ADVANCED BIONICS

PATIENT SYSTEM HANDBOOK

PRECISION

Spinal Cord Stimulation System

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Patient System Handbook

9055072-001 Rev D

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Guarantees

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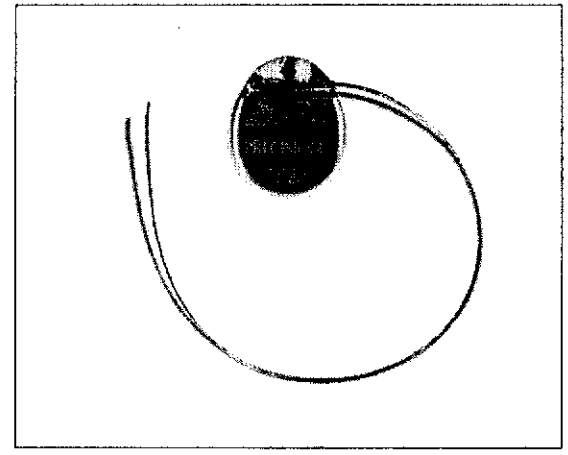
1 Introduction

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

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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. Going forward with this therapy, your health professionals will work with you to find the most comfortable level of paresthesia to cover the painful areas through adjusting the 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: 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 implanted pulse generator (IPG), 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.

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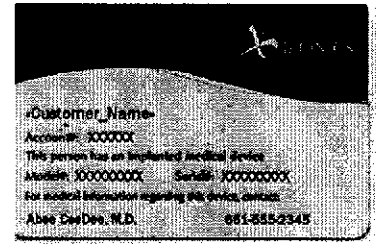
For your Precision system, it's important to learn 1) what to be aware of for safety, 2) how to use the Remote Control, and 3) how to re-charge the implant. These subjects are covered on the following pages, and we encourage you to read this manual entirely. If you have any questions, or need clarification of anything contained here, feel free to contact our Customer Service department at (866) 360-4747.

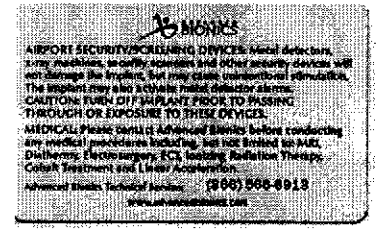
Before you continue, however, first check to be sure that all of the following items were included in your Patient Kit. (And check to be sure you have your Temporary Patient Identification Card; be sure to keep it with you until you receive your permanent card.) If any item is missing, please call our Customer Service department at (866) 360-4747.

(1) Remote Control
(1) (IPG) Charger
(1) Charger Base Station
(1) Transformer
(1) Belt Clip Holster
(1) Velcro® Charging Belt
(1) Charger Adhesives (52 pieces)
(1) Remote Control Battery
(1) Carrying Case

Front



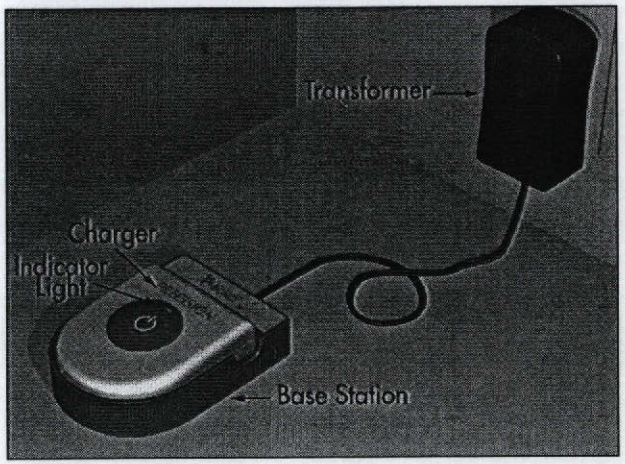
Back



Permanent Patient Identification Card

Find a convenient electrical outlet, one that won't expose the parts to water or direct heat, and plug in the transformer. Next, connect the transformer to the Charger Base Station and locate the Base Station on a flat surface. Finally, place the Charger in the Base Station with the blue power 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 53.



3 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.

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4 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

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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 ± 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.

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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

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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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Ohnmeiss, D., R. Rashbaum, M. Bogdanffy. Prospective Outcome Evaluation of Spinal Cord Stimulation in Patients With Intractable Leg Pain. Spine, 21:1344-1351, 1996.

