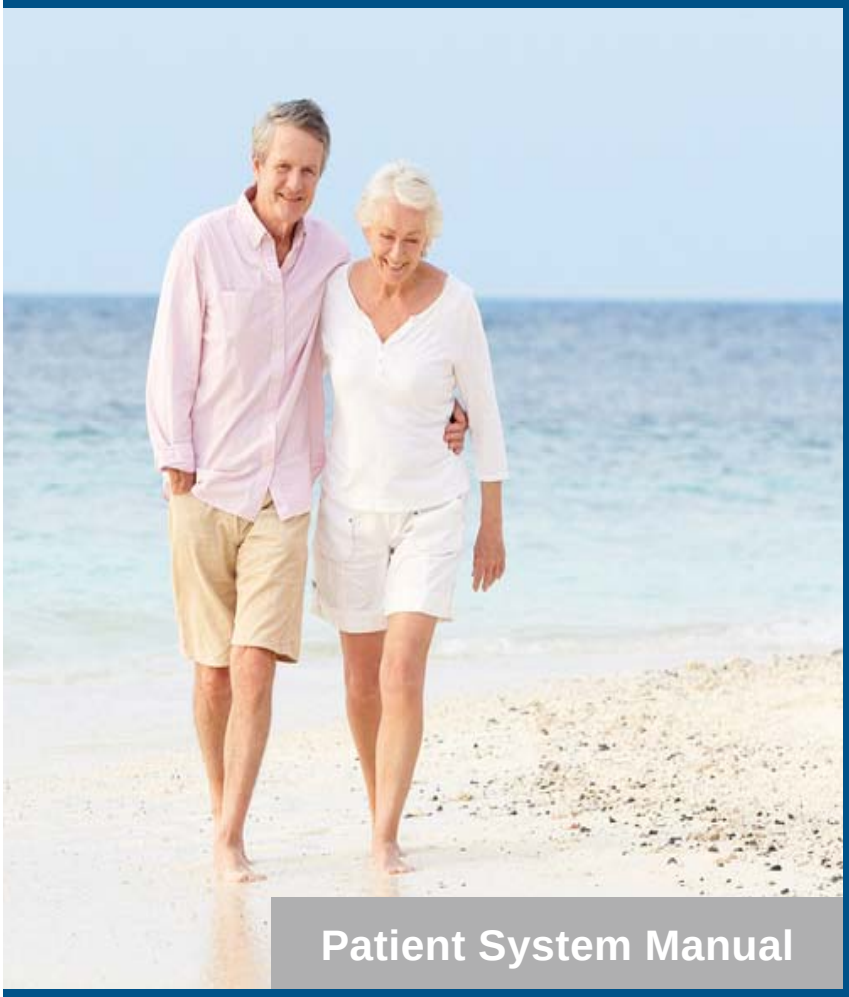
algovita™



Algovita™ Spinal Cord Stimulation System

Programmer Charger Model 4200

Pocket Programmer Model 4100

Patient System Manual

ALGOSTIM, LLC

℞ ONLY

CE 0123

2014

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FCC Information (US Only)
The following is communications regulation information about the Algovita Programmer Charger and Pocket Programmer.
Programmer Charger FCC ID: 2ABU84200
Pocket Programmer FCC ID: 2ABU84100

These devices comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) These devices may not cause harmful interference, and (2) These devices must accept any interference received including interference that may cause undesired operation.
Important: Changes and modifications to the products not authorized by Algostim, LLC could void the FCC certification and negate your authority to operate these products.

Explanation of Symbols Used on Packaging and Programmers

Symbol	Explanation
CE 0123 2014	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive AIMD 90/385/EEC and R&TTE Directive 1999/5/EC.
Rx ONLY	Caution: Federal Law (USA) restricts this device to sale on or by the order of a physician.
FC	This device complies with Part 15 of the Federal Communication Commission rules
EC REP	Authorized representative in Europe
	Consult instructions for use
	Caution
SN	Serial number
REF	Catalogue number
MODEL	Model
	Fragile, handle with care
	Keep dry
	Temperature limitation
	Atmospheric pressure limitation

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Symbol	Explanation
	Humidity limitation
	Keep away from sunlight
	Do not use if package is damaged
	Non-ionizing radiation
	Manufacturer
	Date of manufacture
	Type BF equipment
	Class II Equipment
	Not for general waste
	Recycle
	Contents
	Telephone

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1. Introduction

Your doctor has prescribed an Algovita™ Spinal Cord Stimulation (SCS) System for the management of your chronic pain. SCS is a therapy that has helped many patients reduce their pain.

About this Manual

This Patient System Manual describes your SCS system and provides important safety information about living with your SCS system. This manual also provides instructions on how to use, charge, and care for the programmers that allow you to adjust your SCS system. Read this manual completely and contact your doctor if you have questions or if there is any information you do not understand.

This manual applies to the Algovita Programmer Charger Model 4200 and Algovita Pocket Programmer Model 4100 for use with Algovita Stimulator Models 2408 and 2412.

Spinal Cord Stimulation Therapy

Your SCS system delivers mild electrical pulses, called stimulation, to a specific area in your spinal cord associated with a pain site such as a right or left leg. The stimulation modifies pain signals traveling from the pain site, through your spinal cord, and to your brain, altering how the brain perceives the pain. Patients feel stimulation as a tingling sensation that masks or covers their pain.

How well the stimulation covers your pain may change as you change position, participate in different activities, or if you have a change in symptoms. Your doctor has programmed your stimulator with different programs, each designed to meet your stimulation needs in these different situations. In addition, the SCS system allows you to adjust some stimulation settings within a program, such as increasing or decreasing the strength of stimulation.

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Over time, you and your doctor will work together to fine-tune the programming of your SCS system so it best manages your pain. It is important to understand that SCS helps you manage your pain and does not cure pain or eliminate its cause.

Your doctor may have you use the SCS system alone, or your doctor my prescribe other pain management therapies to be used in conjunction with your SCS system.

Spinal Cord Stimulation System

Figure 1. Algovita SCS System

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Your SCS system *(Figure 1)* has an implanted, rechargeable stimulator connected to one or more leads. The stimulator produces the stimulation that travels through the leads, then through the metal electrodes near the lead tip, to your spinal cord.

A Programmer Charger and a Pocket Programmer allow you to adjust your stimulation. To charge your stimulator, the Programmer Charger is used with the charging paddle and either an adjustable belt or adhesive patch.

- **Stimulator—**Contains a rechargeable battery and the electronics that produce stimulation. The stimulator is also known as an implanted pulse generator (IPG).
- **Leads—**Coated wires that carry stimulation from the stimulator to the spinal cord. One, two, or three leads may be implanted. Some SCS systems use an extension to extend the length of the leads.
- **Programmer Charger—**Allows you to adjust your stimulation, charge your stimulator, and check your stimulator battery charge levels.
  - » **Charging paddle—**When you charge your stimulator, the charging paddle is attached to the Programmer Charger and placed over your stimulator.
  - » **Adjustable belt or adhesive patches—**Used to keep the charging paddle in position while charging the stimulator.
- **Pocket Programmer—**Small programmer that allows you access to the most common functions used for adjusting your stimulation. Also allows you to check your stimulator battery charge levels.

After Your Surgery

After surgery, your doctor provided you with complete instructions on postoperative care. During the first two weeks, it is important to use care so that the incision heals properly and the stimulator and leads remain securely in place.

During the two weeks following surgery:

- Do not lift objects weighing more than 5 pounds (2 kilograms).
- Do not engage in rigorous physical activity such as twisting, bending, or climbing.
- If new leads were implanted, do not stretch your arms over your head.

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As the incision heals, you may temporarily have some pain in the area where your stimulator was implanted. If pain is severe, or if discomfort continues beyond two weeks, contact your doctor.

If you notice redness and/or persistent drainage around an incision during this time, contact your doctor to check for infection. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

Make sure to follow your doctor's instructions, including instructions on care of your incision, restricted and recommended activities, and scheduling your follow-up appointments. If you have any questions, contact your doctor.

Patient Identification Card

When your SCS system was implanted, your doctor gave you a temporary patient identification card.

Your identification card contains information about you, your SCS system, and your doctor. Make sure to carry your identification card with you at all times. Showing your identification card may allow you to bypass security devices.

If you move, change doctors, or lose your identification card contact Algostim Customer Service for a replacement card.

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2. Important Safety Information

Purpose of the Spinal Cord Stimulation System (Indications for Use)

The Algovita Spinal Cord Stimulation (SCS) System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain.

Contraindications

Diathermy: Shortwave, microwave and/or therapeutic ultrasound diathermy must not be used on SCS patients. The energy generated by diathermy can be transferred through the SCS system, causing tissue damage at the lead site which may result in severe injury or death.

Failed Stimulation Trial. Patients who have failed to receive effective pain relief during a stimulation trial.

Warnings

Ablation. Make sure that your doctor knows you have an implanted SCS system before receiving ablation. Safety has not been established for radiofrequency (RF) or microwave ablation in patients who have an SCS system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Electrocautery. Make sure that your doctor knows you have an implanted SCS system before receiving electrocautery. If used improperly, electrocautery may damage your SCS system or result in severe injury.

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Electromagnetic Interference (EMI). EMI is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with stimulator function. The Algovita SCS System is designed to be immune from common sources of electromagnetic interference. Strong EMI can result in:

- **Serious injury**, resulting from heating of the implanted components that causes damage to surrounding tissue
- **System damage**, resulting in loss or change in symptom control requiring surgical replacement
- **Operational changes to the stimulator**, causing stimulation to turn on or off, resetting to default clinician settings, or losing stimulation which can result in a return of symptoms
- **Unexpected changes in stimulation**, causing a momentary increase in stimulation which may cause an uncomfortable or jolting sensation

If any system components (stimulator, leads, lead fragments, or extensions) remain implanted in the patient after a partial system explant, the patient is still susceptible to the above listed adverse effects.

The most common sources of EMI are discussed below.

- **Hospital or Medical Environments**

  Always inform healthcare personnel that you have an implanted Algovita SCS System (and show your patient identification card) before any procedure is performed. Many diagnostic procedures, such as x-rays and ultrasounds, may be performed without affecting the Algovita SCS System. However other diagnostic and therapeutic equipment with higher energy levels may interfere with the Algovita SCS System. Refer to the individual contraindications, warnings, and precautions for specific information.

- **Home, Work, or Public Environments**

  Avoid or exercise caution when in the presence of the following potential sources of EMI that may affect the operation of the stimulator:

  » Radiofrequency identification (RFID) sources

  » **Theft detectors or security screeners such as those used at entrances or exits**

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of department stores, libraries, and other public establishments, and airport security screening devices. Patients should exercise caution when approaching such a device and should request assistance to bypass the device. If the patient must proceed through the device, the patient should turn the stimulator off and proceed with caution, moving through the center of the screener as quickly as possible.

- Power lines and transmission towers
- Electric substations, power generators and large transformers
- Portable and mobile RF communications equipment
- Electric arc welding equipment
- Electric steel furnaces
- Electric induction heaters
- Electric fences
- Body fat measurement scales
- Jackhammers
- Stun guns

The following commonly used items should not affect the operation of the stimulator:

- Cell phones and Bluetooth devices
- Electric toothbrushes, electric shavers, and hair trimmers
- Microwave ovens
- Appliances such as washing machines, dryers, electric stoves, toasters, blenders, electric can openers, and food processors
- Electric blankets and heating pads
- Personal computers, electric typewriters, copiers, and fax machines
- Televisions, AM/FM radios, stereos, personal music players
- Vacuum cleaners and electric brooms

For additional information about devices that generate electromagnetic interference contact your doctor.

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Heat Due to Charging. Do not charge your stimulator while you are sleeping. While charging, the charging paddle may become too warm, which may result in a burn. Failure to use the adjustable belt or an adhesive patch as shown in the charging instructions may also result in a burn.

Other Active Implanted Medical Devices. Algovita SCS System interactions with other active implantable medical devices (such as pacemakers, defibrillators, implanted spinal cord and peripheral nerve stimulators, deep brain stimulators, implantable infusion pumps, cochlear implants, and vagus nerve stimulators) are not known. If you have another implanted device, make sure your doctor knows that you have an implanted SCS system, so that medical decisions can be made and appropriate safety measures taken.

Magnetic Resonance Imaging (MRI). As a patient with an Algovita SCS system, you must not be exposed to MRI. The electromagnetic field generated by an MRI may forcefully dislodge your stimulator or leads, damage the stimulator electronics, and induce voltage through the lead that may cause an uncomfortable or jolting sensation or serious injury. The adverse effects listed above may also occur if your SCS system is explanted and any system components or fragments of components remain implanted. The adverse effects listed above may also occur if your SCS system is explanted and any system components or fragments of components remain implanted.

Programmer Interaction with Other Implanted Devices. Do not charge your stimulator or use your Programmer Charger or Pocket Programmer to change your program settings when you are near a person who has a pacemaker, defibrillator, SCS system, or other implanted device. The effects of Algovita programmers on other implanted devices are unknown.

Programmer Modification. Do not modify the programmers or charging accessories. Modification of any SCS system component may result in damage to the system, compromised system integrity, and harm or injury to the patient.

Stimulator Case Damage. Burns may result if the stimulator case is ruptured or pierced, exposing patient tissue to battery chemicals.

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Precautions

Patient Populations

Use in Pediatric, Pregnant, or Nursing Patients. Safety and effectiveness of SCS has not been established for pediatric patients, for use during pregnancy, or for use with nursing patients.

Other Medical Procedures and Therapies

System Interaction with Other Medical Therapies and Procedures. Make sure that your doctor knows you have an implanted SCS system before receiving any of the following therapies or procedures:

- **Diagnostic ultrasound** (eg, carotid and Doppler scans) has no adverse effect on your SCS system, although the stimulator may interfere with the scan by deflecting the ultrasonic beam.
- **Diagnostic x-rays.** The effects of diagnostic x-rays on a stimulator are typically transient because interference occurs only during the time of x-ray exposure. In some cases, the stimulator may need to be reprogrammed.

The following therapies or procedures may turn your stimulation off or may cause permanent damage to your stimulator, particularly if used in close proximity to the stimulator.

These therapies or procedures may result in loss of therapy and additional surgery to remove or replace components of the Algovita SCS System. If a health care provider decides that one of these therapies or procedures is medically required, contact the doctor who implanted your SCS system for further information.

- Radiotherapy
- Lithotripsy
- External defibrillation
- Radiation therapy
- Ultrasonic scanning

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- High-output ultrasound
- Transcranial magnetic stimulation (TMS)
- Electroconvulsive therapy (ECT)
- CT scans may damage your stimulator if stimulation is on. CT scans are unlikely to damage the stimulator if stimulation is turned off.

TENS Unit. Do not place transcutaneous electrical nerve stimulation (TENS) electrodes so that the current passes over any part of your SCS system. If you believe that use of a TENS unit may be interfering with your stimulator, discontinue use and consult your doctor.

Patient Activities

Adverse Effects from Environmental Conditions. Seek medical guidance before entering environments that may adversely affect the operation of your stimulator.

To avoid adverse effects to you or damage to your SCS system, avoid:

- Areas protected by a warning notice preventing entry by patients who have a pacemaker implanted
- Scuba diving below 5 meters (16 feet), hyperbaric chamber pressures exceeding 1.5 atmospheres absolute pressure, or other activities with large atmospheric pressure variations.
- Extreme environmental temperatures

Automobiles and Other Equipment. Turn your stimulation off before operating an automobile, other motorized vehicle, or potentially dangerous machinery or equipment. Sudden stimulation changes, if they occur, may distract you from attentive operation of the vehicle or equipment.

Cell Phones. While interference with cell phones is not anticipated, cell phone technology continues to change, and interaction with your SCS system is possible. If you have a concern about cell phone interaction with your SCS system, contact your doctor.

