Physician Implant Manual

DRAFT

CAUTION:

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MP9055182 Rev A

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Introduction

Manual Overview

This manual provides basic information for the implantation and operation of the Precision™ Implantable Pulse Generator (IPG), Model SC-1110. 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 BionicNavigator™ Software Guide.

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-6000-02.

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 Advanced Bionics PRECISION™ Spinal Cord Stimulator System (PRECISION™ 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 the following: failed back surgery syndrome, intractable low back pain and leg pain.

Precision System Clinical Summary

Determination of the safety and effectiveness of the PRECISION System was based on available published clinical studies for similar implanted spinal cord stimulation systems. The PRECISION System is similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the PRECISION System for the treatment chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

Efficacy Evaluation

Three (3) clinical literature studies were used to support the effectiveness of the PRECISION System (Ohnmeiss et al. 1996, Villavincencio et al. 2000, Hassenbach SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was depicted from the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, a totally implantable spinal cord stimulator was used in association with a percutaneous and/or surgical lead. These studies provide the same diagnostic or therapeutic intervention

for the same disease/conditions and patient population as the PRECISION System.

The prospective study by Ohnmeiss et al. 1996, examined the long-term effectiveness of SCS in patients with intractable leg pain. Forty patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP (Sickness Impact Profile), isometric lower extremity testing, and patient questionnaires. An intent-to-treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, 25% of the implanted patients had greater than 50% improvement in pain rating.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Three patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1 patient had the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study performed by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome (CRPS I and II), 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In this study, 27/41 patients, 66%, had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%), reported greater than 50% reduction

in pain. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, one patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis performed by Hassenbusch SJ et al. 1995 included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opiods. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. Five patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were 4 (10%) patients who underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: “On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?” 16/26 patients (62%) had greater than 50% pain relief with SCS. In this study, 2/16 (13%) had greater than 50% pain relief with

opioids. Mean follow-up was 2.1 $\pm$ 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

Safety Evaluation

Eleven studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the PRECISION System. The studies included a total of 1056 patients that were trialed with SCS systems and 880 patients that received implants. The table below depicts the number of patients, the number of events, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that citations cover both IPG and RF Systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

Table 1: Summary of Risks Identified in the Retrospective Clinical Studies

Risks	# Patients With Adverse Event	Intent-to-Treat Basis N = 1056	Implanted Patient Basis N = 880
Lead Migration	175	16.6%	19.9%
Infection	39	3.7%	4.4%
Epidural Hemorrhage	0	0%	0%
Seroma	0	0%	0%
Hematoma	1	0.1%	0.1%
Paralysis	0	0%	0%
CSF Leak	5	0.5%	0.6%

Over/Under Stimulation, Ineffective Pain Control	46	4.4%	5.2%
Intermittent Stimulation	0	0%	0%
Pain Over Implant	16	1.5%	1.8%
Allergic Reaction	6	0.6%	0.7%
Skin Erosion	0	0%	0%
Lead Breakage	35	3.3%	4.0%
Hardware Malfunction	22	2.1%	2.5%
Loose Connection	0	0%	0%
Battery Failure	2	0.2%	0.2%
Other	45	4.3%	5.1%

Clinical Experience-Safety

Clinical data has been collected during a clinical study of the PRECISION™ System. As of January 15, 2004, 35 subjects were enrolled in the study at multiple sites and 26 subjects had a successful trial stimulation period and were implanted with the PRECISION™ System. The follow-up period for the 26 implanted patients ranged from 2 weeks to 6 months. The following major adverse events were reported.

Table 2: Clinical Experience Safety

Type	Number of Patients	Resolution
Lead Migration	1	Lead repositioning and subsequent replacement
Output malfunction	1	Device replaced

Infection	1	Infection treated
Pain	1	Lead explanted

Other minor adverse events reported by at least one patient included: receiver malfunction, skin irritation, unpleasant stimulation, CSF leak, infection at implant site, lead migration, and OR cable malfunction. Two of the subjects reported multiple events.

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Contraindications

Patients contraindicated for permanent SCS therapy are those who:

- are unable to operate the SCS system
- have failed trial stimulation by failing to receive effective pain relief
- are poor surgical risks
- are pregnant

Safety Information

Warnings

Magnetic Resonance Imaging (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.

Pediatric Use. The safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

Diathermy. Shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on 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. The IPG, whether it is turned on or off, may be damaged.

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. Patients should be advised to turn down the amplitude or turn off the IPG before making posture changes. If unpleasant sensations occur, the IPG should be turned off immediately.

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 such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices. It is recommended that patients request assistance to bypass the device. If they must proceed through the device, the patient should turn off the stimulator and proceed with caution, ensuring to move through the center of the screener as quickly as possible.
- Power lines or power generators
- Electric steel furnaces and arc welders
- Large, magnetized stereo speakers

Precautions

Physician training is required.

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: *Do not use monopolar cautery.*
- 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 15. 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.

Cell Phones. While we don't anticipate any interference with cell phones, the full effects of interaction with cell phones are unknown at this time.

