

Axonics SNM System® Remote Control

Remote Control User Manual

Model 2301

!USA Rx ONLY



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Caution: The Axonics Sacral Neuromodulation System should be used only on the order of a doctor

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Introduction

The Axonics Sacral Neuromodulation (SNM) therapy is provided to relieve the symptoms of urinary and fecal dysfunction. Patients are given a Remote Control to monitor the battery status and settings of their Axonics SNM System.

This manual describes how to use the Remote Control.

Axonics recommends you read this manual before using your Remote Control.

Manual Overview

This manual describes the steps for safe use of your Remote Control. The manual includes:

- Description of Remote Control buttons, indicators and functions
- Steps for using your Remote Control
- Troubleshooting Remote Control issues
- Additional information about the Remote Control

Note: The Remote Control may behave differently when communicating with the Trial Stimulator (TS) and the Permanent Stimulator (PS). This manual will highlight when certain behavior is specific to the TS or PS. Otherwise both stimulators are referred to commonly as the Stimulator.

Refer to your Therapy Guide which is provided by your doctor for more information regarding your system.

Remote Control Precautions

- If you have other active implants (such as a pacemaker), the Remote Control may cause issues with such implant(s). Contact your doctor if you experience issues or have any questions.
- If you have cochlear implants, the external portion of these implants should be kept away from the Remote Control. This will help avoid and/or reduce unwanted audible clicks.
- Some equipment may generate signals, called Electromagnetic Interference or EMI. EMI can block the Remote Control's signals to the Stimulator. If you have issues using your Remote Control, move away from such sources. This includes computer monitors, cellular telephones and other electronic equipment.

Warning: Do not attempt to modify or service this product. If there is an issue with the product, please consult your doctor.

Recommended Use and Care

DO

- ✓ Carry your Remote Control with you at all times in case you need to adjust your stimulation or check the battery status of your Stimulator.
- ✓ If you need to store your Remote Control, put it in a cool, dry place away from direct heat and light.
- ✓ Clean your Remote Control with a damp, soft cloth as needed.
- ✓ Bring your Remote Control to all visits with your healthcare provider.

DO NOT

- ✗ Do not drop the Remote Control in liquid or clean it with harsh cleaners.
- ✗ Do not drop the Remote Control or mishandle it in a way that causes damage.
- ✗ Do not use the Remote Control near flammable or explosive gases.
- ✗ Do not allow other people to use your Remote Control.

How to Use Your Remote Control

The Remote Control allows you to monitor your stimulation level and the need to recharge the PS. This section describes how to use your Remote Control to:

- Monitor Stimulator battery status and stimulation level
- Turn up or turn down your stimulation level
- Turn your stimulation on and off
- Monitor charging of your Stimulator (*PS only*)
- Change your stimulation program (*TS only*)
- Receive notice of errors in your Remote Control or Stimulator
- Perform a system check prior to an MRI exam

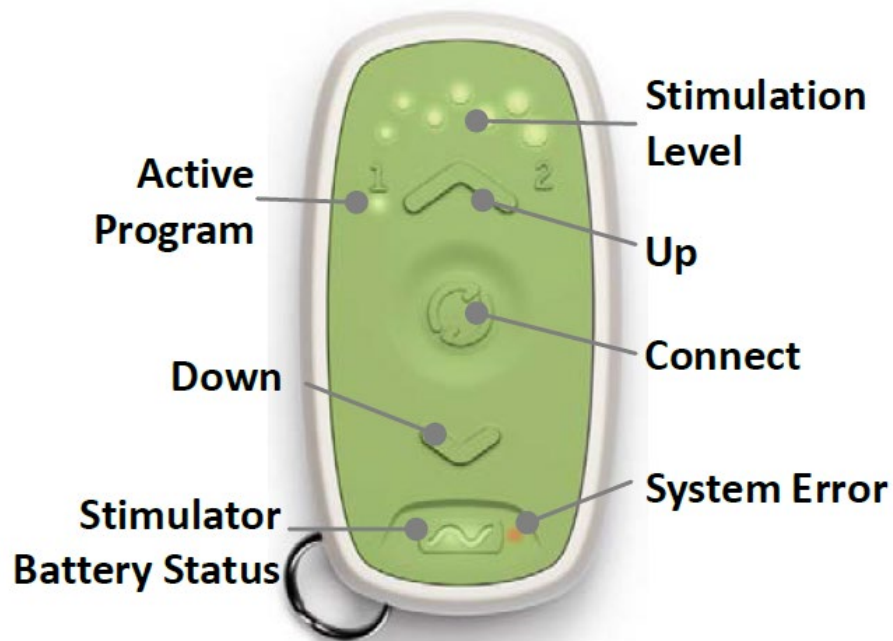
While your Remote Control is pre-programmed to connect to your device, this manual refers to various device model numbers. Before using this manual, find your model number on your Patient ID card.

