Material Specification

Title: **IFU, Algovita SCS, Trial Stimulator Manual for Clinicians**	
Document Number and Revision **0300-000026-06**	Page 1 of 2
Prepared By: Amy Kosbau	Approved By:

Do not print the material specification notes pages when printing the literature piece.
Do not count the material specification notes pages in the literature piece page count.

1.0 PURPOSE

To define all parameters necessary to assure conformance to appropriate specifications.

2.0 SCOPE

This specification describes the configuration and content for the IFU, Algovita SCS, Trial Stimulator Manual for Clinicians

3.0 RESPONSIBILITY

It is the responsibility of the product development engineer, manufacturing engineer or labeling engineer to maintain this document in accordance with Algostim requirements.

4.0 MATERIAL CHARACTERISTICS

4.1 Content: The content of the instructions for use document shall be defined in the files and PDF provided by Algostim.

4.2 Material: The paper shall be:

4.2.1 Front/Back Cover: 80# uncoated cover

4.2.2 Inner Pages: 40# white smooth opaque text stock.

4.3 Color:

4.3.1 4-color

4.4 Physical Size:

4.4.1 All dimensions are in inches unless otherwise noted.

4.4.2 7.25 ± .20 length x 6.50 ± .20 width

4.5 Type of Binding: Perfect Bound

4.6 Other:

4.6.1 Literature Piece Page Count (including covers, excluding specification notes pages) 34

4.7 Language Translation Requirements & Configuration:

4.7.1 English (en)

5.0 STORAGE CONDITION

Store in dry location.

6.0 QUALITY CHARACTERISTICS

6.1 Clarity of Text: The text shall be easily readable and free of smears and smudges. Graphics content, layout and text shall be consistent with that in the document (pdf) provided by the customer.

6.2 Workmanship: The booklet shall be uniformly cut along its edges and free of significant rough edges or paper slivers.

6.3 Color: Color shall be uniform throughout each lot.

6.4 Lot Quality: Any lot of material, which does not meet the requirements of this specification, is subject to return. Greatbatch Medical reserves the right to return entire lots of material which fail to meet the requirements of this specification.

7.0 PACKAGING/LABELING

7.1 Each package provided by the supplier shall be labeled with: Greatbatch part number, revision level of this specification document, quantity, supplier name, and date of manufacturing.

7.2 A Certificate of Conformance is required with each shipment to include quantity, material characteristics, Greatbatch part number, revision, PO, lot and date of manufacturing.

NOTE: Graphics Content and Layout to be shown and per Algostim file.

algovita™

Algovita™ Spinal Cord Stimulation System

Trial Stimulator Model 4300

External Pulse Generator (EPG)

Trial Stimulator Manual for Clinicians

ALGOSTIM, LLC

CE 0123

℞ ONLY

2014

Algovita™ is a trademark of QIG Group, LLC

FCC Information (US Only)
The following is communications regulation information about the Algovita Trial Stimulator and Pocket Programmer.
Trial Stimulator FCC ID: 2ABU84300
Pocket Programmer FCC ID: 2ABU84100

These devices comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) These devices may not cause harmful interference, and (2) These devices must accept any interference received including interference that may cause undesired operation.
Important: Changes and modifications to the products not authorized by Algostim, LLC could void the FCC certification and negate your authority to operate these products.

Refer to the Information for Prescribers Manual for indications, contraindications, warnings, precautions, adverse events, clinical study results, and related information.

Contents

Explanation of Symbols Used on Packaging and Trial Stimulator

Symbol	Explanation
CE 0123 2014	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive AIMD 90/385/EEC and R&TTE Directive 1999/5/EC
Rx ONLY	Caution: Federal Law (USA) restricts this device to sale on or by the order of a physician
FC	This device complies with Part 15 of the Federal Communication Commission rules
EC REP	Authorized representative in Europe
	Caution
	Consult instructions for use
SN	Serial number
	Manufacturer
	Date of manufacture
REF	Catalogue number
MODEL	Model
	Temperature limit
	Humidity limitation

Symbol	Explanation
	Fragile, handle with care
	Keep dry
	Atmospheric pressure limitation
	Keep away from sunlight
	Do not use if package is damaged
	Non-ionizing radiation
	Type BF equipment
	Battery
	Class II equipment
	Not for general waste
	Recycle
	Contents
	Telephone

Introduction

The Algovita™ Trial Stimulator Model 4300 (*Figure 1*) is part of the Algovita Spinal Cord Stimulation (SCS) System, a rechargeable, 24-electrode, SCS system for the treatment of chronic pain.

