Lower Esophageal Sphincter Stimulation System

Programmer Manual

Revision B

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.

© EndoStim B.V. 2017

All Rights Reserved

Explanation of Symbols on Labels

SYMBOL	DESCRIPTION
	Manufacturer
YYYY-MM	Date of Manufacture
CE 0344	Affixed in compliance with European Directive 90/385/EEC 0344 = Notified Body Number
	Consult instructions for use.
	Do Not Use if Package is Damaged or Opened
CC°C FF°F cc°C ff°F	Transport Temperature Limits
REF XXXX	Part Number
SN XXXX	Serial Number
	Type B Applied Part
	Caution
	Power Indicator

SYMBOL	DESCRIPTION
	Intentional Radiator
	Signal Strength Indicator
	USB Connector
	MR Unsafe

TABLE OF CONTENTS

Explanation of Symbols on Labels i

TABLE OF CONTENTS iii

List of Acronyms and Abbreviations v

Use of this Manual 1

Programmer 1
- Connect the Programmer 3
- Maintenance 3
- Handling and Storage 4
- Service Life and Disposal 4
- Environment of Use and Operator Profile 4

Instructions for Use: Program an IPG 6
- Launch the Software 6
- Initiate a Programming Session 10
- Program IPG Time 11
- Access IPG Statistics 11
- Measure Lead Impedance 12
- Program Stimulation Amplitude and Polarity 12
- Program Stimulation Session Times 14
- Program Cyclic Mode Stimulation All Day 15
- Program Cyclic Mode Stimulation at Night Only 15
- Advanced Parameters 17
- Advanced Stimulation Parameters 17
- Advanced Sensing Parameters 17
- Impedance Tracker Parameters 18
- Upgrade Features 19
- Usage Tracking 19
- Report Features 22
- Upgrading the IPG Firmware 24
- Terminate Stimulation 26
- Reset the IPG 26
- Shut Down the Programmer 26

MRI Information for the Programmer System 27
- Programmer Specifications 27

Safety Shutdown with a Magnet.....27
Electromagnetic Interference 27
Electromagnetic Emissions 28
ESD and Power Fluctuations 29
Radiated Electromagnetic Fields.....30
Recommended Separation Distances.....33
Range and Tolerance of Displayed Values 34
Service and Warranty.....35

List of Acronyms and Abbreviations

CISPR	International special committee on Radio Interference
IPG	Implantable Pulse Generator
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
RF	Radio Frequency
PC	Personal Computer

Use of this Manual

This manual is intended to supplement the EndoStim Lower Esophageal Sphincter Stimulation System Clinician Manual. The user should consult that manual for details on the following topics:

- EndoStim Lower Esophageal Sphincter Stimulation System description and components
- Indications and Contraindications
- Potential Adverse Effects/Events
- Precautions and Warnings

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

The Programmer has 2 components (Figure 1):

- Programmer Wand
- Programmer Tablet PC with Software

Figure 1 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).

Powering the Programmer

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

If the tablet PC is connected to Mains, the Programmer software disables power to all computer USB ports and provides a popup warning (Figure 2). The popup warning message terminates once the tablet PC is disconnected from the Mains and you press “Retry. The Programmer shuts down if you press “Close.”

Figure 2 Programmer Connection to Mains Warning

Notes:

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

Connect the Programmer

Connect the USB end of the Programmer to the USB port of the tablet PC.

Note: The Programmer should only be connected to the USB port of the provide tablet PC running 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 attempt to load any other software 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	15-80 % 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	0-5,000 m (0-16,404 ft)	0-3,048 m (0-10,000 ft)

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

Powering the tablet PC will launch the Programmer software. The launch screen appears (Figure 3). Swipe upward on the touch screen to enable the password screen (Figure 4).

Figure 3 EndoStim Programmer Launch Screen

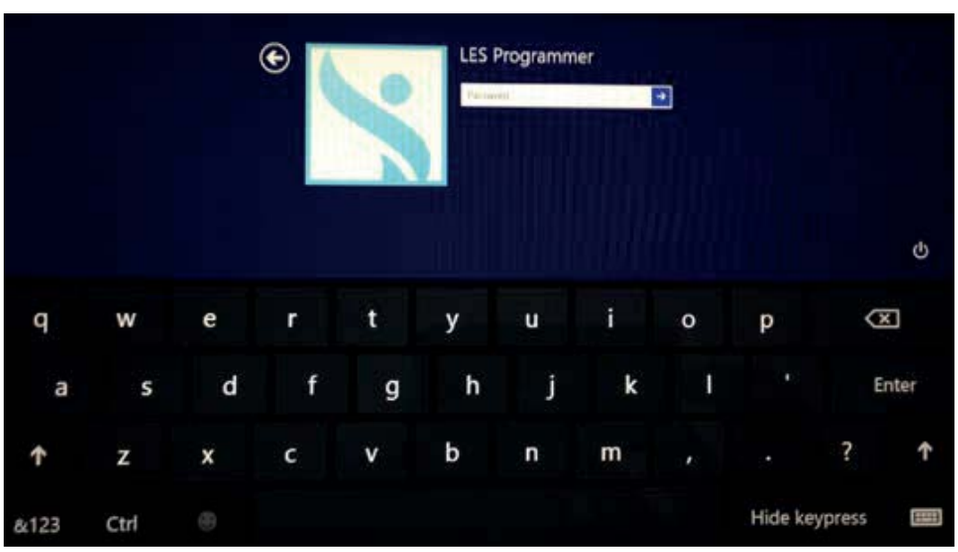


Figure 4 EndoStim Programmer Password Screen (keyboard only present when using Lenovo tablet)

Enter the password and press “Accept” or press Enter. The Programmer Main Screen appears (Figure 5).

