Axonics

Sacral Neuromodulation System
Trial Stimulator Manual
Model 1601
Rx only

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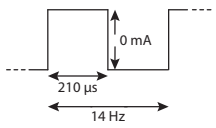
LABEL SYMBOLS

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

Symbol	Description	Symbol	Description
	Axonics Trial Stimulator		Do not reuse
	Trial Stimulator default waveform with 14 Hz frequency, 0 mA amplitude and 210 µs pulse width	IP24	Protection from the amount of dust and splashing water that would interfere with the operation of the device.
SN	Product Serial Number		Do not use if package is damaged
	Manufacturer	EC REP	Authorized representative in the European community
REF	Product Model Number	!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
	Manufacturing Date		Warning / Caution
	Non-ionizing electromagnetic radiation	IC	Industry Canada certification number

Symbol	Description	Symbol	Description
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)		Product cannot be discarded in trash. See instructions on disposal of the product.
	Refer to instructions for use (Consult accompanying documents)		IEC 60601-1/EN60601-1, Type BF Equipment
	Temperature limitation		Classified by CSA with respect to safety
	Humidity limitation		This device complies with all Australian Communications and Media Authority (ACMA) regulatory arrangements and electrical equipment safety requirements
	Pressure limitation	**FCC ID**	US Federal Communications Commission device identification

TABLE OF CONTENTS

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.

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.

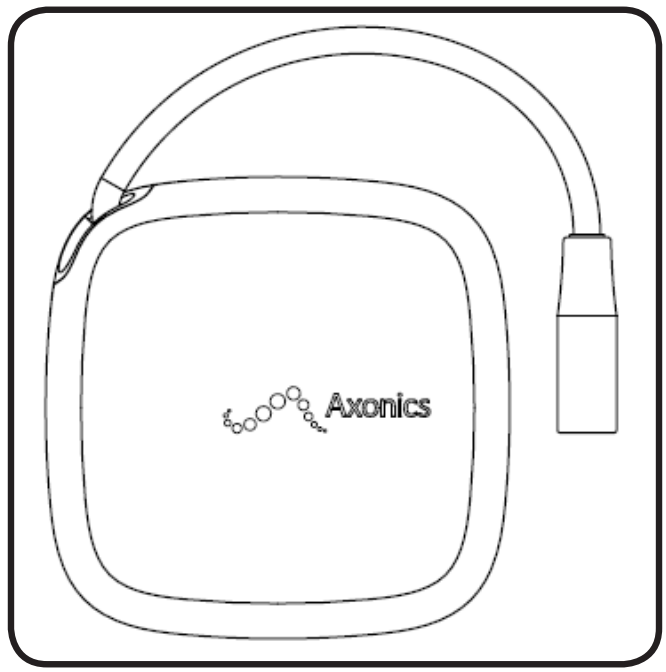


Figure 1: Axonics Trial Stimulator (TS).

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.

CONTRAINDICATIONS

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

WARNINGS

Prohibited Medical Procedure

Diathermy

Shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (collectively described as diathermy) CANNOT be performed on patients implanted with the Axonics SNM System. Diathermy can transmit energy through the implanted system, potentially causing tissue damage at the location of the implanted electrodes, resulting in severe injury.

Magnetic Resonance Imaging (MRI)

An MRI should not be conducted on an individual undergoing a trial period of SNM therapy utilizing the external TS.

Other Medical Procedures

The following additional medical procedures that may adversely affect the patient or Axonics SNM System should be avoided during the trial period:

- Lithotripsy
- Monopolar electro surgery
- Microwave and Radio-frequency (RF) ablation
- Radiation therapy
- Ultrasound or scanning equipment

Electromagnetic interference (EMI)

EMI is energy that can interfere with the function of the Axonics SNM System. This energy can be generated by equipment found at home, work, or in public. The Axonics SNM System includes features that provide protection from EMI. Most electrical devices encountered in a normal day are unlikely to affect the operation of the TS. While everyday electrical devices are unlikely to affect the TS, there are strong sources of EMI that may temporarily affect the operation of your stimulator, including anti-theft detectors found in stores used to detect stolen merchandise. If patients encounter any of these electrical devices, they should walk as far away from the sides of the anti-theft detector when passing through.

At the Airport, Courthouses, etc.

If patients encounter walkthrough metal detectors or security archways they should walk-through at a normal pace. These detectors should not affect the Stimulator. Hand-held security wands should be passed over the Stimulator quickly and should not affect the stimulator. Full-body security scanners (millimeter wave scanners) are used by the Transportation Security Administration (TSA) and are considered safe in patients that have a stimulator.

