NUVECTRA®

Algovita® Spinal Cord Stimulation Clinician Programming Manual

Mobile Clinician Programmer Application Model 4510

Bridge Communicator Model 4110-xx

CE 0123

℞ ONLY XXXX

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Refer to the Information for Prescribers Manual for indications, contraindications, warnings, precautions, adverse events, clinical summary, and related information.

FCC Information (US Only)

Refer to the Apple® iPad User Guide at support.apple.com for its communications regulation information.

The following is communications regulation information about the Bridge Communicator.

Bridge Communicator FCC ID: 2ABU84110 contains FCC ID: QOQ11

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.

Important: Changes and modifications to the products not authorized by Nuvectra could void the FCC certification and negate your authority to operate these products.

Contents

Packaging Symbols Glossary v
Terminology vi

1. Introduction 7
About this Manual 7
Spinal Cord Stimulation System 7
Related Documents 8

2. Important Safety Information 11
Warnings 11
Precautions 11

3. About the Clinician Programmer 13
Using the Ribbon 13
Using the Navigation Menu 14

4. Getting Started 17
Logging In to the Clinician Programmer 17
Pairing a Bridge Communicator to the Clinician Programmer 17

5. Managing Patients 19
Using the Patient Directory 19
Adding a Patient 20

6. Configuring Stimulators and Leads 23
Adding a Stimulator 23
Adding Leads 24
Deleting Leads 25
Deleting a Stimulator 26

7. Programming 27
Understanding the Programming Screen 28
Using Programming Functions 30
Configuring the Subprogram 30
Shifting the Amplitude 32
Performing Impedance Checks 33

8. Managing Programs 35
Adding a Program 37
Adding a Subprogram 38
Deleting a Program or Subprogram 39
Managing a Disabled Program 39

9. Patient Report 41

10. Stimulator Settings 43
Accessing Stimulator Settings 43
Stimulator Battery 44
Auto Tune 45
Impedance Check 46
Patient Adjustments 47
Patient Devices 48

11. Care, Cleaning, Replacement, and Servicing 49
Care and Handling 49
Cleaning 49

Replacement and Servicing 49
Disposal 49
12. Charging the Bridge Communicator. 51
13. Troubleshooting 53
Nuvectra Customer Service 53
Clinician Programmer Troubleshooting 53
Charging a Fully Discharged Implantable Stimulator 56
Setting the Implantable Stimulator Depth 56
14. System Specifications 57
iPad Specifications 57
Bridge Communicator Specifications 57
Wireless Information 60
Wireless Quality of Service 61
Medical Implant Communication Service (MICS) 61
Bluetooth Wireless Technology 61
Wireless Security 61
Medical Implant Communication Service (MICS) 61
Bluetooth Wireless Technology 61
Electromagnetic Compatibility Declaration 61
Compliances and Authorizations. 62
15. Glossary 63

Packaging Symbols Glossary

Symbol	Details
REF	**Title:** Catalog Number **Standard:** ISO 15223-1 **Reference Number:** 5.1.6[1] **Description:** Indicates the manufacturer's catalog number so that the medical device can be identified.
SN	**Title:** Serial Number **Standard:** ISO 15223-1 **Reference Number:** 5.1.7[1] **Description:** Indicates the manufacturer's serial number so that the medical device can be identified.
LOT	**Title:** Batch Code **Standard:** ISO 15223-1 **Reference Number:** 5.1.7[1] **Description:** Indicates the manufacturer's batch codes so that the medical device's batch or lot can be identified.
	Title: Manufacturer **Standard:** ISO 15223-1 **Reference Number:** 5.1.1[1] **Description:** Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Title: Date of Manufacture **Standard:** ISO 15223-1 **Reference Number:** 5.1.3[1] **Description:** Indicates the date when the medical device was manufactured.
EC REP	**Title:** Authorized Representative in the European Community **Standard:** ISO 15223-1 **Reference Number:** 5.1.2[1] **Description:** Indicates the Authorized Representative in the European Community.
	Title: Consult Instructions for Use **Standard:** ISO 15223-1 **Reference Number:** 5.4.3[1] **Description:** Indicates the need for the user to consult the instructions for use.
	Title: Caution **Standard:** ISO 15223-1 **Reference Number:** 5.4.4[1] **Description:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Title: Packaging Unit **Standard:** ISO 7000:2014 **Reference Number:** 2794[2] **Description:** Indicates the number of pieces in the package.
	Title: Do not use if package is damaged. **Standard:** ISO 15223-1 **Reference Number:** 5.2.8[1] **Description:** Indicates a medical device that should not be used if the package has been damaged or opened.
	Title: Keep Dry **Standard:** ISO 15223-1 **Reference Number:** 5.3.4[1] **Description:** Indicates a medical device that needs to be protected from moisture.
	Title: Temperature Limit **Standard:** ISO 15223-1 **Reference Number:** 5.3.7[1] **Description:** Indicates the temperature limits to which the medical device can be safely exposed.
	Title: Humidity Limitation **Standard:** ISO 15223-1 **Reference Number:** 5.3.8[1] **Description:** Indicates the range of humidity to which the medical device can be safely exposed.
	Title: Atmospheric Pressure Limitation **Standard:** ISO 15223-1 **Reference Number:** 5.3.9[1] **Description:** Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Symbol	Details
	Title: Fragile, handle with care. **Standard:** ISO 15223-1 **Reference Number:** 5.3.1[1] **Description:** Indicates a medical device that can be broken or damaged if not handled carefully.
	Title: MR Unsafe **Standard:** ASTM F 2503-13 **Reference Number:** 7.3.3[3] **Description:** An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
	Title: Non-ionizing Electromagnetic Radiation **Standard:** IEC/TR 60878 **Reference Number:** 5140[4] **Description:** To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems, e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	Title: Class II Equipment **Standard:** IEC/TR 60878 **Reference Number:** 5172[4] **Description:** To identify equipment meeting the safety requirements specified for class II equipment according to IEC 61140.
	Title: WEEE Waste of Electrical and Electronic Equipment Symbol for the Marking on EEE **Standard:** BS EN 50419:2006[5] **Description:** Indicates that when end user wishes to discard this product it must be sent to separate collection facilities for recovery and recycling in the EU.
	Title: Type BF Applied Part **Standard:** ISO 7000/IEC 60417 **Reference Number:** 5333[2] **Description:** To identify a type BF applied part complying with IEC 60601.
ONLY	**Title:** Rx Only **Standard:** 21 CFR Part 801.109 paragraph (b)(1) **Description:** Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Title: European Conformity **Standard:** 93/42/EEC Annex 12 **Description:** Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety, and environmental protection legislation.

1. ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements
2. ISO 7000:2014 Graphical symbols for use on equipment-Registered symbols
3. ASTM F 2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
4. IEC/TR 60878:2015 Graphical symbols for electrical equipment in medical practice
5. BS EN 50419:2006 Marking of Electrical Equipment in accordance with Article 11(2) of Directive 2012/19/EU (WEEE)

Terminology

This manual and the Clinician Programmer use the following terms interchangeably:

- *trial stimulator* and *External Pulse Generator (EPG)*
- *implantable stimulator* and *Implantable Pulse Generator (IPG)*
- *stimulator* to represent both a trial stimulator and an implantable stimulator
- *Clinician Programmer* to represent the Clinician Programmer Application

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1. Introduction

About this Manual

This Clinician Programming Manual provides instructions on using the Algovita® Clinician Programmer Application and on using, charging, and caring for the Bridge Communicator. The Algovita® Spinal Cord Stimulation (SCS) System delivers mild electrical pulses to a specific area in the spinal cord. Patients may feel stimulation as a tingling sensation (paresthesia) that masks or covers their pain.

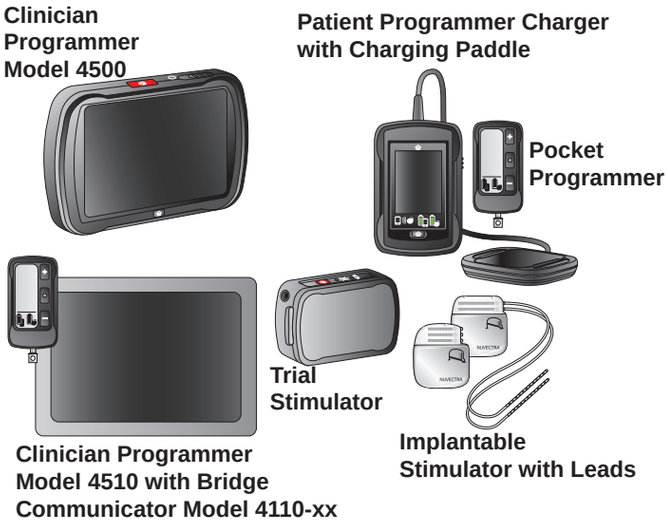
This manual applies to Model 4510 Algovita Clinician Programmer Application and Model 4110-xx Bridge Communicator for use with Algovita Stimulator Models 2408 and 2412, and Algovita Trial Stimulator Model 4300.

Clinicians use the Clinician Programmer intraoperatively to check system integrity and determine lead placement. They use it postoperatively to evaluate and program stimulation therapy, and to associate the Bridge Communicator, Patient Programmer Charger, and Pocket Programmer with a stimulator.

Spinal Cord Stimulation System

The Algovita SCS System is a rechargeable, 24-electrode, SCS system for the treatment of chronic pain. The implanted components of the SCS system consist of an implantable stimulator and leads with optional extensions. During a stimulation trial, trial leads are placed percutaneously, with the end of the trial lead externalized and connected to a trial stimulator. The trial stimulator replaces the implantable stimulator during intraoperative test stimulation and during the stimulation trial.

Note: During stimulation trials, you can use a commercially available ground pad with the Algovita SCS System.



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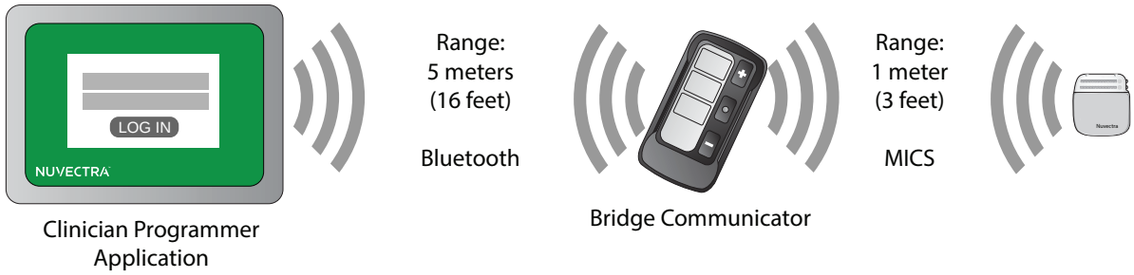
The Clinician Programmer Model 4510 runs on an Apple® iPad®. The Clinician Programmer Application communicates with a stimulator via the Bridge Communicator. The Clinician Programmer Application communicates with the Bridge Communicator Model 4110-xx via Bluetooth®, and the Bridge Communicator communicates with the stimulator via Medical Implant Communication Service (MICS). The Bridge Communicator communicates with a stimulator within a 1 meter (3 feet) range, allowing the clinician to keep the Bridge Communicator outside the sterile field during an implant procedure. The Clinician Programmer Application communicates with a Bridge Communicator within a 5 meter (16 feet) range.



