AXONICS F-15®
Neurostimulator

Implant Manual
Recharge-Free | Model 4101

Rx only

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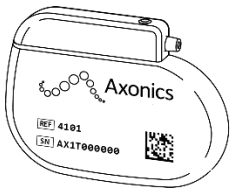
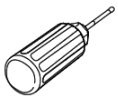
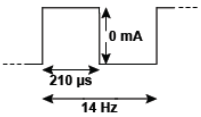
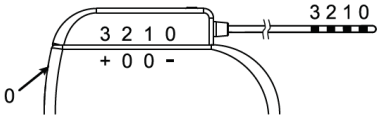
LABEL SYMBOLS

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
	Neurostimulator default electrode configuration: Electrode 0: negative (-) Electrode 1: Off (0) Electrode 2: Off (0) Electrode 3: Positive (+) Case: Off (0)
	Product Serial Number
	Manufacturer
	Product Model Number
	Manufacturing Date
	Non-ionizing electromagnetic radiation
	Refer to instructions for use available electronically.
	Temperature limitation
	Humidity limitation
	Pressure limitation
	Do not reuse
	Sterilized using Ethylene oxide

	Description
	Use by
	Do not use if package is damaged
	Do not re-sterilize
	Open here
!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
	Product Literature
MR	Magnetic Resonance (MR) Conditional
IC	Industry Canada certification number
	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
	This device is packaged in two sterile barriers
1201 +	The Neurostimulator is connected to the Axonics Tined Lead Model 1201 (also included in Model 2201)

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INTRODUCTION

This manual provides information about the Axonics Sacral Neuromodulation (SNM) System Neurostimulator (Model 4101), 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; this includes the re-use of non-reusable product. 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 ^{o}C to 55 ^{o}C
- Humidity (short term: 3 days): 15% to 95%
- Pressure (short term): 57 kPa to 106 kPa

If the Neurostimulator 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.

WIRELESS COMMUNICATION

Model: 4101
FCC ID: 2AEEGT
IC: 20225-T

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 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 µW ERP/EIRP as specified in EU: EN ETSI 301-839 and USA: FCC 47 CFR Part 95; Subpart I. The Remote Control or Clinician Programmer must 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 can communicate with a Neurostimulator. 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

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