



**OPTIMIZER[®] Smart
Implantable Pulse Generator**

INSTRUCTIONS FOR USE

Federal (US) law restricts this device to sale by or on the order of a physician

Impulse Dynamics (USA), Inc
30 Ramland Road South, Suite 204
Orangeburg, NY 10962-2698
U.S.A.

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OMNI™ is a trademark of Impulse Dynamics.
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Please read the complete documentation provided before you use the device.

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The OPTIMIZER® Smart system and the CCM™ technology are protected by several U.S. Patents. For an up-to-date list of relevant patents and patent applications, visit our patents page: <http://www.impulse-dynamics.com/us/patents>.

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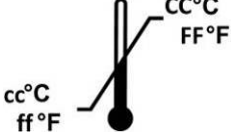










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EXPLANATION OF SYMBOLS ON LABELS

SYMBOL	DESCRIPTION
	Manufacturer
	Date of Manufacture
	Consult instructions for use.
	Caution, consult accompanying documents
	Transport Temperature Limits
	Sterilized with Ethylene Oxide
	Use By
	Do Not Reuse
	Part Number
	Lot Number
	Serial Number
	Open Here
	Torque Wrench
	Port Plug
	Do Not Use if Package is Damaged

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1. THE OPTIMIZER SMART SYSTEM: AN OVERVIEW

The OPTIMIZER Smart system is intended for the treatment of moderate to severe heart failure, as defined in the Indication for Use (Section 2).” The system comprises the following components:

- Programmable OPTIMIZER Smart Implantable Pulse Generator (IPG), Model CCM X10; port plug, #2 torque wrench for securing the implanted leads
- OMNI Smart Programmer, model OMNI™ II (with OMNI Smart Software)
- OPTIMIZER Smart Charger, model Mini Charger
- Implantable leads: 2 ventricular leads and 1 atrial lead.

1.1 Description of the OPTIMIZER Smart IPG

The OPTIMIZER Smart Implantable Pulse Generator (IPG) is a programmable device with an internal battery and telemetry functions. The system is intended to treat heart failure, a condition wherein the heart muscle does not pump blood as well as it should, resulting in reduced cardiac output. The OPTIMIZER Smart IPG monitors the heart’s intrinsic activity and delivers CCM™ signals to cardiac tissue during the ventricular absolute refractory period, when the cardiac tissue is not capable of activation, thus rendering the CCM™ signal as non-excitatory. CCM™ signal delivery is synchronized with the detected local electrical activity and is capable of achieving the desired effect on the tissue, i.e. treating heart failure by increasing the cardiac output, or increasing the contractility of cardiac muscle.

The above-mentioned programmability of the OPTIMIZER Smart IPG implies that medical personnel can tailor the operating parameters to each patient’s individual requirements with the OMNI Smart Programmer. The OPTIMIZER Smart IPG is powered by a rechargeable battery (see Section 1.4), which can be recharged transcutaneously by inductive power transfer with the OPTIMIZER Mini Charger.

The OPTIMIZER Smart IPG and the OMNI Smart Programmer communicate via telemetry (for details, see Appendix III). Telemetry is used for IPG programming as well as for obtaining diagnostic data by device interrogation. The programmer records device data, maintains a system log, stores standard programs for later use, provides an option to program “safe” parameters in an emergency, etc.

The OPTIMIZER Smart IPG is connected to three (3) implantable leads, two (2) leads are implanted in the right ventricle and one (1) lead implanted in the right atrium. The OPTIMIZER Smart IPG is compatible with standard pacemaker leads equipped with IS-1 connectors.

The implanting physician can select any standard ventricular pacing leads with the following characteristics:

- Bipolar lead approved for transvenous intracardiac ventricular pacing.
- Standard IS-1 bipolar connector.
- Maximum lead diameter 8 French
- Active fixation with electrically-active corkscrew distal electrode with a minimal electrically-active surface area of 3.6 mm².
- Distal (Tip) electrode coated with low-polarization coating (e.g. titanium nitride or iridium oxide).
- Proximal (Ring) electrode electrically-active surface of at least 3.6 mm², and Tip-Ring spacing between 8 and 30 mm
- Maximum total wire resistance of 200 Ω

