



PHYSICIAN IMPLANT MANUAL

Implantable Pulse Generator
model SC1100

PRECISION[™]
Spinal Cord Stimulation System



Physician Implant Manual

CAUTION. Investigational device. Limited by federal law to investigational use.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

The Precision System components should be serviced only by Advanced Bionics. Do not attempt to open or repair any of the components. Unauthorized opening of or attempts to repair components will void the warranty.

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Introduction

Manual Overview

This manual provides basic information for the implantation and operation of the Precision™ Implantable Pulse Generator (IPG), SC Model 1100. This information includes an overview of accessories for programming and powering the IPG, clinical and surgical considerations, storage and handling requirements, and relevant precautions concerning an implanted neurostimulator. Additional information on system components and operation can be found in the Precision Physician Systems Handbook.

Device Description

The Advanced Bionics® Precision implantable pulse generator system is intended to treat chronic pain by electrically stimulating the spinal cord. The multi-channel, multi-electrode device capability provides flexibility in conjunction with ease of programming. A rechargeable battery increases IPG longevity and output capability while reducing size and device replacement surgeries. The implant is controlled by a handheld Remote Control, and can be engaged by a clinician computer using proprietary BionicNavigator™ software. Periodically, the implant battery requires replenishing with an RF charging device provided in the Patient Take Home Kit SC-6000.

Features

- Stimulation electrode field navigation
- Sixteen independent current-controlled electrodes
- Four programmable stimulation areas per program; four possible programs
- Long-life operation
- High-range parameter capability
- Small size
- Two-foot programming range

Indications for Use

The Precision is indicated for the management of chronic intractable pain of the trunk and limbs utilizing spinal cord stimulation.

Patient Selection

The therapy is generally most effective in patients who suffer neuropathic pain. Careful patient selection, therefore, is an important factor in achieving efficacious outcomes. It is recommended that patients be screened for psychological factors that could reduce the likelihood of therapeutic success. (Specific information regarding patient selection is included in the Physician Systems Handbook.) Most successful outcomes occur with the following:

- Identifiable pathology
- Pain of neuropathic origin
- Psychological screening
- Patient understanding of risks, benefits and limitations, and a commitment to a successful therapy
- Successful externalized stimulation trial prior to acceptance of permanent IPG implantation

Contraindications

Patients contraindicated for permanent SCS therapy are those who:

- do not meet psychological selection criteria
- have failed trial stimulation
- are poor surgical risks
- are pregnant

Safety Instructions

Warnings

Pregnancy. The safety and/or effectiveness of neurostimulation during pregnancy has not been established.

Diathermy. Shortwave, microwave and/or therapeutic ultrasound diathermy are categorically contraindicated for SCS patients. The energy generated by diathermy can be transferred through the stimulator system, causing tissue damage at the lead site and resulting in severe injury or death.

Implanted Stimulation Devices. Spinal cord stimulators may interfere with the operation of implanted sensing stimulators such as pacemakers or cardioverter defibrillators. The effects of implanted stimulation devices on neurostimulators is unknown.

Implant Damage. Burns may result if the pulse generator case is ruptured or pierced and patient tissue is exposed to battery chemicals. Do not implant the device if the case is damaged.

Postural Changes. Patients should be advised that changes in posture or abrupt movements may cause decreases, or uncomfortable or painful increases in the perceived stimulation level.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the stimulator off, or cause uncomfortable or jolting stimulation. Patients should be counseled to avoid or exercise care around:

- Theft detectors or security screeners
- Power lines or power generators
- Electric steel furnaces and arc welders
- Large, magnetized stereo speakers

Precautions

MRI. Patients implanted with the Precision SCS system should not be subjected to MRI. MRI exposure may result in dislodgement of implanted components, heating of the neurostimulator, damage to the device electronics and/or voltage induction through the leads and stimulator causing an uncomfortable or “jolting” sensation.

Medical Devices/Therapies. The following medical therapies or procedures may turn stimulation off or may cause permanent damage to the implant, particularly if used in close proximity to the device:

- lithotripsy
- electrocautery
- external defibrillation
- radiation therapy
- ultrasonic scanning
- high-output ultrasound

If any of the above is required by medical necessity, refer to “Instructions for the Physician” on page 6. Ultimately, however, the device may require explantation as a result of damage to the device.

Automobiles and Other Equipment. Patients should not operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with therapeutic stimulation switched on. Stimulation must be turned off first. Sudden stimulation changes, if they occur, may distract patients from attentive operation of the vehicle or equipment.