The Remote Control is compatible with the following Axonics model numbers:

- Permanent Stimulator: Model 1101
- Trial Stimulator: Model 1601

Note: *Do not make stimulation changes regularly. Your doctor should change your stimulation settings if needed. Axonics recommends you only change your stimulation if you experience discomfort.*

Summary of Buttons and Lights



Stimulation Level	Shows the strength of stimulation.
Up	Turn up stimulation level or Turn on stimulation to default level.
Connect	Connect or disconnect the Remote Control to the Stimulator.
Down	Turn down stimulation level or Turn off stimulation.
Active Program	Shows which stimulation program is active.
System Error	Shows there is an error in the Remote Control or Stimulator.
Stimulator Battery Status	For TS, shows how long until the battery is depleted. For PS, shows if the battery needs charging.

Note: For a detailed description of the lights see the section *View Stimulator status*

How Your Remote Control Communicates with Your Stimulator

The Remote Control sends and receives signals to and from the Stimulator. Your Remote Control must be near the Stimulator to send and receive signals. Only the Remote Control given to you by your doctor can send and receive signals to and from your Stimulator.



To use your Remote Control, hold it comfortably in front of you. The Remote Control should be held on the same side of the body as the Stimulator.

Use Scenarios

The following pages show how to use your Remote Control to:

- 1) Connect to your Stimulator.
- 2) View Stimulator status.
- 3) Turn down your stimulation level.
- 4) Turn up your stimulation level.
- 5) Turn your stimulation off.
- 6) Turn your stimulation on.
- 7) Monitor battery charge status (PS only).
- 8) Change your stimulation program (TS only).
- 9) See a system error.
- 10) Perform a system check prior to an MRI exam
- 11) Turn off your Remote Control.

Note: *If you have issues using your Remote Control, please refer to the Troubleshooting section of this manual. For more help please contact your doctor.*