**Pacing Leads Suitable for use with the OPTIMIZER IPG for CCM Signal Delivery
Current Offerings as of January 2, 2019**

Requirement for CCM	Pacing Leads Suitable for use with OPTIMIZER IPG					
	Medtronic CapSureFix Novus MRI™ SureScan™ 4076, 5076, 5086 Leads	Medtronic SelectSecure™ MRI SureScan™ 3830 Lead	Abbott (St Jude) 2088TC Tendril STS lead	Abbott (St Jude) LPA1200M Tendril MRI Lead	Boston Scientific Ingevity 7740, 7741, 7742 Leads	Biotronik Solia-S Leads
Bipolar lead approved for transvenous intracardiac ventricular pacing	YES	YES	YES	YES	YES	YES
Standard IS-1 bipolar connector	YES	YES	YES	YES	YES	YES
Active fixation with electrically-active corkscrew distal electrode with a minimal electrically-active surface area of 3.6 mm ²	YES, 4.2 mm ²	YES, 3.6 mm ²	YES, 6.9 mm ²	YES, 6.0 mm ²	YES, 4.5 mm ²	YES, 4.5 mm ²
Distal electrode coated with low-polarization coating (e.g. titanium nitride or iridium oxide)	YES, titanium nitride coating	YES, titanium nitride coating	YES, titanium nitride coating	YES, titanium nitride coating	YES, IROX™ (iridium oxide) coating	YES, “Fractal Iridium” (iridium oxide) coating

Note: The leads qualified for delivering CCM™ signals from OPTIMIZER IPGs must be commercial models that are FDA approved.

The implanting physician can select an atrial lead according to his/her preference.

1.2 OPTIMIZER Smart IPG Lead Connectors

The connector block accepts three (3) bipolar IS-1-BI connectors. The terminals are marked as follows:

- “A”: Atrium
- “V”: Ventricle
- “LS”: Local sense

1.3 OPTIMIZER Smart IPG Physical Characteristics

Height (mm)	69.4 ± 2.0
Width (mm)	47.5 ± 0.5
Thickness (mm)	11.5 ± 0.5
Volume (cm ³)	30.5 ± 0.5
Mass (g)	46 ± 3.0
Exposed metallic surface ^a (cm ²)	58.1
X-ray ID The ID comprises the following 3 elements:	ID OS y “y” is replaced by the letter code for the year of manufacture (see Appendix I).
<ul style="list-style-type: none"> • Impulse Dynamics Manufacturer ID: “ID” • Model number code: “OS” for OPTIMIZER Smart • Year code: A for 2015, B for 2016, C for 2017, etc. 	
Materials in contact with human tissue ^b	Titanium, Epoxy resin, Silicone rubber
Lead connectors	3.2 mm; IS-1/VS-1
^a When using unipolar ventricular or atrial sensing, the case of the OPTIMIZER Smart device serves as indifferent electrode. The local sense (LS) polarity is always bipolar. ^b Tests have revealed that these materials are biocompatible. The OPTIMIZER Smart IPG does not cause any temperature elevation capable of damaging the surrounding tissue.	



**Figure 1: OPTIMIZER Smart IPG
(front view)**



**Figure 2: OPTIMIZER Smart IPG
(back view)**

1.4 OPTIMIZER Smart IPG Battery

The OPTIMIZER Smart IPG is powered by a Model QL0200I-A lithium-ion battery (Li-Ion) manufactured by Quallion and has a usable capacity of 0.2 Ah. The current consumption of the OPTIMIZER Smart IPG is highly dependent on the energy of the CCM™ signals delivered to the patient.

1.5 OPTIMIZER Smart IPG Rechargeable Battery Behavior

The battery voltage of the OPTIMIZER Smart IPG, when its rechargeable battery is fully charged, is approximately 4.1 V. When battery voltage falls to 3.3 V, the device places itself in Standby (OOO) mode and stops performing any function except telemetric communication with the Programmer and OPTIMIZER Mini Charger. The device will return to normal behavior once the voltage rises above 3.4 V. If the battery voltage drops below 3.0 V, the device disconnects its circuitry from the battery and stops performing any function, including telemetric communication with the Programmer. The device will return to Standby (OOO) mode when the apparent battery voltage exceeds 3.0V. The latter can be achieved by initiating a recharging session since the induced voltage in the IPG's charging circuit exceeds 3.0 V and the IPG can be directly powered from the inductively transferred energy.