Rainov, N.G., V. Heidecke, and W. Burkert. "Short Test-Period Spinal Cord Stimulation for Failed Back Surgery Syndrome." Minim Invasive Neurosurg, 39(2):41-44, 1996.

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Spieglemann, R. and W.A. Friedman. "Spinal Cord Stimulation: A Contemporary Series." Neurosurg 28:65-71, 1991.

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Villavicencio, A.T., J.C. Leveque, L. Rubin, K. Bulsara, and J.P. Gorecki. "Laminectomy versus percutaneous electrode placement for spinal cord stimulation." Neurosurgery, 46:399-406, 2000.

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5 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

6 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

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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:

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- 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 power button and observing the screen. The IPG may need to be recharged before stimulation can be re-started. (See "Charging the Implant" on page 53 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.

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7 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 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 67.)

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 Battery. Do not try to use a AA (1.5-volt) battery in the Remote Control unit. The control will only operate with the special 3.6-volt battery available from 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.

8 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:

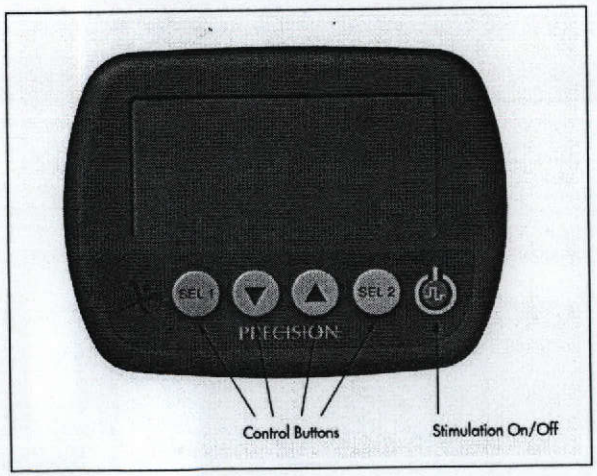
- The lead(s) which deliver stimulation may move from their original implanted location, resulting in undesirable changes in stimulation and subsequent reduction in pain relief.
- System failure, which can occur at any time due to random failure(s) of the components or the battery. These events, which may include 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 my 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.
- Weakness, clumsiness, numbness or pain below the level of implantation.
- Persistent pain at the IPG or lead site.

9 The Remote Control

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, in a pocket, purse, or in your immediate vicinity.*



The Remote Control is used to:

- Turn stimulation On and Off
- Change stimulation levels
- Activate or save new programs

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- Change stimulation options (If enabled by the clinician. See "Stimulation Level Control" on page 41.)
- Check your implant battery status. When the remote communicates with your implant, the implant battery status is sent to the remote. If the implant battery is in need of recharging, the remote will then indicate this to you.

Each button function label shown on the screen is related to the control button below it. As you move through the screen, the function labels for the buttons will change accordingly.

Basic Operation

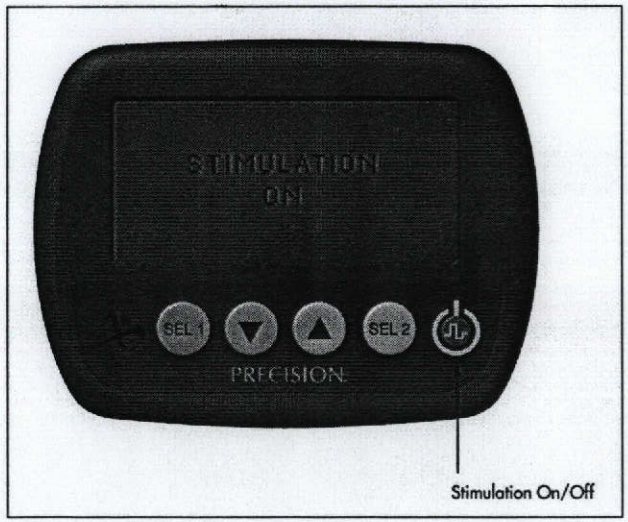
When it is not being used, the Remote Control is in a "sleep" mode. Press any button and the Remote Control will wake up and look for the implant. Once connected, you can make adjustments. When you are done, the Remote Control will go to sleep after 60 seconds.

Good communication between the implant and the Remote Control is very important. This is the reason you'll often see the message "Connecting..." while you are adjusting the stimulation. This is normal because the Remote Control continually checks for the implant.

