Lower Esophageal Sphincter Stimulation System

Clinician Manual

Revision D

(With EndoStim II LES Stimulator Model 1006)

CE 0344

Year of Authorization: 2013

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

Read all accompanying documentation before using the device.

Manufacturer:

EndoStim B.V.
Toernooiveld 300
6525 EC, Nijmegen
The Netherlands
+31 (0)243 50 1331
Internet: www.endostim.com

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

No part of this manual may be reproduced or transmitted in any way or by any means, either electronic or mechanical, for any purpose without the express written consent of EndoStim B.V.

Explanation of Symbols on Labels

SYMBOL	DESCRIPTION
	Manufacturer
YYYY-MM	Date of Manufacture
CE 0344	Affixed in compliance with European directives 0344 = Notified Body Number for Directive 90/385/EEC
	Consult instructions for use.
	Do Not Use if Package is Damaged or Opened
CC°C FF°F cc°C ff°F	Transport Temperature Limits
STERILE EO	Sterilized with Ethylene Oxide
YYYY-MM-DD	Use By
	Do Not Reuse
STERILIZE	Do not resterilize
REF XXXX	Part Number

SYMBOL	DESCRIPTION
LOT XXXX	Lot Number
SN XXXX	Serial Number
	Open Here
	Torque Wrench
	Type B Applied Part
	Caution
	Power Indicator
	Intentional Radiator
	Signal Strength Indicator
	USB Connector
MR	MR Conditional
MR	MR Unsafe

TABLE OF CONTENTS

Explanation of Symbols on Labels i

TABLE OF CONTENTS iii

List of Acronyms and Abbreviations v

Device Description 1
- Contents of all Packages 1

Indications and Contraindications 3
- Indications 3
- Contraindication 3
- Precautions 3

Potential Adverse Effects/Events 4
- Implantation of the System 4
- Use of the System 5

Warnings and Precautions 6
- Cremation and Incineration 6
- Reuse 6
- Environmental Hazards 6
- Electrocautery 7
- RF Ablation 8
- Medical Diathermy 8
- Defibrillation 9
- Therapeutic Radiation 9
- Magnetic Resonance Imaging (MRI) 10
- Lithotripsy 10
- Therapeutic and Diagnostic Ultrasound 10
- Effects on Other Implanted Devices 11
- Transcutaneous Electrical Nerve Stimulator 11
- Home Appliances 11
- Antitheft Systems 12
- Industrial Machinery 12
- Radio Transmitters 12
- Cellular Phones 13
- Airport Screening Systems 13
- Magnets 13

General Precaution 13

System Overview.....14
Implantable Pulse Generator.....14
Implantable Bipolar Stimulating Lead 17
Programmer 18
Maintenance 20
Handling and Storage.....20
Service Life and Disposal 21

Implant the EndoStim System.....22

MRI Information for the EndoStim System.....22
Potential Interactions with the EndoStim System.....34
Warnings and Precautions.....35
Preparing the Patient prior to MRI Procedure 40
Beginning of the MRI Procedure 41
During the MRI Procedure.....41
After the MRI Procedure 42

System Specifications 43
IPG Specifications 43
IPG Battery Characteristics and Specifications.....43
Lead Characteristics and Specifications.....44
Programmer Specifications.....45
Safety Shutdown with a Magnet.....45
Electromagnetic Interference 45
Electromagnetic Emissions 46
ESD and Power Fluctuations.....47
Radiated Electromagnetic Fields.....48
Recommended Separation Distances.....50
Range and Tolerance of Displayed Values 51
Service and Warranty.....51

List of Acronyms and Abbreviations

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

Device Description

Contents of all Packages

Model 1003 EndoStim Lead Package

- 1 Model 1003 EndoStim Implantable Bipolar Stimulating Lead (45 cm)
- 1 Set of peel-off labels for Lead

Model 1006 EndoStim LES Stimulator Package

- 1 Model 1006 EndoStim II Implantable Pulse Generator
- 1 Torque wrench (Allen-type)
- 1 Set peel-off labels for IPG

