EndoStim

# Lower Esophageal Sphincter Stimulation System

## Clinician Manual

Revision C

CE 1588

EndoStim® is a registered trademark of EndoStim B.V.

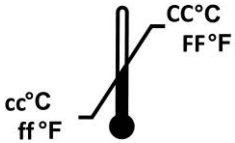
Read all accompanying documentation before using the device.

Manufacturer:

EndoStim B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands

The information contained in this document may be changed without notice.

# Explanation of Symbols on Labels

| SYMBOL | DESCRIPTION |
|---|---|
|  | Manufacturer |
|   | Date of Manufacture |
|   | Conformité Européenne 1588 = Notified Body Number for R&TTE |
|  | Consult instructions for use. |
|  | Do Not Use if Package is Damaged or Opened |
|   | Transport Temperature Limits |
|   | Sterilized with Ethylene Oxide |
|   | Use By |
|  | Do Not Reuse |
|   | Do not resterilize |
|   | Part Number |
|   | Lot Number |

| SYMBOL | DESCRIPTION |
|---|---|
| SN XXXX | Serial Number |
|  | Open Here |
|  | Torque Wrench |
|  | Type B Applied Part |
|  | Caution |
|  | Power Indicator |
|  | Intentional Radiator |
|  | Signal Strength Indicator |
|  | USB Connector |

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# List of Acronyms and Abbreviations

| | |
|---|---|
| BMI | Body Mass Index |
| CISPR | International special committee on Radio Interference |
| IPG | Implantable Pulse Generator |
| MRI | Magnetic Resonance Imaging |
| NMR | Nuclear Resonance Imaging |
| RF | Radio Frequency |
| T2DM | Type 2 Diabetes Mellitus |
| TENS | Transcutaneous Electrical Nerve Stimulation |

# Device Description

## Contents of all Packages

### *Model 1002 EndoStim LES Stimulator Package*

- 1 EndoStim Implantable Pulse Generator
- 1 Torque wrench (Allen-type)
- 1 Set peel-off labels

### *Model 1003 EndoStim Implantable Bipolar Lead Package*

- 1 Implantable bipolar lead
- 2 Silicone stopper discs
- 1 Set of peel-off labels

### *Model 1007 EndoStim LES Programmer System (USB)*

- Model 1504 EndoStim LES Programmer USB Wand
- Model 1505 EndoStim LES Programmer Software

### *Accessories*

- Magnet

# Indications and Contraindications

## Indications

**The EndoStim® Lower Esophageal Sphincter (LES) Stimulation System is intended for the treatment of patients with chronic gastroesophageal reflux disease (GERD) with symptom duration of 6 months or longer that has been shown to be refractory to pharmaceutical treatment.**

## Contraindications

The EndoStim Lower Esophageal Sphincter Stimulation System is contraindicated for individuals with the following conditions or needs:

- Significant cardiac arrhythmia, or ectopy, or significant cardiovascular disease.
- Pregnant or nursing.

The following treatments are contraindicated for patients implanted with the EndoStim device:

- Magnetic Resonance Imaging (MRI) procedure
- Nuclear Magnetic Resonance (NMR) imaging procedure
- Medical diathermy
- Transcutaneous Electrical Nerve Stimulation (TENS) exposure in the abdominal region

## Precautions

The EndoStim Lower Esophageal Sphincter Stimulation System has not been evaluated in the following populations. Patients with the following conditions should be considered prior to implant

- Large (greater than 3 cm) hiatal hernia
- Severe Grade D esophagitis
- Long segment Barrett's esophagus or Barrett's esophagus with dysplasia

- Severe esophageal dysmotility
- Significant uncontrolled autoimmune disorder such as Scleroderma, Dematomyositis, CREST syndrome, Sjogren's Syndrome, or Sharp's Syndrome, that effects esophageal motility
- Severe obesity with a body mass index (BMI) greater than 35 $kg/m^2$
- Type 1 diabetes mellitus
- Uncontrolled type 2 diabetes mellitus (T2DM) defined as HbA1c > 9.5 in the previous 6 months, or has T2DM for more than 10 years
- Suspected or confirmed esophageal or gastric cancer
- Esophageal or gastric varices
- Dysphagia due to severe esophageal peptic structure, excluding Schatzki's ring
- History of any active malignancy
- History of previous esophago-gastric surgery such as laparoscopic fundoplication or an esophageal myotomy
- Other implanted devices
- Younger than 21 years old
- Significant psychiatric disorder that may interfere with therapy

# Potential Adverse Effects/Events

## Implantation of the System

Potential adverse effects/events associated with the implantation of the implantable pulse generator (IPG) and lead include, but are not limited to, the following: death; pulmonary embolism; partial or complete ileus; peritonitis; esophageal perforation by the electrodes; infection; inflammation; injury to organs within the abdominal cavity; intravenous site complications; pneumonia; bleeding; incisional hernia; allergic or abnormal reaction to anesthetic agents; pain; and fever.

## Use of the System

Additional adverse effects that could be associated with the EndoStim System include, but are not limited to, the following: lead/electrode dislodgement; lead erosion or perforation into the esophagus or stomach; IPG migration in the subcutaneous space; IPG erosion through the skin; diaphragmatic stimulation; stimulation of abdominal muscle; irritation and/or inflammatory response to the IPG and/or the lead; allergic reaction to materials; hematoma; infection; dysphagia; odynophagia; cardiac arrhythmia; nausea; and discomfort. LES stimulation ceases when the battery in the IPG is completely discharged.

There is a potential that any system component could malfunction (e.g., software bug), become damaged (e.g., lead fracture), or the patient's incision could become infected. System component malfunction or other clinical circumstances (e.g., sepsis) may require noninvasive corrective actions or possibly even a surgical revision (repositioning, replacement, or removal) of the malfunctioning component(s).

It is recommended to shut the system down if the patient experiences severe sensation or muscle or diaphragm stimulation.

**Notes**:

- If necessary, use the Programmer to adjust the stimulation amplitude to eliminate any pain, discomfort, or sensation that may be related to stimulation. Reducing stimulation amplitude is the only recommended adjustment. After verifying the IPG is functioning as previously programmed, it is recommend reducing stimulation amplitude, incrementally in voltage steps of 0.5mA, until the adverse effect resolves. If such attempts are not successful, it may be necessary to use the Programmer or a magnet to shut down the system.
- A dramatic increase of the lead impedance may indicate a partial or complete lead dislodgement. Patient symptoms should be monitored and, if deteriorating, x-ray or fluoroscopy is recommended to assess the lead and electrode location.