Note: *If you have trouble communicating with the implant, the message "No Response" will appear on the Remote Control screen. See "Help" on page 61 for more information.*

Stimulation On and Off

The Remote Control uses a "dedicated" stimulation on/off switch. You may press the stimulation power button *at any time* to turn stimulation on or off. You don't have to be concerned about whether or not the Remote Control is awake.



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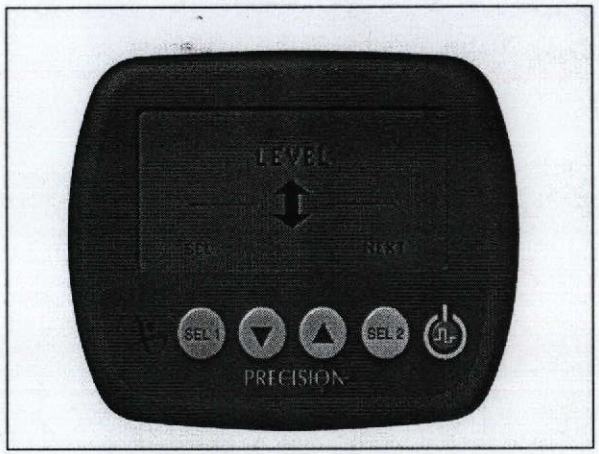
Stimulation Level Control

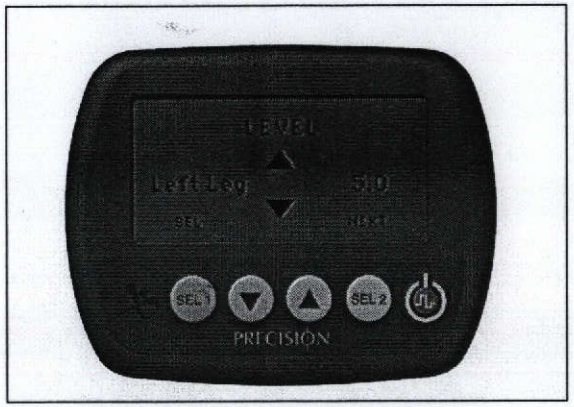
After stimulation is turned on, the Remote Control displays the main screen. From here, you may press the ▼ (down) or ▲ (up) button to adjust the stimulation level (or intensity) until you are comfortable. The main screen controls *all* stimulation, whether you have one area of pain control... or more than one.



Note: • *In some cases, health professionals can give you control over more than one stimulation area.*

- *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 stimulation therapy, contact your health professional to determine what is possible.*

Selecting Areas (for Stimulation Control)



1. From the main screen, press the **SEL 1** button as necessary to cycle through your programmed areas. Each area is given a number (1 through 4) or a name, for example Left Leg.

Note: *If you only have one area of control, that area will appear each time you press SEL 1.*

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

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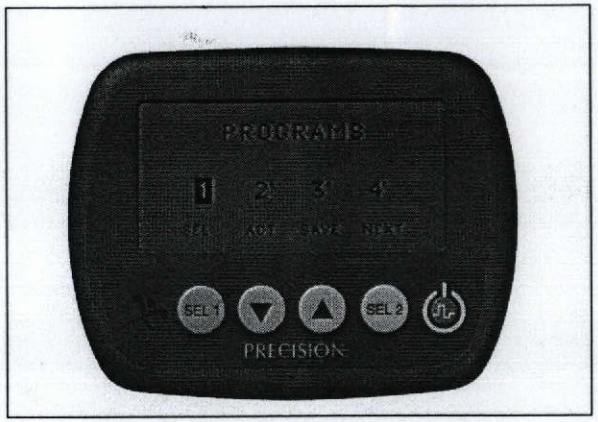
Selecting Programs (for Stimulation Control)

Your Remote Control can store up to four stimulation programs that might have been set up by your healthcare professional. Each saved *program* will have certain differences in the settings. These differences allow you to vary your stimulation in many ways. You may have been encouraged to try using specific programs for different circumstances, postural positions or times in your daily routine. Program flexibility gives you and your healthcare professional a way to continually "fine-tune" your therapy.

