Axonics

Sacral Neuromodulation System

Clinician Programmer Manual

Model 1501

Rx ONLY

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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 Model 1501 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 1101 Neurostimulator
- Axonics Model 1201 Tined Lead

Purpose

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

Note: The CP is required to implant a tined lead or program a Neurostimulator for chronic SNM therapy. Confirm the availability and operation of a CP prior to beginning a lead implant procedure.

Note: The Model 1501 Clinician Programmer only communicates with the implanted Neurostimulator (Model 1101). It does not communicate with the Trial Stimulator (Model 1601). Use the Model 2501 Clinician Programmer to communicate with the Trial Stimulator and implant a PNE lead or Tined lead for an external trial.

Package Contents

- Axonics Model 1501 Clinician Programmer
- Power Supply
- Product Literature

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

Indications

Axonics SNM Therapy for urinary control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

Precautions

Clinician Training

- **Implanting clinicians** should be trained on the implantation and use of the Axonics SNM System.
- **Prescribing clinicians** should be experienced in the diagnosis and treatment of lower urinary tract symptoms and should be trained on the use of the Axonics SNM System.

Use in Specific Populations

The safety and effectiveness of this therapy has not been established for:

- Pregnant women, the unborn fetus, and during delivery
- Pediatric use (patients under the age of 16)
- Patients with neurological disease origins, such as multiple sclerosis or diabetes
- Bilateral stimulation

Contraindications

The Axonics SNM System is contraindicated for the following patients:

- Patients who have not demonstrated an appropriate response to test stimulation; or
- Patients who are unable to operate the Axonics SNM System.

PRECAUTIONS

Parameter adjustment – The steps below should be taken to prevent sudden stimulation changes that lead to an uncomfortable jolting or shocking feeling:

- Stimulation parameters should be changed in small increments.
- The stimulation amplitude should be allowed to ramp to full amplitude slowly.
- Before disconnecting a stimulation cable or turning stimulation on or off, the stimulation amplitude should be decreased to 0.0 mA.

Sensitivity to stimulation – Some patients, especially those that are very sensitive to stimulation, may be able to sense the telemetry signals associated with the CP communicating with the Neurostimulator.

Programmer interaction with flammable atmospheres – The CP is not intended to be used in the presence of flammable gases, and the consequences of using the CP in such an environment is not known.

Programmer interaction with other active implanted devices – When a patient has a Neurostimulator and another active implanted device (for example, a pacemaker, defibrillator, or another neurostimulator), the RF signal used to program any of these devices may reset or reprogram the other devices.

Whenever the settings for these devices are changed, a clinician familiar with each device should check the program settings of each device before the patient is released (or as soon as possible). Patients should contact their physician immediately if they experience symptoms that are likely to be related to the devices or their medical condition.

Telemetry signal disruption from EMI – The Neurostimulator should not be programmed near equipment that may generate electromagnetic interference (EMI) as the equipment may interfere with the CP's ability to communicate with the Neurostimulator. If EMI is suspected to be interrupting programming, the CP and the Neurostimulator should be moved away from the likely source of EMI.

Unintended use – The CP is intended for use during implantation and programming of the Axonics SNM System. It should only be used with manufacturer provided accessories. Do not use the CP for stimulation or other purposes not described in this manual. Unintended use can result in user or patient injury.

Accidental electrode contact – Avoid accidental contact between connected but unapplied electrodes and other conductive parts, including those connected to protective earth.

WARNINGS

⚠ **Warning:** Do not attempt to modify or service this product. If there is an issue with the product, please consult an Axonics representative.

⚠ **Warning:** This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

⚠ **Warning:** Shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (collectively described as diathermy) CANNOT be performed during implantation of the Axonics SNM System or on patients implanted with the Axonics SNM System. Diathermy can transmit energy through the CP and accessories or the implanted system, potentially causing tissue damage at the location of the surface or implanted electrodes, resulting in severe injury.

DEVICE SPECIFICATIONS

Operating Characteristics

Power source: Lithium-ion battery (rechargeable)

External power source: Powerbox EMX30

Input Power: 100 – 240 VAC, 47 – 63 Hz, 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

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 °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 CP 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.

Maintenance

At least once a year, the CP should be inspected for visible damage and should be charged and powered on to confirm the **Log-In** screen is still accessible. Significant physical damage or an inability to power on the device should be reported to the manufacturer and the device should not be used.

Handling and Disposal

- **Cleaning:** The CP can be wiped with a cloth lightly moistened with water. No other cleaning agents should be used.
- **Replacement:** If the CP is lost or not working, contact Axonics.
- **Disposal:** Do not incinerate the CP as the battery may explode. If the CP is no longer needed, contact Axonics to return the device.

Wireless Communication

Radiofrequency telemetry

Model: 1501

IC: 20225-C

FCC ID: 2AEEGC

Quality of Wireless Service:

- This device operates in the 402-405 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 USA: FCC 47 CFR Part 95; Subpart I. The CP has to be within 1 meter from the implant 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 **General 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 disabled in all intended user screens. Do not plug any devices into this USB 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 auto run executables.

Note: The USB port is for Axonics use only and its functionality is protected.

START UP AND GENERAL FUNCTIONS

This section describes the process of starting up the Clinician Programmer (CP) and provides instructions on several key CP functions that are encountered in multiple screens when using the CP.

The following sections include:

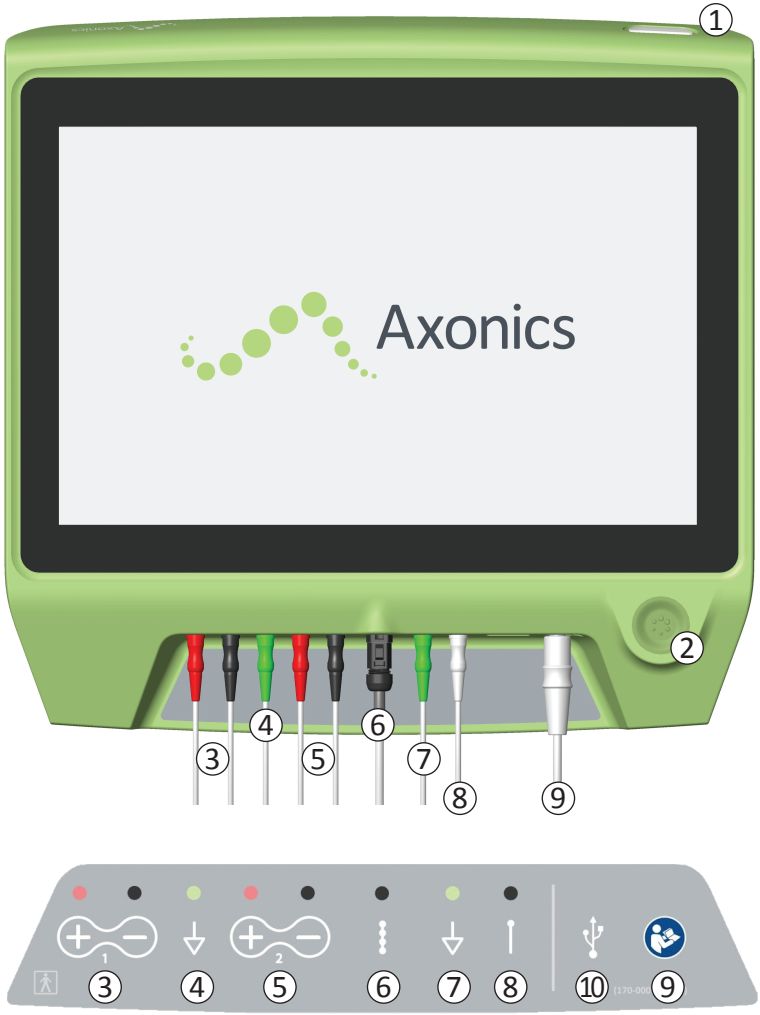
Getting Started

- Summary of CP Buttons and Connections
- Turning the CP on and off
- Logging-in to the CP
- Navigating the **Home** screen

General functions

- Description of Battery Level Icons and Charging
- Introduction to Clinician Programmer Prompts
- Understanding Impedance Values
- Controlling Stimulation Amplitude

Summary of Clinician Programmer Buttons and Connections



The CP has two physical buttons:

① Power Button – turns the CP on and off.

② Stimulation Button – turns test stimulation on and off (select screens only)

The CP has a Connector Panel with plugs for the cables that are used with the CP. The symbols on the Connector Panel indicate which cable should be used with each plug:

③ Not Used

④ Not Used

⑤ Not Used

⑥ Tined Lead Test Stimulation

⑦ Stimulation Ground

⑧ Foramen Needle Test Stimulation

⑨ Power Input

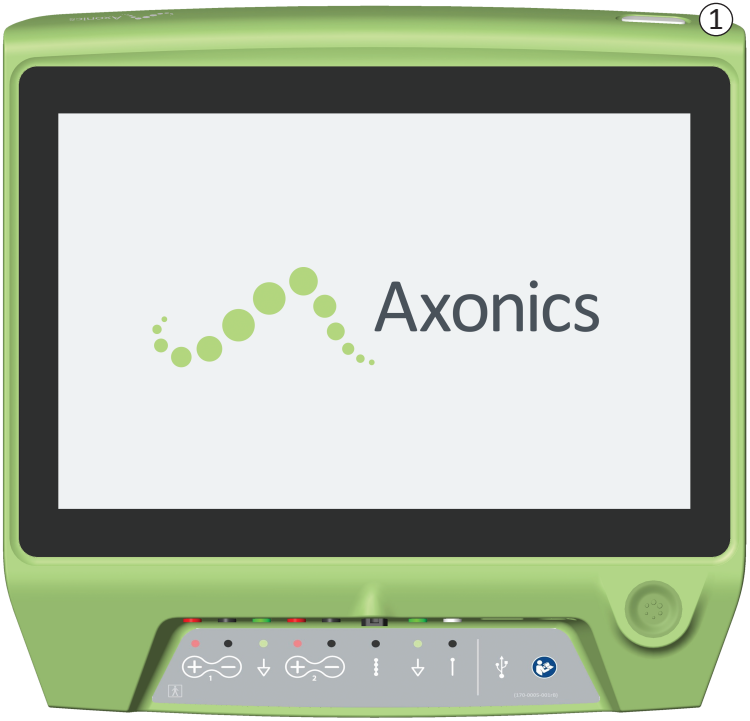
⑩ USB port

The purposes and uses of these buttons and connections are described throughout this manual.

NOTE: EMG functionality is disabled in this model.

NOTE: USB port is disabled in this model.

Turning the Clinician Programmer On and Off



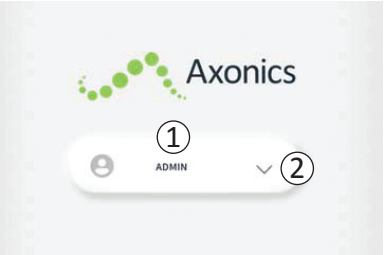
Turning on the CP

- Press and hold the power button (1) to turn on the CP.
- The CP screen will show the Axonics logo as the CP starts up.
- The CP will proceed to the password protected **Log-In** screen.

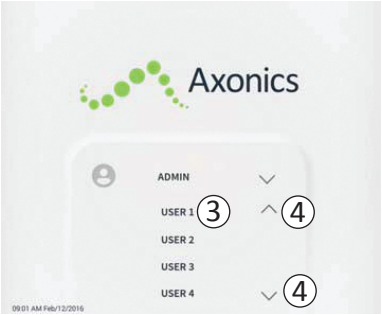
Turning off the CP

- From any CP screen, press and hold the power button (1) to turn off the CP.

Logging-in to the Clinician Programmer



- When the CP is turned on, it will start-up at the **Log-In** screen.
- By default, the “ADMIN” user name will appear on the **Log-In** screen (①).
- Press “ADMIN” to log in using that user name.
- Press the down arrow to the right of the user name to select a different user name (②). There will not be a down arrow if no additional user names exist.

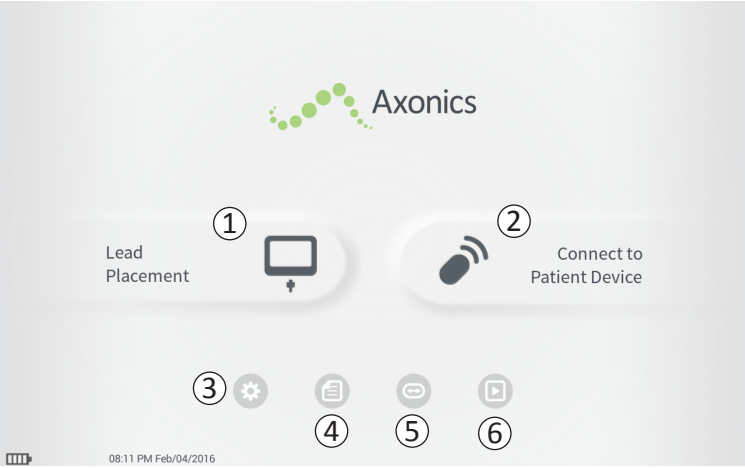


- A short list of names will appear when the down arrow is pressed.
- Press a user name to select it to log in (③).
- More names can be accessed by scrolling up and down the list using the arrows on the right (④).

- A key pad will appear when a user name is selected.
- Enter the 4-digit passcode associated with the selected user name to log-in to the CP.
- Press “Cancel” to switch user names(⑤).

Note: The CP will automatically log-out a user after 30 minutes of inactivity.

Navigating the Home Screen



The **Home** screen will appear after successful log-in to the CP. The **Home** screen provides access to the main functions of the CP, including:

① **Lead Placement** – Deliver test stimulation during a lead placement procedure.

② **Connect to Patient Device** – Check the status of and program a Neurostimulator.