# Warnings and Precautions

## Cremation and Incineration

The IPG contains a sealed chemical power cell (lithium battery). For this reason, never incinerate an IPG. Be sure that the IPG is explanted before a deceased patient is cremated. Contact your local waste management officials for other information about the environmentally safe collection and disposal of the IPG.

## Reuse

The IPG and implanted lead are intended for single use only.

## Environmental Hazards

The following discussion reflects a conservative approach to the issue of patient safety in the presence of potential environmental hazards. Design features in the IPG minimize the potential for such hazards, but they cannot be ruled out completely.

**Notes**:

- Do not use any other electrical equipment adjacent to the EndoStim System. If the components cannot be kept separate, then monitor devices to assure normal operation.
- Portable and mobile RF (radio frequency) equipment can interfere with the normal operation of the EndoStim System. The portable and mobile RF equipment should be considered in any situation where the EndoStim System devices are not acting as expected. Other equipment may interfere with these devices, even if that equipment complies with CISPR emission limits.

As with any medical device system, all the components of the EndoStim System can be affected by magnetic, electrical, and electromagnetic signals of sufficient strength. On rare occasions, interfering signals could inhibit electrical stimulation delivery or, alternatively, trigger inappropriate delivery of electrical stimulation signals. In addition, certain sources can couple sufficient energy into the IPG to damage the circuitry of the IPG and/or LES tissue adjacent to the electrodes. The physician may wish to discuss these risks with the patient.

The susceptibility of a particular unit will also depend on the location of the IPG pocket, the nature of the interference, and the programmed operating parameters.

Because of the diversity of potential causes of electromagnetic interference, EndoStim cannot characterize and describe within this manual the effects of all potential sources of interference.

**Warning**: Advise patients to be cautious when in the vicinity of equipment that generates electrical or magnetic fields and to seek medical advice before entering an area posted with a warning for pacemaker patients (or other medical implantable devices).

## Electrocautery

The surgical use of electrocautery can cause the IPG to become inactive and possibly lose statistical data. Electrocautery may damage the IPG and lead. Application of electrocautery close to an IPG can also cause damage to the LES tissue, possibly producing burns.

If electrocautery is required, apply it in short bursts; position the ground plate on the patient to minimize current flow through the IPG and lead. To reduce the possibility of adverse effects, program the IPG to the OFF mode. Check the IPG for proper operation immediately following the procedure. If the unit is in the DOWN mode, follow the Reset procedure.

## RF Ablation

RF Ablation can cause the IPG to revert to its DOWN mode, with possible loss of statistics data. If sufficient energy is coupled into the system, the unit may be damaged. Application of RF ablation in close proximity to the electrodes of an implanted IPG can also cause a direct coupling of radio-frequency energy through the leads and electrodes to the LES tissue, possibly producing burns.

If RF ablation is necessary, position the ground plate as far from the IPG and lead as possible. Avoid direct contact with the ablation catheter and the IPG and lead. Program the IPG to the OFF mode to reduce the possibility of adverse effects. Check the IPG for proper operation immediately following the procedure. If the unit is found in the DOWN mode, follow the Reset procedure.

## Medical Diathermy

Medical diathermy (short-wave thermal induction) is generally contraindicated for patients implanted with active medical devices. It is unknown how the IPG will operate if subjected to the intense fields of energy. Although damage to either the circuitry of the IPG or LES tissue is improbable, it cannot be ruled out.

If medical diathermy is required, apply it away from the immediate vicinity of the IPG and lead. Programming the IPG to the OFF mode reduces the possibility of adverse effects. Check the IPG for proper operation immediately following the procedure. If the unit is in the DOWN mode, follow the Reset procedure.

**Contraindication:** Patients and physicians should be advised that exposure to medical diathermy is contraindicated in patients implanted with the EndoStim System.

## Defibrillation

Any implanted active medical device can be damaged by cardiac defibrillation procedures. In addition, the defibrillation current can cause damage to LES tissue adjacent to the electrodes and/or to tissue surrounding the IPG. The defibrillation current may also cause the IPG to revert to its DOWN mode, with possible loss of statistics data. If sufficient energy is coupled into the system, the unit may be damaged. If defibrillation is necessary, position the paddles as far away from the implanted system as possible; avoid placing the IPG in the defibrillation current path between the paddles.

Following defibrillation, closely monitor the performance of the IPG. If an operational abnormality is detected, consider repositioning or replacing the lead and/or reprogramming (or replacing) the IPG. If the IPG changes to the DOWN mode, follow the Reset procedure.

## Therapeutic Radiation

Therapeutic equipment that produces ionizing radiation, such as linear accelerators and cobalt machines used in cancer treatment, can damage the type of circuitry used in most active implantable medical devices. Since the effect is cumulative, both dose rate and total radiation dosage determine whether, and to what extent, damage will occur. Please note that any damage to the IPG may not be immediately detected.

In addition, the electromagnetic fields generated by some therapeutic machines as part of the energy “steering” process can affect the operation of the IPG.

The effects of radiation therapy can range from temporary disturbance to permanent damage. Therefore, if such therapy is used, protect the IPG with local radiation shielding, and monitor its performance during and after treatment. If tissue near the implant site must be irradiated, it may be advisable to relocate the IPG.

## MRI and NMR Imaging

A conservative approach recommends that patients implanted with an IPG not be exposed to Nuclear Magnetic Resonance (NMR) Imaging and Magnetic Resonance Imaging (MRI). The EndoStim System has not been tested for safety or operation after exposure to this environment.

**Contraindication:** Patients and physicians should be advised that exposure to Nuclear Magnetic Resonance (NMR) Imaging or Magnetic Resonance Imaging (MRI) is contraindicated when implanted with the EndoStim System.

## Lithotripsy

Direct exposure of an IPG to lithotripsy shock waves can cause damage to the IPG. If the implant site is outside of the shock-wave path, no clear contraindication to the use of lithotripsy can be established.

As a precaution, programming the IPG to the OFF mode reduces the possibility of adverse effects. Check the IPG for proper operation immediately following the procedure. If the unit is found in the DOWN mode, follow the Reset procedure.

## Therapeutic and Diagnostic Ultrasound

Direct exposure of an IPG to diagnostic ultrasound can cause damage to the IPG. The IPG may inadvertently concentrate the ultrasonic field and cause harm to the patient.