To select and activate programs:

1. Press the **SEL 2 [NEXT]** button from the main screen to go to the program screen.
2. Press the **SEL 1 [SEL]** button as many times as necessary to choose the program you want to activate.
3. Once the desired program is highlighted, press **▼ [ACT; activate]** and that program will start running after a couple of seconds.

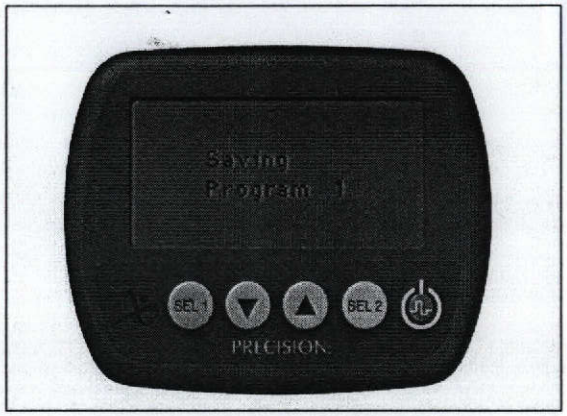


Note: *You might not have four (the maximum) programs saved in your Remote Control. Empty program slots will have an * (asterisk) symbol beside the program number. If you try to activate an empty program, nothing will happen.*

Once you have selected and activated a program, you can adjust the stimulation level using the ▼ (down) or ▲ (up) button.

If you make a stimulation level adjustment and decide that you prefer it, go back and select the program again then press ▲ **[SAVE]**. The program will be updated with the new level.

You may also save to an empty program slot (*) if one is available.



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Options

Under some circumstances, and depending on your treatment prescription, your healthcare provider may have given you a level of control beyond selectable programs by making special *options* available to you. This feature allows you to change certain preset stimulation settings, and/or restore the original clinic settings for programs that you might have changed. The latter is an advantage if you've made a program adjustment that you're not satisfied with.

If you've been told about program options and instructed in how to use them, you may realize that you probably won't use this special feature very often. However, if your Remote Control has been set up to access options, follow the steps below to make changes.

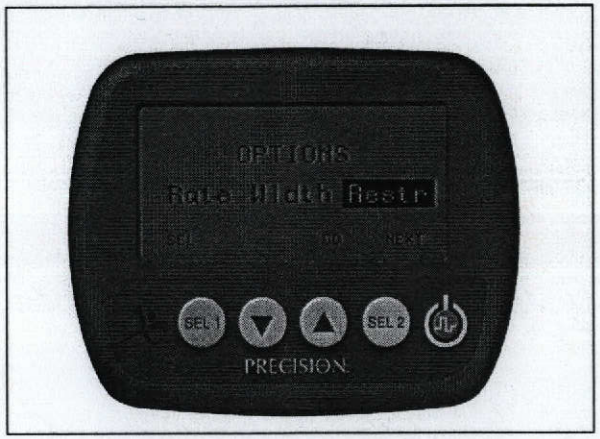
There are three *possible* options. One of these, RESTORE, is not a stimulation setting but is similar to an "undo" feature, returning a program to settings from the clinic. The other two options are stimulation settings that can affect the feeling of stimulation:

- *rate*, or how many times-per-second your implant sends a stimulation pulse, and
- *width* (for pulse width), or how long each stimulation pulse lasts.

Note: *Any one or both of these may be locked out of the options feature by your clinician. Your choices would have been discussed with you at your first programming session.*

To Use Options

1. From the program screen, press *and hold* **SEL 2** until you see the options screen.
2. From the options screen, press **SEL 1** to move through the choices shown on the screen.
3. When the option you want is highlighted, press ▲ **[GO]**.



Note: *If you change your mind about adjusting options, press* **SEL 2 [NEXT]** *to return to the main screen.*

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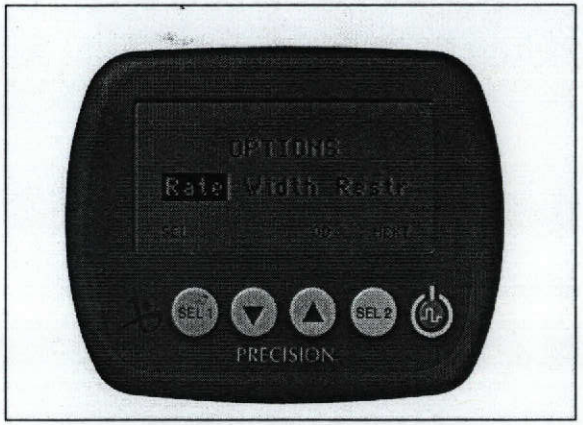
If you selected Rate or Width



1. If the pain area you want to "option" is not displayed on the screen, first press **SEL 1** to find the area.
2. When the desired area is displayed, press ▼ or ▲ to decrease or increase the Rate or Width (whichever you chose) to that area.
3. If you want to adjust the same option for another area, press **SEL 1** to find the area.