Post Operative. During the two weeks following surgery, it is important to use extreme care so that appropriate healing will secure the implanted components and close the surgical incisions: Do not exercise or attempt to move heavy objects, and avoid deep bending and stretching. Temporarily, there may be some pain in the area of the implant as the incisions heal. If discomfort continues beyond two weeks, contact your physician. If you notice excessive redness around the wound areas during this time, contact your physician to check for infection and administer proper treatment. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

Implant Location. Never attempt to change the orientation or "flip" the implant. Do not "finger" or play with the implant. If the implant flips over in your body it cannot be charged. If you know that the device has turned, or if stimulation cannot be turned on after charging, contact your physician to arrange an evaluation of the system. In some cases, the skin over your implant may become very thin over time. If this occurs, contact your physician.

Lead Location. In some instances a lead can move from its original location, and stimulation at the intended pain site can be lost. If this occurs, consult your physician who may able to restore stimulation by reprogramming the implant in the clinic or repositioning the lead during another operation.

Device Failure. Implants can fail at any time due to random component failure, loss of battery functionality, or lead breakage. If the device stops working even after complete charging (up to four hours), turn off the implant and contact your physician so that the system can be evaluated.

Storage. Do not expose the Remote Control or Charging System components to excessively hot or cold conditions. Do not leave the devices in your car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat. If the Remote Control or the Charging System is to be stored for a period of time, be careful that the storage temperature does not exceed -20–60 °C (-4–140 °F).

Handling. Handle the system components and accessories with care. Do not drop them or submerge them in water. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components. (See “Limited Warranty” on page 54.)

Component Disposal. Do not dispose of the Remote Control or Charger in fire. The battery in these devices can explode in fire. Dispose of used batteries in accordance with local regulations. The IPG should be explanted in the case of cremation, and returned to Advanced Bionics.

Remote Control, Charging System Cleaning. The components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Residue from soapy detergents should be removed with a damp cloth. Do not use abrasive cleansers for cleaning.

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.
- Undesirable stimulation may occur over time due to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections and/or lead failure.
- The patient may experience painful electrical stimulation of the chest wall as a result of stimulation of certain nerve roots several weeks after surgery.

- Over time, the implant may move from its original position.
- Weakness, clumsiness, numbness or pain below the level of implantation.
- Persistent pain at the IPG or lead site.

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:

- Turn off stimulation at least five minutes before the procedure or application.
- All equipment, including ground plates and paddles, must be used as far away from the IPG as possible.
- Bipolar electrocautery is recommended. Do not use monopolar electrocautery.
- 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.

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.

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.

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.

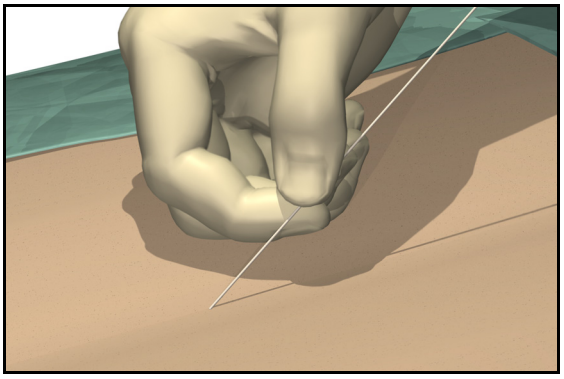
Percutaneous Lead/Extension Removal

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

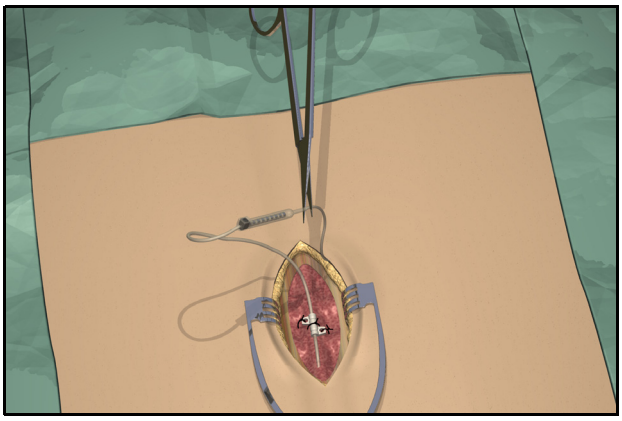
Remove the lead(s) completely and discard them.



Option B. Extension Removal

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

2. Cut the lead extension at the connector.

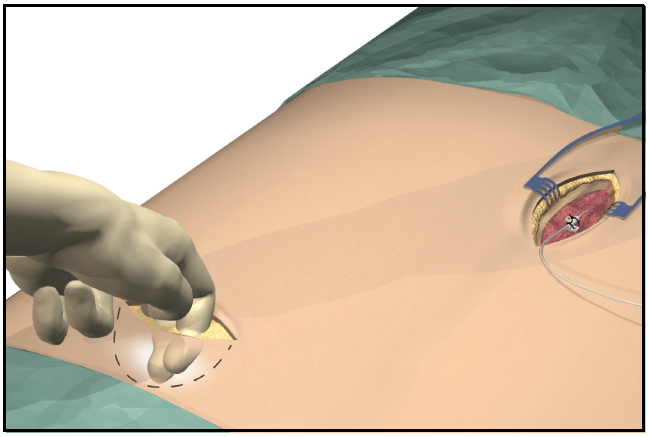


3. Pull the lead extension through the tunnel and away from body at the externalized site.
4. Loosen the connector setscrew using the torque wrench provided. Disconnect and discard the connector.

