



Sleep Remote™

2580

CE
0344

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Explanation of Symbols



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



Turn therapy off button



Decrease stimulation strength button



Increase stimulation strength button



Replace sleep remote batteries status light



Generator battery may be low status light



Communication with your generator has been interrupted due to Electromagnetic Interference (EMI) status light



Bluetooth® pairing is in process status light



Stimulation strength is at the upper limit status light

Symbols from the labeling:

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
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1; ISO 7000-2493
	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
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1; ISO 7000-3082
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1; ISO 7000-2497
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1; ISO 7000-2606
	Keep dry	Indicates a medical device that needs to be protected from moisture	ISO 15223-1; ISO 7000-0626

Symbol	Title	Description	Standard Reference
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1; ISO 7000-0533
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223-1; ISO 7000-2621
	Relative humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1; ISO 7000-2620
	Authorized representative in the European Union	Indicates the authorized representative in the European Union	ISO 15223-1; ISO 20417
	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland	ISO 15223-1; ISO 20417
	Importer of record	Indicates the entity importing the medical device into the locale	ISO 15223; ISO 7000-3725
	Medical device	Indicates the item is a medical device	ISO 15223-1
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1
	Packaging unit/quantity	Indicates the number of pieces in the package	IEC 60417; ISO 7000-2794
	Type BF Applied part protection against electrical shock	To identify a type BF applied part complying with IEC 60601-1	IEC 60601-1; ISO 7000-5333
	Collect Separately	Do not dispose of electronic products in the general waste stream	BS EN 50419

Symbol	Title	Description	Standard Reference
IP22	Degree of ingress protection	Protected against solid foreign objects of 12,5 mm Ø and greater. Protection against vertically falling water drops when tilted up to 15°	IEC 60601-1; IEC 60529

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 40 for more detailed information.

	MR unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503
	Giteki; technical conformity mark	Complies with Japan radio law	Article 38 and Notice 88
	Federal Communications Commission (FCC) compliance mark (USA)	Complies with United States Regulations for Radio Frequency Devices	CFR Title 47
	CE marking	Signifies European technical conformity.	EU 2017-745 Annex V

Inspire Sleep Remote Quick Guide

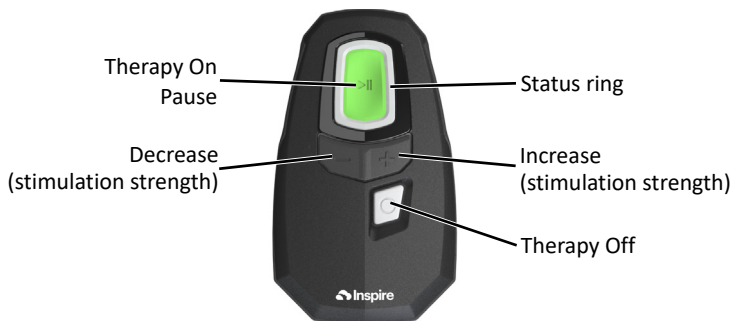


Figure 1. Sleep remote front view

Status Ring Light:	Means:
White — Solid	Therapy is off
Green — Solid	Therapy is on and stimulation is active
Green — Slowly dimming and brightening	Therapy is on and stimulation is paused or therapy is in start delay
Orange — Flashing bars	An orange status light on the back of the sleep remote is on. Turn the sleep remote over and review the status lights.

Turning Therapy On

Note: If audio has been disabled, you will not hear audio tones.

- Press the Therapy On (▶||) button and hold the sleep remote over your generator for 10 seconds or until you hear 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 you hear an audio tone.

Note: Removing the batteries from your sleep remote will not turn off the therapy.

Decreasing Stimulation Strength

- Press the Decrease button () and hold the sleep remote over your generator for 10 seconds or until you hear an audio tone.
- If you hear 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 you hear an audio tone.
- If you hear 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 you hear an audio tone.

