DRAFT

Patient System Handbook

CAUTION:

Federal law restricts this device to sale, distribution and use by or on the order of a physician.

MP9055184 Rev A

Guarantees

Advanced Bionics Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

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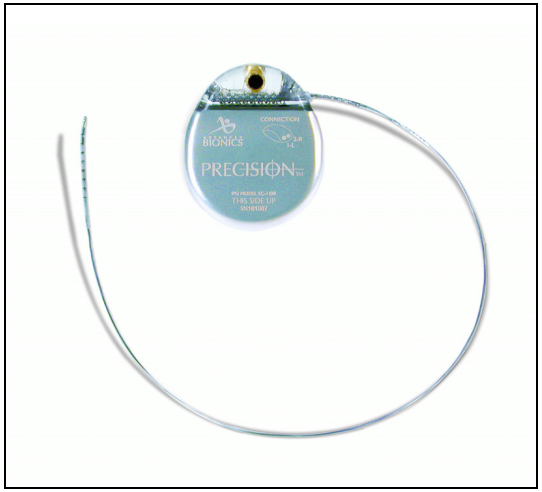
Table of Contents

1 Introduction

The Advanced Bionics® Precision™ SCS (Spinal Cord Stimulation) system is prescribed for the management of chronic pain. The system electrically stimulates the spinal cord to alter the perception of pain signals that move along the nerve pathways on either side of the spine. *Paresthesia* is the term that describes the light, tingling sensation—the "feeling"—of spinal cord stimulation.



Before receiving your new implant, you had the opportunity to test stimulation therapy and decide if it would work for you. By choosing to have a stimulator surgically implanted, you

confirmed that *paresthesia* is capable of providing you with good to excellent pain relief. As you go forward with this therapy, your health professionals will work with you to find the most comfortable level of paresthesia to cover the painful areas by adjusting your implant's settings. Although you may have pain areas that cannot be reached by spinal cord stimulation, the goal is to bring you the most effective pain relief possible. The more you help and work with your health professionals, the more likely you are to achieve the best outcome possible from your new Precision system.

Advanced Bionics is an organization dedicated to helping you manage your pain. We will help you make the most of this therapy for an improved quality of life.

2 System Description

The Precision system includes both implanted and external components: During your surgery, one or more wires called **leads** were placed along your spinal cord where pain signals to the brain can be intercepted. The lead was then attached to an implantable pulse generator (IPG), also referred to as an **implant**. The IPG is commonly placed in the abdomen, upper buttock, or subclavicular area. The implant sends a small electrical current to a series of stimulating contacts, called **electrodes**, at the end of the lead. The battery-powered implant is controlled by a hand-held programmer or **Remote Control,** and is periodically recharged using a separate **Charging System**.

The Remote Control, the heart of the Precision system, is a powerful yet easy to use tool for managing every aspect of your pain treatment—from controlling the level, or strength, of stimulation to accessing special treatment programs and program options.

To make the most of your Precision system, it's important to learn:

1. what to be aware of for safety,
2. how to use the Remote Control, and
3. how to recharge the implant.

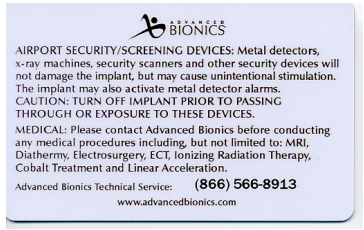
These subjects are covered on the following pages, and we encourage you to read this manual entirely. If you have any questions, or need clarification of anything contained in this manual, feel free to contact our Customer Service Department at (866) 360-4747.

Before reading more about the Precision System, first check that all of the following items were included in your Patient Kit. (And check to be sure you have your Temporary Patient Identification Card; keep it with you until you receive your permanent card.) If any item is missing, please call our Customer Service department for a replacement.

(1) Remote Control
(1) Charger
(1) Charger Base Station
(1) Power Supply
(1) Remote Control Cover
(1) Velcro® Charging Belt
(1) Charger Adhesives (52 pieces)
(1) Remote Control Batteries (3)
(1) Carrying Case

Front

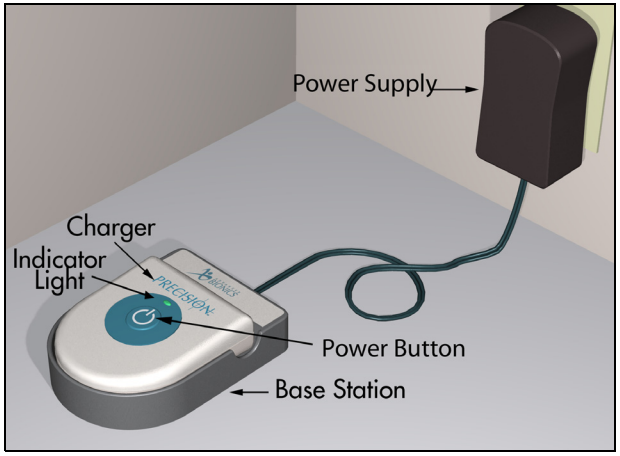
Back



Permanent Patient Identification Card

Find a convenient electrical outlet, one that won't expose the Charging System parts to water or direct heat, and plug in the Base Station Power Supply. Next, connect the Power Supply to the Base Station, and locate the Base Station on a flat surface. Finally, place the Charger in the Base Station with the stimulation on/off button facing up.

For now, that's all you need to do to get started. For more information on the Charging System and its use, see "Charging the Implant" on page 51.



3 Safety Information

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 two weeks to six 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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Burchiel, K.J., V.C. Anderson, F.D. Brown, R.G. Fessler, W.A. Friedman, S. Pelofsky, R.L. Weiner, J. Oakley,and D. Shatin. “Prospective, Multicenter Study of Spinal Cord Stimulation for Relief of Chronic Back and Extremity Pain.” Spine, 21:2786-2793, 1996.