③ **CP Settings** - Change CP settings, including default stimulation settings.

Additional information about each of these functions is included in the following sections of this manual.

④,⑤,⑥ These buttons are for use by the Manufacturer only.

Description of Battery Level Icons and Charging

Determining the CP Battery Level

The battery icon shows the CP battery level. This icon is always displayed in the bottom left corner of the screen when the CP is on.

The number of bars on the battery icon indicates the CP battery level, and bars disappear from right-to-left as battery charge is depleted. The battery levels shown on this page are as follows:

Partially Full to Full (2 to 4 bars)

When 4 bars are present the battery is full or nearly full. At 4 or 3 bars, the battery bars are white. When the battery drops to 2 bars, the bars are yellow indicating less than half the battery charge is remaining.

Low

When the battery level is low, the battery displays 1 red bar.

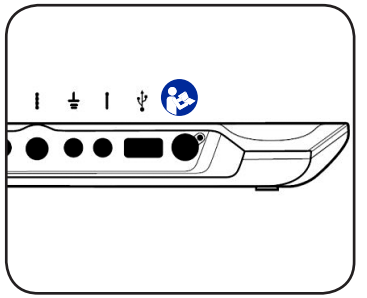
Note: A procedure should not be started with a low battery to avoid the CP battery dying during the procedure.

Two minutes before the CP automatically shuts down due to a critically low battery, the user will be prompted to charge the CP. This prompt can only be disabled by plugging in and charging the CP.

Charging

When the device is charging, the battery icon shows 4 green bars and a lightning bolt. Charging a fully depleted CP can take up to 6 hours.

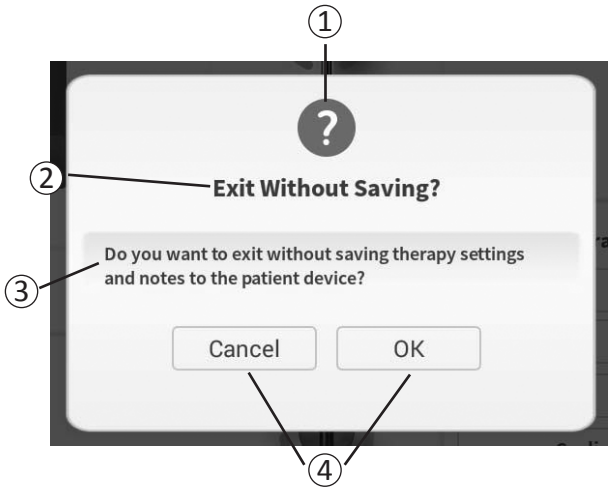
How to Charge the CP



To charge the CP, plug the power supply into a power outlet and into the CP. The power supply plugs into the CP at the right end of the Connection Panel and is indicated by the “Refer to manual” symbol .

Note: Charge the CP after each use. A full battery should last for approximately 3-4 hours of use. If multiple implant procedures are scheduled on a single day, charge the CP between procedures to ensure the battery does not run out. Always keep the CP power supply with the CP.

Note: The CP should provide 5 or more years of service. With repeated charging, the CP battery may lose capacity. Notify Axonics if you experience a significant change in the operating time for a fully charged CP battery.



Prompts will present information during CP use in order to confirm user intent and to provide information on action progress and errors. Each prompt presents the following information:

1. **Prompt type** – An icon indicating the general purpose of the prompt (e.g., progress indicator, error alert)
2. **Headline** – The general topic of the prompt
3. **Message** – A statement of the reason for the prompt
4. **Response button(s)** – A button or buttons appear for prompts which require a response from the user

Types of Prompts

An icon will be part of each prompt to indicate the purpose of the prompt. Icons include:

Prompt	Purpose	Prompt Icon
Query	Requires confirmation to proceed in situations where inputs may result in system performance issue or disruption in the workflow. If applicable, the Progress Prompt will appear after input.	?
Progress Prompt	A momentary display appears to confirm the progress and completion of a task. No action required.	
Error	A device issue has occurred, compromising device function. This issue may or may not be reversible.	!
CP Failure	A serious Clinician Programmer issue has occurred, compromising device function. The Clinician Programmer will automatically shut down. User may restart Clinician Programmer to see if issue persists.	!

Understanding Impedance Values

Impedance values are important indicators when delivering test stimulation or stimulating with the Stimulator. The impedance values provided by the CP are icons representing the quality of the circuit being used to deliver stimulation.

Impedance can be tested when a Ω button is present. When the button is pressed, the CP will display either:

- A single impedance icon corresponding to the connection for foramen needle stimulation.
- 4 impedance icons, each corresponding to the connection for one of the electrodes on the tined lead.

The impedance icon can have one of 4 states:

Ω **Good**
The impedance level indicates a good connection and is preferred for stimulation.

Ω **OK**
The impedance level indicates an acceptable connection and is allowed for stimulation.

Ω OPEN **Bad – Open**
The impedance level indicates an open circuit and stimulation is not possible.

Ω SHORT **Bad – Short**
The impedance level indicates a short circuit and stimulation is not recommended.

Note: See the manual sections on Troubleshooting for steps to resolve out of range (“Bad”) impedance values.

The stimulation bar (①) controls the stimulation amplitude during test stimulation for lead placement and Neurostimulator programming. When available, the stimulation bar is on the right side of the **CP** screen. The stimulation bar includes:

② A digital display of the stimulation amplitude level.

- When stimulation is *OFF*, this display shows in grey the desired, or programmed, stimulation amplitude.
- When stimulation is *ON*, this display shows in blue the output, or delivered, stimulation amplitude.

Note: For extreme stimulation settings (including high amplitude, pulse width, and/or rate) and impedance values (e.g., high impedance values) the output stimulation amplitude that is delivered to the patient may be less than the programmed stimulation amplitude. Increasing the pulse width in this situation may provide sufficient charge delivery to obtain the desired stimulation response. Refer to the table at the end of this section for a summary of maximum achievable stimulation amplitudes under different stimulation conditions. Axonics recommends testing alternative electrode configurations – particularly those with lower impedances if available – to attempt to reduce the stimulation output required to obtain the desired stimulation response.

③ Up arrow and down arrow buttons to increase and decrease stimulation amplitude incrementally.

- By default, the amplitude changes in 0.05mA increments if the amplitude is <1.30mA. At amplitudes above 1.30mA, the default incremental change is 0.10mA.
- In the **CP Settings** screen, the increment of amplitude change can be changed from the default to a fixed increment of 0.05mA or 0.10mA.
- Incremental stimulation amplitude changes can be made when stimulation is off or on.

④ A slider bar indicates the level of stimulation and can be moved up or down to make large changes to the stimulation amplitude. **Note:** The slider bar can only be used to change stimulation amplitude when stimulation is off.

⑤ The gray box between the up and down arrows represents the programmable range of stimulation amplitude, which is 0 to 12.5mA. At high electrode impedances, the delivered stimulation amplitude may be lower than the programmed amplitude.

⑥ When stimulation is on, the area under the slider bar will turn dark gray with horizontal blue bars.

⑦ Stimulation may be set to increase amplitude automatically if "Auto" is selected.

Stimulation amplitude can be adjusted in two modes: manual or automatic.

Manual amplitude adjustment

Manual amplitude adjustment is the default mode and is active when "Auto" (⑦) is in the light gray, inactive state. In the manual amplitude adjustment mode, stimulation amplitude is changed by moving the slider bar (④) or by pressing the up and down arrows (③). Stimulation is turned on by pressing the stimulation button (⑧), which lights up when stimulation is on. When stimulation is on, the amplitude can only be adjusted using the up and down arrows. Stimulation is turned off by pressing the stimulation button (⑧) again.

Note: For test stimulation during lead placement and Neurostimulator programming, the stimulation amplitude will start at the programmed level and will not ramp from zero.

Automatic amplitude adjustment

In the automatic amplitude adjustment mode the stimulation amplitude automatically increases from 0mA to the amplitude value set by the user. The amplitude increase can be stopped, or stimulation can be turned off, at any time.

To use the automatic amplitude adjustment feature:

- Use the slider bar (④) and up and down arrows (③) to set a desired stimulation amplitude.
- Press “Auto” (⑦). “Auto” will be dark gray when automatic amplitude adjustment is active.
- Press the stimulation button (⑧) to turn on stimulation.
- The stimulation amplitude will start increasing from 0mA at a rate of 0.2mA per second, and the output stimulation amplitude will be visible in the digital display (②) at the top of the stimulation bar. A red bar on the stimulation bar will represent the stimulation amplitude as it increases (⑨).

  Note: The stimulation bar and up and down arrows are not accessible to adjust stimulation.
- To stop the increase in stimulation amplitude while still delivering stimulation, press “Auto” (⑦).
- To stop stimulation altogether, press the stimulation button (⑧).

Stimulation output ranges

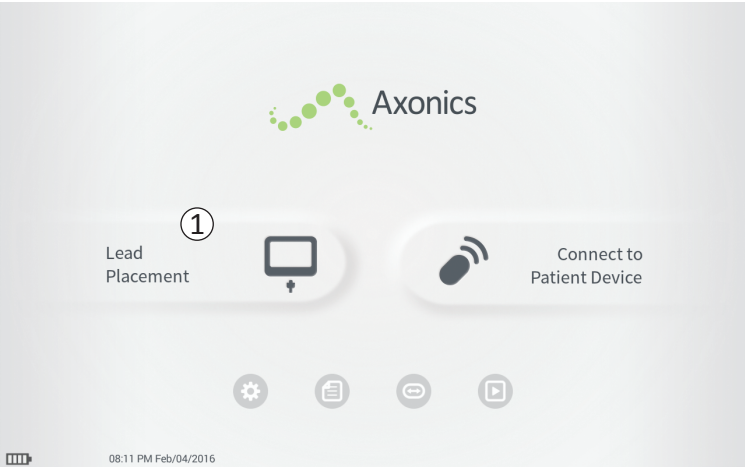
Maximum stimulation current is dependent on the stimulation settings and impedance values. In the event of high impedances values or high frequency and pulse width, the output stimulation amplitude may be less than the programmed stimulation amplitude. Typical settings are 14 Hz and 210 µs with impedance from 600 – 1500 Ohms.

Load (Ohms)	Achievable amplitude (mA)		
	14 Hz, 210 µS (nominal stimulation)	50 Hz, 300 µS (moderate stimulation)	130 Hz, 450 µS (high stimulation)
5000	2.5	2.2	2.0
2000	5.0	4.5	2.5
700	12.5	9.0	3.5
400	12.5	12.5	4.0
Impedances below 400 is considered a short circuit and impedances above 6000 is considered an open circuit.			

If the stimulator is delivering less current than programmed on the CP, when stimulation is active the blue number above the stimulation bar shows the actual delivered stimulation current.

If stimulation amplitude is being adjusted and no change in patient response is observed, the user should compare the delivered current (blue display above the stimulation bar when stimulation is on) to the programmed current (gray display above the stimulation bar when stimulation is off) to determine if the system is delivering the programmed current.

TEST STIMULATION DURING LEAD IMPLANTATION

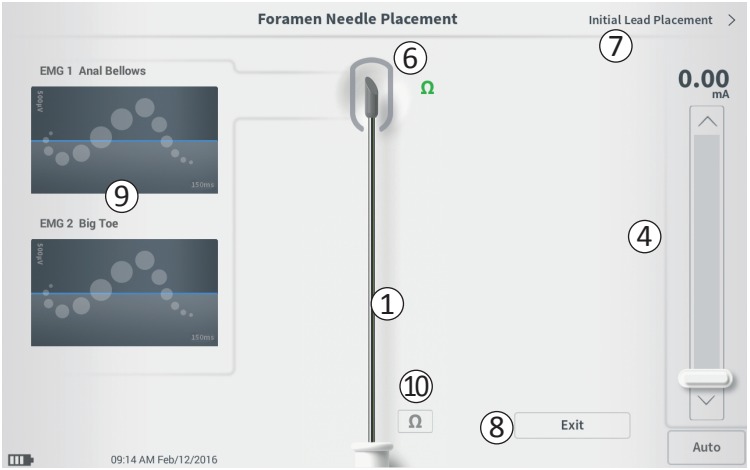


During tined lead implant procedures, the CP is used to deliver test stimulation to the foramen needle and the tined lead. The test stimulation allows confirmation that the needle and lead are placed close to the sacral nerve.

This section describes how to use the Lead Placement module of the CP during a tined lead implant procedure.

Press “Lead Placement” (1) on the **Home** screen to start foramen needle test stimulation.

Foramen Needle Test Stimulation



Pressing “Lead Placement” on the **Home** screen opens the **Foramen Needle Placement** screen. This screen shows a visual representation of the foramen needle (①) and allows test stimulation of the foramen needle. To stimulate using the foramen needle:

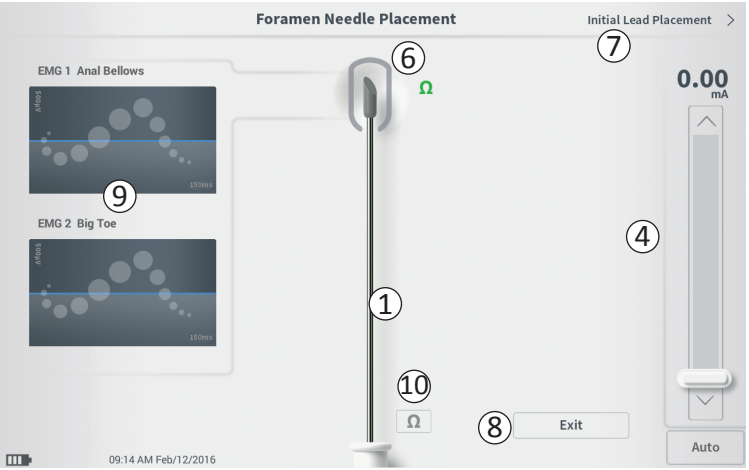
- Connect the foramen needle test stimulation cable to the CP (②) and to the foramen needle. Also connect the stimulation ground cable to the CP (③) and to the patient (see the *Tined Lead Implant Manual* for more details on connecting to the foramen needle and the patient).

