DRAFT

Patient Trial Handbook

CAUTION:

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

MP9055185 Rev A

Guarantees

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Table of Contents

1 Introduction

Welcome to the “Trial Phase” of the Advanced Bionics® Precision™ pain management program. You’re about to test a pain treatment therapy that could result in a dramatic change in your life and your lifestyle. The trial you’ve agreed to participate in is intended to give you and your physician a chance to evaluate *spinal cord stimulation* (SCS) as an appropriate and effective long-term therapy option for your chronic pain.

At the end of the trial period (approximately one week) you and your physician will meet to discuss your experience with spinal cord stimulation. The doctor will also want to explore your feelings about a permanent SCS implant so that, together, both of you can determine whether long-term treatment with spinal cord stimulation is an appropriate option for you. To prepare yourself for this important decision, you may want to spend at least some of the trial period carefully evaluating spinal cord stimulation.

What is Spinal Cord Stimulation?

Most pain signals travel from the source problem or injury area to nerve pathways to the spine, then up the spine and to the brain. SCS uses electrical stimulation of the spinal cord to block the perception of those signals. To apply the stimulation, a small electrical pulse generator is connected to one or two wires, called leads, which are placed along your spinal cord. The stimulator, internal or external, sends pulses of a low electrical current to a series of metal contacts, called electrodes, located at the end of the lead(s). The "feeling" produced by this stimulation is a light sensation called *paresthesia*. Thousands of SCS patients consider paresthesia not only a pleasant substitute feeling, but also an effective and welcome relief from pain.

It's important to understand that spinal cord stimulation cannot *cure* pain or eliminate its cause. It does, however, provide control of and relief from certain types of pain over the area where the paresthesia is felt. Spinal cord stimulation is a treatment choice designed to provide you with the most effective pain relief over the widest pain area possible. When that goal is reached with the Precision™ system, you should experience good to excellent relief from chronic pain.

Caretaking During the Trial

To speed-up your recovery following the surgery, your physician might require bed rest for the first several hours after the surgery; administer antibiotics; schedule a mid-trial follow-up visit; and limit your physical activity, including driving.

CAUTION: If your doctor approves of you driving during the trial, always turn off the Trial Stimulator before getting behind the wheel. Please ask for specific instructions about what you may do and should not do during the trial, and follow all instructions carefully!

Be aware that some changes in posture can cause a decrease or (at times) an uncomfortable increase in the strength of the stimulation. Keep the Remote Control with you at all times so that you can make adjustments quickly if necessary.

You can help the recovery process by:

- Keeping your incision dry. Be sure you understand instructions about cleaning the incision and sponge-bathing. You must not bathe or shower during the trial.
- Checking the wound occasionally for signs of redness or the presence of fluid.
- Notifying your physician's office if you develop a fever, or if you experience increased pain at the incision site.
- Limiting most physical activity during the trial.

During sleep, bathing or for comfort, turn off the Trial Stimulator, remove it from the pocket, and disconnect the leads (see “The Trial Stimulator” on page 12 for information on disconnecting the leads).

The position and stability of your leads is a vitally important part of the trial experience. Remember that, when they were placed along your spine, the leads were specifically located according to where you felt stimulation covering your pain. You want the leads to stay in place! So, to prevent them from moving:

- Do not lift objects of more than 5 pounds.
- Do not engage in rigorous activity such as twisting, bending or climbing.
- Do not raise your arms above your head.
- Do not pull or jiggle the leads.

Again, call your doctor if you have any questions about an activity that you’re not sure is appropriate for you during the trial.

How to Use This Manual During the Trial

You will probably want to refer to this manual often during the trial period. For that reason, the content is arranged in the order you are most likely to need it.

Overview: The Trial Journal. This section describes the SCS Trial Journal which is included at the back of this manual. The journal is made up of a brief questionnaire, a simple chart, and a stimulation activity log. *Start your journal the first full day following surgery.*

Using the Medical Equipment. Turn to this section when you're ready to learn about the many ways available for managing stimulation using the Remote Control unit to program the Trial Stimulator. Depending upon the instructions you receive from your doctor you may not need all of the information here during the trial, but it may help you in the future.