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 manipulation and IPG flipping.*

• *Implant charging could become ineffective at depths greater than 3/4 inch (2.0 cm).*

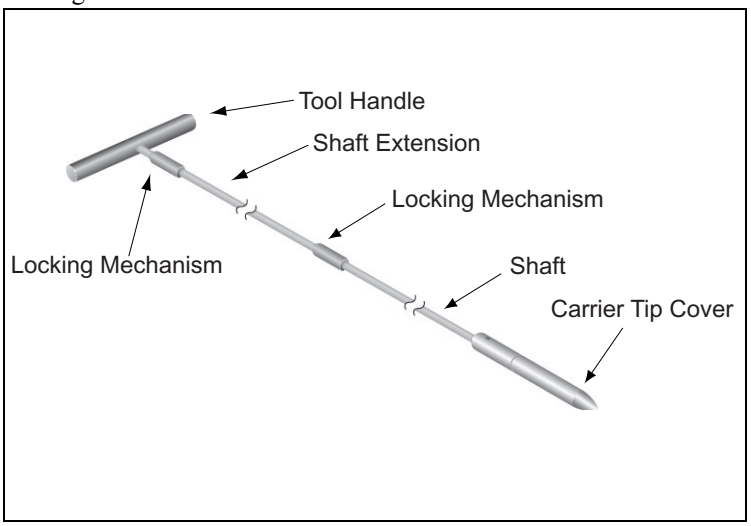
Tool Assembly

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

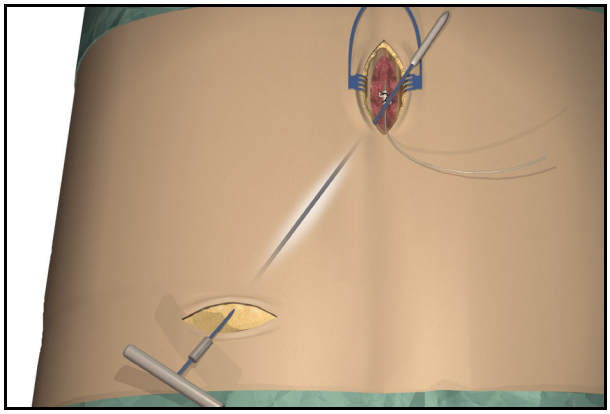
1. Mark the desired route of the tunnel.
2. Administer the appropriate local anesthetic along the tunneling path.

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.

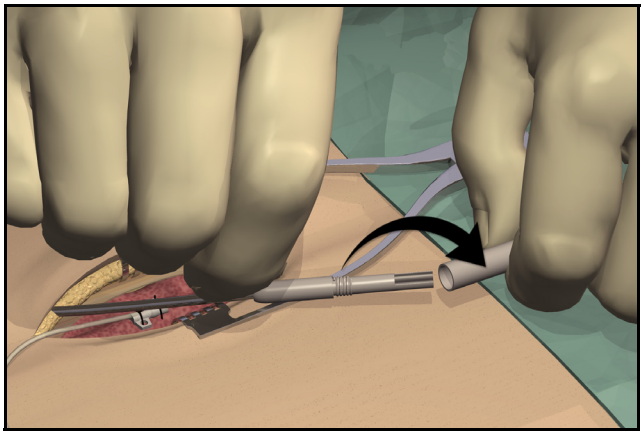
   CAUTION: Do not bend locking joints.

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



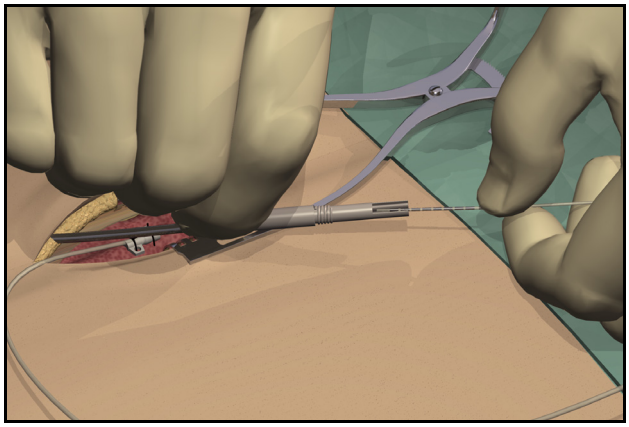
Note: *Deep tunneling is not recommended.*

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.



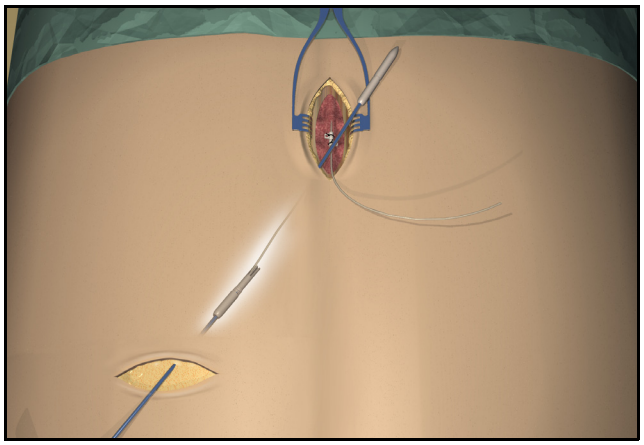
Note: *You may feel the tip slide back before the cover begins to unscrew.*