Additionally, patients should minimize their exposure by not lingering in the immediate area of the security systems. Some anti-theft detectors may not be visible. If patients feel poorly, they should walk away from the area and anti-theft detectors and security scanners.

Case Damage

The Trial Stimulator contains battery chemicals that could cause severe burns if the case were ruptured or pierced.

Effects on other implanted devices

The effect of the Axonics SNM System on the operation of other implanted devices is not known. This includes devices such as cardiac devices, other Neurostimulators, and implantable drug pumps. In particular, if the Axonics device is on the body near one of these devices, they may have sensing problems and/or inappropriate device responses. Clinicians involved with both devices should investigate potential interference issues before surgery. The programming of the devices may need to be optimized to provide maximum benefit from both devices.

Trial Stimulator interaction with implanted cardiac devices

When a patient needs both an Axonics SNM System and an implanted cardiac device, interactions between the two devices should be discussed by the patients' physicians before surgery. Such devices may include pacemakers or defibrillators. The physicians involved may include cardiologists, electrophysiologists, urologists, and urogynecologist. To reduce potential interference, the TS

should be worn on opposite side of the body. It should also be worn as far away as practical from an implanted cardiac device.

The stimulation pulses produced by the Axonics SNM System may interact with cardiac devices that sense cardiac activity. This may lead to inappropriate behavior of the cardiac device.

Unauthorized modifications to the Trial Stimulator

No modification of any component of the Axonics SNM System is allowed. Modification may result in more risks and hazards.

PRECAUTIONS

Clinician programming

Parameter adjustment – The steps below should be taken to prevent sudden stimulation changes that lead to an uncomfortable jolting or shocking feeling:

- Stimulation parameters should be changed in small increments
- The stimulation amplitude should be allowed to ramp to full amplitude slowly
- Before disconnecting the stimulation cable or turning the simulation on or off, the stimulation amplitude should be decreased to 0.0 mA

Sensitivity to stimulation – Patients who are very sensitive to stimulation, may be able to sense the telemetry signals associated with reprogramming.

Programmer interaction with a cochlear implant – Patients with cochlear implants should keep the external portion of their cochlear implant as far from the Clinician Programmer (CP) or Remote Control as possible. This will help minimize unintended audible clicks or other sounds.

Programmer interaction with flammable atmospheres – The CP is not intended to be used in the presence of a flammable gas. The consequences of using the CP in such an environment is not known.

Programmer interaction with other active implanted devices – When a patient has a TS and another active implanted device the Radio Frequency (RF) signal used to program any of these devices may reset or reprogram the other devices. These devices include a pacemaker, defibrillator, or another neurostimulator.

Whenever the settings for these devices are changed, a clinician familiar with each device should check the program settings of each device before the patient is released (or as soon as possible). Patients should contact their physician immediately if they experience symptoms that are likely to be related to the devices or their medical condition.

Telemetry signal disruption from EMI – The TS should not be programmed near equipment that may generate EMI. The equipment may interfere with the CP or Remote Control's ability to communicate with the TS. If EMI is suspected to be interrupting programming, the CP or Remote Control and the TS should be moved away from the likely source of EMI.

Interference during medical imaging – The TS should be turned off, disconnected, and removed prior to medical imaging (x-ray, CT). The components of the trial system may distort images or impede the ability to see certain internal structures when performing imaging tests.

Electromagnetic interference (EMI)

Patients may encounter additional equipment that generates EMI. This equipment is unlikely to affect the Axonics SNM System if the patients follows these guidelines:

Bone growth stimulators – The external coils of bone growth stimulators should be kept at least 45 cm (18 in) away from the Axonics SNM System. Do not use a bone growth stimulator if it is not working as intended.

Dental drills and ultrasonic probes – The drill or probe should be kept 15 cm (6 in) away from the Neurostimulator. The Neurostimulator should be turned off.

Electrolysis – The electrolysis wand should be kept at least 15 cm (6 in) away from the Neurostimulator. The Neurostimulator should be turned off.

Electromagnetic field devices – The following equipment or environments should be avoided or patients should exercise caution around:

- Antenna of citizens band (CB) radio or ham radio
- Electric arc welding equipment
- Electric induction heaters such as those used in industry to bend plastic
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (generally safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets or other equipment that generates strong magnetic fields

- Microwave communication transmitters (generally safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (generally safe if outside the fenced area)

Laser procedures – The laser should not be directed at the Neurostimulator. The Neurostimulator should be turned off.