2 Overview: The Trial Journal

All trials or tryouts require careful record keeping of times or scores, and your SCS trial is no exception. In order for you and your doctor to decide to move on to the next step—a permanent implant— you'll both need a way to review the details of each of your SCS trial days. The easiest way to do that is with the help of a journal. Your journal, which can be found at the back of this manual, consists of the following:

Pain Profile

You may think of the Pain Profile as a way to make a starting point for this trial and for the journal. The simple questions you answer here will establish a detailed, personal description of your pain condition. The profile includes a simple graph called a Visual Analog Scale (VAS), commonly used to measure the before-and-after pain levels of SCS trial patients. You may have completed a VAS before in your doctor's office or at a clinic. Once your VAS

score is marked, it becomes an important tool for determining your progress at the end of the trial.

The Journal

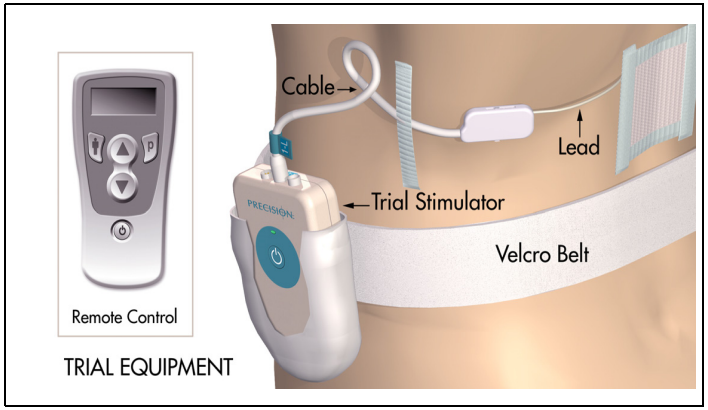
Seven log pages are included in your journal. We suggest that you begin keeping the log starting with the **first full day** following your surgery. An explanation of the columns follows:

- Activity: Please name the activity whether it's getting out of bed, washing the dishes, or walking the dog.
- Time: Fill in the approximate time (starting, during or ending) of the activity.
- VAS: Use this column to enter a Visual Analog Scale pain score for what your pain level was during the activity. The VAS score is a number between zero (0) and ten (10), where 10 is the worst pain imaginable and 0 is no pain. Rate the pain level you had while doing the activity.
- STIM ON (Program No.) or STIM OFF: Indicate if stimulation was on or off during the activity. If you know which program you were using, write the program number (1, 2, 3 or 4).

3 Using the Medical Equipment

The Trial Stimulator System

The Trial Stimulator is a temporary external spinal cord stimulator that is connected to the lead(s) placed along the spinal cord. You will use this external system to test how effective stimulation is in relieving your pain.



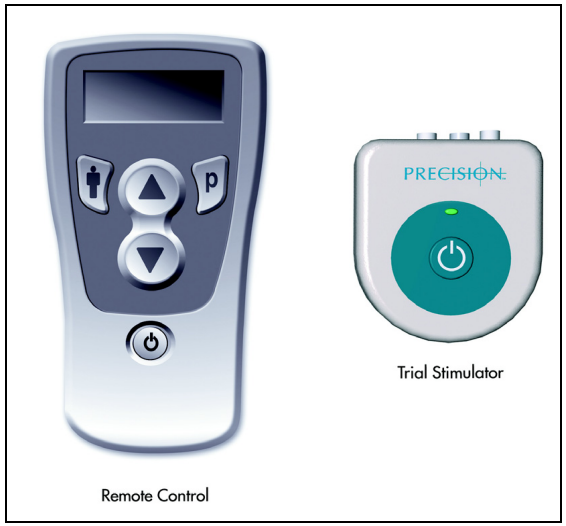
TRIAL EQUIPMENT

The Trial System includes:

- **Trial Stimulator**
- **Lead(s)**—An implantable wire that sends stimulation pulses to the spinal cord. You may have one or two leads.
- **Remote Control**—A small battery powered computer used to adjust stimulation.
- **Cable(s)**—Thin plastic-coated wire(s) used to attach the Trial Stimulator to the lead.
- **Velcro® Belt**—A waist wrap/pocket for wearing the Trial Stimulator.

Taking Care of Your Trial Equipment

All of the items that were sent home with you from the hospital are important to your trial success, so please follow the instructions listed.



- Handle the Trial Stimulator and the Remote Control with care. These items are well-designed, quality-tested electronic components. However, they can be damaged if they're dropped on a hard surface.
- Never submerge the Trial Stimulator or the Remote Control in water, or leave them outside in the rain, extreme heat, or extreme cold. Avoid all sources of water that can come into contact with the Remote Control and the Trial Stimulator.
- Always turn off the Trial Stimulator, remove it from the belt pocket, and disconnect and secure the leads before taking a sponge bath.

