



Axonics

Sacral Neuromodulation System

Neurostimulator Implant Manual

Model 1101 Neurostimulator

Rx only

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Table of contents

TABLE OF CONTENTS..... 2

INTRODUCTION..... 6

AXONICS SNM THERAPY FOR URINARY CONTROL ...ERROR! BOOKMARK NOT DEFINED.

IndicationsError! Bookmark not defined.

PrecautionsError! Bookmark not defined.
Clinician training **Error! Bookmark not defined.**
Use in specific populations **Error! Bookmark not defined.**

CONTRAINDICATIONS ERROR! BOOKMARK NOT DEFINED.

WARNINGS.ERROR! BOOKMARK NOT DEFINED.

Diathermy.....Error! Bookmark not defined.

Magnetic Resonance Imaging (MRI)..... Error! Bookmark not

defined.

Electromagnetic interference (EMI) Error! Bookmark not defined.

Case Damage.....Error! Bookmark not defined.

Effects on other implanted devices Error! Bookmark not defined.

PRECAUTIONS..... ERROR! BOOKMARK NOT DEFINED.

Clinician programming.....Error! Bookmark not defined.

Patient activitiesError! Bookmark not defined.

Patient programming and Remote Control .. Error! Bookmark not defined.

Storage and Usage Environment..... **7**

Sterilization.....Error! Bookmark not defined.

System implantError! Bookmark not defined.

INDIVIDUALIZATION OF TREATMENT. ERROR! BOOKMARK NOT DEFINED.

ADVERSE EVENTS..... ERROR! BOOKMARK NOT DEFINED.

PATIENT COUNSELING INFORMATION ERROR! BOOKMARK NOT DEFINED.

COMPONENT DISPOSAL ERROR! BOOKMARK NOT DEFINED.

DEVICE DESCRIPTIONERROR! BOOKMARK NOT DEFINED.

Figure 1: Axonics Neurostimulator..... Error! Bookmark not defined.

Package contentsError! Bookmark not defined.

System registration form and Patient identification cardError! Bookmark not defined.

SPECIFICATIONS ERROR! BOOKMARK NOT DEFINED.

X-RAY IDENTIFICATION ERROR! BOOKMARK NOT DEFINED.

Procedure suppliesError! Bookmark not defined.

Neurostimulator Preparation ...Error! Bookmark not defined.

Creating the Neurostimulator pocket..... Error! Bookmark not defined.

Connecting the lead to the Neurostimulator Error! Bookmark not defined.

Implanting the NeurostimulatorError! Bookmark not defined.

Completing the implant procedure Error! Bookmark not defined.

Post-surgery treatmentError! Bookmark not defined.

Replacing the Neurostimulator.Error! Bookmark not defined.

LABEL SYMBOLS..... 8

WIRELESS COMMUNICATION.....12

INTRODUCTION

This manual provides information about the Axonics Sacral Neuromodulation (SNM) System Neurostimulator (Model 1101), which is a part of the Axonics SNM System. The Neurostimulator is connected to the Axonics tined lead (Model 1201 or 2201).

Storage and Usage Environment

Component packaging – Any component that has been compromised in any way should not be implanted. Do not implant the component if any of the following have occurred:

- The storage package or sterile pack has been damaged, pierced, or altered, as sterility cannot be guaranteed, which may lead to infection.
- The component itself shows any signs of damage. The component may not function properly.
- The use-by date has expired. In this case, component sterility cannot be guaranteed and infection may occur.
- The sterile component was dropped onto a non-sterile surface. In this case, the sterility cannot be guaranteed and infection may occur.

Usage environment:

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

- Temperature: 20 °C to 45 °C
- Pressure: The Neurostimulator should function at up to 10 m (33 feet) underwater (200 kPa) and at altitudes up to 3000 m (10,000 feet) associated with activities like hiking and skydiving (as low as 70 kPa)

Shipping and Storage environment:

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



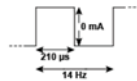
- Temperature (short term: 3 days): -10 °C to 55 °C

- 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): 57 kPa to 106 kPa
- Pressure (long term): 70 kPa to 106 kPa














If the Neurostimulator was stored at temperatures outside of this range, it should not be used 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 Neurostimulator
	Axonics Torque Wrench
	Neurostimulator default waveform with 14 Hz frequency, 0 mA amplitude and 210 μs pulse width

	<p>Neurostimulator default electrode configuration:</p> <p>Electrode 0: negative (-)</p> <p>Electrode 1: Off (0)</p> <p>Electrode 2: Off (0)</p> <p>Electrode 3: Positive (+)</p> <p>Case: Off (0)</p>
	<p>Product Serial Number</p>
	<p>Manufacturer</p>
	<p>Product Model Number</p>
	<p>Manufacturing Date</p>
	<p>Non ionizing electromagnetic radiation</p>
	<p>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)</p>
	<p>Refer to instructions for use (Consult accompanying documents)</p>
	<p>Temperature limitation</p>

	Humidity limitation
	Pressure limitation
	Do not reuse
	Sterilized using Ethylene oxide
	Use by
	Do not use if package is damaged
	Do not re-sterilize
	Authorized representative in the European community
	Open here
	For USA audiences only Caution: U.S. Federal law restricts this device for sale by or on the order of a physician
	Warning / Caution
	Product Literature
	Magnetic Resonance (MR) Conditional

IC	Industry Canada certification number
 R-NZ	This device complies with all applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements and applicable electrical equipment safety requirements

WIRELESS COMMUNICATION

Model: 1101
FCC ID: 2AEEGX
IC: 20225-X

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 Neurostimulator 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 402-405 MHz frequency and the maximum effective radiated power of the Neurostimulator communication is below the limit of 25 μ W ERP/EIRP as specified in EU: EN ETSI 301-839 and USA: FCC 47 CFR Part 95; Subpart I. The Remote Control, Clinician Programmer, or Charger have to be within 1 meter from the implant for successful communication.

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



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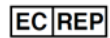
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