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

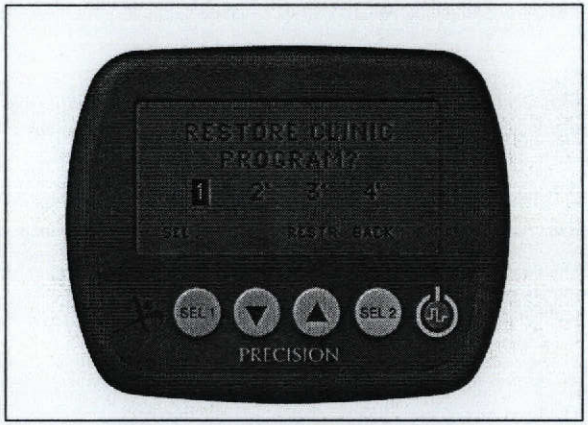
4. When you've made all of your changes for one option, press **SEL 2 [BACK]** to return to the options screen.

5. Press **SEL 1** to work with another option (as described above), or press **SEL 2 [NEXT]** to return to the main screen.

If you selected Restore

Press **SEL 1** as necessary to highlight the program you want to restore, then press ▲ **[GO]**.

The Remote Control will display a question for you to confirm; press ▲ **[RESTR]**. You'll then see a message that the selected program is being restored. When the operation is complete, the remote will return automatically to the main screen.



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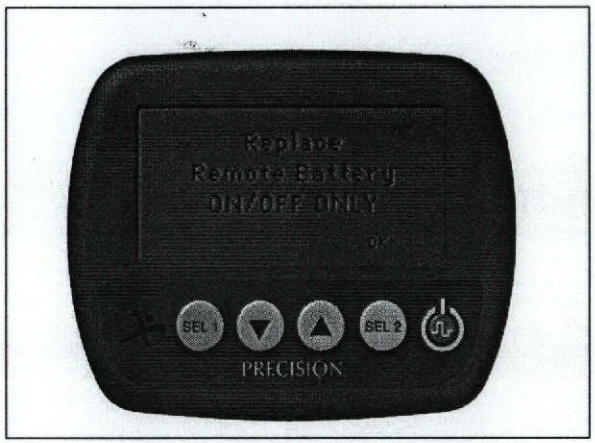
Remote Control Battery Replacement

If the Remote Control needs a new battery, a message will be displayed.

Following the low battery message you will only be able to turn the implant on and off. If you try to use any button except the power button, you will be reminded "Replace Remote Battery ON/OFF ONLY."



The battery for your Remote Control is a special 3.6-volt battery available only from Advanced Bionics. Do not attempt to use a 1.5-volt AA battery in the Remote Control.

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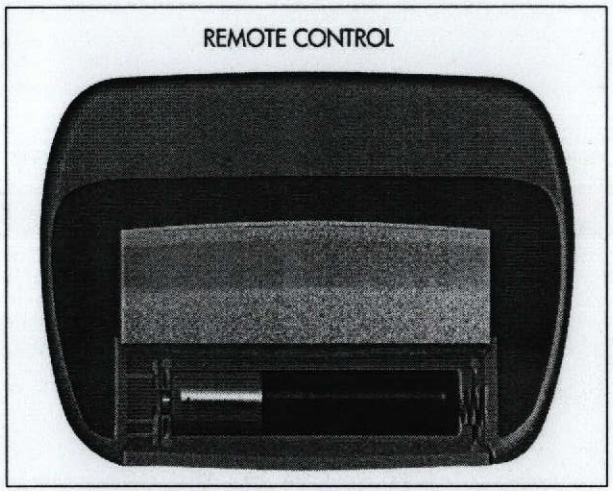
If you do not have an extra battery in your Patient Take Home Kit, call Advanced Bionics Customer Service Department at (866) 360-4747 to request a new battery.