- Carry your Temporary Patient Identification card (given to you by your healthcare provider) throughout the trial.

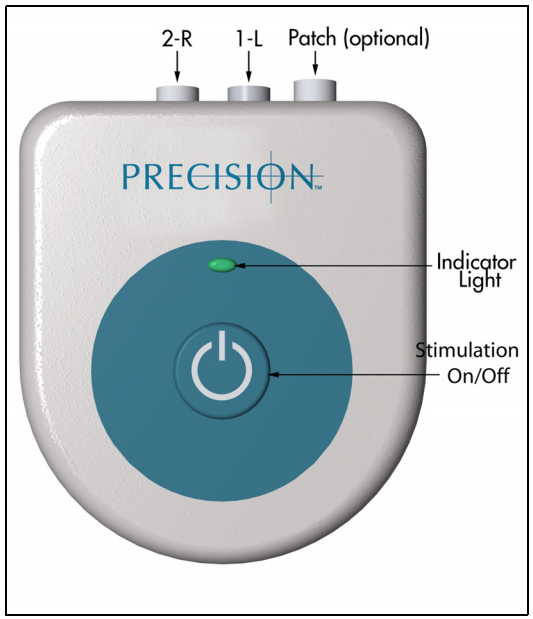
The Trial Stimulator

To turn stimulation on or off, press the ⏻ button on the stimulator or on the Remote Control. When the stimulator is on, the indicator light will blink.

CAUTION: Always turn the stimulator off before connecting or disconnecting your lead(s).

Disconnecting the Trial Stimulator

The Trial Stimulator has connectors for both left and right leads, and a third connector for a patch electrode. Whether you have one or two leads, your doctor probably placed identifying labels on them before connecting them to matching plugs on the stimulator. These labels are intended to

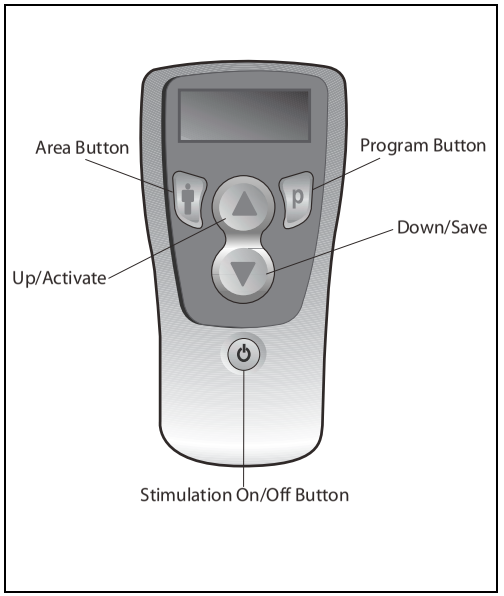


make it as easy as possible for you to connect the leads properly. *Remember to check the label(s) each time you need to reconnect the leads.*

Note: *If you were given a patch electrode for stimulation, an extra one is provided in case the adhesive wears out. When connecting a new patch electrode, be sure to plug it into the connector securely.*

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.*



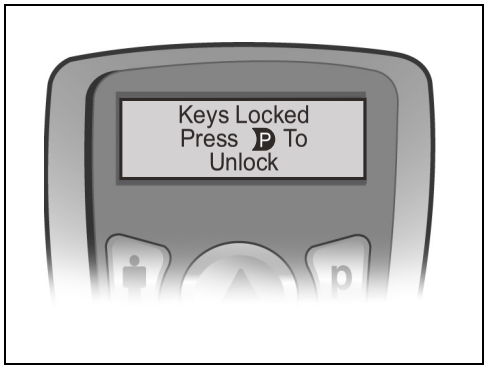
The Remote Control is used to:

- Turn stimulation on and off
- Change stimulation levels
- Activate or save new programs

Each button on the remote activates one of the stimulation functions which are described on the following pages. If you have a successful trial and later receive the permanent Precision stimulator, you'll learn about additional Remote Control features that are not described here.

Basic Operation

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 the stimulator 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 Trial Stimulator.