6. 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.*

7. Gently pull the tunneling tool back through the tunnel.

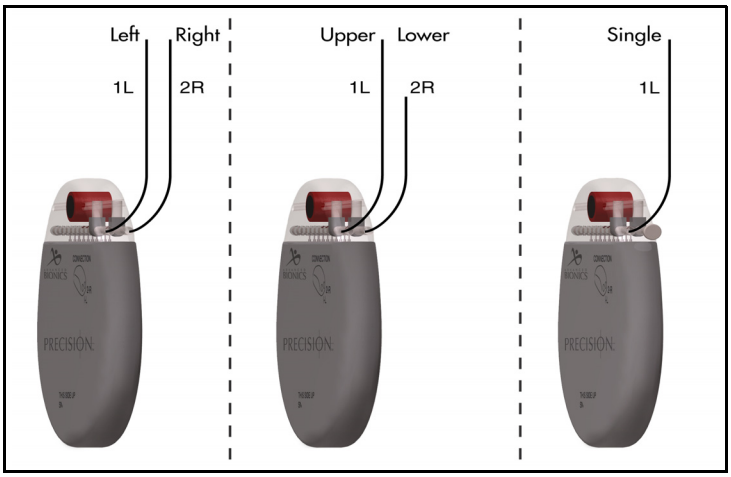


8. Gently lift the lead(s) out of the locking groove(s).
9. Wipe off any fluids from the proximal end of the lead(s).

Connecting To the IPG

Dual Lead Connection

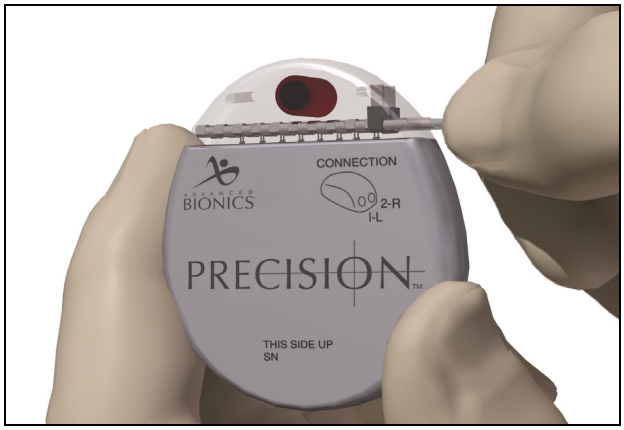
- Superior (upper or left) leads connect to IPG port 1-L.
- Inferior (lower or right) leads connect to IPG port 2-R.



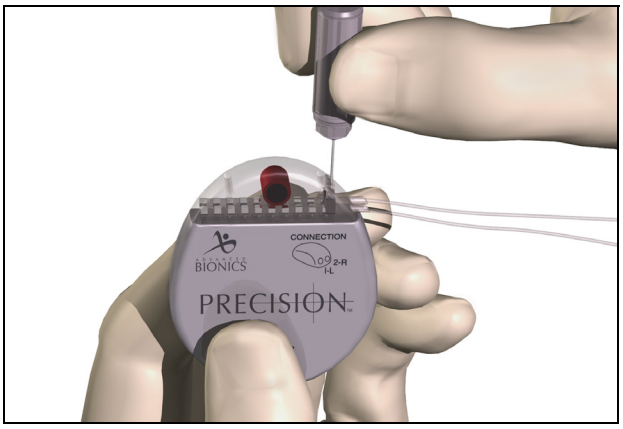
Single Lead Connection

- 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.



CAUTION: Ensure that the lead is fully inserted before tightening the setscrew to prevent lead damage.

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.*
- *If there appears to be an obstruction when inserting the lead, lead extension, or connector plug, use the torque wrench to loosen (counterclockwise) the setscrew and/or gently rotate the lead to help advance the proximal end.*

3. Place the IPG in the subcutaneous pocket with "This Side Up" facing towards the skin.
4. Coil excess lead or extension under the IPG.

Note: *To confirm good connections, check impedances before tightening the setscrew.*

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 and remove 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.

Rechargable 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. Advanced Bionics recommends any recharge schedule (daily, bi-daily, weekly, bi-weekly) that fits the patient's schedule and lifestyle while maintaining sufficient charge to maintain stimulation.

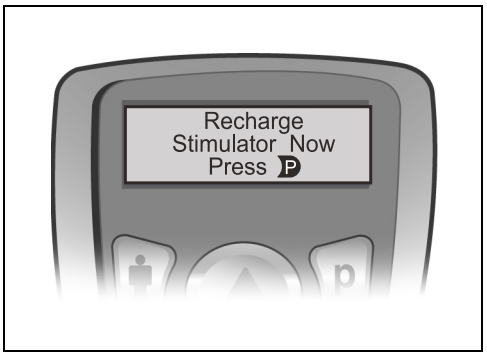
The Clinician Programmer will estimate charging time based on 24 hours per day of stimulation at the programmed settings. Recharge time can range from ten minutes to four hours. Patients should be instructed to charge until the Charger emits an end of charge beep signal. The recharging process is important, but simple.

The rechargeable implant battery should provide at least five years of service. Over time and repeated charging, the battery in the implant will lose its ability to recover its full capacity. As a result, the implant may require increased recharge time and/or shorter intervals between charges after five years of service. The implant will need replacement when stimulation can no longer be maintained with routine charging.

