Sacral Neuromodulation System

Trial Stimulator Manual

Model 1601

Rx only

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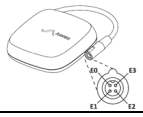
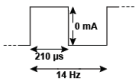
LABEL SYMBOLS

This section explains the symbols found on the product and packaging.

Symbol	Description
	Axonics Trial Stimulator
	Trial Stimulator default waveform with 14 Hz frequency, 0 mA amplitude and 210 µs pulse width
SN	Product Serial Number
	Manufacturer
REF	Product Model Number
	Manufacturing Date
	Non ionizing electromagnetic radiation
CE 2797	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (Notified Body reviewed) and RED 2014/53/EU (self-certified)
	Refer to instructions for use (Consult accompanying documents)
	Temperature limitation
	Humidity limitation
	Pressure limitation
	Do not reuse
IP24	Protection from the amount of dust and splashing water that would interfere with the operation of the device.
	Do not use if package is damaged
EC REP	Authorized representative in the European community
!USA Rx ONLY	For USA audiences only Caution: U.S. Federal law restricts this device for sale by or on the order of a physician
⚠	Warning / Caution
IC	Industry Canada certification number

Symbol	Description
	Product cannot be discarded in trash. See instructions on disposal of the product.
	IEC 60601-1/EN60601-1, Type BF Equipment
	Classified by CSA with respect to safety
	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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INTRODUCTION

This manual provides information about the Axonics Sacral Neuromodulation (SNM) System Trial Stimulator (Model 1601), which is a part of the Axonics SNM Trial System. The Trial Stimulator (TS) is used to provide temporary electrical stimulation to the S3 or S4 sacral nerve. There are two types of trials for which the TS is used. For a basic trial, the TS connects to a Peripheral Nerve Evaluation (PNE) lead to deliver temporary electrical stimulation. For an advanced trial, the TS connects to a tined lead to deliver temporary electrical stimulation.

Purpose of the trial system

The Axonics SNM Trial System is used for a test period to evaluate if a subject should be treated with the Axonics SNM System.

Indications, Warnings, and Precautions

Refer to Information for Prescribers booklet for warnings, precautions, adverse events, patient selection and clinical summary.

CONTRAINDICATIONS

The Axonics SNM Trial System is contraindicated for patients who are unable to operate the Axonics SNM Trial System.

DEVICE DESCRIPTION

The Axonics TS (**Figure 1**) is part of the Axonics SNM System. The TS is a programmable device that is worn on the outside of the body. The TS delivers electrical stimulation to the sacral nerve via connections to either a permanent or temporary lead.

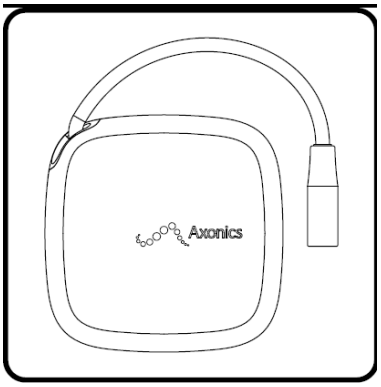

Figure 1: Axonics Trial Stimulator (TS).

Package contents

The **TS** package contains the following:

- TS
- Belt
- TS Manual (this document)

The contents of the package are NOT STERILE. The contents of the package are intended for single use only.

Storage and Usage Environment

Component packaging –Do not use the component if any of the following have occurred:

- The storage package has been damaged, pierced, or altered. In this case, sterility cannot be guaranteed and infection may occur.
- The component itself shows any signs of damage. The component may not function properly.
- The use-by date has expired. In this case, component performance cannot be guaranteed.

Usage environment:

The following lists the appropriate temperature, humidity, and pressure usage conditions for use of the TS:

- Temperature: 5 °C to 40 °C
- Humidity: 15% to 95%
- Pressure: 106 kPa to 70 kPa

Shipping and Storage environment:

The following lists the appropriate temperature, humidity, and pressure conditions for shipping and storing the TS:

- Temperature (short term: 3 days): -25 ^{o}C to 70 ^{o}C
- Temperature (long term): 20 ^{o}C to 30 ^{o}C
- Humidity (short term: 3 days): 15% to 95%
- Humidity (long term): 30% to 85%
- Pressure (short term: 3 days): 57 kPa to 106 kPa
- Pressure (long term): 70 kPa to 106 kPa

If the TS is exposed to extreme temperatures, it may be permanently damaged and should not be used, even if it has returned to a temperature that is within the specified operating range

Sterilization

The contents of this package are not sterile. This device is for single use only and should not be sterilized.