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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

Warnings

Magnetic Resonance Imaging (MRI). You should **not** be exposed to Magnetic Resonance Imaging (MRI). Exposure to this diagnostic technology may result in dislodgement of your IPG or lead(s), heating of the IPG, severe damage to the IPG electronics and/or increased voltage through the leads or IPG which can cause an uncomfortable or “jolting” sensation.

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

Diathermy. As an SCS patient, you should not have any form of diathermy as either as treatment for a medical condition or as part of a surgical procedure. The high energy and heat generated by diathermy can be transferred through your stimulator system, causing tissue damage at the lead site and, possibly, severe injury or death. The IPG, whether it is turned on or off, may be damaged.

Cardiac Pacemakers. Spinal cord stimulators may interfere with the operation of implanted sensing stimulators, such as pacemakers and implantable cardiac defibrillators (ICDs). Be sure your physicians are aware of your spinal cord stimulator before going forward with other implantable device therapies so that medical decisions can be made and appropriate safety measures taken.

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.

Posture. Changes in posture or abrupt movements may cause decreases, or uncomfortable or painful increases in the perceived stimulation level. Keep the Remote Control with you at

all times, and turn the stimulation down or off before making posture changes. If unpleasant sensations occur, the stimulation should be turned off immediately.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the stimulator off, or cause uncomfortable or jolting stimulation. 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 you request assistance to bypass the device. If you must proceed through the device, turn off the stimulator and proceed with caution, and move through the center of the screener as quickly as possible.
- Power lines or power generators
- Electric steel furnaces and arc welder
- Large magnetized stereo speakers

As you approach these devices you may become aware of changing stimulation levels. In rare instances, you could experience an increase in stimulation level to the point that the sensation is uncomfortably strong or possibly “jolting.” If this happens, turn off the IPG. If the IPG suddenly turns off by itself, first move away from the area. Next, check the implant status with the Remote Control by pressing the Stimulation On/Off button and observing the

screen. The IPG may need to be recharged before stimulation can be re-started. (See "Charging the Implant" on page 51 for additional information.)

Always be aware of your surroundings, particularly near theft detectors/security screeners. Ask for assistance to go around these devices if you feel at all uncomfortable.

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 — high-output sound or shock waves often used to treat gall stones and kidney stones
- electrocautery — the use of a heated electric probe to stop bleeding during surgery
- external defibrillation — the use of electrically charged paddles to restart the heart in an emergency
- radiation therapy — ionizing energy commonly used to treat cancer

- ultrasonic scanning — very high frequency sound waves used to produce images of internal organs or tissue for diagnostic purposes
- high-output ultrasound — high frequency sound waves which may be applied as physical therapy to treat certain bone/muscle injuries, or for muscle stimulation, or to improve blood flow

Before having procedures, medical therapies, or diagnostics, have your healthcare professional call our Customer Service department at (866) 360-4747 for proper instructions.

Automobiles and Other Equipment. Do not operate an automobile, other motorized vehicle, or any potentially dangerous machinery/equipment with therapeutic stimulation switched on. Turn off stimulation first. Sudden stimulation changes, if they occur, may distract you from attentive operation of the vehicle or equipment.

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 stimulation 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. Avoid all sources of water that can come into contact with the devices. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components. (See “Limited Warranty” on page 65.)

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.

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.

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:

- The lead(s) which deliver stimulation may move from their original implanted location, resulting in undesireable 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 battery leakage, device failure, lead breakage, hardware malfunctions, loose connections,

electrical shorts or open circuits and lead insulation breaches, can result in ineffective pain control.

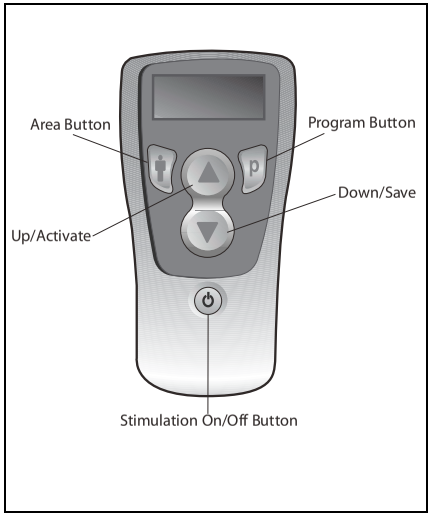
- Your body may react negatively to the materials used to manufacture the stimulator or the leads. You may notice redness, warmth or swelling of the implant area.
- The skin over your implant may become thin and increasingly tender over time. A seroma may be formed.
- The most common surgical procedural risks are temporary pain at the implant site and infection. However, since the leads are placed in the fluid surrounding your spinal cord, there is a small risk that spinal fluid may leak from the lead insertion site following surgery. Very rarely, you may develop an internal blood clot (hematoma) or blister (seroma); or you may experience brain hemorrhage or paralysis. Your spinal cord may become compressed.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.
- MRI. Exposure to magnetic resonance imaging (MRI) can result in noticeable heat near the implant or the leads; may distort or destroy the image needed for diagnosis; and may produce enough electromagnetic interference (EMI) to erase

the implant programming, destroy the leads, or cause the leads to move from their intended location.

- 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.
- You may experience painful electrical stimulation of your chest wall as a result of stimulation of certain nerve roots several weeks after surgery.
- Over time, your implant may move from its original position.
- You may experience weakness, clumsiness, numbness or pain below the level of implantation.
- You may experience persistent pain at the IPG or lead site.

4 The Remote Control

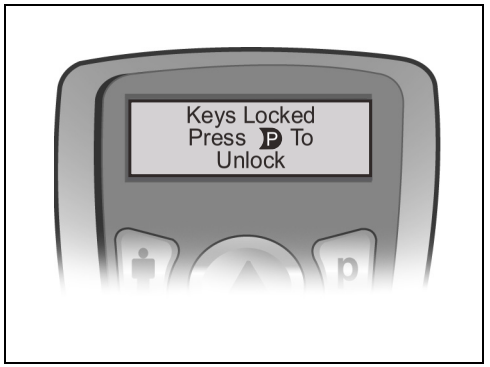
Each button on the Remote Control activates one or more of the stimulation functions which are described in detail on the following pages of this section.