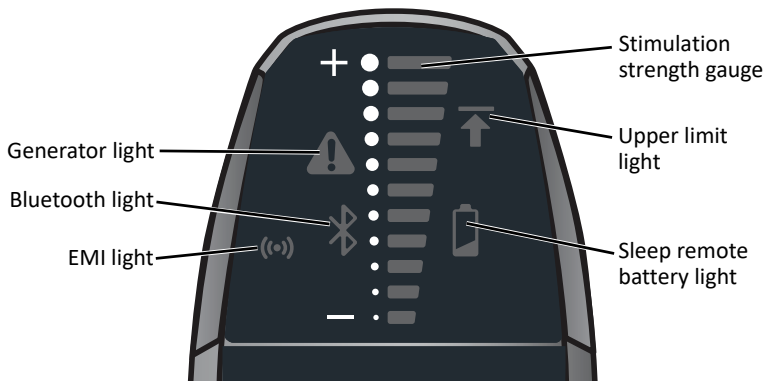


Figure 2. Sleep remote back view

Status Indicators



Replace sleep remote batteries



If the light is on, your generator battery may be low or therapy disabled, call your doctor



If the light is on and flashing, communication with your generator has been interrupted due to Electromagnetic Interference (EMI). Refer to “Interference” on page 8.



Stimulation strength is at the upper limit



Stimulation strength gauge



If this light is flashing the sleep remote is in Bluetooth® pairing mode and can be paired to your phone. If solid, a software update is occurring.

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

Two repeating beeps of the same tone



- Sleep remote is updating the generator

- Wait until complete and the success tone is played

- Update may take several seconds

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Glossary

Apnea — A temporary absence of breathing.

Bluetooth® — A short-range wireless technology standard that is used for exchanging data between fixed and mobile devices over short distances using UHF radio waves in the ISM bands, from 2.402 GHz to 2.48 GHz.

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. Your doctor may also refer to your generator as an IPG, neurostimulator or implantable pulse generator.

Hypoglossal Nerve — The nerve that controls tongue movement.

Lead — A thin, implanted wire with a protective coating that connects to the generator.

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.

Ramp — A duration of therapy in which the stimulation strength gradually increases until it reaches the full stimulation strength set by the clinician. Ramp duration allows the patient to ease into therapy for comfort.

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. Your doctor has given you an Inspire remote (Figure 1-1). The Model 2580 Sleep Remote is intended for use with Inspire Implantable Generators. Use your sleep remote to turn your therapy on and off and adjust the strength of stimulation.



Figure 1-1. Inspire Sleep Remote

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 AA or LR6 alkaline batteries
- Sleep Remote Manual with Quick Guide
- Sleep Remote carrying case

Note: Please contact your healthcare provider if your package is damaged.

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.

Your Inspire System

The implanted components of the Inspire System consist of the generator, and lead(s).

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.

For detailed information about the components included with your Inspire system, refer to your Inspire Patient Manual or contact your doctor.

Intended Use

The Inspire Sleep Remote, in conjunction with the Inspire UAS System, is intended to treat moderate to severe obstructive sleep apnea ($15 \leq \text{AHI} \leq 65$) by improving airway patency through stimulation of the hypoglossal nerve, synchronous with respiration, to elicit a neuromuscular response at the base of the tongue.

Therapy Summary

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

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.

Note: Some generators have a Ramp feature that enables therapy to start at a lower stimulation level and slowly increase to the full stimulation strength. If this feature is enabled, the clinician can

program Ramp to begin after the start delay or use Ramp without any delay time.

Additional Therapy Information

For additional information, such as therapy indications, contraindications, risks, benefits, and surgical procedure description, refer to the Inspire Patient Manual found at <https://manuals.inspiresleep.com>.

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.

Is it normal for the stimulation sensation to change when I change position?

Yes, it is normal to notice minor changes in stimulation sensation when you change sleeping positions.

Can I use my therapy while sleeping in an airplane?

Yes, you can use the therapy in an airplane.

Can adjustments be made to my start delay or pause delay?

Yes. Your clinician can make start delay adjustments in 5-minute increments from 5-75 minutes. Similarly, your clinician can adjust the pause delay in 5-minute increments from 5-30 minutes.

