

Axonics SNM System® Charging System

Charging System User Manual
Models 1401, 9005, and 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 provided to relieve the symptoms of fecal 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.

This manual describes how to use your Charging System.

The manual includes:

- Overview of Charging System buttons, 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.

Refer to Your Patient Therapy Guide

Refer to the Patient Therapy Guide that was provided by your doctor for additional information about your Axonics SNM System, including:

- Indications for Use
- Contraindications
- System Warnings
- System Precautions
- Patient Activity Precautions

Charging System Components



Charger
Charges the Stimulator



Charge Belt
Holds the Charger over the Stimulator



Dock
Stores and charges the Charger




Carrier
Holds the Charger over the Stimulator



Power Supply
Connects the Dock to a power source

Precautions

- If you have other active implants (such as a pacemaker), the Charger may cause issues with such implant(s). Contact your doctor if you experience issues or have any questions.
- Some equipment may generate signals, called Electromagnetic Interference or EMI, that block the Charger's signals to the Stimulator. If you have issues using your Charger, move away from such sources, including computer monitors, cellular telephones, and other electronic equipment.
- Do not use the Charger over an open wound. The Charger, carrier, and charge belt are not sterile. Contact with an open wound could cause an infection.
- Do not use the power supply near water. Use in these conditions could result in shock or serious injury.
- If you experience skin irritation, redness or heating at the site of charging, do not continue charging.
- Do not sit or lie on the Charger during charging as this may apply unwanted pressure at the charge site. Consult your doctor if you have irritation or discomfort during charging.

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

DO

- ✓ Develop a habit for charging that fits your schedule (e.g., every Sunday while watching your favorite TV show). You do not need to wait for the Stimulator battery to be low to charge.
- ✓ Store your Charger on the Dock between uses. Keep the Dock plugged in so the Charger will be ready when you want to charge.
- ✓ Clean your Charger and Dock with a damp, soft cloth as needed.
- ✓ Only use the power supply provided with the Dock.

DO NOT

- ✗ Do not let your Stimulator stay at a low battery level for long periods of time (e.g., weeks).
- ✗ Do not drop the Charger in liquid or clean it with harsh cleaners.
- ✗ Do not use the Charger near flammable or explosive gases.
- ✗ Do not place the Charger over clothes when charging. It will take longer to charge.
- ✗ Do not use the Charger under a blanket or heavy clothing. This may cause the charger to heat up.

The Charging System allows you to easily and comfortably recharge your Stimulator battery. When the Charger is placed on the skin over the implanted Stimulator, the Charger will charge the Stimulator battery. Charging a low Stimulator battery will take 1 to 4 hours depending on the depth of the Stimulator and how the Charger is placed over the Stimulator. A Carrier or a Belt can be used to hold the Charger in place while charging. This section shows you the Charger's buttons, lights, and sounds. It also shows you the ideal placement of your Charger over your Stimulator.

Note: If you notice a change in device performance or when you reach 15 years of implantation, please consult your physician to discuss your options.

Charger Buttons and Lights

The Charger has a button and two lights that help you use the Charger.

Power Button	Turns on or off the Charger
Power Light	Shows if the Charger has enough battery to charge your Stimulator
Error Light	Shows if the Charger has an issue



1. The power button can be pressed to turn the Charger on and off. When ON, the power light will come on.
2. The power light will be
 - Green: this means you can fully charge the Stimulator.
 - Solid Orange: this means you may not be able to fully charge the Stimulator. If you need to recharge the Stimulator, you should charge your Charger first.
 - Flashing Orange: this means you need to charge the Charger.
 - Red: this means there is an error. Turn the Charger off then back on. If the red light is still on, call your doctor and ask for a new Charger.

Charger Sounds and Vibrations

What you hear or feel:	What it means:
One long tone	Charger is over the Stimulator and charging has started.
3 beeps + vibration (repeats)	Charging has been interrupted and is not complete.
Three rising tones	Stimulator battery is fully charged.



To set up your Charging System, you need to charge your Charger on the Dock.

- Plug the power supply into a wall outlet and then into your Dock.
- Place the Charger on the Dock. The power light on the Charger will flash green to indicate that the Charger is charging. It can take up to 6 hours to fully charge the Charger. The power light will be solid green when the Charger is fully charged.
- Leaving your Charger on the Dock continuously will not harm the Charger.