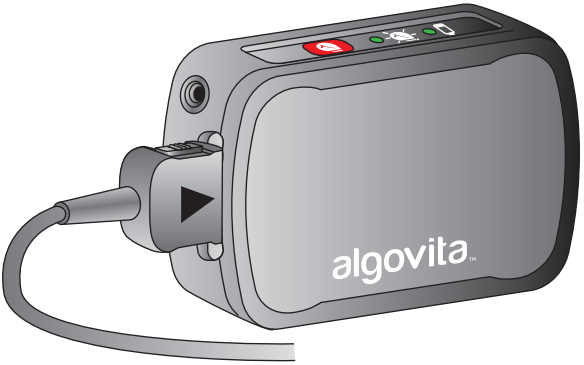

Figure 1. Algovita Trial Stimulator Model 4300

The trial stimulator is the external pulse generator (EPG) for the Algovita SCS System. The EPG is used by the physician during intraoperative test stimulation and is used by the patient as part of the Algovita Trial Stimulation System.

The EPG allows the physician to program system configurations identical to either the Algovita Stimulator Model 2408 (3x8 channel) or the Stimulator Model 2412 (2x12 channel).

The EPG is programmed using the Clinician Programmer. During a stimulation trial, the patient controls the EPG using the Pocket Programmer.

Package Contents

- Trial Stimulator Model 4300
- Trial Stimulator Pouch
- AAA Batteries (2)
- Product Literature

Important Safety Information

Contraindications

Diathermy. Shortwave, microwave and/or therapeutic ultrasound diathermy must not be used on SCS patients. The energy generated by diathermy can be transferred through the SCS system, causing tissue damage at the lead site which may result in severe injury or death.

Warnings

Electrocautery. Electrocautery devices should not be used in close proximity to an SCS trial system. Contact between an active electrode and an implanted SCS system component can cause direct stimulation of the spinal cord, which may result in severe injury to the patient

If use of electrocautery is necessary:

1. Turn the EPG off.
2. Use bipolar cautery.
3. Verify system and therapy function after electrocautery use.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn stimulation off or change the strength of stimulation, which may cause an uncomfortable or jolting sensation. If uncomfortable stimulation occurs, advise patients to move away from the area or turn stimulation off.

Patients should also exercise care around:

- **Theft detectors or security screeners such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices.** Patients should exercise caution when approaching such a device and should request assistance to bypass the device. If the patient must proceed through the device, the patient should turn the EPG off and proceed with caution, moving through the center of the screener as quickly as possible.
- Power lines or power generators
- Electric steel furnaces and arc welders
- Large, magnetized stereo speakers
- Therapeutic magnets

Interaction with Implanted Sensing Stimulators and Other Implanted Devices. SCS systems may interfere with the operation of implanted sensing stimulators such as pacemakers or cardioverter defibrillators (ICDs). If other implanted devices are indicated for the patient, careful screening is required to determine if safe results can be achieved before permanently implementing concurrent electrical therapies. The effects of implanted SCS systems on other implanted devices are unknown.

Magnetic resonance imaging (MRI). Patients with the Algovita SCS system must not be exposed to MRI. The electromagnetic field generated by an MRI may forcefully dislodge the IPG or leads, damage the IPG electronics, and induce voltage through the lead that may cause an uncomfortable or jolting sensation or serious injury. The Algovita SCS System components have not been tested for heating or migration in the MR environment. Introducing an Algovita SCS patient into an MRI scanner may result in severe patient injury, death, or device malfunction.

Modification. Do not modify the EPG. Modification of any SCS system component may result in damage to the system, compromised system integrity, and harm or injury to the patient.

Radio-frequency or microwave ablation. Safety has not been established for radiofrequency (RF) or microwave ablation in patients who have an SCS system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Precautions

System Interaction with Other Medical Treatments and Procedures. An IPG may interact with the following therapies or procedures:

- **Diagnostic x-rays.** The effects of diagnostic x-rays on a stimulator are typically transient because interference occurs only during the time of x-ray exposure. In some cases, the EPG may need to be reprogrammed.