Note:

- The Bridge Communicator Model 4110-xx only functions as a communication device for the Clinician Programmer Application Model 4510. The Bridge Communicator cannot control stimulation.
- The patient's Pocket Programmer Model 4100 cannot be used as a Bridge Communicator.

Related Documents

Refer to the appropriate Algovita SCS System manual for use instructions. Refer to the Information for Prescribers Manual for indications, contraindications, warnings, precautions, adverse events, summary of clinical evaluation, and related information.

The following documents are part of the Algovita SCS System documentation suite.

- *System Implant Manual: Using Percutaneous Leads* provides procedures for placing the leads for a stimulation trial, implanting all components for a system implant with a percutaneous lead, and replacing percutaneous leads.
- *System Implant Manual: Using Trial Leads* provides procedures for placing the leads for a temporary lead trial.
- *System Implant Manual: Using Paddle Leads* provides the procedures for implanting all components for a system implant with a paddle lead and a paddle lead replacement.
- *Implant Manual for Extensions* provides the procedures for replacing the extension.
- *Implant Manual for Stimulator* provides the instructions for the replacement of an Algovita Stimulator Model 2408 or 2412. For complete instructions on implanting an implantable stimulator as part of a system implant, refer to the system manual packaged in the lead kit.
- *Trial Stimulator Manual for Clinician* provides instructions to the clinician on using the trial stimulator.
- Patient System Manual describes for a patient the Algovita SCS System and provides important safety information about living with the SCS system. This manual also provides instructions on how to use, charge, and care for the programmers that patients use to adjust their SCS system.
- *Patient Stimulation Trial Manual* describes for a patient the trial Algovita SCS System and provides important safety information about living with the SCS system. This manual also provides instructions on how to use, charge, and care for the programmers that patients use to adjust their SCS system.
- *Patient Magnet Manual* describes for a patient how to use the patient magnet, optional with the Algovita SCS System.
- *Programmer Charger Quick Reference* is a quick reference guide for patients for the Programmer Charger, and includes information on selecting programs, adjusting stimulation strength, and turning stimulation on and off.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 8 7/12/19 9:20 AM

- *Pocket Programmer Quick Reference* is a quick reference guide for patients for the Pocket Programmer, and includes information on selecting programs, adjusting stimulation strength, and turning stimulation on and off.
- *Algovita® Spinal Cord Stimulation System MRI Procedure Guidelines Manual* provides complete instructions and information on contraindications, warnings, precautions, and instructions for MR conditions of use.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 9 7/12/19 9:20 AM

0300-000176-001 Rev.2 SCS CP_Mobile.indb 10 7/12/19 9:20 AM

2. Important Safety Information

Warnings

Programmer Interaction with Other Implanted Devices. Do not use the Clinician Programmer to change program settings when near a person who has a pacemaker or other implanted devices. The effects of the Algovita System Clinician Programmer on other implanted devices are unknown.

Modification. Do not modify the Clinician Programmer, Bridge Communicator, or charging accessories. Modification of any Algovita System component may result in damage to the system, compromised system integrity, and harm or injury to the patient.

Precautions

Adjusting Program Settings. Avoid adjusting stimulator program settings to levels far above the pain relief response threshold. High settings may cause discomfort and increase the need for more frequent charging.

Component Compatibility. Use only the Clinician Programmer, Bridge Communicator and accompanying charger cord to charge the Bridge Communicator or adjust stimulation. The effects of non-Algovita components on an Algovita SCS System are unknown.

Electromagnetic Interference. Do not attempt to program near equipment that may generate electromagnetic interference (EMI) as it may interfere with the programmer's ability to communicate with other Algovita System components. If EMI disrupts programming, move the iPad or Bridge Communicator away from the source of EMI. Examples of sources of EMI are Magnetic Resonance Imaging (MRI), lithotripsy, computer monitors, cellular and cordless telephones, motorized wheelchairs, x-ray equipment, and other monitoring equipment. Interrupting programming may result in incorrect or incomplete programming.

Flammable Atmospheres. Avoid using the iPad or Bridge Communicator in flammable or explosive environments (e.g., an anesthetic mixture with air, oxygen, or nitrous oxide). Using a battery-powered device near flammable or explosive atmospheres can produce a spark which may cause injury.

iPad Charge Depleted. Depleting the battery charge on the iPad during use will shut down the Clinician Programmer Application. Any unsaved information is lost, but saved information is retained.

Magnetic Resonance Imaging (MRI). Do not take the iPad, Bridge Communicator, or power cord into an MR environment, such as an MR scanner room. The iPad, Bridge Communicator, and power cord are MR Unsafe. External devices are MR Unsafe, do not allow the external devices into the MRI scanner (magnet) room. Please refer to the *Algovita SCS System MRI Procedure Guidelines (0300-000175-001(USA) or 0300-000148-001 (OUS))* for full information.

Damaged Packaging. Do not use an Algovita System component if the package is damaged or open. If a component is damaged, the Algovita System may not function properly.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 11 7/12/19 9:20 AM

0300-000176-001 Rev.2 SCS CP_Mobile.indb 12 7/12/19 9:20 AM

3. About the Clinician Programmer

A program is a combination of settings for delivering stimulation to one or more pain sites. Using the Clinician Programmer, you configure programs before transferring them to the stimulator for a patient's use. You assign (pair) a Pocket Programmer and Patient Programmer Charger with the patient's Algovita System using the Clinician Programmer. You can also display and configure the current stimulator status, perform diagnostics on the stimulator, and display usage logs.

Using the Ribbon

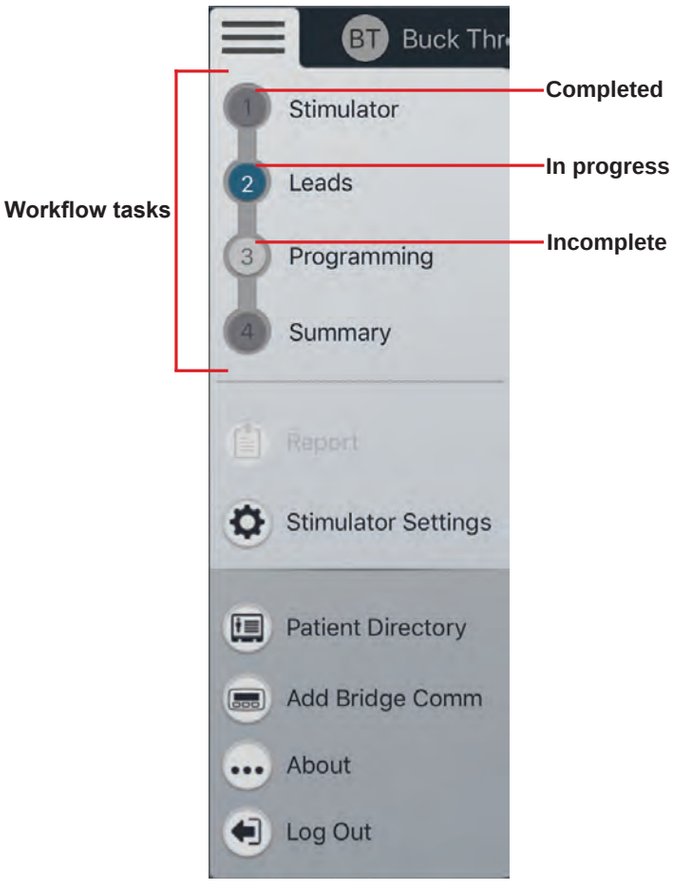
A ribbon displays across the top of the application for most of the application screens.

	Stimulation. Tap ON or OFF to turn stimulation on or off. The blinking green light indicates stimulation is on. The light blinks quickly to indicate stimulation is ramping up, then the blinking slows when ramping finishes. The blinking green light turns off to indicate stimulation is off.
	Bridge Communicator Status and Battery Level. Indicates when the Clinician Programmer is connected to and communicating with the Bridge Communicator. Shows the battery level for the Bridge Communicator. **Note:** Before using the Clinician Programmer with a patient, make sure that it is connected to and communicating with the Bridge Communicator. If the Clinician Programmer cannot connect to the Bridge Communicator, verify that the Bridge Communicator is paired with the Clinician Programmer and is within 5 meters (16 feet) of the Clinician Programmer.
	Stimulator Status and Battery Level. Indicates when the Clinician Programmer is communicating with the stimulator. Shows the battery charge level for the stimulator. The Clinician Programmer automatically attempts to connect to the stimulator when you navigate from the Patient Directory to another patient screen. **Note:** If the Clinician Programmer cannot connect to a stimulator, verify that: • the stimulator is on and not connected to another device, such as a Programmer Charger or another Clinician Programmer; • the Bridge Communicator is paired with the Clinician Programmer, is in Bluetooth mode, and is within 1 meter (3 feet) of the stimulator; • the Clinician Programmer is within 5 meters (16 feet) of the Bridge Communicator; • the iPad Bluetooth is on.

Using the Navigation Menu

Use the items in the Navigation menu to configure and view patient programs and stimulator settings. Access the Navigation menu by tapping on the ribbon.

The top list in the Navigation menu includes workflow tasks. The clinician advances through the workflow to configure components, and create and manage programs. The task in progress is blue.



1 - Stimulator	Configure and view stimulator information. Refer to *Adding a Stimulator on page 23*.
2 - Leads	Configure and view lead information and port connections. Refer to *Adding Leads on page 24.*
3 - Programming	Create and configure programs, including electrode configuration and settings (amplitude, pulse width, and frequency). Optionally, conduct impedance checks. Refer to *Programming on page 27.* **Note:** When you finish programming, go to the Summary screen to save the changes and upload the programs to the stimulator.
4 - Summary	Save programs, review current program settings, and create or delete programs. Refer to *Managing Programs on page 35*.
Report	Generate a PDF report that includes information about a patient's stimulator, leads, and programs. Refer to *Patient Report on page 41*. **Note**: Report is only available when you are viewing the Summary screen.

Stimulator Settings	Configure and view stimulator settings. Refer to *Stimulator Settings on page 43.*
Patient Directory	View patients added to the Clinician Programmer. Refer to *Using the Patient Directory on page 19.*
Add Bridge Comm	Pair a Bridge Communicator with the Clinician Programmer. Refer to *Pairing a Bridge Communicator to the Clinician Programmer on page 17.*
About	View information about the application such as model numbers, software version numbers, and trademarks and licenses information.
Log Out	Log out of the Clinician Programmer.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 15 7/12/19 9:20 AM

0300-000176-001 Rev.2 SCS CP_Mobile.indb 16 7/12/19 9:20 AM

4. Getting Started

Before using the Clinician Programmer, make sure that Bluetooth is on. Refer to the Apple iPad User Guide at support.apple.com for instructions.

After you log in to the Clinician Programmer, pair the Bridge Communicator with the Clinician Programmer to enable communication between the Clinician Programmer and a stimulator.

Logging In to the Clinician Programmer

The first time you launch the Clinician Programmer, verify that you have an internet connection in order to use the login credentials provided by Nuvectra. You can optionally set up a Touch ID® within iPad Settings and use your finger for future log-ins. It is also recommended to turn off all Apple iPad system-level notifications and alerts in the iPad settings feature. Responding to any system-level alert or notification while using the Clinician Programmer Application results in the user being automatically logged out of the Clinician Programmer Application.