Where to Place the Charger

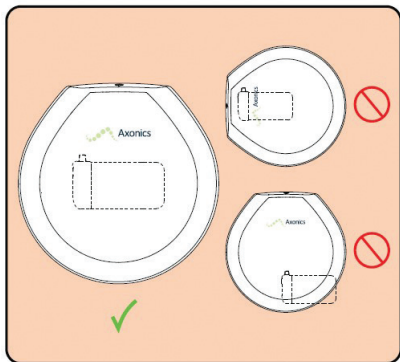
For best charging, place the Charger over your implanted Stimulator.

You should place your Charger with the button facing up if your Stimulator is placed horizontally (as shown to the right). Your doctor will inform you if your Stimulator is placed in a different way.

The white outline on the bottom of the Charger represents how the Charger should be placed over the Stimulator.

Good placement will ensure fast charging.

The following section will provide the detailed steps for placing the Charger over your Stimulator.



The Axonics Charging System allows you to choose how you want to charge:

- Choose how often you want to charge. Charging more often means shorter charge times.
- Choose from 2 options for holding your Charger in place during charging. You can use the Carrier or the Charge Belt
- Choose what you want to do while you charge. The Axonics Charging System lets you do basic household activities while charging.

The following pages show the steps to charge your Stimulator.

The steps include:

- Turn the Charger on
- Choose how to charge
- Place the Charger over the Stimulator
- Complete Charging

1) Turn the Charger On

① Pick up the Charger from the Dock.



② The Charger power light should be on. If not, press the power button to turn on the Charger.



Note: See section *Charger Button and Lights* for information on the states of the charger power button.

Note: The Charger will turn itself off if it does not detect the Stimulator within 5 minutes

2) Choose How to Charge

The Axonics Charging System allows you to choose how you want to hold your Charger on your skin:



A) Carrier

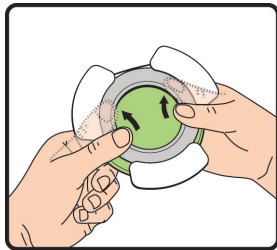
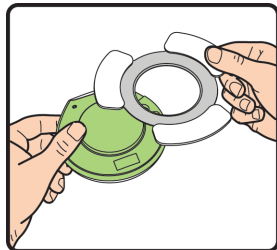


B) Belt

2A) Attach the Carrier

- 1 Press the carrier onto the bottom of the Charger. The adhesive pads on the carrier should face away from the Charger. Start by pressing with both fingers at the bottom of the inner circle of the carrier. Slide your fingers in opposite directions to the top of the carrier.
- 2 Peel back the protective liner to expose the adhesive on the Carrier.
- 3 The Charger is ready to be put on your body.

Note: Use a new carrier every time you charge to make sure the Charger stays in place.



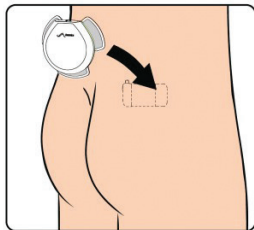
- ① Press the green ring of the Belt onto the bottom of the Charger. Start by pressing with both fingers at the bottom of the inner circle of the ring. Slide your fingers in opposite directions to the top of the ring.
- ② The Charger is ready to be put on your body



Note: The Charger should be placed on the side of the Belt where green stitching is visible around the green ring.

3) Place the Charger Over the Stimulator

- 1 Hold the Charger over your Stimulator. Continue to slowly move the Charger in that area until you hear one long tone. This indicates the Charger is properly aligned and is charging the Stimulator. The power light on the Charger will flash green when the Charger is charging the Stimulator.

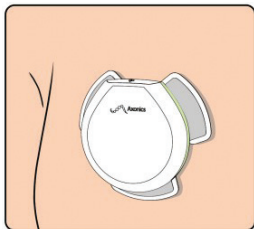


Note: If your Stimulator battery has been inactive for an extended period (several weeks or longer), the Charger may need to be placed over the Stimulator for several minutes before the long tone is heard.

- 2 Fix the Charger in place.
 - Press the adhesive areas of the Carrier onto your skin, or
 - Tighten the Belt around your waist.

Note: The Carrier can be removed and placed on the skin again if the location of the Carrier needs to be adjusted.

Note: The Charge Belt should be worn directly against the body. Longer charge times will be needed if worn over clothing.