Adverse Effects

Potential risks are involved with any surgery. The possible risks of implanting a pulse generator as part of a system to deliver spinal cord stimulation include:

- Lead migration, resulting in undesirable changes in stimulation and subsequent reduction in pain relief.
- System failure, which can occur at any time due to random failure(s) of the components or the battery. These events, which may include device failure, lead breakage, hardware malfunctions, loose connections, electrical shorts or open circuits and lead insulation breaches, can result in ineffective pain control.
- Tissue reaction to implanted materials can occur.
- Skin erosion at the IPG site can occur over time.
- Possible surgical procedural risks are: temporary pain at the implant site, infection, cerebrospinal fluid (CSF) leakage and, although rare, epidural hemorrhage, seroma, hematoma and paralysis.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.
- Exposure to MRI can result in heating of tissue, image artifacts, induced voltages in the neurostimulator and/or leads, lead dislodgement.

Instructions for the Physician

Implanted Stimulation Devices. If such implanted devices are indicated for the patient, careful screening is required to determine if safe results can be achieved before permanently implementing concurrent electrical therapies.

Postural Changes. Depending on the activity level of the patient, postural changes may affect stimulation intensity. Instruct patients to keep the Remote Control at hand at all times, and ensure that they understand how to adjust stimulation levels.

Medical Devices/Therapies. If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation therapy, ultrasonic scanning, or high-output ultrasound:

- Adjust stimulation to its lowest level before the procedure or application, then turn off IPG.
- All equipment, including ground plates and paddles, must be used as far away from the IPG as possible.
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the IPG.
- Equipment should be set to the lowest energy setting clinically indicated.
- Instruct patients to confirm IPG functionality following treatment by turning on the IPG and gradually increasing stimulation to the desired level.

Package Contents

- (1) Precision Pulse Generator
- (1) Hex Wrench
- (1) Tunneling Tool
- (1) Tunneling Tool Extension
- (1) IPG Pocket Template
- (1) Skin Marker
- (2) Connector Plugs
- (1) Device Registration Form
- (1) Temporary Patient Identification Card
- (1) Manual

Patient Identification

Please ensure that the patient receives a completed temporary identification card following surgery. Permanent cards will be mailed directly to the patient following patient registration.

Sterilization

- Before implanting the IPG, inspect the condition of the sterilization indicator and the sterile package before opening the package and using the contents. *Do not use the contents if the indicator lines are not red, if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.*
- Do not resterilize the IPG. If resterilization is required, obtain a sterile device for implantation.
- The IPG is for single use only. Do not reuse.

Handling

Handle the IPG and implanted accessories with care.

- Keep sharp instruments away from the components.
- Do not use the IPG if it has been dropped on a hard surface from a height of more than one foot.
- Do not incinerate an IPG. Improper disposal of the device could result in an explosion. Devices should be explanted in the case of cremation, and returned to Advanced Bionics Corporation.

Storage

- Store the IPG between 0° C and 45° C (32° F and 113° F). Devices should always be kept in temperature regulated areas within the acceptable temperature range. IPG damage can occur at temperatures outside of this range.

Guidelines for Permanent Implantation

This section details the procedures for

- tunneling the lead/extension as part of an IPG implant, and
- connection of lead/extension to the IPG.

The Tunneling Tool Assembly used in this procedure is provided with the Precision device as part of the IPG Kit.

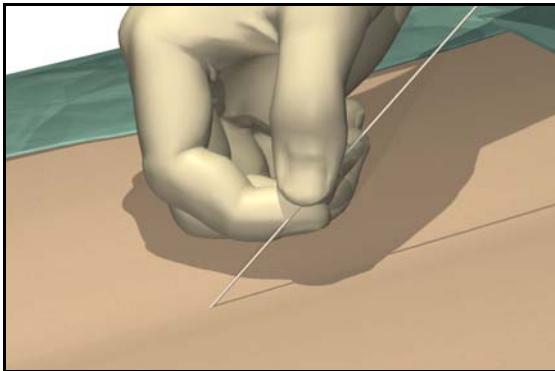
Percutaneous Lead/Extension Removal

Before revising a trial system for chronic stimulation, the nonsterile portion of the lead or extension must be removed. The method chosen from the choices below will depend upon how the patient was prepared for the trial phase.

Remove bandages and properly cleanse the exit site.

