Axonics

Sacral Neuromodulation System

Clinician Programmer Manual

Model 2501 Clinician Programmer

Rx only

Refer to the appropriate clinician manuals for additional information on the Axonics SNM System, including contraindications, warnings, precautions, adverse events, individualization of treatment, patient selection, and implant procedures.

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Introduction

This manual provides information about the Axonics Sacral Neuromodulation (SNM) System Clinician Programmer (CP). The CP can be used during implantation and programming of the following Axonics SNM System components:

- Axonics Model 1601 Trial Stimulator
- Axonics Model 1901 PNE Lead
- Axonics Model 1201 Tined Lead

The CP can provide test stimulation during lead implantation and can wirelessly communicate with the Stimulator to check device status and program the device.

Note: The CP is required to implant a lead or program a Stimulator. Confirm the availability and operation of a CP prior to beginning a lead implant procedure.

Package Contents

- Axonics Model 2501 Clinician Programmer
- Power Supply
- Product Literature

Caution: Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

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.

Warnings

Device Specifications

Operating characteristics

Power source: Lithium-ion battery (rechargeable)

External power source: Powerbox EMX30

Input Power: 100 – 240 VAC, 47 – 63 Hz, 0.3 - 0.6 A

Output Power: 15 V, 2 A

Battery life*: 3 hours per charge; 5-years expected lifetime

Dimensions: 257 mm (w) x 246 mm (h) x 22 mm (d) Weight: 1125 g

Material:

- Housing: Polycarbonate and ABS resin blend
- Buttons: Silicone with polyurethane coating

Screen: Touch-screen, LCD display, 1280 x 800 pixels

CP Test Stimulation Output:

- Maximum Amplitude: 12.5 mA
- Frequency: 14 Hz
- Pulse width: 210 µs

***Note:** *Battery life may vary depending on frequency of use*

Storage and Usage Environment

Usage environment

The following lists the appropriate temperature, humidity, and pressure condition for use of the Axonics CP:

- Temperature: 5 °C to 35 °C
- Humidity: 15% to 95%
- Pressure: 70 kPa to 106 kPa

Device Specifications

Shipping and Storage environment

The following lists the appropriate temperature, humidity, and pressure condition for shipping and storage of the Axonics CP:

- 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 CP is stored at temperatures outside of the operating range, the CP should not be used until it has come to the operating temperature range.

Device Specifications

Wireless Communication

- Radiofrequency telemetry
- Model: 2501
- FCC ID: 2AEEGC
- IC: 20225-C
- Quality of Wireless Service:
    - This device operates in the 401-406 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 EN ETSI 302-537 and USA: FCC 47 CFR Part 95; Subpart I. The CP has to be within 1 meter from the Stimulator for successful communication.
- Wireless Security:
    - Any CP can communicate with a Stimulator. Additional mechanisms exist to ensure the integrity of radio data.

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.

Note: FCC Compliance information can be accessed on the CP in the **Clinician Programmer Settings** screen.

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

Note: The USB port on Clinician Programmer is used for the purpose of transferring (copying) the session reports to a USB flash drive. Do not plug any other devices into this port. Some examples of devices that are prohibited are: USB with WiFi or Bluetooth, USB Data Transfer Cable, USB mouse, USB keyboard, or USB flash drives with autorun executables.

Note: The USB port is disabled in all screens except, **Reports List** screen (see section **Reports List**). In this screen the session reports can be transferred to a USB flash drive. In the Reports List screen, the stimulation functions are not accessible and are disabled. The reports are transferred (copied) in PDF format.

Note: A Wireless connection through the USB port is not an intended use. This wireless functionality is disabled in the Clinician Programmer.

Label Symbols

Symbols	Description	Symbols	Description
SN	Product Serial Number		Pressure limitation
	Manufacturer		Classified by CSA with respect to safety
REF	Product Model Number		Do not use if package is damaged
	Manufacturing Date	EC REP	Authorized representative in the European community
	IEC 60601-1/EN60601-1, Type BF Equipment	IPX0	The device does not offer protection against water
	Non-ionizing electromagnetic radiation	IC	Industry Canada certification number
!USA Rx ONLY	For USA audiences only: Caution: US Federal law restricts this device for sale by or on the order of a physician	CE 0086	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)
	Refer to instructions for use (Consult accompanying documents)		Follow instructions for use (operator manual)
	Temperature limitation		EMG ground or Stimulation ground
	Humidity limitation		Tined Lead Test Stimulation
	EMG Channel 1		EMG Channel 2
	Foramen Needle Test Stimulation		USB port
	This device complies with all applicable Australian Communications and Media Authority (ACMA) regulatory arrangements and applicable electrical equipment safety requirements		

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