The following therapies or procedures may turn your stimulation off or may cause permanent damage to your stimulator, particularly if used in close proximity to the EPG.

- Radiotherapy
- Lithotripsy
- External defibrillation
- Radiation therapy
- Ultrasonic scanning
- High-output ultrasound

- CT scans may damage the EPG if stimulation is on. CT scans are unlikely to damage the EPG if stimulation is turned off.

If any of the therapies or procedures listed above are required by medical necessity:

- Adjust stimulation to its lowest level before the procedure or application then turn the EPG off.
- All equipment, including ground plates and paddles, must be used as far away from the EPG as possible.
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the EPG.
- Set equipment to the lowest energy setting clinically indicated.
- Verify SCS system and therapy function following treatment.

Component Compatibility. Use only the Clinician Programmer, or an Algovita patient programmers and accessories in your Algovita SCS System to adjust stimulation. The effects of non-Algovita components on an Algovita SCS System are unknown.

Flammable Atmospheres. Avoid using the EPG in flammable or explosive environments (eg, an anesthetic mixture with air, oxygen, or nitrous oxide). Using a battery-powered device near flammable or explosive atmospheres can produce a spark which may cause injury..

Adverse Events

There are potential risks involved with any surgery. The possible risks of using a trial stimulation system are similar to the risks that can occur with other spinal procedures. These risks include:

- The most common risks are temporary pain at the incision or infection.
- There is a small possibility of developing a cerebral spinal fluid (CSF) leak.
- In rare cases bleeding (epidural hemorrhage), a blood clot (hematoma), or a pocket of fluid (seroma) may develop at the location where leads are placed.
- In rare cases, injury to the spinal cord may occur, resulting in paralysis.
- The use of blood thinners may increase the risk of complications such as blood clots (hematomas), which may produce paralysis.

The possible risks of using a trial stimulation system to evaluate a treatment for chronic pain include:

- The leads may shift or move from the location where they were originally implanted. Such a change in location may cause changes in stimulation, sometimes unpleasant, and/or reduce

the pain relief provided by the SCS system.

- The SCS system may fail at some point, due to a random component or battery failure. Examples of failure include lead or lead insulation break, loose connection, electrical short, or component malfunction. A failure may reduce or stop the pain relief provided by the SCS system.
- A patient may have an allergic reaction or become irritated by materials that are used to manufacture the SCS system components. Signs of a negative reaction are persistent redness, swelling, or warmth at the area where the system is implanted
- A patient may have ongoing pain in the area where a lead or extension is located.
- A patient may have unpleasant or painful stimulation. Such changes in stimulation may occur if stimulation settings are changed too quickly, a lead moves or breaks, or there is a loose electrical connection in your SCS system.
- A patient may experience weakness or numbness in areas below your SCS system location.
- A patient may experience changes in stimulation, painful stimulation, or problems with the operation of the SCS system due to electromagnetic interference from other electrical devices, medical equipment, or medical procedures.

EPG Description

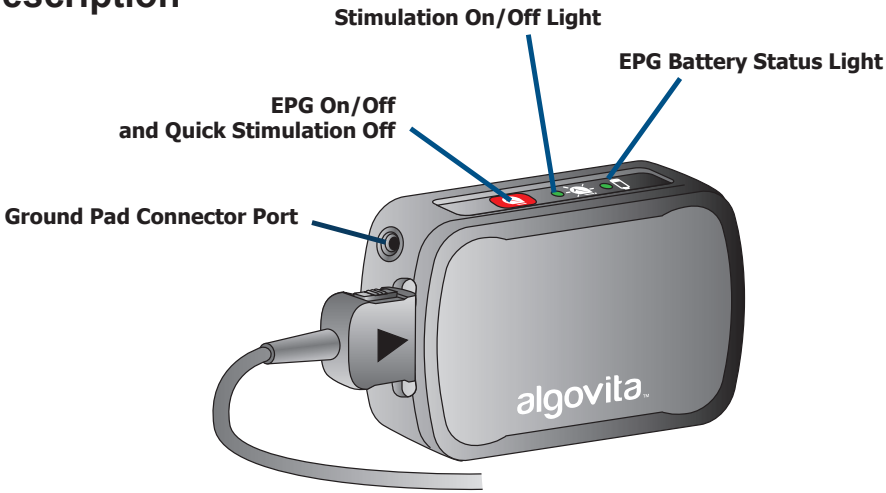

Figure 2. EPG button and status lights

The button on the EPG (*Figure 2*) allows you to turn the EPG on and off and turn stimulation off. Turn stimulation on using the Clinician Programmer or one of the patient programmers. The lights on the EPG allow you to verify if the EPG or stimulation is on or off.

