Axonics

Sacral Neuromodulation System

Trial Stimulator Manual

Model 1601

Rx only

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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.

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:

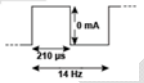
The following lists the appropriate temperature, humidity, and pressure conditions for shipping and storing the TS:

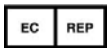
- Temperature (short term: 3 days): -25 °C to 70 °C
- Temperature (long term): 20 °C to 30 °C
- Humidity (short term: 3 days): 15% to 95%
- Humidity (long term): 30% to 85%
- Pressure (short term: 3 days): 57 kPa to 106 kPa
- Pressure (long term): 70 kPa to 106 kPa

If the TS was stored at temperatures outside of this range, do not use it until it has returned to the operating temperature range.

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
	Product Serial Number
	Manufacturer
	Product Model Number
	Manufacturing Date
	Non ionizing electromagnetic radiation
	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
	Authorized representative in the European community
	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
	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 applicable electrical equipment safety requirements

WIRELESS COMMUNICATION

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

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.

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