I wake up and notice my Inspire therapy is turned off (solid white light on the remote). Can I adjust my sleep cycle duration?

Yes, your clinician can adjust this in one hour increments through 15 hours. We recommend setting this to the longest possible duration that you would sleep.

Why don't I feel stimulation in the middle of the night or in the morning?

After Inspire has been on for a period of time, your body will adjust to the pulses. You can hold your hand under your chin to feel the pulses when the therapy is active.

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 Inspire Medical Systems Inc. at manuals.inspiresleep.com to view the digital version or 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 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. See below for typical examples of equipment in your

home that may cause electromagnetic interference (EMI). Use these recommendations if you are experiencing interference with the communication between your remote and your generator.

Equipment:	Recommendations:
Home wireless products such as: • <i>Wireless Qi chargers</i> • <i>Wi-Fi networking devices</i> • <i>Walkie-talkies, 15–30 watts</i> • <i>Laptop Computers</i> • <i>Tablets</i> • <i>Mobile/cell phones</i>	Keep 6 feet (1.5 meters) away from home wireless devices when using your sleep remote. Note: Your sleep remote is designed to communicate with mobile/cell phones using Bluetooth Low Energy; however, using your phone simultaneously with your patient remote may interfere with communication with your generator.
Home electromagnetic devices such as: • <i>Electric and magnetic blankets</i> • <i>Electric and magnetic pillows</i> • <i>Wearable electromagnetic devices</i> • <i>HAM, marine, or amateur radios, 15 watts or less</i> • <i>CB radio 5 watts or less</i> • <i>Uninterrupted Power Source (UPS)</i> • <i>Wireless gaming controllers</i> • <i>Remote car starters</i>	Keep 1 foot (0.3 meters) away from home electromagnetic devices when using your sleep remote.

Summary of Safety and Clinical Performance

A summary of the safety and clinical performance (SSCP) for the Inspire remote is available at:

<https://ec.europa.eu/tools/eudamed>. Search for the device using the basic UDI-DI: 0810098652580UX.

SECURITY

Overview

Your Sleep Remote is not capable of communicating directly to the Internet and does not manage or store any Personally Identifiable Information (PII). Your Sleep Remote will only accept communication requests from authenticated and authorized devices. All therapy usage and statistics information that is uploaded from your Sleep Remote is encrypted in transit.

Your Sleep Remote logs potential security events such as failed authorization or authentication events. These logs are stored encrypted and are included with the therapy usage and statistics uploads, and can be provided to Inspire Medical Systems for investigation purposes if necessary. The security logs do not contain any personal information.

How to Secure Your Sleep Remote

Inspire recommends you take the following precautions to ensure the security of your Sleep Remote:

1. Your Sleep Remote is capable of communicating over BLE with the Inspire Mobile App when locally available. When available, accept software updates for your phone OS and the Inspire Mobile App for the most up-to-date security protection.
2. Restrict access to your Sleep Remote to trusted users and phones only.
3. If you get a new remote or stop using Inspire Therapy, return your Sleep Remote to Inspire Medical Systems for secure decommissioning.
4. Notify Inspire Medical Systems of any suspected security event.

Reference “Manufacturer’s Information” on page 34 to contact Inspire Medical Systems regarding secure decommissioning or to report a suspected security event.

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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 held directly over your generator and facing away from you as shown below (Figure 4-1).