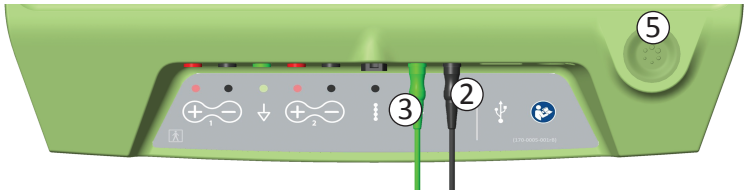
Note: The test stimulation cable is sterile and can be used in the sterile field.

Note: The stimulation ground cable is not sterile. Do not place the ground electrode in the sterile field.

Note: The CP is not sterile and cannot be sterilized. When using the CP in a sterile field, place it into a sterile bag.

- Next, press the “Impedance” button (⑩) to confirm the foramen needle is connected. A qualitative indication of the impedance (“Good”, “OK”, or “Bad”) will appear for 3 seconds next to the tip of the foramen needle graphic (⑥). See the section *Understanding Impedance Values* for more information about the qualitative impedance indicators.
- To deliver stimulation, set the desired stimulation amplitude on the Stimulation Bar (④) (see *Controlling Stimulation Amplitude* for more information).
  Next press the stimulation button(⑤) to turn on stimulation. The stimulation button will light up when stimulation is on.



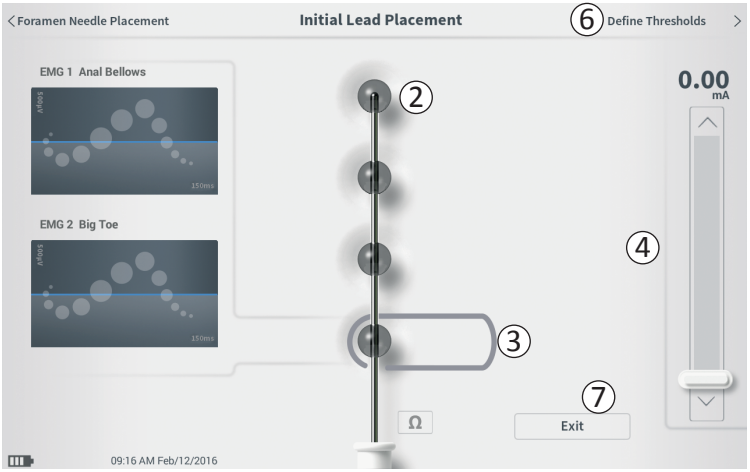


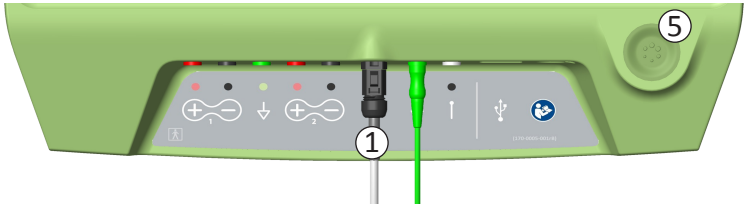
- Only stimulation amplitude is adjustable during foramen needle stimulation. The stimulation frequency is 14 Hz, and the pulse width is 210µs.

Note: The stimulation cable can be disconnected from the foramen needle without causing stimulation to be turned off. This allows stimulation to be delivered on demand by tapping the mini-clip portion of the cable against the appropriate area of the needle.

- The area around the tip of the foramen needle graphic (⑥) will be colored to reflect the proximity of the needle to the sacral nerve. This information is used to evaluate the proximity of the needle to the sacral nerve once the appropriate muscle responses are observed (anal bellows and big toe flexion).
  - **Grey** (unassigned): Stimulation level is zero.
  - **Green** ("good"): Stimulation level between 0 and 3 mA. Placement is acceptable.
  - **Yellow** ("okay"): Stimulation level between 3 and 4 mA. Axonics recommends adjusting the needle placement.
  - **Red** ("not recommended"): Stimulation level between 4 and 12.5 mA. Axonics strongly recommends adjusting the needle placement.
- Press "Initial Lead Placement" (⑦) in the upper right to move on to place the tined lead.
- To exit back to **Home** screen, please "Exit" (⑧).

Initial Tined Lead Placement





When the tined lead is initially placed through the introducer sheath, the CP provides test stimulation to help determine if the lead electrodes are near the sacral nerve. This section explains how the **Initial Lead Placement** screen can assist in determining if the lead is in an appropriate location.

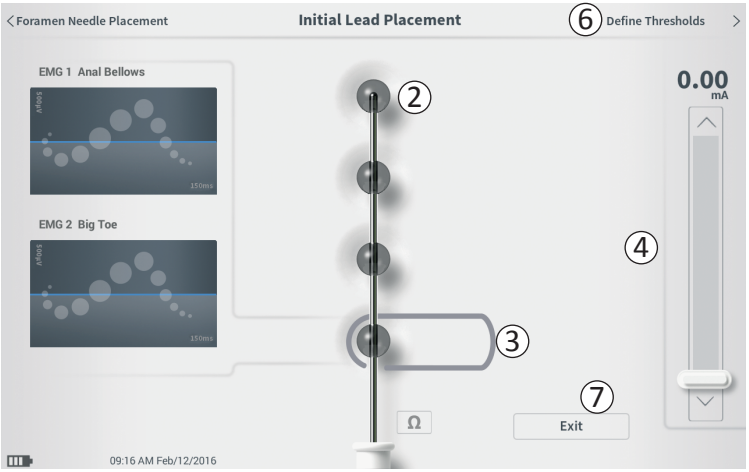
The I**nitial Lead Placement** screen allows automated, sequential stimulation of each electrode to check the lead placement.

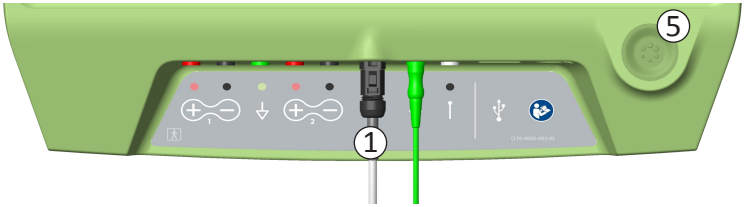
Plug the tined lead test stimulation cable into the CP (①). See the *Tined Lead Implant Manual* for instructions on connecting the tined lead test stimulation cable to the tined lead.

Press the impedance button to check the connection with the tined lead. If the impedance for any electrode(s) is “Bad”, adjust the tined lead connection and the ground pad, then recheck the impedance. See manual section *Understanding Impedance Values* for more information about the qualitative impedance indicators.

To check the initial tined lead placement:

- Select an electrode. The top electrode on the **CP** screen represents the electrode nearest to the tip of the lead (EO) (②). The rectangle around the electrode indicates it has been selected (③).
- Select the stimulation amplitude (④) and turn on stimulation by pressing the stimulation button (⑤). (See manual section *Controlling Stimulation Amplitude* for more information).





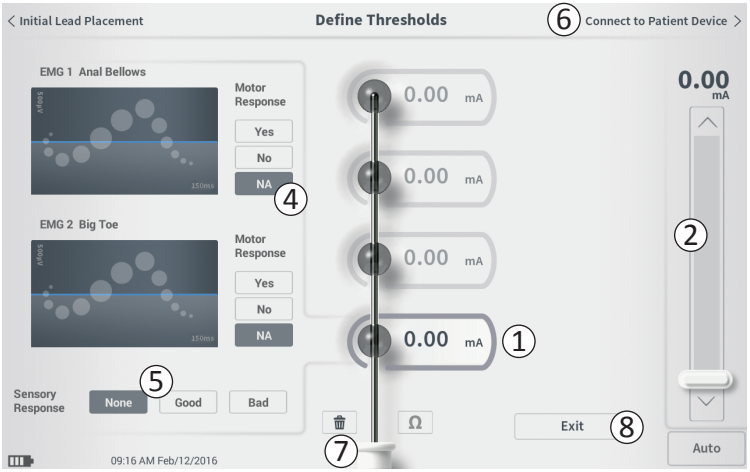
- The CP will deliver 1 second of stimulation to each electrode at the selected amplitude. The rectangle around the electrode will indicate which electrode is actively stimulating at a given time.
- Observe the response to stimulation (motor and/ or sensory). The combination of the selected stimulation amplitude and the evoked responses inform whether tined lead placement is generally acceptable or not.

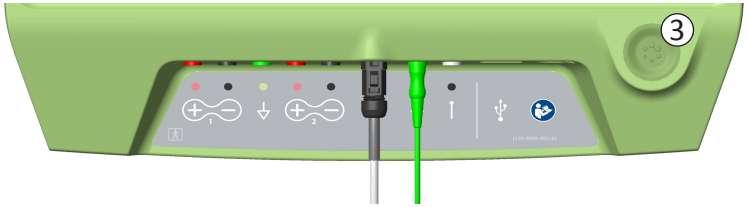
After reviewing the stimulation responses, select the path forward:

- If the location is satisfactory, move on to the **Define Thresholds** screen (⑥) to characterize the stimulation response for each electrode.
- If the tined lead location is not satisfactory, reposition the tined lead and repeat this process.
- If the tined lead needs to be removed and the foramen needle replaced, return to the **Foramen Needle Test Stimulation** screen to test stimulate the foramen needle.
- To exit the tined lead placement procedure, press “Exit” (⑦).

Note: It may be desired to proceed directly to the **Define Threshold** screen to simultaneously test initial lead placement and characterize the response to stimulation at each electrode.

Define Tined Lead Thresholds





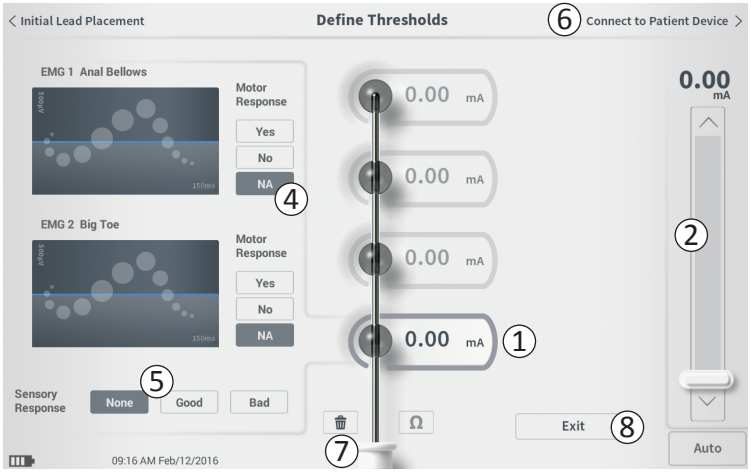
After the initial placement of the tined lead, the CP is used to deliver test stimulation to characterize the placement of the tined lead. This section explains how the CP is used to test and record the responses and response thresholds for stimulation with each electrode of the tined lead.

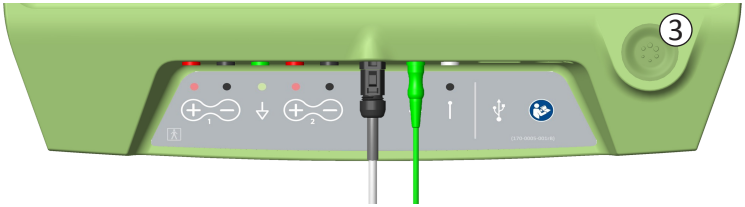
Upon entering the **Define Thresholds** screen, the most proximal electrode (E3) is selected by default. A different electrode can be selected by pressing that electrode on the **CP** screen. A gray box is visible around each electrode until stimulation is delivered with the selected electrode (①). The box changes color depending on the stimulation amplitude and the motor and sensory responses evoked. When stimulation is at the minimum amplitude that evokes the desired physiological response (motor and/or sensory), the color around the electrode indicates the quality of that electrode:

- **Grey** (unassigned): Stimulation level is zero.
- **Green** ("good"): Stimulation level between 0 and 3 mA. Placement is acceptable.
- **Yellow** ("okay"): Stimulation level between 3 and 4 mA. Axonics recommends adjusting the lead placement.
- **Red** ("not recommended"): Stimulation level between 4 and 12.5 mA. Axonics strongly recommends adjusting the lead placement.

The threshold value of the selected electrode is updated each time a new test stimulation occurs.

Define Tined Lead Thresholds



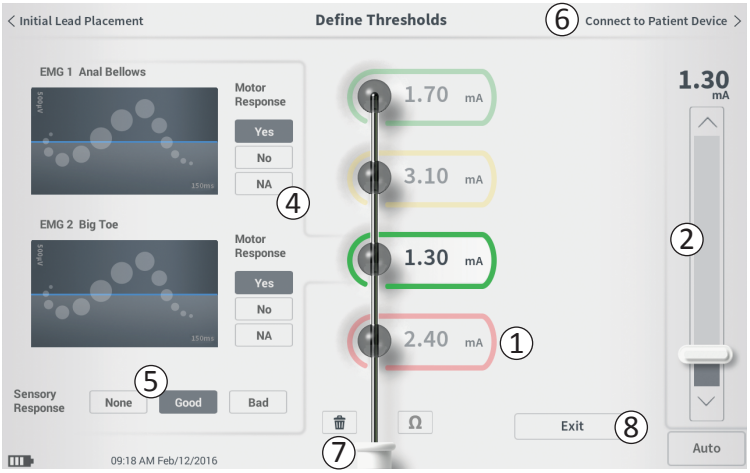


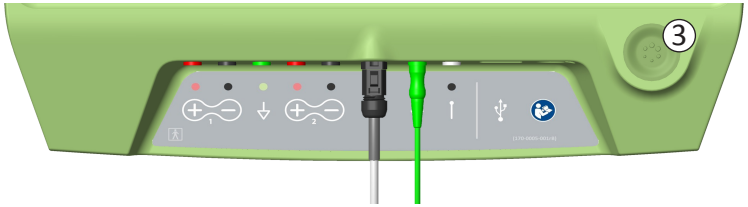
To explore the response to stimulation with one electrode:

- Select the electrode by pressing the electrode on the screen. The top electrode on the **CP** screen represents the electrode nearest to the tip of the lead. The rectangle around the selected electrode will not be faded (1).
- Adjust the stimulation amplitude (2). Press the stimulation button to stimulate (3). (See manual section *Controlling Stimulation Amplitude* for more information).
- The stimulation amplitude will be displayed next to the electrode. For each electrode, the threshold saved is the last amplitude used to deliver stimulation.
- Manually record the motor (4) and sensory (5) responses to stimulation by pressing the appropriate buttons.
- Select a new electrode to stimulate or move on to connect to a Neurostimulator (6).