Therapeutic ultrasound may be used if the implant site is distant and clearly outside of the ultrasonic field. Programming the IPG to OFF mode reduces the possibility of adverse effects. Check the IPG to assure operation immediately following the procedure. If the unit is found in the DOWN mode, follow the Reset procedure.

## Effects on Other Implanted Devices

The EndoStim system may affect the operation of other implanted devices, such as cardiac devices, other neurostimulators, and implantable drug pumps. Physical proximity may cause sensing problems and inappropriate device responses. Clinicians involved with both devices should evaluate any potential interference problems before surgery.

## Transcutaneous Electrical Nerve Stimulator

Transcutaneous Electrical Nerve Stimulator (TENS) therapy is generally contraindicated for patients who have active implantable medical devices. The high-voltage pulses delivered by TENS units to the body can interfere with the operation of the IPG.

If a TENS device must be used, place the TENS electrodes as far from the IPG and lead as possible. The TENS electrodes should also be placed as close as possible to each other to reduce current spread. The operation of the IPG should be monitored closely during TENS use. As a precaution, programming the IPG to the OFF mode reduces the possibility of adverse effects.

**Contraindication:** Patients and physicians should be advised that exposure to TENS in the abdominal region is contraindicated for patients implanted with the EndoStim System.

## Home Appliances

Home and commercial microwave ovens in good condition, and used as intended, will not affect the IPG. Even a defective oven that exposes the IPG to direct microwave energy may not damage the unit itself. Ovens using electromagnetic induction can cause the device to go into magnet mode (disable stimulation therapy output).

Inform patients about the possibility of interference from some electric razors, electric power tools and electrical ignition systems, including those used on gasoline-powered devices. In general, patients who have an IPG may operate gasoline-powered devices if protective hoods, shrouds, and other shielding remain in place.

## Antitheft Systems

Certain types of antitheft devices, such as those used at entrances/exits of retail stores, libraries and other establishments, can interfere with the IPG. Most commonly, interference may result in electrical stimulation delivery inhibition. Instruct patients to walk at a normal pace and avoid lingering when passing through the entrances and exits of these establishments.

## Industrial Machinery

High voltage power lines, electric arc welders, electric smelting furnaces, and power-generating equipment can interfere with the operation of the IPG. For this reason, the intensities and modulation characteristics of the electromagnetic fields encountered by patients as a result of their occupation and lifestyle should be considered. When appropriate, give specific warnings.

## Radio Transmitters

Communications equipment such as radio and TV transmitters (including amateur "ham" transmitters, microwave transmitters and CB transmitters with high-power linear amplifiers) and radar transmitters can interfere with the operation of the IPG. Discuss this with patients whose occupations may expose them to these electromagnetic fields. When appropriate, give specific warnings.

## Cellular Phones

Cellular and other portable telephones can interfere with the operation of the IPG. Potential effects may result from either the radio frequency emitted by these telephones or the magnet within the phone's speaker. These effects may include inhibition or inappropriate triggering of electrical stimulation delivery when the phone is in close proximity (within 25 cm) to the IPG and the lead.

Advise patients to hold the phone to the ear opposite the side of the implanted IPG. Patients should not carry the phone in a breast pocket or on a belt over or within 25 cm of the implanted IPG because some phones emit signals when they are turned on though not in use.

## Airport Screening Systems

Globally, passenger-screening systems encountered in airports may interfere with the IPG. Most commonly, interference may result in electrical stimulation inhibition. Instruct patients to inform security personnel about the implanted medical device, to show their identification card, and to walk at a normal pace when passing through the portal of these systems. No damage to the implanted system should occur.

## Magnets

Application of a magnet directly over the IPG for at least 2 consecutive seconds, followed by 2 consecutive seconds without a magnet, will terminate therapy for 24 hours.

## General Precaution

The EndoStim System may fail to properly operate for any number of reasons, including but not limited to: random component failure (including the battery), lead failure (including electrical shorts, opens, and insulation faults), and software errors. The frequency of these events cannot be predicted.

# System Overview

This section provides descriptions of all the components for the Model 1008 EndoStim® Lower Esophageal Sphincter Stimulation System. Throughout the instructions in this manual, you may see the terms stimulator and IPG (implantable pulse generator). These terms refer to the same type of device.

The system consists of an IPG, bipolar stimulating lead, and a Programmer.


**Figure 1 EndoStim LES System**

## Implantable Pulse Generator

### *General Description*

The EndoStim implantable pulse generator (IPG) (Figure 2), is an internally powered (lithium battery) device that delivers electrical stimulation pulses to the lower esophageal sphincter (LES). The IPG is hermetically sealed in a titanium case (Figure 2). It delivers electrical pulses to the LES via a bipolar IS-1 BI header connector port (Figure 3) that connects the IPG and lead. The IPG is sterilized with ethylene oxide.


**Figure 2** EndoStim LES Stimulator


**Figure 3** IPG Header Connector

The programmable IPG communicates with the external Programmer via telemetry. Medical and technical personnel use the Programmer to program parameters that control the IPG function. The IPG may be programmed specifically for individual patients by changing the settings parameters within the implanted device. In addition, the Programmer can access performance data that the IPG collects during its normal operation.

### *Handling and Storage*

Do not implant the IPG if the package is damaged or if the IPG has been dropped from a height of 30 cm or more. Return damaged packages to EndoStim B.V.

Store the IPG at a temperature range of 20°C to 25°C and in a dry location. Do not allow the sterile packaging to become damp or wet because sterilization of the contents may be compromised. Exposure to temperatures below 0°C may cause a change in the parameter values of the IPG to the DOWN mode (no output). Once the IPG is removed from the extreme environment, it will either return to the programmed settings, or it will remain in the DOWN mode. In the latter case, follow the Reset procedure. If unsuccessful, the unit should be returned to EndoStim B.V.

### *Re-sterilization and Re-Use*

The IPG and torque wrench are single-use devices. Do not re-sterilize the IPG or torque wrench. Do not re-use an explanted IPG: the device must not be used for implantation in another patient.

### *X-Ray Identification*

A radiopaque marker placed within the IPG allows the model number and year of manufacture to be identified by normal X-ray techniques. The manufacturer's identification code for EndoStim is E, the code for the EndoStim IPG model is A, and the code for the year of manufacture is XX, where XX is replaced by the last two digits of the calendar year in which the device was manufactured.