Note: *If there is a problem communicating with the stimulator, the message “No Response” will appear on the Remote Control screen. See “Help” on page 51 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

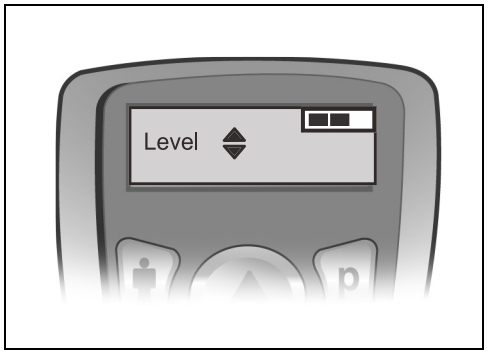
The Remote Control uses a "dedicated" stimulation on/off switch.You may press ⏻ *at any time—even during the remote's sleep or idle mode*—to turn stimulation on or off. The remote will briefly display a message notifying you of the on or off status.

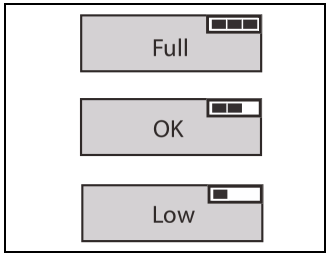
The Level Screen

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 Trial Stimulator 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 21.

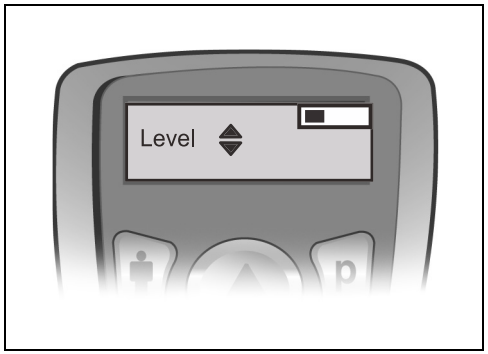
The Level screen also displays a bar graphic in the upper right corner to indicate the battery charge level of your stimulator. The graphic is very easy to understand: Three filled-in bars means that the battery is fully-charged. As the battery strength wears down, depending on your stimulation settings and usage, the bars will “empty” accordingly. For complete information on maintaining the battery for uninterrupted delivery of the therapy prescribed for you, see “Battery Information” on page 26.





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 ▲ (increase) or ▼ (decrease) 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

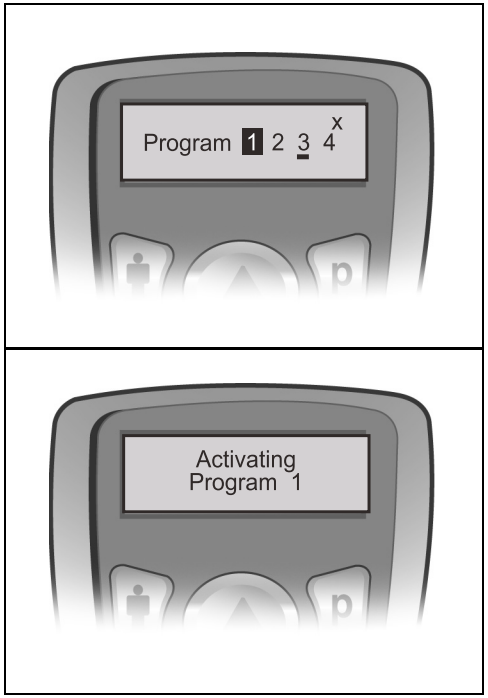
A stimulation program may provide paresthesia to cover a single pain area, or up to four areas, depending on how the program was set up by your clinician. Your Remote Control can store up to four programs—numbered 1 through 4—for you to select and activate at any time. Often, the programs will have certain 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 and you will hear an alert beep.*

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

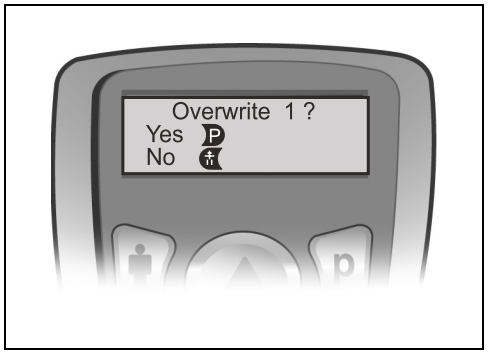
Saving Program Changes

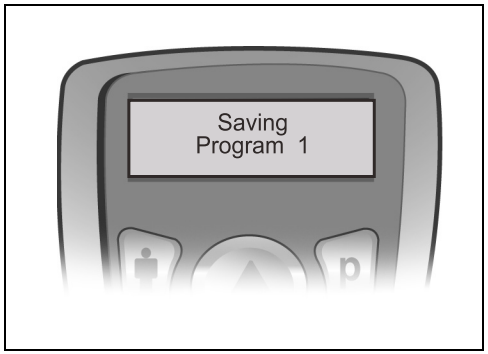
If you do make a stimulation level adjustment and decide that you prefer it to the original setting, you can save the new level and make it a permanent part of the program:

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.