Note: Only stimulation amplitude is adjustable during test stimulation. The stimulation frequency is 14 Hz, and the pulse width is 210µs.

Note: Press the impedance button to check the connection with the tined lead. If the impedance for any electrode(s) is “Bad”, adjust the tined lead connection and the ground pad, then recheck the impedance. See manual section *Understanding Impedance Values* for more information about the qualitative impedance indicators.





Manually recording the motor and sensory responses

Motor and sensory responses associated with stimulation at each electrode can be manually recorded.

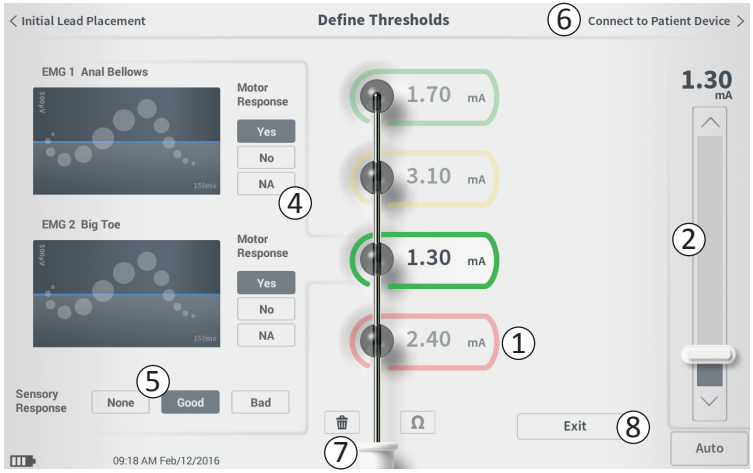
Entering the motor and sensory responses is optional. For example, if the patient is not awake during the implant procedure, the sensory response can be left as “None.”

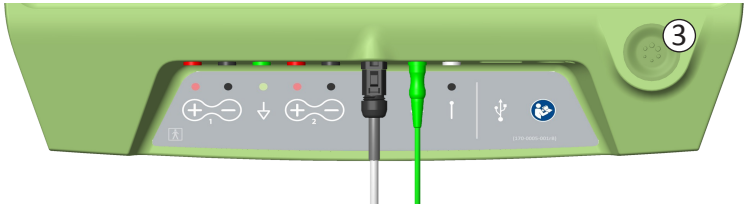
If saved, the response data and stimulation thresholds are displayed when communicating with a Neurostimulator. This data can be used to inform which stimulation settings to use for therapy, and the CP will provide recommended electrode configurations based on this information. For example, if the stimulation with a particular electrode elicited a “bad” sensation, that electrode will not be included in recommended electrode configurations.

Clear All Thresholds

The ‘Clear All’ button 🗑 (⑦) - appears once a threshold value has been obtained (at the first test stimulation).

Pressing this button will clear established thresholds on all electrodes and allows this process to be started over. This option may be useful if the tined lead is repositioned, for example.





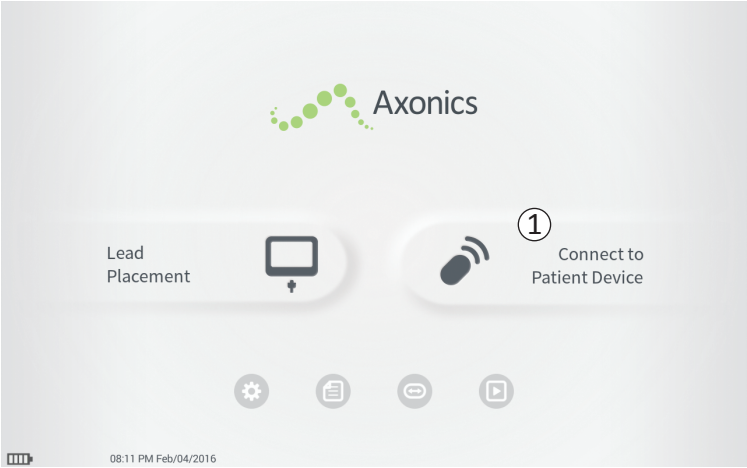
Connect to Patient Device

After thresholds are established for each electrode, there are two options:

Press “Connect to Patient Device” (⑥) to connect to a Neurostimulator if the Neurostimulator will be implanted during the same procedure.

Press “Exit” (⑧) to exit the **Lead Placement** module and return to the **Home** screen.

Note: Threshold data will be lost if the “Exit” button is used. To transfer thresholds, use “Connect to Patient Device” and connect to a Neurostimulator.



The CP can connect to a patient's implanted Axonics Neurostimulator (Model 1101) to check the status of the device and program the device. This section explains how to:

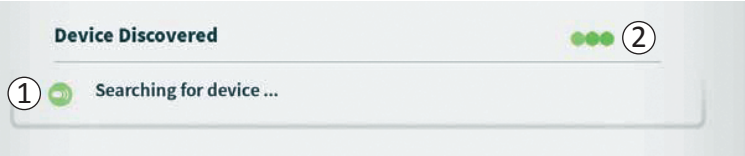
- Connect to a Neurostimulator
- Set-up a new Neurostimulator
- View Neurostimulator status
- Program a Neurostimulator's stimulation settings

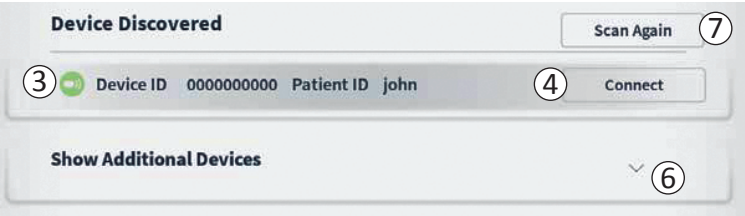
Connect to a Neurostimulator

There are two ways to access the **CP** screen that connects to a Neurostimulator:

From the **Home** screen, press "Connect to Patient Device" (1).

After implanting a tined lead, press "Connect to Patient Device" on the **Define Thresholds** screen.





The CP will automatically search for the nearest Neurostimulator (①). A scrolling search icon will appear when the CP is searching for Neurostimulators (②).

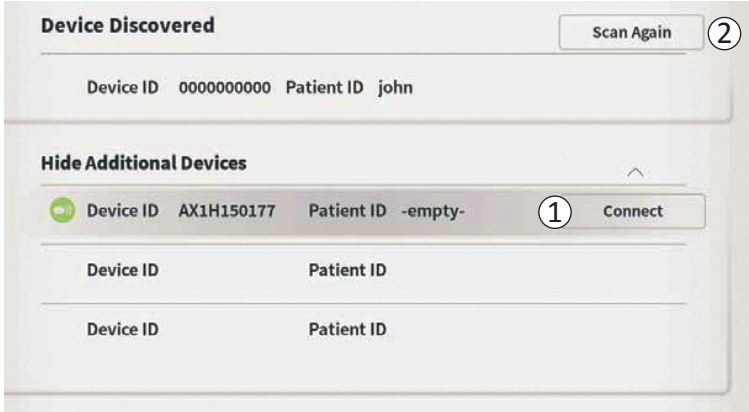
The CP will display the nearest patient device (③). Check the Device ID and the Patient ID to determine if this is the correct device. New devices will not have Patient IDs.

Press “Connect”(④) to connect to the displayed device.

The CP will display a prompt while it connects to and retrieves data from the Neurostimulator (⑤). When connected to the device, the CP will automatically open the **Patient Device** screen.

Additional devices can be displayed by the CP if the first device found is not the targeted Neurostimulator. Press the down arrow next to “Show Additional Devices” (⑥). This will display up to 3 additional devices found in proximity of the CP.

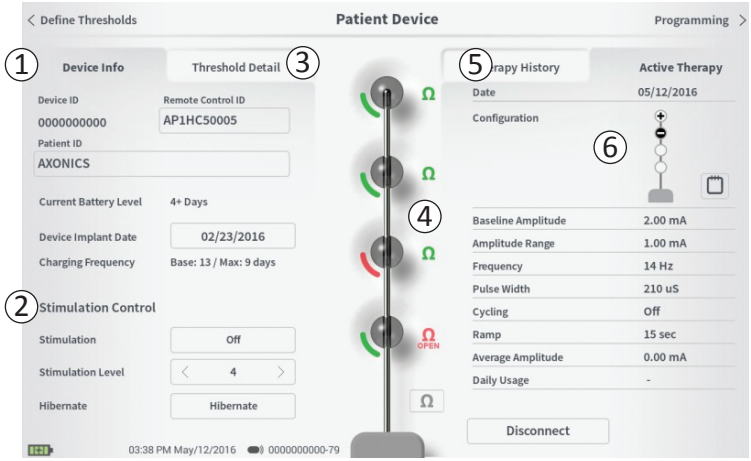
Note: Hold the CP within 1 meter (~ 3 feet) of the targeted device to find the device. If the desired device is not found, move closer and search again by pressing “Scan Again” (⑦).



To connect to one of the “Additional Devices”, press the device name to select a device. Press “Connect” when it appears to the right of the Patient ID (①) to connect to the device. The CP will display a prompt with a progress indicator as it connects to the patient device. The CP will automatically open the **Patient Device** screen when connected to the selected device.

Note: The list of available devices can be updated by pressing the “Scan Again” button (②). Move closer to the targeted device to increase the likelihood that the CP finds the device.

Patient Device Screen Overview



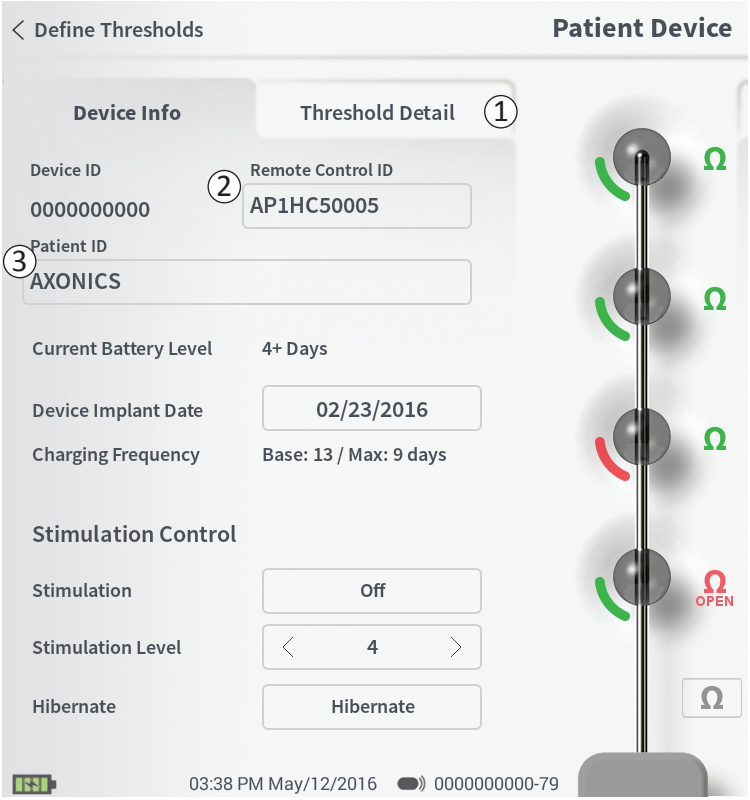
The **Patient Device** screen will be displayed when the CP connects to a Neurostimulator. The **Patient Device** screen is used to:

- Set up new Neurostimulators
- Check the status of Neurostimulators

The following information and functions are available on the **Patient Device** screen:

① Basic device information
② Stimulation control module
③ Threshold detail
④ Electrode impedances
⑤ Therapy History
⑥ Current stimulation settings

The following sections provide further detail on the information and functions available on the **Patient Device** screen.



There are several steps to set up a new Neurostimulator.

A. A prompt will appear when a new Neurostimulator is connected after a lead implant, asking for permission to transfer threshold data that was recorded during the tined lead placement procedure. A summary of the threshold data will then be saved to the device for reference during programming sessions. This threshold data summary can be viewed in the “Threshold Detail” tab of the **Patient Device** screen (1).

