

3032PatEN_fcv.fm 10/30/15 8:54 am
4.625 x 6 inches (117 mm x 152 mm)

Inspire Medical Confidential
Inspire 002



INSPIRE SLEEP REMOTE™

Inspire Sleep Remote Model 2500

Rx Only

200-161-101 Rev A

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

-  Therapy on
-  Therapy off
-  Stimulation strength decrease
-  Stimulation strength increase
-  Sleep remote batteries
-  Generator status
-  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 43 for more detailed information.

Inspire Sleep Remote™ Quick Guide

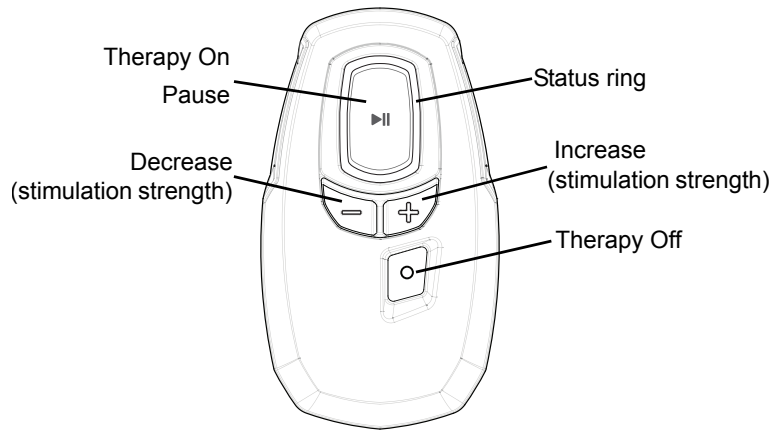


Figure 1. Sleep remote front view

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

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 you hear an audio tone.
- When therapy is turned on you will feel a brief stimulation.

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.

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.

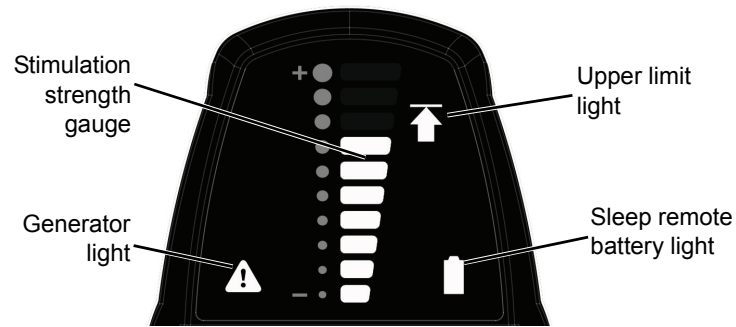


Figure 2. Sleep remote back view

Status Indicators



Replace sleep remote batteries



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



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 you hear two beeps with a rising tone, you have found the generator location.
- If you hear three rapid beeps, you have not found the generator location. Try again.

Audio Tones

Two beeps with a rising tone



- 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.

Diathermy — A medical treatment applied to the outside of the body that delivers energy into the body. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically used to relieve pain, stiffness and muscle spasms, reduce joint contractures (in other words, shortening of muscles or tendons), reduce swelling and pain after surgery, and promote wound healing.

Electromagnetic Disturbance — An electromagnetic event that may degrade the performance of a device.

Electromagnetic Interference (EMI) — The effect of an electromagnetic disturbance that prevents the generator or sleep remote from working properly. For example, electromagnetic interference could prevent your generator from communicating with your sleep remote.

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.

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Inspire Medical Confidential
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xiv English Inspire Sleep Remote

200-161-101 Rev A

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.