Psychotherapeutic procedures – Equipment used for psychotherapeutic procedures may induce electrical currents which may cause heating at the lead electrodes and could result in tissue damage. Equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) during psychotherapeutic procedures have not been established as safe to operate in a patient with a Neurostimulator. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Radiation therapy – Neurostimulator operation may be affected by high-radiation exposure. Sources of high-radiation should not be directed at the Neurostimulator. Neurostimulator damage due to high-radiation exposure may not be immediately evident, and exposure should be limited using appropriate measures, including shielding and adjusting the beam angle to avoid exposure to the Neurostimulator.

Transcutaneous electrical nerve stimulation (TENS) – TENS electrodes should not be placed in locations where the TENS current passes over any component of the Axonics SNM System. Discontinue using TENS if it starts affecting the performance of the Axonics SNM System.

If a patient thinks that an EMI generating equipment or environment is affecting the function of their Axonics SNM System, the patient should:

1. Move away from the equipment or object.
2. Turn off the equipment or object. (if possible)
3. Use the patient Remote Control to adjust stimulation if necessary and to confirm the system is functioning appropriately.

If the patient is unable to eliminate the interference or believes the interference has altered the effectiveness of their therapy, the patient should contact their clinician.

Sources of strong EMI can result in the following:

- **Serious patient injury**, resulting from heating of the Trial Stimulator and/or leads. This may damage the surrounding tissue.

- **System damage**, which may require surgical replacement due to change in symptom control.
- **Operational changes to the Trial Stimulator**, causing it to turn on or off or to reset the settings, resulting in loss of stimulation or return of symptoms. Re-programming by the clinician may be needed.
- **Unexpected changes in stimulation** which may be experienced as a jolting or shocking sensation. While the sensation may be uncomfortable, the device would not be damaged nor would it cause direct injury to the patient. In rare cases, the change in stimulation may cause the patient to fall and be injured.

Patient activities

Activities requiring twisting or stretching – Patients should avoid activities that may strain the connections between the implanted components of the Axonics SNM System and the TS. For example, movements that include bending, twisting, bouncing, or stretching may pull on the connection between the TS and the lead(s). This may potentially cause movement of the lead or discomfort and may result in an unsuccessful trial period due to lack of adequate stimulation of the sacral nerve. Clinicians should ask their patients about the activities in which they participate and inform them of the need for restricting and minimizing activities during the trial stimulation period.

Component manipulation by patient (Twiddler's syndrome) – Clinicians should advise patients to refrain from manipulating the components of the Axonics SNM System. Manipulation may cause device damage, lead migration, skin erosion, or uncomfortable stimulation.

Scuba diving or hyperbaric chambers – Patients should not scuba dive or use a hyperbaric chamber during their trial stimulation period.

Skydiving, skiing, or hiking in the mountains – Patients should not sky-dive, ski or go hiking during the trial stimulation period.

Unexpected changes in stimulation – EMI, postural changes, and other activities may cause a perceived increase in stimulation. Some patients may find this uncomfortable (a jolting or shocking feeling). Before engaging in activities that receiving a jolt would be unsafe for the patient or those around them, patients should lower the stimulation amplitude to the lowest setting and turn off the TS. Patients should also discuss these activities with their clinician.

Showering and bathing during the trial stimulation period – Patients should not expose the TS to water during the trial stimulation period. They may take sponge baths during the trial stimulation period. However, patients will have to remove the

TS and keep their lead implant site and their surgical dressings dry. Patients should be advised on avoiding showers and baths by their physician.

Patient programming and Remote Control

Patient access to Remote Control – Patients should carry their Remote Control with them at all times. This will allow them to adjust the stimulation amplitude and/or turn on/off the TS.

Remote Control may affect other implanted devices – Patients should avoid placing the Remote Control over or near other active implanted medical devices (for example: pacemaker, defibrillator and other neurostimulators).

Remote Control handling – Patients should avoid

- Immersing the Remote Control in liquid as this could damage the device.
- Dropping the device or mishandling it in any way that may damage it.

Patients should clean the device with damp soft cloth.

Remote Control use – Patients should avoid operating the Remote Control when near flammable or explosive gases.

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 °C to 70 °C

- Temperature (long term): 20 °C to 30 °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.

System implant

Compatibility – For proper therapy, use only Axonics SNM components. The use of non-Axonics components with the Axonics SNM System may result in damage to Axonics components, loss of stimulation, or patient injury.

Use of non-Axonics components will void Axonics warranty coverage.