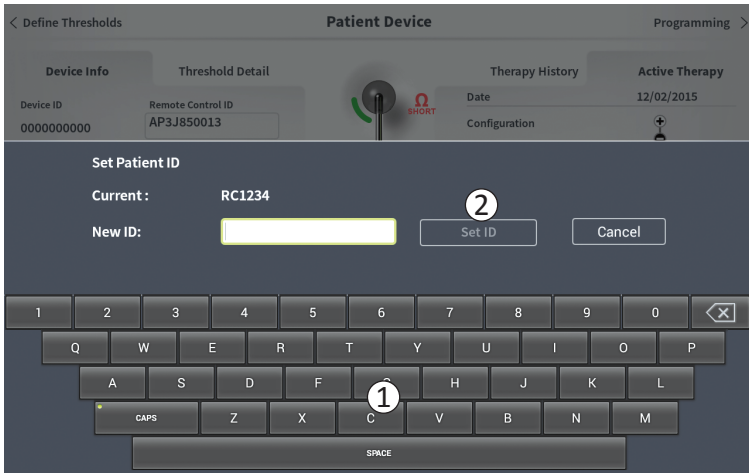
B. Input the serial number of the patient’s Remote Control in the Remote Control ID field (2). This pairs the Remote Control to the Neurostimulator, allowing the Neurostimulator to receive commands from the Remote Control.

Note: The Neurostimulator can only communicate with the Remote Control that is entered in this field.

C. Enter the patient identifier associated with this device into the Patient ID field (3).

D. Enter the date of the Neurostimulator implant procedure in the Device Implant Date field.

These fields, including the Patient ID and the Remote Control serial number can be updated at any time as needed.



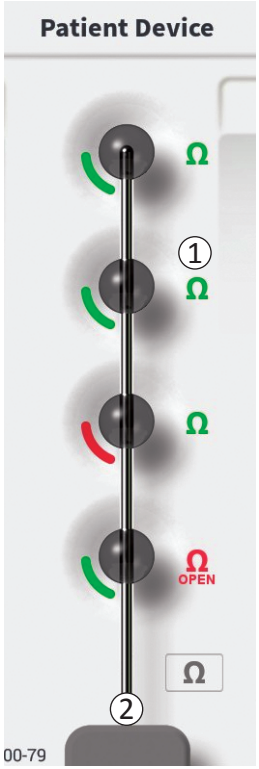
Entering Device Information

To edit one of the fields in the *Device Info* section:

- Press the corresponding box.
- A keyboard will pop-up on the lower part of the screen (①).
- Enter the desired information.
  - The Patient ID must be a minimum of 4 characters.

  Note: In order to limit data security risks, do not use the patient's name as the Patient ID.

  - The Remote Control ID must be the 10 character alpha-numeric serial number of the Remote Control being paired to the Neurostimulator.
- Press "Set ID" (②) to save the input ID (keyboard will disappear).



Checking the tined lead connection

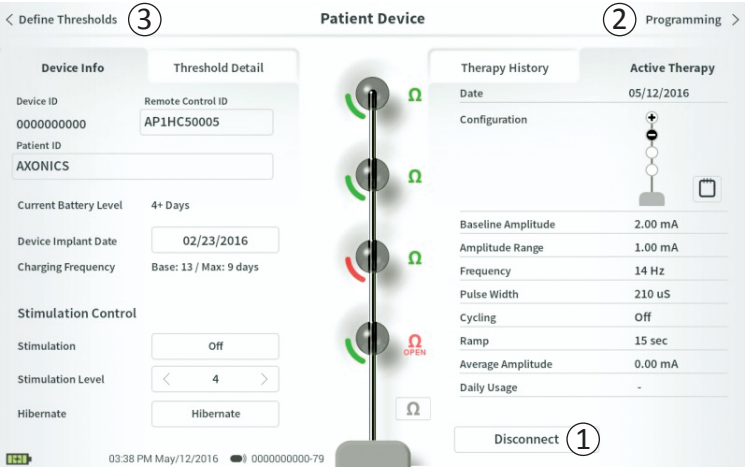
An icon showing the impedance status of each electrode is shown to the right of the graphic representation of each electrode (①). See manual section *Understanding Impedance Values* for more information about the qualitative impedance indicators.

The CP automatically checks impedance when it first connects to the Neurostimulator. To check the impedances again, press the impedance button: Ω (②).

Impedances may change from green to yellow as fibrous tissue encapsulates the electrodes. This change will not affect a patient's therapy because the current-controlled Neurostimulator automatically compensates for impedance changes. However, such changes may require the Neurostimulator to be recharged more frequently.

Impedance changes from green or yellow to red may indicate an open circuit, which may be caused by a tined lead fracture or other problem with the device.

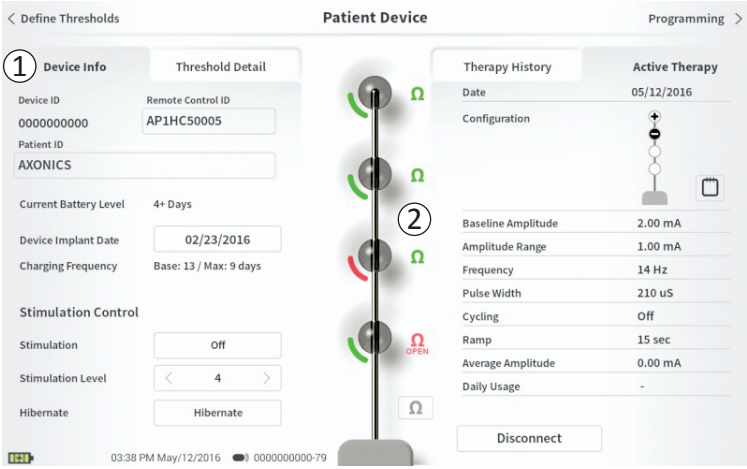
Note: If any impedances are red during Neurostimulator implantation, reconnect the tined lead. Ensure the white marker near the proximal end of the tined lead is seated within the Neurostimulator header.



Completing Set-Up

When set up is complete, the **Patient Device** screen is exited by:

- Pressing “Disconnect” (①) to end the connection with the Neurostimulator and return to the **Home** screen.
- Pressing “Programming” (②) to proceed to set the Neurostimulator stimulation settings.
- Pressing the “Define Thresholds” (③) to redefine the stimulation thresholds for each electrode.



The **Patient Device** screen for a Neurostimulator that has already been set-up and programmed will include the following information about the status of the device:

Device information (①): This section includes basic information about the Neurostimulator, including patient ID, Remote Control ID, and Implant Date. It also contains an estimate of how often the Neurostimulator needs to be charged at the current stimulation settings. Next to "Charging Frequency" the CP displays the expected charge frequency when stimulation is delivered at the programmed (or "base") amplitude and when stimulation is delivered at the maximum amplitude (or "max"). This information should be provided to the patient when their device is programmed.

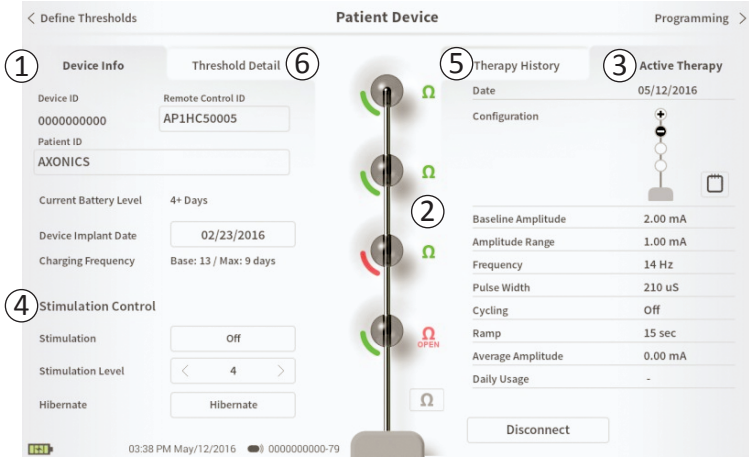
Note: If a patient reports that their Neurostimulator battery is lasting <50% of the displayed "Charging Frequency", the Neurostimulator may have exceeded its useful life and may need to be replaced.

Note: When a Neurostimulator has been implanted for 15 years, replacement should be considered.

Lead impedances (②): An icon showing the impedance status of each electrode is shown to the right of each electrode. See manual section *Understanding Impedance Values* for more information about the qualitative impedance indicators.

The CP automatically checks impedance when it connects to the Neurostimulator. To check the impedances again, press the impedance button: Ω .

For more information on lead impedances, see *Checking the Tined Lead Connection* in manual section Setting up a New Neurostimulator.



Active Therapy (③): This area shows the current stimulation settings for the therapy programmed to the Neurostimulator.

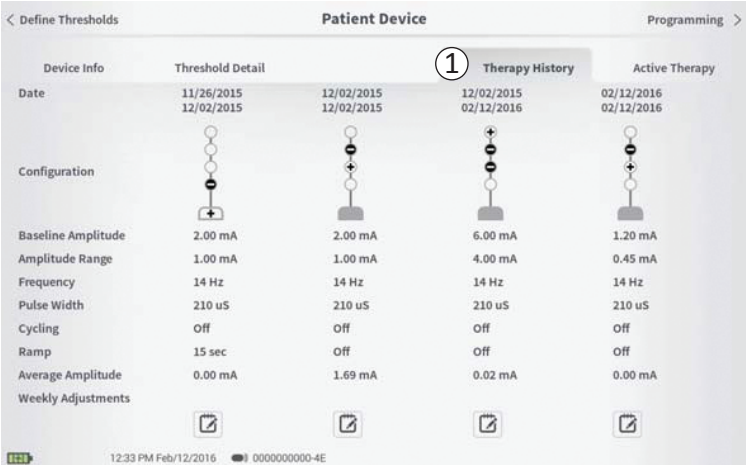
Additionally, the active stimulation settings can be adjusted in the **Stimulation Control Module** (④). This area is intended for basic adjustments to the stimulation being delivered. It is not intended for reprogramming.

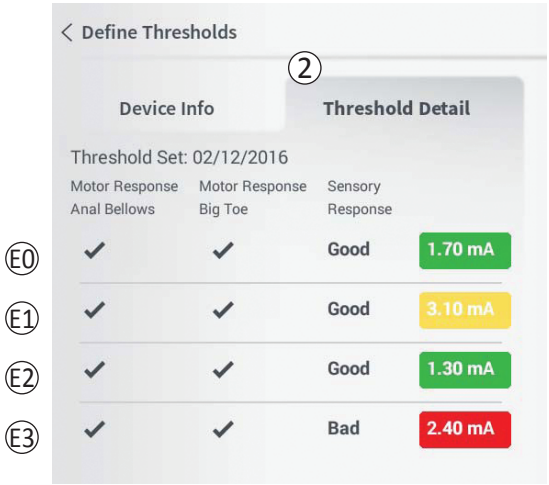
Controls in this module include:

- "Stimulation Level": Increase or decrease the stimulation level. This allows control of the stimulation level as the patient would with their patient Remote Control. Possible levels range from 1-7.
- "Stimulation": Turn stimulation on or off. If stimulation is turned on, it will come on at the stimulation level shown below the "Stimulation" button.
- "Hibernate": Put the device in *"Hibernate Mode."*

Note: The CP, including this button, cannot be used to bring a device out of Hibernate Mode. For more information see the following manual section on Hibernate Mode.

Additional information can be accessed via the "Therapy History" (⑤) and "Threshold Detail" (⑥) tabs on the **Patient Device** screen.



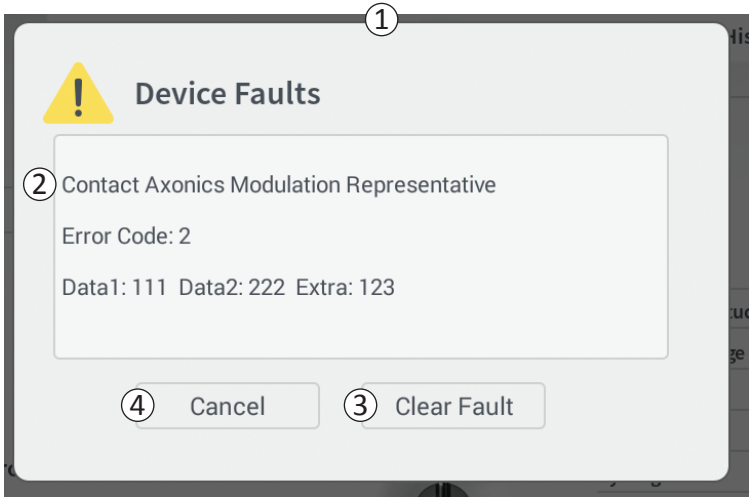


Therapy History tab (①)

This tab shows the stimulation settings saved to the Neurostimulator in the previous 4 programming sessions. For each set of stimulation settings, additional information is provided including the time period the settings were used and notes entered during the programming session.

Threshold Detail tab (②)

This tab summarizes the stimulation threshold data previously captured. For each electrode, the tab shows the motor response, sensory response, and threshold stimulation amplitude recorded during the tined lead implantation procedure or during a programming session. The color around the threshold amplitude indicates the qualitative assessment of the electrode placement (Red = “Poor”, Yellow = “OK”, Green = “Good”).

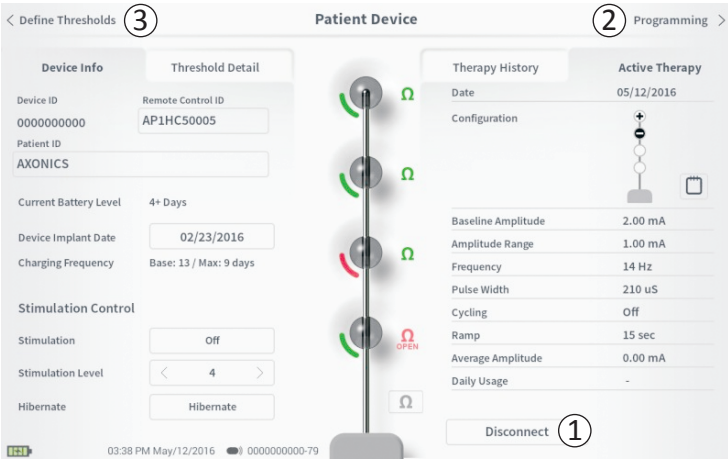


Neurostimulator Errors

If a Neurostimulator error is present, a “Query Fault” button will appear to the right of the “Disconnect” button in the lower right corner of the **Patient Device** screen.

