# LABEL SYMBOLS

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Axonics Neurostimulator" /></td>
<td><strong>Axonics Neurostimulator</strong></td>
</tr>
<tr>
<td><img src="image" alt="Axonics Torque Wrench" /></td>
<td><strong>Axonics Torque Wrench</strong></td>
</tr>
<tr>
<td><img src="image" alt="Neurostimulator default waveform" /></td>
<td><strong>Neurostimulator default waveform with 14 Hz frequency, 0 mA amplitude and 210 µs pulse width</strong></td>
</tr>
</tbody>
</table>
| ![Neurostimulator default electrode configuration](image) | **Neurostimulator default electrode configuration:**  
  Electrode 0: negative (-)  
  Electrode 1: Off (0)  
  Electrode 2: Off (0)  
  Electrode 3: Positive (+)  
  Case: Off (0) |
<p>| <img src="image" alt="SN" /> | <strong>Product Serial Number</strong> |</p>
<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="symbol.png" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Product Model Number" /></td>
<td>Product Model Number</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Manufacturing Date" /></td>
<td>Manufacturing Date</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Non ionizing electromagnetic radiation" /></td>
<td>Non ionizing electromagnetic radiation</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Conformité Européenne" /></td>
<td>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)</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Refer to instructions for use" /></td>
<td>Refer to instructions for use (Consult accompanying documents)</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Temperature limitation" /></td>
<td>Temperature limitation</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Humidity limitation" /></td>
<td>Humidity limitation</td>
</tr>
<tr>
<td><img src="symbol.png" alt="Pressure limitation" /></td>
<td>Pressure limitation</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image1.png" alt="Symbol" /></td>
<td>Do not reuse</td>
</tr>
<tr>
<td><img src="image2.png" alt="Symbol" /></td>
<td>Sterilized using Ethylene oxide</td>
</tr>
<tr>
<td><img src="image3.png" alt="Symbol" /></td>
<td>Use by</td>
</tr>
<tr>
<td><img src="image4.png" alt="Symbol" /></td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td><img src="image5.png" alt="Symbol" /></td>
<td>Do not re-sterilize</td>
</tr>
<tr>
<td><img src="image6.png" alt="Symbol" /></td>
<td>Authorized representative in the European community</td>
</tr>
<tr>
<td><img src="image7.png" alt="Symbol" /></td>
<td>Open here</td>
</tr>
<tr>
<td><img src="image8.png" alt="Symbol" /></td>
<td>For USA audiences only</td>
</tr>
<tr>
<td><img src="image9.png" alt="Symbol" /></td>
<td>Caution: U.S. Federal law restricts this device for sale by or on the order of a physician</td>
</tr>
<tr>
<td><img src="image10.png" alt="Symbol" /></td>
<td>Warning / Caution</td>
</tr>
<tr>
<td><img src="image11.png" alt="Symbol" /></td>
<td>Product Literature</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td>![MR]</td>
<td>Magnetic Resonance (MR) Conditional</td>
</tr>
<tr>
<td>IC</td>
<td>Industry Canada certification number</td>
</tr>
<tr>
<td>![Checkmark]</td>
<td>This device complies with all applicable Australian Communications and Media Authority (ACMA) regulatory arrangements and electrical equipment safety requirements</td>
</tr>
<tr>
<td>FCC ID</td>
<td>US Federal Communications Commission device identification</td>
</tr>
</tbody>
</table>
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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).

Indications, Warnings, and Precautions

- Refer to Indications for Use insert for indications and contraindications
- Refer to Information for Prescribers booklet for warnings, precautions, adverse events, patient selection and clinical summary.
- Refer to MRI Physician Guidelines for MRI specific conditions and contraindications.
DEVICE DESCRIPTION

The Axonics Neurostimulator (Figure 1) is part of the Axonics SNM System. The Neurostimulator is a programmable device that is connected to the Axonics tined lead, which conducts stimulation pulses to the sacral nerve.

Figure 1: Axonics Neurostimulator.

Package Contents

The Neurostimulator package contains the following:

- Neurostimulator
- Torque wrench
- System registration form
- Patient identification card
- Neurostimulator Implant Manual (this document)

The contents of the inner package are STERILE. The contents of the Neurostimulator package are intended for single use only.
System Registration Form and Patient Identification Card

The system registration form registers the device and creates a record of the device in Axonics’ implant data system.

The patient identification card is also packaged with this device. The patient should carry the identification card at all times.
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 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 have been sterilized using ethylene oxide. This device is for single use only and should not be re-sterilized.
SPECIFICATIONS

Table 1 shows the Neurostimulator physical specifications. For detailed descriptions and specifications for other components and accessories, refer to the product literature packaged with those devices.