Option A. Temporary Lead Removal

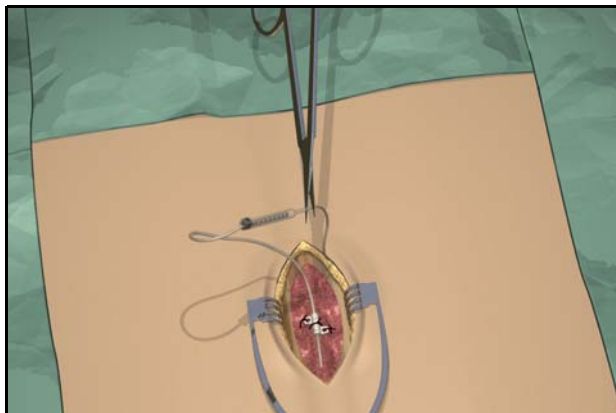
Remove the lead(s) completely and discard them.



Option B. Extension Removal

1. Open the midline incision to expose the lead and connector.

2. Cut the lead extension at the connector.

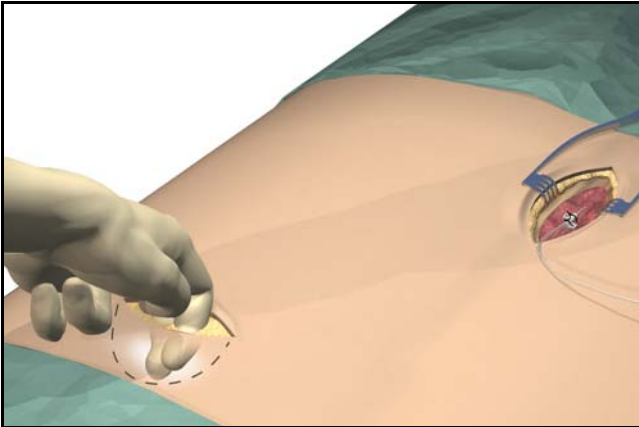


3. Pull the lead extension through the tunnel and away from body at the externalized site.
4. Loosen the connector setscrew using the torque wrench provided. Disconnect and discard the connector.

Note: *Connect a new lead extension, if necessary, to reach the selected IPG site.*

IPG Implantation

1. Ensure that the area surrounding the lead entry site is incised to a dimension that will accommodate the tunneling tool. Check that the lead is securely sutured with the suture sleeve.
2. Select and mark the intended IPG site several inches away from the previously externalized leads, and create an incision at the top of the implant site. (Common sites are the abdomen, upper buttock, or subclavicular area.)
3. Create a subcutaneous pocket no larger than the IPG outline at a depth less than 3/4 inch (2.0 cm) from the surface.



Note: • *Using the template will help guide the correct pocket sizing. It is important to keep the pocket small to reduce the chances of patient twiddling and IPG flipping afforded by larger pockets.*



- *Implant charging frequency or time will increase with pocket depths greater than 3/4 inch (2.0 cm), and could become ineffective at greater depths.*

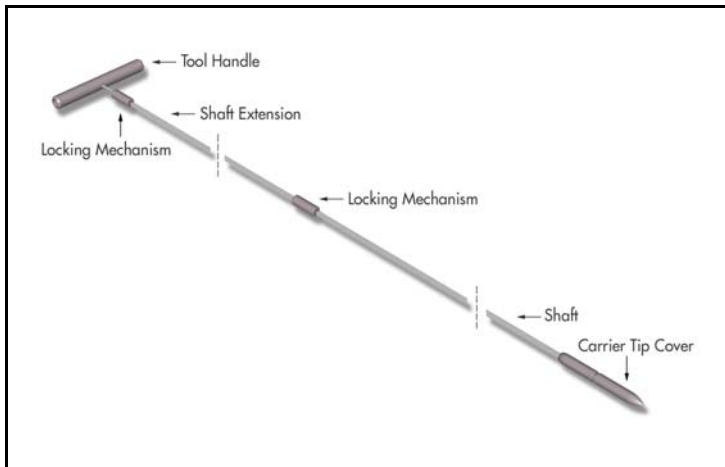
Tool Assembly

The tunneling tool provided with the IPG includes a shaft extender to be used for up to two leads.

1. Attach the handle to the tunneling tool shaft by turning the locking mechanism clockwise.

Note: For more length, attach the shaft extension to the handle, and then attach the carrier shaft.