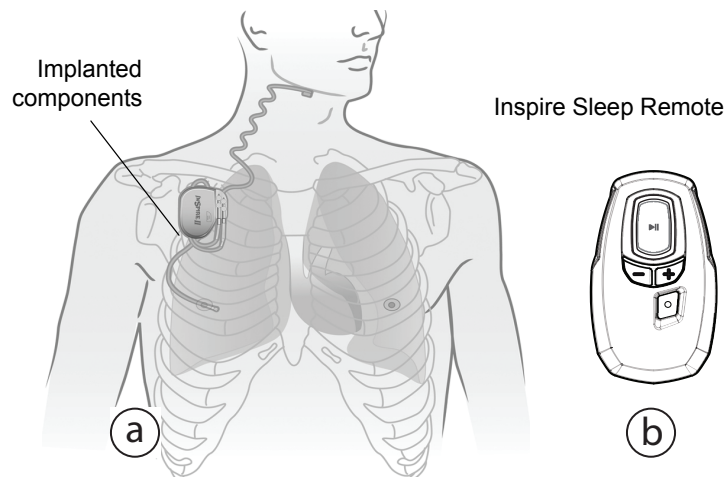


Figure 3. Inspire system

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

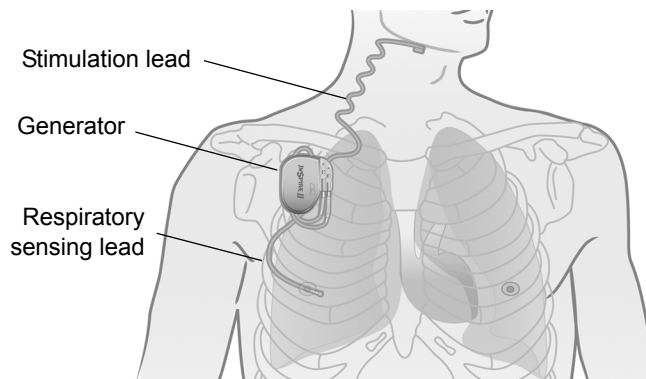


Figure 4. *Implanted components of the Inspire system*

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.

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.

How long will my generator battery last?

For information on battery life and replacement, refer to your Inspire Patient Manual.

**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 position.

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

3. Safety Information

Warnings

For additional warnings and safety information, refer to your Inspire Patient Manual.

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

Precautions

Medical Procedures

Consult your doctor regarding the following medical procedures. These procedures may cause permanent damage to the generator, particularly if used in close proximity to the device:

- Dental drills and ultrasonic probes
- Electrolysis
- Bone growth stimulators
- Laser procedures
- Radiation therapy

- High-output ultrasonics / lithotripsy (If lithotripsy must be used, consult your doctor.)

For additional safety information, refer to your Inspire Patient Manual.

Electromagnetic Interference

The following equipment or environments could generate enough electromagnetic disturbance to potentially create unwanted stimulation from your generator. Avoid them if possible.

- Antennas of citizen band (CB) or ham radios
- Electric arc welding equipment
- Electric induction heaters
- Electric steel furnaces
- Equipment used for decreasing or eliminating magnetic fields
- High-voltage areas (safe when outside the fenced area)
- Linear power amplifiers
- Microwave communication transmitters (safe when outside the fenced area)
- Perfusion systems (for example, hospital equipment used for maintaining blood flow)
- Power lines or power generators
- Resistance welders
- Television and radio transmitting towers (safe when outside the fenced area)

If you suspect that equipment is causing unwanted stimulation or interfering with the implanted 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. Inform the equipment owner or operator about the interference. 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 electromagnetic interference, contact your doctor.

For additional safety information, refer to your Inspire Patient Manual.

Theft Detector or Security Screening Devices

Use care when approaching theft detectors and security devices (such as those found in airports, libraries, department stores, and government buildings). When approaching these devices, do the following:

1. Show the security personnel your Inspire Identification Card and ask for a manual search. If security personnel use a handheld security wand, ask them not to hold the security wand near the generator longer than needed.
2. If you must pass through the theft detector or security screening device, make sure your therapy is off. When

walking through the device, keep as far from it as possible.

Note: Some theft detectors might not be visible.

3. Proceed through the security device. Do not linger near or lean on the security device.

For additional safety information, refer to your Inspire Patient Manual.

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.

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.

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. The sleep remote batteries may pose a choking hazard. Also, children or pets may damage the sleep remote.

Component manipulation (twiddler's syndrome). Do not manipulate (move) or rub your generator or leads through your skin; this is sometimes called "twiddler's syndrome." Manipulation can cause damage to the components, lead dislodgement, skin damage, or unintended stimulation.

Scuba diving or hyperbaric chambers. Do not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) can damage your generator or leads. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

Skydiving, skiing, or hiking in the mountains. High altitudes should not affect the generator; however, you should consider the movements involved in such activities, and take precaution to not put undue stress on your generator or leads. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or break a lead, requiring additional surgery to repair or replace the lead.

For additional safety information, refer to your Inspire Patient Manual.

MRI and Other Medical Procedures

If you need or desire a procedure like MRI or diathermy, consult your Inspire Patient Manual or your doctor to determine if the medical procedure is safe for you.

The sleep remote contains metal and should be kept away from MRI equipment.