Manipulating Your Stimulator. Do not rub or manipulate your stimulator through your skin. Rubbing or manipulation can change the orientation of the stimulator or flip the stimulator over in your body. Manipulation can also cause damage to your system,

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lead dislodgement, skin erosion, or stimulation at the implant site. If the stimulator flips, communication between the programmers and the stimulator may be compromised and charging time may be increased.

Postural Changes. Changes in posture or abrupt movements may cause decreases, or uncomfortable or painful increases in your perceived stimulation level. Before making postural changes, or if unpleasant sensations occur while making postural changes, turn your stimulation down or off.

Programmer Charger and Pocket Programmer

Component Compatibility. Use only the programmers and accessories in your Algovita SCS System to charge your stimulator, charge your programmers, or adjust your stimulation. The effects of non-Algovita components on an Algovita SCS System are unknown.

Electromagnetic Interference (EMI). Your Pocket Programmer and Programmer Charger have been tested for compatibility with different electromagnetic fields. The levels of EMI in your home environment may exceed the levels tested. If your Pocket Programmer or Programmer Charger does not function as expected, please refer to the troubleshooting guide in this manual or contact your doctor.

Flammable Atmospheres. Avoid using the Programmer Charger or Pocket Programmer in flammable or explosive environments (for example during vehicle refueling). Using a battery-powered device near flammable or explosive atmospheres can produce a spark which may cause injury.

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Adverse Events

There are potential risks involved with any surgery. The possible risks of having an SCS system implanted are similar to the risks that can occur with other spinal procedures. These risks include:

- The most common risks are temporary pain at your incision or infection.
- There is a small possibility that you may have a cerebral spinal fluid (CSF) leak.
- In rare cases you may develop bleeding (epidural hemorrhage), a blood clot (hematoma), or a pocket of fluid (seroma) at the location where your leads are placed.
- In rare cases, injury to the spinal cord may occur, resulting in paralysis.
- The use of blood thinners may increase the risk of complications such as blood clots (hematomas), which may produce paralysis

The possible risks of having an SCS system to treat your chronic pain include:

- Your leads may shift or move from the location where they were originally implanted. Such a change in location may cause changes in stimulation, sometimes unpleasant, and/or reduce the pain relief provided by your SCS system.
- Your SCS system may fail at some point, due to a random component or battery failure. Examples of failure include battery leakage, lead or lead insulation break, loose connection, electrical short, or component malfunction. A failure may reduce or stop the pain relief provided by your SCS system.
- Your body may have an allergic reaction or become irritated by materials that are used to manufacture your SCS system components. Signs of a negative reaction are persistent redness, swelling, or warmth at the area where your system is implanted
- The skin at the location of your stimulator may become thinner and more sensitive over time. It is also possible that a pocket of fluid (seroma) may collect in the stimulator location.
- You may have ongoing pain in the area where your stimulator, a lead, or an extension is located.
- You may have unpleasant or painful stimulation. Such changes in stimulation may occur if your stimulation settings are changed too quickly, a lead moves or breaks, or

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there is a loose electrical connection in your SCS system.

- Over time, your stimulator may move from the location where it was first implanted.
- You may experience weakness or numbness in areas below your SCS system location.
- You may experience changes in stimulation, painful stimulation, or problems with the operation of your SCS system due to electromagnetic interference from other electrical devices, medical equipment, or medical procedures.
- Epidural mass formation at lead—Over the course of months or years, an epidural mass could form around your implanted SCS lead, which could compress your spinal cord. The effect of spinal cord compression could range from muscle weakness to progressive loss of function in all four limbs. If you experience a change in neurological function, contact your doctor.

If any adverse events occur, contact your doctor.

Limitations of the Clinical Data

The clinical data used to support the effectiveness of the Algovita system were based on published studies from medical journals. The studies were open label, in that patients knew they were receiving stimulation. Open label studies may cause an overestimation of the treatment effect in investigator and subject ratings. Also, open label studies do not assess the magnitude of the placebo response, regression to the mean, the effect of changes in medications or other treatments to alleviate pain or changes in the underlying severity of the pain disorder.

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3. Using Your Programmer Charger

Your Programmer Charger *(Figure 2)* is a rechargeable programmer that allows you to adjust your stimulation, charge your stimulator, and check your Programmer Charger and stimulator battery charge levels.

For information on checking your stimulator battery charge level and charging your stimulator, see *Chapter 5. Charging Your Stimulator Battery on page 53.*

For information on checking your Programmer Charger battery charge level and charging your Programmer Charger, see *Chapter 6. Charging Your Programmer Batteries on page 63.*

Figure 2. Programmer Charger

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How the Programmer Charger Works

Your Programmer Charger wirelessly communicates with your stimulator. When you turn your Programmer Charger on within 3 feet (1 meter) of your stimulator, the Programmer Charger automatically communicates with your stimulator.

Programs and Sub-programs

A program is a combination of stimulation settings used to deliver stimulation to one or more pain sites in your body. Your doctor has created one or more programs designed to meet your stimulation needs for specific activities, symptoms, or times of day. These programs are stored on your stimulator and can be accessed and adjusted using your Programmer Charger or Pocket Programmer.

A program is made up of one or more sub-programs, with each sub-program delivering stimulation. For example, you may have a program with one sub-program that delivers stimulation to your right leg. You may have another program with two sub-programs, where one sub-program delivers stimulation to your right leg and the other sub-program simultaneously delivers stimulation to your left leg.

When a program is delivering stimulation, it is called the active program.

Stimulation Settings You Can Adjust

For each program, you can adjust the strength of your stimulation. If your doctor has allowed, you may also be able to adjust the strength of sub-programs. You may also be allowed to adjust the pulse width and frequency of your stimulation.

- **Strength.** Strength is the intensity of your stimulation. Using either your Programmer Charger or your Pocket Programmer, you can increase or decrease the stimulation strength of a program.
- **Optional—Available if your doctor allowed.**
  - » **Strength of a sub-program.** If any of your programs are made up of more than one sub-program, your doctor may have allowed you to adjust the strength of each sub-program separately.
  - » **Pulse width.** Pulse width is the duration of each electrical pulse that makes up

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your stimulation. If your doctor has allowed, you can adjust the pulse width with your Programmer Charger. Adjusting the pulse width may affect the size or shape of the area where you feel stimulation. Adjusting the pulse width may also change the intensity of your stimulation.

» **Frequency.** Frequency is the number of times the electrical pulses that make up your stimulation are delivered per second. Adjusting the frequency may change the sensation you feel from your stimulation. If your doctor has allowed, you can adjust the frequency of your stimulation with your Programmer Charger.

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Home Screen

The Programmer Charger Home screen *(Figure 3)* displays either 6 or 8 buttons, depending on if your doctor has allowed you the option of adjusting the frequency and pulse width of your stimulation programs.

When a button is grayed out, it is temporarily unavailable. For example, when the charging paddle is not connected to the Programmer Charger, the Charge Status button is grayed out and you cannot charge your stimulator.

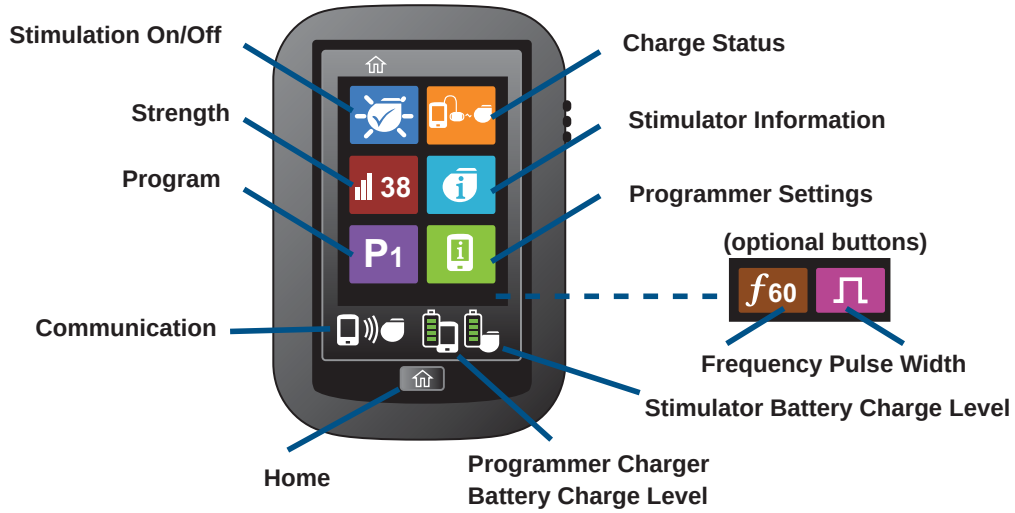

Figure 3. Home screen buttons and icons

The Home screen buttons allow you to check your current stimulation settings and go to screens where you can adjust your stimulation and programmer settings.

- **Stimulation On/Off—**Check if stimulation is on or off. Turn stimulation on or off.
- **Strength—**When stimulation is on, check the strength for the active program. When stimulation is off, check the strength of the most recently active program. Increase or decrease the strength of stimulation for the active program.
- **Program—**When stimulation is on, check the program number of the active program

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or select a new program. When stimulation is off, check the program number of the most recently active program or select a new program to become active when stimulation is turned on.

- **Charge Status—**Charge your stimulator battery.
- **Stimulator Information—**Check the stimulator serial numbers. Return the strength, pulse width, frequency, stimulation on/off, and active program back to what was set by your doctor.
- **Programmer Settings—**Set Programmer Charger settings such as date, time, date/time format, volume, screen brightness, button click on/off. Calibrate your Programmer Charger touch screen. Check Programmer Charger serial numbers and related information.
- **Frequency (optional)—**If this button is displayed, check the frequency of the active program. Increase or decrease the frequency of stimulation.
- **Pulse Width (optional)—**If this button is displayed, increase or decrease the pulse width of stimulation.
- **Communication—**Check if your Programmer Charger has established communication with your stimulator.
- **Home—**From any screen, return to the Home screen. The Home screen icons display your current communication and battery charge level status.
- **Programmer Charger Battery Charge Level—**Check the amount of charge in your Programmer Charger battery.
- **Stimulator Battery Charge Level—**Check the amount of charge in your stimulator battery.

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Turning the Programmer Charger On or Off

If not used for 5 minutes, the Programmer Charger turns off. The Programmer Charger does not turn off if a Programmer Charger or stimulator battery is charging.

To turn the Programmer Charger on:

1. Make sure your Programmer Charger is within 1 meter (3 feet) of your stimulator.
2. Slide the gray Power On/Off button down (*Figure 4*) and hold for approximately 2 seconds. While your Programmer Charger is establishing communication with your stimulator, a connecting screen appears.

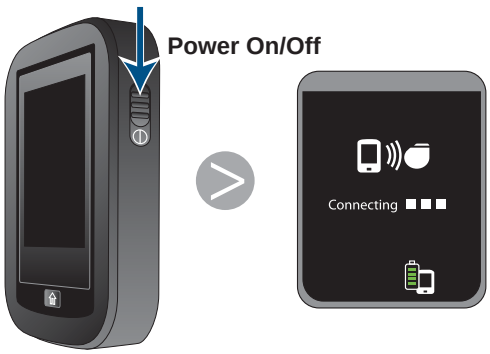

Figure 4. Turning power on or off

Note: If the Not able to connect screen appears (*Figure 5*):

Figure 5. Not able to connect screen

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» Make sure your Programmer Charger is within 1 meter (3 feet) of your stimulator, then tap **Retry**.

» If you tapped **Retry**, and your Programmer Charger still cannot establish communication with your stimulator, see *Programmer Charger Help Guidelines on page 99*.

When the Programmer Charger establishes communication with your stimulator, the Home screen, the Communication icon, and the Stimulator Battery Charge Level icons appear (*Figure 6*).

Figure 6. Communication with stimulator established

To turn the Programmer Charger off:

- Slide the Power On/Off button down and hold for 2 seconds (*Figure 4*).

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Turning Stimulation On or Off

The Stimulation On/Off button shows if your stimulation is on or off.

- When stimulation is on, the Program and Strength buttons display the active program and its current strength.
- When stimulation is off:
  - » The program displayed on the Program button will become active when stimulation is turned on.
  - » The Strength button is not available, so the button is grayed out, and the strength cannot be adjusted.
- A new program can be selected while stimulation is on or off.

To turn stimulation on or off:

If you are turning stimulation on, your stimulator starts the program displayed on the Program button.

As the program starts, the strength slowly ramps up to the strength set for that program. The Strength setting is visible on the Strength button.

1. Tap or on the Home screen (*Figure 7*).

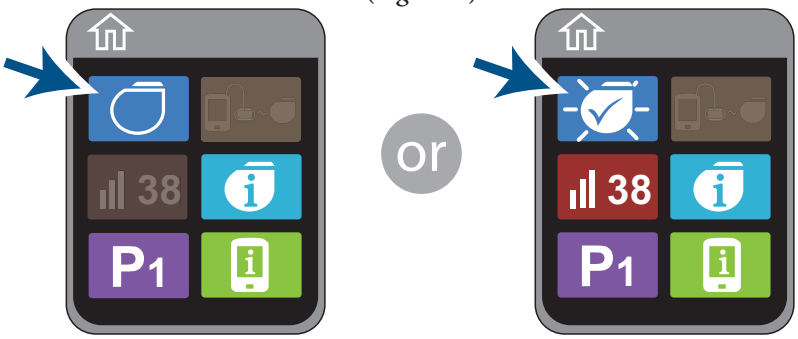

Figure 7. Stimulator Off and Stimulation On buttons

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The Stimulation On/Off screen appears (*Figure 8*). A white frame borders the button with the current stimulation status.

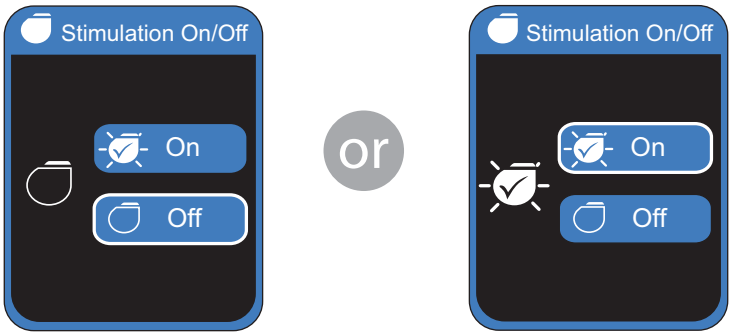

Figure 8. Current stimulation status

2. Tap or to turn stimulation on or off (*Figure 9*)).

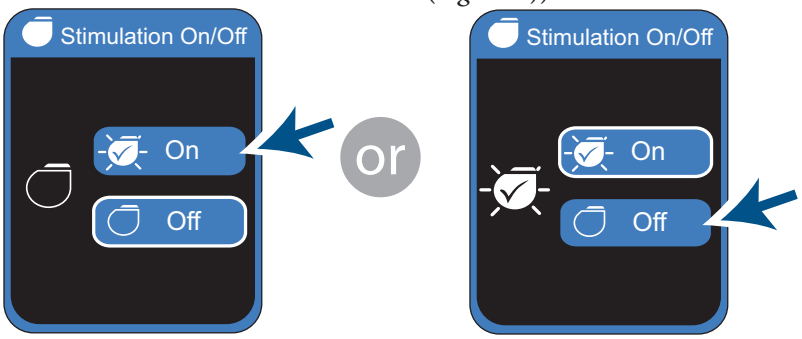

Figure 9. Turning stimulation on or off

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If you are turning stimulation on, a notification screen appears (*Figure 10*) while your stimulator starts the program and the strength slowly ramps up to the strength set for that program. If the strength is high enough, you may feel stimulation.