SPECIFICATIONS

Table 1 shows the TS physical specifications. For detailed descriptions and specifications for other components and accessories, refer to the product literature packaged with those devices.

Table 1. TS specifications

Physical Attributes	Height	45 mm
	Length	45 mm
	Thickness	12.5 mm
	Weight	20 grams
	Volume	25 cc
	IP Rating	IP24
	Case material	Polycarbonate/ABS
Stimulation Characteristics	Frequency	2-130 Hz
	Pulse Width	60-450 µs
	Amplitude	0-12.5 mA
	Minimum Amplitude Step Size	0.05 mA
	Ramping	0-30 s
	# of Programs	2
	Mode of Operation	Current-Controlled
Power Source	Battery	Lithium-ion (non-rechargeable)
	Size	27 mm x 25 mm x 5.2 mm
	Weight	4.5 grams
	Expected Battery life*	Nominal: 60 days
		Worst case: 45 days

Note: All dimensions are approximate.

*Battery life estimated at nominal and worst case stimulation settings.

Nominal: 1 mA, 14 Hz, 210 µs, continuous stimulation, impedance = 1,600 Ohms

Worst case: 4 mA, 14Hz, 210 µs, continuous stimulation, impedance = 1,600 Ohms

The TS may be wiped with a cloth lightly dampened with sterile water or isopropyl alcohol.

Activating the Trial Stimulator

The following section describes the process for activating the TS for delivering stimulation. This should be performed when an Axonics lead has already been implanted and a Clinician Programmer is available.

1. Press the button on the back of the TS (**Figure 2).** The green light next to the button will start to flash. The green light will flash for 90 seconds.
   a. If you connect a CP to the TS before 90 seconds expires, the TS will remain active and can be programmed. After programming is complete and the TS is disconnected from the CP, the green light will not be on. However, the TS will remain active.
   b. If a CP does not connect to the TS, the TS will return to hibernate mode. It can be turned on again by pressing the button on the back of the TS.

Notes:

- If a red light flashes there is an error with the TS. Connect the CP for detailed error information. Refer to the CP manual for detailed troubleshooting information.
- If there is no flashing light when you press the button, try pressing the button again. Confirm you are pressing the button as shown in **Figure 2**. If there is no light after multiple attempts at pressing the button, do not use this TS. Activate a new TS. If the issue persists with a new TS, contact Axonics.

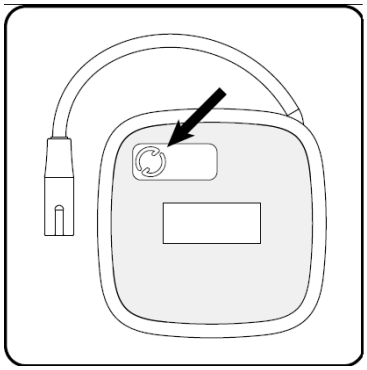

Figure 2: Activate the TS by pressing the button on the back of the stimulator

Connecting the Trial Stimulator to the Tined Lead or PNE Lead

The following section describes the process for connecting the TS to the cables used to connect to the tined lead or the PNE lead. This should be performed when an Axonics lead has already been implanted and the appropriate cables are available. For a trial using the PNE lead, the Basic Trial Cable should be connected to the TS. For a trial using the tined lead, a Percutaneous Extension (PE) cable should be connected to the TS.

1. Align the raised base on the TS connector with the raised bar on the Basic Trial Cable or the grey colored bar on the PE **(Figure 3)**.
2. Press the connectors together to connect the Basic Trial Cable or PE to the extension of the TS (**Figure** 3**).**
3. Use the CP to check the TS impedances to verify the TS and cable is connected correctly.

Notes:

- There will not be any gap between the connectors when fully inserted.
- Use the CP to check the electrode impedances to confirm that the cables are connected.

