the provisions of this exclusion of warranties for tools shall be deemed void or unenforceable, the remaining provisions shall continue to have full force and effect.
- 2. LIMITED WARRANTY FOR PRODUCTS OTHER THAN TOOLS.** This limited warranty is available if products other than tools fail to function within normal tolerances due to defects in materials or workmanship that manifest during the specified warranty period.

During the operational life of an IPG, battery energy is consumed to monitor the patient's breathing and provide therapy. On the basis of individual patient physiology, certain patients may require more frequent therapy, thus requiring replacement of the IPG in less than the warranty period shown below. This is considered normal for those patients and not a malfunction or defect in the IPG.

If the purchaser complies with the Terms and Conditions, Inspire Medical Systems will issue a limited warranty toward the purchase of a new Inspire Medical Systems IPG product. The limited warranty credit amount will be the full purchase price of either the original unit or the replacement unit, whichever is less.

- For patient products, for example, IPG, lead, Inspire Sleep Remote, Inspire Medical Systems will issue a credit to the hospital conducting replacement surgery on behalf of the original patient. Any cost reductions extended as a result of this warranty shall be fully and accurately reflected on the patients' bill and reported to that applicable payor using the appropriate methodology.
- For physician products, for example, physician programmer, Inspire Medical Systems will issue a credit to the original purchaser of the product.

A. Terms and Conditions

1. The product labeling must indicate a limited warranty exists.
2. For implantable products, this limited warranty applies only for a product replacement in the original patient.
3. All registration materials must be completed and returned to Inspire Medical Systems within 30 days of first use.
4. The product must be replaced with an Inspire Medical Systems product.
5. If the product is implantable, it must be implanted before the product expires and implanted with other Inspire Medical Systems products.

6. The product must be returned to Inspire Medical Systems, 5500 Wayzata Blvd, Suite 1600, Golden Valley, MN 55416 within 30 days that the product first fails to function within normal tolerances. The product may be returned at no cost to you. Contact your Inspire Medical Systems representative for information on how to return the product.
7. Inspire Medical Systems will inspect the returned product and determine whether a limited warranty credit is due.
8. All products returned to Inspire Medical Systems become its property.

This limited warranty represents the entire obligation of Inspire Medical Systems for products other than tools and is made IN LIEU OF any other warranties, whether express or implied, including MERCHANTABILITY or fitness for a particular purpose.

Inspire Medical Systems will not be liable for any damages, whether direct, consequential, or incidental caused by product defects, failures, or malfunctions, whether such claims are based on warranty, contract, tort or otherwise.

No person has any authority to bind Inspire Medical Systems to any warranty or representation except those specifically contained herein.

This limited warranty gives specific legal rights, and you may also have other rights, which vary from state to state. If one or more of the provisions of this limited warranty shall be deemed void or unenforceable, the remaining provisions shall continue to have full force and effect.

B. Limited Warranty Period

The applicable limited warranty period for each product is listed and calculated as follows:

1. Three (3) years from date an IPG or lead is implanted in the patient.
2. One (1) year from the date a physician or Inspire Sleep Remote is first used.



Manufacturer

Inspire Medical Systems, Inc.
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