To launch the Clinician Programmer Application:

1. Tap on your iPad.
2. Log in with your Nuvectra username and password, or a Touch ID.

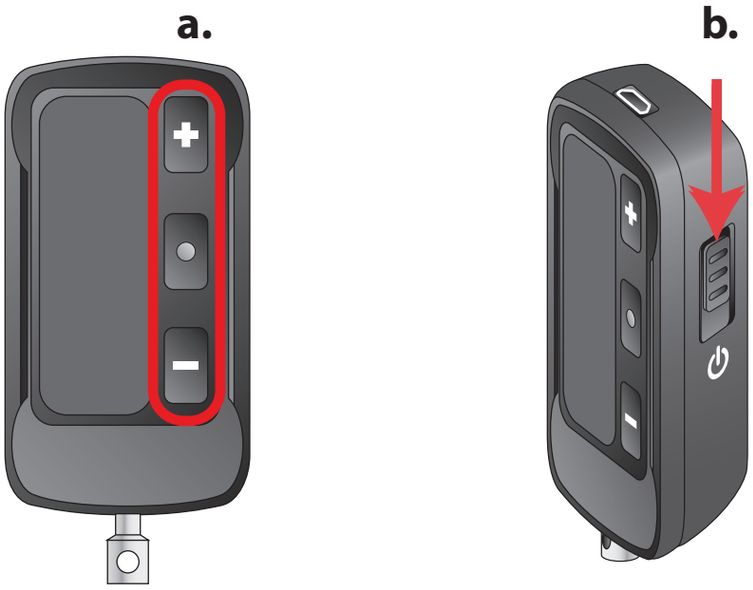
If you are unable to authenticate the Clinician Programmer Application for first time use, the Clinician Programmer should retry upon a predefined timeout when a token is not received.

If you are unable to log in, call Nuvectra Customer Service toll-free at 1-844-727-7897 within the United States or 1-214-618-4980.

Pairing a Bridge Communicator to the Clinician Programmer

To pair the Bridge Communicator with the Clinician Programmer:

1. Place the Bridge Communicator in Bluetooth mode.
   a. Tap and hold one of the buttons shown in image a. **Do not** use the red QSO button.
   b. While holding the button from step a, slide the Power On/Off button down and hold for two seconds or until **bl** displays (**bl** displays on the Bridge Communicator when it is communicating via Bluetooth).
   c. Release all buttons after **bl** displays.



   d. Verify that a **P** displays and is blinking (Bridge Communicator is ready to pair).

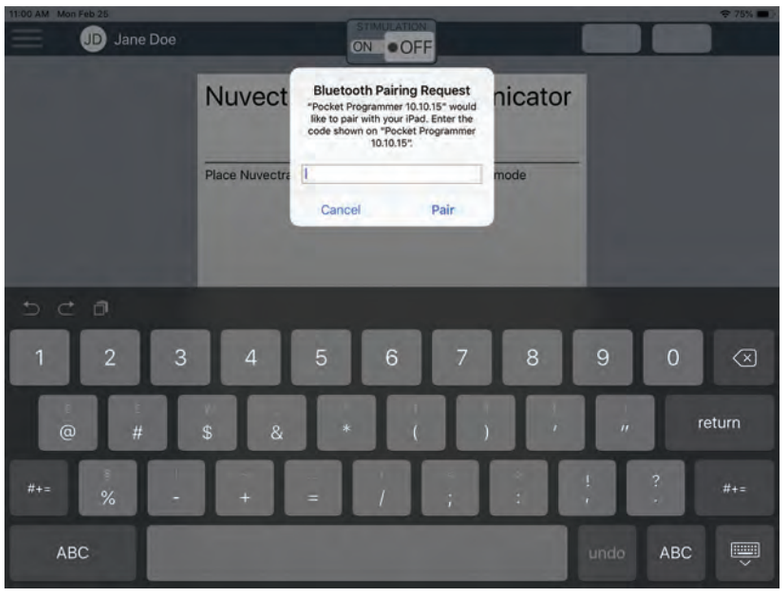
   Note: Ready to pair status will time out after two minutes.

2. On the Clinician Programmer, select **Add Bridge Comm** from the Navigation menu.

   The application begins scanning for a Bridge Communicator that is within 5 meters (16 feet) of the Clinician Programmer Application.

   The Clinician Programmer displays Bridge Communicators that are in range.

3. On the Clinician Programmer, tap the left or right triangles to scroll through the carousel of communicators if more than one is in range.
4. Tap **Select** for the serial number that matches your Bridge Communicator.
5. If prompted, tap a button (not the red QSO button) and slide the On/Off button down and hold for two seconds until **P** displays.
6. Enter the four-digit code displayed on the Bridge Communicator into the popup window on the Clinician Programmer. Enter the code displayed from left to right and top to bottom.



7. Tap **Pair** in the popup window.

5. Managing Patients

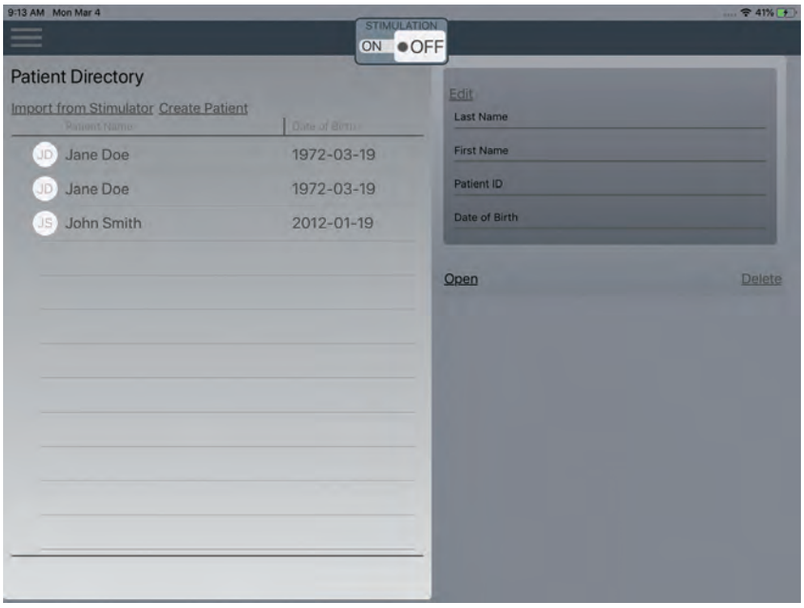
To program stimulation for a patient, add the patient to the Patient Directory. For a new patient without an existing stimulator, you manually create the patient. For a patient with an existing stimulator, you import the information from their stimulator.

Using the Patient Directory

Add patients and select patients using the Patient Directory.

To access the Patient Directory:

1. Log in to the Clinician Programmer or tap the Navigation menu and select **Patient Directory**.
   The Patient Directory screen displays.
2. Scroll up or down in the Patient Directory to view additional patients.
3. Tap to select a patient.



Item	Description
Import from Stimulator	Add a patient using information stored on the stimulator.
Create Patient	Add a patient that does not have a programmed stimulator.
Edit	Modify name, ID, and date of birth for the selected patient.
Open	Access lead, stimulator, and program information for the selected patient.
Delete	Delete the selected patient from the Clinician Programmer. **Note**: This does not delete information from the stimulator assigned to the patient.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 19 7/12/19 9:20 AM

Adding a Patient

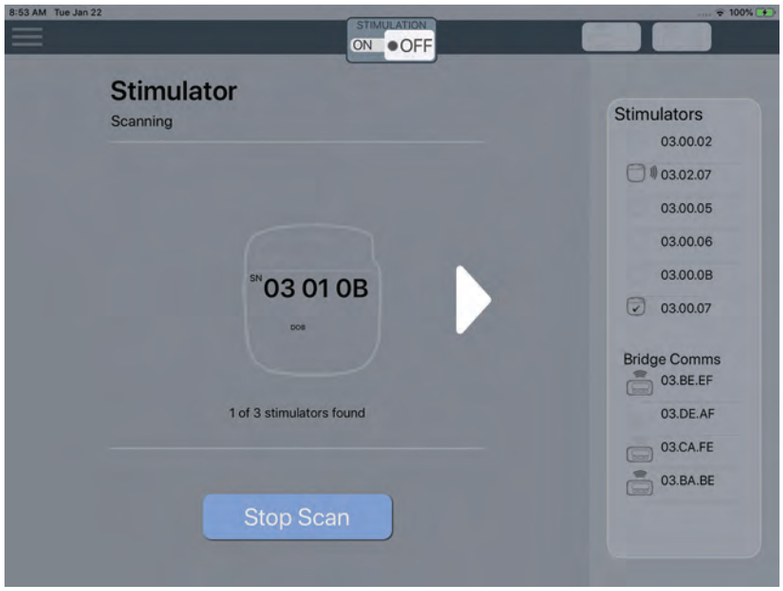
Note: When you add a patient with an existing stimulator, the Clinician Programmer imports patient information stored on the stimulator.

For patients with an existing stimulator, add a patient by importing information from their stimulator. For new patients with an empty stimulator, create the patient first, then add the stimulator.

To add a patient from a stimulator:

1. Move the Bridge Communicator within 1 meter (3 feet) of the stimulator, and the Clinician Programmer Application within 5 meters (16 feet) of the Bridge Communicator.
2. Tap **Import from stimulator** on the Patient Directory screen.

   The Clinician Programmer scans for stimulators and Bridge Communicators within range. The pane on the right of the screen shows stimulators that are in range and their communication status. It also shows Bridge Communicators that are in range and whether the Clinician Programmer is actively communicating with them. Tap the patient's stimulator when found or optionally tap **Stop Scan** to stop the scanning process at any time.
3. Tap the triangles on either side of the displayed stimular to view stimulators in range.



4. Tap the stimulator that matches the patient's stimulator.

   The trial simulator serial number is on the label on the back of the stimulator. The implantable stimulator packaging material and the front of the implantable stimulator includes the serial number.

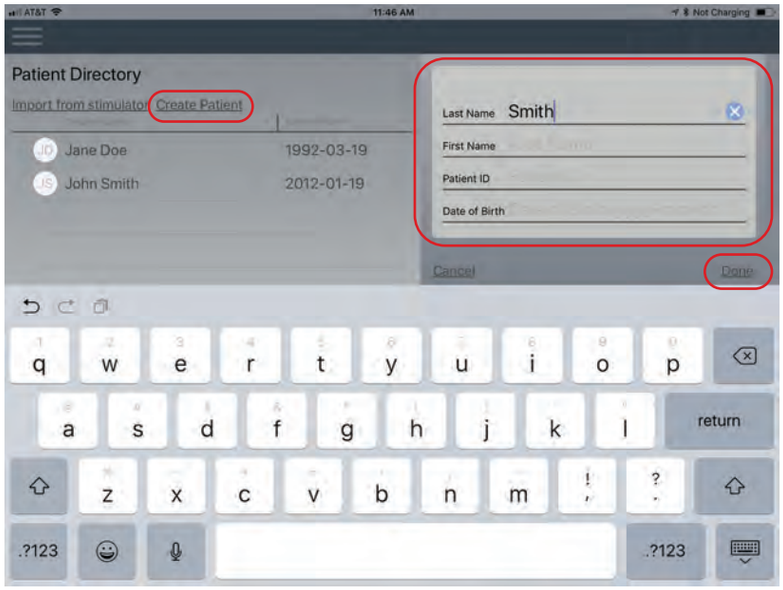
   Note: If a stimulator does not display in the list, make sure it is on, nearby, and not connected to another Clinician Programmer, Programmer Charger, or Pocket Programmer by turning the programmers off or moving them out of range.

