

Physician Trial Kit Model SC-7005-02

Trial Stimulator Model SC-5110

Remote Control Model SC-5210

CAUTION:

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

The Advanced Bionics® Trial Stimulator is intended to be used during a screening trial to assess the efficacy of spinal cord stimulation in the treatment of patients with chronic pain of the trunk or limbs. The Trial Stimulator communicates with, and is controlled by, both a patient programmer (the Remote Control) and a clinician programmer via a wireless link.

The Remote Control unit is a hand-held device for patient control of both the external Trial Stimulator and the permanent, implantable pulse generator (IPG) models of the Precision™ SCS device.

Following set up of the Remote Control by the clinician, the Trial Stimulator is able to respond to patient control of:

- stimulation on/off functions
- stimulation amplitude and other (optional) parameters
- stimulation delivery areas
- individualized stimulation therapy programs.

Patient use instructions are outlined in the Patient Trial Handbook.

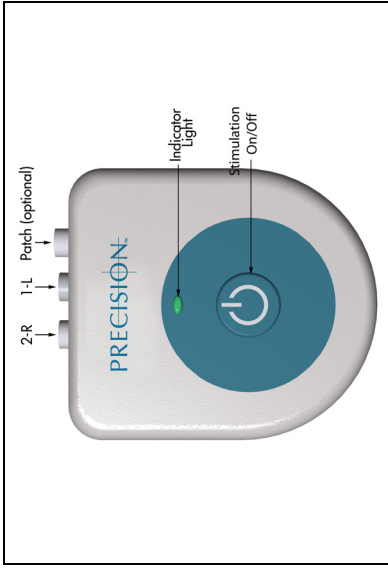
PRECISION™

Physician Trial Kit

CAUTION:

- To avoid unexpected stimulation results, never make connections while the Trial Stimulator is on.
- The battery used in the Trial Stimulator may present a risk of fire or chemical burn if mis-treated. Do not disassemble, heat above 100°C (212°F), or incinerate.
- Handle the devices with care. Although durability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other destructive handling, can cause permanent damage.
- Avoid all sources of water that can come into contact with the devices.
- Do not expose the devices to extreme temperatures. Store between 5 – 40 °C (41 – 104 °F).
- Do not dispose of the devices in fire.

Trial Stimulator

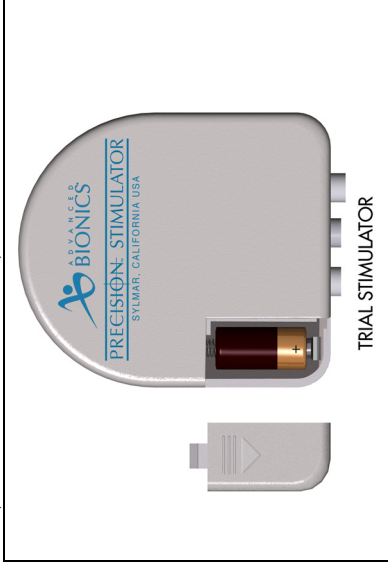


General Instructions

1. Ensure that the Trial Stimulator is equipped with a new 6-volt battery before conducting intraoperative stimulation testing, and for each new

trial. (A battery is included in the Patient Trial Kit.)

2. Before connecting the OR Cable for intraoperative testing, ensure that the Trial Stimulator is off (no indicator light). Turn the stimulator on for testing, then return it to off before disconnecting the test cables.
3. When fitting the patient with the Trial Stimulator, ensure that the OR Cables are properly connected and labelled. Superior (upper or left) leads connect to socket 1-L. Inferior (lower or right) leads connect to socket 2-R. If only a single lead is being used, connect it to 1-L.
4. Before releasing the patient, ensure that he/she understands:
 - Basic control of the Trial Stimulator using the Remote Control, and that stimulation may be turned on and off with the  button on either unit.
 - How to disconnect and reconnect the OR Cable(s) *with the power off*.
 - How to replace the Trial Stimulator battery. (See illustration below)



NOTE: Immediately following a Trial Stimulator battery replacement, the linked Remote Control will display an error/reset message. Press **p** to reset the stimulator .

Remote Control

Battery Information

The Remote Control uses three AAA batteries. The device will issue warnings when its batteries are low and when the Trial Stimulator battery needs replacement. Instruct patients to pay close attention to all battery messages.

NOTE: The first time it comes on following a battery replacement, the Remote Control will reload information from the implanted or external stimulator. The remote must be within communication range (two feet) of the stimulator during this period.

Battery Replacement

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



Physician Trial Kit Model SC 7005-02

General Instructions

1. To turn stimulation on or off, press the **⏻** button.
If the Remote Control is in sleep/idle mode and you press any button other than **⏻**, the remote will display a “Keys Locked” message. You must press **p** to unlock the “function” buttons when reactivating the Remote Control from sleep mode.
2. To increase or decrease the stimulation level of all programmed therapy areas, press either **▲** or **▼**.



3. To change the stimulation level of just one area:
a) From the level screen, press **⏻** as many times as necessary to find the desired area by name or number.
b) Press **▲** or **▼** to make the change.



4. To activate a stimulation program:

- a) Press **p** from the level screen.
- b) From the program screen press **p** as many times as necessary to highlight the desired program.

- c) Press **▲** to activate the selected program.



Once the program is running, you may change the stimulation level by pressing **▲** or **▼**.

To save the new level in a program, return to the program screen, select the intended program number, and press **▼**.

5. To access patient options:

Rate

1. Press and hold **⏻** from the level screen to activate the Rate Area 1 screen.
2. Press **⏻** (normal press) as necessary to cycle to the area you want to adjust, then press **▲** or **▼** to increase or decrease the Rate.

Pulse Width

1. From the level screen press and hold **⏻** to access the Rate Area 1 screen.
2. From *any* Rate screen, press and hold **⏻** again to access the Width Area 1 screen.
3. Press **⏻** (normal press) as necessary to cycle to the desired area.

4. Press **▲** or **▼** to increase or decrease Pulse Width.

To save a Rate or Pulse Width change--

1. Press **p** from the level screen.
2. From the program screen press **p** as necessary to cycle to the active program.
3. With the program highlighted, press **▼** to save changes.

Restore

1. Press and hold **p** to access the Restore screen.
2. Press **p** again as necessary to highlight the program you want to restore, then press **▲**.
3. Respond to the confirmation screen to complete the operation.

Maintenance

The Trial Stimulator and Remote Control may be cleaned with a cloth lightly dampened with water or a mild household cleaner. Do not use abrasive cleansers on the devices, and do not sterilize them.

Technical Service

If you have questions concerning the Remote Control or the Trial Stimulator, please contact Advanced Bionics' Technical Service Department:

- Phone: (866) 566-8913
- Fax: (661) 362-1503
- Address: Advanced Bionics® Corporation
Pain Management Division
25129 Rye Canyon Loop
Valencia, CA 91355

Limited Warranty

Advanced Bionics® warrants to the purchaser that the Precision™ Trial Stimulator and Remote Control are free from defects in workmanship and materials for a period of one (1) year from the date of purchase.

A Stimulator or Remote Control unit that fails to function within normal tolerances within one (1) year from the date of 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:

The product registration card must be completed and returned to Advanced Bionics® within 30 days of receipt of product in order to obtain warranty rights.

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, failure to operate the system and its components in accordance with manufacturer’s instructions; (c) unauthorized attempts to repair, maintain, or modify the equipment; or (d) attachment of any equipment not supplied by Advanced Bionics® without prior approval.

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.