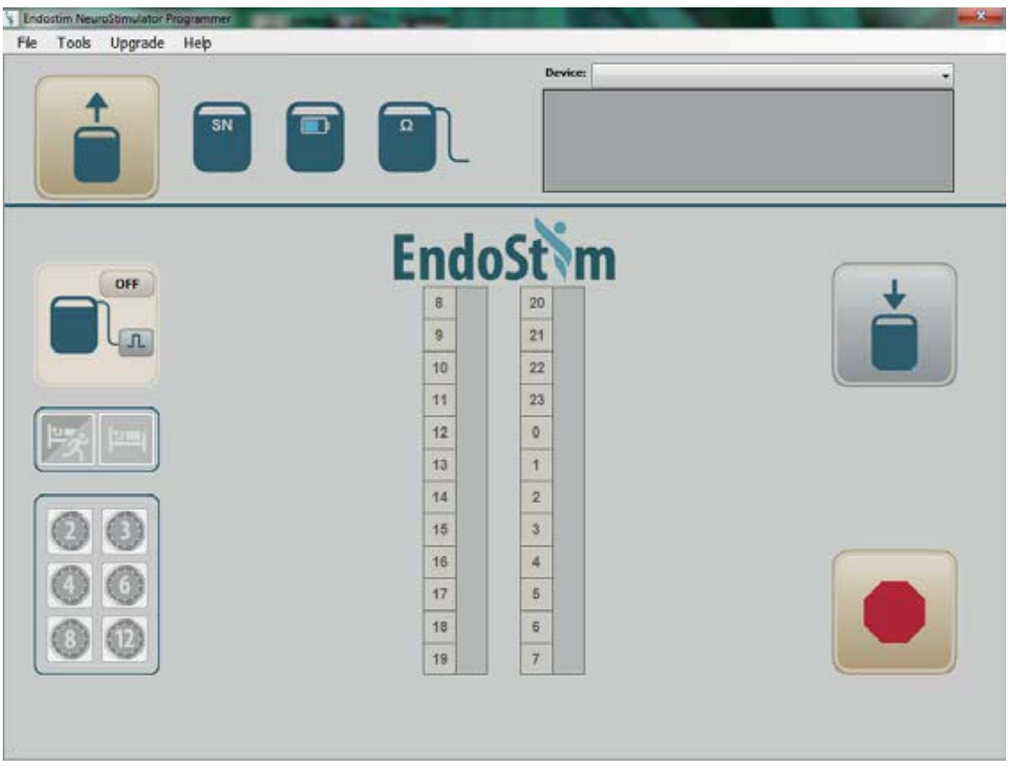


Figure 5 EndoStim Programmer Main Screen

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 Click on this icon to interrogate the IPG.
	Serial Number The serial number of the IPG is displayed here.
	Battery Voltage The battery voltage of the IPG is displayed here.
	Lead Impedance 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
EndoStim	***Default Parameters Button*** Click on the logo to program the IPG to default parameters.
	Stimulation Amplitude and Polarity Click on the top button of this icon OFF to select the stimulation amplitude. Click on the lower icon to change polarity.
	Program Click on this icon to program the IPG.
	Urgent Programming Click on this icon to terminate stimulation output from the IPG
	Cyclic Mode Stimulation Type *All Day* – Click on this icon to schedule cyclic stimulation sessions all day. *Night Only* – Click on this icon to schedule cyclic stimulation therapy while the patient is sleeping based on automated position detection. *Custom Mode* – Deselect *All Day* and *Night Only* modes to freely select time slots in the stimulation interval schedule below the EndoStim logo.
	Cyclic Mode Stimulation Interval Click on the number icon to select the stimulation interval for Cyclic Modes *All Day* and *Night Only*. For example, selecting the icon with the '2' sets the stimulation interval to every '2 hours'. In the *All Day* mode the cycles are displayed in the 'setting timing' schedule beneath the EndoStim logo. In the *Night Only* mode the cyclic modes are applied, however not visible in the 'setting timing' schedule because the stimulation starts when sleep is detected independently of the time at that moment.

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* will not allow for programming two stimulation sessions immediately adjacent to each other.

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.

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

Press the Interrogate icon at the far left of the Information section. Upon initial interrogation, the Statistics, Time, and Visit Information (if Report Functionality is enabled, see below) windows will automatically appear (see below for more details).