## Implantable Bipolar Stimulating Lead

### *General Description*

The EndoStim lead, called the Implantable Bipolar Stimulating Lead, is used in conjunction with the IPG. The lead has an IS-1-BI connector[1] at the proximal end for attachment to the IPG (Figure 4). The lead is sterilized with ethylene oxide.

The lead delivers stimulation pulses to the tissue through stitch electrodes at the distal end. During implantation, the stitch electrodes of the leads are sutured into the LES and secured into place. The electrodes of the bipolar lead are implanted in the sero-muscular layer of the LES (Figure 5).

**Figure 4** EndoStim Lead and IPG

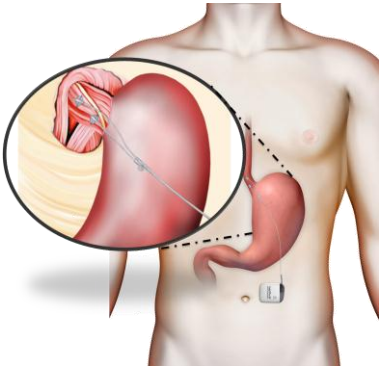

**Figure 5** Implanted EndoStim Lead and IPG

[1] Implants for Surgery – Cardiac Pacemakers – Part 3: Low-profile connectors [IS-1] for implantable pacemakers, ISO 5841-3:2000(E)

| | |
|---|---|

### *Physical Characteristics*

The implantable lead is constructed of biocompatible materials: an inner and outer silicone rubber sheathing, cobalt/nickel conductors, and platinum-iridium stitch electrodes. A curved stainless steel suture needle is affixed to the end of each stitch electrode. The lead is 45 cm in length from the IS-1-BI connector tip to the end of the platinum-iridium electrodes. The lead bifurcates after 35 cm into individual, unipolar leads, with the length of each unipolar lead being 10 cm.

### *Handling and Storage*

Do not implant the lead if the package is damaged or if the lead has been dropped from a height of 30 cm or more. Return damaged packages to EndoStim, B.V.

Store the lead at a temperature range of 20°C to 25°C and in a dry location. Do not allow the packaging to become damp or wet because sterilization of the contents may be compromised.

### *Re-Sterilization and Re-Use*

The lead is a single-use device. Do not re-sterilize the lead or silicone stoppers. Do not re-use an explanted lead; the device must not be used for implantation in another patient.

## Programmer

### *General Description*

Use the EndoStim LES System Programmer to interrogate and program the IPG. The Programmer software runs on an IEC60950 certified laptop personal computer (PC), which runs on battery power. Communication between the Programmer and the IPG is accomplished with the Programmer placed directly over the implant site. The Programmer communicates via magnetic induction telemetry with the IPG implanted in the patient.

**Note**: Avoid skin contact between the patient's skin and the Programmer Wand, when possible, to avoid any potential cross-contamination from previous use of the Programmer.

The Programmer can

- Read (interrogate) IPG parameters as currently programmed
- Modify IPG parameters
- Retrieve statistics accumulated by the IPG as it operates
- Log the activity of the IPG
- Store standard programs for future use

The Programmer has 2 components (Figure 6):

- Programmer Wand
- Programmer Software

**Figure 6** EndoStim LES System Programmer

### *Electrical Characteristics*

The Programmer is internally-powered Type B equipment that is suitable for continuous use. The Programmer is considered an applied part and the Programmer laptop is considered out of the patient environment (at least 1.5 meters from the patient).

### *Loading the Software*

You must install the Programmer software on an IEC60950 certified laptop that has Microsoft® Windows® 7. The minimum functional requirements of the computer are the same as those required for Microsoft Windows 7. The computer must support a screen resolution of 1024 x 768. Follow these steps to install the software:

1. Close all open applications.
2. Insert the CD into the CD or DVD drive.
3. Wait for the computer to recognize the CD and open a folder.
4. Double-click the icon EndoStim Neurostimulator Setup Win7.
5. Click "Yes" if prompted to allow software access.
6. The computer restarts immediately.
7. At the "Setup Welcome" screen, click "Next."
8. At the "Choose User" screen, choose the appropriate user(s).
9. At the "Choose Components" screen, ensure that all boxes are checked.
10. At the "Choose Install Location" screen, choose the desired location for the software to install.
11. At the "Insert Application Password" screen, type the password you want to use in both locations; then click "Accept."
12. At the "Installation Complete" screen, click "Next."
13. At the "Completion" screen, click "Finish."

### *Powering the Programmer*

The Programmer is powered from the USB port of the laptop (5V, 0.5A). Connecting the laptop to Mains is not allowed while the Programmer is connected. Operate the Programmer using only the laptop computer battery. Use the AC connection only when recharging the laptop, and ensure that the USB cable is disconnected from the laptop.

If the laptop is connected to Mains, the Programmer software disables power to all computer USB ports and provides a popup warning (Figure 7). The popup warning message terminates once the laptop is disconnected from the Mains and you press “Retry. The Programmer shuts down if you press “Close.”

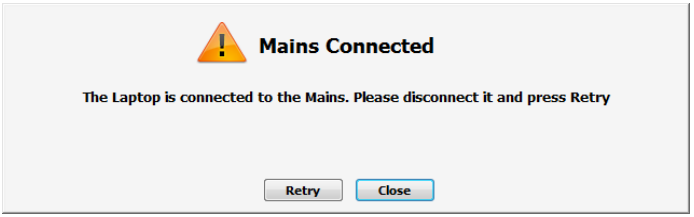


**Figure 7** Programmer Connection to Mains Warning

**Notes**:

- When recharging the laptop, connect the laptop charger to the Mains per labeling on the laptop charger.
- It is recommended that you routinely charge the battery of the laptop between uses.

## Connect the Programmer

Connect the USB end of the Programmer to the USB port of the laptop computer.

**Note**: The Programmer should only be connected to the USB port of an IEC60950 certified laptop that runs on battery power only.

## Maintenance

The Programmer Wand does not contain any user serviceable parts. If any Programmer Wand parts become damaged or loose, or it does not function properly, return the Programmer Wand to EndoStim B.V.

After each use, it is recommended that you disconnect the Programmer Wand from the USB port of the laptop computer. To clean the Programmer, use a soft cloth dampened with distilled water, methanol, or isopropyl alcohol to wipe the exterior case of the Programming Wand. Do not use solvents or cleaning cloths infused with chemical cleaning agents.