1) Connect to your Stimulator

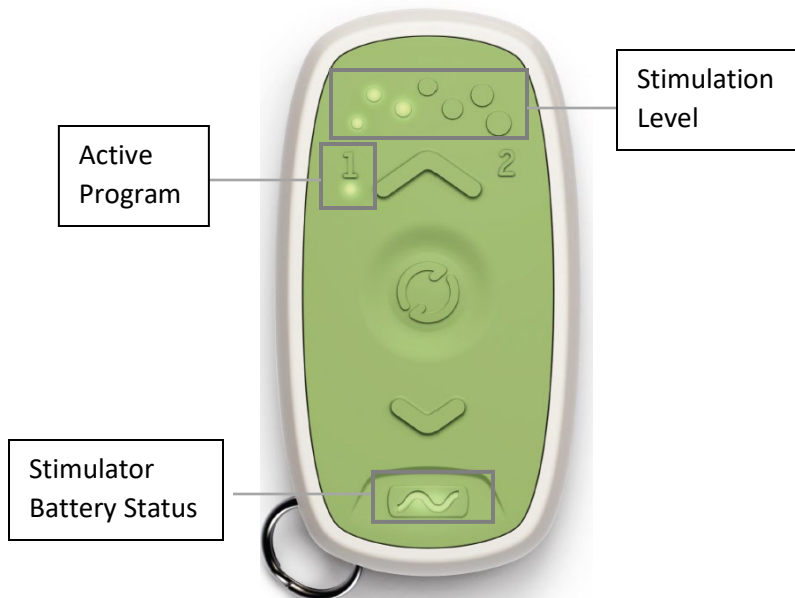


- 1 Hold the Remote Control on the same side of your body as the Stimulator. Press the “Connect” button on the center of the Remote Control.
- 2 The stimulation level lights will flash. Flashing lights mean the Remote Control is trying to connect to the Stimulator. It may take up to 25 seconds for the Remote Control to connect to the Stimulator.
- 3 Watch for the stimulation level lights to stop flashing and the stimulator battery light to turn on. This means the Remote Control is communicating with the Stimulator. *(If no light is visible connection has failed. See Troubleshooting.)*

Note: The most common issue is not having your Remote Control close enough to the Stimulator. If your initial connection attempt fails, move the Remote Control closer to the Stimulator and retry.

Note: Moving the Remote Control while connected to the Stimulator may result in loss of communication.

2) View Stimulator Status



Stimulator battery status lights



Solid green: Stimulator battery will last for 4 or more days

Flashing green (PS only): Stimulator battery is charging



Solid orange: Stimulator battery will last for 2 to 4 days

Flashing orange: Stimulator battery will last for 2 days or less

Stimulation level lights



No stimulation



Default level set by your doctor



Maximum level

Active Program

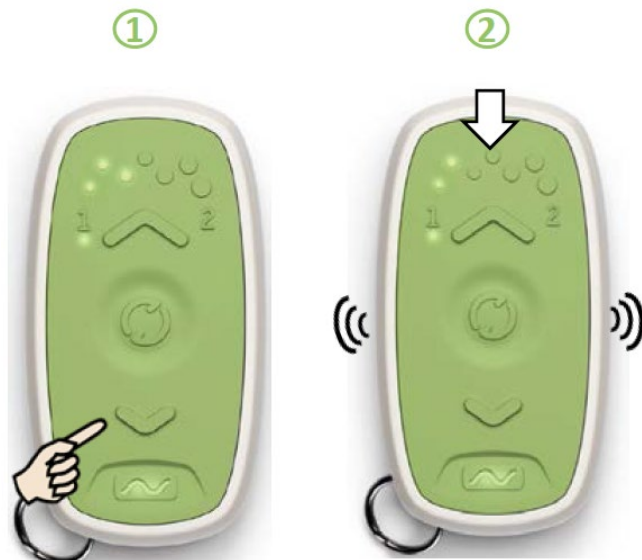


Program 1 is active



Program 2 is active (TS only)

3) Turn Down Your Stimulation Level

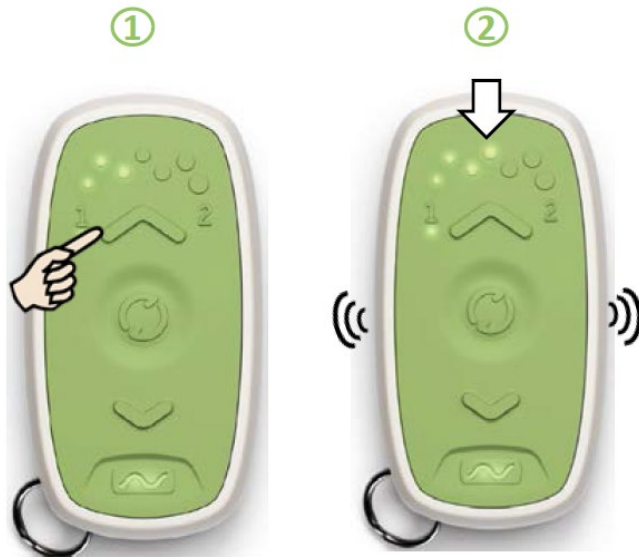


If you experience discomfort, you can use your Remote Control to turn down stimulation.