Battery Information

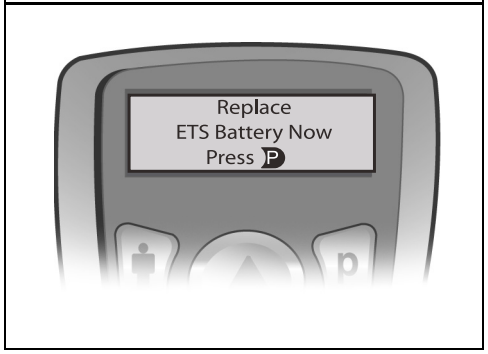
When the Remote Control batteries are at a low power level, the message shown here will be displayed. It is a good idea to replace the batteries at this point. *If you continue to use the remote without replacing the batteries, you will eventually see the message "Replace Remote Battery."* Do not ignore the message to replace the batteries!

When you press **P** from the Remote Battery Low screen, the Remote Control will make a check of the Trial Stimulator's battery status also.

- If the Trial Stimulator's battery is full/OK, the Remote Control will return to the Level screen without displaying a message.

- If the stimulator's battery is low, this message will be displayed.

- If the stimulator's battery is very low, this message will be displayed.



Respond to *all* battery messages as soon as possible to prevent an interruption of stimulation therapy during your trial period.

Remote Control 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 cover on the case and slide the cover into position until it snaps closed.

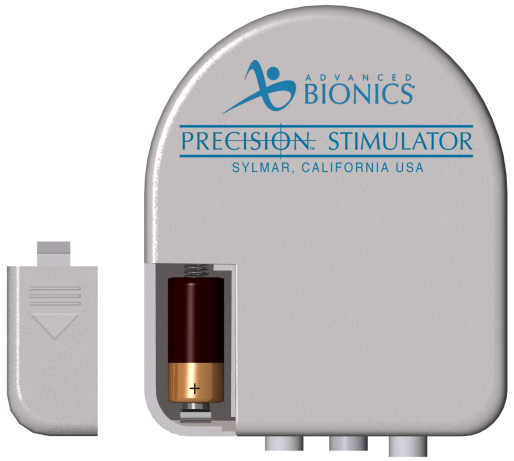
The Remote Control will connect to your Trial Stimulator in approximately 30 seconds.

Trial Stimulator Battery Replacement

It's not likely to happen over the short term of your SCS trial period, but your Trial Stimulator battery may drain to a very low level. If this happens, install a new battery right away.

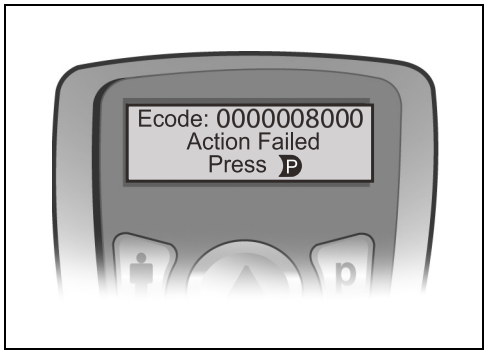
Be sure that stimulation is off (the indicator light is *not* blinking) before opening the Trial Stimulator's battery compartment. Replace the old battery with a 6-volt battery (lithium Duracell 28L) available at most drug and convenience stores.

1. On the rear of the unit, press down on the ridged area of the battery compartment cover and push the cover off of the case.
2. Remove the old battery and place the new battery in the compartment matching the positive (+) and negative (-) markings.
3. Close the compartment by sliding the cover on the stimulator case in the opposite direction.



TRIAL STIMULATOR

When the new battery is installed, you will see this screen on the Remote Control display. Don't be concerned by the "Action Failed" message; simply press **p** to continue.



When **p** is pressed, the Remote Control will go into idle mode (the display will be blank):

- To turn on stimulation immediately, press ⏻.
- To perform any other action, first press any key to "wake up" the Remote Control, then press **p** to unlock the remote's buttons.