IPG Battery Status

When the patient Remote Control communicates with the implant, the battery status is sent to the remote, which will display a message when the stimulator battery is low and when the stimulator battery is empty. When the remote indicates a low battery (message: Recharge Stimulator Soon) the implant should be recharged as soon as possible. Failure to recharge will lead to loss of stimulation in less than 24

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



If the patient reports that stimulation has stopped but does not also report having seen the Remote Control warning messages “Recharge Stimulator Now” and “Must Recharge,” instruct the patient to check the implant battery status with the Remote Control first. If the message sequence is displayed, inform the user that the IPG must be recharged within three days or he/she runs the risk of needing to return to the clinic for reprogramming.

If the patient reports seeing a “No Response” message on the Remote Control screen, the lack of communication is probably due to a low battery. Instruct the patient to recharge the implant, and then try using the remote again.

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 amber-colored, 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. Advanced Bionics recommends using the Velcro® belt for 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 of the Charger.*)

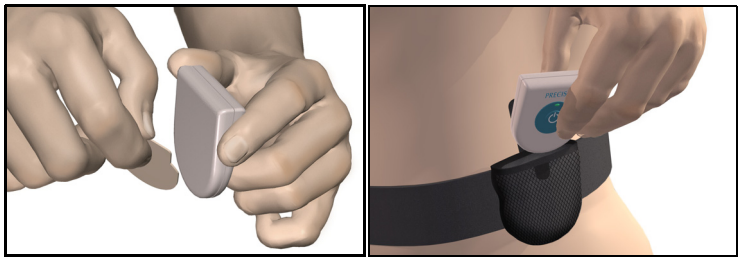
Note: *If the implant is not recharged as recommended, stimulation will eventually stop due to a low battery. If this happens, the implant must be recharged within three days from loss of stimulation. If stimulation stops and you have lost or cannot get to your charger within five days, contact Customer Service immediately at (866) 360-4747.*

If discontinuing stimulation for an extended period of time, the implant should first be fully charged. Additionally, the implant should be fully charged every month if stimulation is not used.

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).

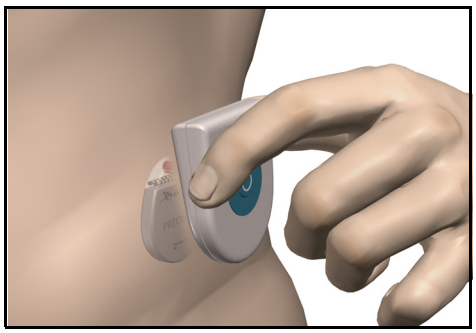
   OR

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



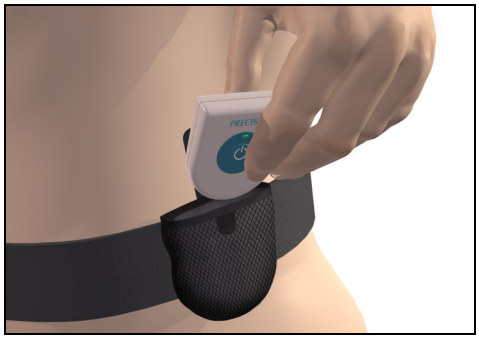
4. Press the power button, the large blue center of the Charger, to turn on the Charger. The indicator light will return to the status color (green or amber), and the Charger will begin beeping steadily to signal that it is searching for the implant.

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.*

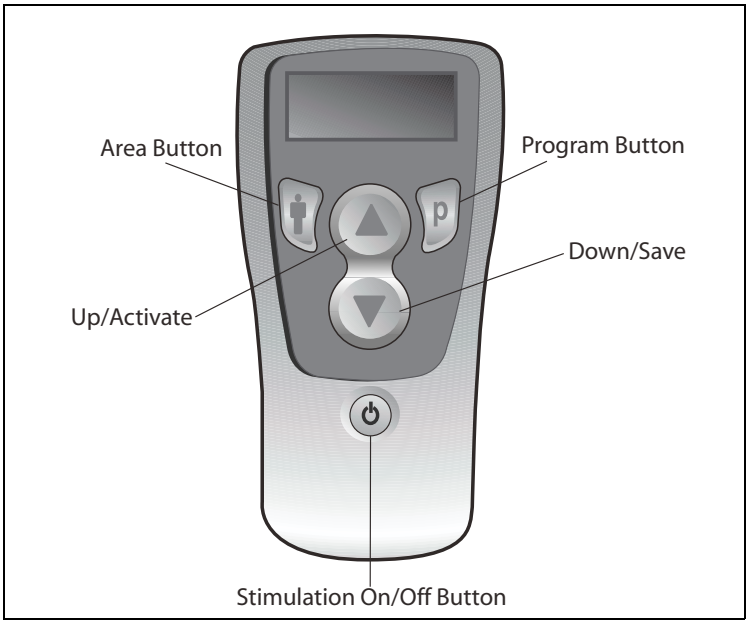
6. When the Charger emits a distinct double beep, the implant is charged.



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. When it is not being used, the remote is in an idle (or sleep) mode from which it can be reactivated by any button press. During normal patient use, the device will transition to idle mode automatically after 60 seconds of non-use.



Some remote functions (i.e., patient Options and Clinician Mode) are accessed via a “long button press” (press and hold for approximately three seconds). These are identified in the appropriate sections following.

Stimulation On/Off

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

Stimulation Amplitude

The Level screen is the Remote Control's "default" screen. The remote will automatically return to this screen within 15 seconds of any button activity.