Component failures – The components of the Axonics SNM System may fail at any time. Failures such as electrical shorts, open circuits, and insulation breaches are unpredictable. Also, the TS battery will eventually run out and can provide no more than 60 days of stimulation.

Component handling – Handle the components of the Axonics SNM System with extreme care. They may be damaged by excessive force or sharp instruments. Such damage can lead to intermittent stimulation or loss of stimulation altogether and may require surgery to replace.

POTENTIAL ADVERSE EVENTS SUMMARY

Implantation and use of the Axonics SNM System incurs risk beyond those normally associated with surgery. Some risks may necessitate surgical intervention. The risks during the trial stimulation period include, but are not limited to the following:

- Adverse change in voiding function (bladder)
- Allergic or immune system response to the implanted materials that could result in device rejections
- Change in sensation or magnitude of stimulation which has been described as uncomfortable (jolting or shocking) by some patients

- Device fracture/failure
- Device migration
- Electrical shock
- Infection
- Pain or irritation at Stimulator and/or lead site
- Seroma, hemorrhage, and/or hematoma
- Suspected lead migration
- Suspected nerve injury (including numbness)
- Suspected technical device malfunction
- Transient electric shock or tingling
- Unintended nerve activation
- Heating or burn at Stimulator site
- Lack of effectiveness
- Reoperation/Revision
- Undesirable change in pelvic function

INDIVIDUALIZATION OF TREATMENT

Fully inform the patient about the risks and benefits of SNM therapy. This includes risks of the surgical procedure, follow-up responsibilities, and self-care requirements. In order to achieve optimal benefits from the therapy, the Axonics SNM System requires a long-term commitment to post-surgical management.

Patient selection – Select the patients carefully to ensure they meet the following criteria:

- The patient is an appropriate surgical candidate. Give special consideration for the lead length, implant depth, and ability to successfully implant the lead and route the lead to the Neurostimulator
- The patient can properly operate the Axonics SNM System. This includes the ability to use the Remote Control, to detect alignment of the Charger, and to understand when charging is complete
- The patient does not have a history of sensitivity to stimulation

PATIENT COUNSELING INFORMATION

Clinicians should provide the following:

- Information about the components of the Axonics SNM System
- Instructions for using the Remote Control

Also, the clinician should provide each patient with a copy of the Axonics SNM System Patient Therapy Guide. The clinician should review the following sections with him/her:

- Getting the Axonics SNM System
- Living with the Axonics SNM System

Clinicians should also instruct their patients as follows:

- Patients should tell their healthcare professionals, including their primary doctor and dentist, that they have a trial SNM system. Patients should bring their Patient Therapy Guide to all medical and dental appointments. This will help resolve any questions that their healthcare professional may have regarding any precautions to take to avoid potential device problems.
- Patients should always carry their Remote Control. This allows patients to change the stimulation amplitude and/or turn the TS on or off
- Patients should always bring their Remote Control to appointments related to their Axonics SNM System, including all programming sessions
- Patients should contact their physician if they have any unusual signs or symptoms

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.

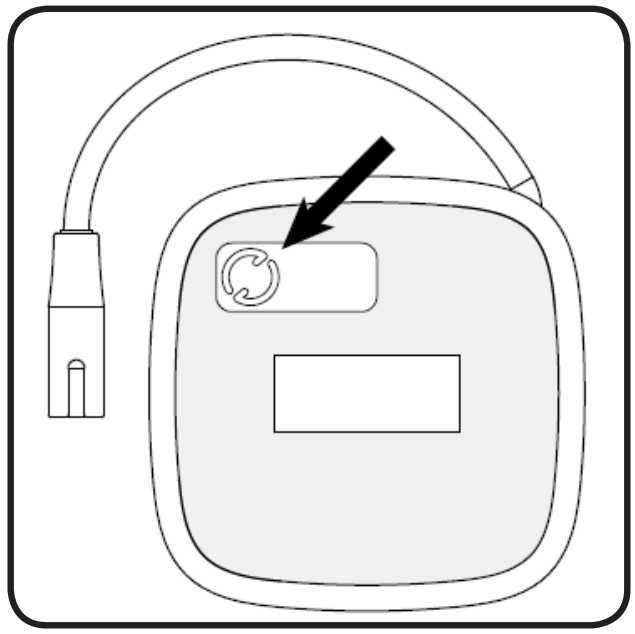


Figure 2: Activate the TS by pressing the button on the back of the stimulator

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.