Buttons and Basic Operation

To use most Remote Control functions, you will simply press a button as you would on a TV remote control. Other functions require a “long press,” which is described in “Selecting Options” on page 41.

When it is not being used, the Remote Control sets itself in a “sleep” or idle mode and the display screen is blank. When you press any button except ⏻ (stimulation on/off) during this sleep mode, the Remote Control will “wake up” and display the screen shown on the right. After you unlock the buttons by pressing **p** , the remote will immediately look for your implant and then connect with it, allowing you to make adjustments to your stimulation. When you are finished using it (no buttons are being pressed), the remote will return to the sleep mode within a minute or so.



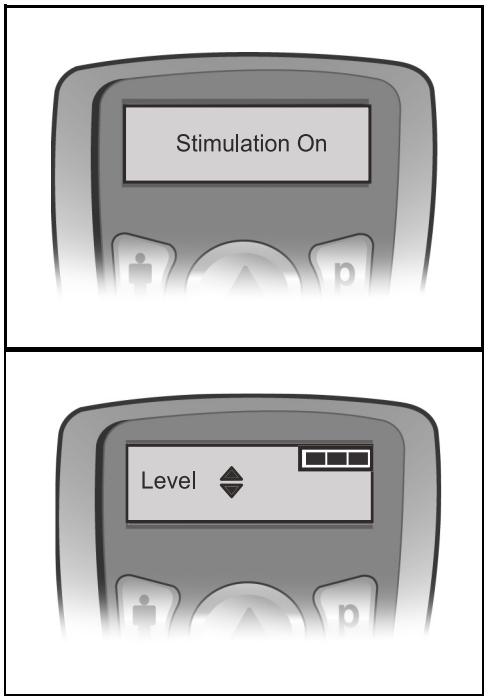
Good communication between your implant and the Remote Control is very important. For that reason, you will sometimes see the message “Connecting...” while you are using the Remote Control because it is always checking for the implant.

Note: *If there is a problem communicating with the implant, the message “No Response” will appear on the Remote Control screen. See “Help” on page 59 for more information.*

The Remote Control unit is your direct link to choices available for tailoring spinal cord stimulation to suit your comfort and convenience requirements. *Keep the Remote Control with you at all times.*

Stimulation On and Off

The Remote Control uses a “dedicated” stimulation on/off switch.You may press ⏻ *at any time—even during the remote’s sleep or idle mode*—to turn stimulation on or off. The remote will briefly display a message notifying you of the on or off status.

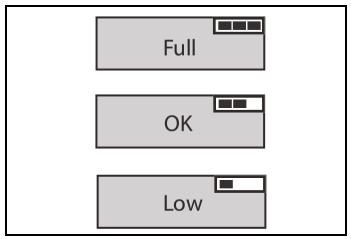


The Level Screen

Whenever stimulation is turned on, or after the Remote Control is awakened from sleep/idle mode, the remote display defaults to the Level screen. When you press the ▲ or ▼ button from this display, you’re able to increase or decrease the stimulation strength, or level, of *all* of your pain areas at once (if your implant was programmed to treat more than one

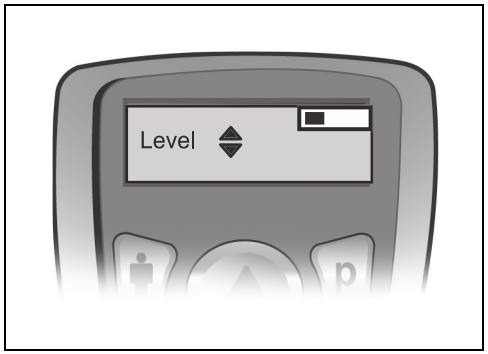
area). To learn about adjusting the stimulation of individual areas, please see “Selecting Areas for Level Control” on page 34.

The Level screen also displays a bar graphic in the upper right corner to indicate the battery charge level of your implant. The graphic is very easy to understand: Three filled-in bars means that your IPG has a fully-charged battery. As the battery strength wears down, depending on your stimulation settings and usage, the bars will “empty” accordingly. For complete information on maintaining your implant’s battery for uninterrupted delivery of the therapy prescribed for you, see “Charging the Implant” on page 51.



Note: • *Remember, the Level screen will remain on the display for approximately one minute if you don't press a button to perform an action with the Remote Control. After a minute, the remote will go into idle mode and the display will go blank.*

• *Multiple area control is available only if your system has been programmed to deliver stimulation to separate areas. If you do not have separate area control (for example, left leg vs. right leg) but feel that separate control might improve your therapy, contact your health professional to determine what is possible.*



Stimulation Level Control

Occasionally, you may see one of the accompanying messages on the Remote Control screen while changing the stimulation level. These displays, and a "beep" from the Remote Control, alert you that you have reached either a maximum or a minimum level:

The bar replacing the up arrow means that you have reached the maximum allowable level and can only *decrease* the stimulation setting. The bar replacing the down arrow means that you have reached the minimum level and can only *increase* the stimulation setting.

Selecting Areas for Level Control

Your Remote Control may have as many as four therapy areas stored for your use. Each area will have a name or a number (1 through 4) which was assigned during your programming at the clinic.The stimulation level for each of these areas is controlled from an individual “area level” screen. To change the stimulation strength of a single area:

1. From the main Level screen, press the button as many times as necessary to cycle through your programmed area Level screens.

Note: *Button presses will move from one area to the next and will eventually return you to the Level screen.*

2. When the named or numbered area that you want to adjust is shown on the screen, press ▲ or ▼ to change the stimulation level for that area.

When you’ve finished making your change, the Remote Control will return to the Level screen.