To create a patient:

0300-000176-001 Rev.2 SCS CP_Mobile.indb 20 7/12/19 9:20 AM

1. Tap **Create Patient** on the Patient Directory screen.
2. Enter patient information using the keyboard.

   The required fields are **Last Name, First Name**, and **Date of Birth**. The date of birth must be in the format yyyy-mm-dd.
3. Tap **Done**.



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6. Configuring Stimulators and Leads

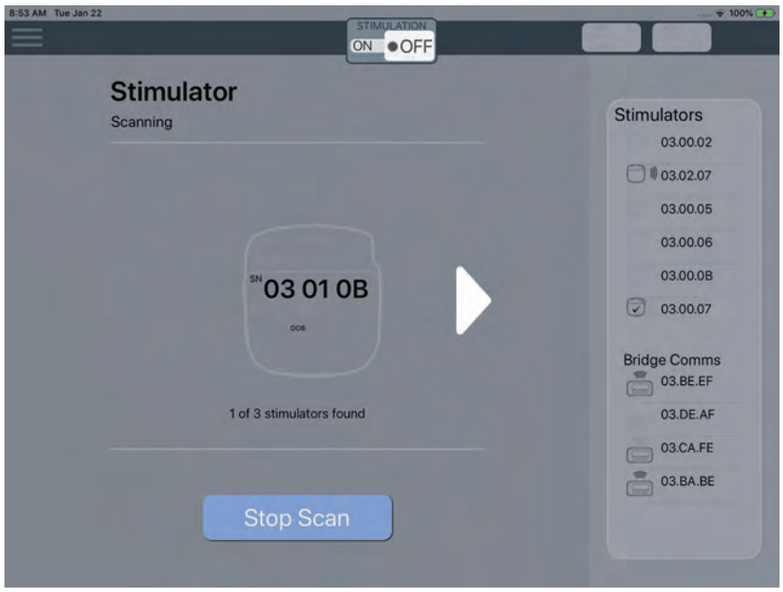
When you create a patient, the Clinician Programmer prompts you to add a stimulator. For a patient already assigned a stimulator, you can access information about stimulators and leads through the Navigation menu.

Adding a Stimulator

To add a stimulator:

1. Select **Stimulator** from the Navigation menu.
2. Tap **Scan**.

   The Clinician Programmer scans for stimulators within range.
3. Tap the triangles on either side of the stimular to view the stimulators within range.



4. Tap the stimulator that matches the patient's stimulator.

   The trial simulator serial number is on the label on the back of the stimulator. The implantable stimulator packaging material and the front of the implantable stimulator includes the serial number.

   Note: If a stimulator does not display in the list, make sure it is on, nearby, sufficiently charged, and not connected to another Clinician Programmer, Programmer Charger, or Pocket Programmer by turning the programmers off or moving them out of range.

Adding Leads

To add a lead:

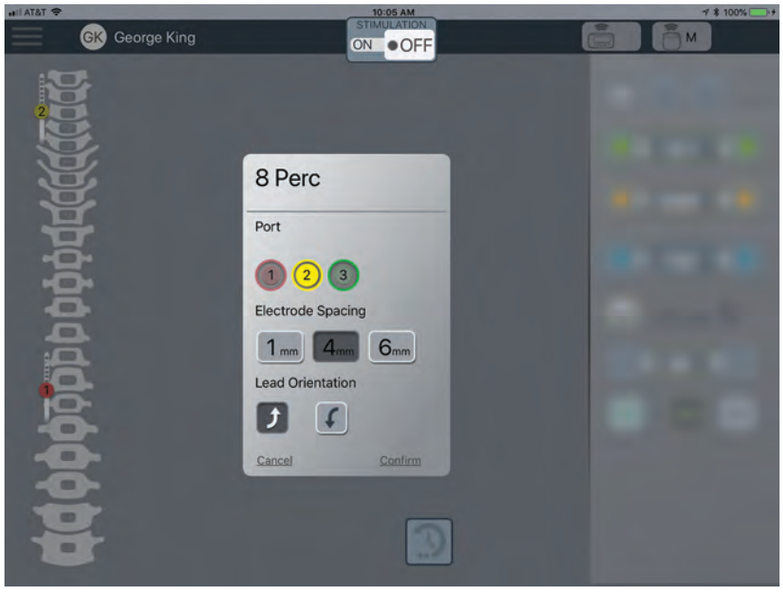
1. Select **Leads** from the Navigation menu.
   The Leads screen displays.
2. Tap **ADD LEAD**.

3. Tap the arrows to scroll through the carousel to find the patient's lead type.
   Note: If the patient has a three port stimulator, the 8 Perc lead is the only lead available.

4. Tap **Select**.
5. Tap at any time to undo any changes made in the Leads screen.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 24 7/12/19 9:20 AM

6. Tap the port number to which you want to connect the lead.
7. Optionally, select the electrode spacing.
8. Select the orientation of the lead by tapping the retrograde or anterograde arrow.



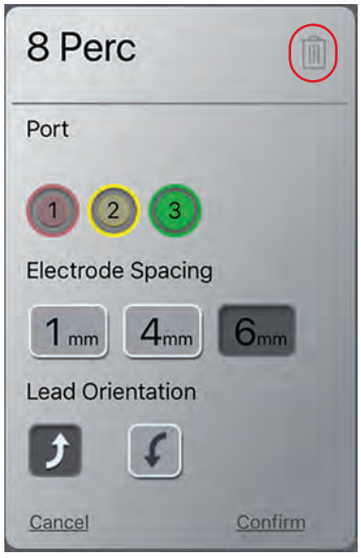
9. Tap **Confirm**.
   The lead displays on the spine image. The lead is colored and numbered according to its corresponding port.
10. Drag the lead to the location that represents the implant location.

Deleting Leads

Note: Removing a lead deletes programs associated with the lead. If a lead has associated programs, confirm that you still wish to delete the lead by tapping **Delete** in the Remove Lead popup.

To remove a lead:

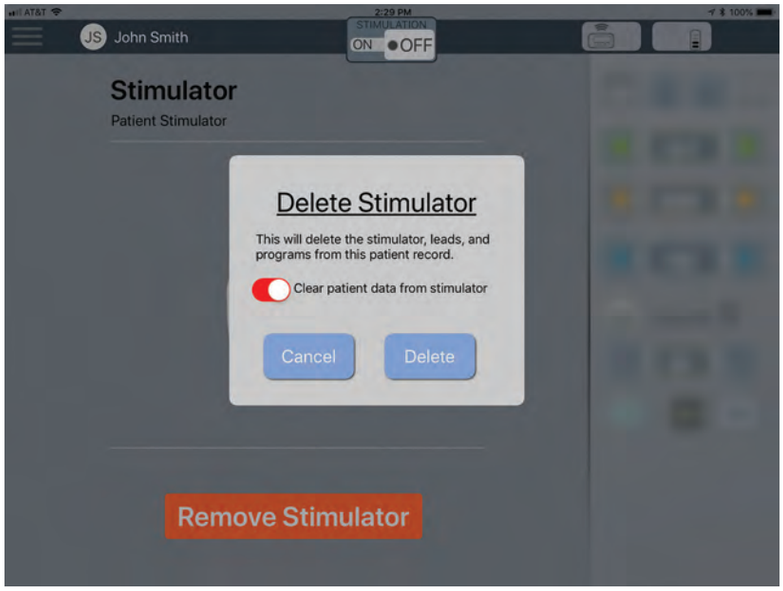
1. Tap the lead on the spine image.
   The Lead popup displays.
2. Tap .



Deleting a Stimulator

To delete a stimulator:

1. Tap the Navigation menu and select **Stimulator**.
2. Tap **Remove Stimulator**.
3. Optionally, slide the **Clear patient data from stimulator** radio button on to clear the stimulator of any patient data, including programs. The default setting is off for implantable stimulators and on for trial stimulators.
4. Tap **Delete**.



7. Programming

Use the Programming screen to create and edit programs and subprograms. Patients can have up to ten programs. A program is made of one to four subprograms. The clinician can also run individual subprograms from the Programming screen.

Note: The clinician can run subprograms or programs using the Clinician Programmer, but patients can only run programs. When a patient runs a program, the subprograms run sequentially.

Within a subprogram you configure stimulating electrodes, the polarity of the electrodes, and the amplitude allocation for the electrodes. Also adjust the stimulation values (frequency, pulse width, and amplitude), the operating ranges of the amplitude, pulse width, and frequency, and the range in which patients can increase and decrease the strength (amplitude) of their stimulation.

Work with the patient and adjust program settings until effective therapy is confirmed with the patient. Use the lowest settings possible that provide effective treatment. High settings may cause discomfort to the patient and may increase the need for more frequent charging of the pulse generator. Always review programs with the patient.

Programming Workflow

From the Programming screen, complete the following:

1. Optionally, tap the program name to edit the name of the program. The program names defined here show up on the Patient Programmer Charger to help the patient identify which program they are selecting.
2. Optionally, tap a subprogram number (S1–S4) then a subprogram name to edit the name of the subprogram.
3. Optionally, perform an impedance check.
4. Add and configure electrodes to deliver stimulation for a subprogram.
5. Within the subprogram, adjust the stimulation parameters.
6. Deliver test stimulation and adjust stimulation parameters as needed to deliver proper therapy to the patient.
7. Advance to the Summary screen to save and view program settings and adjust them as necessary. You can also add more programs or subprograms using the Summary screen.

   Note: When you advance to the Summary screen, the program configuration is automatically saved and synchronized to the stimulator.

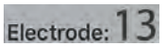
0300-000176-001 Rev.2 SCS CP_Mobile.indb 27 7/12/19 9:20 AM

Understanding the Programming Screen

Use the Programming screen to configure electrodes and set stimulation parameters for a subprogram. A subprogram requires at least one anode and one cathode. You can configure the implantable stimulator enclosure or trial stimulator ground pad as an electrode by tapping the can icon on the Programming screen. You can use a commercially available ground pad for the trial stimulator.

Note: During a trial, do not send the patient home with a program that uses the can as an anode or cathode when the patient does not have a ground pad.

You can manually adjust the allocation for each configured electrode if there are at least two configured electrodes of the same polarity. The Clinician Programmer does not change a locked electrode when balancing the amplitude allocation. The Clinician Programmer ensures that the sum of the amplitude allocation is always 100% of the set amplitude.