The Remote Control must be connected to the Stimulator (see *Connect to Your Stimulator*).

1. Press the “Down” button one time.
2.
 - A. *Permanent Stimulator*: Watch for the stimulation level lights to decrease by one. The Remote Control will vibrate. This may take 3 seconds.
 - B. *Trial Stimulator*: The Remote Control will vibrate and the stimulation level lights will flash. After multiple adjustments the stimulation level may change. This may take 3 seconds.

4) Turn Up Your Stimulation Level



The Remote Control must be connected to the Stimulator (see *Connect to Your Stimulator*).

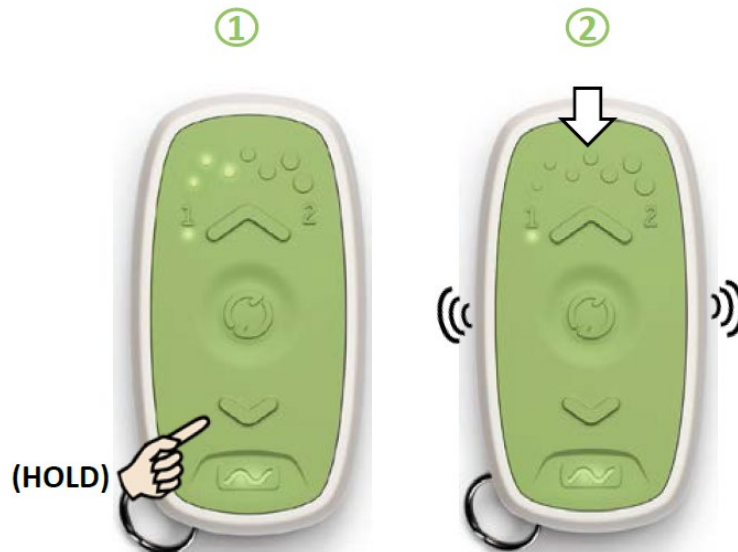
1. Press the “Up” button one time.

2A. *Permanent Stimulator:* Watch for the stimulation level lights to increase by one. The Remote Control will vibrate. This may take 3 seconds.

2B. *Trial Stimulator:* The Remote Control will vibrate and the stimulation level lights will flash. After multiple adjustments the stimulation level lights may change. This may take 3 seconds.

Note: Stimulation level can only be turned up by one level at a time. It may take up to 30 seconds for the stimulation level to fully increase, depending on your stimulation settings. Make sure the stimulation level is comfortable before turning up again.

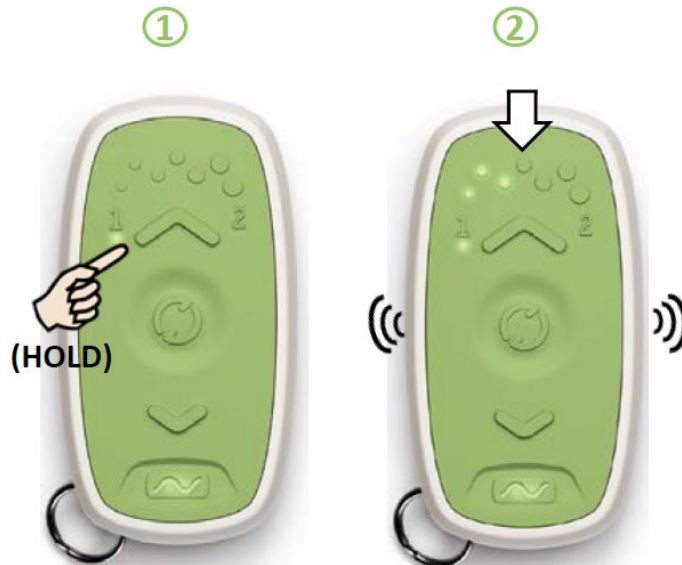
5) Turn Your Stimulation Off



If you experience extreme discomfort, you can use your Remote Control to turn off stimulation. The Remote Control must be connected to the Stimulator (see *Connect to Your Stimulator*).