Model 1011 EndoStim LES Stimulator and Lead Package

- 1 Model 1006 EndoStim II Implantable Pulse Generator
- 1 Model 1003 EndoStim Implantable Bipolar Stimulating Lead (45 cm)
- 1 Torque wrench (Allen-type)
- 1 Set peel-off labels for IPG
- 1 Set of peel-off labels for Lead

Model 1012 EndoStim LES Programmer System

- 1 Model 1504 EndoStim LES Programmer USB Wand
- 1 Model 1522 Tablet PC with EndoStim LES Programmer Software

Model 1015 EndoStim Lead Package

- 1 Model 1015 EndoStim Implantable Bipolar Stimulating Lead (61 cm)
- 1 Set of peel-off labels for Lead

Model 1016 EndoStim LES Stimulator and Lead Package

- 1 Model 1006 EndoStim II Implantable Pulse Generator
- 1 Model 1015 EndoStim Implantable Bipolar Stimulating

Lead (61 cm)

- 1 Torque wrench (Allen-type)
- 1 Set peel-off labels for IPG
- Set of peel-off labels for Lead Accessories
- Standard pulse generator and lead accessories – magnet, lead cap, lead extenders, torque wrench

Indications and Contraindications

Indications

The EndoStim LES Stimulation System is intended for the treatment of patients with chronic Gastroesophageal Reflux Disease (GERD) with symptom duration of 6 months or longer.

Contraindication

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:

- 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 that has not been repaired
- Severe Grade D esophagitis
- Long segment Barrett's esophagus or Barrett's esophagus with dysplasia
- Significant uncontrolled autoimmune disorder such as Scleroderma, Dematomyositis, CREST syndrome, Sjogren's Syndrome, or Sharp's Syndrome, that affects esophageal motility

- Severe obesity that in the opinion of the surgeon increases the risk of a laparoscopic implant procedure
- 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 advanced malignancy
- History of previous surgery such that directly involves the lower esophageal sphincter or the EndoStim electrode implant site, e.g., fundoplication or an esophageal myotomy
- Other implanted electro-medical devices
- Younger than 21 years old

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.

Dropping and Damage

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.

Do not implant the Lead if the package is damaged or if the IPG has been dropped from a height of 30 cm or more.

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

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.

Magnetic Resonance Imaging (MRI)

The EndoStim System is MR conditional and highly specific conditions must be followed to ensure patient safety. This ONLY applies to

- 3-Tesla/128-MHz MR systems using a transmit/receive RF body coil or local coil
- 1.5-Tesla/64-MHz MR systems using a transmit/receive RF local coil (e.g., head coil).

Other conditions must be followed to ensure patient safety. Failure to carefully follow all labeling conditions may result in serious patient injury and/or damage to 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 pacemakers, implantable cardioverter defibrillators (ICDs), other neurostimulation systems, and implantable drug infusion 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 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 II 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. 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 II 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 II IPG model is B, 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

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 leads are 45 cm/61 cm in length from the IS-1-BI connector tip to the end of the platinum-iridium electrodes. The lead bifurcates after 35 cm/51 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 tablet 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 Tablet PC with 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 tablet PC is considered out of the patient environment (at least 1.5 meters from the patient).

The Programmer can communicate to the IPG at a maximum distance of 5.0 cm.

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 tablet PC. To clean the Programmer, use a soft cloth dampened with distilled water, methanol, or isopropyl alcohol to wipe the exterior case of the Programmer 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 tablet PC may be different than the Programmer. Check tablet PC user manual for tablet PC 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 tablet PC 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 tablet PC 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.

Implant the EndoStim System

Laparoscopic surgery is generally used for the implantation of the EndoStim System. An open surgical approach may be appropriate for some patients, such as those having bariatric surgery. 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.