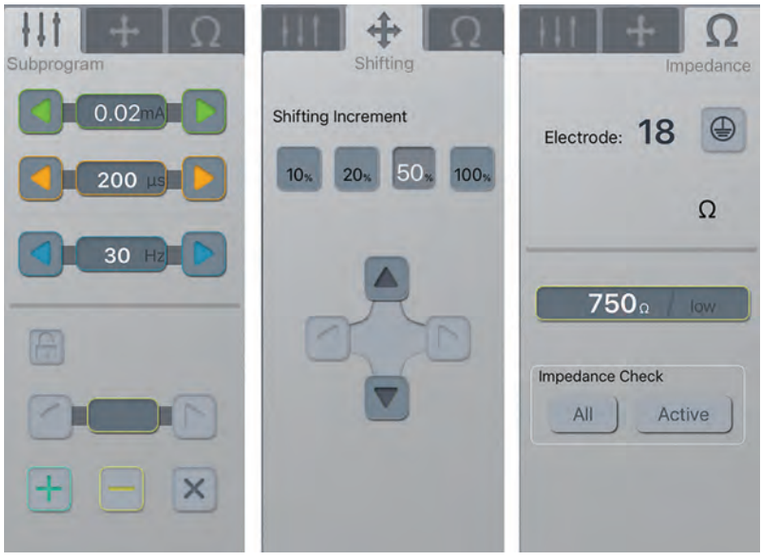
	Indicates an electrode. Gray is inactive, yellow is a cathode, blue is an anode. • Percentage is the percentage of the subprogram amplitude allocated to the electrode. • The electrode number is in the lower right. • Electrode polarity is in the lower left. • The can displays at the bottom right of the right-most lead. You can program the can like an electrode.
	Port Indicator. The port (lead) on which the program stimulates. For a three bore stimulator, red is port 1, yellow is port 2, and green is port 3. For a two bore stimulator, red is port 1 and green is port 2. **Note**: Colors indicate port location and may not match flags used during the implant procedure.
	Undo any unsaved changes.
	The name of the program. Tap to change the program name. The program name is visible to the patient on the Patient Programmer Charger.
	The name of the subprogram. Tap to change the subprogram name.
	The number of the subprogram. Tap to configure a subprogram.
	Locks a selected electrode from automatic amplitude adjustments. Tap the electrode then tap the lock to lock the selected electrode. A small lock icon displays next to the locked electrode. To unlock the electrode, tap the locked electrode and tap the lock again.
	The currently selected electrode.
	The subprogram amplitude allocation applied to the selected electrode or can. Tap arrows to adjust the percentage of amplitude allocated to the electrode. **Note**: Adjusting the percentage allocated to the electrode also adjusts the amplitude allocated to other assigned electrodes that are unlocked. A subprogram must have at least two electrodes to adjust the amplitude allocation.
	Removes the selected electrode or can from the subprogram.
	Sets the polarity of the electrode or can.
	Controls stimulation for the current subprogram or entire program. The blinking green light indicates stimulation is on. The blinking green light turns off to indicate stimulation is off. Tap ON or OFF to turn stimulation on or off. Select **Subprogram** or **Program**. Upon starting stimulation, stimulation ramps to the amplitude value for the subprogram. When stimulation is on and you are switching between subprograms, the stimulation for the currently selected subprogram ramps down before switching and ramping the stimulation for the newly selected subprogram.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 29 7/12/19 9:20 AM

Using Programming Functions

Access different programing functions through the programming tabs.

- Subprogram: configure electrodes and adjust their amplitude, pulse width, and frequency. Refer to *Configuring the Subprogram on page 30.*
- Shifting: shift amplitude allocation up and down a lead. Refer to *Shifting the Amplitude on page 32.*
- Impedance: conduct an impedance check. Refer to *Performing Impedance Checks on page 33.*



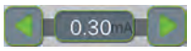
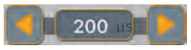
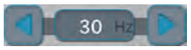
Configuring the Subprogram

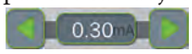
Select electrodes for the subprogram and set stimulation parameters.

1. Tap an electrode on a lead (or optionally the can) in the Programming screen.
2. Tap + or − to assign the polarity of the electrode (or can).
3. Add additional electrodes.
4. Optionally for each electrode, tap the left or right arrow to adjust the amplitude allocation percentage for that electrode.

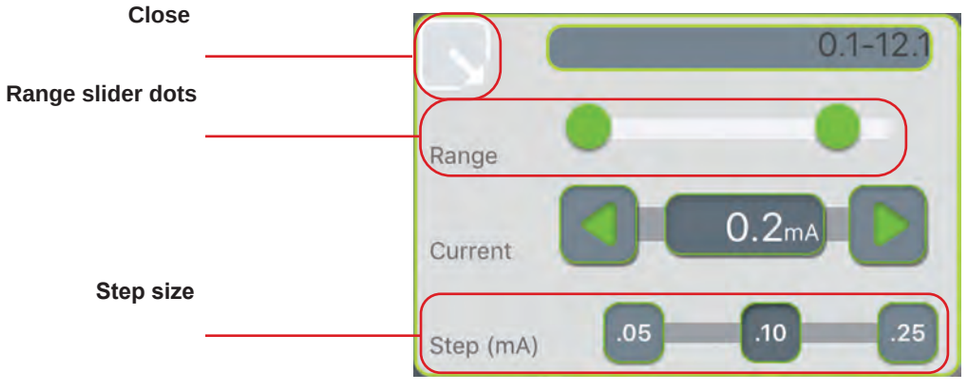
5. Tap the Subprogram tab.
6. Set the stimulation parameters (amplitude, pulse width, and frequency) for the subprogram by tapping on the left and right arrows for each stimulation parameter.

   Note: Adjusting the frequency for a subprogram adjusts the frequency for all subprograms within the program.

	The amplitude of the pulse in milliamps (mA). • The amplitude for an electrode cannot exceed 15 mA. • The total amplitude for a subprogram cannot exceed 30 mA. • The amplitude for a subprogram can be set from 0–15 mA for one electrode per polarity, or 15–30 mA for two or more electrodes per polarity.
	The pulse width in microseconds (µs). The pulse width range is 20–1500 µs.
	The frequency of the pulse in Hertz (Hz). The frequency range is 2–2000 Hz.

7. Adjust the stimulation parameter ranges. The range also sets the ranges that the patient can adjust.
   a. Tap the displayed amplitude (mA), pulse width (µs), or frequency (Hz) value  on the Subprogram tab.
   b. The range slider popup displays.
   c. Tap and drag the slider dots to set the minimum and maximum values.

      Note: For amplitude, you can adjust the step. The step is the rate at which the amplitude value increases or decreases when tapping the arrows.
   d. Close the popup.



8. Tap **Summary** on the Navigation menu to advance to the Summary screen and save program settings.

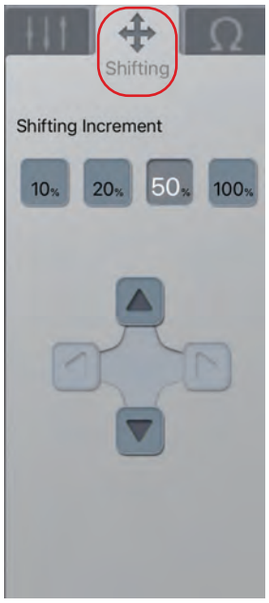
Shifting the Amplitude

Shifting moves the amplitude allocation between and across leads.

To shift the electrode configuration:

1. Tap the Shifting tab on the Programming screen.
2. Tap the desired rate for the Shifting Increment.
3. Use the up, down, left, or right arrows to shift the amplitude allocation.

Note: Shifting arrow availability is determined by lead placement.



Optionally, lock an electrode from shifting by tapping the electrode on the Programming screen. A small blue lock icon displays on the locked electrode.

Note: The shifting lock is different from the subprogram automatic amplitude adjustment lock.

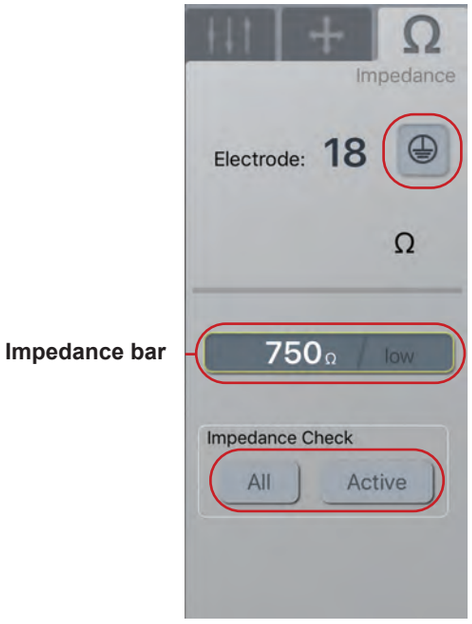
0300-000176-001 Rev.2 SCS CP_Mobile.indb 32 7/12/19 9:20 AM

Performing Impedance Checks

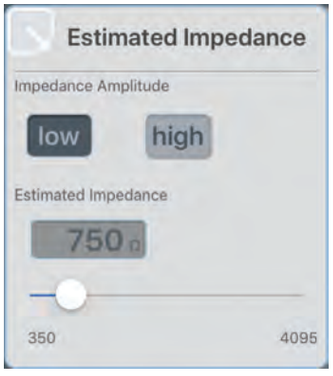
Check the impedance between the stimulator and the electrodes by performing an impedance check.

To perform an impedance check:

1. Tap the Impedance tab on the Programming screen.



2. Tap an electrode or the can (stimulator housing) on the Programming screen, then tap to assign the electrode or can as the sink (the direction of the current flow). If you do not select another electrode, the default sink is the can.
3. Optionally, tap the Impedance bar and select the impedance amplitude (the amplitude at which the stimulator performs the impedance check) by tapping **low** or **high** in the Estimated Impedance popup. The default setting is low. Low is 0.2 mA and high is 0.5 mA. When performing an impedance check, start with the low amplitude setting to avoid patient discomfort.



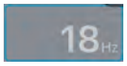
4. Close the popup.
5. Tap **All** to perform an impedance check on all electrodes or tap the **Active** button to perform an impedance check on only the active programmed electrodes.
6. Optionally, use the Estimated Impedance slider in the popup to adjust the estimated impedance level for stimulation. Contact Nuvectra Customer Service for more information about this advanced feature.

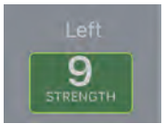
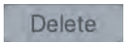
   Over time, the impedance at the stimulation site may increase and the slider may need adjusting. You can determine an estimated impedance by performing an impedance check and reviewing the reported values for active contacts. Indicate the estimated impedance using the Estimated Impedance slider. The default value is the lowest impedance expected for safety of the patient and prolonged battery charge of the pulse generator. If impedance increases without adjusting the Estimated Impedance slider, the patient may experience a lessening of strength in stimulation.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 34 7/12/19 9:20 AM

8. Managing Programs

Manage programs from the Summary screen. Running a program runs the subprograms consecutively. You can adjust the strength, frequency, and pulse width for a program from the Summary screen when stimulation is turned on.

	Add a program.
	Add a subprogram.
	Program number and name. A run time indicator displays around the circle of the program number. The run time is a percentage of the run time in relation to all of the programs ran. Modifying a program or subprogram resets the run time for that program.
	Program Strength (amplitude). When stimulation is turned on, tap and use the popup arrows to adjust the value. The program strength is the highest subprogram strength. **Note**: Patients see amplitude as strength on their programmers.
	Program frequency. When stimulation is turned on, tap and use the popup arrows to adjust the value.
	Subprogram pulse width. When stimulation is turned on, tap and use the popup arrows to adjust the value.
	Program name and run time in hours.