The remaining 3 icons in the Information section of the Programmer screen should automatically be updated with appropriate values as shown in Figure 6.

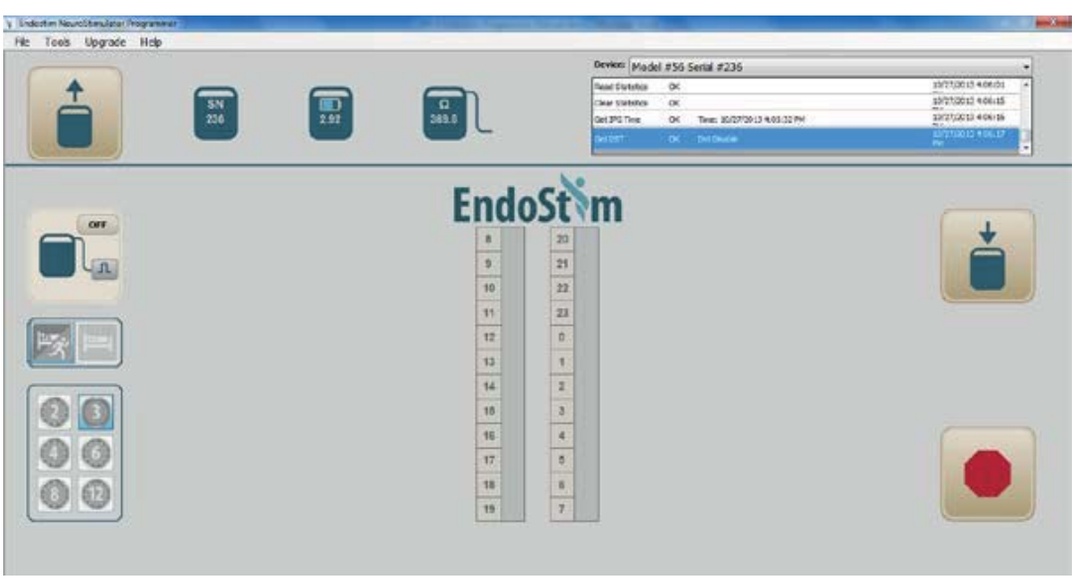


Figure 6 Information on the Main Screen

Program IPG Time

The Time dialog window opens (Figure 7) on initial interrogation and by selecting the pull-down menu *Tools→Time*.

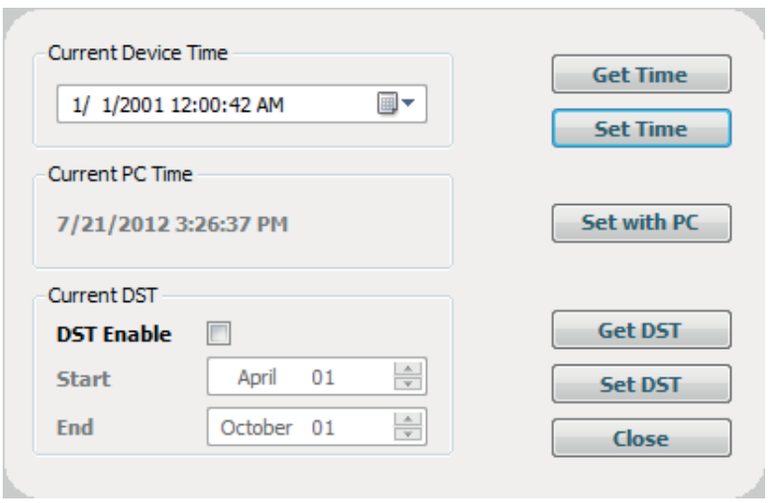


Figure 7 EndoStim Programmer Time Dialog

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.

Access IPG Statistics

1. The IPG keeps track of various statistics. These can be downloaded by the Programmer. The IPG statistics display upon initial interrogation.
2. To access the IPG statistics after initial interrogation, select the pull-down menu *Tools→Read Statistics*. The Statistics window opens (Figure 8).

Figure 8 EndoStim Programmer Statistics Window

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

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

Measure Lead Impedance

To measure lead impedance, click on the interrogate icon ( ). 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. Please contact EndoStim if this text is displayed in the icon.

Program Stimulation Amplitude and Polarity

1. Select the upper icon OFF inside 'Stimulation Amplitude and Polarity' icon . This will provide a popup menu of stimulation amplitude options (Figure 9).

Figure 9 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. Clicking the icon again changes the polarity of stimulation to alternate between each session. The icon looks like . Click the Program icon .

Program Stimulation Session Times

In Custom Mode the stimulation sessions can be programmed using the vertical bars in the middle of the main screen. Between 1 and 24 sessions per day can be programmed by clicking on the desired time slots.

1. Deselect *All Day* and *Night Only* cyclic modes.
2. 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 10). A box can be removed by a click on the dark box of the stimulation session.
3. Click on the Program icon .