Note: *When there is no button activity for more than 60 seconds, the Remote Control will transition to idle mode and the display screen will be blank.*

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

The Level screen also displays a bar graphic in the upper right corner to indicate the battery charge level of the implant. Three filled-in bars represents a fully-charged battery. As the battery strength is reduced, depending on the patient's stimulation settings and usage, the bars will "empty" accordingly. Patients are encouraged to recharge the implant at the first "Recharge Battery Soon" message displayed by the Remote Control.

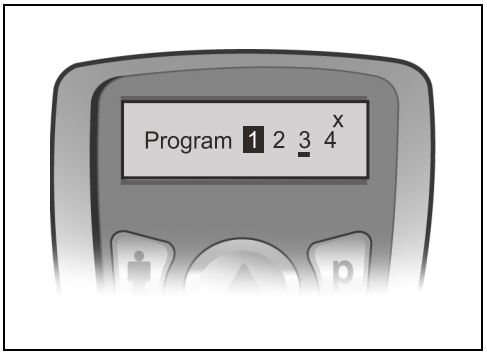
Coverage Area Selection

1. Press the button as needed from the Level screen to cycle to a specific stimulation coverage area.
2. Press the ▲ or ▼ button to adjust the amplitude of the selected area.

Program Selection

Note: *The most recently retrieved or saved program will be underlined. Empty program slots are denoted by an* X.

1. Press the **p** button as needed from the Level screen to cycle to a specific saved program.
2. Press ▲ to activate the selected program.

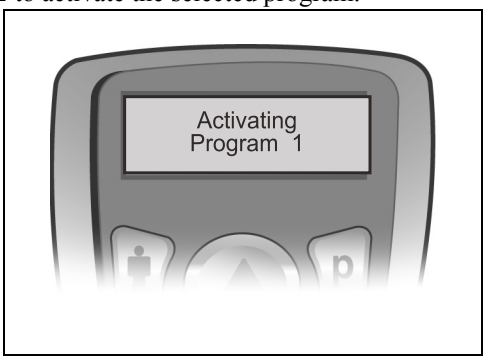


Modifying and Saving Programs

1. Press **p** as needed from the Level screen to cycle to the desired program.

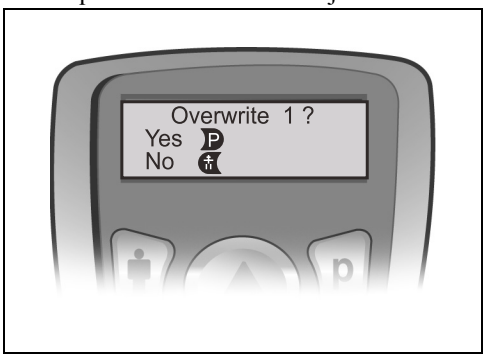
Note: *The most recently retrieved or saved program will be underlined. Empty program slots are denoted by an X.*

2. Press ▲ to activate the selected program.



3. After the remote times out to the Level screen, you may change the amplitude of all areas in the program, or you may adjust the Rate or Pulse Width of an individual area by navigating to the Options settings (see “Options” on page 40).

4. To save/store changes, select the program again and press ▼. You will be required to confirm the adjustment first.



5. Press **p** to confirm, or press the 🚹 button to cancel the operation.

Note: *To save the modifications as a new program, simply select an empty (X) program slot and press ▼instead of overwriting the existing program*.

Options

With the Precision SCS system, the Rate and Pulse Width parameters are generally considered programming "options" in that relatively few patients will actually use these settings. By default, Rate and Pulse Width are off-limits to the patient Remote Control unless you allow access using BionicNavigator software.

Another option, "Restore," is readily available to all patients. The Restore feature allows patients to return a program to the original settings you programmed for them at the initial fitting or at a follow-up.

To Access the Rate and Pulse Width Options:

1. Press and hold the button for three seconds (a long button press) or until the Rate Area 1 screen appears.

2. As necessary, press the button normally to cycle to the area you wish to adjust.

3. When the desired area screen is displayed, press ▲ or ▼ to increase or decrease the Rate.
4. To continue with a Pulse Width adjustment, press and hold the Area button from any Rate Area screen to navigate to Pulse Width Area 1.
5. As necessary, press the button normally to cycle to the area you wish to adjust.
6. When the desired area screen is displayed, press ▲ or ▼ to increase or decrease the Pulse Width.

To Access the Restore Option

1. Press and hold **p** to reach Restore Program 1.
2. If necessary, press the **p** button again (normal press) to cycle through the programs and select the program to be restored.
3. Press ▲ to restore the last clinic-programmed settings..

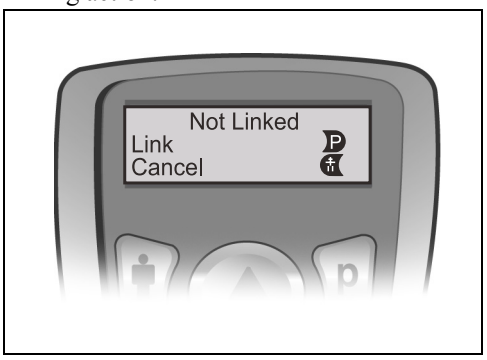
Device Linking

A Remote Control can communicate with only one stimulator at a time. This prevents the remote from accidentally controlling an unintended device. For this reason, the initial step in the linking process involves the Remote Control identifying, by telemetry, the intended

