

Axonics SNM System® Remote Control

Remote Control User Manual

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Axonics SNM System® Remote Control

EN

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 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.

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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.

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 FCC ID: 2AEEGP IC: 20225-P</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.









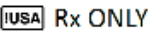






Axonics Patient Support

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: +1-949-396-6320
- Hours: M-F, 8:00 am - 5:00 pm (Pacific Time)

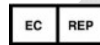
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Label Symbols

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
	Conformité Européenne (European Conformity): 2018. 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 applicable electrical equipment safety requirements.



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