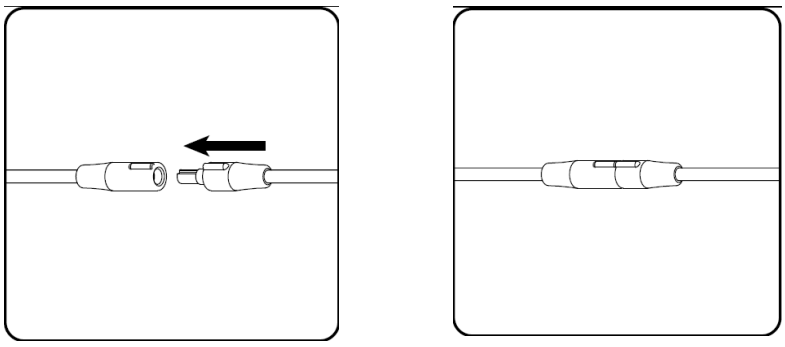

Figure 3: Align the raised grey bar on the TS with the raised bar on the Basic Trial Cable (shown) or the grey line on the PE (not shown). Plug the Basic Trial Cable or PE fully into the extension of the TS.

Inserting TS into the Belt

The following section describes the placing the TS into the provided belt. This procedure should be performed when an Axonics lead has already been implanted.

1. Fit the belt around the patient's waist. Fasten and adjust the belt width as necessary **(Figure 4)**. The belt should be worn such that it is comfortable for the patient. The pouch for the TS is located above the patient's hip.
2. Slide the TS into the pouch on the belt. Position the TS extension looped around the TS (**Figure 5).** The TS is fully inserted when it passes the narrow point of the pouch.
3. Coil any excess cable and place it in the pouch.

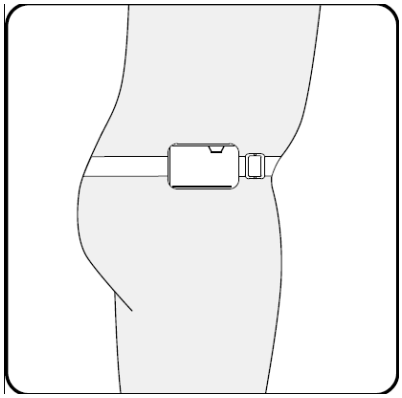

Figure 4: Fasten the belt on the patient's body and adjust the width as necessary

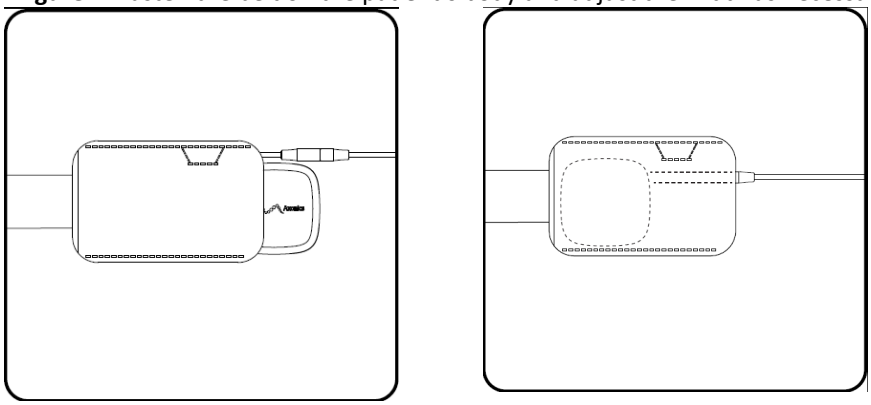

Figure 5: Insert the TS into the pouch on the belt.

REPLACEMENT AND DISPOSAL

Replacement: If the TS is lost, visibly damaged, or not working, the patient should contact their physician to get a new TS.

Disposal: At the end of a trial stim period, the patient should return the TS to their physician. If return is not possible, the patient should follow local government rules to dispose of the TS.

Warning: Do not throw the TS in a fire as the battery may explode.

WIRELESS COMMUNICATION

Model: 1601
IC: 20225-E
FCC ID: 2AEEGE

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 TS are not authorized by Axonics could void FCC and IC certification and negate the user's authority to use the product.

Quality of Wireless Service: This device operates in the 401-402 MHz and 405-406 MHz frequency and the maximum effective radiated power of the TS communication is below the limit of 25 µW ERP/ERIP as specified in EU: EN ETSI 302-537 and USA: FCC 47 CFR Part 95; Subpart I. The Remote Control or Clinician Programmer have to be within 1 meter from the TS for successful communication.

Wireless Security: The TS can only communicate with a single Remote Control that is paired to it using the Clinician Programmer. Any Axonics Clinician Programmer can communicate with a TS. Additional mechanisms exist to ensure the integrity of radio data.

CUSTOMER SERVICE

For questions regarding the Axonics SNM System, call our Customer Support Center toll-free at +1-877-929-6642.

Additional information and product manuals can be found at our website: www.axonics.com

Axonics

EC REP

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