Recommended Operating Room Equipment for Laparoscopic Procedure

At a minimum, to perform the laparoscopic procedure, have the following sterile instruments ready:

- Laparoscopic tower (30°/0° optical probe)
- Endoscopic equipment
- Needle holder (laparoscopic)
- Laparoscopic graspers and dissectors
- Laparoscopic scissors
- Harmonic scalpel (recommended)
- Coagulation hook (optional)
- Liver retractor (a fixed type retractor e.g. Nathanson is recommended)
- 10/12 mm laparoscopic port (1)
- 5 mm laparoscopic ports (3-4)
- Clip application tool: (a 10 mm multi-use reloadable device is recommended)
- 3-0 Ethibond Excel (or any other non-resorbable multi-filament) with a tapered round bodied, short needle for suturing the electrode butterflies, and 0-Ethibond for suture of the crura (if needed)
- Basic surgical instrument kit for the creation of the subcutaneous pocket

A video recording system is also recommended.

Pre-Operative Considerations

Determine the surgical site for implanting the IPG. Discuss the position with the patient so they are comfortable with the location of the device and surgical scar with regard to sleeping, posture, and exposure. It is recommended to make a horizontal incision of 4.0 cm at the level of the upper edge of the umbilicus (Figure 7). Mark the surgical area before scrubbing and prepping the patient for the procedure.

Figure 7 Skin Incision (solid line) and IPG subcutaneous pocket (dotted line)

Prepare the EndoStim Programmer System

Before the surgical procedure, make sure the Tablet PC is fully charged by plugging the power supply into a nearby outlet (at least 4 hours are required for full charging), arrange the Tablet PC and EndoStim USB Programmer Wand on a portable table. Prior to using the programmer, disconnect the power supply from the Tablet PC and connect the programmer wand to the USB port. Power on the Tablet PC and log in (password is “EndoStim”), verify date and time using the “tools” menu and selecting “System Time”.

It is recommended that you recharge the tablet PC immediately after every use.

Implant the IPG and Lead

Note: Always have a backup lead and IPG in the OR before starting an implant procedure.

Prepare the Patient and Laparoscopic Ports

1. Prep and drape the patient as appropriate for a laparoscopic procedure.
2. Position 4 - 5 laparoscopic ports as shown in Figure 8 (or use a working position that is appropriate). This plan is based on the surgeon working in the lateral right position. If the surgeon prefers to work in the French position, ports should be as for any other laparoscopic lower esophageal intervention. The suggested port positions include:
    - One port for optics and insufflation
    - One port for the liver retractor
    - Two working ports
    - One assistant port
    - One of the ports should be a 10mm one to accommodate the 10 mm clips applier

    The assistant port may be placed along the IPG incision line, preferably at its left lateral angle. Place the table in a reverse Trendelenburg position.

Figure 8 Port Positions

Prepare the Esophagus

1. Retract the liver to completely expose the entire length of the abdominal esophagus. Retract the stomach close to the cardia.
2. For EndoStim electrode implantation, a rectangular area of 3 cm by 2 cm on the frontal right aspect of the lower esophagus should be prepared (Figure 10). The anterior vagal branch should be preserved.
3. Gain access to the right side of the hiatus through the Pars Flaccida. By blunt dissection and harmonic scalpel use, expose the muscle surface of the anterior and right aspects of the lower esophagus. Dissect the fat pad and underlying ligaments to expose the esophageal muscle (dissection of the adventitia is not needed). It is recommended to use a harmonic scalpel, although it is acceptable to carefully use a cautery hook.
4. In case the abdominal segment is shorter than 3 cm, but no relevant looseness is observed, consider dissecting the

anterior phreno-esophageal ligament (PEL). Such dissection may improve the available length for electrode placement (Figure 9).

5. Prepare a rectangular area, 3 cm by 2 cm, on the frontal right aspect of the lower esophagus (Figure 10).

Figure 9 Potential PEL Anterior Dissection

Figure 10 Preparing the Esophagus

Introduce the Lead

1. The lead is packaged in a double blister pack. Open the outer blister near the sterile field and have a sterile operator grasp the internal blister pack.
2. After removing the lead from the internal blister, remove both silicone protecting covers from the attached suture needles.
3. Introduce the lead through one of the working ports into the abdominal cavity.
4. Use fingers to advance the lead (connector first) inside the port. Once the connector reaches the abdominal cavity, gently use a grasper from the abdominal side to hold the thick reinforced sections of the cable in order to fully pull the lead into the abdominal cavity.
5. Place the lead on the left lower omentum to free the implantation field from unnecessary lead loops.