- **EPG On/Off**—Turn the EPG on or off by pressing the button for 5 seconds.
- **Quick Stimulation Off**—Turns stimulation off by pressing the button for 2 seconds.
- **Stimulation On/Off Light**—Check if stimulation is on or off.
- **EPG Battery Status Light**—Check if the EPG is on and the battery charge level is above 25% (flashes green) or below 25% (flashes red).
- **Ground Pad Connector Port—**This port is used to connect an optional (electrophysiology) ground pad to the EPG. The ground pad is required with the use of the Algostim Computer Aided Stimulation Programming (CASP) feature. See the *Clinician Programming Manual* for instructions on using CASP.

Turning the EPG On or Off

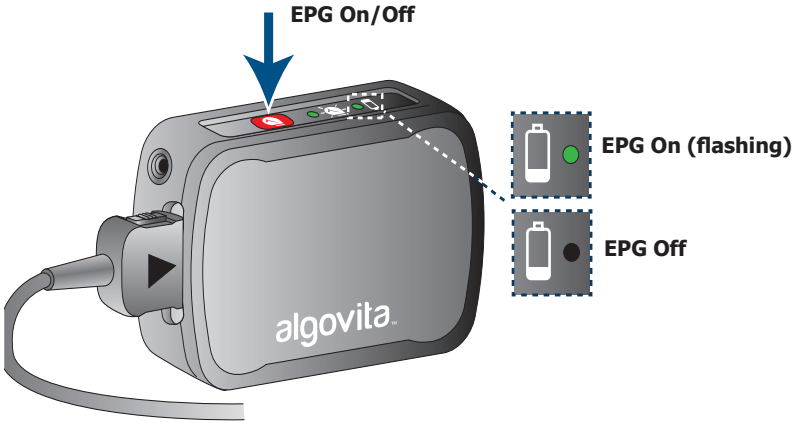

Figure 3. Turning the EPG on or off

Before turning stimulation on, the EPG must be on (*Figure 3*).

To turn the EPG on:

- Press the **EPG On/Off** button (*Figure 3*) and hold for approximately 5 seconds. After a short delay, the EPG turns on, and the EPG Battery Status light flashes green. When the EPG turns on, stimulation is off.

  Notes:

  » If the EPG Battery Status light flashes red, replace the EPG batteries. For instructions, see *Changing the EPG Batteries on page 16*.

  » Turn stimulation on using the Clinician Programmer or one of the patient programmers.

To turn the EPG off:

- Press the **EPG On/Off button** (*Figure 3*) and hold for approximately 5 seconds. The EPG Battery Status light turns off.

  Note: The EPG On/Off button and Quick Stimulation Off button are the same button. Pressing and holding the EPG On/Off button for approximately 2 seconds turns stimulation off.

Quick Stimulation Off

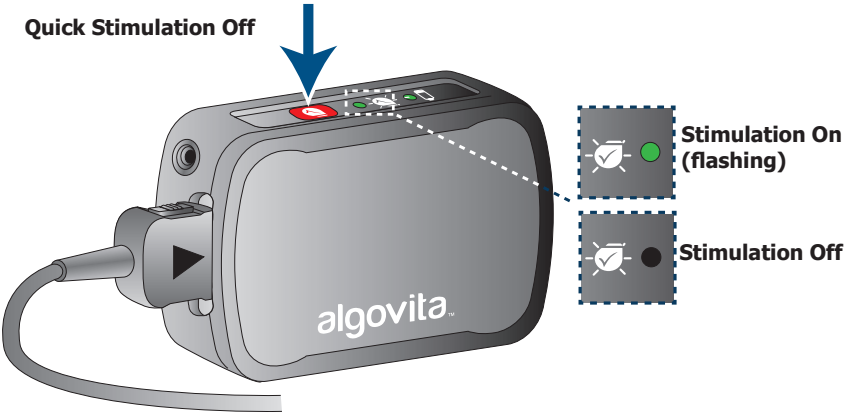

Figure 4. Quickly turning stimulation off

To quickly turn stimulation off using the EPG:

- Press the **Quick Stimulation Off** button (*Figure 4*) and hold for approximately 2 seconds. After a short delay, stimulation turns off, and the Stimulation On/Off light turns off.