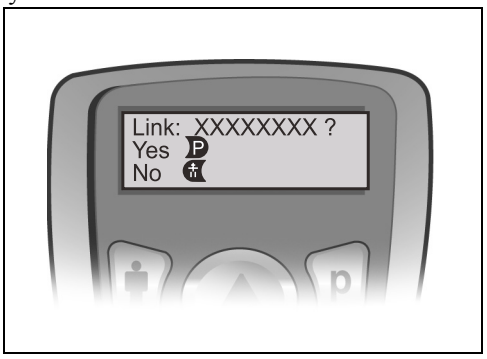
stimulator for communication.The second step in establishing the link depends on:

- Whether the stimulator is an External Trial Stimulator (ETS) or an IPG;
- Whether the Remote Control or the stimulator has stored programs or whether they are clear of programs;
- Where a different program set is present in both devices, which set is to be cleared.

An un-linked Remote Control will display the following message upon first activation (when any button is pressed) or immediately following a de-linking action:

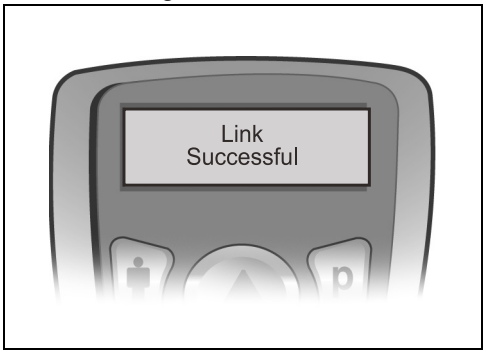


1. Press **p** to initiate communication between the remote and the stimulator within telemetry range. The remote will identify the device by ID number.



2. Press **p** to confirm and continue.

The Precision system software will automatically detect whether the stimulator is a trial or a permanent device, and whether program sets are available and where. If both the Remote Control and the target stimulator are clear of programs, the link is completed immediately and you will see this message:



However, if programs are present in either device during linking, you will be required to respond to one or more “decision” screens to guide the remote to complete the linking with the desired program set saved

to the desired device (remote or stimulator). You may also need to enter the clinician's password.

If an error occurs during the process or if the password is incorrect linking will be aborted. For further information, including information about the clinician's password, see "To Clear Link" following.

Clinician Options

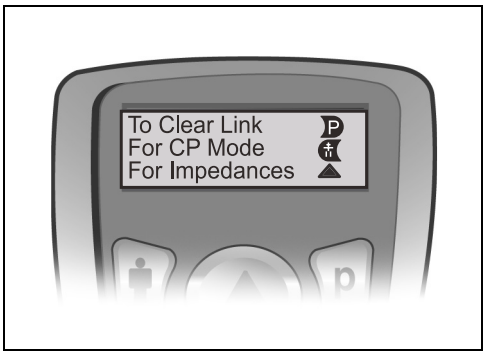
Patient-restricted clinician screens provide access to:

- Remote Control and stimulator clearing and relinking
- Communication with the clinician programmer
- Electrode impedance monitoring

To access clinician screens:

1. Press the and p buttons simultaneously for approximately three seconds. The Enter Clinician Options screen will appear as shown below.
2. Press the appropriate button to select an option.

   Each option is discussed in sequence below.



To Clear Link

When the **p** button is pressed from the Enter Clinician Options screen, you will immediately be required to enter the clinician's password in order to continue.

To enter the password:

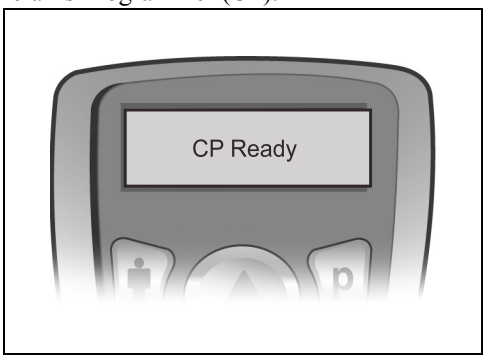
The first character is highlighted when the Enter Password screen opens. To select/confirm any character and/or move to the next character position, press **p** . To scroll through possible characters, use ▲ or ▼.

When clearing a link: If the password is entered correctly, the link between the Remote Control and the "previous" stimulator is broken immediately , and the remote displays the Not Linked screen. The Remote Control's programs remain intact. If the password is entered *incorrectly*, the process is aborted and the remote will return to the Enter Clinician Options screen.

Note: *If the password is entered incorrectly during an attempt to link the Remote Control, the process is aborted and the remote returns to the Idle screen.*

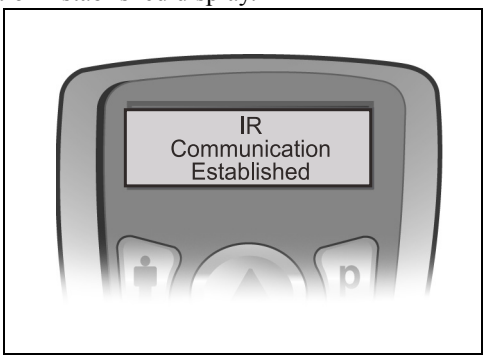
For CP Mode

1. From the Enter Clinician Mode screen (See page 44), press the button to prepare the Remote Control for communication with the Clinician's Programmer (CP).