Figure 10. Starting stimulation program notification screen

The Stimulation On/Off screen appears (*Figure 11*) A white frame borders the button with the new stimulation status

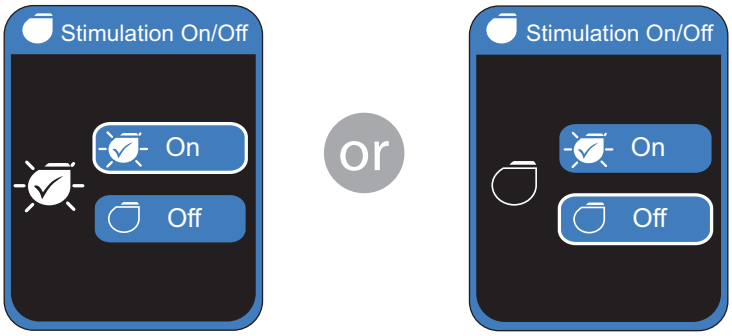

Figure 11. New stimulation status

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3. Tap (*Figure 12*) to return to the Home screen. The new stimulation status is displayed on the Stimulation On/Off button.

Figure 12. Returning to the Home screen

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Quick Stimulation Off

Pressing the Quick Stimulation Off button quickly turns your stimulation off.

To quickly turn stimulation off:

1. Make sure your Programmer Charger is turned on.

   Note: If your Programmer Charger is turned off, pressing the Quick Stimulation Off button turns your stimulation off, but only after first taking the time to turn your Programmer Charger on.

2. Make sure the Programmer Charger is within 1 meter (3 feet) of your stimulator.
3. Locate the red Quick Stimulation Off button on the left side of your Programmer Charger.
4. Press and hold the Quick Stimulation Off button (*Figure 13*). Your stimulation turns off, and the Home screen appears with the Stimulation Off button displayed.

Figure 13. Using Quick Stimulation Off button

5. If you do not want to restart stimulation using the same program at the same strength, do either of the following before turning stimulation on again:
   - » Select a new program.
   - » Return all stimulation settings for all programs to those set by your doctor. (For instructions, see *Resetting Stimulation Settings on page 37).*

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Selecting a Program

- When stimulation is on, the Program button displays the active program.
- When stimulation is off, the Program button displays the program that will become active when stimulation is turned on.
- A new program can be selected while stimulation is on or off.

Caution: Select the program that your doctor has recommended for a certain activity or posture. Use of another program may cause an uncomfortable or jolting sensation when stimulation is turned on.

To select a program:

1. Tap P# on the Home screen (*Figure 14*). The Program screen appears. The active program is outlined in white, and the program number is displayed on the left side of the screen.

Figure 14. Displaying the Program screen

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2. If ▼ and ▲ are displayed, you have more than 4 programs available (*Figure 15*). To view more programs, tap ▼.

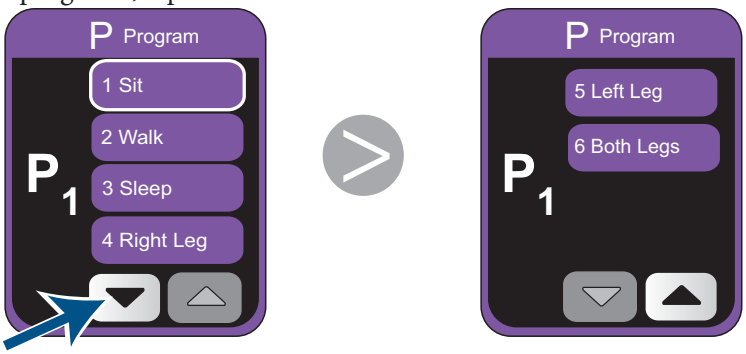

Figure 15. Viewing additional programs

3. To select a program, tap a program button (*Figure 16*). A notification screen appears while the stimulator ramps down the strength of the current program, then ramps up the strength of the new program.

   When ramping is complete, the Program screen appears with the newly active program outlined in white and the new program number is displayed on the left side of the screen.

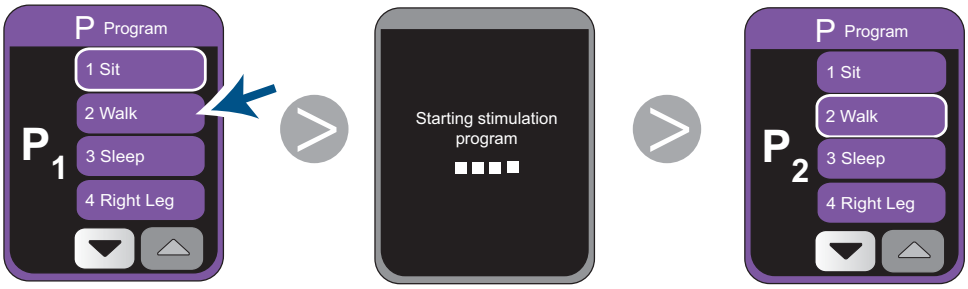

Figure 16. Selecting a program

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4. Tap to return to the Home screen (*Figure 17*). The newly active program is displayed on the Program button.

Figure 17. Returning to the Home screen

Adjusting Stimulation Strength

Strength is the intensity of your stimulation.

- When stimulation is on:
  - » The Strength button displays the strength of the active program. If the active program has more than one sub-program, the strength of the sub-program with highest strength is displayed
  - » You can increase or decrease the strength of an active program within a range set by your doctor.
- When stimulation is off:
  - » The Strength button displays the strength for the most recently active program, which will become active when stimulation is turned on.
  - » The Strength button is not available, so the button is grayed out, and the strength cannot be adjusted.

Caution: To prevent a possible uncomfortable or jolting sensation, avoid adjusting your strength to levels far above your pain relief threshold.

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To adjust the strength of a program:

1. Verify that your stimulation is on .
2. Tap # on the Home screen. (*Figure 18*). The Strength screen appears with the strength displayed on the left side of the screen.

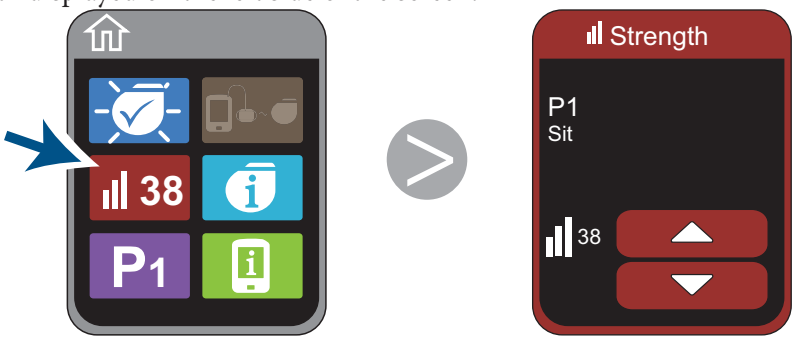

Figure 18. Displaying the Strength screen

3. Tap or to increase or decrease the strength of your stimulation (*Figure 19*). If is displayed, the active program has more than one sub-program and your doctor has allowed you the option of fine-tuning your stimulation by increasing or decreasing the strength of all sub-programs at the same time or each sub-program separately.
   - » The first Strength screen displays the name of the program. Tapping or increases or decreases the strength of all sub-programs in the program.
   - » Each subsequent Strength screen displays the name of the sub-programs that make up a program.
     - Tap to advance to a Strength screen for the each sub-program.
     - Tap or to increase or decrease the strength a sub-program.

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Note: To quickly increase or decrease the strength, press and hold ▲ or ▼.

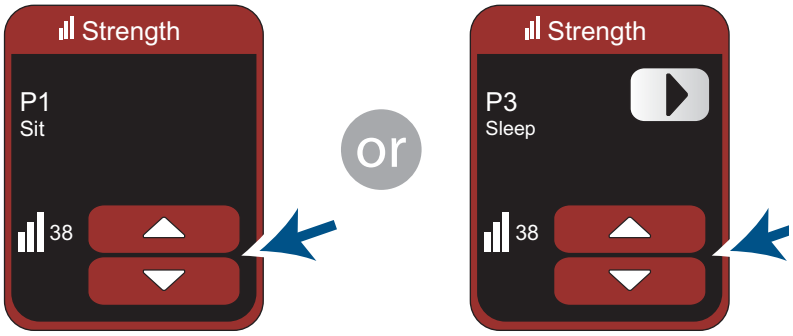

Figure 19. Increasing or decreasing the stimulation strength

4. Tap ⌂ (*Figure 20*) to return to the Home screen. The new strength is displayed on the Strength button.

Figure 20. Returning to the Home screen

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Optional Stimulation Settings

If or is displayed on your Home screen, your doctor has allowed you the option of adjusting the frequency or pulse width of your stimulation.

Adjusting Frequency

Frequency is the number of times the electrical pulses that make up your stimulation are delivered per second. Adjusting the frequency may change the sensation you feel from your stimulation.

- When stimulation is on:
  - » The Frequency button displays the frequency of the active program.
  - » You can increase or decrease the frequency of an active program within a range set by your doctor.
- When stimulation is off:
  - » The Frequency button displays the frequency for the most recently active program, which will become active when stimulation is turned on.
  - » The Frequency button is not available, so the button is grayed out and the frequency cannot be adjusted.

To adjust the frequency of a program:

1. Verify that your stimulation is on .
2. Tap on the Home screen (*Figure 21*). The Frequency screen appears with the frequency displayed on the left side of the screen.

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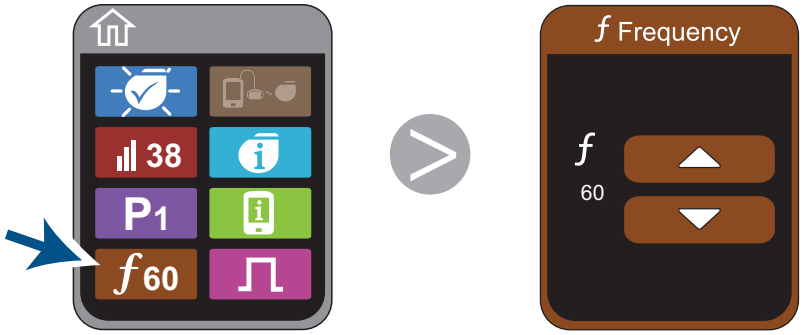

Figure 21. Displaying the Frequency screen

3. Tap ▲ or ▼ to increase or decrease the frequency of the program (*Figure 22*).

Notes:

» Frequency does not increase or decrease in steps of 1. Your doctor chose the set of frequencies that provide you with options appropriate for your therapy.

» To quickly increase or decrease the frequency, press and hold ▲ or ▼.

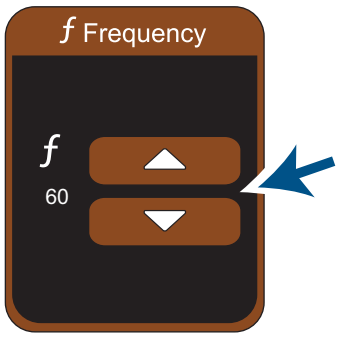

Figure 22. Increasing or decreasing the frequency

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4. Tap (*Figure 23*) to return to the Home screen. The new frequency is displayed on the Frequency button.

Figure 23. Returning to the Home screen

Adjusting Pulse Width

Pulse width is the duration of each electrical pulse that makes up your stimulation. Adjusting the pulse width may affect the size or shape of the area where you feel stimulation. Adjusting the pulse width may also change the intensity of your stimulation.

- When stimulation is on, you can increase or decrease the pulse width of each sub-program in an active program within a range set by your doctor.
- When stimulation is off, the pulse width button is not available, so the button is grayed out, and the pulse width cannot be adjusted.

To adjust the pulse width of a program:

1. Verify that your stimulation is on .
2. Tap on the Home screen(*Figure 24*). The Pulse Width screen appears with the pulse width displayed on the left side of the screen.

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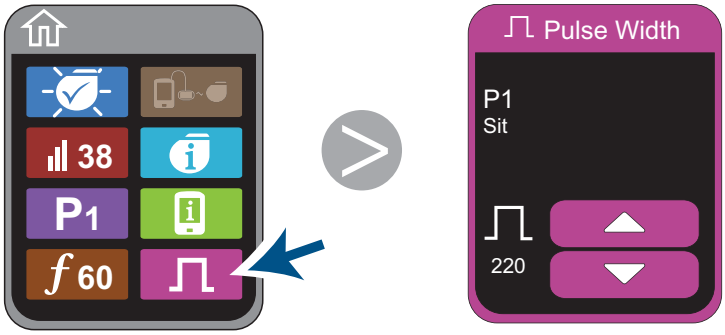

Figure 24. Displaying the Pulse Width screen

3. Tap ▲ or ▼ to increase or decrease the pulse width of the program (*Figure 25*).

   If ▶ is displayed, the active program has more than one sub-program, and your doctor has allowed you the option of fine-tuning your stimulation by increasing or decreasing the pulse width of each sub-program separately. Unlike strength, you cannot adjust the pulse width of all sub-programs at the same time.

   » The first Pulse Width screen displays the name of the first sub-program. Tapping ▲ or ▼ increases or decreases the pulse width of the sub-program.

   » Tap ▶ to advance to the Pulse Width screen for the next sub-program.

   Note: To quickly increase or decrease the pulse width, press and hold ▲ or ▼.

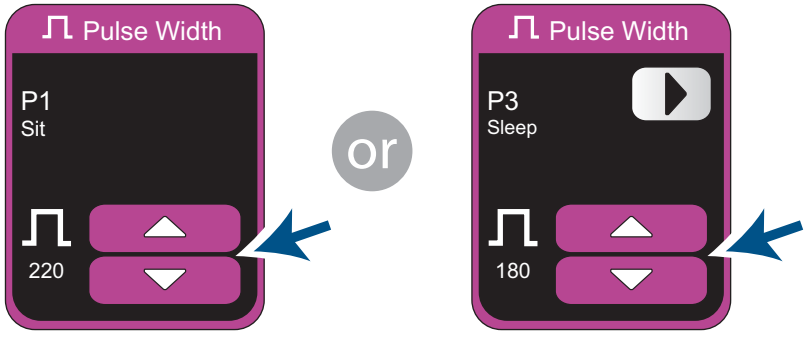

Figure 25. Increasing or decreasing the pulse width

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4. Tap (*Figure 26*) to return to the Home screen.

Figure 26. Returning to the Home screen

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Resetting Stimulation Settings

Resetting the stimulation settings returns all settings for all programs to what was set by your doctor. Strength, pulse width, frequency, stimulation on/off, and which program is active are reset.

To reset stimulation settings for all programs:

1. If your stimulation is on , turn your stimulation off . (For instructions on turning Stimulation off, see *Turning Stimulation On or Off on page 22).*
2. Tap on the Home screen (*Figure 27*). The Stimulator Information screen appears.

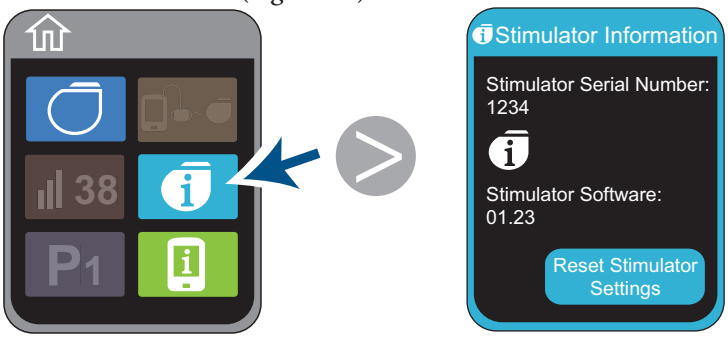

Figure 27. Displaying the Stimulator Information screen

3. Tap Reset Stimulator Settings. (*Figure 28*). A screen appears asking if you want to reset the stimulation settings for all programs.

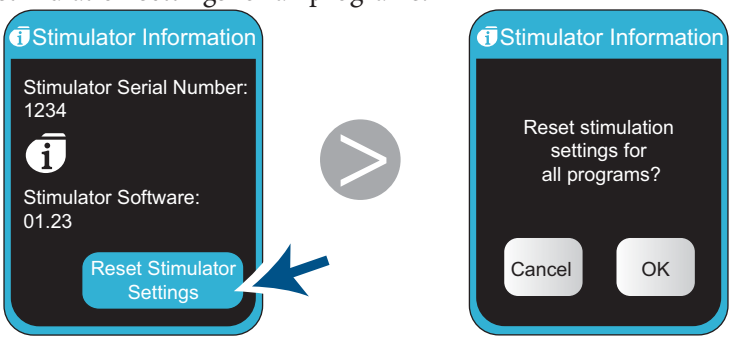

Figure 28. Resetting the stimulation settings for all programs

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4. Tap **OK** (*Figure 29*). The Reset Complete screen appears. The stimulation settings for all programs have been reset.