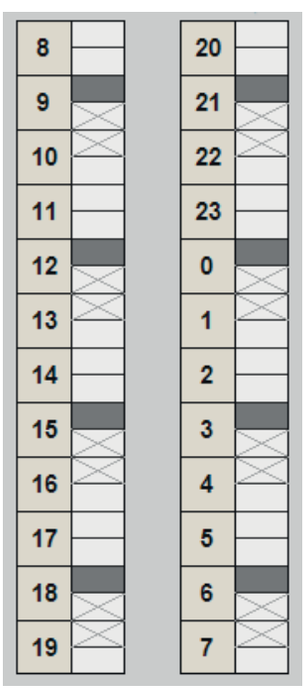


Figure 10 Stimulation Session Times
In this example, the stimulation sessions are at 09:00, 12:00, 15:00, 18:00, 21:00, 0:00, 03:00 and 06:00.

Program Cyclic Mode Stimulation All Day

An automatically repeating stimulation session can be programmed throughout the day. To enable stimulation sessions all day, click on the All Day icon and select the stimulation interval from the Cyclic Mode Stimulation Interval icons (Figure 11). Click on the Program icon .

Figure 11 Cyclic Mode Stimulation Interval
In example, the stimulation sessions occur once every 3 hours

Program Cyclic Mode Stimulation at Night Only

The IPG includes a sensor that detects when the patient is supine and stationary for up to 60 minutes. 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. For manual setting of sleep detection parameters, see paragraph 'Advanced Parameter Settings'.

To enable stimulation sessions when the patient is asleep, click on the Night Only icon and select the stimulation interval from the Cyclic Mode Stimulation Interval icons (Figure 12). The Cyclic Mode Stimulation Intervals are applied, although not displayed in the session timing because stimulation starts when sleep is detected. Click on the Program icon .

Figure 12 Cyclic Mode Stimulation Interval
In example, the stimulation sessions occur once every 4 hours starting when patient goes to sleep

If the sleep sensor has not yet been calibrated, the following message will be presented (Figure 13).

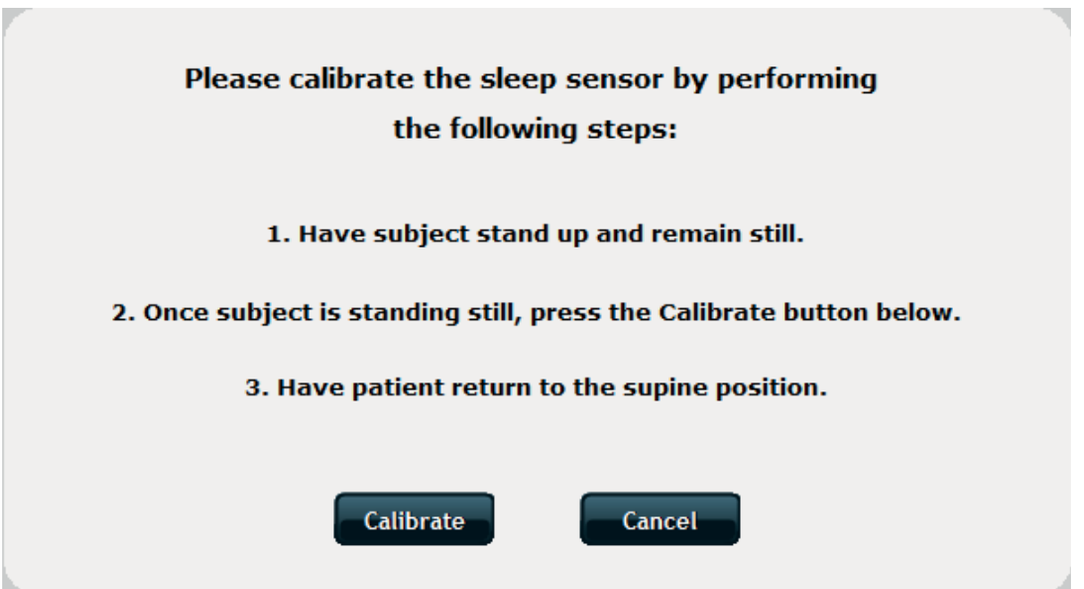


Figure 13 Sleep Sensor Calibration Message

If the sleep sensor has been calibrated within the last 30 days, the following message will be presented allowing the option of using the previous calibration (Figure 14).

Figure 14 Sleep Sensor Calibration Usage Message

To enable stimulation sessions when the patient is awake, follow the instructions above for *Program Stimulation Session Times*.

Advanced Parameters

If more therapy flexibility is required, more options can be found by selecting the pull-down menu *Tools→Advanced* (Figure 15).

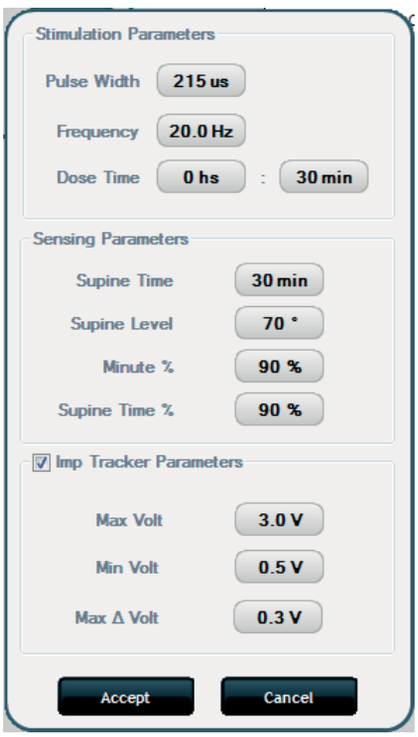


Figure 15 Advanced Stimulation Parameters

Advanced Stimulation Parameters

These parameters are used to control the stimulation waveform delivered to the electrodes.