To replace the Remote Control battery

1. On the rear of the remote, slide the battery compartment lock lever to the left to unlock the cover.
2. Press down on the ridged area below the lever using your thumb to release the cover.
3. Open the cover and remove the old battery.
4. Replace the new battery in the slot, matching the positive (+) and negative (-) markings.
5. Close the compartment by sliding the lock lever to the right.



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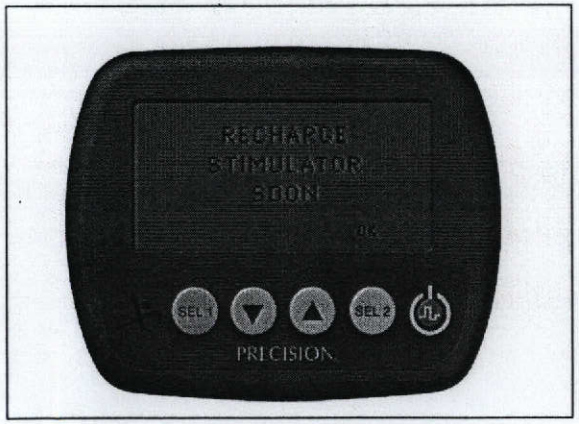
The Remote Control will connect and reload information from the implant in approximately 30 seconds.

10 Charging the Implant

To provide stimulation, your implant uses a rechargeable battery. You should be given guidelines on when to charge your implant. The Remote Control will also provide battery status when your implant is low. When the remote indicates a low battery (remote 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.



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Based on your stimulation settings, you may charge once a day, every other day, once a week, or twice a week. You should be aware that if you do not charge your implant, stimulation will eventually stop until you charge again. Remember to schedule this important time. Charging the implant is a simple process requiring little effort.

The clinician's programmer software gives your healthcare provider recommendations for recharging your implant.

Getting Started

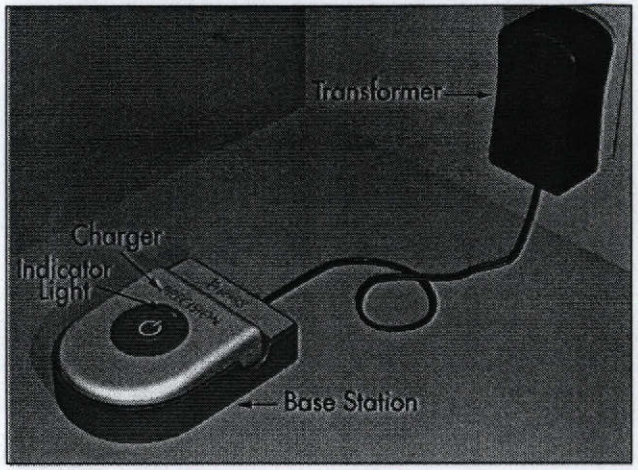
The Charging System for your implant consists of the Charger unit, a Base Station, and a transformer (plug). Adaptors are included for use in countries other than the U.S. The Base Station is designed to remain connected into a power outlet, and the Charger placed within to keep it ready for use.

1. Find a convenient place with a flat, clear surface to keep the Base Station plugged in.
2. Plug the transformer into a standard AC wall outlet, then plug the cord into the Base Station.
3. Place the Charger in the base.

When charging, you can opt to use either a Velcro® belt, or adhesive patches. To get started using a Velcro® belt, you can cut it to your size for comfort. We recommend using the adhesive patches since they maintain nearly perfect alignment between the implant and the Charger. The patch adhesive is made of non-reactive material suitable for most sensitive skin types.

The Charger is completely ready and able to fully charge your implant when the ready-indicator is green. If the light is yellow, 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 (so you may need to charge sooner than you normally would).

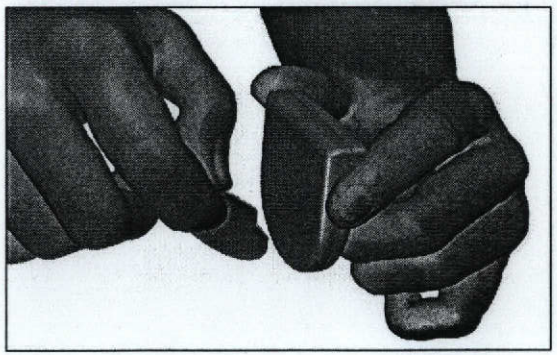
- Green – ready for full charge
- Yellow – partial charge
- Off – not ready for charging