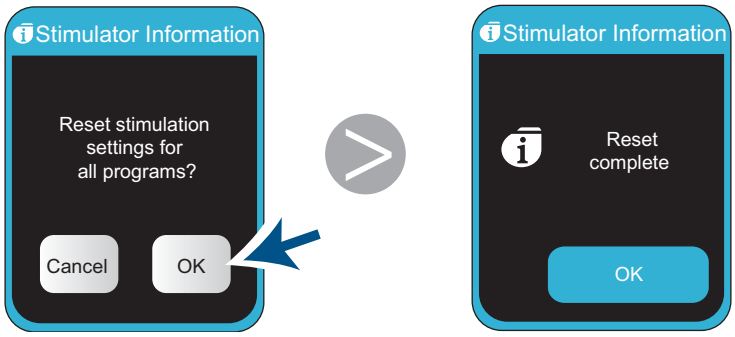

Figure 29. Simulation settings have been reset

5. Tap **OK** (*Figure 30*). The Stimulator Information screen appears.

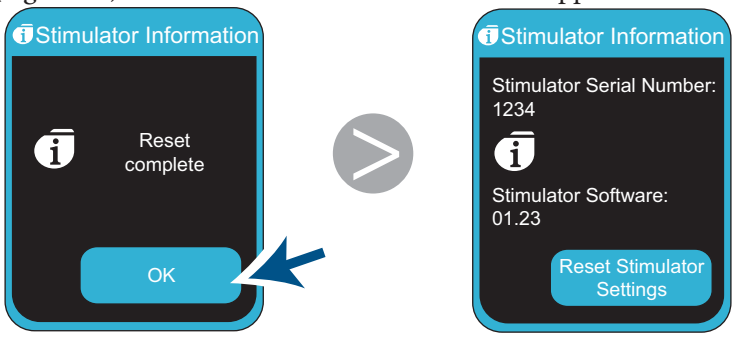

Figure 30. Returning to the Stimulator Information screen

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6. Tap (*Figure 31*) to return to the Home screen.

Figure 31. Returning to the Home screen

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4. Using Your Pocket Programmer

Your Pocket Programmer *(Figure 32)* is a small, rechargeable programmer that allows you access to the most commonly used programmer functions: turning your stimulation on or off, adjusting your stimulation strength, selecting a new program, and checking your Pocket Programmer and stimulator battery charge levels.

Your Pocket Programmer wirelessly communicates with your stimulator. When you turn your Pocket Programmer on within 3 feet (1 meter) of your stimulator, the Pocket Programmer automatically communicates with your stimulator.

Figure 32. Pocket Programmer

For information on checking your stimulator battery charge level and charging your stimulator, see *Chapter 5. Charging Your Stimulator Battery on page 53.*

For information on checking your Pocket Programmer battery charge level and charging your Pocket Programmer, see *Chapter 6. Charging Your Programmer Batteries on page 63.*

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Pocket Programmer Screen and Buttons

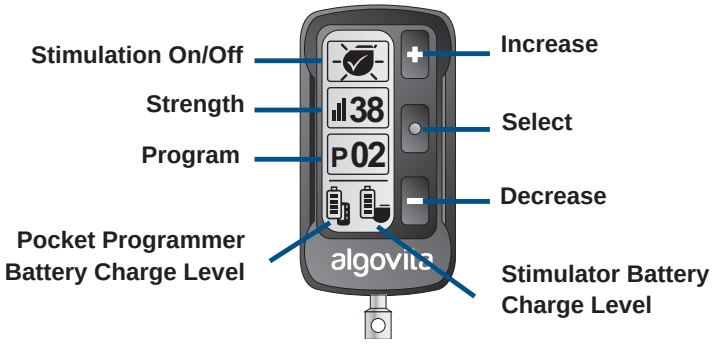

Figure 33. Pocket Programmer screen buttons and icons

Using the Pocket Programmer, you can turn stimulation on and off, change which program is delivering stimulation, and change the strength of stimulation *(Figure 33)*.

Pocket Programmer screen icons

- **Stimulation On/Off—**Check if stimulation is on or off.
- **Strength—** When stimulation is on, check the strength for the active program. When stimulation is off, check the strength of the most recently active program.
- **Program—** When stimulation is on, check the program number of the active program or select a new program. When stimulation is off, check the program number of the most recently active program.
- **Pocket Programmer Battery Charge Level—**Check the amount of charge in your Pocket Programmer battery.
- **Stimulator Battery Charge Level—**Check the amount of charge in your stimulator battery.

Pocket Programmer screen buttons

- **Increase—**Press to increase the program number or strength.
- **Select—**Press to scroll down the screen icons, turn stimulation on or off, or activate a new program or strength.
- **Decrease—** Press to decrease the program number or strength.

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Turning the Pocket Programmer On or Off

If you do not press any buttons for 1 minute, the Pocket Programmer turns off. The Pocket Programmer does not turn off if its battery is charging.

To turn the Pocket Programmer on:

1. Make sure Pocket Programmer is within 1 meter (3 feet) of your stimulator.
2. Slide the black Power On/Off button down (*Figure 34*) and hold for approximately 2 seconds. While your Pocket Programmer is establishing communication with your stimulator, a rectangle scrolls down the screen.

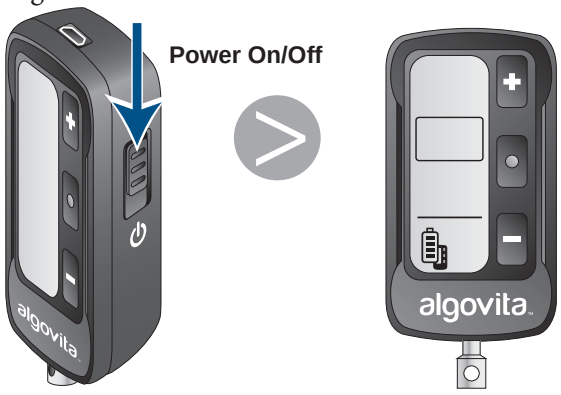

Figure 34. Turning power on or off

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Note: If your Pocket Programmer cannot establish a connection with your stimulator, three blank rectangles are displayed on the screen (*Figure 35*):

Figure 35. Not able to connect to stimulator

» Make sure your Pocket Programmer is within 1 meter (3 feet) of your stimulator, then turn your Pocket Programmer off then on again.

» If your Pocket Programmer still cannot establish communication with your stimulator, see *Pocket Programmer Help Guidelines on page 102.*

When the Pocket Programmer establishes communication with your stimulator, the Pocket Programmer screen and the Stimulator Battery Charge Level icon appear (*Figure 36*).

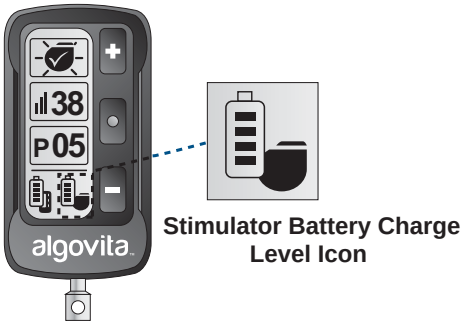

Figure 36. Communication with stimulator established

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To turn the Pocket Programmer off:

- Slide the Power On/Off button down and hold for 2 seconds (*Figure 34*).

Turning Stimulation On or Off

The Stimulation On/Off button shows if your stimulation is on or off.

- When stimulation is on, the Program and Strength buttons display the active program and its current strength.
- When stimulation is off:
  - » The program displayed on the Program button will become active when stimulation is turned on.
  - » The Strength button is not available, so the strength cannot be adjusted.
- A new program can be selected while stimulation is on or off.

To turn stimulation on or off:

If you are turning stimulation on, your stimulator starts the program displayed on the Program icon.

As the program starts, the strength slowly ramps up to the strength set for that program. The Strength setting is visible on the Strength icon.

1. Repeatedly press until or blinks (*Figure 37*).

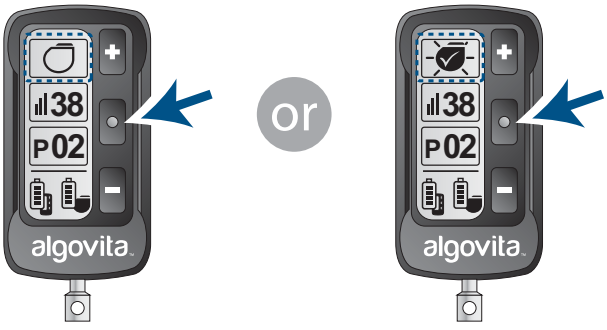

Figure 37. Selecting the Stimulation On or Stimulation Off icon

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2. While the icon is blinking, press + or − to select or (*Figure 38*). The icon keeps blinking.

Figure 38. Changing Stimulation On or Stimulation Off icon

3. While the icon is blinking, press (*Figure 39*) or wait 5 seconds to confirm the new setting.

   If you are turning stimulation on, the border around the Stimulation On/Off icon blinks as the program starts and the strength slowly ramps up to the strength set for that program.

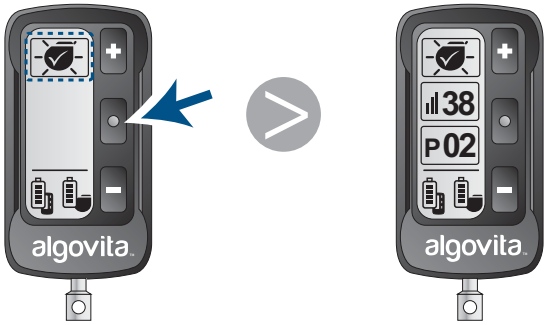

Figure 39. Confirming new setting

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Quick Stimulation Off

Pressing the Quick Stimulation Off button quickly turns your stimulation off.

To quickly turn stimulation off:

1. Make sure the Pocket Programmer is within 1 meter (3 feet) of your stimulator.
2. Locate the red Quick Stimulation Off button on the left side of your Pocket Programmer.
3. Press and hold the Quick Stimulation Off button (*Figure 40*). The Pocket Programmer screen appears with the Stimulation Off icon displayed.

Figure 40. Using Quick Stimulation Off button

4. If you do not want to restart stimulation using the same program at the same strength, do either of the following before turning stimulation on again:
   - » Select a new program.
   - » Use your Programmer Charger to return all stimulation settings for all programs to those set by your doctor. (For instructions, see *Resetting Stimulation Settings on page 37.)*

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Adjusting Stimulation Strength

Strength is the intensity of your stimulation.

- When stimulation is on:
  - » The Strength icon displays the strength of the active program. If the active program has more than one sub-program, the strength of the sub-program with highest strength is displayed.
  - » You can increase or decrease the strength of an active program within a range set by your doctor.
- When stimulation is off:
  - » The Strength icon displays the strength for the program that will become active when stimulation is turned on.
  - » The Strength icon is not available, and the strength cannot be adjusted.

Caution: To prevent a possible uncomfortable or jolting sensation, avoid adjusting your strength to levels far above your pain relief threshold.

To adjust the strength of a program:

1. Verify that your stimulation is on.
2. Repeatedly press until blinks (*Figure 41*).

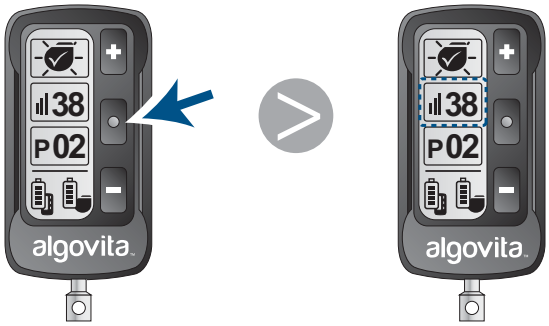

Figure 41. Selecting the Strength icon

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3. While # is blinking, press + or − to increase or decrease the strength of your stimulation (*Figure 42*).

   Note: To quickly increase or decrease the strength, press and hold + or −.

Figure 42. Increasing or decreasing the strength

4. Press ○ (*Figure 43*) or wait 5 seconds to confirm the new setting.

   When the setting is confirmed, # stops blinking.

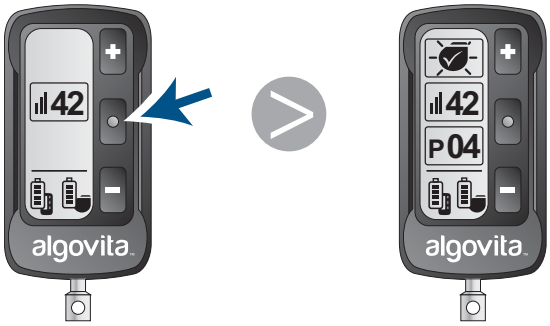

Figure 43. Confirming new setting

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Selecting a Program

- When stimulation is on, the Program icon displays the active program.
- When stimulation is off, the Program icon displays the program that will become active when stimulation is turned on.
- A new program can be selected while stimulation is on or off.

Caution: Select the program that your doctor has recommended for a certain activity or posture. Use of another program may cause an uncomfortable or jolting sensation when stimulation is turned on.

To select a program:

1. Repeatedly press until blinks (*Figure 44*).

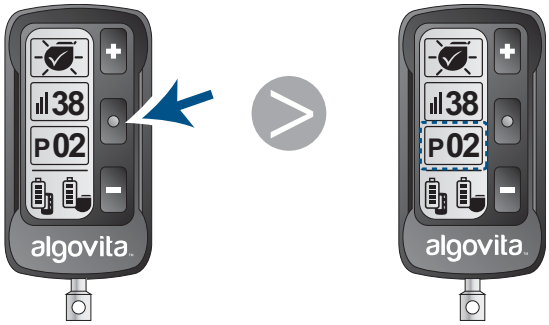

Figure 44. Selecting the Program icon

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2. While P # is blinking, press + or − to select a new program (*Figure 45*).

Figure 45. Selecting the new program

3. Press or wait 5 seconds to confirm the new setting (*Figure 46*).

   If stimulation is on, the border around the Program icon blinks while the stimulator turns off the current program, then ramps up the strength of the new program.

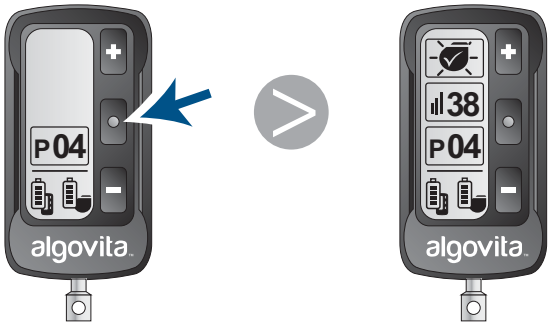

Figure 46. Confirming new setting

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5. Charging Your Stimulator Battery

Your stimulator has a rechargeable battery that can be charged any time the battery charge level is below 100%. How often you need to charge your stimulator depends on your stimulation settings and the amount of time you use stimulation. The stimulator battery is expected to last a minimum of 10 years, but may be more or less depending on your stimulation settings. Over time, you may have to recharge your stimulator battery more frequently. Eventually, your stimulator will need to be replaced surgically.

The higher your stimulation settings and the more often you use stimulation, the more often your stimulator battery will need to be charged. Charging time may range from several minutes to more than 4 hours.

To make sure that stimulation is always available, make sure to check your stimulator battery charge level every day. Develop a routine where you keep your stimulator charged. Consult with your doctor if stimulation cannot be maintained with routine charging.

Checking Your Stimulator Battery Charge Level

When your Programmer Charger or Pocket Programmer is communicating with your stimulator, the Stimulator Battery Charge Level icon is displayed (*Figure 47*).