2. Thread the tip cover onto the tunneling tool and tighten by turning clockwise.



Tunneling The Lead

1. Mark the desired route of the tunnel.
2. Administer the appropriate local anesthetic along the tunneling path.

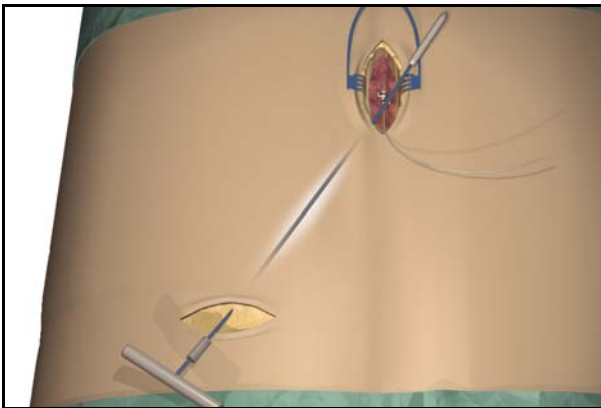
Note: Check that the tunneling tool tip is securely threaded onto the carrier.

3. OPTIONAL. If necessary, bend the tool shaft to conform to the patient's body.



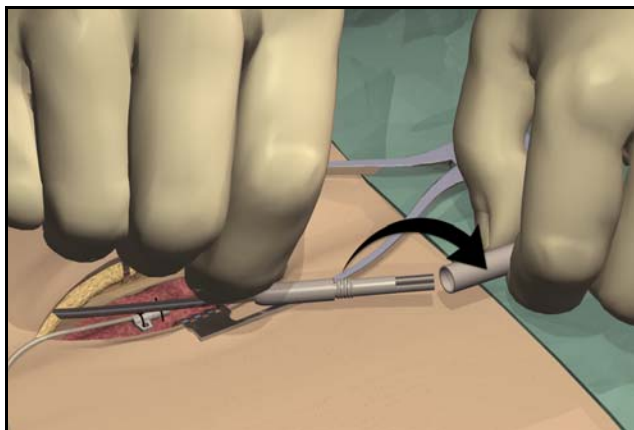
Do not bend locking joints.

4. Create a subcutaneous tunnel from the IPG site to the midline incision.



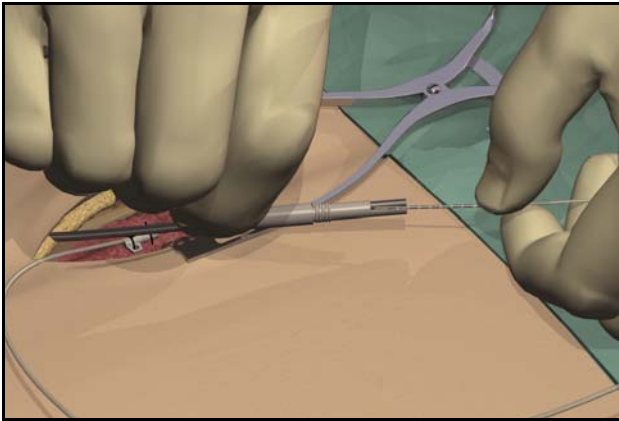
Note: Deep tunneling is not recommended.

5. Once the tunneling tip is completely exposed at midline, press it toward the shaft and turn it counterclockwise to remove it for access to the carrier.



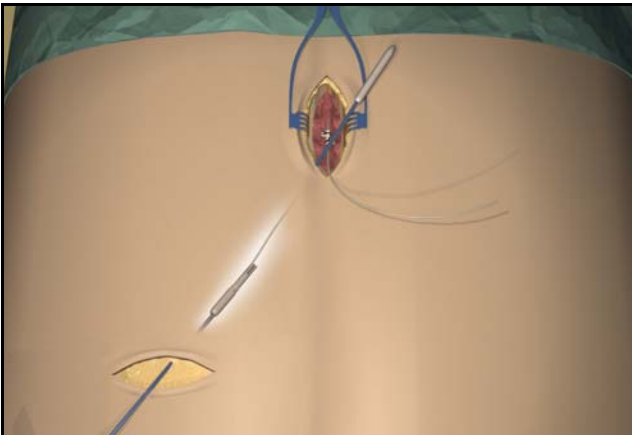
Note: *You may feel the tip slide back before the cover begins to unscrew.*

- Carefully position each lead or extension into the carrier shaft and press the lead/extension into the groove.



Note: *If necessary, swivel the carrier by pulling it away from the handle and turning it to get better access to the cavities.*

- Gently pull the tunneling tool back through the tunnel.