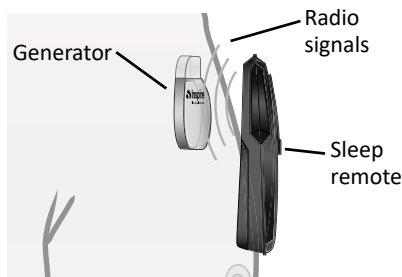


Figure 4-1. Communication between sleep remote and generator

Sleep Remote Buttons

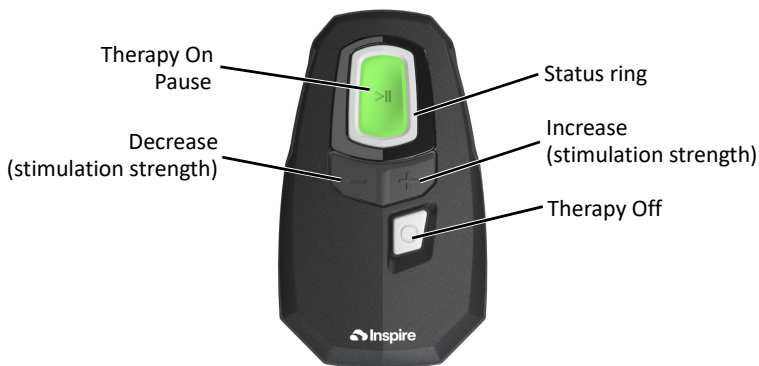


Figure 4-2. Sleep remote buttons

The sleep remote buttons (Figure 4-2) 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:



Turn therapy on. If therapy is on, pause therapy.



Turn therapy off



Decrease the stimulation strength



Increase the stimulation strength

Status Ring



Figure 4-3. Status ring

The sleep remote has a status ring (Figure 4-3) 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:
White — Solid	Therapy is off
Green — Solid	Therapy is on and stimulation is active
Green — Slowly dimming and brightening	Therapy is on and stimulation is paused or therapy is in start delay
Orange — Flashing bars	An orange status light on the back of the sleep remote is on. Turn the sleep remote over and review the status lights.

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 4-4). 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.

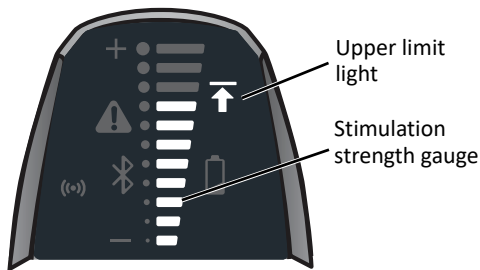


Figure 4-4. Stimulation strength gauge

To check your stimulation strength:

Pick up the sleep remote. The stimulation strength gauge indicates your current stimulation strength.

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 Note: The upper limit that your doctor set may not be the uppermost bar.
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

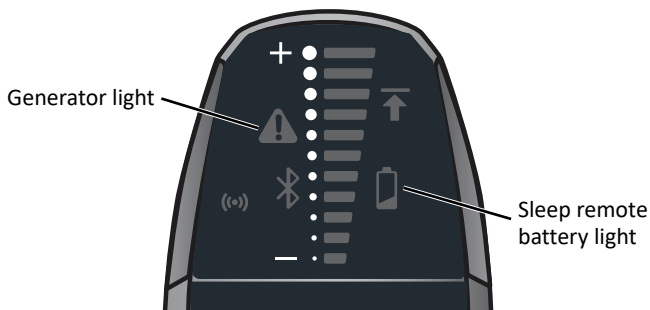


Figure 4-5. Status lights

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 4-5).

Note: When either status light turns on, the status ring on the front of the sleep remote will flash orange. 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

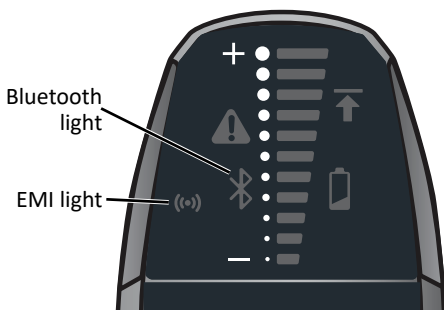


Figure 4-6. Status lights

Status light:	Means:	
EMI light flashing		Communication with your generator has been interrupted by electromagnetic interference (EMI). Six audio beeps will sound. Move away from potential sources of interference, and try again. Refer to “Interference” on page 8.
Bluetooth light is on		Sleep remote is in pairing mode.*

***Note:** The Inspire Mobile App is not required to use Inspire therapy and is not available in all regions.

Bluetooth Pairing with a Mobile Phone

Note: The Inspire Mobile App is not required to use the Inspire therapy and is not available in all regions.