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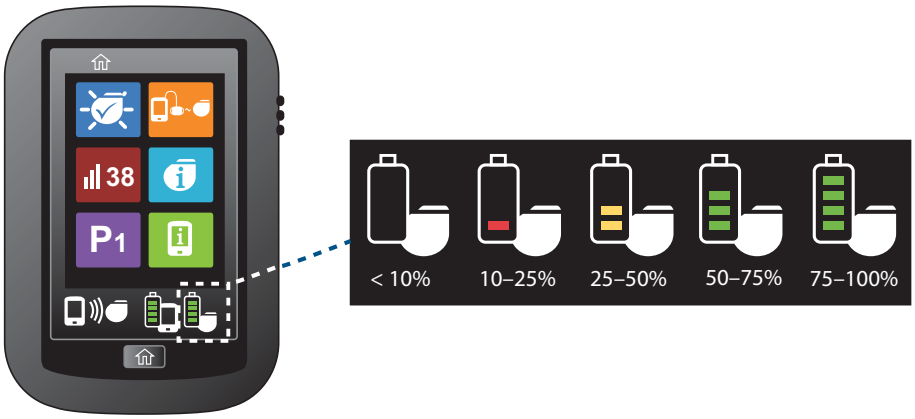

Figure 47. Stimulator Battery Charge Level icon and battery charge levels

When your stimulator battery is fully charged, four green bars are displayed. When the charge level drops below 10%, the icon flashes. In either case, if the Programmer Charger volume is set high enough, you may hear a soft beep.

Caution: Charge your stimulator battery immediately if your stimulator battery charge level displays 0 bars. If the battery charge level drops too far below 10%, stimulation will become unavailable until the battery is charged.

Note: Your Pocket Programmer displays a black and white stimulator battery charge level icon.

Charging Your Stimulator Battery

Warning: Do not charge your stimulator while you are sleeping. While charging, the charging paddle may become too warm, which could result in a burn. Failure to use the adjustable belt or an adhesive patch as shown in the charging instructions may result in a burn.

Cautions:

- Do not place the charging paddle on an unhealed wound. The charging paddle is not sterile, and contact with an unhealed wound may result in an infection.

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- Keep metal objects away from the charging paddle while charging. Metal objects can affect the communication between the Programmer Charger and the stimulator, increasing stimulator charge time.
- The charging paddle may become warm during use. If the warmth is uncomfortable, you may place a cotton cloth between the charging paddle and your skin to avoid discomfort.
- If you have prolonged skin irritation or redness at the charging site, contact your doctor.

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To charge the stimulator battery:

Note: If the air temperature is greater than 35°C (95°F), charging may stop and a message saying that the charging paddle is over temperature may appear. If this message appears, wait 5–10 minutes and try charging again.

1. Make sure the Programmer Charger is sufficiently charged or connected to the AC power adapter.
   a. Make sure the Programmer Charger Battery Charge Level icon displays at least 3 bars (*Figure 48*).

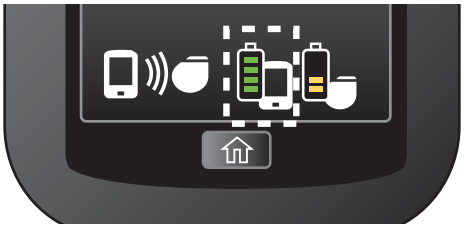

Figure 48. Programmer Charger Battery Charge Level icon

   b. If the Programmer Charger Battery Charge Level icon displays fewer than 3 bars, the Programmer Charger battery may not have enough charge to fully charge your stimulator.

      If needed, connect the AC power adapter to the Programmer Charger and plug the power adapter into a wall outlet (for detailed instructions, see *Charging Your Programmer Charger Battery on page 63).*

      Warning: When charging your stimulator, do not use the AC power adapter near water or during a lightning storm. Electric shock, serious injury, or death may result.

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2. Connect the charging paddle to the Programmer Charger (*Figure 49*). The icon becomes available.

Figure 49. Connecting the charging paddle.

3. Tap on the Home screen (*Figure 50*). The Charge Status screen appears.

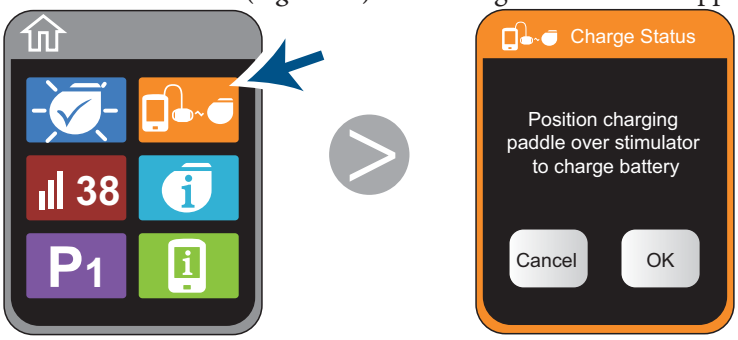

Figure 50. Displaying the Charge Status screen

4. The charging paddle will need to stay aligned over your stimulator while the stimulator is charging. Use ***either*** the adjustable belt ***or*** an adhesive patch to hold the charging paddle in place.

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» **Adjustable belt**—Slide the charging paddle through the belt loops so the belt runs across the back of the charging paddle, not across the charging surface (*Figure 51*).

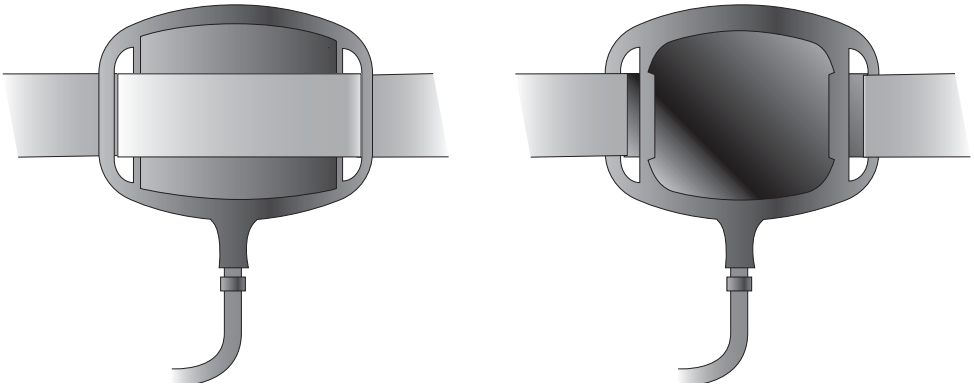

Figure 51. Attaching the adjustable belt

» **Adhesive patch** (*Figure 52*)

- Peel the protective paper from the back (blank side) of an adhesive patch.
- Secure the patch to the charging paddle charging surface.
- Remove the protective paper from the front of the patch, but do not adhere the adhesive patch to your skin until the final charging paddle position is determined.

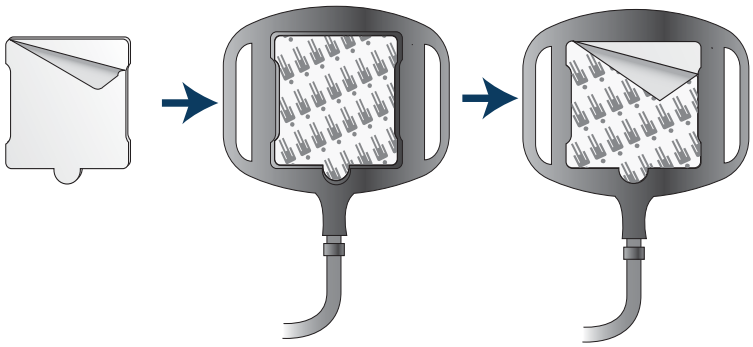

Figure 52. Attaching an adhesive patch

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5. Position the charging paddle over your stimulator, then tap **OK** (*Figure 53*).

Figure 53. Positioning the charging paddle

6. Move the paddle back and forth over your stimulator until the alignment icon appears.(*Figure 54*).

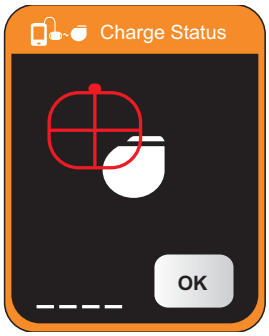

Figure 54. Aligning the charging paddle for maximum efficiency

7. Adjust the position of the charging paddle so it is aligned for maximum charging efficiency (*Figure 55*).

   When aligned for maximum charging efficiency:

   » The alignment icon is green and is centered over the stimulator icon.

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» Up to five strength bars appear on the bottom left corner of the screen. The more strength bars visible, the higher the charging efficiency. The maximum number of strength bars available varies by patient.

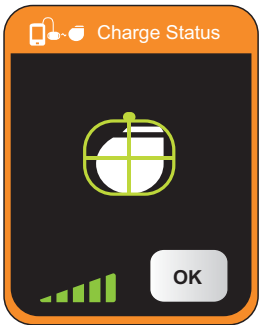

Figure 55. Aligning the charging paddle for maximum efficiency

8. Maintaining the charging paddle position, tighten the belt or press the charging paddle with the adhesive patch securely to your skin. Tap **OK** on the Charge Status screen (*Figure 56*). A Charging in Progress screen appears.

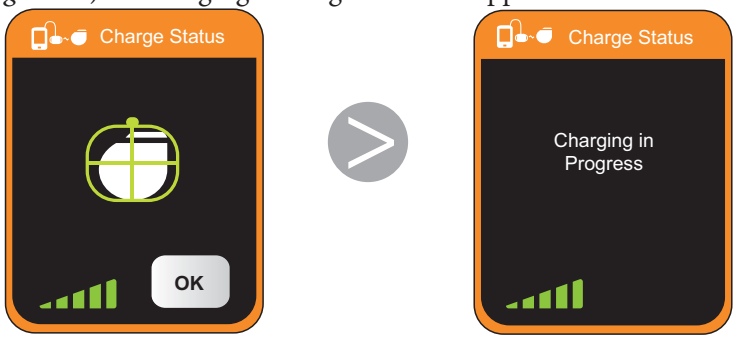

Figure 56. Stimulator charging in progress

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As the stimulator battery charges up to each charge level (25%, 50% 75%, and 100%) the associated bar on the Stimulator Battery Charge Level icon appears and flashes (*Figure 57*).

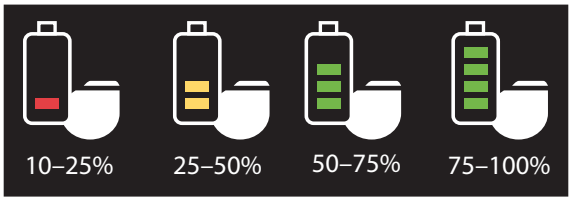

Figure 57. Stimulator battery charge levels

Note: If a notification screen appears saying that the system is unable to complete charging (*Figure 58*), the charging paddle has moved out of alignment with your stimulator or your charging paddle is disconnected from your Programmer Charger. If the Programmer Charger volume is set high enough, you may hear a soft beep.

» Tap OK to return to the Home screen.

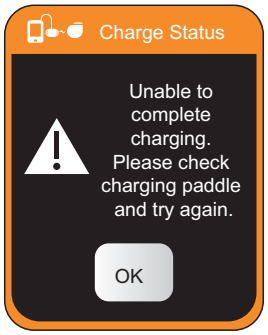

Figure 58. Unable to complete charging notification

When the stimulator is fully charged, a Charging Complete screen appears (*Figure 59*), the Stimulator Battery Charge Level icon displays 4 bars, and the icon bars stop flashing. If the Programmer Charger volume is set high enough, you may hear a soft beep.

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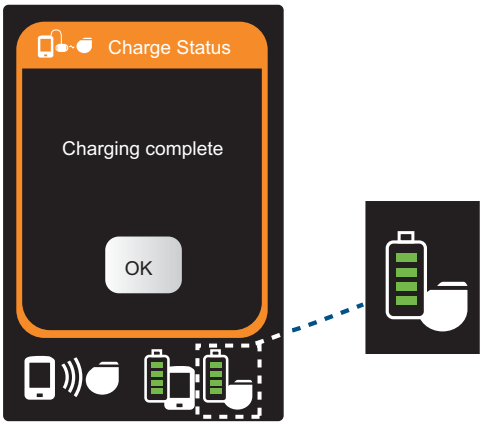

Figure 59. Stimulator charging complete

9. Tap **OK** to return to the Home screen (*Figure 60*).

Figure 60. Returning to the Home screen

10. If you choose to disconnect the charging paddle, grasp the charging paddle connector where it connects into the Programmer Charger.

    Caution: When disconnecting the charging paddle, make sure not to pull on the cable below the connector. Pulling on the cable may damage the charging paddle cable, preventing your Programmer Charger from charging your stimulator.

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6. Charging Your Programmer Batteries

Your Programmer Charger and Pocket Programmer have rechargeable batteries that can be charged any time their battery charge level is below 100%. When the programmer batteries are charged, the programmers are portable.

If a programmer battery charge level is low, you can connect the AC power adapter and still use the programmer to make changes such as selecting a new program or adjusting your stimulation settings.

To keep your programmers portable, make sure to develop a routine where you routinely check your programmer battery charge levels and charge your programmers as needed.

Charging Your Programmer Charger Battery

When the Programmer Charger battery is fully charged, the Programmer Charger Battery Charge Level icon (*Figure 61*) displays 4 bars.

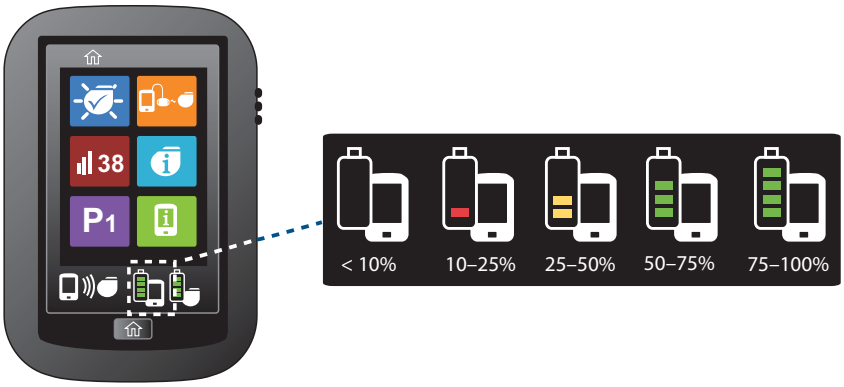

Figure 61. Programmer Charger battery charge levels

If the Programmer Charger battery charge level drops below 10%, the battery level icon will flash 0 bars before the Programmer Charger turns off.

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Caution: If you store the Programmer Charger for an extended period of time, make sure to periodically charge its battery. The Programmer Charger uses a very small amount of battery charge while turned off and may become non-rechargeable if not periodically charged.

To charge the Programmer Charger battery:

Warning: If you are charging your stimulator at the same time that you are charging your Programmer Charger battery, do not use the AC power adapter near water or during a lightning storm. Electric shock, serious injury, or death may result.

1. Connect the AC power adapter to the Programmer Charger (*Figure 62*) and plug the power adapter into a wall outlet.

   Notes:

   » Refer to the Programmer Power Cord Model 4010 Instructions for Use, packaged with the Model 4010 Programmer Power Cord, for complete information about the AC power adapter.

   » International adapter plugs are packaged with the programmers.