  Notes:

  » The Clinician Programmer includes a Quick Stimulation Off icon on stimulation screens, and a Quick Stimulation Off button on the top of the Clinician Programmer.

  » If you are unable to turn stimulation off, press the tabs on either side of the trial cable connector, and disconnect the trial cable from the EPG.

  » The Quick Stimulation Off button and the EPG On/Off button are the same button. Pressing and holding the Quick Stimulation Off button for approximately 5 seconds turns the EPG off.

  » Turn stimulation on using the Clinician Programmer.

Using the EPG During Intraoperative Test Stimulation

After placing the leads and connecting the leads to the trial cable, connect the trial cable to the EPG, turn the EPG on, then turn stimulation on using the Clinician Programmer. During intraoperative test stimulation, use the Clinician Programmer to program the EPG. For additional procedural instructions, see the system implant manual packaged with the lead. For programming instructions, see the *Clinician Programming Manual*.

Connecting the Trial Cable to the EPG

Caution: The trial cable is a single-use component; do not resterilize the trial cable because of risk of infection.

To connect the trial cable to the EPG:

1. Check that stimulation is off.

   Caution: Connecting the trial cable to the EPG with stimulation on may cause an uncomfortable or jolting sensation.

2. To prevent the lead from pulling out from the spine, secure the trial cable to the drape before passing the end of the cable off the sterile field.
3. After the cable end is passed off the sterile field, tape the non-sterile end on top of the sterile drape, to prevent the non-sterile cable end from falling back into the sterile field.
4. With the arrow on the trial cable end and the Algovita logo facing the same direction, connect the trial cable to the EPG (*Figure 5*).

   Caution: Maintain adequate slack on the trial cable. Do not pull the trial cable taut. Pulling on the cable may dislodge the lead, which may result in loss of stimulation.

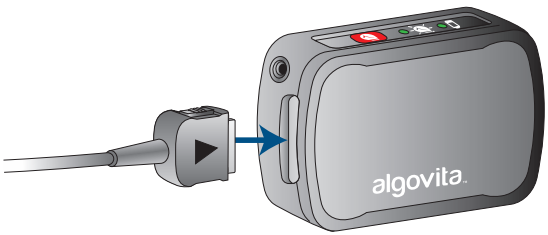

Figure 5. Connecting the trial cable to the EPG

5. Turn the EPG on.
6. Turn stimulation on using the Clinician Programmer.

Disconnecting the Trial Cable from the EPG

To disconnect the trial cable from the EPG:

1. If you want to save battery power, turn the EPG off.
2. While squeezing both tabs on the trial cable connector (*Figure 6*), gently disconnect the cable from the EPG

   Caution: Do not pull directly on the trial cable. Pulling on the trial cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result in loss of stimulation and may require another trial procedure to replace the lead.

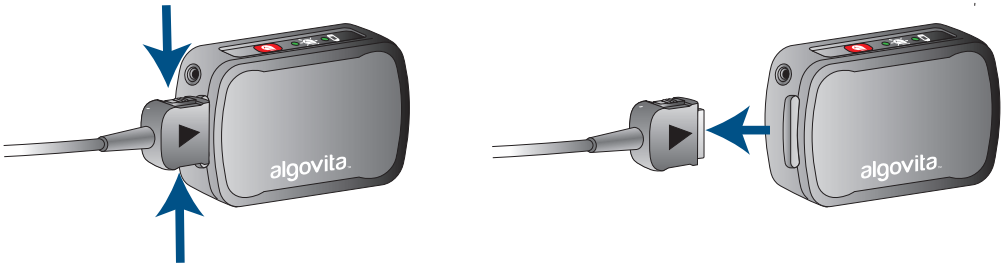

Figure 6. Disconnecting the trial cable

Stimulation Trial

The patient uses the EPG during the stimulation trial. For detailed instructions on preparing the patient for a stimulation trial and evaluating a stimulation trial, see the system implant manual packaged with the leads.