Your sleep remote can connect to the Inspire Mobile App. See instructions below:

1. Download and install the Inspire Mobile App on your iOS or Android device and follow the mobile app instructions.
2. Remove the battery compartment cover. Go to “Checking the Sleep Remote Battery Status” on page 36 for more detailed information on removing the battery cover.
3. Push and hold the blue pairing button (Figure 4-7) for 3 seconds until the Bluetooth light turns on.

Note: The Bluetooth indicator will blink every second while the sleep remote is in pairing mode.

4. Wait for several seconds while the sleep remote securely pairs with the device.
5. When requested by the Inspire Mobile App, press the pairing button one time to confirm pairing.
6. The Bluetooth light will turn off when pairing is complete.

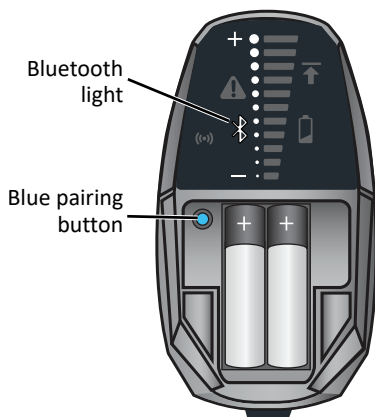


Figure 4-7. Bluetooth pairing with a mobile phone

Audio Tones

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

Note: You cannot adjust the volume of audio tones.

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 23.)
- 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 29.)
- 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 30.)
- You tried to increase stimulation during Ramp (if your clinician has enabled this feature).



Six rapid beeps

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



Two beeps that repeat

- The sleep remote is updating the generator. Wait until you hear the success tone indicating the updating is complete. This update may take several seconds.
-

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 4-8).

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.

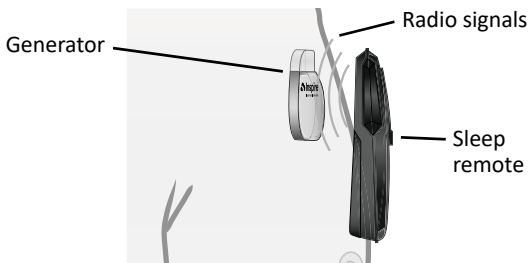


Figure 4-8. Communication between sleep remote and generator

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 4-9).



Figure 4-9. 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. Press the Therapy Off button (○).
2. Position the sleep remote directly over your generator and against your body. The buttons should face away from your body (Figure 4-9).
3. Adjust the sleep remote position until the rear surface of the remote, opposite the Therapy On button (▶||), is directly over your generator (Figure 4-1).
4. Wait 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.

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.

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 4-10).



Figure 4-10. 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 4-10).
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 4-10).
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.

Note: Stimulation strength cannot be increased during Ramp duration if it is enabled. You will hear three beeps if you attempt to increase during Ramp duration.

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 16.)

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

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 or you are in Ramp therapy.

2. Position the sleep remote directly over your generator and against your body with the buttons facing away from your body (Figure 4-10).
3. Wait until the sleep remote produces a tone or 10 seconds pass.

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 16).

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

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 4-10).
3. Wait until the sleep remote produces a tone or 10 seconds pass.

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 that the sleep remote is attempting to make a change to your generator.



Figure 4-11. 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

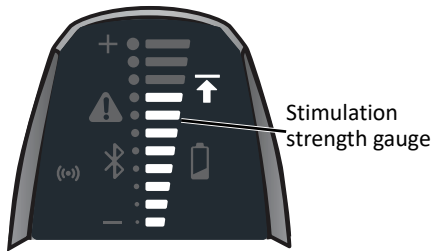


Figure 4-12. Stimulation strength gauge

Stimulation Strength Gauge:	Means:
Whole gauge blinking white	Turning therapy off
Whole gauge blinking green	Turning therapy on or pausing therapy
One step on the gauge is blinking	Increasing or decreasing stimulation strength. The newly selected stimulation strength step is blinking.