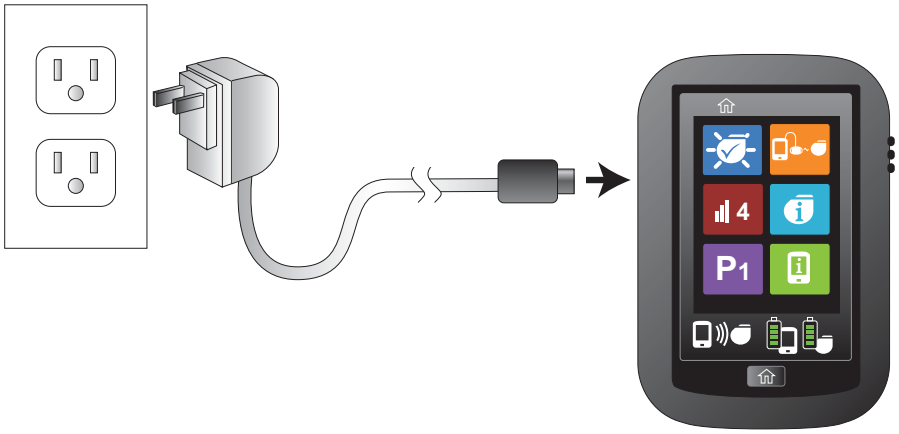

Figure 62. Connecting the AC power adapter

As the Programmer Charger battery charges up to each charge level (25%, 50% 75%,

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and 100%) the associated bar on the Programmer Charger Battery Charge Level icon appears and flashes (*Figure 63*). When the Programmer Charger is fully charged, the icon displays 4 bars and the icon bars stop flashing.

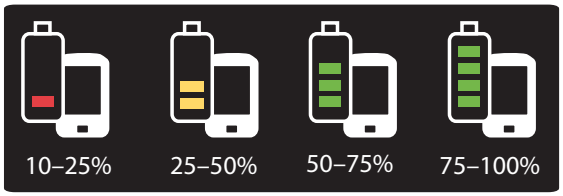

Figure 63. Programmer Charger battery charge levels

Charging Your Pocket Programmer Battery

When the Pocket Programmer battery is fully charged, the Pocket Programmer Battery Charge Level icon (*Figure 64*) displays 4 bars.

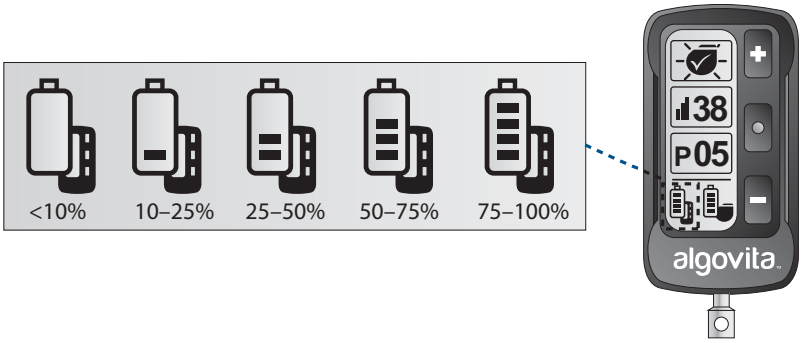

Figure 64. Pocket Programmer battery charge levels

If the Pocket Programmer battery charge level drops below 10%, the battery level icon will flash 0 bars before the Pocket Programmer turns off.

Caution: If you store the Pocket Programmer for an extended period of time, make sure to periodically charge the battery. The Pocket Programmer uses a very small amount of battery charge while turned off and may become non-rechargeable if not periodically charged.

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To charge the Pocket Programmer battery:

- Connect the AC power adapter to the Pocket Programmer (*Figure 65*) and plug the power adapter into a wall outlet.

  Notes:

  » Refer to the Programmer Power Cord Model 4010 Instructions for Use, packaged with the Model 4010 Programmer Power Cord, for complete information about the AC power adapter.

  » International adapter plugs are packaged with the programmers.

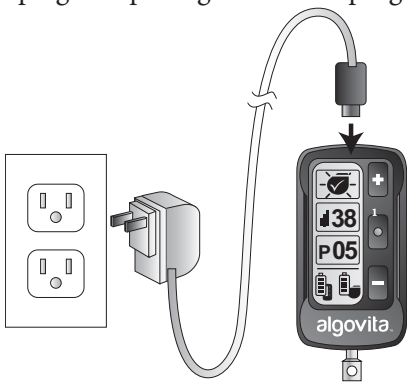

Figure 65. Connecting the AC power adapter

As the Pocket Programmer battery charges up to each charge level (25%, 50% 75%, and 100%) the associated bar on the Pocket Programmer Battery Charge Level icon appears and flashes (*Figure 66*). When the Pocket Programmer is fully charged, the icon displays 4 bars and the icon bars stop flashing.

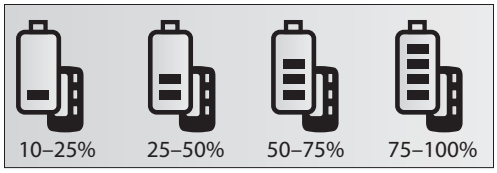

Figure 66. Pocket Programmer battery charge levels

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7. Programmer Charger Settings and System Information

The Programmer Settings screen on your Programmer Charger allows you to change a number of Programmer Charger settings and to view SCS system serial and version numbers.

Programmer Charger settings you can change:

- Set time, date, and date/time format
- Adjust volume of notification beep
- Adjust screen brightness
- Turn the button clicking sound on or off
- Calibrate the touch screen

Spinal cord stimulation system serial and version numbers:

- Programmer Charger serial and version numbers
- Stimulator serial and version numbers

Programmer Charger settings reserved for use by your doctor:

- Advanced settings

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Programmer Charger Settings

The Programmer Charger settings you can change are time, date, date/time format, volume of notification beep, screen brightness, button click. Also, if you tap buttons and incorrect screens appears you can also calibrate the touch screen.

Setting the Date

The Programmer Charger date and time are used to track how long your stimulator has been implanted.

To set the date:

1. Tap on the Home screen (*Figure 67*). The Programmer Settings screen appears.

Figure 67. Displaying the Programmer Settings screen

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2. Tap Date # # # # (*Figure 68*). The Date screen appears.

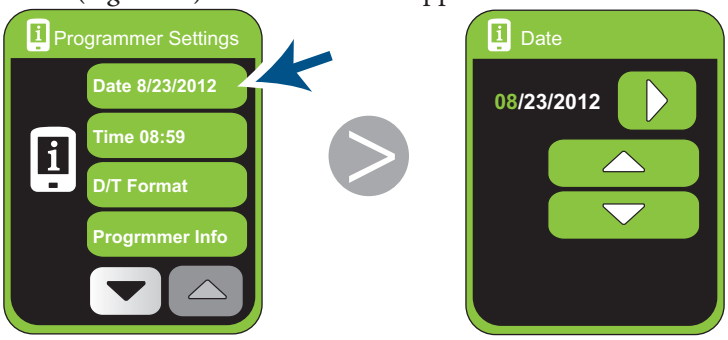

Figure 68. Displaying the Date screen

3. Tap until the month, day, or year that you want to change is highlighted in green (*Figure 69*).

Figure 69. Highlighting the month, day, or year

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4. Tap or to increase or decrease the highlighted number (*Figure 70*).

Figure 70. Increasing or decreasing the highlighted number

5. Repeat steps 3 and 4 as needed.
6. Tap (*Figure 71*) to return to the Home screen.

Figure 71. Returning to the Home screen

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Setting the Time

The Programmer Charger date and time are used to track how long your stimulator has been implanted.

To set the time:

1. Tap on the Home screen (*Figure 72*). The Programmer Settings screen appears.

Figure 72. Displaying the Programmer Settings screen

2. Tap (*Figure 73*). The Time screen appears.

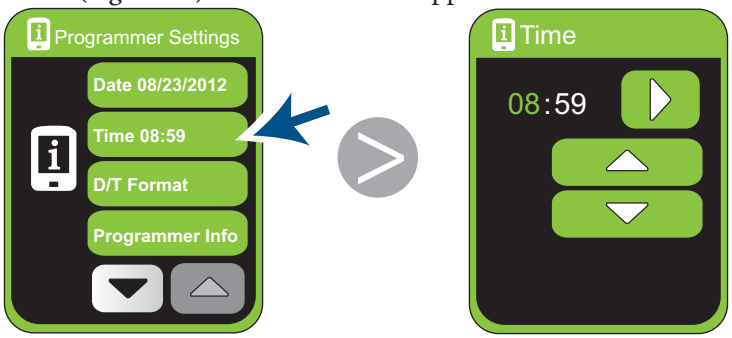

Figure 73. Displaying the Time screen

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3. Tap until the hour or minute that you want to change is highlighted in green (*Figure 74*).

Figure 74. Highlighting the hour or minute

4. Tap or to increase or decrease the highlighted number (*Figure 75*).

Figure 75. Increasing or decreasing the highlighted number

5. Repeat steps 3 and 4 as needed.

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6. Tap (*Figure 76*) to return to the Home screen.

Figure 76. Returning to the Home screen

Setting the Date/Time Format

To set the date/time format:

1. Tap on the Home screen (*Figure 77*). The Programmer Settings screen appears.

Figure 77. Displaying the Programmer Settings screen

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2. Tap D/T Format (*Figure 78*). The Date/Time Format screen appears.

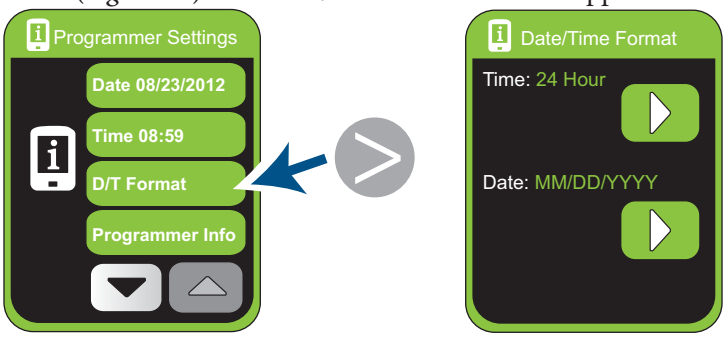

Figure 78. Displaying the Date/Time Format screen

3. Tap the appropriate ▶ until the desired date or time format is displayed (*Figure 79*).

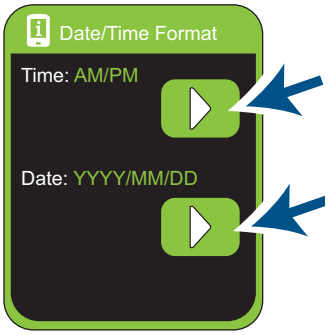

Figure 79. Displaying the date or time format

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4. Tap (*Figure 80*) to return to the Home screen.

Figure 80. Returning to the Home screen

Adjusting the Volume of the Notification Beeps

The Programmer Charger beeps softly when the stimulator battery charge level is too low, when stimulator battery charging is complete, and when some notification screens appear. The volume of the beep can be increased or decreased.

To adjust the volume:

1. Tap on the Home screen (*Figure 81*). The Programmer Settings screen appears.

Figure 81. Displaying the Programmer Settings screen

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2. Tap ▼ (*Figure 82*). Additional buttons on the Programmer Settings screen appear with the Volume button displaying the current volume.

Figure 82. Viewing additional settings buttons

3. Tap Volume # (*Figure 83*). The Volume screen appears.

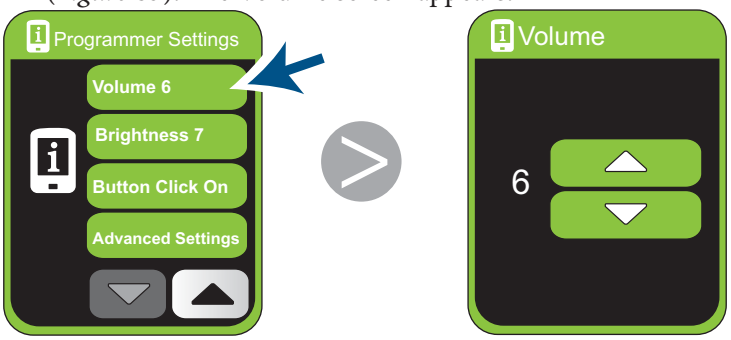

Figure 83. Displaying the Volume screen

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4. Tap or to increase or decrease the volume (*Figure 84*).

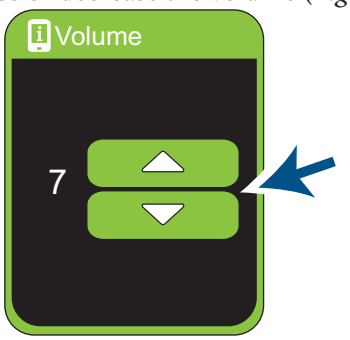

Figure 84. Increasing or decreasing the volume

5. Tap (*Figure 85*) to return to the Home screen.

Figure 85. Returning to the Home screen

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Adjusting the Screen Brightness

To adjust the screen brightness:

1. Tap on the Home screen (*Figure 86*). The Programmer Settings screen appears.

Figure 86. Displaying the Programmer Settings screen

2. Tap (*Figure 87*). Additional buttons on the Programmer Settings screen appear. The Brightness button displays the current screen brightness.

Figure 87. Viewing additional settings buttons

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3. Tap Brightness # (*Figure 88*). The Brightness screen appears.

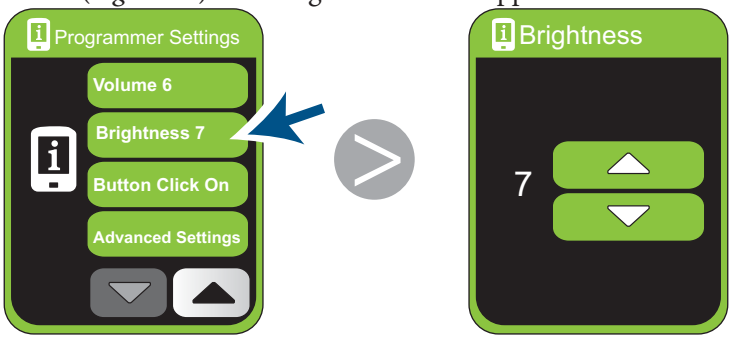

Figure 88. Displaying the Brightness screen

4. Tap ▲ or ▼ to increase or decrease the screen brightness (*Figure 89*).

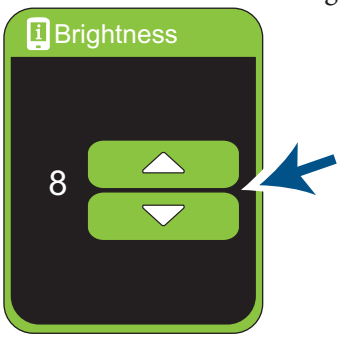

Figure 89. Increasing or decreasing the screen brightness

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5. Tap (*Figure 90*) to return to the Home screen.

Figure 90. Returning to the Home screen

Turning the Button Click On or Off

Your Programmer Charger makes a click each time you tap a button. The button click can be turned on or off.

To turn the button click on or off:

1. Tap on the Home screen (*Figure 91*). The Programmer Settings screen appears.

Figure 91. Displaying the Programmer Settings screen

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2. Tap ▼ (*Figure 92*). Additional buttons on the Programmer Settings screen appear with the Button Click button displaying whether the button click is on or off.

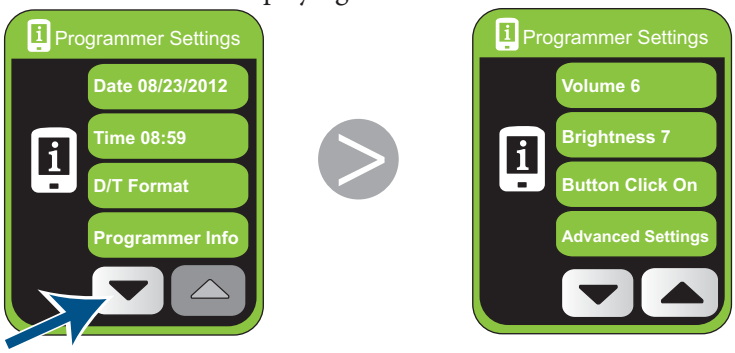

Figure 92. Viewing additional settings buttons

3. Tap Button Click On/Off (*Figure 93*). The Button Click screen appears. A white frame borders the button with the active status.