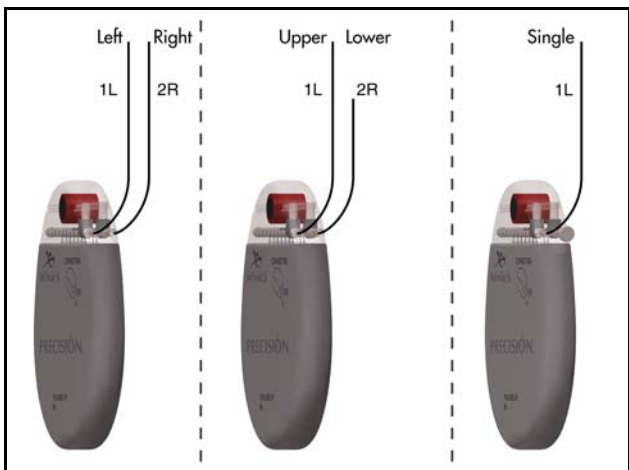


8. Gently lift the lead(s) out of the locking groove(s).
9. Wipe off any fluids from the proximal end of the lead(s).

Connecting To the IPG

Dual Lead Connection

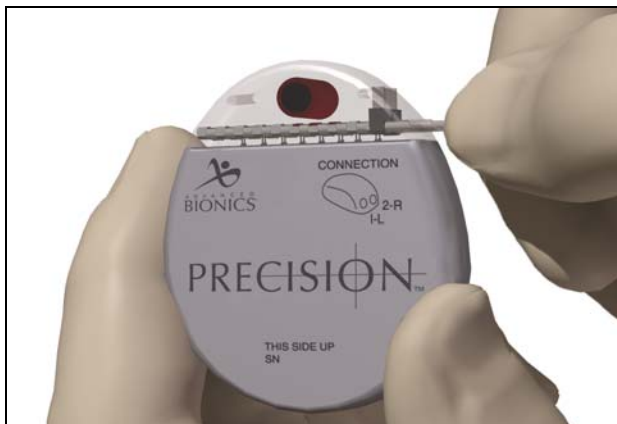
- Superior (upper or left) leads connect to IPG port 1-L.
- Inferior (lower or right) leads connect to IPG port 2-R.



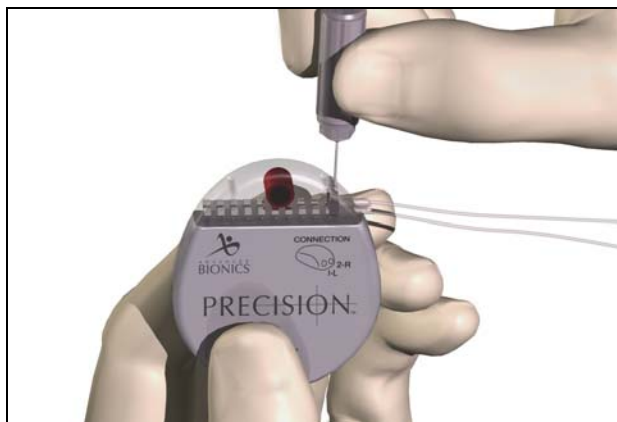
Single Lead Connection

- Connect a single lead to IPG port 1-L.
- Plug port 2-R with the connector plug supplied in the IPG Kit.

1. Fully insert the lead(s) into the IPG port(s). When the lead is properly inserted, the lead will stop and the retention ring will be located under the setscrew.



2. Pass the torque wrench through the slit in the septum located on the top of the IPG header and tighten both set screws, one at a time, until the torque wrench “clicks,” indicating lock.



- Note:**
- *If the connector plug is used in port 2-R, it is still necessary to tighten the setscrew as described.*
 - *The wrench is torque-limited and cannot be overtightened.*
 - *Ensure that the lead is fully inserted before tightening the setscrew to prevent lead damage.*
3. Place the IPG in the subcutaneous pocket with “This Side Up” facing anterior towards the skin.
 4. Coil excess lead or extension under the IPG.

Note: *To confirm good connections, check impedances.*

5. Secure the IPG in the pocket by suturing through the holes in the connector.
6. Close and dress the wound(s).

IPG Explant or Replacement

1. Turn off the IPG.
2. Surgically open the IPG pocket and withdraw the device.
3. Unscrew the connector setscrews to release the leads.
4. For replacement, connect the new IPG following steps 1-6 of “Connecting to the IPG,” preceding. Or, to terminate therapy, surgically remove the implanted lead system.

Rechargeable Implant System

The Precision spinal cord stimulator is rechargeable. Depending on stimulation power usage and programming, the majority of patients will need to recharge the implant once per week. High power users will require more frequent charging.

The clinician programmer will estimate charging time based on 24 hours per day of stimulation at the programmed settings. Patients should be instructed to charge until the charger emits an end of charge beep signal.