Mobile Devices and Common Household Electrical Items

Most of the electrical devices that you encounter in an ordinary day are unlikely to affect your Inspire system. However, electromagnetic interference can impact you and your Inspire system in certain situations. The following equipment is unlikely to affect your system if you follow these guidelines:

- *Mobile phones and other radio-frequency sources (tablet computers, AM/FM radios, cordless and conventional telephones):* Keep these items at least 15 cm (6 in) away from the generator.
- *Induction range:* Keep the generator away from the burners while the burners are turned on. Induction ranges, unlike conventional electric stoves, produce magnetic fields to generate heat.
- *Power tools:* Keep the motor away from the generator and leads.
- *Sewing machines or salon hair dryer:* Keep the generator away from the motors.

Some devices can interfere with the communication between your generator and sleep remote.

- *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).

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 electromagnetic 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 placed directly over your generator (Figure 5).

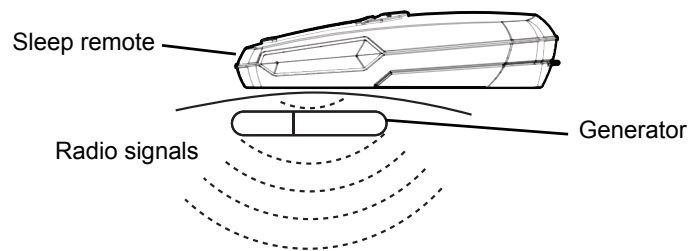


Figure 5. Communication between sleep remote and generator

Sleep Remote Buttons

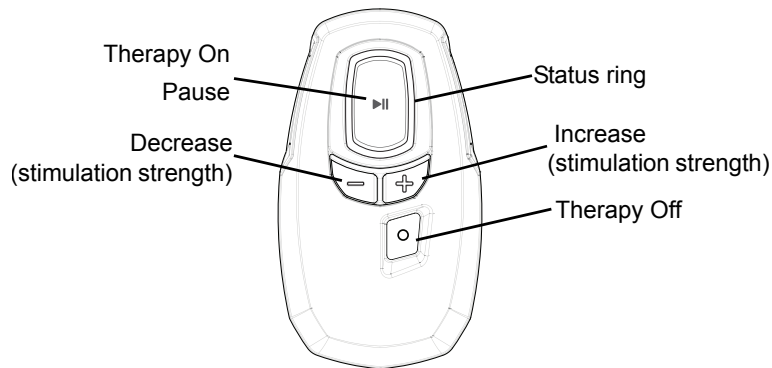


Figure 6. Sleep remote buttons

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:
	Turn therapy on. If therapy is on, pause therapy.
	Turn therapy off
	Decrease the stimulation strength
	Increase the stimulation strength

Status Ring

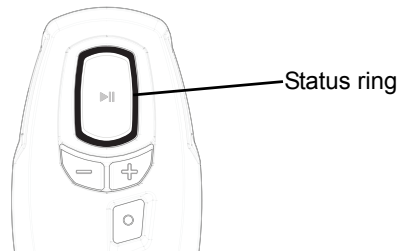


Figure 7. Status ring

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.

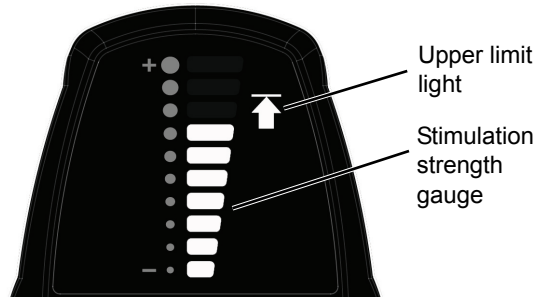


Figure 8. Stimulation strength gauge

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

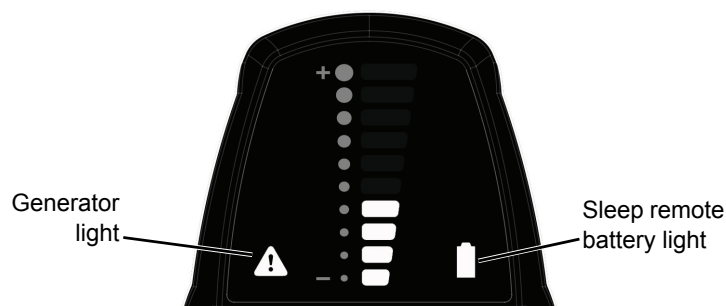


Figure 9. Status lights

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	 	Replace sleep remote batteries, because low batteries may be preventing normal sleep remote operation. If condition persists, contact your doctor. Your sleep remote may not be working properly.
Generator light flashing		Communication with your generator has been interrupted by electromagnetic interference. Move away from potential sources of interference, and try again.