Preparing the EPG for a Stimulation Trial

Before beginning a new stimulation trial:

- Inspect the EPG and make sure it is not damaged.
- Clean the EPG. Follow your healthcare facility's procedures in the cleaning of medical devices or use the procedure *Cleaning the EPG After Use on page 18*.
- Make sure the EPG has new batteries installed.
- Make sure the EPG has been cleared of previously stored data. See the *Clinician Programming Manual* for instructions on clearing data from the EPG.

After the Stimulation Trial

After the stimulation trial, the patient returns the trial stimulation system to the physician.

When returned, clean the EPG. Follow your healthcare facility's procedures in the cleaning of medical devices or use the procedure *Cleaning the EPG After Use on page 18*.

If you and the patient determine that an Algovita SCS system will be implanted, and you want to move the program settings from the EPG to an IPG, see Swapping an EPG for an IPG in the *Clinician Programming Manual* for information.

Changing the EPG Batteries

The EPG is powered by two AAA batteries. Replace the EPG batteries before each stimulation trial or when the batteries are low or depleted. If the EPG loses power, the program settings remain at the settings last programmed, whether set by the clinician or changed by the patient.

Caution: Do not leave depleted batteries in the EPG. The batteries may corrode and cause damage to the electronic components. If the EPG is not to be used for several weeks, remove the batteries.

Checking the Battery Charge Status

The EPG has a flashing EPG Battery Status Light (*Figure 7*).

- When the battery charge level is above 25%, the light flashes green.
- When the EPG battery charge level is at or below 25%, the light flashes red. If the light is flashing red, change the EPG batteries in order to maintain stimulation.
- If the EPG battery is depleted, the EPG will not turn on.

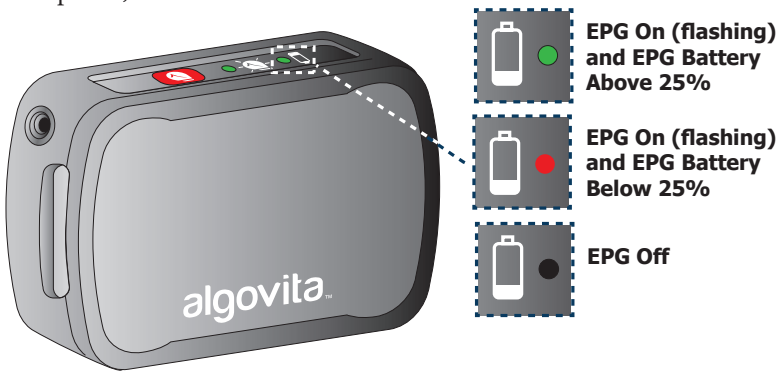

Figure 7. EPG Battery Status Light

Note: The Clinician Programmer may also be used to check the EPG battery charge status. See the *Clinician Programming Manual* for detailed information.

Changing the Batteries

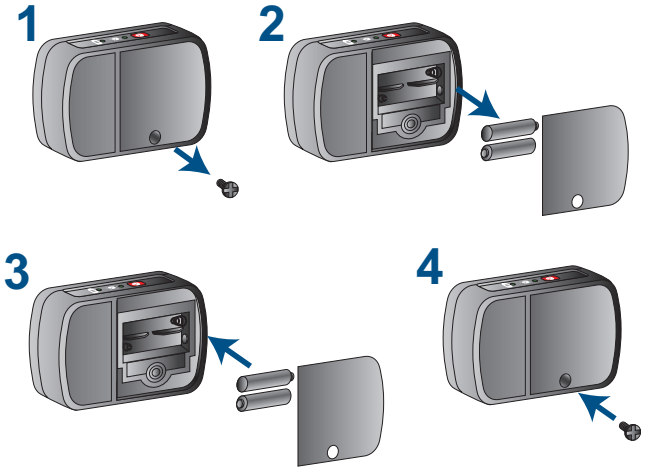

Figure 8. Replacing the EPG batteries

To change the EPG batteries *(Figure 8)***:**

1. Using a Phillips screwdriver, loosen the screw on battery compartment cover.
2. Remove the battery compartment cover and batteries.
3. Insert the new batteries following the polarity diagram in the battery compartment.
4. Replace the battery compartment cover, then insert and tighten the screw.