- 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).
- Dose Time — This sets the duration of the stimulation session. It is recommended to set this anywhere between 20 – 30 minutes.

Advanced Sensing Parameters

These parameters are used to control the supine sensor to trigger Cyclic Mode Stimulation at Night Only.

- 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%.

Impedance Tracker Parameters

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.

- Max Volt — This is the maximum amount of voltage allowed to deliver the desired stimulation current. When enabled, this parameter auto-adjusts to twice that of the calculated voltage based on measured lead impedance and desired stimulation current, but can also be manually controlled. It is recommended to allow the value to auto-adjust.
- Min Volt — This is the minimum amount of voltage allowed to deliver the desired stimulation current. When enabled, this parameter auto-adjusts to half that of the calculated voltage based on measured lead impedance and desired stimulation current, but can also be manually controlled. It is recommended to allow the value to auto-adjust.
- Max Δ Volt — This is the maximum change of voltage allowed between stimulation sessions. When enabled, this parameter auto-adjusts to 10% that of Max Volt, but can also be manually controlled. It is recommended to allow the value to auto-adjust.

Upgrade Features

Usage Tracking

To review the usage of the programmer including the total patients and IPG upgrades, select from the pull-down menus *Upgrade→Usage Tracking*. This will pop up a dialog box with the total patients available to be programmed, the total patients currently programmed, the total IPG upgrades, and the total IPG upgrades used (Figure 16).

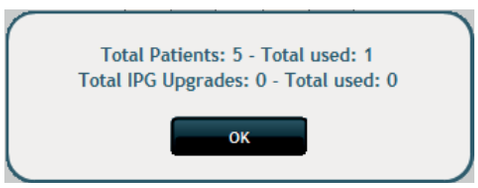


Figure 16 Usage Tracking Dialog

Increase Patient Support

To increase the total number of patients available to be programmed, select from the pull-down menus *Upgrade→Increase Patient Support*. This will pop up a dialog box with multiple fields including your hardware key, the current number of patients supported, the number of requested patients, and a text box to enter your EndoStim code to increase the patient support (Figure 17). Contact an EndoStim representative for further details.

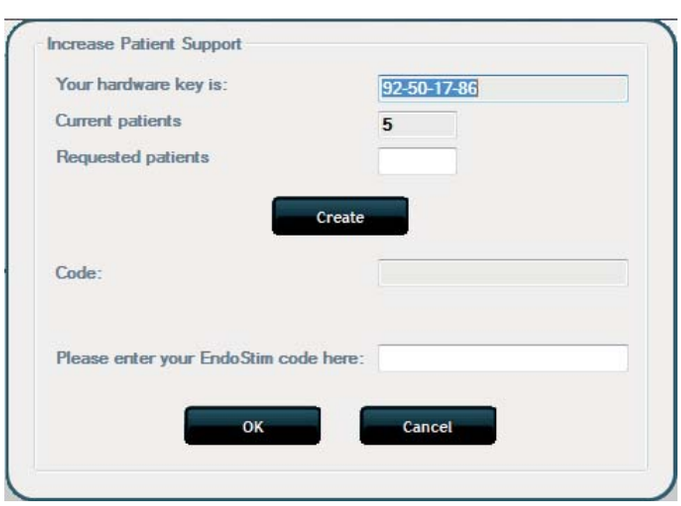


Figure 17 Increase Patient Support Dialog

Increase IPG Upgrade Support

To increase the number of IPG upgrades, select from the pull-down menus *Upgrade→Increase IPG Upgrade Support*. This will pop up a dialog box with multiple fields including your hardware key, the current number of IPG upgrades, the number of requested upgrades, and a text box to enter your EndoStim code to increase the IPG upgrade support (Figure 18). Contact an EndoStim representative for instructions on completing the fields above.