Note: Take care to avoid damage to the lead body and electrodes by the laparoscopic instruments. Gently grasp the lead at all times. Avoid grasping the exposed electrodes (the metal segment just ahead of the silicone butterfly). Avoid aggressive grasping and lead kinking.

Implant the Electrodes

1. Grasp the needle of the black-dotted electrode close to its base (near the nylon thread); insert the needle close to the esophageal midline with bite exit below diaphragm (Figure 12). Perform a long superficial bite to ensure maximum electrode coverage.
2. Pull and flip the needle backwards as it comes out from the esophageal wall; avoid injury to the diaphragm or liver. Pull the nylon suture applying short cranial strokes or slide it over your other hand's instrument until the silicone butterfly fully contacts the esophageal wall adjacent to the point of electrode insertion into the muscle.

Figure 10 Implant Electrode

3. Implant the non-dotted electrode just below the first one with tendency to the right esophageal wall; allow a few

millimeters of longitudinal overlap between the electrodes. Consider a lateral distance of 10 ± 2 mm between the electrodes.

4. Fully position the lower electrode using the technique described in step 2 above.
5. Perform an endoscopic check before final fixation to ensure that there is no full thickness penetration of either of the electrodes.

   If penetration has occurred, the electrode would need to be withdrawn and re-inserted.
6. Apply 2 titanium clips to the nylon suture at the exit point from the esophageal muscle, ensuring that the clip is not closing over an exposed electrode segment. Cut the nylon suture as close as possible to the needle, leaving a minimum length of 3 cm of nylon suture.
7. Remove the suture needles from the abdominal cavity.
8. Affix the silicone butterfly anchor to the esophageal muscle wall using sutures (3-0 Ethibond or other non-resorbable, multi-filament threads). Using the shortest needle available, apply a stitch to both sides of the butterfly anchor. It is recommended to take the bites behind (caudal) the butterfly holes to ensure proper flat final position of the butterflies.
9. Suturing may be performed as required to approximate the crura (anterior or posterior).
10. Inspect the liver and other organs near the electrodes for any potential injuries.
11. Close or cauterize all bleeding vessels to obtain complete hemostasis.

Create the Pocket for the IPG

1. Desufflate the abdomen before making an incision for the IPG pocket.

2. Make the incision along the skin mark drawn earlier (Figure 7).
3. Gain access to the fascia and then use finger(s) to create a subcutaneous pocket appropriate for the size of the IPG. The pocket size should be slightly larger than the IPG size.

   Note: The maximum allowed depth is 3 cm. In case the subcutaneous fat is thicker than 3 cm, the IPG would need to be placed inside the fat and an anchor stitch to the underlying fascia should be used.
4. Re-insufflate the abdominal cavity

Routing the Lead to the Subcutaneous Pocket

1. Use a 5 mm port to puncture the fascia at the upper lateral end of the incision, pointing directly up, towards the lead route, to pull out the lead connector.
2. At the lateral end of the skin incision, push the upper lip of the incision with the tip of the port 1-2 cm towards the rib cage and puncture the fascia (Figure 12). Do this above the lateral upper angle of the pocket.

Figure 12 Skin Incision

3. Insert a grasper, grasp the metal end of the lead connector, align it with the grasper axis and pull out. It might be necessary to pull the port together with the grasper.