Programs

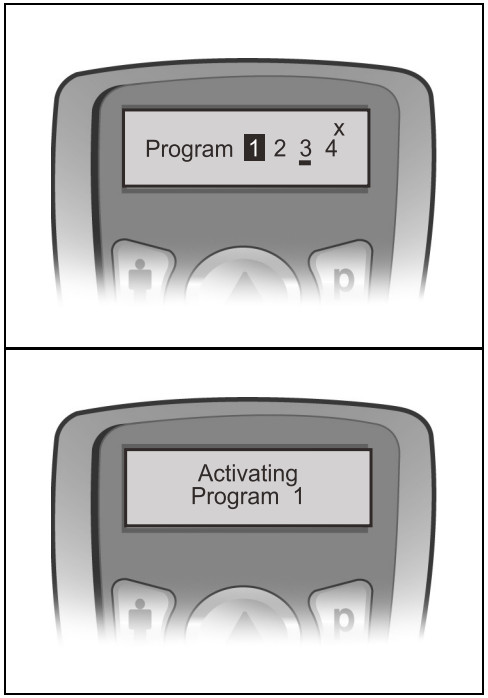
A stimulation program may provide paresthesia to cover a single pain area, or up to four areas, depending on how the program was set up by your clinician. Your Remote Control can store up to four programs—numbered 1 through 4—for you to select and activate at any time. Often, the programs will have certain differences in the settings to allow you to vary your stimulation in several ways. You may have been encouraged to try using specific programs for different circumstances, or different body positions, or different times in your daily routine. Programs and their flexibility give you and your healthcare professional a way to continually “fine tune” your therapy.

Selecting and Activating Programs

1. Press the **p** button from the Level screen to go to the Program screen.

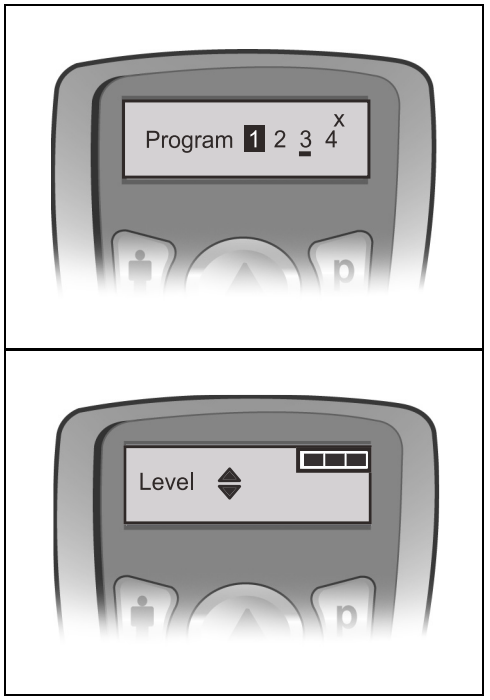
   From the Program screen, each additional **p** button press cycles you through the program numbers. The black highlight box shows where you are in the cycle. Pressing **p** from program 4 returns you to the Level screen.

2. Press **p** until the program you want is highlighted, then press ▲ to activate the program.



Note: • *You might not have four programs saved in your Remote Control. Empty program slots will have an **X** beside the program number. If you try to activate an empty program, nothing will happen.*

• *An underline beneath a program number means that program was the most recently activated, saved (see below), or restored (see page 44) program.*

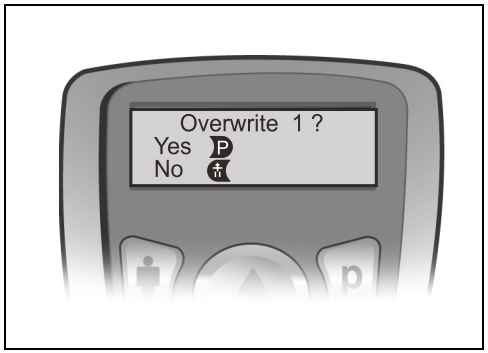


Once you have selected and activated a program, the Remote Control will return to the Level screen. Use the ▲ or ▼ to adjust the stimulation level of the program, if you wish.

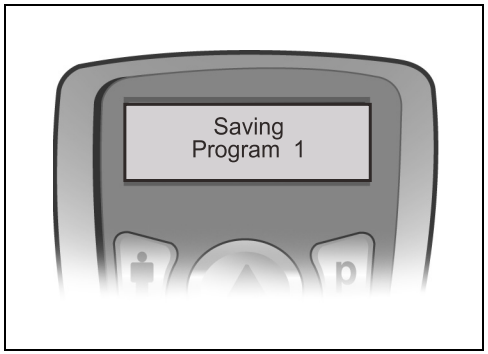
Saving Program Changes

If you do make a stimulation level adjustment and decide that you prefer it to the original setting, you can save the new level (or any other change) and make it a permanent part of the program:

1. After making a change to a program, press **p** from any screen to return to the Program screen.
2. From the Program screen, press **p** as many times as necessary to select the active program; that is, the program that is currently running and the one you've just changed.
3. With the active program selected, press ▼ to save the change in the remote's memory.



The Remote Control will first ask you to confirm that you want to "overwrite" the program; press the appropriate button.



If you confirm the change (Yes, or **p**), the program will be updated and saved. If you decide not to make a permanent change, pressing 🚹 will return you to the Program screen.

You may also save a program change as a completely new program if an empty program slot (X) is available: Simply select the empty slot using **p** and press ▼. After saving the new program, the Remote Control will return to the Level screen.

Options

Under some circumstances, and depending on your treatment prescription, your healthcare provider may have given you therapy control beyond selectable programs by making special *options* available to you. Program options make it possible for you to change certain preset stimulation settings, and/or return changed programs to their original clinic settings. The ability to go back to original settings allows you to change your mind... then change your mind again... about how satisfied you are with your stimulation paresthesia.

If you've been told about program options and instructed in how to use them, you may realize that you probably won't "exercise" your option settings very often. However, if your Remote Control has been set up to access options, please follow the steps detailed in "Selecting Options" on page 41 to make adjustments.