- 1 Press and Hold the “Down” button for 5 seconds.
- 2 Watch for the stimulation level lights to all turn off. The Remote Control will vibrate. This may take 3 seconds.

6) Turn Your Stimulation On



The Remote Control must be connected to the Stimulator (see *Connect to Your Stimulator*).

- 1 Press and Hold the “Up” button for 5 seconds.
- 2 Watch for the stimulation level lights to light up. The Remote Control will vibrate. This may take 3 seconds.

Note: Stimulation level will be at the level set before turning the Stimulator off.

Note: You should not need to regularly turn your stimulation off and on. Your doctor should adjust your stimulation if needed.

7) Monitor Charge Status – *Permanent Stimulator only*



The Stimulation Battery Status light will flash green when your Stimulator is charging. When charging is done or if charging stops for any reason, the Stimulation Battery Status light will stop flashing.

See the Charging System manual for more information about charging your Stimulator.

8) Change Your Stimulation Program – *Trial Stimulator only*



The Remote Control allows you to change the active program (providing stimulation) if your doctor has set 2 programs to your external Trial Stimulator. Only change your program if instructed by your doctor. The Remote Control must be connected to the Stimulator (see *Connect to Your Stimulator*).

1. Press and hold the “Connect” button for at least 5 seconds.
2. The Remote Control will vibrate and you will see either:
 - i. The active program light change from “1” to “2” (or vice versa) to indicate that the program has changed, or
 - ii. The currently active program light flashes for 4 seconds and does not change to the other program. This indicates that the Stimulator was unable to change programs (see Troubleshooting)
3. Press and release the “Up” button to turn on stimulation. You will see one solid stimulation level LED. Continue to turn up stimulation until you feel the stimulation (the sensation should not be uncomfortable).

9) See a System Error



When you try to connect to your Stimulator, the Remote Control will check for errors.

Permanent Stimulator: Call your doctor if the red error light is on.

Trial Stimulator: The red light may mean that your Stimulator is disconnected from the cable. Check that the Stimulator is still connected to the cable coming from your back. Connect the Stimulator to the cable, if not already connected. Turn off the Remote Control. Next, turn on the Remote Control and try to increase the stimulation level. If the red light is still on, try changing the stimulation program. If the red light is still on, call your doctor.

Red light flashes – Ask for a new Remote Control.

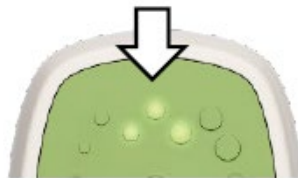
Red light is on at all times – The doctor needs to test your Stimulator. Make an appointment to see your doctor.

10) Perform an MRI Readiness system check prior to a Full Body MRI exam –
Permanent Stimulator only

Bring the Remote Control and your patient ID card to the MRI appointment. Use the Remote Control to perform an MRI Readiness check of your system prior to an MRI. Do this before the MRI scan and outside the MR scanner room.

Do not bring the Remote Control into the MR scanner room.

- A. If the Remote Control is off, connect it to the Stimulator (see *Connect to Your Stimulator*).
 - B. Turn stimulation off by pressing the down arrow until all the stimulation level lights are off at the top of the Remote Control (see *Turn Your Stimulation Off*).
- Note:** Release the Down button after stimulation is turned off and prior to performing the next step.
- C. Press and hold the Down button for at least 5 seconds.
 - i. If the system is ready for MRI scan, stimulation level lights 3, 4 and 5 will light up and the Remote Control will vibrate. All other lights will be off.