Connect the Lead to the IPG

1. Clean body fluids and tissue residues from the lead by wiping the lead connector with saline and then dry gauze just prior to connecting to the IPG.
2. After removing the IPG from the inner sterile blister, and prior to inserting the lead connector pin, inspect the bipolar connector terminal (cavity) to ensure that no setscrew is protruding into each cavity.
3. Use the torque wrench (screwdriver) to back off any setscrew found to be protruding beyond the wall of the header cavity by turning it counter-clockwise.
4. Turn the setscrew only enough to pull its tip back out of the header cavity. Do not back the setscrew completely out of the terminal block. Leave the wrench in the septum until the lead is secure. This allows a pathway for venting trapped air when the lead is inserted.
5. Firmly push the connector into the cavity. Inspect the lead to ensure that the tip of the connector protrudes beyond the inner setscrew. To prevent any damage to the setscrew heads, make sure that the screwdriver tip is well inserted in the setscrew hexagonal cavity before tightening it. While tightening, maintain lead insertion pressure to prevent the lead from sliding backwards.
6. Turn the screwdriver clockwise until three audible clicks are heard; this ensures proper tightening torque. The lead connector is now plugged into the IPG, but the IPG is still not in the subcutaneous pocket.

Measure Lead Impedance (IPG out of pocket)

See EndoStim Programmer manual for instructions.

Place the IPG in the Subcutaneous Pocket

1. Place the IPG into the subcutaneous pocket using a delicate rotational maneuver (Figure 13). Ensure that the EndoStim logo faces up. Once the IPG is partially inserted inside the pocket use a delicate clockwise rotational maneuver to bring it to its final horizontal position (Figure 14).

Figure 13 IPG Pocket Insertion

2. While placing the IPG into the subcutaneous pocket, any lead excess should be pulled inside the abdominal cavity by gentle grasping.

Intra-abdominal lead routing

1. Place the lead excess at the left abdominal side, retract the omental fat and small bowel (as needed) and place the lead body as deep as possible inside the groove formed along the left abdominal wall. The upper part of the lead should pass in front of the spleen or around it depending on the patient's dimensions. This should minimize any portion of the lead crossing bowl loops, keeping it away from the midline to facilitate future surgical procedures.

2. Ensure that any curve taken by the lead is gentle. This should reduce the chance for kinks and premature failure (Figure 14).

Figure 14 Lead Routing and final IPG Position

Note: To reduce the chances of lead erosions into abdominal organs or electrode dislodgements due to increased abdominal pressure do the following: Route the lead body along the groove formed between the left abdominal wall and the intestinal pack, then slightly covering it with the omental fat. Gently turn the lead as high as possible just below or around the spleen, if possible. This routing places the lead body at the periphery of the abdominal cavity, minimizing the direct effect of higher pressure on the lead position and avoids potential damage at a future laparotomy.

3. Before removing the port, check that no inadvertent injury to tissue/organs has occurred and that all active bleeding has been addressed.

Measure Lead Impedance (IPG in pocket)

See EndoStim Programmer manual for instructions.

Surgical Pocket Closure

1. Withdraw the ports and close the puncture lesions.
2. Carefully suture the subcutaneous layer above the IPG before suturing the skin. An intra-dermal skin closure is recommended for aesthetic reasons.
3. It is recommended to apply antibiotic ointment over the sutures and cover with a sterile dressing.

Post-Operative Care

Instruct the patient to wear a compression binder over the pocket for at least 30 days post operatively. This will reduce the chances for fluid accumulation and the possible formation of seroma. Nauseous patients and especially those who had crural approximation should be prescribed anti-emetic medications for a few days post-operatively in order to prevent retching and vomiting which could lead to electrode dislodgement. Provide instructions for standard post-operative treatment and follow up appointments.

- Note: To temporarily disable stimulation therapy, apply a magnet directly over the IPG for at least 2 consecutive seconds, followed by 2 consecutive seconds without the magnet. This will terminate therapy for 24 hours.

See EndoStim Programmer manual for instructions regarding device-related follow-up activities.

MRI Information for the EndoStim System

It is important to read the section in its entirety before conducting any magnetic resonance imaging (MRI) examination on a patient implanted with the EndoStim System.

Contact an EndoStim representative with any questions regarding the following MRI information.

If all the instructions below are followed, **MRI examination using a transmit/receive body coil may only be performed using a 3-Tesla/128-MHz system (with Lead Model 1003 only)**. MRI examinations of specific regions using a transmit/receive RF local coil (e.g., head coil) may be safely performed at 1.5-Tesla/64-MHz or 3-Tesla/128-MHz *only*. Failure to carefully follow the specific information presented in this document may result in serious patient injury and/or damage to the EndoStim System.

