

Axonics SNM System® Charging System

Charging System User Manual

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Charging System Manual

EN

User Manual

Model 1401, 9005, 9008

!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 prescribed to relieve the symptoms of urinary dysfunction. Patients are given a Charging System to charge their Stimulator battery.

This manual describes how to use the Charging System.

Axonics recommends you read this manual before using your Charging System.

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Manual overview

This manual describes how to use your Charging System. The manual includes:

- Overview of Charging System button, lights and functions
- Steps for using your Charging System
- Troubleshooting Charging System issues
- Additional information about the Charging System

If you have issues with your Charging System, ask your doctor for assistance.

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Specifications

Environmental Specifications – Charger, Dock, Power Supply, Carrier and Belt

Charger 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	93 mm x 24.4 mm
Weight	Approximately 175 g
Expected Battery Life*	5 years

Communication	<p>Radiofrequency telemetry</p> <p>Model: 1401, IC: 20225-D, FCC ID: 2AEEGD</p> <p>Quality of Wireless Service: This device operates on 402-405 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 Charger has to be within 1 meter from the implant for successful communication.</p> <p>Wireless Security: Any Charger can communicate with your Stimulator. Additional mechanisms exist to ensure the integrity of radio data.</p>
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* Expected battery life based on typical and worst case use scenario

Dock Specifications

Item	Specification
Power source	Powerbox EMX30
Input Power	100-240 VAC, 47-63 Hz, 15V, 2A
Size	19.5 mm x 93.0 mm
Weight	Approximately 150 g
Expected Usable Life*	5 years

Carrier and Belt Specifications

Item	Specification
Carrier	
Material	Polypropylene
Adhesive	Medical grade silicone adhesive
Belt	
Material – Band	Breathoprene
Material – Ring	Polypropylene

Length	Regular: 112 cm (44 inches) Extended: 152 cm (60 inches)
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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 licence-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 Charging System are not authorized by Axonics and could void FCC and IC certification and negate your authority to use the product.

Axonics Patient Support








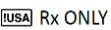













Please contact your doctor if you have questions about your health or the Axonics SNM therapy.

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)

Label Symbols

Symbol	Description
	Product Serial Number
	Product Lot Number
	Manufacturer
	Product Model Number
	Manufacturing Date
	IEC 60601-1/EN60601-1, Type BF Equipment
	Non ionizing electromagnetic radiation
	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
	Classified by CSA with respect to safety
	Follow instructions for use (operator manual)
	Do not use if package is damaged
	Authorized representative in the European community
IP24	Protection from the amount of dust and splashing water that would interfere with the operation of the device.
IP22	Protection from the amount of dust and vertically dripping water that would interfere with the operation of the device.
IC	Industry Canada certification number
	Hand wash only
	Do not tumble dry
	Conformité Européenne (European Conformity):2016. This symbol means that the device fully complies with AIMD Directive 90/385/EEC (Notified Body reviewed) and RED 2014/53/EU (self-certified)
	Power on/off button
	This device complies with all applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements and applicable electrical equipment safety.



Axonics Modulation Technologies, Inc.
26 Technology Drive
Irvine, CA 92618 (USA)
www.axonicsmodulation.com
Tel. +1-949-396-6320
Fax +1-949-396-6321



HealthLink Europe Services BV
De Tweeling 20-22
5215 MC 's - Hertogenbosch
The Netherlands



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