When the “Query Fault” button is pressed, a pop-up will appear (①) with a description of the error (②). To resume the communication session and try to resolve the error with reprogramming, press “Clear Fault” (③) to remove the error notification from the Neurostimulator. If additional errors exist, the pop-up will display information about the next error, which will also need to be cleared.

Press “Cancel” to exit the pop-up (④). If the pop-up is exited without clearing the errors, the ability to program the Neurostimulator may be impaired.



Disconnecting

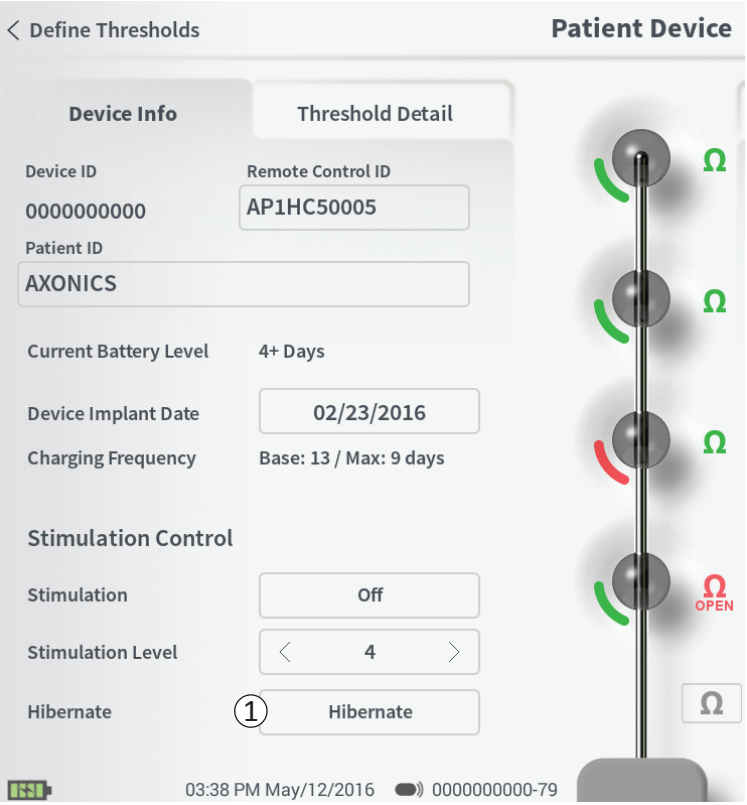
To disconnect from the Neurostimulator, press “Disconnect” in the lower right (①).

Proceed to Neurostimulator Programming

From the **Patient Device** screen, navigate to additional screens to:

- Program the stimulation settings to the Neurostimulator (②).
- Record new stimulation thresholds for each electrode (③).

Hibernate Mode



The Neurostimulator can be put into Hibernate Mode if there is a need to not deliver stimulation for a prolonged period of time (e.g., months). For example, if a patient becomes pregnant and needs to discontinue stimulation during the pregnancy, put the device in Hibernate Mode. Hibernate Mode puts the Neurostimulator in a power- conserving state to preserve the battery of the Neurostimulator.

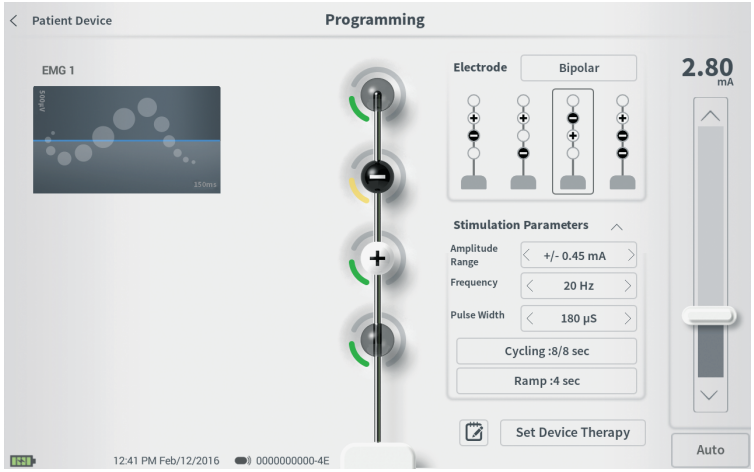
The patient does not need to periodically charge the Neurostimulator when it is in Hibernate Mode.

Note: Make sure the Neurostimulator battery has a full charge when it is put in Hibernate Mode. If the battery is not full, charge the Neurostimulator before putting it in Hibernate Mode. This will ensure the battery is preserved for long periods in Hibernate Mode.

How to put the Neurostimulator into Hibernate Mode: Press the “Hibernate” button (1). A prompt will ask for confirmation before putting the Neurostimulator into Hibernate Mode. The Neurostimulator will automatically disconnect from the CP and the CP will return to the **Home** screen when the Neurostimulator is in Hibernate Mode.

Note: The CP and patient Remote Control will not be able to communicate with the Neurostimulator when it is in Hibernate Mode.

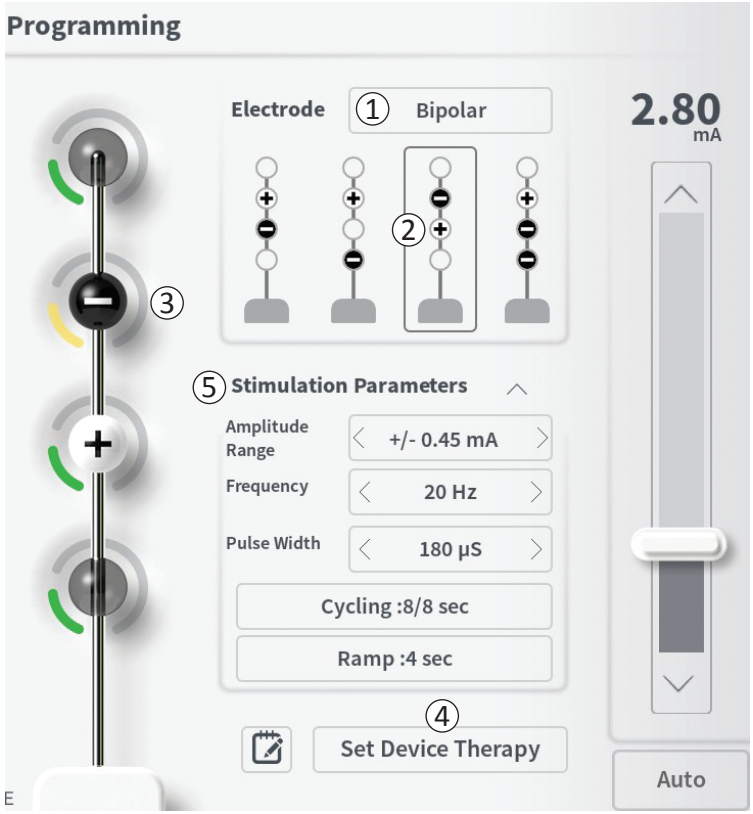
How to wake up the Neurostimulator from Hibernate Mode: Place the Charger over the Neurostimulator to wake the device from Hibernate Mode. The Charger may not provide the normal feedback for aligning the Charger with the Neurostimulator, and it may take several minutes for the Neurostimulator to wake up. Check to see if the Neurostimulator is awake by trying to connect with the CP or the paired Remote Control.



To program the stimulation settings of the Neurostimulator, first:

- Connect to the Neurostimulator (see manual section Connecting to a Neurostimulator).
- Navigate to the **Programming** screen from the **Patient Device** screen by pressing “Programming” in the top right corner of the **Patient Device** screen.

The **Programming** screen enables adjustment of the stimulation parameters and delivery of test stimulation. Additional features include the ability to capture programming session notes.



Electrode Configuration

The CP provides the ability to switch between monopolar and bipolar stimulation modes, to use automatically generated recommended electrode configurations, and to manually set which electrodes are active and inactive during stimulation.

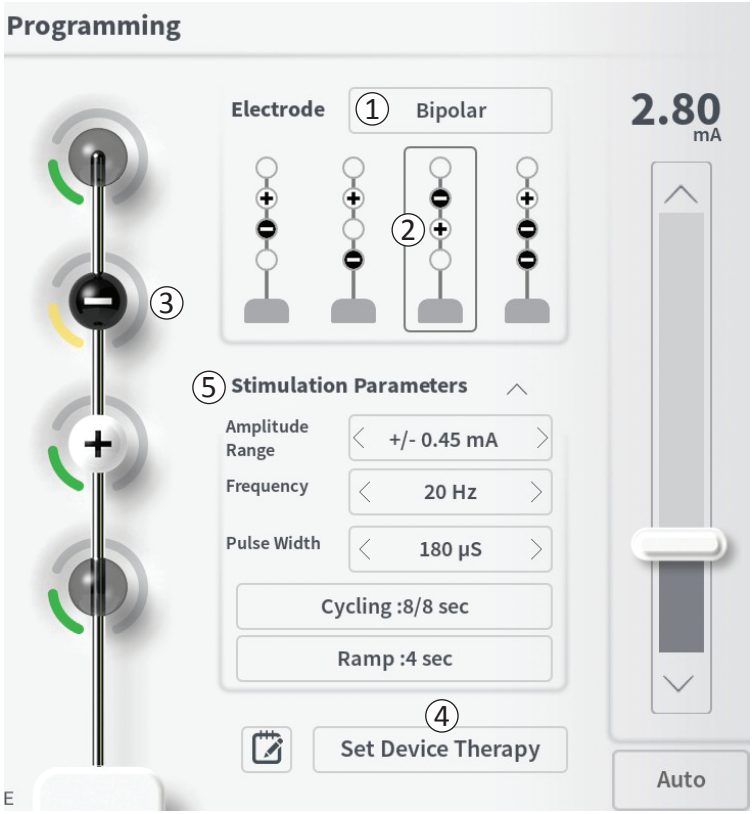
Monopolar vs Bipolar Stimulation

The **Programming** screen allows the electrode configuration to be set to be “Monopolar” or “Bipolar” (①). If “Monopolar” is selected, the Neurostimulator is set as the anode and tined lead electrodes can only be assigned as cathodes. If “Bipolar” is selected, a tined lead electrode must be selected as an anode to deliver stimulation.

Electrode Recommendations

The **Programming** screen displays up to four recommended electrode configurations (②). These recommendations are intended to provide directional guidance regarding which electrode configurations to test. The recommendations are generated based on the stimulation thresholds and motor and sensory responses recorded during tined lead placement or subsequent redefining of the thresholds. Ultimately, electrode configuration selection should be based on patient comfort and symptom reduction. To set the electrode configuration to a recommended configuration, press the image of the recommendation.

Note: If thresholds are not saved to the Neurostimulator, no electrode recommendations are provided.



Manually changing electrode configuration

The electrode configuration can be manually set by pressing the electrode representations (③) to toggle each electrode between its possible states. There are 3 possible electrode states:

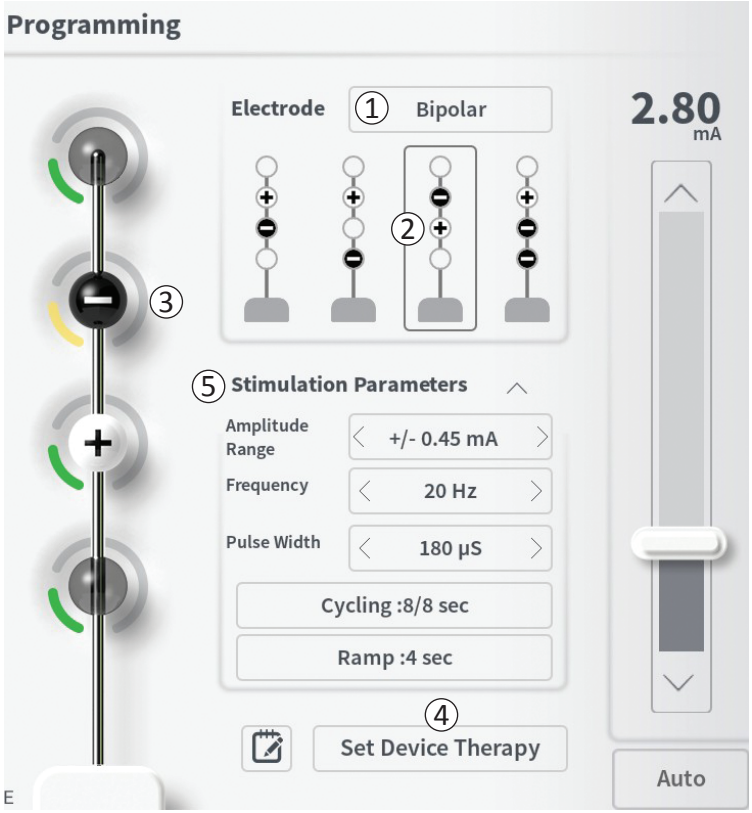
Cathode (or “-”)

Anode (or “+”)

Unassigned

If the electrode configuration is in “Monopolar” mode, the Neurostimulator is set as the anode (“+”) and the electrodes can be toggled between cathode (“-”) and unassigned.

Note: When manually adjusting electrode assignment, invalid configurations may be created. An alert will pop up if an attempt is made to exit this screen, stimulate, or set the therapy settings (④) with an invalid electrode configuration selected.



Typical invalid electrode configurations include:

- More than 2 cathodes
- 2 cathodes that are not adjacent electrodes
- More than 1 anode

Adjusting parameters

Several adjustable stimulation parameters are shown in the "Stimulation Parameters" box (5).

To adjust frequency, amplitude range, and pulse width:

- Press the left and right arrows to the sides of the current value to incrementally decrease and increase the parameter.