Potential Interactions with the EndoStim System

MRI-Related Heating

The MRI uses radiofrequency (RF) energy which may cause excessive heating of the pulse generator and lead of the EndoStim System during the MRI examination.

Notes:

High specific absorption rate (SAR) RF power levels can increase the risk of heating.

Excessive heating of the lead may occur even if the IPG is explanted.

Magnetic Field Interactions

MRI uses a powerful static magnetic field which may exert force and torque on implanted pulse generators that could result in movement or displacement. Tests performed at1.5-Tesla and 3-Tesla indicated that this is not a concern for the EndoStim System.

Warnings and Precautions

EndoStim Programmer System

The EndoStim Programmer contains ferromagnetic materials. These materials could make the Programmer susceptible to the powerful static magnetic field of the MR system. Therefore, the EndoStim Programmer System is considered MR Unsafe, meaning that it cannot be present and/or used in the same room as the MR system. The pre- and post-exposure implanted pulse generator programming requirements (detailed below) must be performed *outside* of the MR system room.

Other Implanted Systems

Prior to MRI examination, the patient should be evaluated for other implanted medical devices, especially electronically-activated devices or abandoned leads. An X-ray may be used to determine if the patient has other implanted medical devices. Lead looping in the subcutaneous pocket around the EndoStim pulse generator has not been evaluated in terms of interaction with MRI scanners. If it is determined from X-ray, or from surgical procedure at implant, that lead looping did occur, the clinician or radiologist should judge whether the benefit of the MRI outweighs the unknown risk of lead looping around a pulse generator.

The decision to perform an MRI examination must be made by the MRI-trained radiologist, and the patient's physician, in consideration of the risks and benefits to the patient.

MR System Type

1.5-Tesla/64-MHz and 3-Tesla/128-MHz MR closed bore systems are the only types of equipment permitted for use for a patient with the EndoStim System. There is no restriction on the MRI manufacturer.

Other MR systems (e.g., 0.7-Tesla, etc.) are not permitted for use and may cause serious patient injury and/or damage to the EndoStim System. Table 2 shows a summary of the MRI compatibility for each device combination.

Table 2 MRI System Compatibility

MODEL		1.5T		3T	
IPG	Lead	Local Coil	Body Coil	Local Coil	Body Coil
1002*	1003	Yes	No	No	No
1002*	1015	No	No	No	No
1006	1003	Yes	No	Yes	Yes
1006	1015	Yes	No	Yes	No

*See Clinician Manual CM-07 for instructions for this model.

3-Tesla/128-MHz MR System RF Coil

A transmit/receive RF body coil is permitted for use in a patient with the EndoStim System.

A transmit/receive RF local coil is also permitted for use in a patient with the EndoStim System.

Brain/head imaging may be performed using a transmit/receive RF head coil. The diagram below illustrates the required placement of the transmit/receive RF head coil, as shown in grey.

Figure 15 Brain MR Imaging Region with Head RF Coil

Extremity imaging may be performed using an appropriate transmit/receive RF local coil. The diagrams below illustrate several examples of the required placement of the transmit/receive RF local coil, as shown in grey. Imaging using wrist/hand coils is not recommended.

Figure 16 MR Imaging Region Knee and Ankle with Local RF Coil

If these instructions are not followed, higher than normal heating may occur at the lead electrodes. If the patient has a broken lead (as evidenced by high lead impedance during device interrogation and/or X-ray), higher than normal heating can also occur at the break if in the area of the transmission of the RF energy. Excessive heating can cause tissue damage or serious patient injury.

Caution: Lead Model 1015 (61 cm) has not been studied using a 3-Tesla/128-MHz MRI body coil and should not be subjected to imaging using a body coil.

Consult the MR system manufacturer for questions regarding the type of RF coil in use with the 3-Tesla/128-Hz MR system.