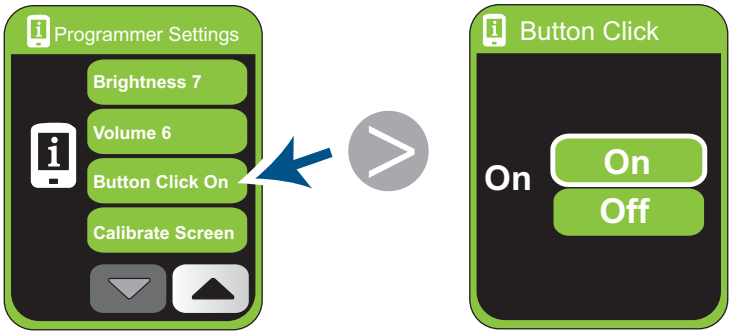

Figure 93. Displaying the Button Click screen

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4. Tap On or Off to turn the button click on or off (*Figure 94*).

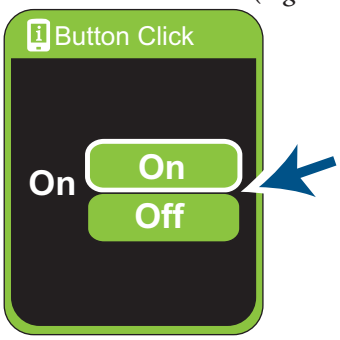

Figure 94. Turning the button click on or off

5. Tap (*Figure 95*) to return to the Home screen.

Figure 95. Returning to the Home screen

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Calibrating the Touch Screen

If you tap a button and an incorrect screen appears, or while charging your stimulator, you have difficulty centering the alignment icon over the stimulator icon, calibrate your Programmer Charger touch screen.

Notes:

- The Quick Stimulation Off button is not available while the screen is calibrating.
- The Calibration Screen button is grayed out and not available when the stimulator is charging.
- Stimulation must be off to calibrate the touch screen.

To calibrate the touch screen:

1. If your stimulation is on , turn your stimulation off. (For instructions on turning stimulation off, see *Turning Stimulation On or Off on page 22).*
2. Tap on the Home screen (*Figure 96*). The Programmer Settings screen appears.

Figure 96. Displaying the Programmer Settings screen

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3. Tap ▼ (*Figure 97*) until the Programmer Settings screen with the Calibrate Screen button appears.

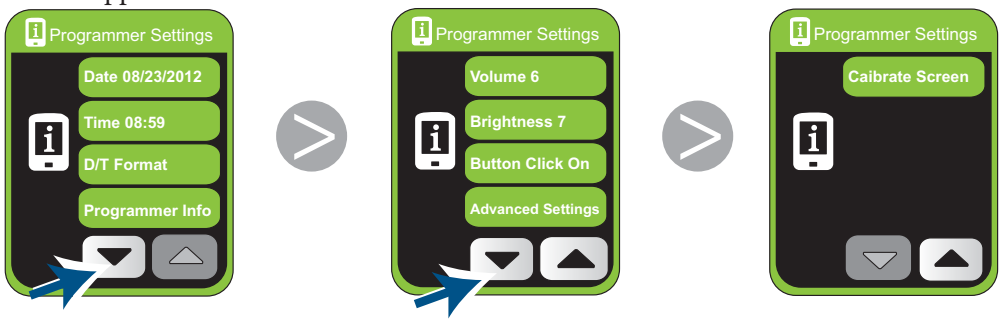

Figure 97. Viewing additional settings buttons

4. Tap Calibrate Screen (*Figure 98*). The first calibration screen appears.

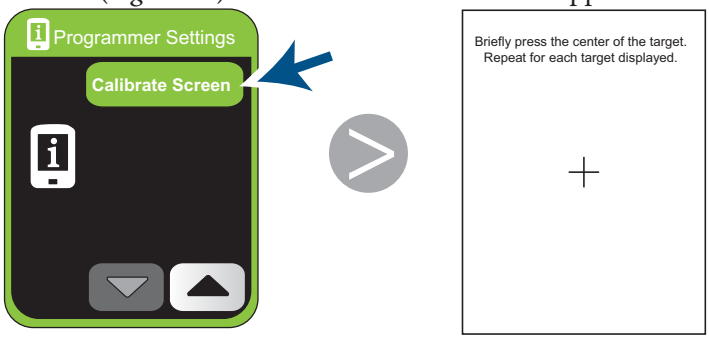

Figure 98. Displaying the calibrate screen

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5. On each calibration screen that appears, press the + and hold for approximately 2 seconds (*Figure 99*). A screen with a 30-second timer appears.

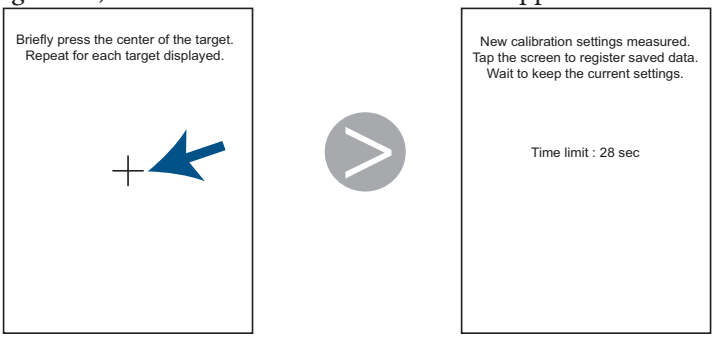

Figure 99. Calibrating the touch screen

6. To save the new calibration settings, tap anywhere on the screen before the 30-second timer expires (*Figure 100*). The Programmer Charger returns to the Programmer Settings screen.

Figure 100. Returning to the Programmer Settings screen

7. If you want to return to the Home screen, tap .

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SCS System Serial and Version Numbers

The Programmer Charger and stimulator serial and version numbers can be accessed through the Programmer Settings screen.

Programmer Charger Information

The Programmer Information screen displays your Programmer Charger serial number and version information.

To check Programmer Charger information:

1. Tap on the Home screen (*Figure 101*). The Programmer Settings screen appears.

Figure 101. Displaying the Programmer Settings screen

2. Tap (*Figure 102*). The Programmer Info screen appears.

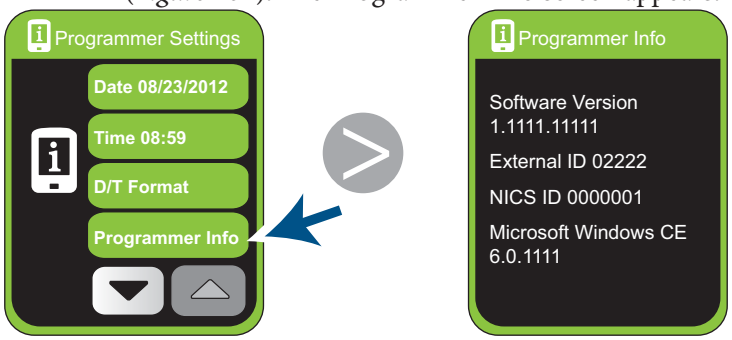

Figure 102. Displaying the Programmer Information screen

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3. Tap (*Figure 103*) to return to the Home screen.

Figure 103. Returning to the Home screen

Stimulator Information

The Stimulator Information screen displays your stimulator serial number and version information.

To check stimulator information:

1. Tap on the Home screen (*Figure 104*). The Stimulator Information screen appears.

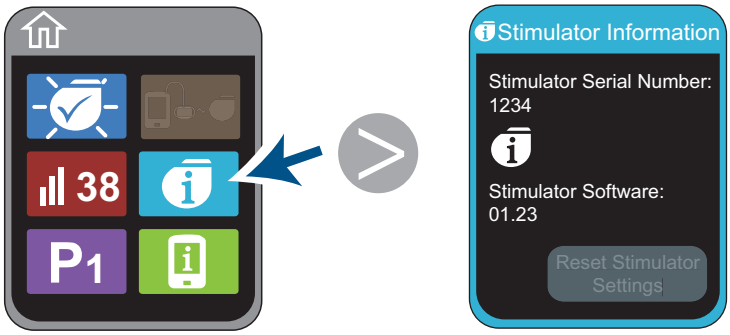

Figure 104. Displaying the Stimulator Information screen

2. Tap to return to the Home screen.

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Programmer Charger Advanced Settings

The advanced settings are protected by a password and are reserved for use by your doctor.

If you tap the Advanced Settings button:

1. Tap **Cancel** on the Notification screen (*Figure 105*) to return to the Home screen.

Figure 105. Returning to the Home screen

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8. Care, Service, Replacement, and Disposal

Care and Handling

Handle the Programmer Charger and Pocket Programmer and accessories with care.

- Keep your programmers and accessories out of the reach of children and pets.
- Use the programmers and accessories only as explained to you by your doctor or as presented in this manual.
- Follow all warnings and precautions in *Chapter 2. Important Safety Information*.
- Do not drop your programmers. Protect the programmers from sharp objects and physical shocks. Mishandling can permanently damage a programmer.
- Do not open or attempt to repair the programmers or accessories.

Cleaning

- Your Programmer Charger, Pocket Programmer, AC power adapter, and charging paddle are not waterproof. Do not immerse them in liquid or allow moisture to get inside the cases.
- If dirty, clean the outside of the programmers with a slightly damp cloth. Do not clean your programmers with bleach, nail polish remover, or similar substances.
- Clean the programmer screens with a household glass cleaner that does not contain ammonia.
- Hand wash the adjustable belt if necessary, then hang to dry.

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Programmer Storage

Caution: If you store the Programmer Charger or Pocket Programmer for an extended period of time, make sure to periodically charge the battery. The programmers use a very small amount of battery charge while turned off and may become non-rechargeable if not periodically charged.

The sensitive electronics of the programmers can be damaged by temperature extremes, particularly high heat.

- Do not expose the programmers to excessively hot or cold conditions, including leaving the programmers in your car or outdoors for extended periods of time.
- If the programmers are to be stored for a period of time, be careful that the storage temperature is not less than -20°C (-4° F) or greater than 60°C (140° F).

Service and Replacement

Programmers

Periodic servicing of the Programmer Charger or Pocket Programmer is not required. The programmers have no user-serviceable parts.

Only Algostim, LLC should service or repair the programmers. Do not attempt to open or repair the programmers. Unauthorized repairs will void the warranty.

If your programmer needs service or repair, contact your doctor or Algostim Customer Service.

When contacting Algostim Customer Service, have the programmer serial number available. The serial number is located on the back of the programmer.

If you lose a programmer, contact your doctor for a replacement. When you receive the new programmer, make sure to complete and mail the warranty registration. Depending on your insurance coverage, you may be responsible for the cost of a replacement programmer.

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Note: The Limited Warranty does not cover loss or theft of a programmer or damage caused by misuse. For additional information, refer to the Limited Warranty packaged with this manual.

Accessories

If you lose a charging paddle, AC power adapter, or other accessory contact your doctor.

To reorder adhesive patches, contact Algostim Customer Service.

Programmer and Stimulator Disposal

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

Programmer Disposal

Your Programmer Charger and Pocket Programmer contain rechargeable lithium batteries. Do not incinerate or dispose of the programmers in general household trash. When no longer needed, preferably return your programmers to your doctor or to Algostim, LLC for proper disposal. Otherwise consult local regulations for proper disposal of electronic devices.

Stimulator Disposal

Dispose of stimulators according to local environmental regulations. The stimulator should be explanted before cremation and returned to Algostim, LLC. The cremation process may cause the stimulator battery to explode.

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9. Troubleshooting

If you have a problem with your stimulation, your Programmer Charger or your Pocket Programmer, you can try to resolve the problem using the solutions in the following tables.

The tables are divided into the following sections:

- Stimulation Troubleshooting—Possible solutions if you are having problems with your stimulation.
- Programmer Charger Troubleshooting
  - » Messages—What to do when you see a message displayed on your Programmer Charger.
  - » Help Guidelines—Help with problems such as turning your Programmer Charger on, inability to increase the strength of your stimulation, or difficulty centering the alignment icon.
- Pocket Programmer Troubleshooting
  - » Messages—What to do when you see a message displayed on your Pocket Programmer.
  - » Help Guidelines—Help with problems such as turning your Pocket Programmer on and inability to increase the strength of your stimulation.

If you need further assistance in setting up, using, maintaining, or troubleshooting your SCS system, or if the problem is not described in this chapter, contact your doctor or Algostim Customer Service.

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Stimulation Troubleshooting

If you are having problems with your stimulation, and you do not find an answer in this table, contact your doctor or Algostim Customer Service.

Table 1. Stimulation Troubleshooting

Problem	Possible Cause	Possible Solution
You no longer feel stimulation.	Your stimulator battery charge level is low to deliver stimulation.	Charge your stimulator battery. For information on charging stimulator batteries, see *Charging Your Stimulator Battery on page 54.*
	The strength of the active program is low.	Increase the strength of the active program.
	Stimulation may be off.	Although unlikely, your stimulation may have been turned off by EMI from security gates or other electronic devices. Verify that stimulation is on.
You have noticed changes (increases or decreases) in your stimulation strength.	A change in your body position are affected your stimulation strength.	Keep your Programmer Charger or Pocket Programmer with you to adjust the strength and or select a new program.
Your programmer has established communication with your stimulator, but you cannot increase or decrease the strength of your stimulation.	You reached the upper or lower strength limit in the active program. These limits are set by your doctor.	Select a new program. Talk to your doctor about changing existing program settings or adding new programs.

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Programmer Charger Troubleshooting

The Programmer Charger messages table explains what to do when you see a message displayed. The help guidelines table provides answers to other questions you may have while using your Programmer Charger.

Programmer Charger Messages

If you see a message that is not in this table, or if the instructions in this table do not solve your problem, contact your doctor or Algostim Customer Service.

Table 2. Programmer Charger Messages

Message	Description	What to Do
An error (E01–E30) was detected in your stimulator. Stimulation has been disabled. Please see your physician.	If the message number is between E01 and E30, an error has occurred that prevents your stimulator from delivering stimulation. Stimulation will not be available until your doctor resolves this error.	Contact your doctor for more information.
An error (E31–E50) was detected in your stimulator.	If the message number is between E31 and E50, some programs or other features may not be available. Stimulation is still available.	1. Tap OK. 2. Write down the message and contact your doctor for more information.
An error (#) was detected in your stimulator. One or more programs have been disabled.	Some programs are not available. Stimulation is still available.	1. Tap OK. 2. Write down the message and contact your doctor for more information.
Error. Recharging performance may be limited.	An error has occurred that affects your ability to recharge your stimulator.	1. Tap OK. 2. Write down the message. 3. Contact your doctor for more information.

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Table 2. Programmer Charger Messages		
Message	**Description**	**What to Do**
Implant date is not set, see your physician.	The date that your stimulator was implanted is stored on your stimulator. Stimulation is still available.	1. Tap OK. 2. Write down the message and contact your doctor for more information. Your doctor can set the implant date at your next appointment.
Not able to connect to stimulator	Your Programmer Charger is not able to establish a connection to your stimulator.	1. Make sure your Programmer Charger is within 1 meter (3 feet) of your stimulator. 2. Tap Retry. 3. If your Programmer Charger still cannot establish communication, your Programmer Charger or stimulator battery charge level may be too low. For information on charging batteries, see: - *Charging Your Programmer Charger Battery on page 63*. - *Checking Your Stimulator Battery Charge Level on page 53*. 4. If your Programmer Charger still cannot establish communication, tap Cancel. 5. Connect the charging paddle, align the charging paddle over your stimulator, and start charging your stimulator.