Estimated charge times for 1-4 stimulation areas set to stimulate at 40 pulses-per-second and 210 μ s per area:

	1 Area	2 Areas	4 Areas
	Nominal Power	Medium Power	High Power
Total Current	< 4 mA	4-8 mA	> 8 mA
Per Week	1 hour 30 min.	4 hours	
Per Day	15 min.	30 min.	1 hour

*Beginning of Life

IPG Battery Status

The patient Remote Control will display when the stimulator battery is low and when the stimulator battery is empty. If the IPG is not recharged before depletion, stimulation will automatically shut off

and the implant will need to be charged for approximately 2 hours before reactivation.



Charging Steps

The Charger Base Station should be plugged in and the charger placed in the cradle until the indicator light is green. If the indicator is not green, the charger may not be able to fully charge the implant.

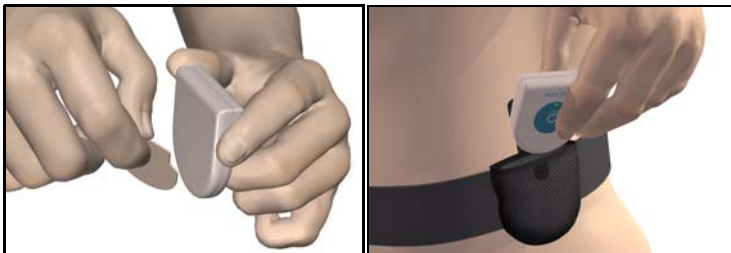
Users may wear the charger over the implant using a Velcro® belt or adhesive patches. The patches are preferred to maintain proper alignment throughout charging.

1. While the Charger is seated in the Base Station, check that the indicator light is green.
2. Remove the Charger from the Base Station. (*The indicator light will go out, regardless of the ready status.*)

3. Apply the adhesive to the backside of the Charger by peeling the clear device side liner from the patch and applying the patch to the device, as shown, and then remove the skin side beige liner from the adhesive (only good for one fixation).

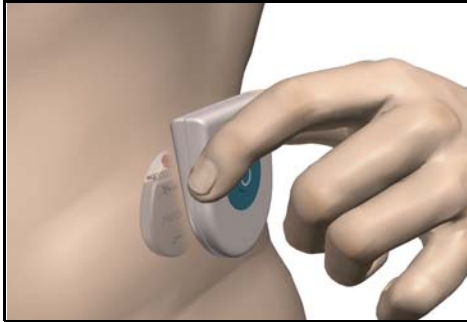
OR

Place the Charger into the Velcro[®] belt with the power button facing out.



4. Press the power button, the large blue center of the Charger, to turn on the Charger. The indicator light will return to the status position, and the Charger will begin beeping steadily to signal that it is searching for the implant.

5. Locate the Charger over the IPG. When the Charger is correctly aligned with the IPG, the beeping will stop. Press the Charger with the adhesive, or secure the Velcro[®] belt at this time.



Note: • *If the Charger loses contact with the IPG during charging, the steady alignment beep will sound. Readjust the belt or reapply the adhesive.*

6. When the Charger emits a distinct double beep, the implant is charged.



Patient Remote Control

Basic Operation

The Remote Control communicates with the implant through a radio frequency (RF) telemetry link from a distance of up to two feet. The Remote Control turns on automatically when any button is pressed. During normal patient use, the Remote Control will turn off automatically after 60 seconds of non-use. Button functions are identified above the buttons on the LCD screen. These function identifiers may change depending upon the actions being performed.



Note: *Electronic interference and poor orientation can result in a lack of communication that will be displayed as “No Response” on the device’s LCD screen. If this occurs, move the remote closer to the IPG and try the previous action again.*

Basic Programming

Stimulation On/Off

The stimulation is turned on and off with a dedicated power switch on the Remote Control keypad. Simply press the stimulation power button at any time to change the on/off state of the implant.

Stimulation Amplitude

Press the ▼ or ▲ button from the main screen to decrease or increase amplitude.



Coverage Area Selection

Press the **SEL 1 [SEL]** button from the main screen to cycle to a specific stimulation coverage area. Press the ▼ or ▲ button to adjust the amplitude of the selected area.

Program Selection

Press the **SEL 2 [NEXT]** button to display the program screen. Press the **SEL 1 [SEL]** button to cycle through saved programs. Program selections can be either activated (press ▼) or saved (press ▲) from this screen.



Options

Press and hold the **SEL 2** button for 3 seconds to access the Rate and (Pulse) Width parameters and the program restore function. Use the **SEL 1** button to highlight the desired option, then press **▲ [GO]**.