**Warnings**:

- The Programmer is not protected against the ingress of water (IXP0). Avoid immersing the Programmer in any fluids.
- Do not use the Programmer in the presence of flammable anesthetics.
- Do not sterilize the Programmer.
- Do not connect any other equipment to the Programmer.
- Do not modify the Programmer in any way.

## Handling and Storage

Do not use the Programmer if the package is damaged or if the Programmer has been dropped from a height of 1 meter or more. Return damaged packages to EndoStim B.V.

The Programmer environmental conditions are found in Table 1.

**Table 1 Environmental Conditions for the Programmer**

| Condition | Shipping | Operating and Storage |
|---|---|---|
| Temperature | -20-70 ºC (-4-158 ºF) | 5-37 ºC (41-104 ºF) |
| Humidity | 15-93 % non-condensing | 15-93 % non-condensing |
| Atmospheric Pressure | 54.0-101.3 kPa (7.8-14.7 psi) | 54.0-101.3 kPa (7.8-14.7 psi) |
| Altitude | 0-5000 m (0-16,404 ft) | 0-5000 m (0-16,404 ft) |

Environmental conditions for the laptop may be different than the Programmer. Check laptop user manual for laptop environmental ranges and assume worst case condition.

## Service Life and Disposal

The life of service is expected to be 5 years. The Programmer should be returned to EndoStim B.V. when disposal is required.

### *Environment of Use and Operator Profile*

The operators of the Programmer include physicians in charge of either implanting or monitoring an IPG, and trained medical personnel who assist physicians. Operators will be familiar with operation of electronic medical equipment, particularly IPGs, and programmers and / or the operators will have been trained on the operation of the EndoStim Programmer.

The Programmer is used in an operating room where the IPG is being implanted. When in the operating room, the Programmer should be brought into the sterile field through a sterile sleeve while the laptop remains outside the sterile field. The surgeon should place the Programmer over the IPG while an appropriate person outside the sterile field operates the Programmer.

The Programmer is also used in a clinical room where patients with an implanted IPG are monitored. When in the clinic, the clinician should place the Programmer over the IPG and have either an assistant or the patient hold the Programmer in place. The patient can sit or lie down. The laptop should be outside the patient environment, at least 1.5 meters away, and operated by the clinician.

To be compliant with electromagnetic compatibility requirements (interference characteristics), the Programmer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, verify that the Programmer functions properly. It is recommended to have an additional Programmer present at each implant and clinic visit.

# Instructions for Use: Program an IPG

## Launch the Software

Double-click the EndoStim icon on the desktop to launch the Programmer software. The password screen appears (Figure 8).

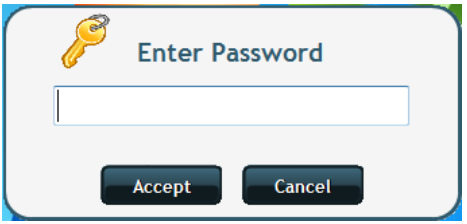


**Figure 8** EndoStim Programmer Password Screen

Enter the password and press "Accept" or press Enter. The Programmer Main Screen appears (Figure 9).

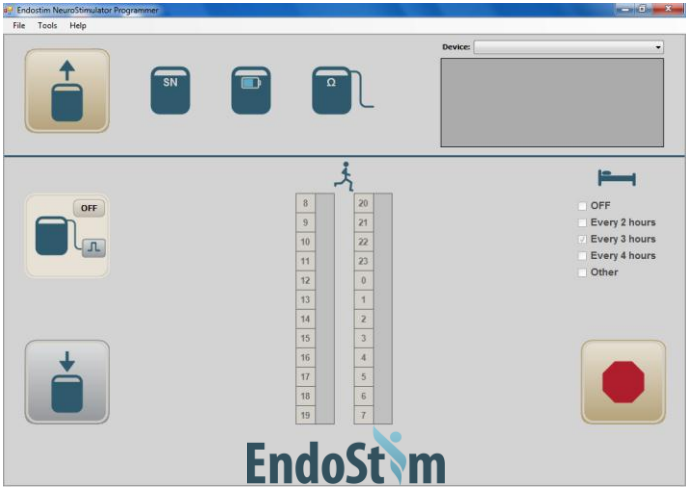


**Figure 9** EndoStim Programmer Main Screen

The screen is divided into two sections, Information and Programming.

- Information — The top section (above the solid horizontal line) contains icons for retrieving and displaying device information. These are labeled below:

| ICON | DESCRIPTION |
|---|---|
|  | Interrogate<br>Click on this icon to interrogate the IPG. |
|  | Serial Number<br>The serial number of the IPG is displayed here. |
|  | Battery Voltage<br>The battery voltage of the IPG is displayed here. |
|  | Lead Impedance<br>The lead impedance is displayed here. |

- Programming — The lower section (below the solid horizontal line) contains icons for programming the device parameters. These are labeled below:

| ICON | DESCRIPTION |
|---|---|
|   | Stimulation Amplitude and Polarity<br>Click on the top button of this icon   to program the stimulation amplitude. Click on the lower icon  to reverse polarity. |
|  | Program<br>Click on this icon to program the IPG. |
|  | Urgent Programming<br>The battery voltage of the IPG is displayed here. |
|  | Stimulation Session Timing – Awake<br>Click on the time icons below this icon to schedule stimulation sessions while the patient is awake. |
|  | Stimulation Session Timing – Asleep<br>Click on the options below this icon to schedule stimulation therapy while the patient is sleeping. |

**NOTE:** The Programmer automatically disables certain parameters and icons based upon values of other parameters or states of other icons. For an icon example, the *Program* icon will not be active unless a parameter was changed. For a parameter example, the *Stimulation Session Timing – Awake* will not allow for programming two stimulation sessions immediately adjacent to each other (see Figure 14 below).

## Initiate a Programming Session

To initiate a programming session, place the Programming Wand over the IPG. Red and green LED lights indicate 2 types of communication:

- Communication — At least one of the Signal Strength LEDs blinks about once per second.
- Stronger communication — Green LEDs at the top blink
- Weaker communication — Red LEDs at the bottom blink.

Press the Interrogate icon  at the far left of the Information section. The remaining 3 icons in the Information section of the Programmer screen should be filled in with appropriate values as shown in Figure 10.