Note: *The remote will remain CP Ready for 15 minutes.*

2. Place the remote and the IR dongle in the IR Holder with their communication ports facing.
3. Plug the dongle's USB connector into the slot in the CP and power-on the programmer.
4. Launch the BionicNavigator software and wait for the IR Communication Established display.

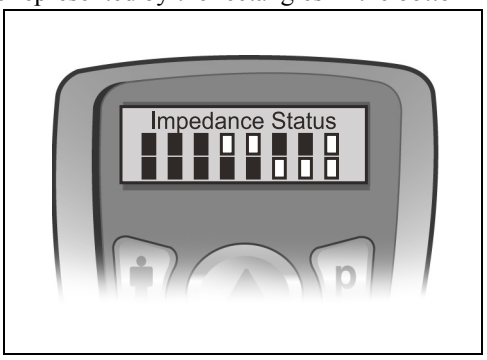


For Impedances

When ▲ is selected from the Enter Clinician Options screen, the Remote Control will take the measurements via telemetry; this will take a few seconds.

Eventually, the remote will display the Electrode Impedance Status screen.

Electrodes 1 through 8 (lead position 1-L) are represented by the rectangles in the top row; electrodes 9 through 16 (lead position 2-R) are represented by the rectangles in the bottom row.



Electrodes within the acceptable impedance range are displayed as solid rectangles; high impedance electrodes (above 4500 ohms) are represented by hollow rectangles.

Note: • *The Remote Control will terminate the CP Ready state and transition to the idle mode if there is no IR signal after 15 minutes.*

- *All buttons are active during CP Ready and pressing any button returns the Remote Control to the Level screen.*
- *Stimulation may be turned on or off during CP Ready.*
- *Once IR Communication is established, the Remote Control will terminate communication and transition to the idle mode if there is no IR activity after 15 minutes.*
- *All buttons are active during IR Communication and pressing any button returns the Remote Control to the Level screen.*

- *Whenever the remote is re-activated from idle mode the display will default to the Level screen.*

Programmer Communication

The Clinician Programmer can communicate with either an External Trial Stimulator or an IPG. In order to begin a programming session, the CP and the Remote Control IR 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 Programmer with the BionicNavigator software to program the IPG and transfer programs to the Remote Control, see the BionicNavigator Software Guide.

Specifications and Technical Data

Parameter	Range	Default
Areas (Channels)	4	—
Amplitude	0 – 20 mA[a]	0 mA
Rate	0 – 1200 pps[b]	40 pps
Width	0 – 1000 µsec	210 µsec
Cycle	0 – 90 min, OFF	OFF
Ramp ON	1 – 10 secs	3 secs
Contacts	1 – 16; +, -, OFF	1 – 16: OFF

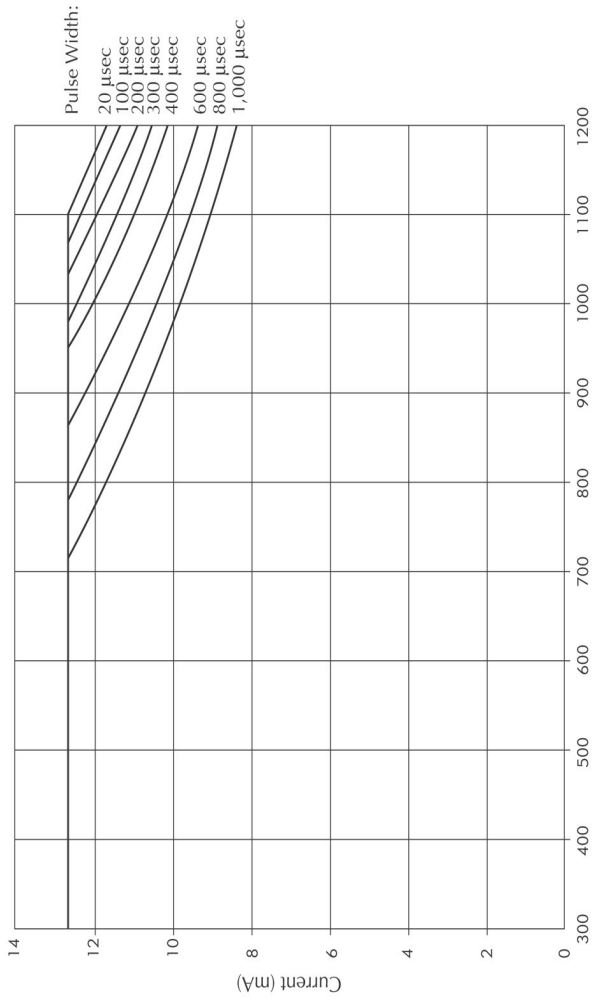
a.The Precision System includes programmable coverage areas with each individual electrode contact limited to 12.7 mA. A programming interlock is enforced to limit the coverage area output current to 20 mA or less. For example, a maximum current output of 12.7 mA on a first electrode would limit the total summed current output on remaining electrodes to 7.3 mA within one coverage area.

b.Only one Area is available if the rate is 130 pps.

Materials

Case	Titanium
Header	Epoxy
Strain Relief	Silicone
Size/Volume	55mm x 45mm x 11mm / 22 cm^3 (including header)

Maximum Current Amplitude per Electrode versus Impedance



Note: Maximum output capability is frequency independent

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 1110, 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.

The following is federal government communications regulation information about the Precision™ System.

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

Changes of modifications to this product not authorized by Advanced Bionics Corporation could void the FCC Certification and negate your authority to operate this product.