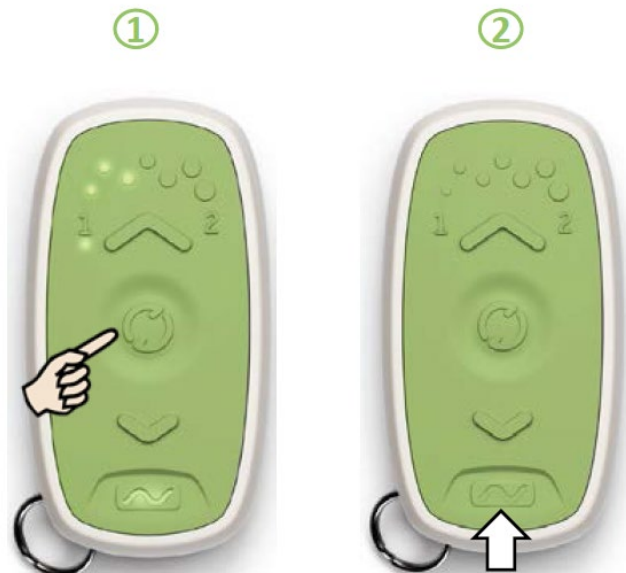
- ii. If the system is not ready for MRI scan, the System Error light will be solid red and the Remote Control will vibrate. All other lights will be off.



These lights will be seen for 15 seconds after which the PR will turn off.

Note: If you see a red flashing light, turn the Remote Control off and repeat steps A, B, and C.

11) Turn Off Your Remote Control



The Remote Control must be connected to the Stimulator (see *Connect to Your Stimulator*).

- 1 Press and release the “Connect” button.
- 2 Watch for all the lights on the Remote Control to turn off. This means the Remote Control has stopped communicating with the Stimulator and is off.

Note: The Remote Control will automatically turn off after 12 seconds of no activity by the user.

Troubleshooting

This section will help you solve issues with your Remote Control.

Contact your doctor if you need help.

Summary of issues addressed in this section:

- Remote Control will not communicate to Stimulator.
- System Error light is on.
- Cannot change stimulation level.
- Cannot change stimulation program.
- Damaged Remote Control.
- Discomfort or pain due to stimulation.

Troubleshooting scenarios

Issue	Presentation	Resolution
Remote Control will not connect to Stimulator	Remote Control lights scroll then turns off. Battery Status indicator is not on.	Move Remote Control closer to Stimulator and retry connection. For the PS only, try charging the Stimulator. If issue persists, contact your doctor.
	Remote Control does not respond when "Connect" button is pressed.	Contact your doctor for a new remote.
System Error indicator is visible	Red error light flashes for 12 seconds then turns off.	Disconnect Remote Control from Stimulator; Press "Up" and "Down" buttons to check if they are stuck; Reconnect to Stimulator. If you have 2 programs available, try switching to the other program. If issue persists, contact your doctor.
	Red error light is on all the time.	If you have a TS, check to make sure the Stimulator is connected to the cable coming from your back. Try to adjust stimulation on the Remote Control. If the red light is still on, call your doctor. If you have a PS, call your doctor.
Unable to adjust stimulation level	Remote Control connects to Stimulator but stimulation cannot be turned up or turned down.	Contact your doctor.
	Remote Control lights are scrolling or Remote Control lights are not on.	Reconnect and retry adjustment. Contact your doctor.
Unable to adjust stimulation program	The currently active program light flashes for several seconds when attempting to change the active program.	Only 1 program may be set for your Stimulator. Contact your doctor.
Damage to Remote Control	Remote Control appears physically damaged.	Stop use of the Remote Control. Contact your doctor to discuss replacement.
Discomfort or pain due to stimulation	Constant pain or discomfort in the groin or buttocks.	Turn down stimulation level. If issue persists, turn off stimulation and contact your doctor.