There are three *possible* options. One of these, Restore, is not a stimulation setting but is similar to an *"undo"* feature. It returns a changed program back to its original settings. The other two options are stimulation settings that can affect the overall feeling of the stimulation you receive:

- *Rate*, or how many times-per-second your implant sends a stimulation pulse, and
- *Pulse Width*, or how long each stimulation pulse lasts.

Note: *Restore is available to all patients. However, Rate and/or Pulse Width may not be available to you. Their availability would have been discussed with you at your first programming session.*

Selecting Options

To access the options that may be available through your Remote Control, you will need to use a "long" button press. This simply means that you will *press and hold* a button until a

particular option screen is displayed. The action you take next depends on which option you want to adjust. Follow the appropriate instructions below:

To Adjust Stimulation Rate:

1. From the Level screen, press and hold 🧍 until you see the Rate Area 1 screen. If this is the area you want to adjust, press either ▲ or ▼ to increase or decrease the Rate.
2. **To move to another area**, press 🧍 briefly (a "normal" press) to cycle through your programmed areas until you find the Rate Area screen (2, 3 or 4) that you want.
3. Press either ▲ or ▼ to increase or decrease the Rate.

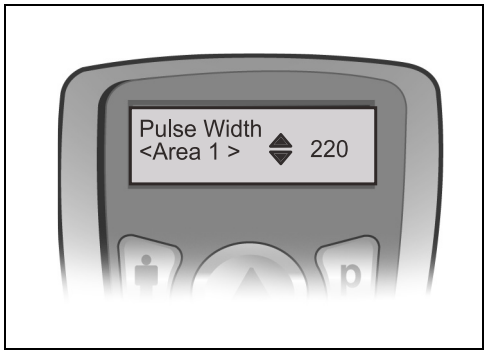
Note: *The Remote Control will beep to notify you if you reach a preset limit while increasing or decreasing the Rate.*

To return to the Level screen from any Rate screen, press and hold 🧍 until Pulse Width Area 1 is displayed, then press and hold 🧍 again to see the Level screen. If you don't have access to the Pulse Width option, the Level screen will appear right away.

To Adjust Stimulation Pulse Width

1. From the Level screen make a long 🧍 button press to Rate Area 1.

Note: *If you don't have access to the Rate option, the long press will take you directly to the Pulse Width Area 1 screen.*



2. If the Rate Area 1 screen is displayed, make another long 🧍 button press to Pulse Width Area 1. If this is the area you want to adjust, press either ▲ or ▼ to increase or decrease the Pulse Width.

3. **To move to another area**, press 🧍 briefly (a "normal" press) to cycle through your programmed areas until you find the Pulse Width Area screen (2, 3 or 4) that you want.

4. Press either ▲ or ▼ to increase or decrease the Pulse Width.

Note: • *You may also find Pulse Width Area 1 by making a long button press from any Rate screen.*

• *The Remote Control will beep to notify you if you reach a preset limit while increasing or decreasing the Pulse Width.*

To return to the Level screen from any Pulse Width screen, press and hold .

To Restore a Clinic Program

Over time, you may have made changes to one or more of the programs originally saved to your Remote Control. The Restore option allows you to return to those original stimulation settings if ever you become dissatisfied with a changed program.

1. From the Level screen, press and hold **p** to reach the Restore screen. Program 1 will be highlighted.

Note: *The highlighted program is the current selection; an underline indicates the last program saved, activated, or restored; an X indicates an empty program slot.*

2. If necessary, press **p** to cycle through the program numbers to select the program you want to restore. When the desired program is highlighted, press ▲. The Remote Control will briefly flash a message confirming the restoration.

Understanding Battery Status Messages

About the Remote Control Batteries

As an SCS patient, it's essential that you appreciate the importance of battery power! The replaceable batteries in your Remote Control and the rechargeable battery in your stimulator work together to provide you with consistent, dependable parasthesia. Always pay close attention to the battery status messages described in this section.

When the Remote Control batteries are at a low power level, the battery message shown here will be displayed. When you press the **p** button from this screen, the remote will make a check of your implant's battery status also.

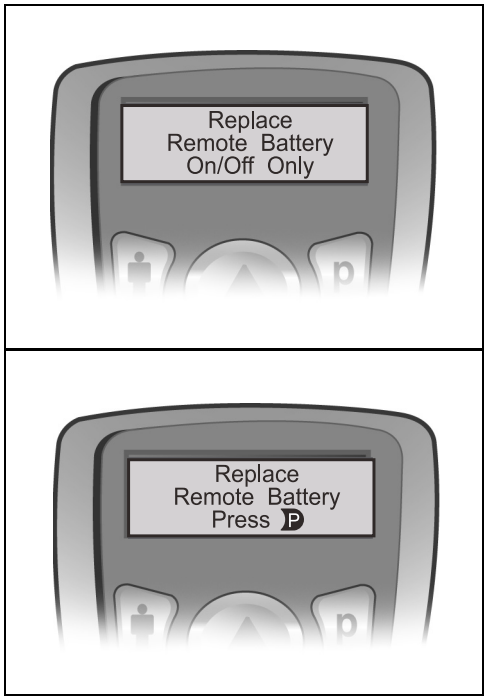
If the implant battery is full or OK, the Remote Control will return to the Level screen. To learn about the messages you will see when the implant's battery is less than full, see page 48.

If you don’t respond to the Remote Battery Low message in a timely manner, the batteries will eventually drain to the point of not having enough power to manage your stimulator.

First, you'd see a message meaning that (because of its low-power condition) the Remote Control can't send stimulation changes to your implant. You will only able to turn stimulation on or off.

Next, you’d see the more urgent message shown opposite. You must respond immediately! When you press **p** , the remote will make another check of your implant battery and may display one of the messages shown on the following page.