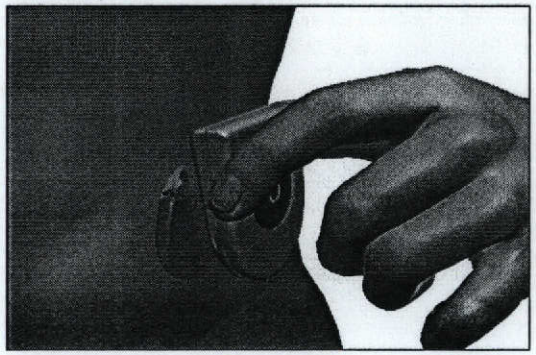


Charging Your Implant

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





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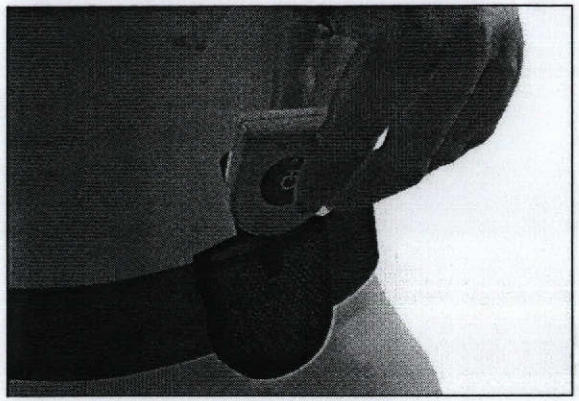
3. Press the power button. The indicator light will return to the status position, and the Charger will begin beeping steadily to signal that it is searching for the implant.
4. Locate the Charger over the implant. When aligned with the implant, the beeping will stop. Secure the Charger over the implant either by pressing the adhesive side to the location, or by attaching the Velcro® belt.

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

11 Help

Stimulation

No Stimulation

1. Toggle the Remote Control implant power 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.

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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

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

Stimulation has stopped if you see this message. You must recharge your implant within 3 days or run the risk of needing to return to the clinic for reprogramming.

"Remote Battery Low" on the Display

The battery in your Remote Control needs to be replaced using the Advanced Bionics 3.6 Volt battery (refer to "Remote Control Battery Replacement" on page 50).

"No Response" on the Display

When the Remote Control displays "No Response," the most likely cause is a low battery. Charge the implant and then try the Remote Control again. Also, it may be that the Remote Control cannot find the implant because of orientation or interference. Move the remote closer and try again. Call our Customer Service Department at (866) 360-4747 if the problem continues.

"Action Unsuccessful" on the Display

When the Remote Control displays "Action Unsuccessful," press [OK] and try the action again. If pressing [OK] does not clear the message, call your physician's office.

Accessories

AA Batteries

Do not use AA Batteries. The Remote Control requires the special 3.6-volt battery from Advanced Bionics, because a standard AA battery is not powerful enough. The two batteries may look the same, but they are very different when it comes to your device.

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

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12 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 1100, is free from defects in workmanship and materials for a period of one (1) year from the date of surgical implant of the IPG. This warranty only applies to the patient (recipient, hereinafter referred to as the patient), and no other individual.

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

IPG. Product claims under Advanced Bionics® Limited Warranty are subject to the following conditions and limitations:

1. The product registration card must be completed and returned to Advanced Bionics® within 30 days of surgery in order to obtain warranty rights.
2. The IPG must be returned to Advanced Bionics® (or authorized agent) within 30 days of malfunction or discovery of defect, and shall be the property of Advanced Bionics®.
3. The IPG must be implanted prior to the "use before" date.
4. Failure of the IPG must be confirmed by Advanced Bionics®. This warranty specifically excludes defects or malfunctions caused by: (**a**) fire, floods, lightning, natural disasters, water damage and other calamities commonly defined as "Acts of God"; (**b**) accident, misuse, abuse, negligence, or 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 5200, 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

ACT. An abbreviation for "activate." When the ACT button is pressed on the Remote Control a specific stimulation program begins operating.

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, Transformer, 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.

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.

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 these options.

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.

RSTR. Restore. An option setting available from the Remote Control.

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

SEL. Select; a Remote Control command.

SLEEP MODE. A time-out period when the Remote Control is not being used.

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.)

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.

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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.

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