***Note:** Rate and Pulse Width are blocked from patient access by default, but may be made available using the Clinician's Programmer.*



For Rate and Pulse Width: When the desired option screen is displayed, first use the **SEL 1** button to find the desired area, then use the ▼ or ▲ button to decrease or increase the parameter setting for that area.

To restore a program: Press **SEL 1** to highlight the desired program, then press **SEL 2 [RESTR]**. The restore function returns a program to the last clinic programmed settings.

Physician Mode

Patient-restricted physician screens provide access to these advanced programming and interrogation functions:

- Communication with the clinician programmer
- Electrode and stimulation parameter programming
- Electrode impedance monitoring
- Remote Control and trial stimulator resetting/re-linking

Entering Physician Mode

1. To access physicians screens, press **SEL 1** and **SEL 2** simultaneously.
2. The Remote Control will request a code. (To obtain the code, refer to the Physician Systems Handbook.) Use the ▲ and ▼ buttons to scroll through the characters, and the **SEL 1 [SEL]** button to advance to the next entry. After entering the code, press **SEL 2 [ENTER]**.

Once the code is entered, the screen will appear as shown.



Device Links and Resets

A Remote Control can communicate with only one stimulator at a time. This prevents the remote device from accidentally controlling an unintended stimulator. To start a trial for a new patient, the remote settings and programs must be reset or cleared.

Change Link (same patient use only)

Change the link when the remote is intended for continued use by the same patient with a new stimulator. All programs set for the patient will be maintained and can be used with the new stimulator. Change the link when:

- converting from a trial stimulator to a permanent IPG
- replacing an IPG



Change Patient

When a Remote Control is to be used with a different patient than was previously using the remote, reset the system. This will clear all previously stored programs and will allow you the option of resetting a trial stimulator when one is detected. **Always** reset the system when using a remote with a different patient, such as when:

- Programming an IPG or trial stimulator of a new or different patient

Changing Links and Resets

1. Access the physician mode and enter the code.
2. When the screen displays “CLINIC OPTIONS PC READY” press ▲ **[RSET]** to access the links and resets.
3. Use **SEL 1** to select “Link” or “Patient” from the following screen, and press ▲ **[RSET]**.

The Remote Control will turn off after breaking the existing link and/or clearing the programs. Press any button to turn on the remote and re-establish the link.

Reading Lead Impedances

From the physician OPTIONS screen, press ▼ **[IMP]** to check lead electrode impedances. It will take a few seconds to display the detected values.

***Note:** Failed electrodes that are not currently assigned will not be displayed on the programming screen. Otherwise, failed anodes will be displayed H+. Failed cathodes will be displayed H-. You may wish to make note of problem contacts from this screen to serve as a programming reference.*

Stimulation Set Up (Programming)

***Note:** When using the Remote Control for a new or different patient, be sure it has been reset. See “Change Patient” on page 29 for instructions.*

1. Enter the physician mode (see “Entering Physician Mode” on page 27) and press **SEL 1 [CLIN]** to access the programming screen.
2. The **SEL 2** button toggles between the electrode configuration and the parameters.

The screen displays the settings and configuration for one programmable area at a time. Up to four independent areas can be configured for each of the four programs available with the IPG.



When there are separately controlled areas of stimulation, the stimulation rates for the individual areas must be in descending order or be equal. This means that Area 1 must have a rate higher than or equal to Area 2, and Area 2 must have a rate higher than or equal to Area 3, and so forth. (Coverage areas are separate groups of electrodes, with independent

programmable parameters, which are combined into a program to achieve optimal pain coverage.)



Separately controlled areas within the same program cannot share the same electrodes when the stimulation is monopolar, utilizing the IPG or external patch electrode as the anode.

Electrode Configuration

1. Electrodes are numbered 1-16 (8 per side), and displayed as shown in the figure below. Use the ▼ (down) and ▲(up) buttons to cycle E1 through E16.



2. When the desired electrode number is reached, configure the polarity (+/-/0) by pressing the **SEL 1** button until the intended polarity is shown on the respective electrode.

Note: *When changing a configuration, the amplitude of the edited area will be reduced to 0.0 and stimulation to all other areas will be turned off.*

3. If you have changed a configuration, gradually increase the amplitude of the edited area to a comfortable level.
4. To restore stimulation at previous levels to all other areas, briefly press the power button once, then press it a second time.

Parameters

1. Use the **SEL 1** button to cycle through various parameters including amplitude, rate, and pulse width, and to program or view another area.
2. Use the ▼ (down) and ▲(up) buttons to adjust the selected parameter.