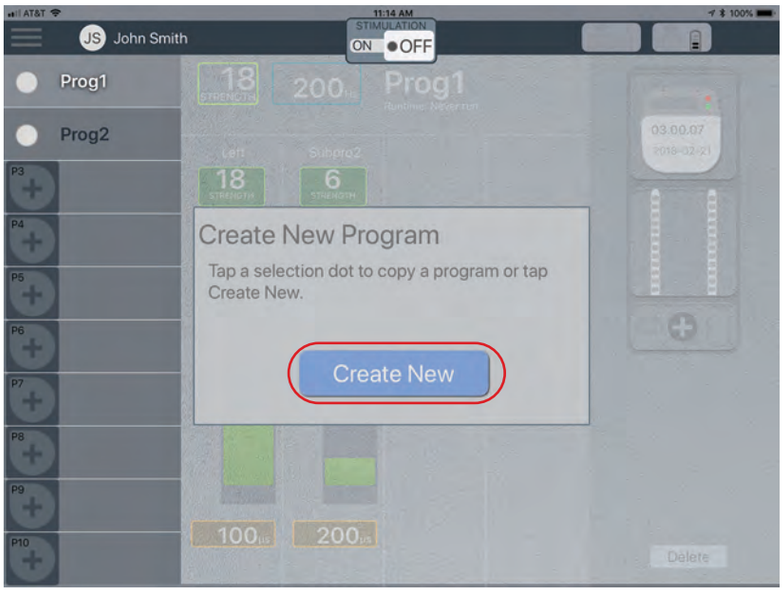
	The subprogram strength. The green bar is a visual indicator of the subprogram strength.
	Delete a program or subprogram. A popup window displays that allows you to choose the programs and subprograms to delete.
	Turn stimulation on to start stimulation for the selected program. Stimulation ramps to the amplitude value for the program.
	Displays the Stimulator Settings screen.
	Displays the Leads screen.
	Pair the Pocket Programmer and Patient Programmer Charger to a stimulator. Refer to *Patient Devices on page 48.*

0300-000176-001 Rev.2 SCS CP_Mobile.indb 36 7/12/19 9:20 AM

Adding a Program

To add a program:

1. Tap .
   The Create New Program popup displays.
2. Tap **Create New** on the popup.



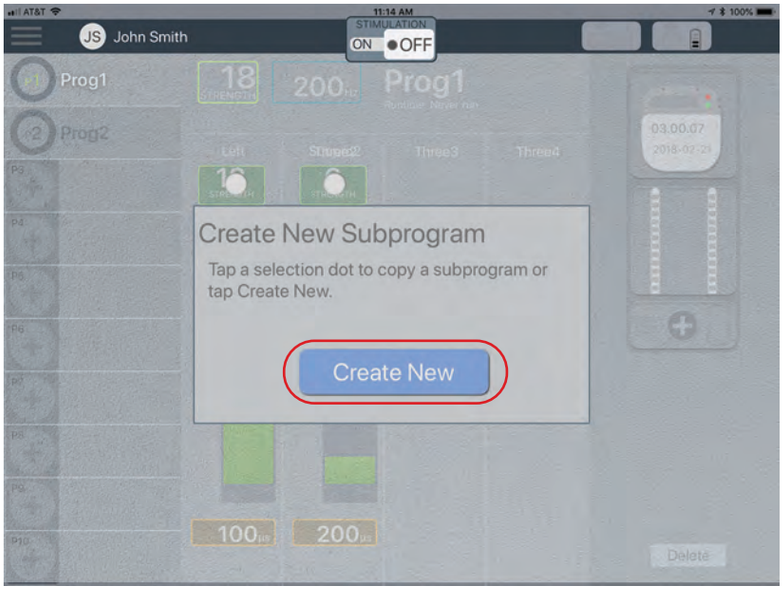
To copy a program:

1. Tap .
   The Create New Program popup displays.
2. Tap a program dot to select an existing program to copy.
3. Tap **Create from Copy**.

Adding a Subprogram

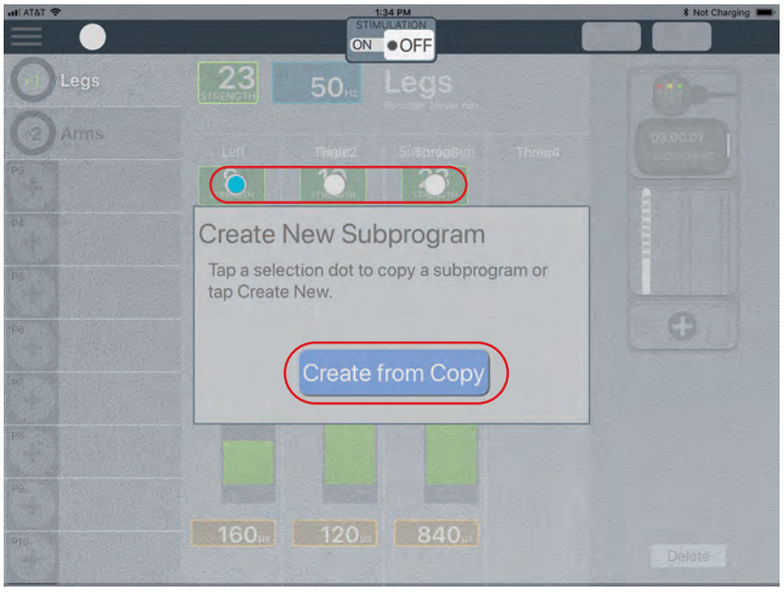
If a program already has four subprograms, you cannot add another subprogram. To add a subprogram:

1. Tap ⊕ in an open subprogram column.
   The Create New Subprogram popup displays.
2. Tap **Create New** on the popup.



To copy a subprogram:

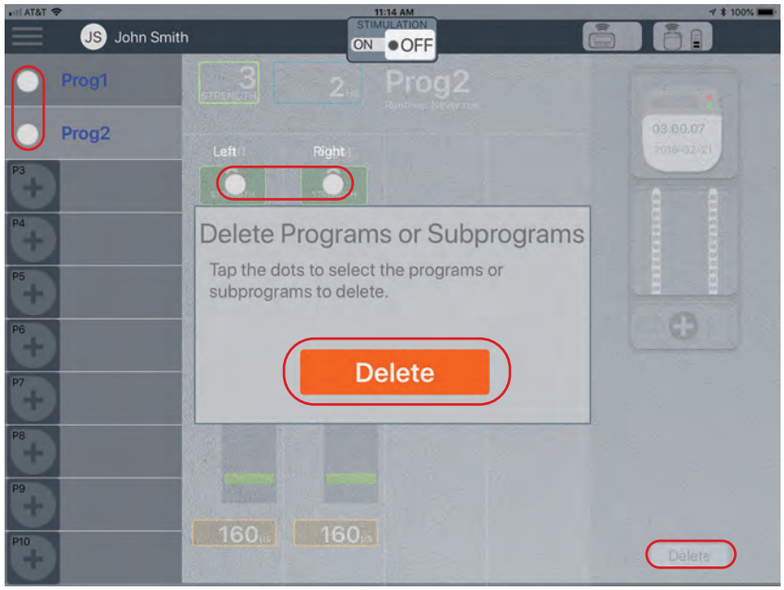
1. Tap ⊕ in an open subprogram column.
   The Create New Subprogram popup displays.
2. Tap a subprogram dot to select an existing subprogram to copy.
3. Tap **Create from Copy**.



Deleting a Program or Subprogram

Deleting a program deletes all its subprograms. To delete a program or subprogram:

1. Tap **Delete** in the bottom right of the Summary screen.
   The Delete Program popup displays.
2. Tap a program or subprogram dot.



3. Tap **Delete** in the popup.

Managing a Disabled Program

If a program has an orange triangle dispalyed next to its number on the Summary screen, the stimulator has disabled the program, and it can no longer run. The stimulator disables programs when background impedance is on and the stimulator detects high impedance. If this happens, run an impedance check and review the program. If the impedance check does not detect errors and the program remains disabled, call Nuvectra Customer Service toll-free at 1-844-727-7897 within the United States or 1-214-618-4980.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 40 7/12/19 9:20 AM

9. Patient Report

You can generate a PDF report that contains information on a patient's system and programs. The bottom of every page displays the user identification, the generation date, and the software version of the Clinician Programmer.

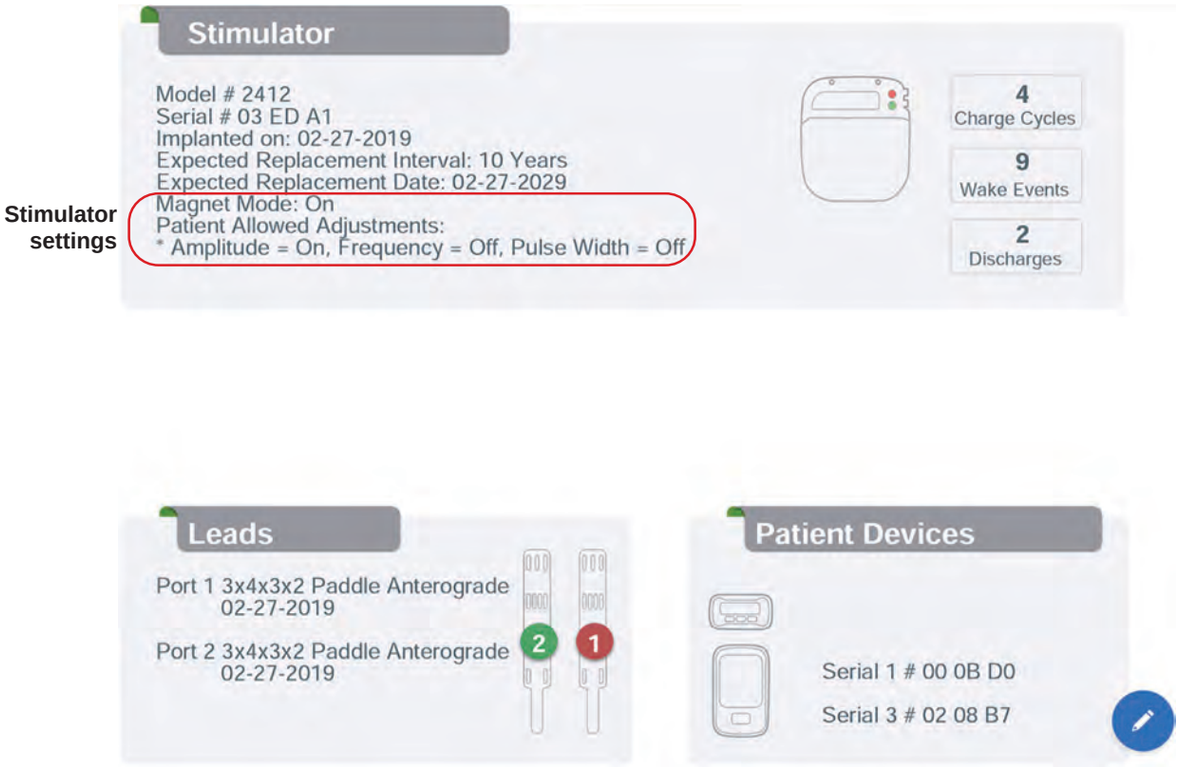
To generate a report:

1. Select **Report** from the Navigation menu.

   Note: Report becomes active only when viewing the Summary screen.

2. Select which method you want to save the report information from the popup.
   - Message (text)
   - Mail (email)
   - Add to Notes (application)
   - Copy to Acrobat (view on-screen and save as PDF)
   - Copy to Books (application)
   - Copy to iTunes U (application)
   - Copy to Mobile CRM (application)

The following is an example of report information:



0300-000176-001 Rev.2 SCS CP_Mobile.indb 41 7/12/19 9:20 AM

P1 Prog1
90 Hz
2-2000
Runtime:
Modified 05-03-19
S1: Left
0.50 mA
300 µs
S2: Right
0.65 mA
260 µs
1
2
−100 %
+25
Can
Can
Can
Can

10. Stimulator Settings

Use the Stimulator Settings to view information about the stimulator, configure background impedance checks, and turn on advanced patient adjustments.