Additional Therapy Information

For additional information, such as therapy indications, contraindications, risks, benefits, and surgical procedure description, refer to the Inspire Patient Manual found at <https://manuals.inspiresleep.com>.

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 Implant Card for verification. This also applies if you encounter similar security devices in other situations.

If you notice that your sleep remote's batteries deplete when you travel, you may want to remove the batteries during the transit portion of your trip(s). Once you arrive at your destination, install the batteries back into your sleep remote.

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

Website: www.inspiresleep.com

Report serious adverse incidents related to use of this device or your generator to the medical device Competent Authority in your country and to Inspire Medical at inspiresleep.com or by telephone at +1-844-672-4357.

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 AA or LR6 alkaline batteries. Replace the batteries when the sleep remote battery light is on or after 6 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 your sleep remote batteries.
 - If the light is off and your sleep remote is responsive, your batteries are good.
 - If no lights come on when you gently shake your sleep remote, replace the batteries. If your sleep remote is still unresponsive after replacing the batteries, contact your doctor.

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 6-1.

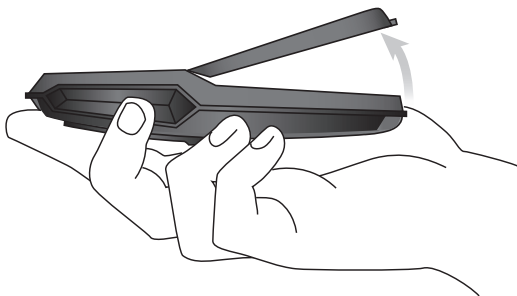


Figure 6-1. Removing the battery compartment cover

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 into the gap between a battery (+) terminal and the housing of the sleep remote.
2. Simultaneously, lightly press down and pull backwards on the battery so that the battery snaps out of place.
3. Remove the battery and repeat steps 1 and 2 to remove the second battery.
4. Position each new battery to match the figure of the battery compartment below (Figure 6-2).

Note: Your sleep remote uses two AA batteries.

Note: Do not use rechargeable batteries in your sleep remote.

5. Gently press down each battery to snap it into place.



Figure 6-2. 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.
- Visually inspect for residual soil and repeat cleaning in the event that residual soil is visible on the device.

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.
- Keep dry.

Checking the Sleep Remote

Pick up or gently shake the sleep remote to display the status. If the lights don't turn on, press the Therapy Off button and wait 10 seconds.

- If the status ring on the front of the remote is illuminated green or white, and all orange status lights on the back of the remote are off, you may resume use of your sleep remote.
- If any status light is on and the status ring is flashing orange, refer to page 18 of this manual to determine the meaning of the status lights.
- If the battery light () is on, replace your remote batteries (refer to page 37).
- If both the low battery () and interference () lights are on, the sleep remote may have an issue. Please contact your doctor as your primary source for all questions and requests. As an additional resource, you may contact Inspire Medical Systems, Inc.

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.

Updating Your Sleep Remote

Inspire will notify you if a software update for your Sleep Remote is available. Installation instructions will be provided at that time.

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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, contact your doctor or Inspire Medical Systems, Inc. For additional contact information, refer to “Manufacturer’s Information” on page 34.

If this happens:	Possible causes:	Try these steps:
Orange bars are flashing left and right on the front of your sleep remote.	• 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 18 and/or page 42.
An orange light ( or  or ) on the back of your sleep remote is on.		• For information on status lights, refer to page 18 and/or page 42.

If this happens:	Possible causes:	Try these steps:
No lights turn on after you press a button.	• Sunlight may obscure your view of the sleep remote lights. • No batteries, depleted batteries, or a battery is placed backwards in the battery compartment.	• 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 37). • If the problem persists, call your doctor.
Both status lights ((••) and ) on the back of the sleep remote are on, and the sleep remote does not work.	• The sleep remote may not be operating properly.	• For information on status lights, refer to page 18 and/or page 42. If all the lights stay on, call your doctor.
You want to check your generator battery without making any other changes.		• 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 42).
You hear three beeps after pressing the Increase (+) or Decrease button (—).	• The stimulation strength is at the upper or lower limit.	• Confirm that the current stimulation strength does not work for you. Contact your doctor to change the stimulation strength limits.