1.5-Tesla/64-MHz MR System RF Coil – Use of Transmit/Receive RF Local Coil, ONLY

A transmit/receive RF local coil is the only type of 1.5-Tesla/64-MHz RF coil permitted for use in a patient with the EndoStim System.

A 1.5-Tesla/64-MHz *transmit/receive RF body coil must not be used.*

No portion of the 1.5-Tesla/64-MHz RF transmit/receive local coil can cover any part of the implantable system. Figure 18 illustrates the region that is considered unsafe for MRI exposure,

Figure 17 Unsafe MR Imaging Region (highlighted in grey)

This exclusion zone is dependent on the typical placement of the EndoStim IPG and Lead. Implanted system components may be located as close as 0cm to the lower (caudal) edge of the transmit/receive RF local coil, but no part may be inside of it.

Figure 16 illustrates the required placement of the 1.5-Tesla/64-MHz transmit/receive RF head coil, as shown in grey. Under no circumstances is the transmit/receive RF head coil allowed to overlap with the off-limits area as shown in Figure 17.

Extremity imaging should be performed using an appropriate 1.5-Tesla/64-MHz transmit/receive RF local coil. Figure 16 illustrates several examples of the required placement of the 1.5-Tesla/64-MHz transmit/receive RF local coil, as shown in grey. Imaging using wrist/hand coils is not recommended.
WARNING: Do not allow the transmit/receive RF head coil to overlap with the off-limits area as shown in Figure 17.

If these instructions are not followed, higher than normal heating may occur at the lead electrodes. If the patient has a broken lead, higher than normal heating can also occur at the break if in the area of the transmission of the RF energy. Excessive heating can cause tissue damage or serious patient injury.

Consult the MR system manufacturer for questions regarding the type of RF coil in use with the 1.5-Tesla/64-MHz MR system.

MRI Parameters

The RF frequency must be 64-MHz or 128-MHz, ONLY, (consistent with 1.5T and 3T MRI scanners, respectively). Exposure to 1.5T or 3T MRI scanners operating at other than those frequencies has not been evaluated, and could lead to tissue damage or serious patient injury. Furthermore, use of other transmit frequencies could cause device damage and/or excessive heating.

The RF power should be limited to a specific absorption rate of 1-W/kg or less, in the head and whole body, for each pulse sequence.

The spatial gradient of the static magnetic field should be limited to 250 Gauss/cm or less. Refer to MRI manufacturer's manual for a specification of maximum spatial gradient.

The gradient magnetic field should be limited to 125T/s/m or less. Refer to MRI manufacturer's manual for a specification of gradient magnetic field.

The isocenter location landmark should be the region of interest ONLY.

Preparing the Patient prior to MRI Procedure

The patient should be informed to bring the Patient ID card to the MRI procedure appointment and to inform the MR system operator that he/she has an active implantable medical device prior to entering the MR system room.

The patient should be informed that the therapy will be turned off until after the MRI procedure is completed.

The IPG should be programmed to OFF (reference section Program Stimulation Amplitude and Polarity).

CAUTION: If the IPG is in End of Life (reference section IPG Battery Characteristics and Specifications), then the IPG mode cannot be programmed or confirmed via telemetry and the MRI procedure may not be performed.

The patient should be informed of all risks associated with undergoing an MRI procedure (reference the Warning and Precautions section in this chapter).

The patient should be informed to immediately inform the MR system operator of any discomfort, stimulation, shocking, or unusual sensation that may occur during the MRI procedure.

The patient should be conscious throughout the MRI examination (i.e., no sedation or anesthesia is allowed).

Beginning of the MRI Procedure

Verify the patient's weight is entered correctly into the MR system's console to ensure that the regional SAR is correctly calculated.

Verify that the appropriate RF coil is being used – only 3-Tesla/128-MHz systems may be used with an RF body coil (with Lead Model 1003 only). RF local coils may be used with either 1.5-Tesla/64-MHz or 3-Tesla/128-MHz systems.

Verify the MRI parameters for compliance with the requirements in this section. If the parameters are not compliant, they should be adjusted to meet the requirements. If this is not possible, the MRI procedure must not be performed.