4 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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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 leads, 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 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 the leads, 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 External Trial Stimulator. If the stimulator suddenly turns off by itself, first move away from the area. Next, check the stimulation status with the Remote Control by pressing the power button and observing the screen.

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 be 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. Avoid all sources of water which can come into contact with the Trial Stimulator and the Remote Control. 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.

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.

5 Help

Stimulation

No Stimulation

1. When stimulating, the Trial Stimulator indicator light will blink. If it is not blinking, toggle the ⏻ button on the Trial Stimulator or the Remote Control. When the Remote Control receives confirmation from the Trial Stimulator, it will display “Stimulation On.”

2. When the indicator light is blinking and you still do not feel stimulation:

a. Check to make sure the lead cable is properly connected to the stimulator. Turn off stimulation before adjusting the cables, and then turn it back on.

b. If you were provided a skin patch electrode, check that it is properly secured to your skin. Make sure to turn off stimulation first, and then turn it back on.

c. Try increasing (▲) the stimulation level. If this does not bring on stimulation, decrease the level (▼) to the original setting.

3. When the indicator light is not blinking and you do not feel stimulation, replace the Trial Stimulator battery.

4. Call your physician's office 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 Coverage is in a Different Area Than at the Doctor's Office

1. If stimulation moves, and you did not activate a different program, you should call your doctor. It is possible that the leads may have moved.

Remote Control Display

“Remote Battery Low” on the Display

The batteries in your Remote Control need to be replaced with three fresh AAA batteries (refer to “Remote Control Battery Replacement” on page 28).

"No Response" on the Display

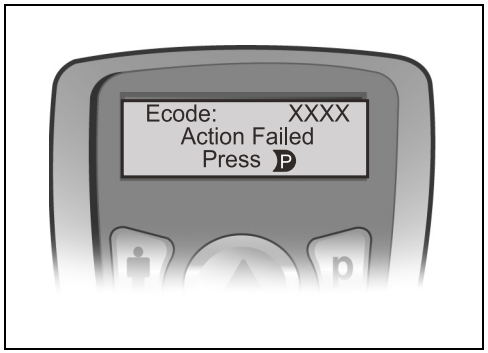
When the Remote Control displays "No Response," there is a communication problem between the remote and the stimulator probably caused by a weak battery. Press the **p** button. If the Remote Control is still not able to communicate with your stimulator, the "No Response" message will appear again; press **p** again. If the remote connects with the stimulator, 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. Replace the Trial Stimulator battery, reactivate the Remote Control (see page 30), and try the action again.

Occasionally, telemetry problems happen because the Remote Control cannot find the stimulator 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.*

A special "Action Failed" error message is displayed by the Remote Control when the Trial Stimulator battery is changed. Please see page 30 for information on how to proceed if you have to change the stimulator battery.

Accessories

Washing the Velcro® Belt

1. 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

Glossary

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.

Area Button icon.

CABLE. Thin plastic coated wire(s) connecting the exposed portion of temporary lead(s) to the Trial Stimulator.

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

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.

EXTERNAL TRIAL STIMULATOR (ETS). An electrical pulse generator used during the Trial Phase of SCS therapy evaluation.

IDLE MODE. A time-out period when the Remote Control is not being used. See also Sleep Mode.

IMPLANT. Small 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.

LABELS. Adhesive tags (2-R) (1-L) placed on the trial lead cables to show where to attach the cables to the Trial Stimulator .

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.

PAIN PROFILE. A record or documentation of pain locations, occurrences, and intensity. A pain "chart" for determining therapy.

PARESTHESIA. Sensation produced by electrical stimulation.

PATCH ELECTRODE. An adhesive patch placed on the skin and attached to the Trial Stimulator only when trial leads are not used.

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.

p Program Button icon.

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. See also 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.)

⏻ Stimulation On/Off Button icon.

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

TRIAL SCREENING. Temporary evaluation of electrical stimulation of the spinal cord.

TRIAL JOURNAL. Questionnaire, chart and activity log used to record information during the Trial Phase.

TRIAL STIMULATOR SYSTEM. Precision system components used during a limited time to evaluate SCS therapy. The Trial Stimulator System consists of an External Trial Stimulator (ETS), temporary or permanent lead(s), lead cable(s), the Remote Control, and a Velcro Belt.

VAS. Visual Analog Scale. Numerical scale/ graph used to chart before-and-after pain levels included in the Pain Profile.

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

Index

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.