Note: *Make a habit of replacing the Remote Control batteries when you first see the Remote Battery Low message. See “Battery Replacement” on page 50.*

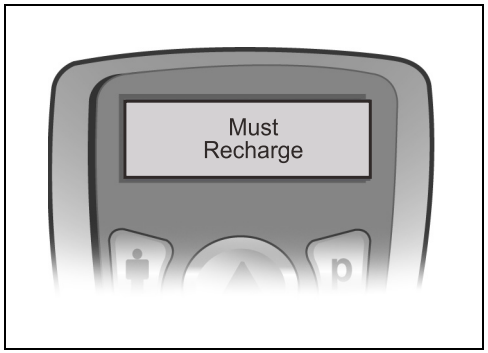


About Your Implant Battery

When the Remote Control checks the condition of your implant battery, you may see one or more of the following messages depending on the battery's charge level:

- If the implant battery is low, the Remote Control will display the message shown at right. Press **p** to return to the Level screen.
- If the implant battery is *very* low, the remote will display this notice to recharge the stimulator battery immediately. Stimulation has most likely been turned off automatically. Pressing **p** from this screen will prompt the message explained on the following page.

The *Must Recharge* message means that your implant has turned itself off and gone into a "hibernation" mode. You may expect a three--four hour charge period before you can resume your therapy.



Battery Replacement

1. On the rear of the remote, push in slightly and slide down the battery compartment cover.
2. Remove the old batteries.
3. Place the three new AAA batteries in the slots, matching the positive (+) and negative (-) markings.
4. Align the battery compartment cover on the case and slide the cover into position until it snaps closed.

The Remote Control will connect to the implant in approximately 30 seconds.

5 Charging the Implant

Your Precision implant uses a rechargeable battery to provide stimulation. The Precision System's programming software gives your healthcare provider recommendations for recharging your implant, and you should be given guidelines on when to charge.

The Remote Control provides an easy-view implant battery charge status graphic on the Level screen as well as messages to inform you of the battery's condition. These messages are explained beginning on page 48.

Based on your stimulation settings, you may charge:

- once a day
- every other day
- once or twice a week.

Following the general recommendations made by your healthcare provider, you have the freedom to establish the charging routine that suits you best. Keep in mind that if you do not charge your implant before it reaches the very low/"hibernation" condition, stimulation will eventually stop until you charge again. But charging the Precision is a such simple process, requiring so little effort, that you should never have to experience an interruption of your pain therapy.

Note: *If the implant is not recharged as recommended, stimulation will 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 for a new charger.*

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.

Getting Started

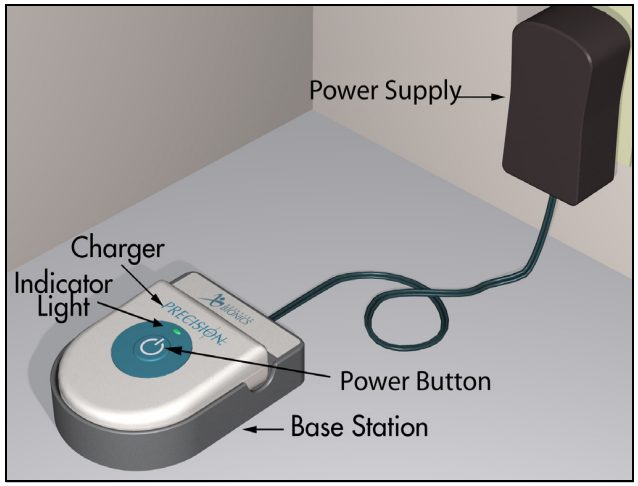
The Charging System for your implant consists of the Charger unit, a Base Station, and a Power Supply. Power plug adaptors are also included for Charging System use in countries other than U.S. The Base Station is designed to remain connected to a power outlet at all times. When it is not being used, keep the Charger on the Base Station so that it is always ready to deliver a charge.

1. Find a convenient place with a flat, clear surface to keep the Base Station plugged in.
2. Plug the Power Supply into a standard AC wall outlet, then plug the other end into the Base Station connector.
3. Place the Charger in the Base Station.

When charging, you can opt to use either a Velcro® belt or adhesive patches to hold the Charger over the implant. Before using the Velcro® belt, you may cut it to a more convenient size, but be careful not to cut too much. The patch adhesives are made of non-reactive material suitable for most sensitive skin types.

Note: *Advanced Bionics recommends the use of the Velcro® belt for charging.*

The Charger is completely ready and able to fully charge your implant when the indicator light is green. If the light is amber-colored, the Charger can only partially charge the implant. It may be used, but it may not be able to return your implant to a full charge (and you may need to charge sooner than you normally would).



Indicator Light Status:

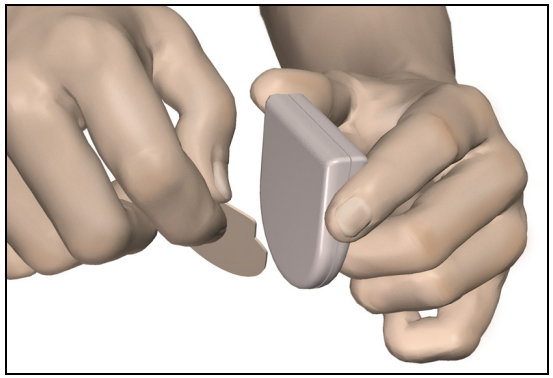
- Green – ready for full charge
- Amber – partial charge
- Off – not ready for charging

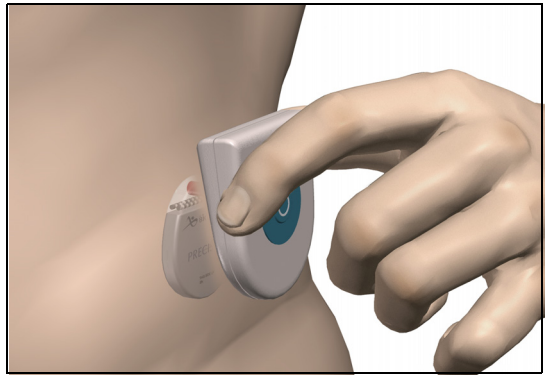
Charging Your Implant

1. When the indicator light is green, remove the Charger from the Base Station. (*The indicator will go off, regardless of the ready status of the Charger.*)

2. Using the Adhesive Patch: Apply the adhesive patch to the backside of the Charger by peeling the clear liner from the patch. Remove the skin side beige liner.