Accessing Stimulator Settings

To access stimulator settings:

1. Select a patient from the Patient Directory.
2. Select Stimulator Settings from the Navigation menu.

	View battery information. Refer to *Stimulator Battery on page 44.*
	View a diagnostic message generated by the stimulator.
	Configure background impedance checks. Refer to *Impedance Check on page 46.*
	Optimize communication between the Patient Programmer Charger and the stimulator. Refer to *Auto Tune on page 45.*
	Restart the stimulator, which stops stimulation and reinitializes the internal settings. **Note**: This does not affect the patient information or programs on the stimulator.
	Turn magnet mode on or off. When on, the patient can use a magnet to stop and start stimulation. Refer to the Patient Magnet Manual for more information. **Note**: Regardless of this setting, you can always use a magnet to stop stimulation.
	Place the stimulator in storage mode. Use the Patient Programmer Charger to take the stimulator out of storage mode.

	Enable the stimulation options the patient can adjust. Refer to *Patient Adjustments on page 47*.
	Restore the stimulator's internal settings and calibrations with an option to generate a calibration report. Restore Settings is not available to all users.
	Displays the Stimulator Settings screen.
	Displays the Leads screen.
	Pair the Pocket Programmer and Patient Programmer Charger to a stimulator. Refer to *Patient Devices on page 48*.

Stimulator Battery

View information about the stimulator battery.

Months Remaining	The number of months until the expected replacement of an implantable stimulator. The date is ten years from the implant date.
Charge Cycles	The number of full battery charges for an implantable stimulator.
Wake Events	The number of times an implantable stimulator exited storage mode.
Discharges	The number of times an implantable stimulator battery depleted.

Auto Tune

Auto Tune optimizes the communication between the stimulator and the Patient Programmer Charger. Auto Tune the stimulator if you or the patient experience reduced communication between the stimulator and the Patient Programmer Charger. This may happen when the tissue surrounding the stimulator changes, such as after healing from surgery or a significant weight change.

- Tap **Tune** to start the Auto Tune.

A successful Auto Tune is indicated by the Success display. If Auto Tune is not successful, retry communication with the stimulator and Programmer Charger. Contact Nuvectra Customer Service if communication problems persist.

Impedance Check

Turn on background impedance checks to enable an implantable stimulator to check impedance each time stimulation stops, or the trial stimulator to check impedance when stimulation starts. If the stimulator detects high impedance for an electrode, the stimulator disables the program and all other programs that use that electrode.

Note: A patient cannot run a disabled program. A patient may have a disabled program if impedance checks were on and they unplugged their trial stimulator while the stimulator was performing an impedance check.

The software provides the ability to select low or high amplitude for background impedance checks. Low impedance is 0.1 mA and high impedance is 0.2 mA. Always perform an initial impedance check using the low setting. If the impedance results are low or high, or the patient did not feel stimulation, perform another check using the high setting.

For more information about performing impedance checks, refer to *Performing Impedance Checks on page 33*.

Patient Adjustments

Enable the stimulation options the patient can adjust within the assigned range. The patient uses the Patient Programmer Charger to make the adjustments.

Subprogram Strength	Patient can adjust stimulation strength for individual subprograms.
Frequency	Patient can adjust the frequency for a program.
Pulse Width	Patient can adjust the pulse width for individual subprograms.

Patient Devices

For a patient to use their Programmer Charger or a Pocket Programmer, pair the Programmer Charger or Pocket Programmer to the stimulator.

To pair programmers to the stimulator:

1. Tap
2. Tap the serial number space and enter the serial numbers located on the label on the back of the programmer. The programmers need not be present when adding them to a stimulator.
3. Tap **Confirm** to send the programmer serial numbers to the stimulator.

4. Verify that the added patient devices are communicating with the stimulator by using each device to turn on programs.

   If the patient needs to pair with their stimulator from home, call Nuvectra Customer Service at 1-214-618-4980 or toll-free at 1-844-727-7897 within the United States.

11. Care, Cleaning, Replacement, and Servicing

Care and Handling

For information about care, handling, and storage of the Apple iPad, refer to the Apple iPad User Guide available at support.apple.com.

Handle the Algovita System components and accessories with care. Do not drop them or submerge them in water. Avoid all sources of water that can come into contact with the devices. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components. See the Limited Warranty for additional information.

Cleaning

The power cord and Bridge Communicator are not waterproof. Do not immerse them in liquid or allow moisture to get inside the cases.

If the Bridge Communicator is dirty, clean the outside with a slightly damp cloth. Do not clean the Bridge Communicator with bleach, nail polish remover, or similar substances.

Replacement and Servicing

Return a non-serviceable iPad or Bridge Communicator to the Nuvectra Information Technology department for service or disposal. Contact Nuvectra Customer Service for replacement and servicing of your Apple iPad or Bridge Communicator. Call Nuvectra Customer Service toll-free at 1-844-727-7897 within the United States or 1-214-618-4980 for assistance.

Disposal

Algovita programmers and stimulators have rechargeable batteries that should be disposed of according to local environmental regulations.

The Bridge Communicator contains rechargeable lithium batteries. Do not incinerate or dispose of the Bridge Communicator in general household trash. When no longer needed, return Bridge Communicators to Nuvectra for proper disposal or consult local regulations for proper disposal of electronic devices.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 49 7/12/19 9:20 AM

0300-000176-001 Rev.2 SCS CP_Mobile.indb 50 7/12/19 9:20 AM

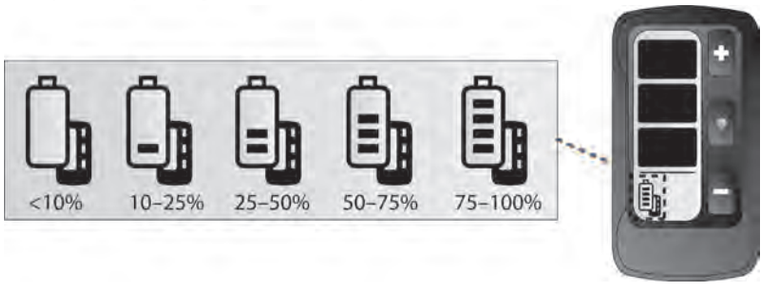
12. Charging the Bridge Communicator

The Bridge Communicator has rechargeable batteries. You can charge the batteries any time the battery level is below 100%. Routinely check your battery levels, and charge a device when needed.

Note:

- For instructions on how to recharge the iPad on which the Clinician Programmer Application resides, refer to the Apple iPad User Guide available at support.apple.com.
- You can use the Clinician Programmer while the iPad or Bridge Communicator are charging.

When the communicator battery is fully charged, the battery level icon displays four bars.



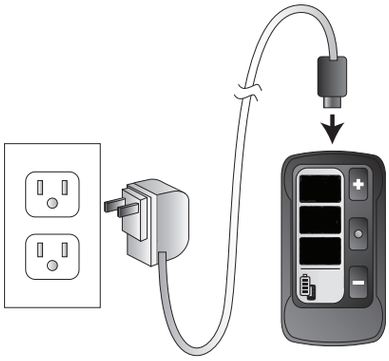
If the battery level drops below 10%, the battery level icon has no bars and flashes before the Bridge Communicator turns off.

Caution: If you store the Bridge Communicator for an extended period of time, make sure to fully charge the battery before storing, and periodically charge the battery at least every six months. The Bridge Communicator uses a small amount of battery charge while turned off and may become non-rechargeable if not periodically charged.

To charge the battery:

- Connect the power cord to the Bridge Communicator and plug the power cord into a power outlet.

  Note: For detailed information on the power cord, refer to the instructions for use packaged with the power cord.



As the battery charges to each battery level (10%, 25%, 50% and 75%) the associated bar on the battery level icon displays and flashes. When the communicator is fully charged, the icon displays four bars and the bars stop flashing.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 51 7/12/19 9:20 AM

0300-000176-001 Rev.2 SCS CP_Mobile.indb 52 7/12/19 9:20 AM

13. Troubleshooting

If the instructions in this chapter do not solve your problem, contact Nuvectra Customer Service.

Nuvectra Customer Service

If you have any questions about the Algovita System, call Nuvectra Customer Service toll-free at 1-844-727-7897 within the United States or 1-214-618-4980.

Clinician Programmer Troubleshooting

Problem	Possible Cause and Solution
Patient does not feel stimulation.	The Clinician Programmer is not connected to the stimulator. **Disconnect the stimulator from any nearby Programmer Chargers, Pocket Programmers, or Clinician Programmers, then tap the stimulator in the Navigation menu to establish a connection.** **Restart stimulation. Refer to** *Adding a Stimulator on page 23.*
	The stimulator battery is depleted, as indicated by the stimulator battery level on the ribbon of the Clinician Programmer. **Note:** Pocket Programmers and Programmer Chargers also display the battery level of a connected stimulator. **Charge the stimulator.**
	Stimulation is not in an optimum location. **Adjust the assignment of the electrodes for the subprograms. Refer to** *Subprogram on page 30.*
	Stimulation is off. Although unlikely, EMI from security gates or other electronic devices may have turned off stimulation. **Restart stimulation.**
	Strength of the active program is too low. **Increase the strength of the active program from the Programming screen. Refer to** *Subprogram on page 30.*
	The impedance at the stimulation site increased. **Conduct an impedance test and review the results. If necessary, adjust the estimated impedance. Refer to** *Impedance on page 33.*
Patient is noticing changes (increases or decreases) in stimulation strength.	A change in body position is affecting stimulation strength. **Patients should keep their Programmer Charger or Pocket Programmer with them to adjust the strength or to select a new program.**
Cannot start stimulation. **Clinician Programmer does not turn on.**	The iPad or Pocket Programmer battery is too low. **Charge the iPad or the Pocket Programmer**.
Stimulation stopped unexpectedly.	The programmers were moved out of range during test stimulaion. **Move the programmers back in range. Refer to** *Introduction on page 7.*

0300-000176-001 Rev.2 SCS CP_Mobile.indb 53 7/12/19 9:20 AM

Problem	Possible Cause and Solution
Cannot increase or decrease the strength, amplitude, frequency, or pulse width for a program.	Increasing or decreasing the value is outside the allowed range. **Adjust the maximum value for the range. Refer to** *Subprogram on page 30.*
	The amplitude may be exceeding maximum values; an electrode cannot exceed 15 mA and a subprogram cannot exceed 30 mA. **Adjust the electrode configuration for optimal stimulation. Refer to** *Subprogram on page 30.*
	The maximum value for the amplitude, frequency, or pulse width range may have been reached. **Adjust the maximum value for the range. For more information, refer to** *Subprogram on page 30.*
	The subprogram may have reached the charge density or lead limits. **Adjust the range for the amplitude, frequency, and pulse width. These parameters are related; adjusting the value of one of these parameters may affect the value of another parameter to stay within charge density and lead limits.**
Cannot change the amplitude on an electrode.	The electrode is locked or there are not two electrodes of the same polarity. **Change the electrode configuration. Refer to** *Subprogram on page 30.*
Trouble communicating with a stimulator.	Environmental conditions for the stimulator changed. **Auto tune the stimulator. Refer to** *Auto Tune on page 45.*

0300-000176-001 Rev.2 SCS CP_Mobile.indb 54 7/12/19 9:20 AM

Clinician Programmer Messages

Some messages may include an error code. If provided, reference the error code when contacting Nuvectra Customer Service.