Remote Control will not turn off	Light(s) will not turn off.	Retry turning the Remote Control off (press and release "Connect" button). Contact your doctor for replacement.
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Additional Information



Replacement and Disposal

Replacement: If your Remote Control is lost or not working, contact your doctor to get a new Remote Control. The Remote Control battery is expected to last up to 5 years. When the battery runs out you should get a new Remote Control.

Disposal: Follow your local government rules to dispose of the Remote Control. If you no longer need a working device, return it to your doctor.

Warning: Do not throw the Remote Control in fire as the battery may explode.

Specifications

Item	Specification
Operating Conditions	
Temperature	5°C - 40°C (41°F – 104°F)
Pressure	70kPa – 106kPa
Humidity	15% - 95%
Storage & Shipment Conditions – Short Term (3 days or less)	
Temperature	-25°C - 70°C (-13°F – 158°F)
Pressure	57kPa – 106kPa
Humidity	15% - 95%
Storage & Shipment Conditions – Long Term (over 3 days)	
Temperature	20°C - 30°C (68°F – 86°F)
Pressure	70kPa – 106kPa
Humidity	30% - 85%
Power source	Lithium-ion battery (non-rechargeable)
Size	7.1 x 3.8 x 1.6 cm
Weight	60g
Expected Battery Life*	5 years
Communication	<p>Radiofrequency telemetry</p> <p>Model: 2301 IC: 20225-P FCC ID: 2AEEGP</p> <p>Quality of Wireless Service: This device operates in the 401-406 MHz frequency and the maximum effective radiated power is below the limit of 25 μW ERP/EIRP as specified in EU: EN ETSI 301 839 and USA: FCC 47 CFR Part 95; Subpart I. The Remote Control has to be within 1 meter from the Stimulator for successful communication.</p> <p>Wireless Security: The Remote Control is uniquely paired to a specific Stimulator. Additional mechanisms exist to ensure the integrity of radio data.</p>

* Expected battery life based on typical use scenario

Specifications

FCC Compliance

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 transmitter is authorized by rule under the Medical Device Radio Communication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radio communication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

IC Compliance

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of this device.

FCC and IC Compliance

This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Note: Changes and modifications to the Remote Control not authorized by Axonics could void FCC and IC certification and negate your authority to use the product.

Axonics Contact Information















Please contact your doctor if you have questions about your health or the Axonics SNM therapy.

Axonics Patient Support

Axonics, located in Irvine, CA (USA) can help answer questions or concerns about your Axonics SNM therapy. Please note that Axonics cannot discuss or comment on your medical condition.

- Call: +1-877-929-6642
- Hours: M-F, 6:00 am - 6:00 pm (Pacific Time)

Label Symbols

Symbol	Description
	Remote Control
	Remote Control User Manual (this document)
SN	Product Serial Number
	Manufacturer
REF	Product Model Number
	Manufacturing Date
	IEC 60601-1/EN60601-1, Type BF Equipment
	Non ionizing electromagnetic radiation
 2797	Conformité Européenne (European Conformity):2019. This symbol means that the device fully complies with AIMD Directive 90/385/EEC (Notified Body reviewed) and RED 2014/53/EU (self-certified)
IC	Industry Canada certification number
	Classified by CSA with respect to safety
	For USA audiences only Caution: US Federal law restricts this device for sale by or on the order of a physician
	Refer to instructions for use (Consult accompanying documents)
	Temperature limitation
	Humidity limitation
	Pressure limitation
	Do not use if package is damaged
EC REP	Authorized representative in the European community
IP57	Protection from the amount of dust that would interfere with the operation of the device. Protection against temporary immersion in water.

	This device complies with all applicable Australian Communications and Media Authority (ACMA) regulatory arrangements and electrical equipment safety requirements
FCC ID	US Federal Communications Commission device identification



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