**Table 1: Neurostimulator Specifications.**

<table>
<thead>
<tr>
<th>Physical Attributes</th>
<th>Height</th>
<th>42 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Length</td>
<td>22 mm</td>
</tr>
<tr>
<td></td>
<td>Thickness</td>
<td>6 mm</td>
</tr>
<tr>
<td></td>
<td>Weight</td>
<td>11 grams</td>
</tr>
<tr>
<td></td>
<td>Volume</td>
<td>5.5 cc</td>
</tr>
<tr>
<td>Radiopaque identifier</td>
<td>AXA</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stimulation Characteristics</th>
<th>Frequency</th>
<th>2-130 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pulse Width</td>
<td>60-450 μs</td>
</tr>
<tr>
<td></td>
<td>Amplitude</td>
<td>0-12.5 mA</td>
</tr>
<tr>
<td></td>
<td>Minimum Amplitude Step Size</td>
<td>0.05 mA</td>
</tr>
<tr>
<td></td>
<td>Ramping</td>
<td>0-30 s</td>
</tr>
<tr>
<td></td>
<td>Stimulation Mode</td>
<td>Continuous or Cycling</td>
</tr>
<tr>
<td></td>
<td>Mode of Operation</td>
<td>Current-Controlled</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Power Source</th>
<th>Battery</th>
<th>Rechargeable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Power Source</td>
<td>50 mAh (3.6V)</td>
</tr>
<tr>
<td></td>
<td>Battery life</td>
<td>15 years (open-ended)*</td>
</tr>
</tbody>
</table>
**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, 14 Hz, 210 µs, continuous stimulation, impedance = 1,600 Ohms.

**Table 2** shows the materials used in the Neurostimulator kit components that come in contact with human tissue.

**Table 2: Human-Contact Materials.**

<table>
<thead>
<tr>
<th>Device</th>
<th>Component</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurostimulator</td>
<td>Neurostimulator case</td>
<td>Titanium-Ceramic</td>
</tr>
<tr>
<td></td>
<td>Neurostimulator header</td>
<td>Epoxy</td>
</tr>
<tr>
<td></td>
<td>Septum and strain relief</td>
<td>Silicone</td>
</tr>
<tr>
<td></td>
<td>Setscrew</td>
<td>Titanium</td>
</tr>
<tr>
<td></td>
<td>Adhesive</td>
<td>Silicone</td>
</tr>
<tr>
<td>Torque wrench</td>
<td>Torque wrench handle</td>
<td>Polyetherimide</td>
</tr>
<tr>
<td></td>
<td>Torque wrench shaft</td>
<td>Stainless steel</td>
</tr>
</tbody>
</table>

**Note:** The Neurostimulator case, which contains the electronics and power source, is hermetically sealed.
X-RAY IDENTIFICATION

The radiopaque marker allows physicians to identify the manufacturer and model number under standard x-ray procedures. For the Axonics Neurostimulator, the designated code is AXA, which appears as light characters on a black background (Figure 2).

Figure 2: The Axonics Neurostimulator radiopaque marker, “AXA”.
NEUROSTIMULATOR IMPLANT PROCEDURE

The following section describes the procedure for implanting the Axonics Neurostimulator. This procedure should be performed when an Axonics tined lead has already been implanted.

Procedure Supplies

In addition to the general surgical tools required by the physician, the following supplies are needed for the preparation, implantation, programming, and Remote Control pairing of the Neurostimulator:

- Axonics Neurostimulator (Model 1101)
- Axonics Charging System (Model 1401)
- Axonics Clinician Programmer (CP) (Model 2501)
- Axonics Remote Control (Model 2301)

⚠ Caution: The user should avoid damaging the Neurostimulator and be especially cautious using sharp instruments as damage to the Neurostimulator may require a surgical replacement.

Neurostimulator Preparation

Use the Charger to activate the Neurostimulator. Before opening the sterile Neurostimulator package, the Clinician Programmer (CP) should be used to communicate with the Neurostimulator to verify the ability to communicate and to check battery status. If the Neurostimulator battery is low, the device should be charged through the box before implantation by using the Charger. Refer to the CP and Charging System Manuals for further instructions.
Creating the Neurostimulator Pocket

1. The Neurostimulator will be placed in a subcutaneous pocket at the anterior surface of the muscle in the upper buttock area. Create a small incision, slightly larger than the smaller dimension of the Neurostimulator, and then bluntly dissect a subcutaneous pocket.

Notes:

- The Neurostimulator should be placed no deeper than 3.0 cm (about 1 in) below the skin and should be parallel to the skin. If the Neurostimulator is too deep or is not parallel to the skin, charging and/or programming the device may be unsuccessful.

- The Neurostimulator should be implanted horizontally (Figure 3) with the ceramic side farthest from the patient’s midline to facilitate charging and programming.

- For a patient with another neurostimulator already implanted, the neurostimulators should be placed as far away as practical and separated by a minimum of 20 cm (8 in).

⚠ Cautions:

- The Neurostimulator implant site should be irrigated with antibiotic solution, and it is recommended that IV antibiotics be administered perioperatively. Do not soak the Neurostimulator in antibiotic solution as this may affect lead connections.

- The Neurostimulator has been sterilized. The Neurostimulator should not be placed on any non-sterile surface. The Neurostimulator should not be placed on skin. An infection may require surgical removal of the implanted system.
2. Use the tunneling tool to create a tunnel from the lead incision site to the neurostimulator pocket. Refer to the Tined Lead Manual for detailed tunneling and lead implant instructions.