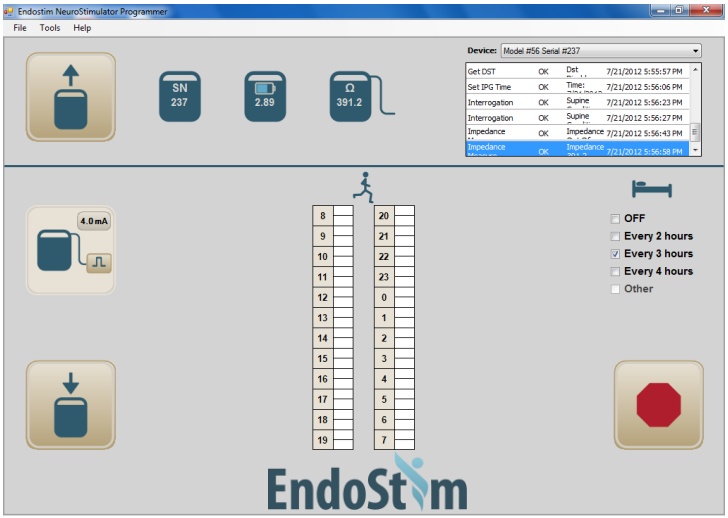


**Figure 10** Information on the Main Screen

## Program IPG Time

Select the pull-down menu *Tools→Time* . The Time dialog window opens (Figure 11 ).

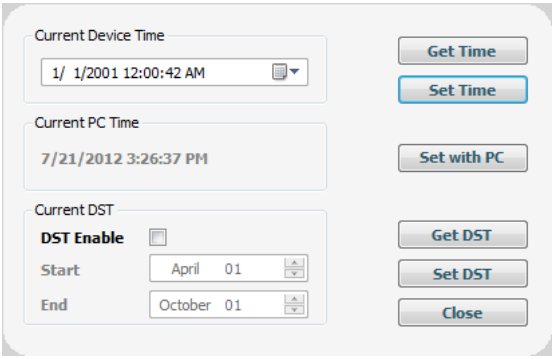


**Figure 11 EndoStim Programmer Time Dialog**

1. Verify that the *System Current Time* matches the PC time.
2. Select *Get Time*. The message *Get Time OK* appears.
3. Select Set With PC Time.
4. If Daylight Savings Time is required, select *DST Enable* and the *Start* date and *Stop* date.
5. Select *Close*.

**Note**: It is important to ensure that the time of day is always the same between the IPG and the Programmer. If the time, or clock, is not synchronized, the patient may receive therapy that is off-schedule. For example, if there is a difference of 1 hour between the IPG and Programmer, the patient may receive therapy during a meal.

## Measure Lead Impedance

To measure lead impedance, select the pull-down menu *Tools→Impedance Measure*. There will be a slight delay while the impedance is being measured, and the impedance will be displayed in the Lead Impedance icon  . If the impedance is too high or too low, the text *Out of Range* appears in the icon. Significant shifts in lead impedance that are not out of range may require adjustments in stimulation amplitude to accommodate for the changes.

## Access IPG Statistics

1. To access the IPG statistics, select the pull-down menu *Tools→Read Statistics* . The Statistics window opens (Figure 12).

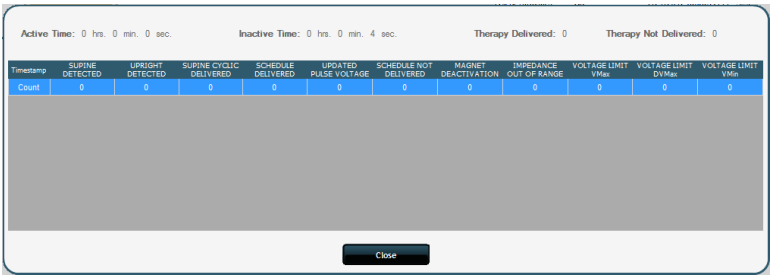


**Figure 12** EndoStim Programmer Statistics Window

2. The statistics window displays the timestamp and total number of stimulation therapy sessions delivered and those not delivered.

3. To reset the statistics, select the pull-down menu *Tools→Clear Statistics* .

## Program Stimulation Amplitude and Polarity

1. Select the upper icon 

inside Stimulation Amplitude and Polarity icon  . This will provide a popup menu of stimulation amplitude options (Figure 13).


**Figure 13** Stimulation Amplitude Options

Select amplitude from the menu and click the Program icon  .

2. Select the lower icon  inside Stimulation Amplitude and Polarity icon  . This icon inverts  and changes the polarity of stimulation between the electrodes. Click the Program icon  .

## Program Stimulation Session Times while Patient is Awake

1. Click on the desired stimulation time boxes for the patient. The boxes fill, followed by an "X" in boxes below indicating that therapy is not possible at those times (Figure 14, abbreviated).
2. Click on the Program icon  .

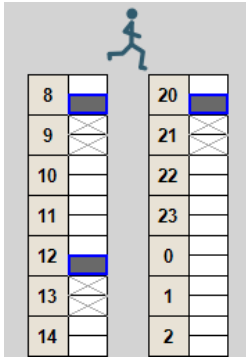


**Figure 14** Stimulation Session Times while Patient is Awake, Example is for stimulation sessions at 08:30, 12:30, and 20:30

## Program Stimulation Session Times while Patient is Asleep

The IPG includes a sensor that detects when the patient is sleeping. A repeating stimulation session can be programmed while the patient is sleeping. This therapy will automatically terminate when the IPG detects that the patient is awake and upright. To enable stimulation sessions when the patient is asleep, click on the desired frequency of stimulation sessions (Figure 15). If no therapy is required for when the patient is asleep, then click "OFF." Click on the Program icon .

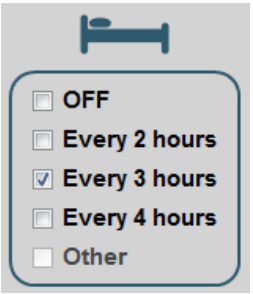


**Figure 15** Stimulation Session Times while Patient is Asleep, Example is for stimulation sessions once every 3 hours starting when patient goes to sleep

## Calibrate Posture Sensor

With the patient standing upright and not moving, select the pull-down menu *Tools→Set Stand Vector*. This calibrates the sensor to the upright position.

## Advanced Parameters

If more therapy flexibility is required, more options can be found by selecting the pull-down menu *Tools→Advanced* (Figure 16).