EPG Care and Storage

The following recommendations are made for the care and storage of the EPG:

- Keep new batteries available.
- Replace low or depleted batteries.
- Do not drop the EPG. Protect the EPG from sharp objects and physical shocks. Mishandling can permanently damage the EPG.
- The sensitive electronics of the EPG can be damaged by temperature extremes, particularly high heat.
  - » Do not expose the EPG to excessively hot or cold conditions, including leaving the EPG in your car or outdoors for extended periods of time.
  - » If the EPG is to be stored for a period of time, be careful that the storage temperature is not less than -20°C (-4°F) or greater than 60°C (140°F).

General EPG Cleaning

- The EPG is not waterproof. Do not immerse the EPG in liquid or allow moisture to get inside the case.
- If the EPG is dirty, clean the outside with a slightly damp cloth. Do not clean the EPG with bleach, nail polish remover, or similar substances.

Cleaning the EPG After Use

After using the EPG for intraoperative test stimulation, clean the EPG before giving it to a patient for a stimulation trial. Also clean the EPG when a patient returns the EPG after a stimulation trial.

Follow your healthcare facility's procedures in the cleaning of medical devices. If your healthcare facility does not have a cleaning procedure:

1. Inspect the EPG for any dirt, debris or residue.
2. Clean the EPG, as appropriate, with hospital-grade isopropyl alcohol (IPA).
3. Before using the EPG, make sure it is clean and dry.

Cleaning the EPG Battery Contacts

The EPG battery contacts may be cleaned periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.

EPG Service and Replacement

The components have no user-serviceable parts. Only Algostim, LLC should service or repair the EPG. Do not attempt to open or repair the EPG. Unauthorized repairs will void the warranty.

If the EPG needs service or repair, contact Algostim Customer Service. When contacting Algostim Customer Service, have the EPG serial numbers available. The serial number is located on the back of the EPG.

Note: The Limited Warranty does not cover loss or theft of the EPG or damage caused by misuse. For additional information, refer to the Limited Warranty packaged with this manual.

Disposal

To dispose of the EPG, consult local regulations for proper disposal of AAA batteries and electronic devices.

Return explanted leads, extensions, anchors to Algostim, LLC. Do not autoclave the components or expose them to ultrasonic cleaning. Dispose of unreturned components according to local environmental regulations.

Troubleshooting

The following tables cover stimulation and EPG troubleshooting. If you are having a problem with your EPG and do not find an answer in these tables, contact Algostim Customer Service.

Table 1. Stimulation and EPG Troubleshooting

Indication	Possible Cause	Possible Solution
You want to turn stimulation off quickly, but stimulation will not turn off.	You are not holding the Quick Stimulation Off button down for the correct amount of time.	Make sure you are holding the Quick Stimulation Off button down for 2 seconds.
	The EPG has malfunctioned.	Press the tabs on either side of the trial cable connector, and disconnect the trial cable from the EPG.
The patient no longer feels stimulation.	The strength of the active program is too low.	Increase the strength of the active program.
	The EPG is turned off.	Turn your EPG on.
	Stimulation is off.	Although unlikely, stimulation may have been turned off by EMI from security gates or other electronic devices. Verify that stimulation is on.
	The EPG batteries are depleted.	Check the EPG battery charge level, and change the batteries if needed.
	A lead has moved or lead has become disconnected from the trial cable.	1. Turn the EPG off. 2. Inspect the trial stimulation system connections and lead location.
The EPG Battery Status Light or the Stimulation On/Off Light are flashing	To conserve battery power, when the status lights are on, they always flash.	
The EPG will not turn on.	You are not holding the EPG On/Off button down long enough.	Make sure you are holding the EPG On/Off button down for 5 seconds.
	The EPG batteries are depleted.	Check the EPG battery charge level, and change the batteries if needed.

Table 1. Stimulation and EPG Troubleshooting		
Indication	**Possible Cause**	**Possible Solution**
The EPG will not turn off.	You are not holding the EPG On/Off button down long enough.	Make sure you are holding the EPG On/Off button down for 5 seconds. Holding this button down for 2 seconds, turns stimulation off.
	The EPG has malfunctioned.	Press the tabs on either side of the trial cable connector, and disconnect the trial cable from the EPG.

Algostim Customer Service

If you have any questions about an Algovita SCS System, call Algostim Customer Service toll-free at 1-844-727-7897 within the United States.