Frequency

- The stimulation frequency can be adjusted from 2-130 Hz. Adjustments are made in 1 Hz increments from 2-50 Hz and 5 Hz increments from 50-130 Hz.

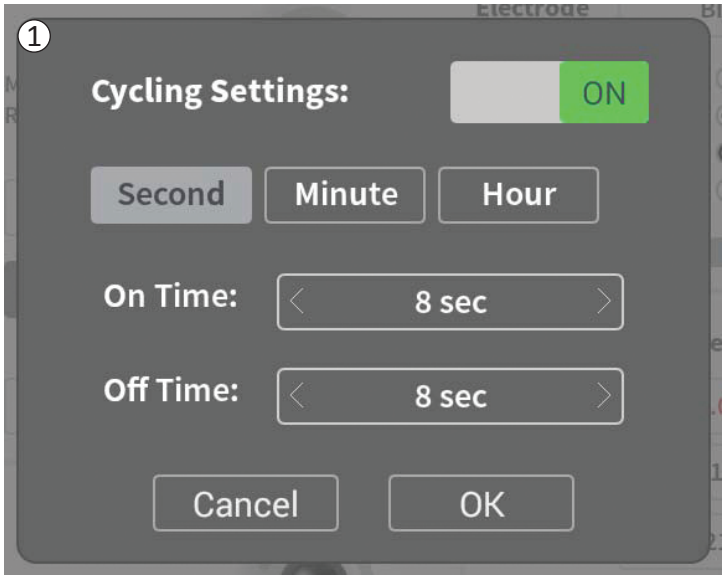
Amplitude Range

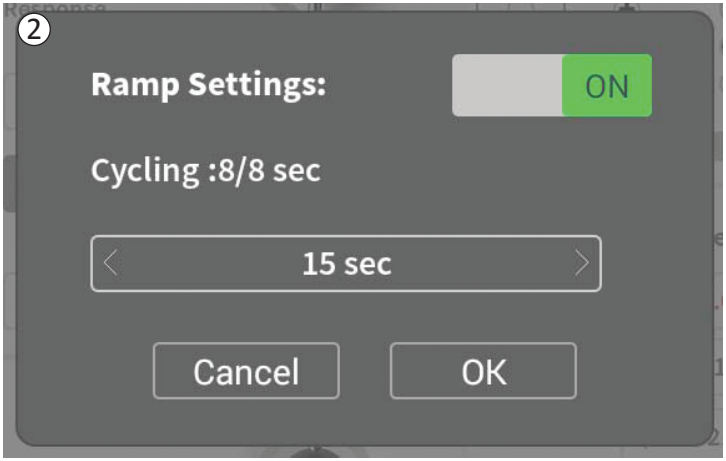
- The baseline stimulation level is set by the stimulation level slider. When therapy is saved to the Neurostimulator, the stimulation amplitude shown will be the default stimulation amplitude.

- The amplitude range sets the highest and lowest stimulation level that the patient can reach using the Remote Control. Use the arrows to the left and right of the Amplitude Range value to adjust it lower or higher.

Note: The amplitude range must be set when programming the Neurostimulator. The Remote Control allows for 3 steps to increase from the baseline stimulation amplitude to the maximum amplitude (defined as the baseline amplitude plus the Amplitude Range). Test the stimulation range from the desired amplitude to the maximum amplitude to ensure it is comfortable for the patient.

- Pulse width can be set between 60 and 450 µs, adjustable in 10 µs increments.





To adjust cycling and ramping:

- Cycling and ramping settings are active when settings have been set to the Neurostimulator.

Note: The cycling and ramping settings are not active during test stimulation. To test cycling and ramping, save the stimulation settings to the Neurostimulator by pressing "Set Device Therapy".

- Press the button for the parameter and a pop-up will appear for adjusting the setting.

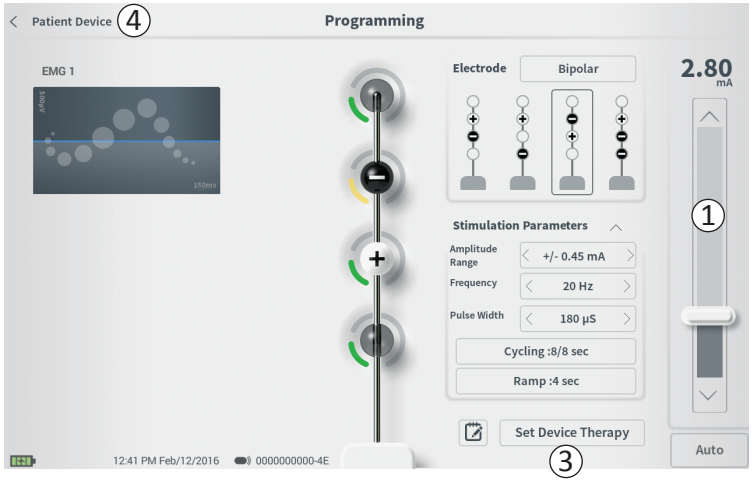
Cycling

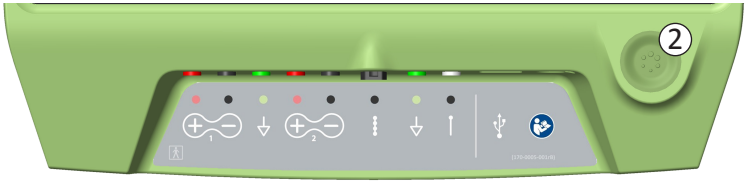
- Allows stimulation to turn on and off automatically at specified intervals.
- The time that stimulation is on and off are independently programmed.
- On and off time can be programmed from 0 (off) to 59 seconds, 1 minute to 59 minutes, and 1 hour to 24 hours.

Note: Cycling time can only be programmed to values longer than Ramping time.

Ramping

- Allows stimulation to ramp up and down between zero amplitude and the targeted stimulation amplitude when stimulation turns on and off.
- Ramping time can be programmed at "Off", 1, 2, 4, 8, 15, or 30 seconds.





Delivering test stimulation

To deliver test stimulation, set the desired stimulation amplitude on the stimulation bar (①) (see manual section *Controlling Stimulation Amplitude* for more information). Then press the stimulation button to deliver stimulation (②). The stimulation button will light up when Stimulation is on.

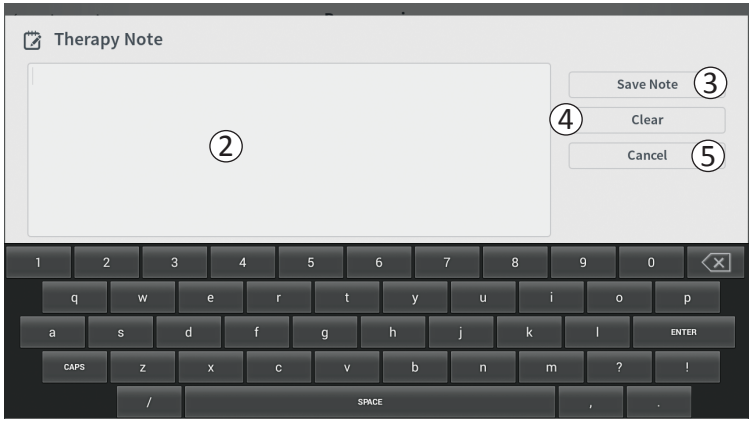
When stimulation is on, the electrode configuration, cycling settings, ramp settings, frequency, and pulse width cannot be changed. Incremental changes can be made to the stimulation amplitude.

Save Therapy

After therapy settings have been configured, press “Set Device Therapy” (③) to save the settings to the Neurostimulator.

To exit, press “Patient Device” to return to the **Patient Device** screen (④).

Note: If “Set Device Therapy” is not pressed prior to exiting, the Neurostimulator settings will revert back to last saved settings when the **Programming** screen is exited. When the **Programming** screen is exited, a prompt will appear requesting confirmation to exit without saving the therapy settings.



Adding Notes

Notes can be added that will be saved when the new stimulation settings are saved. To add a note, press the note icon (①) that is to the left of the "Set Device Therapy" button. This will open the **Therapy Note** screen.

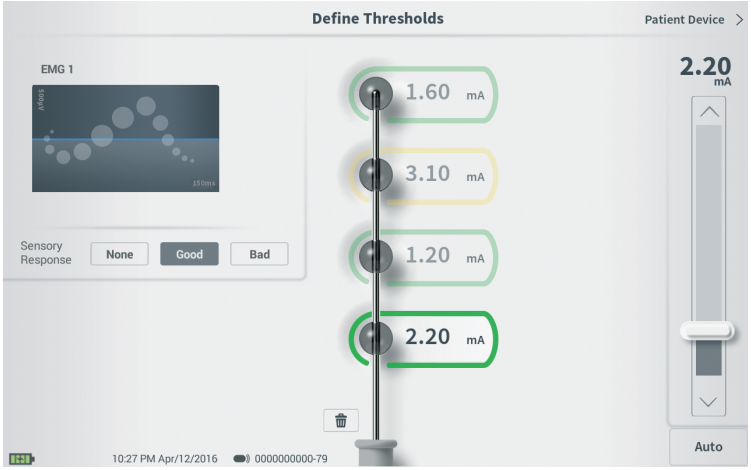
On the **Therapy Note** screen, press the text field (②) to type notes. After entering notes, press "Save Note" to exit and save the note (③) . To delete the note and start over, press "Clear" (④).

Note: The notes section is limited to 300 characters.

To exit without saving the note, press "Cancel" to return to the **Programming** screen (⑤).

Saved notes can be viewed by pressing the notes icon in the "Therapy History" tab on the **Patient Device** screen.

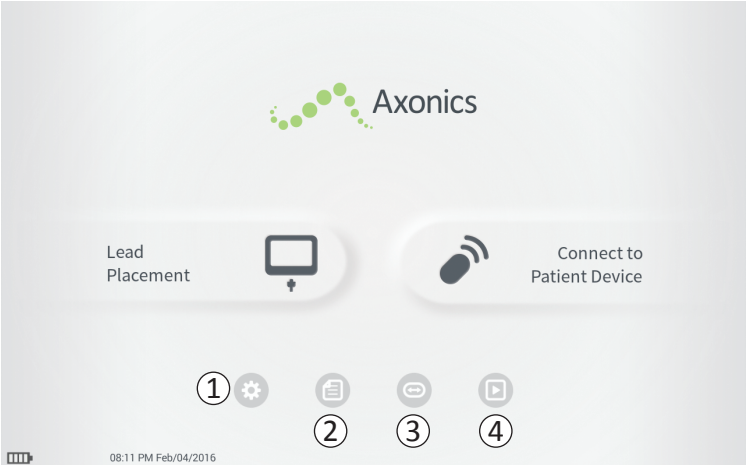
Updating Stimulation Thresholds



The thresholds saved to the Neurostimulator can be updated in the **Define Thresholds** screen. The screen displays the currently saved threshold data until test stimulation is delivered to set new thresholds. For more information on setting thresholds, see *Define Tined Lead Thresholds* in the *Test Stimulation During Lead Implantation* section of this manual.

A prompt will appear when the **Define Thresholds** screen is exited if the thresholds were changed. The new thresholds can be saved and used to generate new electrode recommendations, or the new thresholds can be cancelled and the thresholds will reset to the previous values.

HOME SCREEN TOOLS



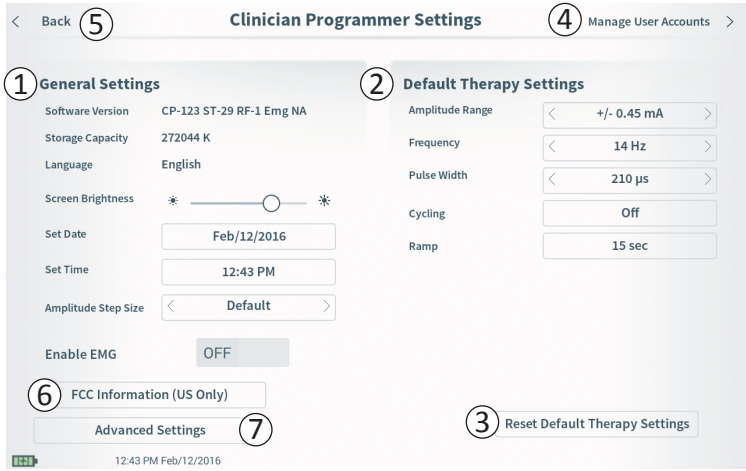
The **Home** screen will appear after successful log-in to the CP or after exiting any CP function (e.g., "Lead Placement"). The **Home** screen provides access to tools to assist in data management and the use of the CP, including:

① **General CP Settings** - Change general CP settings, including default stimulation settings.

User Account Management – Add, modify, or delete user accounts (accessed through the General CP Settings button).

Additional information about each of these functions is included in the following sections of this manual.

②,③,④ These buttons are for use by the Manufacturer only.



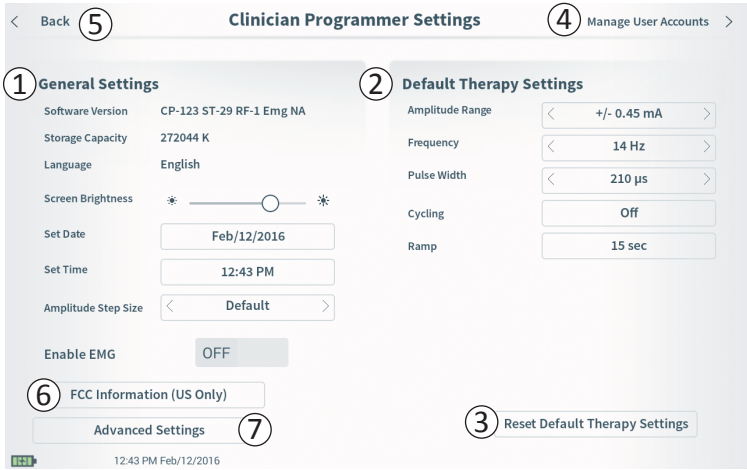
① **General Settings**
The General Settings includes basic CP information and adjustable settings like the time and date displayed by the CP.