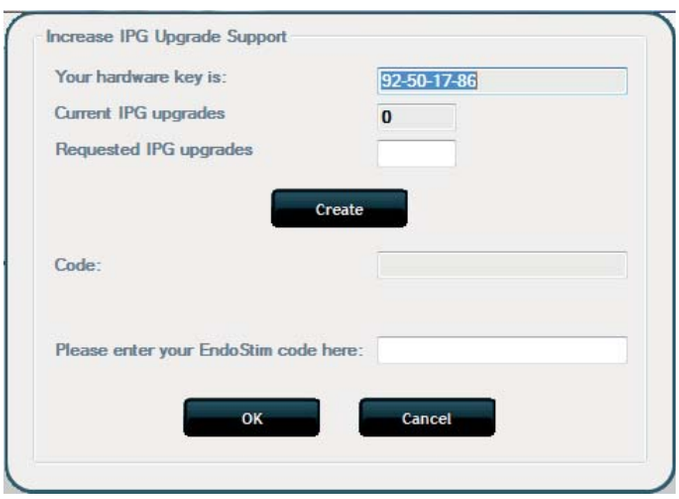


Figure 18 Increase IPG Upgrade Support

Upgrade Programmer Software

To upgrade the programmer software, select from the pull-down menus *Upgrade→Upgrade Programmer Software*. This will pop up a dialog box with multiple fields including your hardware key and a text box to enter your EndoStim code to upgrade the software (Figure 19). Contact an EndoStim representative for instructions on completing the fields above.

EndoStim will send a USB stick with the upgrade software installed. Once received, insert the USB stick in the USB port and select *Upgrade→Upgrade Programmer Software* and insert the appropriate information in the fields. Do not turn the Programmer off once the installation process has started. Remove the USB stick only after the upgrade process has completed.

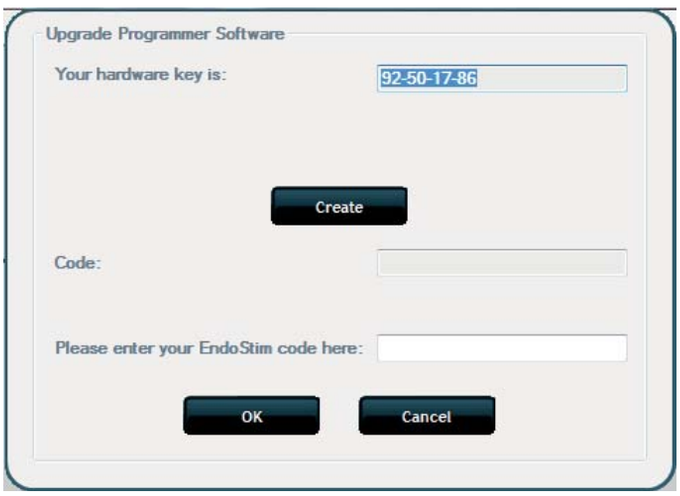


Figure 19 Upgrade Programmer Software

Enable Report Function

To enable the report function, select from the pull-down menus *Upgrade→Enable Report Function*. This will pop up a dialog box with multiple fields including your hardware key and a text box to enter your EndoStim code to enable reporting (Figure 20). Contact an EndoStim representative for instructions on completing the fields above.

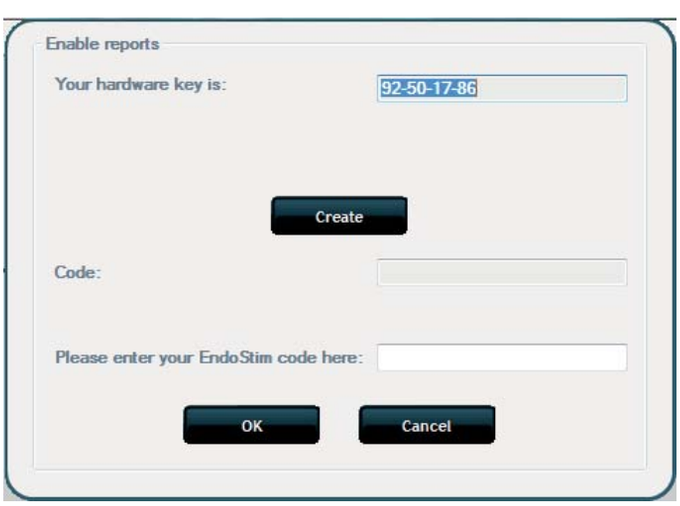


Figure 20 Enable Report Function

Report Features

After a patient visit in which the IPG is interrogated by the programmer, a report including patient information and IPG programmed settings and diagnostic values can be reviewed and exported to a USB memory device.

If enabled, the report functionality will prompt for Type of Visit to be entered upon initial interrogation (Figure 21).

Figure 21 Visit Information Screen

The Type of Visit can be either Pre-Implant or Implant. If Implant is select, a prompt for patient information will display (Figure 22).

Figure 22 Patient Information Screen

The following parameters can be entered:

- Patient Name — This is the name of the patient or any other desired patient descriptor.
- Patient ID — This is the ID assigned to the patient.

- Implanting Surgeon — This is the surgeon that performed the device implant.
- Medical Center of Implant — This is the center where the implant was performed.

Selecting Save will save the information into the database.

Patient data can be edited using the pull-down menu *Tools→Enter Patient Data*.

Subsequent initial interrogations will prompt for more Visit Information to be entered upon initial interrogation (Figure 23).