- ① You will hear a set of rising tones repeat 3 times when charging is complete. The Charger indicator light will turn off. This will take 1 to 4 hours for a low battery, depending on the implant depth of your Stimulator and how well the Charger is aligned over the Stimulator.

Note: If you hear 3 beeps and feel the Charger vibrate, charging was interrupted before completion. See Troubleshooting for potential causes and resolutions.

Note: It is safe to interrupt charging if you need. Partial charging is acceptable if you do not have time to fully charge the Stimulator.

- ② Remove the Charger from your skin by peeling off the Carrier or unstrapping the Belt. Take the Charger off the Carrier or Belt.
- ③ Dispose of the Carrier or store the Belt. Place the Charger on the Dock.

Note: The Charger should provide 5 or more years of service. With repeated charging, the Charger battery may lose capacity or charge the Stimulator more slowly. Notify your doctor if you experience a significant change in the performance of your Charger. For example, notify your doctor if your Charger takes over 6 hours to fully charge on the Dock, or if a fully charged Charger cannot completely charge your Stimulator battery.

This section will help you solve issues with your Charging System.

Contact your doctor if you need help.

Summary of issues addressed in this section:

- Charger is not charging the Stimulator
- Dock is not charging the Charger
- Damaged Charging System
- Stimulator has to be charged more often
- Error light is on

Issue	Presentation	Resolution
Charger is not charging the Stimulator	The power light on the Charger is green. Nothing happens when you place the Charger over the Stimulator.	Retry placing the Charger, making sure the Charger is placed the correct way over your Stimulator (see “Where to Place the Charger”). If you still cannot charge, contact your doctor.
	The power light on the Charger is blank and does not turn on when you press the power button.	Place the Charger on the Dock to charge the Charger. Retry charging when the Charger light is solid green.
	Charging stopped. Three beeps are heard and the Charger vibrated.	Check the Charger power level. If “green”, place the Charger over the Stimulator again. If charging does not start, contact your doctor.

Troubleshooting Scenarios

Issue	Presentation	Resolution
Dock will not charge the Charger	Charger is placed in Dock and the power light does not come on.	Check to make sure the Dock is plugged in to an outlet using the power supply. Next, pick up and put the Charger back in the Dock. Make sure it is lined up with the Dock correctly. If you still cannot charge the Charger, contact your doctor.
	Charger is placed in Dock and red error light comes on.	There is an error in charging the Charger. Turn the Charger off then back on. If the red light is still on, contact your doctor.
Damage to Charger	Charger has visible damage.	Do not use your charger. Contact your doctor to discuss replacement.

Issue	Presentation	Resolution
Stimulator has to be charged more often	Over time, the Stimulator battery provides 50% less stimulation time between charges than it did after initial programming.	If stimulation settings were changed recently, the change in charging frequency is expected. If stimulation settings were not changed, contact your doctor to discuss the change in your Stimulator battery life.
Error light is on	The Charger shows a red light when it is turned on.	There is an error in the Charger. Turn the Charger off then back on. If the red light is still on, contact your doctor.



Replacement: If part of your Charging System is lost or not working, contact your doctor. If you charge using the Carrier, let your doctor know when you have only a few Carriers left so more can be sent to you.

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

Care Instructions

Charger, Dock, and Power Supply: Clean with a damp, soft cloth as needed. Do not use harsh cleaners or abrasive materials to clean these items.

Carrier: Throw away the Carrier after each use. Do not reuse. Reuse could result in the Carrier and Charger falling off, potentially causing damage to the Charger.

Belt: Wash the belt by hand in cold water. Air dry. Do not machine wash or tumble dry as this may damage the belt.

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

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%

Specifications

Charger Specifications

Item	Specification
Power source	Lithium-ion battery (rechargeable)
Size	93 mm x 24.4 mm
Weight	Approximately 175 g
Expected Life*	5 years
Communication	<p>Radiofrequency telemetry Model: 1401, IC: 20225-D, FCC ID: 2AEEGD</p> <p>Quality of Wireless Service: This device operates in the 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>

*Expected 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)

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.








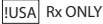




Please contact your doctor if you have questions about your health or the Axonics SNM therapy.










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
	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)
IC	Industry Canada certification number
	Classified by CSA with respect to safety
	Follow instructions for use (operator manual)
	Temperature limitation

	Humidity limitation
	Pressure limitation
	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.
	Hand wash only
	Do not tumble dry
	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)
	Power on/off button
	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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