If this happens:	Possible causes:	Try these steps:
You hear three beeps several seconds after pressing a button.	• A setting in your generator has changed. • Communication with your generator was not successful.	• Review current therapy settings and try your change again.
Stimulation is uncomfortable.		1. Press the Therapy Off button (○). 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 30).
Stimulation is too strong.		• Decrease stimulation (refer to page 30).
Stimulation is not strong enough.		• Increase stimulation (refer to page 29).

If this happens:**Possible causes:****Try these steps:**

You feel that a change took place after you pressed a button, but the sleep remote lights did not change.

- 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 23. Try your change again.
 - Turn off or move away from other electronic devices. Try your change again. (Refer to page 8).
-

If this happens:	Possible causes:	Try these steps:
You do not feel stimulation immediately when turning therapy on.	• Therapy may not have turned on. • Your stimulation may be delayed or paused. • The stimulation strength may be set too low. • Your generator may need attention from your doctor.	• 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. • 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. • 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 29). If you still do not feel stimulation, contact 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.		• Press the Therapy Off button (○) and wait 10 seconds. If the remote lights do not turn on, replace the remote batteries (refer to page 37).
Your sleep remote falls into water.		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.		• The sleep remote is designed to withstand a short drop and still operate normally, even if the case is chipped or otherwise damaged.

If this happens:	Possible causes:	Try these steps:
Cannot pair with mobile phone.	• Incorrect procedure used. • Process not completed within 60 seconds. • The mobile phone's Bluetooth connection is disabled. • App is not available for download.	• Download the Inspire Mobile App, open the app, and follow the app instructions. Refer to "Bluetooth Pairing with a Mobile Phone" on page 20 for more information. • Be sure to press the pairing button to confirm pairing as soon as prompted by the Inspire Mobile App. • Enable the Bluetooth connection in your mobile phone's settings. • The Mobile App is not available in all regions. The Inspire therapy will still function without use of the Mobile App.

If this happens:	Possible causes:	Try these steps:
The Inspire Mobile App is not connecting to the sleep remote.	The sleep remote can only be paired with one device at a time. • The mobile phone's Bluetooth connection is disabled. • Other. • App is not available for download.	• Re-pair with the Inspire Mobile App. Refer to the steps in "Bluetooth Pairing with a Mobile Phone" on page 20. • Enable the Bluetooth connection in your mobile phone's settings. 1. Reset the sleep remote pairing information by holding down the pairing button for 10 seconds. 2. Re-pair with the Inspire Mobile App. Refer to the steps in "Bluetooth Pairing with a Mobile Phone" on page 20 for more information. 3. Restart your mobile phone. • The Mobile App is not available in all regions. The Inspire therapy will still function without use of the Mobile App.

8. Specifications

If the sleep remote has 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. When operating your sleep remote in a warm environment, your remote's temperature may exceed 106 °F (41 °C).

Inspire Sleep Remote	
Power source	2 AA or LR6 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 inHg – 31.3 inHg)
Protection against electric shock	Internally powered equipment
Battery life of sleep remote batteries	6 months (average)
Expected service life of sleep remote	5-year expected (minimum) life

Connections to Additional Equipment

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.

Telemetry

The Inspire Sleep Remote communicates with your generator using telemetry with the following characteristics:

Wireless Technology	Inductive Telemetry
Frequency Band	175 kHz
Modulation Type	ASK (Amplitude-Shift Keying)
Power Output	< -50 dBm (10 nW)
Operating Range	Up to 5 centimeters

Telemetry communication only occurs after a button press and completes within a second or two. If necessary, the sleep remote will automatically retry commands for up to 10 seconds. Retries may be required if the sleep remote is too far from your generator (more than 5 cm away), or if there is electromagnetic interference (EMI) from other nearby devices. There is potential for telemetry interference from devices such as those described on page 8.

If high levels of EMI are detected, the remote will play three rapid beeps and illuminate the EMI status indicator. If this occurs, please move away from the interference source and try again. Also consider relocating sources of interference.