Exiting Clinician's Programming Screen

1. Upon completion, press **SEL 1** and **SEL 2** simultaneously. This will advance to the PROGRAMS screen.
2. Select the program number you wish to save to by pressing **SEL 1**. You can overwrite an existing program or save to an empty program slot (*) if one is available.
3. Press the up button (▲) to save. You will return to the clinician Options screen.

For more information on how to use the physician screen, see the Physician Systems Handbook.

Programmer Communication

The clinician's programmer can communicate with either an external trial stimulator or an IPG. In order to begin a programming session, the clinician programmer and the Remote Control infrared windows must be aligned.

Arrange for the patient to be seated within two feet of the Remote Control to ensure a complete communication link from the programmer to the stimulator.

For instructions on how to use the clinician's programmer with the BionicNavigator software to program the IPG and transfer programs to the Remote Control, see the Physician Systems Handbook.

Specifications and Technical Data

IPG (SC-1100)

Parameter	Range	Default
Areas (Channels)	4	—
Amplitude	0 – 20 mA	0 mA
Rate	0 – 1200 pps	40 pps
Width	0 – 1000 μ sec	210 μ sec
Cycle	0 – 90 min	OFF
Ramp ON	1 – 10 sec	2 sec
Contacts	1 – 16; +, -, OFF	1 – 16: OFF

Materials	Size
Case	Titanium
Header	Epoxy
Strain Relief	Silicone
Size	55mm x 45mm x 11mm

Registration Information

Registering the Implant

In accordance with international practice and regulatory legislation in some countries, a registration form is packed with each Advanced Bionics Corporation neurostimulator.

The purpose of this form is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted lead, accessory or device to gain quick access to pertinent data from the manufacturer.

Fill out the registration form included in the package contents. Return one copy to Advanced Bionics, keep one copy for patient records, and provide one copy to the patient and physician.

Advanced Bionics Corporation
25129 Rye Canyon Loop
Valencia, California 91355
Attention: Customer Service Department

Technical Service

Advanced Bionics Corporation has highly trained service professionals located worldwide to assist you. The Technical Service Department is available to provide technical consultation 24 hours a day.

In North America, please call (866) 566-8913 to speak to a representative.

Limited Warranty

Advanced Bionics® Corporation (hereinafter referred to as Advanced Bionics®) warrants to the patient who receives a Precision™ System that the implanted pulse generator (hereinafter referred to as the IPG, Model SC 1100, is free from defects in workmanship and materials for a period of one (1) year from the date of surgical implant of the IPG. This warranty only applies to the patient (recipient, hereinafter referred to as the patient), and no other individual.

An IPG that fails to function within normal tolerances within (1) year from the date of surgery is covered under this Limited Warranty. The liability of Advanced Bionics® under this warranty shall be limited to: (a) replacement with a functionally equivalent IPG; or (b) full credit equal to the original purchase price to be applied towards the purchase of a new IPG. Product claims under Advanced Bionics® Limited Warranty are subject to the following conditions and limitations:

1. The product registration card must be completed and returned to Advanced Bionics® within 30 days of surgery in order to obtain warranty rights.
2. The IPG must be returned to Advanced Bionics® (or authorized agent) within 30 days of malfunction or discovery of defect, and shall be the property of Advanced Bionics®.
3. The IPG must be implanted prior to the “use before” date.
4. Failure of the IPG must be confirmed by Advanced Bionics®. This warranty specifically excludes defects or malfunctions caused by: (a) fire, floods, lightning, natural disasters, water damage and other calamities commonly defined as “Acts of God”; (b) accident, misuse, abuse, negligence, or the customer’s failure to operate the IPG in accordance with manufacturer’s instructions; (c) unauthorized attempts to repair, maintain, or modify the equipment by the customer or any unauthorized third party; or (d) attachment of any equipment not supplied by Advanced Bionics® without prior approval.

- a. This warranty does not include the leads, extensions or surgical accessories used with the Precision™ IPG.
5. The decision as to product replacement or credit shall be made solely at the discretion of Advanced Bionics®. For a replacement IPG, the warranty will run only to the end of the warranty period for the original IPG that was replaced.

This warranty is in lieu of any other warranty, expressed or implied, including any warranty of merchantability or fitness for intended use. Except as expressly provided by this Limited Warranty, Advanced Bionics® shall not be responsible or liable for any direct, consequential or incidental damages caused by device malfunction, failure or defect, whether the claim is based on warranty, contract, tort or otherwise.



IMAGINE the Possibilities®

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