   Using the Velcro® Belt: Place the Charger in the pocket with the power button facing out.





3. Press the power button. The indicator light will come on again, and the Charger will begin beeping steadily to signal that it is searching for the implant.

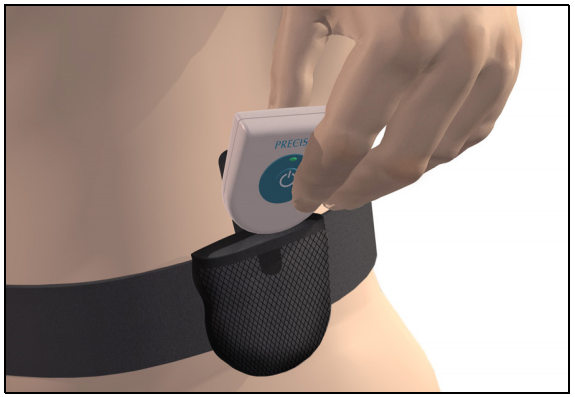
4. Locate the Charger over the implant. When the Charger is aligned with the implant, the beeping will stop.

   Secure the Charger over the implant either by pressing the adhesive side of the patch to the location, or by attaching the Velcro® belt.

Note: *If you accidentally locate the patch in the wrong place, or if the Velcro® belt moves out of alignment, the Charger will start beeping again. Use a new adhesive patch or readjust the belt to place the Charger back into position.*

5. When the Charger emits a distinct double beep, the implant is charged. Switch off the Charger, remove the adhesive patch or Velcro® belt, and return the Charger to the Base Station.

   Do not confuse the end of charge signal (a distinct double beep) with the steady, continuous misalignment signal.



Note: • *Depending on your program parameters, you may expect daily recharging times as low as 10 minutes up to four hours, or weekly recharging times from as low as one hour up to four hours.*

• *The end of a charge signal is a distinct double beep, and the alignment indicator is a steady continuous signal.*

The rechargable implant battery should provide you with at least five years of service. Over time and with repeated charging, the battery in your implant will lose the ability to recover its full capacity. As a result, you may need to recharge your implant for longer periods and/or more often after five years of service. Your implant will need replacement when stimulation can no longer be maintained with routine charging.

6 Help

Stimulation

No Stimulation

1. Toggle the Remote Control stimulation on/off button to make sure that stimulation is ON. If the Remote Control receives confirmation from the implant, it will flash “Stimulation On.”
2. Turn up the level of stimulation from the main screen or area screens.
3. Charge the implant. When the charge is complete, try turning the stimulation on.

4. Call our Customer Service Department at (866) 360-4747 if the above steps do not solve the problem.

Stimulation Increases or Decreases on Its Own

1. Stimulation can change depending on body position (lying down, standing or bending).
2. Always keep the Remote Control with you, so that you can adjust your stimulation levels as needed.

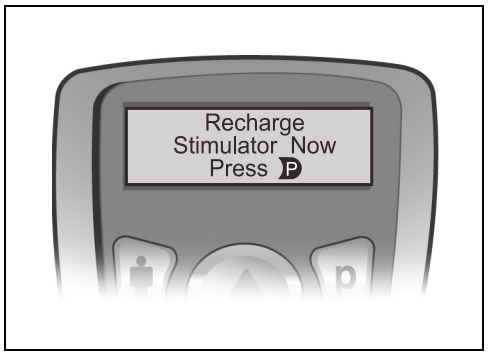
Stimulation Shuts Off

1. When the implant battery needs to be recharged, it will stop stimulating. Check the battery status with the Remote Control and recharge if necessary, then turn stimulation back on. If the implant regularly stops stimulating before you charge, you can charge more often.
2. Although unlikely, anti-theft screeners can turn stimulation off. If you cannot turn the stimulator back on with your Remote Control, you may need to charge the implant.
3. Large magnetized speakers or large power lines that emit interference may also turn off stimulation. If you cannot turn the stimulator back on with your Remote Control, you may need to charge the implant.

Remote Control Display Messages

"Recharge Stimulator Now" and "Must Recharge" on the Display

Stimulation has stopped if you see this message. You will probably need to recharge your implant for as long as 3–4 hours before stimulation resumes.



Remote Battery Low" on the Display

The batteries in your Remote Control need to be replaced with three fresh AAA batteries (refer to "Battery Replacement" on page 50).

"No Response" on the Display

When the Remote Control displays "No Response," there is a communication problem between the remote and the implant probably caused by a weak implant battery. Press the **p** button. If the Remote Control is still not able to communicate with your implant, the "No Response" message will appear again; press **p** again. If the remote connects with your implant, you will be returned to the display you

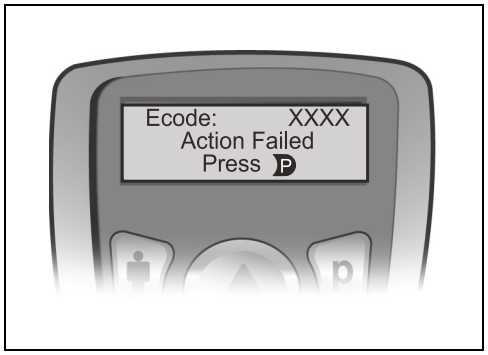
were using before the problem began. If the problem cannot be corrected, the Remote Control will go into sleep mode. Recharge the IPG and check to see if the problem is solved.

Occasionally, telemetry problems happen because the Remote Control cannot find the implant because of orientation or interference. Move the remote closer and then press the **p** button.

Call our Customer Service Department at (866) 360-4747 if the problem continues.

"Action Failed" on the Display

If the Remote Control displays the error screen shown at right, try to make a note of the numbers (the error code) on the top line. Then press **p** , wait a few seconds, and try the action again.