Connecting the Lead to the Neurostimulator

1. The components should be wiped and dried to remove any fluids before making the connections. If necessary, use sterile water or a non-ionic antibiotic solution, then wipe dry.

⚠ Caution: Failure to completely dry the components could lead to undesired stimulation, intermittent stimulation, or loss of therapy.

2. Ensure that the Neurostimulator connector block is dry and clean.
3. Use the torque wrench to turn the setscrew counterclockwise to back up the setscrew. Do not remove the setscrew from the connector block (Figure 4).

![Image: Use the Torque Wrench to Turn the Setscrew Counterclockwise to Back up the Neurostimulator Setscrew and Allow for Insertion of the Lead.]

Figure 4: Use the Torque Wrench to Turn the Setscrew Counterclockwise to **Back up** the Neurostimulator Setscrew and Allow for Insertion of the Lead.

4. Insert the lead into the Neurostimulator connector block until fully seated and the lead cannot be inserted further. Marker D on the lead should be inside the Neurostimulator strain relief (Figure 5). The retention sleeve on the tined lead should be positioned under the Neurostimulator setscrew.
**Cautions:**

- Avoid pulling the lead body taut when implanted.
- Do not attempt to insert the lead into the Neurostimulator if the setscrew is not sufficiently retracted as doing so may cause damage to the lead and/or cause the lead to not seat fully into the connector block.
- Ensure that the setscrew tightens on the retention sleeve, not an electrode. Tightening the setscrew onto the contact could damage the contact, leading to lack of therapy.

**Figure 5:** Insert Lead Fully into the Neurostimulator Connector Block.
5. Fully insert the torque wrench into the hole of the Neurostimulator connector block. Tighten the setscrew by turning the torque wrench clockwise until it clicks (Figure 6).

![Figure 6: Secure the Lead by Tightening the Setscrew Clockwise onto the Retention Sleeve.](image)

**Cautions:**

- Ensure that the torque wrench is fully inserted into the setscrew. Otherwise the setscrew may be damaged, which can result in intermittent or loss of stimulation.

- The torque wrench is designed for single use only and cannot be assured to work appropriately if used for multiple surgeries. Discard the torque wrench after use.

**Implanting the Neurostimulator**

1. Place the Neurostimulator into the subcutaneous pocket. Ensure that the ceramic side is placed away from the patient’s midline to ensure good communication with the Remote Control and ease of
recharging (Figure 3). The etched writing can face either towards or away from the muscle tissue. Ensure that the lead curves gently away from the Neurostimulator with no sharp bends.

**Note:** The Neurostimulator should be placed no deeper than 3.0 cm (about 1 in) below the skin and should be parallel to the skin. If the Neurostimulator is too deep or is not parallel to the skin, telemetry and/or charging may be unsuccessful.

⚠ **Caution:** Do not coil excess length in front of Neurostimulator. Wrap excess length around the perimeter of the Neurostimulator (Figure 7) or place under the Neurostimulator to minimize interference with telemetry during programming.

---

2. Use the Clinician Programmer to check the impedances and ensure good function and connectivity of the system.

**Notes:**

- The Neurostimulator should be in the subcutaneous pocket during system interrogation to ensure proper...
readings.

- Refer to the Clinician Programming Manual for detailed instruction on checking the system integrity and impedances.

3. Use the suture hole in the header to secure the Neurostimulator to the muscle fascia with non-absorbable silk

**Completing the Implant Procedure**

1. Close and dress all incisions.


3. Give a Remote Control and patient ID card to the patient.

⚠ **Caution:** The patient must carry the Remote Control at all times to be able to adjust or turn off the Neurostimulator.

4. Complete the system registration paperwork and return to Axonics.

5. Schedule the patient’s follow-up visits at regular intervals to ensure that the stimulation is programmed optimally.

**Post-Surgery Treatment**

Administer prophylactic antibiotics for 24 hours.

**Replacing the Neurostimulator**

1. Carefully open the implant site and remove the Neurostimulator from the subcutaneous pocket. Avoid
cutting the tined lead to preserve for connection with the new Neurostimulator.

2. Clean the Neurostimulator connector block and lead with sterile water. Wipe both dry with sterile gauze.

3. Use the torque wrench to loosen the setscrew in the Neurostimulator connector block by turning it counterclockwise (Figure 5).

4. Gently remove the lead from the Neurostimulator.

⚠ **Caution:** Replace any device that shows signs of damage, pitting, or corrosion.

5. Set aside the explanted components, which should be returned to Axonics.

6. Connect the lead and replacement Neurostimulator according to the steps above.

Return explanted devices to Axonics using materials provided.
WIRELESS COMMUNICATION
Model: 1101
IC: 20225-X
FCC ID: 2AEEGX

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, 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.
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
EC REP
HealthLink Europe Services BV
De Tweeling 20-22
5215 MC 's-Hertogenbosch
The Netherlands

(2020-05-11)
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Axonics Modulation Technologies, Inc.
110-0127-001 Rev B