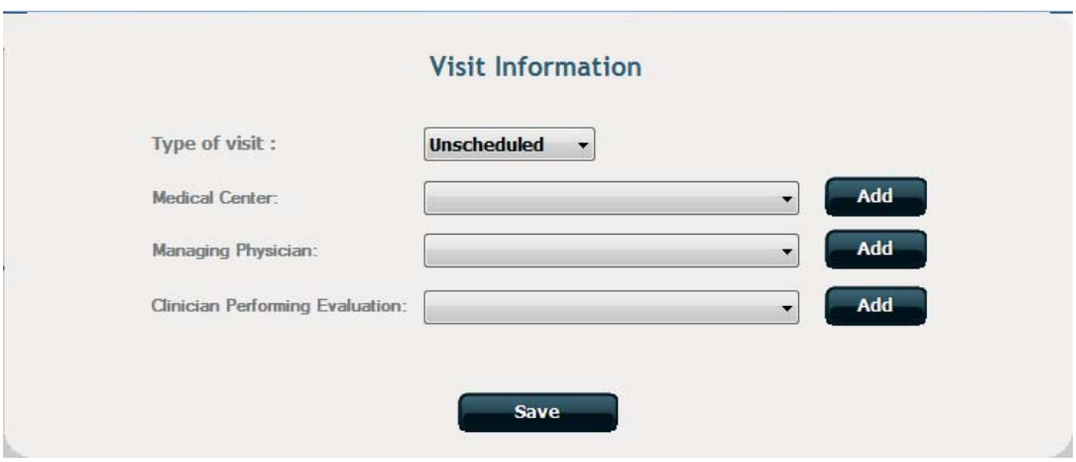


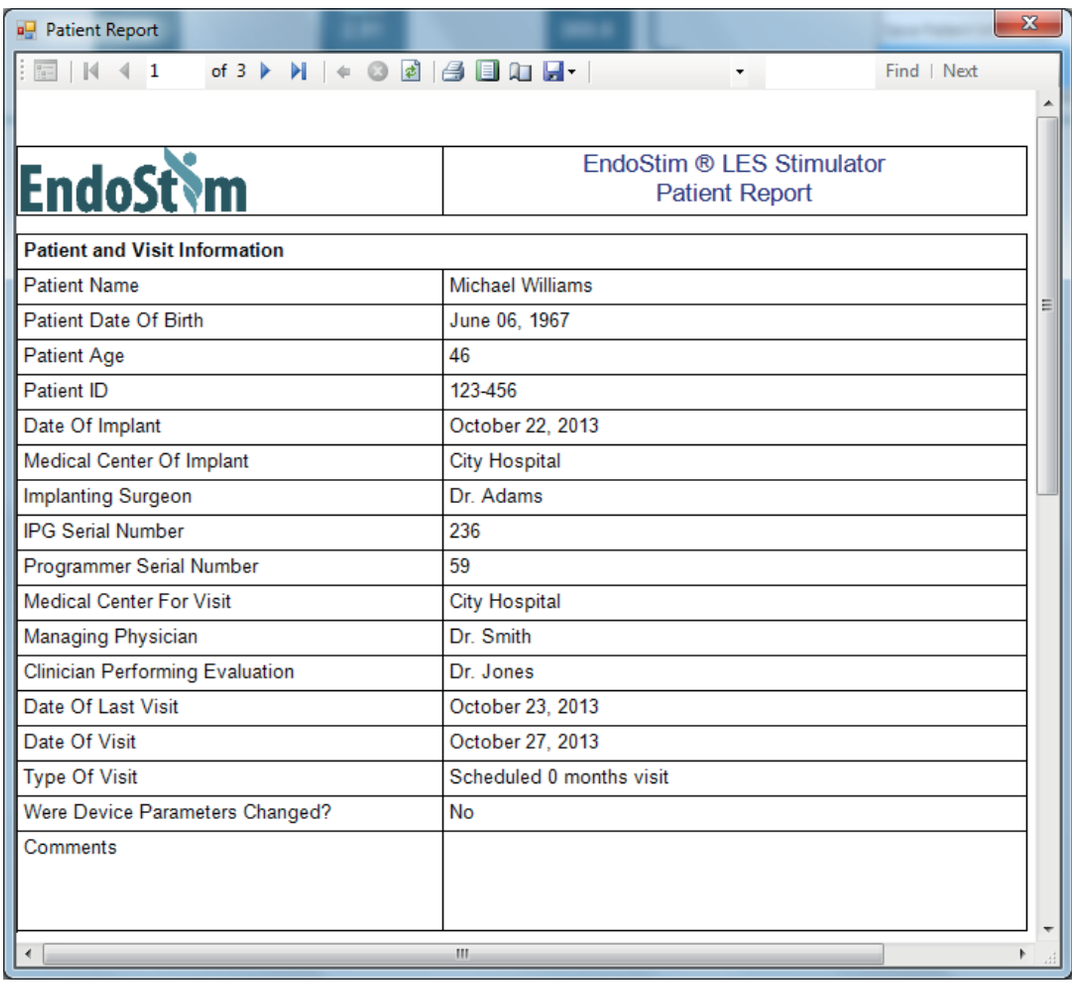
Figure 23 Visit Information Screen

The following parameters can be entered:

- Type of Visit — This is either Post-Implant, Scheduled, or Unscheduled.
- Medical Center — This is location where the visit is being performed. There is an option to add a medical center or select from one previously entered.
- Managing Physician — This is the physician that is managing the patient. There is an option to add a physician or select from one previously entered.
- Clinician Performing Evaluation — This is the clinician using the Programmer for the visit. There is an option to add a clinician or select from one previously entered.