**Figure 16** Advanced Stimulation Parameters

## Advanced Timing Parameters

- Dose Time — This sets the duration of the stimulation session. It is recommended to set this to 30 minutes.
- Block Time — This sets the duration of time after a stimulation session where another stimulation session cannot occur for any reason. It is recommended to set this to 60 minutes.
- Active Time — This sets the duration of the stimulation session. It is recommended to set this to 30 minutes.
- Inactive Time — This sets the duration of the time between consecutive stimulation sessions.

## Advanced Stimulation Parameters

- Pulse Width —This sets the width of the stimulation pulse. It is recommended to set this to 215 μsec.
- Frequency: This sets the rate (or frequency) at which the pulses are delivered. It is recommended to set this to 20 Hz (e.g., 20 pulses per second).

Impedance Tracker: When enabled, this automatically adjusts the stimulation voltage to accommodate changes in lead impedance. This ensures the programmed current is delivered independent of lead impedance. Parameters Max Volt, Min Volt, and Max Δ Volt place boundaries on the amount that changing lead impedance can change stimulation voltage. Click on the

“Recommended” icons to use suggested parameters.

## Advanced Sensing Parameters

- Supine Time — This is the amount of time the patient must maintain the Supine Level and be still. It is recommended to set this to 30 minutes.
- Supine Level — This is the angle, in degrees, that the patient must be to detect a supine position. Patient standing (vertical) is considered 0˚ and lying down (horizontal) is 90˚. It is recommended to set this to 70˚.
- Minute % — This is the percentage of 1 minute segments, within the Supine Time, that the patient remains still and in the Supine Level. It is recommended to set this to 90%.
- Supine Time % — This is the percentage of time, within 1minute, that the patient remains still and in the Supine Level. It is recommended to set this to 90%.

### Terminate Stimulation

To stop stimulation, program the amplitude to OFF on the amplitude icon  , and then select the Program button.

You can also use the *Urgent Programming* icon  to stop stimulation at any time.

### Reset the IPG

To reset the IPG, select the pull-down menu.*Tools→Reset IPG*

### Shut Down the Programmer

To turn off the Programmer:

- Click on the X at the top right of the screen OR select the pull-down menu *File→Exit*.
- Disconnect the USB cable from the computer.
- Turn the computer off.

## Implant the EndoStim System

Laparoscopic surgery is generally used for the implantation of the EndoStim System. An open, bariatric surgical approach may also be appropriate for some patients. Minimal use of narcotics is recommended. Follow standard sterile technique and adhere to standard operating room procedures.

**Warning:** The implanting physician is required to undergo formal training by an EndoStim expert representative prior to implanting the system in humans.

# System Specifications

This section contains specifications and characteristics for all the devices included in the LES system: IPG, Bipolar lead, and Programmer.

## IPG Specifications

**Table 2 Implantable Pulse Generator Specifications**

| Description | Value |
|---|---|
| Height | 65 mm |
| Width | 48 mm |
| Thickness | 12 mm |
| Mass | 50 g |
| Biocompatible materials in contact with human tissue | Titanium<br>Epoxy resin<br>Silicone rubber set plugs |
| Power source | Lithium carbon monoflouride battery |
| Storage temperature | 20°C to 25°C |

## IPG Battery Characteristics and Specifications

The battery voltage at beginning of life is approximately 3.3V and the usable capacity is 2.5 Ah. When battery voltage falls below 2.5V, the device sends information to the Programmer, upon interrogation, that the battery is near the end of life. In addition, stimulation amplitude will be reduced if programmed at greater than 3 times the battery voltage. When battery voltage falls below 2.3V, the device will turn off all stimulation outputs. When the battery voltage falls below 2.1V, communication with the Programmer will no longer be possible.

The longevity of the battery can be estimated based on the different stimulating parameters applied, as described in Table 3.

**Table 3 Estimated IPG Battery Longevity**

| Parameter | Condition 1 | Condition 2 | Condition 3 | Condition 4[d] |
|---|---|---|---|---|
| Pulse Width[a] | 215 μsec | 215 μsec | 215 μsec | 215 μsec |
| Pulse Frequency[a] | 20 Hz | 20 Hz | 20 Hz | 20Hz |
| Pulse Amplitude[b] | 2.0 V | 2.0 V | 1.6 V | 7.5V |
| Hours per Day | 2.5 | 5.0 | 2.5 | 24 |
| Lead Impedance | 400Ω | 400Ω | 200Ω | 750Ω |
| Estimated Life[c] | 13.8 years | 11.2 years | 12.6 years | 1.5 years |

[a] This is the recommended value
[b] Recommended to never exceed 0.01*(Lead Impedance)
[c] This assumes a 12 month shelf life prior to implant
[d] Recommended to never program continuous stimulation (24 hours) outside the clinic environment

## Lead Characteristics and Specifications

**Table 4 Lead Physical Description and Materials**

| Lead | Specification |
|---|---|
| Connector | IS-1 BI |
| Length | 45 cm |
| Mass | 4 g |
| Electrodes | Platinum-iridium |
| Bifurcation | At 35 cm, lead has two 10cm unipolar segments |

## Programmer Specifications

**Table 5 Programmer Specifications**

| Description | Value |
|---|---|
| Height | 140 mm |
| Width | 62.7 mm |
| Thickness | 30.5 mm |
| Mass | 251 g |
| Storage temperature | 5°C to 37°C |

## Safety Shutdown with a Magnet

Therapy signal delivery of the IPG can be shut down for 24 hours if it is exposed to a magnetic field. A standard pacemaker safety magnet can be used.

## Electromagnetic Interference

The center frequency of the EndoStim Programmer transmitter (to the EndoStim IPG) is 20 kHz with a bandwidth of 18 kHz to 22 kHz.

The center frequency of the EndoStim Programmer receiver (from the EndoStim IPG) is 10 kHz to 28 kHz.

## Electromagnetic Emissions

### *Guidance and manufacturer's declaration – electromagnetic emissions*

The EndoStim IPG and Programmer is intended for use in the electromagnetic environment specified in Table 6. The customer or user of the EndoStim IPG and Programmer should assure that it is used in such an environment.

**Table 6 Electromagnetic Emissions**

| The EndoStim IPG and Programmer are intended for use in the electromagnetic environment specified below. The customer or user of EndoStim IPG and Programmer should assure that it is used in such an environment. | | |
|---|---|---|
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The EndoStim IPG and Programmer use RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The EndoStim IPG and Programmer are suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage supply network that supply buildings used for domestic purposes. |
| Harmonic Emissions IEC 61000-3-2 | Not Applicable | |
| Voltage Fluctuations/Flicker Emissions IEC 61000-3-2 | | |

## ESD and Power Fluctuations

### *Guidance and manufacturer's declaration – electromagnetic immunity*

The EndoStim Programmer is intended for use in the electromagnetic environment specified in Table 7. The customer or user of the EndoStim Programmer should assure that it is used in such an environment.