Verify that the Programmer is not in the same room as the MR system.

During the MRI Procedure

The EndoStim System should not activate (turn on) or cause an electrical stimulation.

There may be MRI image artifacts from the EndoStim System if it is to be placed within the transmit/receive RF body coil.

Monitor the patient visually and audibly during, and between, the MR imaging sequences to ensure the patient is not having any difficulty.

During the MRI procedure, the patient may feel vibration of the IPG.

Discontinue the MRI procedure immediately if the patient reports any issues, is unable to respond to any questions, or the IPG movement or vibration is too uncomfortable.

Do not, under any circumstances, attempt to program the IPG while the patient is in the same room as the MR system.

After the MRI Procedure

Verify that the patient has not experienced any adverse effects during the MRI procedure.

Once outside of the MR system room, reset the IPG using the Programmer. Reprogram the parameter values to those prior to the MRI procedure and enable stimulation. Any problem with these programming steps indicates that the IPG may have been damaged due to the MRI examination.

Immediately report any device-related issues to the implanting physician and EndoStim.

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 3 Implantable Pulse Generator Specifications

Description	Value
Height	62 mm
Width	39 mm
Thickness	8.4 mm
Mass	28.5 g
Biocompatible materials in contact with human tissue	Titanium Epoxy resin Silicone rubber set plugs
Power source	Lithium carbon monofluoride 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 4.

Table 4 Estimated IPG Battery Longevity

Parameter	Condition 1	Condition 2	Condition 3	Condition 4
Pulse Width[a]	215 μsec	215 μsec	215 μsec	215 μsec
Pulse Frequency[a]	20 Hz	20 Hz	20 Hz	20Hz
Pulse Amplitude	5.0 mA	5.0 mA	3.5 mA	7.5 mA
Hours per Day	3.0	6.0	4.0	4.0
Estimated Life[b]	8.6 years	6.6 years	7.8 years	5.8 years

[a] This is the recommended value
[b] This assumes a 12 month shelf life prior to implant

Lead Characteristics and Specifications

Table 5 Lead Physical Description and Materials

Lead	Specification
Connector	IS-1 BI
Length	45 cm or 61 cm
Mass	4 g or 5 g
Electrodes	Platinum-iridium
Bifurcation	At 35 cm or 51 cm, lead has two 10cm unipolar segments

Programmer Specifications

Table 6 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 II IPG) is 20 kHz with a bandwidth of 18 kHz to 22 kHz.

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

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions

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

<table>
<tr><th colspan="3">Table 7 Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The EndoStim II IPG and Programmer are intended for use in the electromagnetic environment specified below. The customer or user of EndoStim II IPG and Programmer should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The EndoStim II 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The EndoStim II 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.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td rowspan="2">Not Applicable</td></tr>
<tr><td>Voltage Fluctuations/Flicker Emissions
IEC 61000-3-2</td></tr>
</table>

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 8. The customer or user of the EndoStim Programmer should assure that it is used in such an environment.

Table 8 ESD and Power Fluctuations: Electromagnetic Immunity

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±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 IEC 61000-4-4	Not Applicable	Not Applicable	Mains power should only be used to recharge the tablet PC battery while the unit is powered off.
Surge IEC 61000-4-5	Not Applicable	Not Applicable	Mains power should only be used to recharge the tablet PC battery while the unit is powered off.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable	Not Applicable	Mains power should only be used to recharge the tablet PC battery while the unit is powered off.
Power frequency (50/60 Hz) 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 9. 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 9 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	3 Vrms	$d = 1.17\sqrt{P}$
Conducted RF, IEC 61000-4-6, 150 kHz to 80 MHz inside ISM bands	3 Vrms	3 Vrms	$d = 1.20\sqrt{P}$
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 10 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	100 to 5000 (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 10-40Hz: 2Hz 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%

* If using the older versions of software and/or firmware, the range is 200 – 2000 Ω.

Service and Warranty

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. 2017
CM-09-ENG Rev D Pub. July 2017
All Rights Reserved