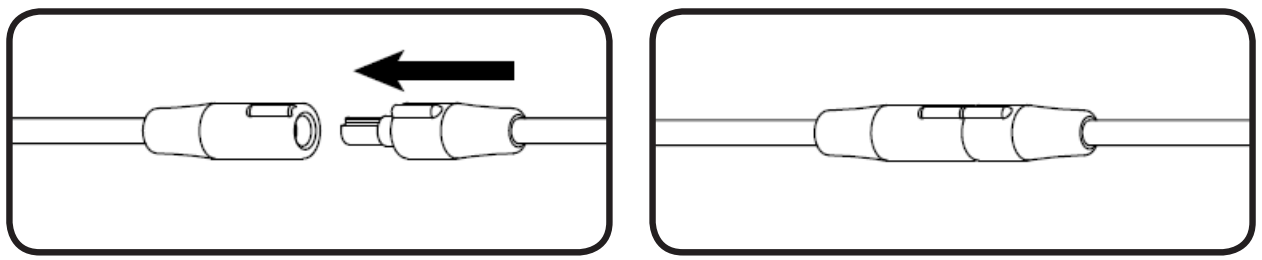


Figure 3: Align the raised grey bar on the TS with the raised bar on the Basic Trial Cable (shown) or the grey line on the PE (not shown). Plug the Basic Trial Cable or PE fully into the extension of the TS.

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.

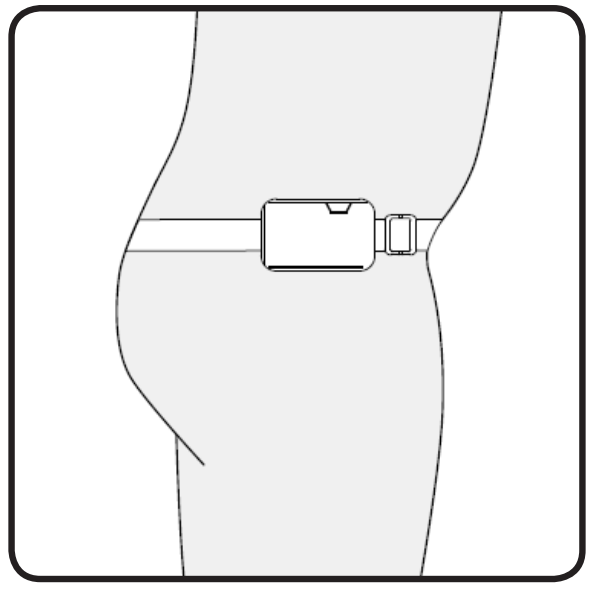


Figure 4: Fasten the belt on the patient's body and adjust the width as necessary.

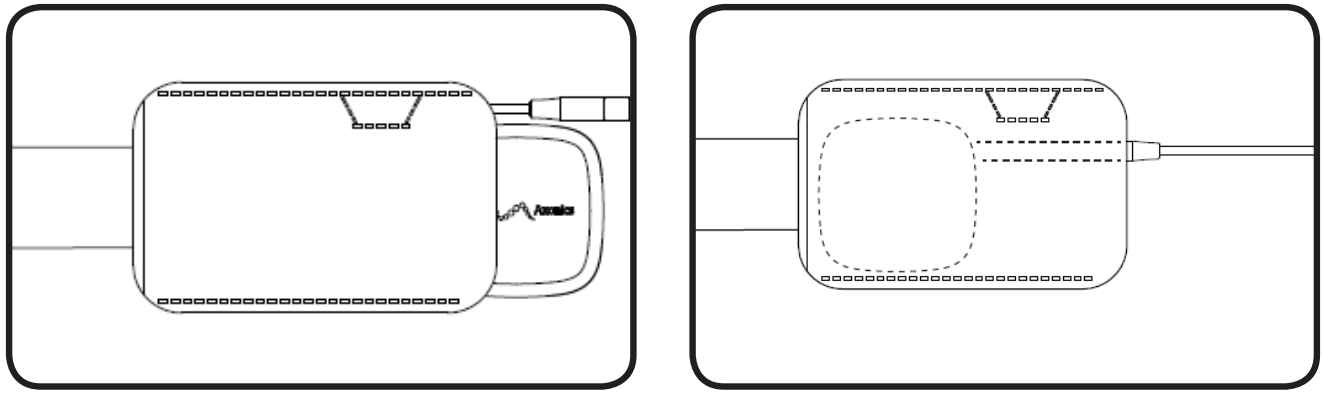


Figure 5: Insert the TS into the pouch on the belt.

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

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

CE :2019
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