**Table 7 ESS and Power Fluctuations: Electromagnetic Immunity**

| Immunity test | IEC 60601 Test level | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst<br><br>IEC 61000-4-4 | Not Applicable | Not Applicable | Mains power should only be used to recharge the laptop computer battery while the unit is powered off. |
| Surge<br><br>IEC 61000-4-5 | Not Applicable | Not Applicable | Mains power should only be used to recharge the laptop computer battery while the unit is powered off. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | Not Applicable | Not Applicable | Mains power should only be used to recharge the laptop computer battery while the unit is powered off. |
| Power frequency<br><br>(50/60 Hz)<br><br>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 residential environment. |

## Radiated Electromagnetic Fields

### *Guidance and manufacturer's declaration – electromagnetic immunity*

The EndoStim Programmer is intended for use in the radiated electromagnetic fields specified in Table 8. The customer or user of the EndoStim Programmer should assure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to any part of the EndoStim Programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

**Table 8 Radiated Electromagnetic Fields: Electromagnetic Immunity**

| Immunity test | IEC 60601Test level | Compliance level | Recommended Separation Distance |
|---|---|---|---|
| Conducted RF, IEC 61000-4-6, 150 kHz to 80 MHz outside ISM bands | 3 Vrms | 3Vrms | $d = 1.17\sqrt{P}$ |
| Conducted RF, IEC 61000-4-6, 150 kHz to 80 MHz inside ISM bands | 3 Vrms | 3Vrms | $d = 1.20\sqrt{P}$ |
| Radiated RF, IEC 61000-4-3, 80 MHz to 800 MHz | 3 V/m | 3 V/m | $d = 1.20\sqrt{P}$ |
| Radiated RF, IEC 61000-4-3, 800 MHz to 2.5 GHz | 3 V/m | 3 V/m | $d = 2.30\sqrt{P}$ |

**Notes**:

- P is the maximum output power 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 radio frequency (RF) transmitter, 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 ionizing radiation symbol:

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

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 EndoStim Programmer is used exceeds the applicable RF compliance level above, the EndoStim Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the EndoStim Programmer.

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

## Recommended Separation Distances

### *Recommended separation distances between portable and mobile RF communications equipment and the EndoStim Programmer*

The EndoStim Programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled (**Table 9**). The customer or user of the EndoStim Programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EndoStim Programmer as recommended (according to the maximum output power of the communications equipment).

**Table 9 Recommended Separation Distances Between RF Equipment and EndoStim Programmer**

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 117\sqrt{P}$ | 80 MHz to 800 MHz $d = 0.35\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 0.70\sqrt{P}$ |
| 0.01 | 0.12 | 0.04 | 0.07 |
| 0.1 | 0.37 | 0.11 | 0.22 |
| 1 | 1.17 | 0.35 | 0.7 |
| 10 | 3.7 | 1.11 | 2.22 |
| 100 | 11.7 | 3.5 | 7.0 |

**Notes:**

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated by 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.

- At 80 MHz and 800 MHz, the higher frequency range applies.

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

## Range and Tolerance of Displayed Values

| **IPG and Lead Parameters** | | | |
|---|---|---|---|
| **Parameter** | **Range** | **Increment** | **Tolerance** |
| Serial | 0001 to 9999 | 1 | N/A |
| Battery | 2.10 to 3.10 (V) | 0.01V | 0.05V |
| Impedance | 200 to 2000 (Ω) | 1 Ω | Max of 100Ω and 20% |
| **Stimulation Parameters** | | | |
| **Parameter** | **Range** | **Increment** | **Tolerance** |
| Pulse Width | 30 to 975 (μsec) | 30μsec | Max of 5% and 15μsec |
| Pulse Amplitude | 2.0 to 10.0 (mA) | 0.5mA | Max of 0.5mA and 20% |
| Pulse Rate | 2 to 80 (Hz) | 2-10Hz: 1Hz<br>10-40Hz: 2Hz<br>40-80Hz: 5Hz | Max of 1% and 100μsec |
| Active Time | 00:00:01 to 23:59:59 | 1sec | 2sec |
| Inactive Time | 00:00:01 to 23:59:59 | 1sec | 2sec |
| Duty Cycle | 1 to 99 (%) | 1% | 1% |
| **Dose Mode Parameters** | | | |
| **Parameter** | **Range** | **Increment** | **Tolerance** |
| Dose Time | 00:00:01 to 23:59:59 | 1sec | 2 sec |
| Block Time | 0.5 to 4.0 (hr) | 0.5hr | 2 sec |
| Dose Schedule | 00:00 to 23:30 | 30min | 2 min |
| **Sensing Parameters** | | | |
| **Parameter** | **Range** | **Increment** | **Tolerance** |
| Supine Time | 1, 5, 30, or 60 (min) | N/A | 1 min |
| Supine Level | 50 to 80 (˚) | 10˚ | 10˚ |

| | | | |
|---|---|---|---|
| Minute % | 70, 80, 90, or 95 (%) | N/A | 1% |
| Supine Time % | 70, 80, 90, or 95 (%) | N/A | 1% |

## Service and Warranty

EndoStim provides emergency device consultation on a 24-hour basis. If you require emergency assistance, please contact the following number +1-866-510-1003.

EndoStim warrants that all IPGs and accessories (including associated firmware and software) will be free from defects in workmanship and materials for a period of 12 months after the original implantation of the IPG (the "Warranty Period").

If it appears that an IPG contains a defect in workmanship or materials, or fails to conform to applicable specifications, EndoStim will replace the defective or non-conforming components free of charge. The Warranty Period for a replaced component shall be the longer of the time remaining on the original Warranty Period or nine months from delivery of the replaced item.

If a system component completely fails to function within the first 72 hours of operation, EndoStim will replace the failed item with a new one.

EndoStim shall not be liable under this warranty if testing and examination discloses that the alleged defect or non-conformity in the system component does not exist or was caused by the end user's misuse, neglect, improper implantation or testing, unauthorized attempts to repair, or by accident, fire, lightning or other hazard.

EndoStim B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands
+1-866-510-1003
Internet: www.endostim.com

Part Number CM-05 Rev. C
Australia