② **Default Therapy Settings**
The “Default Therapy Settings” are the stimulation settings that are pre-set on the **Programming** screen when you connect to a new Neurostimulator. Changes to the default therapy parameters allow the CP user to start the programming session for all new Neurostimulators at their most frequently used or preferred stimulation settings.

③ **Reset Default Therapy Settings**
The “Reset Default Therapy Settings” button returns all “Default Therapy Settings” to their original factory values. The CP will provide a prompt for confirmation to restore default settings.

④ **Navigate to Manage User Accounts**
Press “Manage User Accounts” to access the **User Account** screen where user account can be added, modified, and deleted.

⑤ **Home**
Press “Back” to return to the **Home** screen. Any changes to the **General Settings** will be saved when returning to the **Home** screen.

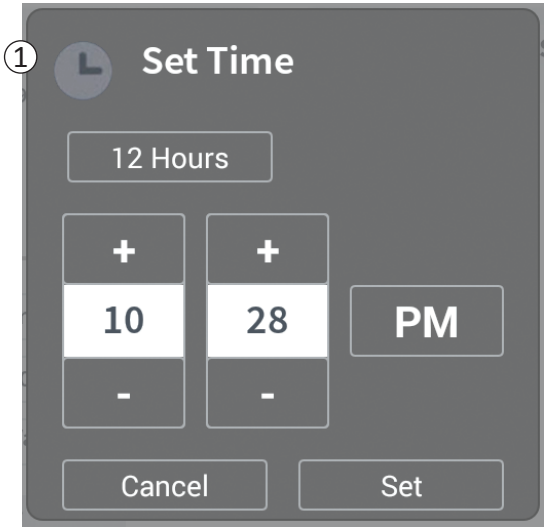


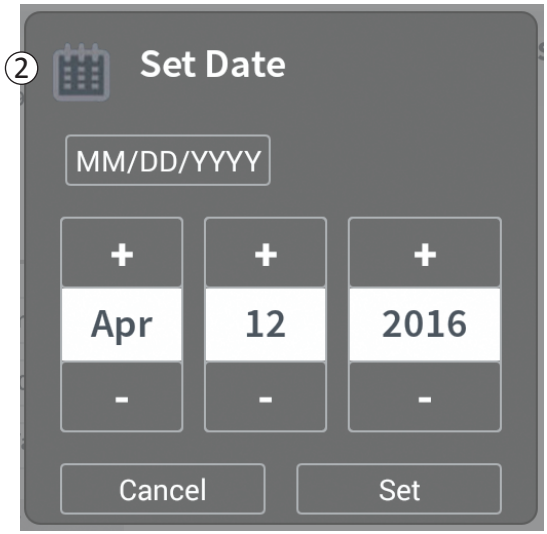
⑥ **FCC Information**

Press this button to see the FCC required information about the wireless communication of this device. This information is also included in this manual in the section *Wireless Communication*.

⑦ **Advanced Settings**

These settings are for manufacturer use only.





① **Set Time**

- Change hour, minute, and time formatting between 12- hour and 24-hour.
- Press 'Set' to confirm and return to **CP Settings** screen.
- Press 'Cancel' to return to **CP Settings** screen without saving changes.

② **Set Date**

- Set month, day, year, and date formatting.
- Press 'Set' to confirm and return to **CP Settings** screen.
- Press 'Cancel' to return to **CP Settings** screen without saving changes.

Multiple functions can be accessed on the **User Account Management** screen, including:

Adding a new user

- Press “Add new User” to add a new user (①).
- Enter the user name of the new user on the keyboard that appears. Press OK.
- Enter a 4-digit passcode for the new user. Press OK.

Deleting a user

- Press the delete icon to the right of a user name to delete that user account (②).
- Enter the 4-digit passcode for the user name to delete in the pop-up window that appears.
- Press “Delete User” in the pop-up window.

Changing a User Passcode

- Press “Change Passcode” to next to the user name (③).
- Enter the current 4-digit passcode for that user name in the pop-up window that appears.
- Enter a new 4-digit passcode for that user. Re-enter to confirm the new passcode.
- Press “Ok” to finalize.

Issues with the CP Display

Issue	Presentation	Resolution
CP does not turn on	CP does not power up, including no light behind power button	• Charge the CP then attempt to turn on the CP. • If the CP still does not turn on, contact Axonics.
	CP power button lights up but **CP** screen is blank	• Turn the CP off by holding the power button, then turn the CP back on. • If the screen still does not display, contact Axonics.
The **CP** touchscreen is unresponsive	CP display is on but does not respond to touch.	• Turn the CP off by holding the power button, then turn the CP back on. • If the screen still does not respond to touch, contact Axonics.
CP screen fails during use	CP display turns blank during use	• Check the CP power light to see if the CP is no longer on. • If the CP is still on, turn the CP off then back on. • If the CP power light is off, charge the CP because the battery may have died. (A message should have displayed about the low battery). After a period of charging, try to turn on the CP. • If the screen still does not display or continues to turn off during use, contact Axonics.

Issues Communicating with a Neurostimulator

Issue	Presentation	Resolution
CP cannot find Neurostimulator	Neurostimulator does not appear in list of devices in the **Connect to Patient Device** screen	• Move closer to the Neurostimulator and hit the “Scan Again” button on the screen to search again. • If the CP cannot find the Neurostimulator when close to the implant site, verify with the patient’s Remote Control (if one has been paired) that the Neurostimulator has battery life and that there is not an error (red light on Remote Control). • If the paired Remote Control also does not connect to the Neurostimulator, charge the Neurostimulator. • If a Remote Control has not been paired, try charging the Neurostimulator • After charging, retry connecting to the Neurostimulator. • If the error light of the paired Remote Control is on or the CP still cannot connect to the Neurostimulator, contact Axonics
Communication with a Neurostimulator is interrupted or lost	Error prompt appears stating that communication with Neurostimulator has been lost. If communication is not re-established, CP will return to **Connect to Patient Device** screen	• Move closer to the Neurostimulator and hit the “Scan Again” button on the screen to search again. • If the CP cannot find the Neurostimulator when close to the implant site, verify with the patient’s Remote Control (if one has been paired) that the Neurostimulator has battery life and that there is not an error (red light on Remote Control). • If the paired Remote Control also does not connect to the Neurostimulator, charge the Neurostimulator. • If a Remote Control has not been paired, try charging the Neurostimulator • After charging, retry connecting to the Neurostimulator. • If the Remote Control error light is on or the CP still cannot connect to the Neurostimulator, contact Axonics.

Issues Delivering Stimulation

Issue	Presentation	Resolution
Stimulation is not being delivered during lead implant procedure	No motor or sensory responses are observed during test stimulation	• If there are no blue bars in the stimulation bar when stimulation is on, there is an issue with the connection. • Check the impedance using the CP. • Confirm the device cables are connected correctly. Replace the cables if impedance is bad when the cables are correctly connected. • If stimulation appears to be on, adjust the needle or lead and stimulation amplitude until a motor or sensory response is observed
Stimulation is not being delivered during Neurostimulator programming	The patient does not report any sensation of stimulation or symptom relief	• Check the lead impedance on the **Patient Device** screen. If there is an impedance issue with the active electrode(s), reprogram the device to only use electrodes with acceptable impedance. • If there is still an issue, confirm that the CP is communicating with the correct Neurostimulator. Try disconnecting and reconnecting the CP to the Neurostimulator.
Lack of or change in stimulation sensation	Patients may report they are not feeling stimulation or the sensation (intensity or location) of stimulation has changed	• If the stimulation sensation is associated with a lack of symptom benefit, the following steps can be taken to assess and troubleshoot the patient's therapy: 1. Check if stimulation is turned on. a. This check can be accomplished by connecting the Clinician Programmer or patient Remote Control to the stimulator. 2. Check the electrode impedances to determine if there is a connection issue (e.g., lead fracture or short). a. A solid red light on the patient Remote Control may indicate a connection (impedance) issue. b. Connecting the stimulator to the Clinician Programmer provides access to detailed impedance data and further information if a device issue is present.

Continued on next page

Issues Delivering Stimulation

Issue	Presentation	Resolution
		Continued from previous page 3. If stimulation is not being felt, increase stimulation amplitude to determine if the desired stimulation response can be achieved. a. If the desired stimulation response cannot be achieved at an amplitude below 4mA, try reprogramming to an alternative electrode configuration. 4. **Note:** Check the delivered stimulation current (blue value above the stimulation bar when stimulation is on) and compare it to the programmed current (grey value above the stimulation bar when stimulation is off). The delivered current may be at its maximum if it is below the programmed current. Increasing the programmed current will not increase the delivered current. See Stimulation Output Ranges in the Controlling Stimulation Amplitude section of the manual for more information on the achievable stimulation current. 5. **Note:** Selecting an electrode configuration with a lower impedance value may allow for greater stimulation current to be delivered. 6. **Note:** If the stimulation amplitude is high (>4mA), selecting another electrode configuration may provide adequate therapy at a lower amplitude. 7. If the above checks and reprogramming do not result in adequate stimulation being delivered, the clinician should consider and investigate other potential causes for the loss or change in stimulation, including but not limited to: lead migration, sub-optimal lead placement, or other factors. 8. A discussion with the patient about when and how stimulation changed may provide insights into the potential issue (e.g., was the change sudden? was it associated with any trauma or impact such as a fall?)

Impedance Issue During Lead Implant

Issue	Presentation	Resolution
Out of range impedance during lead implant procedure	Red impedance icon shows on the **Foramen Needle Placement** screen when impedance is checked for the foramen needle connection.	• Check that the ground pad cable is fully inserted into the CP and the ground pad is firmly attached to the patient. • Check that the clip end of the test stimulation cable is connected to the non-insulated portion of the needle (just below the hub and above the triple dash mark) and that the cable is fully inserted into the CP. • Press the impedance button to refresh the impedance value. • If the impedance is still bad, replace the ground pad and stimulation cable and refresh the impedance. • If the impedance is still bad, replace the foramen needle and then the CP. • Contact Axonics if the impedance remains bad.
	Red impedance icon(s) shows on the **Define Thresholds** screen when impedance is checked for tined lead connection to the tined lead stimulation cable.	• Check that the tined lead test stimulation cable and ground pad are fully inserted into the CP and that the ground pad is on the patient and the clip end of the stimulation cable is connected to the lead. • Make sure the introducer sheath is withdrawn past the most proximal electrode. • Reconnect the clip to the tined lead and check the impedance. If the bad impedance switches to a different electrode(s), reconnect the clip again. • If all the electrodes continue to show bad impedance, replace the ground pad and stimulation cable and refresh the impedance. • If the impedance is still bad, replace the tined lead and then the CP. • Contact Axonics if the impedance remains bad.

Impedance Issue with the Neurostimulator

Issue	Presentation	Resolution
Out of range (“Bad”) impedance during the Neurostimulator implant procedure	Red impedance icon(s) shows on the **Patient Device** screen when impedance is checked after the lead is inserted into the Neurostimulator.	• Make sure the Neurostimulator is in the subcutaneous pocket. Press the impedance button to refresh the impedance values. • If impedance is still red for any electrode(s), disengage the setscrew and remove the lead from the Neurostimulator and wipe it clean. Reinsert the lead into the Neurostimulator connector block until it cannot be inserted any further. The white marker on the proximal end of the lead should be inside the Neurostimulator strain relief. • If the lead cannot go all the way in, back out the set screw (turn counterclockwise) and reinsert the lead. • Press the impedance button to refresh the impedance values. • If impedance is still red for any electrode(s), replace the CP and check the impedance. Next replace the Neurostimulator and check the impedance. Next replace the tined lead. • Contact Axonics if the impedance remains bad.
Out of range (“Bad”) impedance at a follow-up or programming visit	Red impedance icon(s) shows on the **Patient Device** screen when the CP is connected to the Neurostimulator.	• Press the impedance button to refresh impedance values. • If the bad impedance is still present, reprogram the stimulation using electrodes with in-range impedance values. • If no electrodes have in-range impedance values, replace the CP. • If impedance is still bad on all electrodes, device replacement may be necessary. Contact Axonics.

LABEL SYMBOLS

Symbols	Description
SN	Product Serial Number
	Manufacturer
REF	Product Model Number
	Manufacturing Date
	IEC 60601-1/EN60601-1, Type BF Equipment
	Non ionizing electromagnetic radiation
!USA Rx ONLY	For USA audiences only: Caution: US Federal law restricts this device for sale by or on the order of a physician
	Refer to instructions for use (Consult accompanying documents)
	Temperature limitation
	Humidity limitation
	Not used
	Foramen Needle Test Stimulation
	This device complies with all applicable Australian Communications and Media Authority (ACMA) regulatory arrangements and applicable electrical equipment safety requirements

Symbols	Description
	Pressure limitation
C US	Classified by CSA with respect to safety
	Do not use if package is damaged
EC REP	Authorized representative in the European community
IPX0	The device does not offer protection against water
IC	Industry Canada certification number
CE 2797	Conformité Européenne (European Conformity): 2019. This symbol means that the device fully complies with AIMD Directive 90/385/EEC (Notified Body reviewed) and RED 2014/53/EU (self-certified)
	Follow instructions for use (operator manual)
	Stimulation ground
	Tined Lead Test Stimulation
	Not used
	USB port Caution: USB port is for Axonics use only. Do not plug any devices into this port.
FCC ID	US Federal Communications Commission device identification

Axonics

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EC REP

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