Message	Description/Possible Action
Communications problem. Unable to communicate with stimulator. Verify that the Clinician Programmer and the Nuvectra Bridge Communicator are within range of the stimulator. The message includes an error code.	Verify that the iPad and the Bridge Communicator are within range of the stimulator. Refer to *Introduction on page 7*. Restart stimulation and try again. If the error message persists, contact Nuvectra Customer Service.
Communications problem. Unable to communicate with the Nuvectra Bridge Communicator. Ensure it is within range of the iPad.	Verify that the iPad is within range (5 meters [16 feet]) of the Bridge Communicator. Move the Bridge Communicator closer if necessary. If the error message persists, contact Nuvectra Customer Service.
Stimulation stopped. Connection to stimulator interrupted.	The stimulator has a problem and needs to restart. Restart stimulation. If the error message persists, contact Nuvectra Customer Service.
Stimulation stopped. Adjust program before restarting stimulation.	The program is unbalanced or otherwise unacceptable. Adjust program settings and restart stimulation.
Internal error. Unable to save stimulator information.	Indicates an internal error, contact Nuvectra Customer Service.
Communications Problem. Cannot retrieve desired information.	Verify that the iPad and the Bridge Communicator are within range of the stimulator. Refer to *Introduction on page 7*. If the message persists, contact Nuvectra Customer Service.
Communications problem. Cannot connect to stimulator.	
System Error. Unable to complete operation.	Indicates an application error, contact Nuvectra Customer Service.
Bluetooth Error. Enable Bluetooth before continuing.	Turn on Bluetooth in the Apple iPad's settings.
Low Battery. Cannot start stimulation.	Recharge the stimulator.
Cannot start stimulation. No program selected.	Select a program and restart stimulation.
Background impedance. Measured value out of range.	Indicates a background impedance check failure. Check leads and all lead connections. If the message persists, contact Nuvectra Customer Service.
The stimulator reported an issue. The message includes an error code.	Contact Nuvectra Customer Service.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 55 7/12/19 9:20 AM

Charging a Fully Discharged Implantable Stimulator

A patient may need assistance to charge a fully discharged implantable stimulator.

To charge a fully discharged implantable stimulator:

1. Move the Patient Programmer Charger within 1 meter (3 feet) of the implantable stimulator and turn on the Patient Programmer Charger. The Not Able to Connect screen displays.
2. Tap **Cancel** to display the Home screen.
3. Connect the charging paddle to the Patient Programmer Charger.
4. Tap (Charge Status). The Charge Status screen displays.
5. Align the charging paddle over the implantable stimulator. Use either the adjustable belt or an adhesive patch to hold the charging paddle in place.
6. Tap **OK** on the Charge Status screen.
7. Wait until charging completes.
8. Tap **OK** on the Charging Complete screen.
9. Tap (Communication) to connect to the implantable stimulator.

Setting the Implantable Stimulator Depth

Adjust the depth setting if an implantable stimulator is implanted deeper than 1.5 cm (0.59 in) or if the patient has trouble charging the implantable stimulator.

To set the implant depth:

1. Tap (Programmer Settings) on the Home screen of the Patient Programmer Charger.
2. Tap **Advanced Settings** on the Programmer Settings screen.
3. Enter the last two digits of the serial number located on the back of the Patient Programmer Charger, and tap **OK**.
4. Tap **Implant Depth** on the Advanced Settings screen.
5. Select **Deep**.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 56 7/12/19 9:20 AM

14. System Specifications

iPad Specifications

For non-therapy related precautions and Regulatory Statements regarding the use of the iPad, on which the Clinician Programmer application resides, refer to the Apple iPad resources available at support.apple.com.

Bridge Communicator Specifications

The Bridge Communicator complies with Safety/Compatibility standards:

- IEC 60601-1, Medical Electrical Equipment Safety
- IEC 60601-1-2, Electromagnetic Compatibility

This section of the manual provides technical information about the Bridge Communicator.

Bridge Communicator Specifications	
Operating temperature	0°C to 40°C (32°F to 104°F)
Storage temperature	-20°C to 60°C (-4°F to 140°F)
Operating/storage humidity	10% to 85%
Operating/storage atmospheric pressure	70 kPa to 106 kPa (20.7 inHg to 31.3 inHg)
Size (approximate)	3.6 cm x 6.5 cm x 1.8 cm (1.45 in x 2.55 in x 0.72 in)
Weight including battery (approximate)	37.5 grams (1.3 oz)
Battery	Chargeable lithium-ion battery
Mode of operation	Continuous

Bridge Communicator Electromagnetic Compatibility Declaration Tables

This section lists the EMC Declaration tables. The Bridge Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Bridge Communicator should assure that it is used in such an environment. The Bridge Communicator contains RF transmission and receiving capabilities; consequently, it is possible that other portable and mobile RF communications equipment may interfere with the Bridge Communicator.

The power supply cable (maximum length 1500 cm [59 in]) is included in the system testing to demonstrate compliance with the requirements of IEC 60601-1-2 2014. Use of accessories and cables other than those specifically listed may result in increased emissions or decreased immunity of the Bridge Communicator.

The Bridge Communicator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Bridge Communicator should be observed to verify normal operation in the configuration in which it will be used.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 57 7/12/19 9:20 AM

Guidance and manufacturer's declaration – electromagnetic emissions		
The Bridge Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Bridge Communicator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Bridge Communicator uses RF energy primarily for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Bridge Communicator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions			
The Bridge Communicator meets basic safety requirements for use in the electromagnetic environment specified below. The customer or the user of the Bridge Communicator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% UT (30% dip in U_T) for 25 cycles <5% UT (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Bridge Communicator requires continuous operation during power mains interruptions, it is recommended that the Bridge Communicator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic emissions			
The Bridge Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Bridge Communicator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Proximity Fields from RF wireless communication equipment IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz Per table 9 of §8.10 9 to 28 V/m 385 MHz to 5785 MHz	3 Vrms 150kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 9 to 28 V/m 385 MHz to 5785 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Bridge Communicator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d= 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Recommended separation distane E=6/d*sqrt(P) Interference may occur in the vicinity of equipment marked with the following symbol.
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Bridge Communicator is used exceeds the applicable RF compliance level above, the Bridge Communicator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Bridge Communicator. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Bridge Communicator			
The Bridge Communicator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Bridge Communicator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Bridge Communicator as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Wireless Information

Wireless Specifications and Safety	
Bridge Communicator wireless technology operating characteristics	The Bridge Communicator interacts with the stimulator using MedRadio Band: 402 to 405 MHz. The effective radiated power is below the limits as specified in: Europe: Radio Equipment Directive 2014/53/EU USA: FCC 47 CFR Part 95
	The Bridge Communicator interacts with the stimulator using 2.45 GHz. The effective radiated power is below the limits as specified in: Europe: Radio Equipment Directive 2014/53/EU USA: FCC 47 CFR Part 15
Stimulator wireless technology	The stimulator complies with emissions requirements per Radio Equipment Directive 2014/53/EU (402 to 405MHz).
Wireless integrity	The Algovita SCS System employs mechanisms to ensure integrity of the communication area. The stimulator will not respond to any device to which it is not linked.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Wireless Information Table

Wireless Specifications and Safety	
Stimulator wireless technology	The stimulator complies with emissions requirements per RED Standard EN 301 489-27 v2.1.1 (402 to 405MHz).
Wireless integrity	The Algovita SCS System employs mechanisms to ensure integrity of the communication area. The stimulator will not respond to any device to which it is not linked.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 60 7/12/19 9:20 AM

Wireless Quality of Service

Medical Implant Communication Service (MICS)

Medical Implant Communication Service (MICS) is a wireless radio band operating at 402 to 405 MHz. It is used between the Bridge Communicator and the stimulator. MICS has a range of approximately 1 meter (3 feet).

Bluetooth Wireless Technology

Bluetooth wireless technology, a wideband transmission system operating in the 2.4 to 2.4835 GHz ISM band and using wide band modulation techniques, is used between the Bridge Communicator and the iPad. Nuvecta's use of the protocol uses forward error correction (FEC) on data packets, frequency hopping spread spectrum (FHSS), which aids in spectral co-existence, and a very reliable data stream profile. Interrupted or partial messages are invalid and must be resent. If communication errors are detected, the system will automatically retransmit the interrupted message to guarantee delivery of the message. If the wireless connection does not automatically re-establish itself, the user should reposition the Bridge Communicator to re-establish communication.

Wireless Security

Medical Implant Communication Service (MICS)

A model-specific device access code is used to initiate a programming session. Additionally, the MICS link between the Bridge Communicator and the stimulator is encrypted using an AES128 encryption method. Unintentional programming, malicious programming, and eavesdropping are mitigated by close contact with the patient (within 1 meter [3 feet] or closer) that is required to initiate a session and encryption. If the telemetry connection is lost without warning, the user should reposition the Bridge Communicator to re-establish the connection. Interrupted or partial messages are invalid and must be resent.

Bluetooth Wireless Technology

Communication using Bluetooth wireless technology between the Bridge Communicator and the Clinician Programmer application begins with pairing the Clinician Programmer and Bridge Communicator. Pairing can only be accomplished with physical access to the iPad and Bridge Communicator and is only available for a short period of time. During the pairing process, a key is generated by both devices simultaneously. This key is derived from a secret key known only to the pair. Once the key generation is complete, the Clinician Programmer application and Bridge Communicator mutually authenticate each other to verify they have the same key. Once the communication session has been established, data traffic is encrypted to thwart eavesdropping of information.

Electromagnetic Compatibility Declaration

Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radio-frequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Compliances and Authorizations

For compliance with the limits for a Class B digital device, refer to the Apple iPad resources available at support.apple.com/manuals/ipad.

This transmitter is authorized by rule under the Medical Device Radiocommunication 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 Radiocommunication 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.

This transmitter is authorized by rule under the intentional transmitters (47 CFR part 15). This transmitter must not cause harmful interference to stations authorized to operate on a primary bases in the 2400 - 2483.5 MHz band, 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 intentional transmitters. 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 transmissions from this transmitter will be free from interference.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 62 7/12/19 9:20 AM

15. Glossary

Term	Definition
balancing	The automatic allocation of the total amplitude for a polarity of a program to equal 100%.
EPG	External Pulse Generator. Also known as the trial stimulator.
IPG	Implantable Pulse Generator. Also known as the implantable stimulator.
program	A combination of stimulation settings used to deliver stimulation to one or more sites in a patient. A program consists of one or more subprograms.
shifting	Moves amplitude allocation on a lead to identify optimal stimulation.
step	The rate of increase or decrease when adjusting amplitude.
strength	Amplitude increments based on the amplitude of a program. For the patient, strength is the intensity of their stimulation.
subprogram	A combination of stimulation settings. A program consists of one or more subprograms.
can	The stimulator housing or enclosure.
sink	The target direction of electric current flow.

0300-000176-001 Rev.2 SCS CP_Mobile.indb 63 7/12/19 9:20 AM

0300-000176-001 Rev.2 SCS CP_Mobile.indb 64 7/12/19 9:20 AM

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