Selecting Save will save the information into the database.

The report can be reviewed using the pull-down menu *Tools→View Patient Report* (Figure 24).



Patient Report

1 of 3 Find | Next

EndoStim ® LES Stimulator
Patient Report

Patient and Visit Information	
Patient Name	Michael Williams
Patient Date Of Birth	June 06, 1967
Patient Age	46
Patient ID	123-456
Date Of Implant	October 22, 2013
Medical Center Of Implant	City Hospital
Implanting Surgeon	Dr. Adams
IPG Serial Number	236
Programmer Serial Number	59
Medical Center For Visit	City Hospital
Managing Physician	Dr. Smith
Clinician Performing Evaluation	Dr. Jones
Date Of Last Visit	October 23, 2013
Date Of Visit	October 27, 2013
Type Of Visit	Scheduled 0 months visit
Were Device Parameters Changed?	No
Comments	

Figure 24 Patient Report Screen

The pages of the report can be viewed by using the scroll bars (right of screen) and the page selector (top bar of the screen). The report can be saved to a USB memory device in Adobe Acrobat (pdf) format by using the pull-down menu *Tools→Save Patient Report*.

Upgrading the IPG Firmware

If enabled, upgrade the IPG by selecting *Upgrade→Upgrade IPG*. The Programmer screen will change to IPG Upgrade Screen (Figure 25).

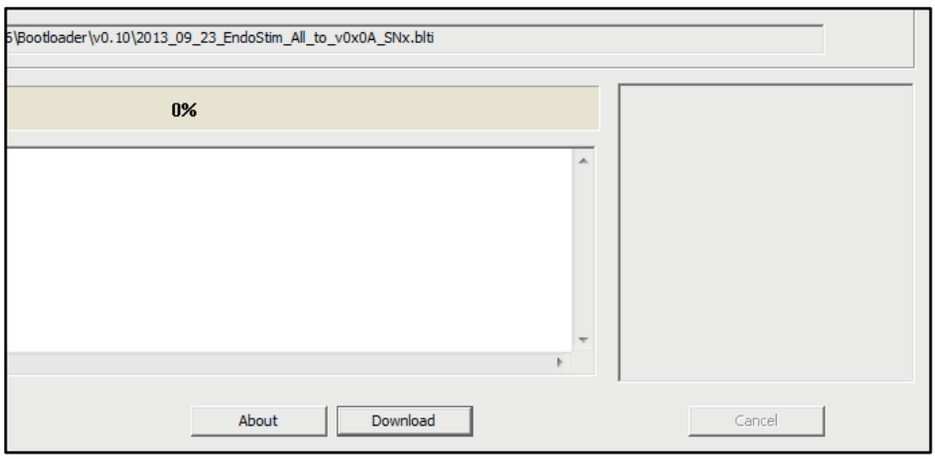


Figure 25 IPG Upgrade Screen

Place the Programmer Wand over the IPG and ensure good communication. Click on the Download button and do not move the Programmer Wand until the upgrade is complete. During the upgrade process, do not move the Programmer Wand, cancel the operation, or turn off the Programmer. The upgrade operation should be repeated if it does not complete successfully or is interrupted for any reason. This can be accomplished by clicking on the Download button again if the IPG Upgrade Screen is still open. If not, select *Upgrade→Upgrade IPG* from the Programmer main screen.

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*

The reset will not erase IPG statistics; however, a reset will disable the therapy (set to OFF) and return the following programmable parameters as follows:

- Pulse Amplitude: OFF
- Pulse Polarity: Normal
- Pulse Width: 215usec
- Frequency: 20Hz
- Dose Time: 30 minutes
- Dose Frequency: Every 3 hours

Shut Down the Programmer

To turn off the Programmer:

- Click on the X at the top right of the screen.
- Disconnect the USB cable from the tablet PC.

MRI Information for the 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.

Please refer to the EndoStim Clinician Manual for more information on MRI exposure.

Programmer Specifications

Table 2 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 3. The customer or user of the EndoStim IPG and Programmer should assure that it is used in such an environment.

<table>
<tr><th colspan="3">Table 3 Electromagnetic Emissions</th></tr>
<tr><td colspan="3">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.</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 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 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 4. The customer or user of the EndoStim Programmer should assure that it is used in such an environment.

Table 4 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 laptop computer 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 laptop computer 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 laptop computer 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 5. 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 5 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 6**). 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 6 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 $d = 1.17\sqrt{P}$	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.

Table 7 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	0.0 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.

Declaration of Conformity

EndoStim declares that this product is in conformity with the essential requirements of Directive 2014/53/EC on Radio Equipment and Directive 90/385/EEC on Active Implantable Medical Devices (AIMD).

For additional information, contact EndoStim at the telephone number and address provided.

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
PR-05-ENG Rev B July 2017
All Rights Reserved