Bluetooth®

The Inspire Sleep Remote can communicate with cell phones using Bluetooth Low Energy (BLE) with the following characteristics:

Wireless Technology	Bluetooth Low Energy
Frequency Band	2.4 GHz ISM Band
Modulation Type	GFSK (Gaussian Frequency-Shift Keying)
Power Output	< +8 dBm (6.3 mW)
Operating Range	Up to 20 feet

BLE is used to transfer therapy usage information and statistics for monitoring with the Inspire Mobile App, where locally available. If the paired Mobile Phone is nearby, data may be transferred after a button press or while the sleep remote is idle. Data cannot be transferred if the Mobile Phone is not present, or if interference prevents communication. BLE communication is not used for the treatment of Obstructive Sleep Apnea and is separate from telemetry communication with your generator.

If data is not transferred, it can be tried again later. The Mobile App will not transfer data unless the transfer completes without error. The patient remote was designed to coexist with other

wireless devices operating nearby. The BLE interface is designed to work when the patient remote is located near devices such as:

- Wi-Fi Routers
- Other 2.4 GHz Wi-Fi Devices
- Other Bluetooth Devices
- High-Powered Radio Transmitters or Antennas

If interference prevents BLE pairing or data upload to the Inspire Mobile App, please move the Inspire Sleep Remote and your Mobile Phone 6 feet away from the interference source and try again. Also consider relocating the source of interference.

Configuration Information

No configuration is required to use the Inspire Sleep Remote to communicate with your generator using telemetry.

In order to use the Inspire Sleep Remote with the Inspire Mobile App, your phone must have Bluetooth enabled and be connected to a data network, where locally available. For more information about pairing with the Inspire Mobile App, please refer to page 20. See “SECURITY” on page 10 for additional guidance on security.

Electromagnetic Compatibility Declarations

Guidance and Manufacturer's Declaration - Electromagnetic Compatibility

The Inspire Sleep Remote (Model 2580) is suitable for use in a home environment or professional health care facility. The customer or the user of the sleep remote should ensure it is used in such an environment.		
IEC/EN 60601-1-2 Test	Compliance	Electromagnetic Environment
Radiated Emissions	CISPR 11 Group 1 Class B	The Inspire Sleep Remote uses RF energy for its intended purposes. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Electrostatic Discharge (ESD)	IEC/EN 61000-4-2 Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Radiated Immunity	IEC/EN 61000-4-3 80 MHz to 2.7 GHz: 10 V/m	The Inspire Sleep Remote should be used in an electromagnetic environment of a common home or health care facility. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity Fields from RF Wireless Communications Equipment Immunity	IEC/EN 61000-4-3 380 to 390 MHz: 27 V/m 430 to 470 MHz: 28 V/m 704 to 787 MHz: 9 V/m 800 to 960 MHz: 28 V/m 1.7 to 1.99 GHz: 28 V/m 2.4 to 2.57 GHz: 28 V/m 5.1 to 5.8 GHz: 9 V/m	
Proximity Magnetic Fields Immunity	IEC/EN 61000-4-39 30 kHz: 8 A/m 134.2 kHz: 65 A/m 13.56 MHz: 7.5 A/m	
Rated Power Frequency Fields Immunity	IEC/EN 61000-4-8 50 Hz and 60 Hz: 30 A/m	Power frequency magnetic fields should be at levels for a common home or health care environment.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Inspire Sleep Remote

Portable and mobile radio-frequency (RF) communications equipment (for example, mobile or cellular phones and amateur radio equipment) can affect medical electrical equipment.

Portable radio-frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sleep Remote. Otherwise, the Sleep Remote's performance could be degraded.

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9. 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 (generators/IPGs/neurostimulators), tools to connect the generator 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 generator, 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 generator in less than the warranty period shown below. This is considered normal for those patients and not a malfunction or defect in the generator.

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 generator 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, generator, 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 generator or lead is implanted in the patient.
2. One (1) year from the date a physician or Inspire Sleep Remote is first used.



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