Please call our Customer Service Department at your earliest convenience to report the error code.

Note: *The remote will go to idle mode when* **p** *is pressed, or within fifteen seconds if* **p** *is not pressed.*

Accessories

Washing the Velcro® Belt

Wash the belt with mild soap and warm water.

Contacting Advanced Bionics

If you have any other questions, or need to contact Advanced Bionics for any reason, you may do so in any of the following ways:

- Customer Service Phone: (866) 360-4747
- Customer Service Fax: (661) 362-1503
- Address: Advanced Bionics® Corporation
  Pain Management Division
  Mann Biomedical Park
  25129 Rye Canyon Loop
  Valencia CA 91355

7 Limited Warranty

Implanted Pulse Generator

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 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.

   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.

Externals

Advanced Bionics® warrants to the patient that the Remote Control device, Model SC-5210, and Charger System (Charger, Model SC-5300, and/or Charger Base Station, Model SC-5305) are free from defects in workmanship and materials for a period of one (1) year from the date of purchase of a new Precision™ Patient Kit.

A Remote Control device or Charger or Charger Base Station component that fails to function within normal tolerances within one (1) year from the date of surgery or purchase is covered under this Limited Warranty. The liability of Advanced Bionics® under this warranty shall be limited to: (**a**) replacement with a functionally equivalent component; or

(**b**) full credit equal to the original purchase price to be applied towards the purchase of a replacement device. 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 or receipt of product in order to obtain warranty rights.
2. The component must be returned to Advanced Bionics® (or authorized agent) within 30 days of malfunction or discovery of defect.
3. The component failure 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 system and its components 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.

4. The decision as to product replacement or credit shall be made solely at the discretion of Advanced Bionics®. For a replacement component, the warranty will run only to the end of the warranty period for the original component 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.

Glossary

 Area Button icon. This figure respresents the area button on the Remote Control.

ADHESIVE PATCH. Non-reactive skin patch designed to temporarily attach the Charger to the skin over the IPG site.

ADVERSE EFFECT. Undesirable result.

AMPLITUDE. The measure-of-strength of delivered stimulation. (See Level.).

AREA. A location on the body such as right leg or left leg where stimulation will occur.

CARDIAC PACEMAKER. A small implantable device used to control the rhythm of the heart.

CHARGER. A portable device used to recharge the battery of the implanted stimulator.

CHARGER BASE STATION. A holder/ power supply that supports the Charger and keeps it in a ready state for recharging the implant.

CHARGING SYSTEM. The Charging System consists of a Charger Base Station, Charger, Power Supply, Velcro charging belt and adhesive patches. The system is used for recharging the implanted stimulator.

CONTROL BUTTONS. Buttons located on the Remote Control; used for adjusting stimulation settings.

DIATHERMY. A therapeutic procedure used to heat body tissue by high-frequency electromagnetic currents.

DISPLAY. The Remote Control screen.

ELECTRICAL PULSE GENERATOR. Also called an implantable pulse generator (IPG); used to send electrical pulses to the spinal cord or other parts of the body.

ELECTRICAL STIMULATION. The energy created by a pulse generator.

ELECTROMAGNETIC INTERFERENCE (EMI). Electromagnetic signals that interfere with a variety of electrical signals including spinal cord stimulation.

IDLE MODE. A time-out period when the Remote Control is not being used. Also known as sleep mode.

IMPLANT. Small implantable electrical pulse generator used to control stimulation.

INCISION. Small surgical cut or opening in the skin.

INDICATOR. A signal light used on the Trial Stimulator and the IPG Charger.

IPG. Implantable Pulse Generator.

LEAD MIGRATION. The movement of a lead away from the spinal cord.

LEAD. A surgical wire that sends electrical stimulation pulses from a pulse generator to the spinal cord.

LEVEL. Term used on the Remote Control screen to identify the amplitude or strength of stimulation pulses.

LONG BUTTON PRESS. To press and hold a button for about 3 seconds.

MRI. Magnetic Resonance Imaging; the use of a nuclear magnetic resonance spectrometer

to produce electronic images of tissues and organs.

OPTIONS. Methods for adjusting stimulation beyond amplitude, or level, using the Remote Control. Your healthcare provider may or may not provide you with all available options.

p Program Button icon. This symbol represents the Program button on the remote control.

PARESTHESIA. Sensation produced by electrical stimulation.

PATIENT IDENTIFICATION CARD. A wallet size card that lists the patient and physician names, and IPG model and serial number.

PERMANENT IMPLANT. A stimulator system, pulse generator and leads, implanted in the body and maintained by a pulse generator battery Charging System.

PRECAUTION. Generally, situations that you should be aware of in order to avoid potentially uncomfortable stimulation sensations and/or damage to your stimulation system.

PROGRAM. Combination of one or more stimulation areas.

PULSE WIDTH. The length of time each stimulation "spark" lasts. An option setting available from the Remote Control.

RATE. The number of times–per-second (speed) at which stimulation pulses are delivered to the spinal cord. An option setting available from the Remote Control.

REMOTE CONTROL. A battery powered hand-held computer used to adjust stimulation.

SAVE. The Remote Control button command used to store a newly created or modified stimulation program.

SLEEP MODE. A time-out period when the Remote Control is not being used. Also known as idle mode.

SPINAL CORD STIMULATION (SCS). A method of applying electrical pulses to the spinal cord to block/mask pain signals to the brain.

STIMULATION. When used as a therapy for pain, an artificially applied, low-level, pulsating electrical "shock" felt as a tingling or pulsating sensation in the area of pain and perceived enough to reduce the awareness of pain.

STIMULATION COVERAGE. Area on the body where stimulation occurs. (See Area.)

SUBCLAVICULAR. Under the collarbone.

SYSTEM FAILURE. Inability of spinal cord stimulator system to deliver stimulation therapy.

WARNING. Potential hazards that you must be aware of to avoid serious situations that may cause injury or death.

WIDTH. See Pulse Width.

Index

S

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.