Outside of the United States, call your product distributor for assistance. If additional assistance is needed, contact Algostim Customer Service +1-214-618-4980.

Specifications

Table 2. Operating Values for Model 4300	
Description	**Value**
Number of programs	1 to 10
Number of sub-programs per program	1 to 4
Electrode configuration	Up to two 12 electrode leads or three 8 electrode leads
Amplitude – upper patient limit	±15.0 mA
Amplitude – lower patient limit	±0.017 mA
Pulse width	20 to 1500 µs (20-µs resolution)
Frequency – upper patient limit	2000 Hz
Frequency – lower patient limit	2 Hz

Table 3. Physical Characteristics for Trial Stimulator Model 4300	
Description	**Value**
Length	86.4 mm / 3.4 in
Width	51 mm / 2.0 in
Thickness	22 mm / 0.85 in
Cable Connector	24 pin contact cable connector

Table 4. Electrical and Operating Characteristics for Trial Stimulator Model 4300	
Description	**Value**
Power source	2 AAA alkaline batteries 1.5v
Operating Type	Continuous

Note: The Ground Pad port may be connected to a standard electrophysiology ground pad using a DIN 42-802 1.5mm touch-proof connector, and is analogous to using the hermetic enclosure of the IPG in stimulation.

Table 5. Storage and Operating Conditions for Trial Stimulator Model 4300	
Parameter	**Value**
Operating temperature	10 to 40° Celsius (50-104°F)
Storage temperature	-20 to 60° Celsius (-4 to 140°F)
Maximum humidity	10% to 85% non-condensing
Minimum atmospheric pressure	70 kPa
Maximum atmospheric pressure	106 kPa

Table 6. Component Materials for Trial Stimulator Model 4300	
Component	**Material**
EPG	Acrylonitrile butadiene styrene Polycarbonate

Electromagnetic Compatibility Declaration

This section lists the EMC Declaration tables. The EPG is intended for use in the electromagnetic environment specified below. The customer or the user of the EPG should assure that it is used in such an environment. The EPG contains RF transmission and receiving capabilities; consequently, it is possible that other portable and mobile RF communications equipment may interfere with the EPG.

The trial cable (maximum length 213 cm [84 in]) and ground pad (maximum length 200 cm [79 in]) were included in the system testing to demonstrate compliance with the requirements of IEC 60601-1-2 2007. Use of accessories and cables other than those specifically listed may result in increased emissions or decreased immunity of the EPG.

The EPG should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the EPG should be observed to verify normal operation in the configuration in which it will be used.

Table 7. Guidance and manufacturer's declaration – electromagnetic emissions

The EPG is intended for use in the electromagnetic environment specified below. The customer or the user of the EPG should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The EPG uses RF energy primarily for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The EPG is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Table 8. Guidance and manufacturer's declaration – electromagnetic emissions			
The EPG is intended for use in the electromagnetic environment specified below. The customer or the user of the EPG should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV	The EPG is a portable device intended for use in hospital or home environments as well as being carried by ambulatory patients.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable	Not applicable – Battery powered device
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable – Battery powered device
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% UT (>95% dip in U_T) for 5 s	Not applicable	Not applicable – Battery powered device
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Table 9. Guidance and manufacturer's declaration – electromagnetic emissions

The EPG is intended for use in the electromagnetic environment specified below. The customer or the user of the EPG should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the EPG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance Not applicable – Battery powered device $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d= 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EPG is used exceeds the applicable RF compliance level above, the EPG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EPG.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 10. Recommended separation distances between portable and mobile RF communications equipment and the EPG

The EPG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EPG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EPG as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Wireless Information

Table 11. Wireless Specifications and Safety	
Programmer wireless technology operating characteristics	The Clinician Programmer interacts with the EPG using MedRadio Band: 402-405 MHz. The effective radiated power is below the limits as specified in: Europe: EN ETSI 301 839-2 USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219
	The Clinician Programmer interacts with the EPG using 2.45 GHz. The effective radiated power is below the limits as specified in: Europe: EN ETSI 300 328 USA: FCC part 15.24
Stimulator wireless technology	The EPG complies with emissions requirements per R&TTE Standard EN 301 839-2 v13.1 (402MHz to 405MHz).
Wireless integrity	The Algovita SCS System employs mechanisms to ensure integrity of the communication area. The EPG will not respond to any device to which it is not linked.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

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