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Table 2. Programmer Charger Messages		
Message	**Description**	**What to Do**
Programmer Communications Failed or Programmer Communications Command Failed		1. Tap OK. 2. Make sure your Programmer Charger is within 1 meter (3 feet) of your stimulator. 3. Tap the Establish Communication button in the bottom left corner of your screen.
Programmer date and time are not set, please set date and time.	Your Programmer Charger has a date and time setting. Stimulation is still available.	1. Tap OK. 2. Set the date and time on your Programmer Charger. For instructions, see *Setting the Date on page 68 and Setting the Time on page 71.*
Stimulation may have been halted by system. Please restart stimulation.	An error occurred, and stimulation may have been turned off.	1. Tap OK. 2. If stimulation is off, turn stimulation on. 3. Continue to use and adjust your stimulation as usual.
Stimulation was halted by system. Please restart stimulation.	An error occurred, and stimulation has been turned off.	1. Tap OK. 2. Turn stimulation on. Continue to use and adjust your stimulation as usual.
Stimulation was stopped by magnet. Please restart stimulation.	You were near a magnet that turned your stimulation off.	1. Tap OK. 2. Turn stimulation on. 3. Continue to use and adjust your stimulation as usual.

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Table 2. Programmer Charger Messages		
Message	**Description**	**What to Do**
The stimulator is not paired with this programmer.	The programmer cannot connect to your stimulator.	Write down the message and contact your doctor for more information.
Unable to complete charging. Charging Paddle Over Temperature. Wait and try again.	Your charging paddle has become too warm to continue charging at this time. This message is more likely to occur when the air temperature is greater than 35°C (95°F).	1. Tap OK. 2. Make sure that you are not sitting or lying on the charging paddle. 3. Wait 5–10 minutes. 4. Make sure the charging paddle is properly aligned over your stimulator, 5. Resume charging.
Unable to complete charging. Please check charging paddle and try again.	An error has occurred that stopped your Programmer Charger from charging your stimulator.	1. Tap OK. 2. Realign the charging paddle over your stimulator. 3. Resume charging.
Unable to complete charging. Stimulator Over Temperature. Wait and try again.	Your stimulator has become too warm to continue charging at this time.	1. Tap OK. 2. Wait 5–10 minutes. 3. Make sure the charging paddle is properly aligned over your stimulator, 4. Resume charging.
Your stimulator has been implanted for (#) months. In the future you may need to charge more frequently.	After your stimulator has been implanted for a number of years, the battery may need more frequent charging. Stimulation is still available.	1. Tap OK. 2. Routinely check your stimulator battery charge level, and charge as needed.

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Programmer Charger Help Guidelines

If the problem you are having with your Programmer Charger is not listed in this table, or if you cannot resolve the problem with the instructions in this table, contact your doctor or Algostim Customer Service.

Table 3. Programmer Charger Help Guidelines

Problem	Possible Cause	Possible Solution
The Programmer Charger will not turn on. The screen is still black after sliding and holding the Power On/Off switch for at least 2 seconds.	The Programmer Charger battery charge level is too low.	Charge the Programmer Charger battery. For information on charging batteries, see *Charging Your Programmer Charger Battery on page 63.*
The Programmer Charger will not turn off.	The Programmer Charger does not turn off if the AC power adapter is plugged into a wall outlet.	
The Programmer Charger turns off after 30 minutes.	In order to extend the Programmer Charger battery life, the Programmer Charger turns off if you do not press or tap any buttons for 30 minutes.	
The Programmer Charger has established communication with the stimulator, but you cannot increase or decrease the strength of your stimulation.	If the increase or decrease arrow is grayed out, you have reached the upper or lower strength limit in the active program. These limits are set by your doctor.	Select a new program. Talk to your doctor about changing existing program settings or adding new programs.
After tapping a button, an incorrect screen appears.	Your Programmer Charger touch screen may be out of calibration.	Calibrate the touchscreen. For information, see *Calibrating the Touch Screen on page 83.*

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Table 3. Programmer Charger Help Guidelines		
Problem	**Possible Cause**	**Possible Solution**
The Programmer Charger battery will not recharge.	Your programmer battery has become non-rechargeable.	Contact your doctor about getting a replacement programmer. You can still use your programmer with the AC power adapter connected.
	The AC power adapter may be damaged.	Contact your doctor about getting a replacement AC power adapter.
While charging your stimulator, you have difficulty centering the alignment icon over the stimulator icon	Your Programmer Charger touch screen is out of calibration.	Calibrate the touchscreen. For information, see *Calibrating the Touch Screen on page 83*.
The Programmer Charger battery icon has a red X over it.	• The Programmer Charger is under a blanket or something else that is preventing it from cooling. • While charging your stimulator and Programmer Charger at the same time (AC power adapter connected), a poorly aligned charging paddle prevented the Programmer Charger battery from fully charging because the stimulator charging was taking too much power. • The Programmer Charger battery is damaged or not rechargeable.	1. Unplug the AC power adaptor. 2. Make sure the Programmer Charger is not under a blanket or something else that is preventing it from cooling. 3. Allow the Programmer Charger to cool. 4. Reconnect the AC power adaptor. 5. If the red X persists and you can only use your Programmer Charger when the AC power adapter is connected, contact your doctor for a new Programmer Charger.

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Table 3. Programmer Charger Help Guidelines		
Problem	**Possible Cause**	**Possible Solution**
The Programmer Charger screen freezes or becomes unresponsive.	The Programmer Charger needs to be reset.	1. Unplug the Programmer Charger from the AC power adapter. 2. Slide and hold the On/Off switch for 5 seconds until the Programmer Charger turns off. 3. Slide and hold the On/Off switch until the Programmer Charger turns on.

Pocket Programmer Troubleshooting

The Pocket Programmer messages table explains what to do when you see a message displayed. The help guidelines table provides answers to other questions you may have while using your Pocket Programmer.

Pocket Programmer Messages

Table 4. Pocket Programmer Messages		
Message	**Description**	**What to Do**
E01 — E30	An error has occurred that prevents your stimulator from delivering stimulation.	Write down the message number and contact your doctor. You will not be able to clear these messages from the screen.
E31 — E50	Your stimulator is still able to provide stimulation, but some programs or other features may not be available.	Write down the message number and contact your doctor. Press the Select button to clear the message from the screen.

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Pocket Programmer Help Guidelines

If the problem you are having with your Pocket Programmer is not listed in this table, or if you cannot resolve the problem with the instructions in this table, contact your doctor or Algostim Customer Service.

Table 5. Pocket Programmer Help Guidelines

Indication	Possible Cause	Possible Solution
The Pocket Programmer will not turn on. The screen is still black after sliding and holding the Power On/Off switch for at least 2 seconds.	The Pocket Programmer battery charge level is too low.	Charge the Pocket Programmer battery. For information on charging batteries, see *Charging Your Pocket Programmer Battery on page 65*.
The Pocket Programmer will not turn off.	The Pocket Programmer does not turn off if the AC power adapter is plugged into a wall outlet.	
The Pocket Programmer turns off after not pressing any buttons for 1 minute.	To extend the life of the Pocket Programmer battery, the programmer turns off when not used for one minute.	Turn the Pocket Programmer back on.
The Program icon is blinking, and you cannot increase or decrease the strength of your stimulation.	You have reached the upper or lower strength limit in the active program. These limits are set by your doctor.	Select a new program. Talk to your doctor about changing existing program settings or adding new programs.

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Table 5. Pocket Programmer Help Guidelines		
Indication	**Possible Cause**	**Possible Solution**
The Pocket Programmer screen continues to display three blank rectangles. 	The Pocket Programmer cannot establish a connection with your stimulator.	1. Make sure your Pocket Programmer is within 1 meter (3 feet) of your stimulator, then turn your Pocket Programmer off then on again. 2. If your Pocket Programmer still cannot establish communication, your Pocket Programmer or stimulator battery charge level may be too low. For information on charging batteries, see: - *Charging Your Pocket Programmer Battery on page 65.* - *Checking Your Stimulator Battery Charge Level on page 53.*
The Pocket Programmer screen freezes or becomes unresponsive.	The Pocket Programmer needs to be reset.	1. Unplug the Pocket Programmer from the AC power adapter. 2. Slide and hold the On/Off switch for 5 seconds until the Pocket Programmer turns off. 3. Slide and hold the On/Off switch until the Pocket Programmer turns on.

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Table 5. Pocket Programmer Help Guidelines		
Indication	**Possible Cause**	**Possible Solution**
The Pocket Programmer battery will not recharge.	Your programmer battery has become non-rechargeable.	Contact your doctor about getting a replacement programmer. You can still use your programmer with the AC power adapter connected.
	The AC power adapter may be damaged.	Contact your doctor about getting a replacement AC power adapter.
How do I charge the stimulator battery with the Pocket Programmer?	The Pocket Programmer cannot charge your stimulator.	Use your Programmer Charger to charge your stimulator battery.

Algostim Customer Service

If you have any questions about an Algovita SCS System, call Algostim Customer Service toll-free at 1-844-727-7897 within the United States.

Outside of the United States, call your physician or product distributor for assistance. If additional assistance is needed, contact Algostim Customer Service +1-214-618-4980.

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10. SCS System Specifications

Component Specifications

This section of the manual provides technical information about your Algovita SCS system. If you have any questions regarding this information, contact your doctor.

Table 6. Programmer Charger Specifications	
Operating temperature	0°C to 40°C (32°F to 104°F)
Charging operating temperature	10°C to 40°C (50°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	700 kPa to 1060 kPa (20.7 in Hg to 31.3 in Hg)
Size (approximate)	122 mm x 81.3 mm x 29.2 mm (4.8 in x 3.2 in x 1.15 in)
Weight including battery (approximate)	240 g (8.5 oz)
Battery	Chargeable lithium-ion battery
Mode of operation	Continuous

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Table 7. Pocket Programmer 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	700 hPa to 1060 hPa (525 mm Hg to 795 mm Hg)
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

Table 8. Implanted Component Materials in Contact with Human Tissue	
Stimulator	Titanium Polysulfone Polyurethane Silicone Silicone rubber
Leads, extensions, and anchors	Polyurethane Platinum/iridium Silicone rubber

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Safety and Compatibility Standards Conformity

Algovita Programmer Charger Model 4100 and Pocket Programmer Model 4200 comply with the following standards:

- IEC 60601-1, Medical Electrical Equipment Safety
- IEC 60601-1-2, Electromagnetic Compatibility
- EN 45502-1, Safety, Marking and Information of Medical Devices

Electromagnetic Compatibility

The Federal Communications Commission (FCC) and various international agencies have rules and regulations meant to minimize interference created by electronics. The Programmer Charger and Pocket Programmer meet US and European regulatory limits for Electromagnetic Compatibility (EMC). EMC is the ability of electronic devices, including computers, to function properly together in the electronic environment.

However, there is no guarantee, depending on the specific circumstances that the Programmer Charger or Pocket Programmer will not interfere with other electronics. Should this equipment cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, you are encouraged to try to correct the interference by doing one or more of the following:

- Relocate the Programmer Charger or Pocket Programmer away from the device being affected.
- Plug the equipment and the Programmer Charger into a different electrical outlet circuit if the Programmer Charger is being used while it is being recharged.

Electromagnetic Compatibility Declaration Tables

This section lists the EMC Declaration tables. The Programmer Charger and Pocket Programmer are intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer Charger and Pocket Programmer should assure that they are used in such an environment. The Programmer Charger and Pocket Programmer contain RF transmission and receiving capabilities; consequently, it is

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possible that other portable and mobile RF communications equipment may interfere with the Programmer Charger and Pocket Programmer.

The power supply cables (maximum length 188 cm [74 in]) and charging paddle (maximum cable length 101 cm [40 in]) were included in the system testing to demonstrate compliance with the requirements of IEC 60601-1-2 2007. Use of accessories and cables other than those specifically listed may result in increased emissions or decreased immunity of the Programmer Charger and Pocket Programmer.

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

Table 9. Guidance and manufacturer's declaration – electromagnetic emissions

The Programmer Charger and Pocket Programmer are intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer Charger and Pocket Programmer should assure that they are used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Programmer Charger and Pocket Programmer use 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 Programmer Charger and Pocket Programmer are 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	

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Table 10. Guidance and manufacturer's declaration – electromagnetic emissions

The Programmer Charger and Pocket Programmer are intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer Charger and Pocket Programmer should assure that they are used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV	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 Programmer Charger and Pocket Programmer requires continuous operation during power mains interruptions, it is recommended that the Programmer Charger and Pocket Programmer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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.			

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Table 11. Guidance and manufacturer's declaration – electromagnetic emissions

The Programmer Charger and Pocket Programmer are intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer Charger and Pocket Programmer should assure that they are 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	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Programmer Charger and Pocket Programmer, 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 2.5 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] 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 Programmer Charger and Pocket Programmer are used exceeds the applicable RF compliance level above, the Programmer Charger and Pocket Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Programmer Charger and Pocket Programmer.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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Table 12. Recommended separation distances between portable and mobile RF communications equipment and the Programmer Charger and Pocket Programmer

The Programmer Charger and Pocket Programmer are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Programmer Charger and Pocket Programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Programmer Charger and Pocket Programmer 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 2.5 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.

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Wireless Information

Table 13. Wireless Specifications and Safety	
Programmer wireless technology operating characteristics	The Programmer Charger and Pocket Programmer interact with the stimulator using MedRadio Band: 402-405 MHz. The effective radiated power is below the limits as specified in: Europe: EN ETSI 301 839-2 USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219
	The Programmer Charger and Pocket Programmer interact with the stimulator using 2.45 GHz. The effective radiated power is below the limits as specified in: Europe: EN ETSI 300 328 USA: FCC part 15.24
Stimulator wireless technology	The stimulator complies with emissions requirements per R&TTE Standard EN 301 839-2 v13.1 (402MHz 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. These limits are designed to provide reasonable protection against harmful interference in a residential installation. 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.

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- 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.

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 (ie, 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 MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 2360-2400 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 MedRadio 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.

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Glossary

Term	Definition
Active program	Program currently delivering stimulation.
Adverse effect	An undesirable result from a therapy, such as a side effect.
Caution	An important statement that describes certain actions that may result in minor or moderate personal injury or damage to your programmer.
Contraindication	A condition or circumstance when a person should not have a SCS system.
Diathermy	A deep tissue heat treatment that uses short wave, ultrasound, or microwave energy. Diathermy is contraindicated when you have an SCS system.
Electrical pulse	Your stimulator delivers mild electrical pulses, called stimulation, to a specific area in your spinal cord.
Electromagnetic interference (EMI)	A strong field of energy near electrical or magnetic devices that could affect the functioning of your stimulator.
Frequency	The number of times the electrical pulses that make up your stimulation are delivered per second. If your doctor has allowed, you can adjust the frequency of your stimulation with your Programmer Charger. Adjusting the frequency may change the you feel from your stimulation.
Implanted pulse generator (IPG)	Another name for a stimulator. See stimulator.
Indication	The purpose of the SCS system in the prescribed treatment of a medical condition.
MRI (Magnetic Resonance Imaging)	A medical imaging technique using a nuclear magnetic resonance spectrometer to produce detailed images of tissues and organs.
Precaution	See caution.

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Term	Definition
Program	A combination of stimulation settings used delivers stimulation to one or more pain sites in your body. A program is made up of one or more sub-programs.
Pulse	See electrical pulse
Spinal cord stimulation (SCS) system	An implanted system that delivers mild electrical pulses to a specific area in the spinal cord. The stimulation modifies pain signals traveling to the brain, altering how the brain perceives the pain. SCS systems are used as a therapy to manage chronic pain.
Pulse width	The duration of each electrical pulse that makes up your stimulation. If your doctor has allowed, you can adjust the pulse width with your Programmer Charger. Adjusting the pulse width may affect the size or shape of the area where you feel stimulation. Adjusting the pulse width may also change the intensity of your stimulation.
Stimulation	The mild electrical pulses that the SCS system delivers to an area of the spinal cord. The stimulation modifies the pain signals traveling from a pain site to the brain, altering how the brain perceives the pain. Patients feel stimulation as a tingling sensation that covers their pain.
Stimulator	The component of the SCS system that contains the battery and electronics that produce stimulation.
Stimulation settings	The combination of settings that make up a program or sub-program.
Strength	The intensity of your stimulation.
Sub-program	A combination of stimulation settings used to deliver stimulation to one pain site in your body. A program is made up of one or more sub-programs.
Therapy	The treatment of a disease or condition.
Warning	An important statement describing an action or situation that could cause serious harm to a patient.

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