It is therefore recommended to charge the OPTIMIZER Mini Charger at least every week. Recharging is also recommended if the device is interrogated and the battery level is at or below 3.5V.

1.6 User Profile and Training

The operators of the OPTIMIZER Smart System include patients, physicians (and trained medical personnel who assist them) and Impulse Dynamics Representatives. Physicians, medical personnel and Company representatives shall be familiar with operation of electronic medical equipment, particularly IPGs, and programmers.

Physicians and medical personnel will have participated in a Company-sponsored training program which will provide both theoretical and hands on training regarding the technology, device features and detailed operating instruction for the IPG, the programmer, and patient charger. The need for future retraining regarding the OPTIMIZER Smart System is determined by Company personnel based on the user's individual implant history and frequency.

Patient training will be limited to the use of the OPTIMIZER Mini Charger and will be provided by Impulse Dynamics Representatives post implant.

2. INDICATIONS¹

The OPTIMIZER Smart System, which delivers CCM™ therapy, is indicated to improve 6-minute hall walk distance, quality of life and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for CRT, and have an LVEF ranging from 25% to 45%.

The OPTIMIZER Smart system delivers non-excitatory CCM™ signals to the heart and has no pacemaker or ICD functions.

3. CONTRAINDICATIONS AND PRECAUTIONS

Use of the OPTIMIZER Smart system is **contraindicated** in:

1. Patients with permanent or long-standing persistent atrial fibrillation or flutter
2. Patients with a mechanical tricuspid valve
3. Patients in whom vascular access for implantation of the leads cannot be obtained

4. WARNINGS

4.1 Potential Complications of Device Implantation

Just like any surgical procedure, implantation of an OPTIMIZER Smart IPG is associated with a certain risk. Complications of IPG implantation reported in the literature include, but are not limited to: arrhythmias induced by the IPG, including life-threatening arrhythmias (e.g. ventricular fibrillation), infection, skin necrosis, device migration,

¹ The safety and performance of the OPTIMIZER Smart System is based on clinical investigations conducted with the prior generation device, the OPTIMIZER IVs and III Systems given the similarities between the Systems with regard to function, intended use, design characteristics, and the CCM™ signals. Summaries of these studies are available on Impulse Dynamics' website.

(<http://www.impulse-dynamics.com/int/for-physicians/clinical-data/>)

hematoma formation, seroma and histotoxic reactions (also see: Potential Adverse Effects, Section 6).

Programming high sensitivities (i.e. sensitivity settings less than 2 mV) may increase the system's susceptibility to electromagnetic interference, which could either inhibit or trigger signal delivery.

Acute and chronic complications reported in the literature include, but are not limited to: lead fracture, lead displacement, atrial or ventricular perforation, and rare cases of pericardial tamponade. Perforation of the ventricular wall can induce direct stimulation of the phrenic nerve or the diaphragm. An impedance change demonstrated on a check-up can be indicative of lead fracture, lead displacement, or perforation (also see: Potential Adverse Effects, Section 6).

In very rare cases (<1%), transvenous lead placement can also lead to venous thrombosis and subsequent SVC syndrome.

Loss of sensing shortly after implant can be the result of lead displacement. In addition, loss of CCM™ signal delivery could be due to a lead fracture.

4.1.1 Atrial and Ventricular Arrhythmias Potentially Caused by Lead Implantation

As noted above, the use of transvenous leads may lead to arrhythmias, some of which may be life-threatening such as ventricular fibrillation and ventricular tachycardia. The use of screw-in leads such as those used for CCM™ signal delivery also have the potential of causing conduction disturbances such as bundle branch block. These can be minimized by performing the implant with the use of fluoroscopic guidance, ensuring that the leads are in appropriate position prior to fixation and by limiting the number of lead manipulations. Please read and follow all directions of the original Physician Manual for the leads that you intend to use to minimize adverse events connected to lead implantation.

4.1.2 Ventricular Arrhythmias Potentially Caused by CCM™ Signals

CCM™ signals are of greater strength than that of typical pacing pulses and are thus capable of eliciting activation of cardiac tissue when delivered outside of the absolute refractory period. CCM™ signals delivered outside of the ventricular absolute refractory period thus have the potential of causing signal-induced arrhythmias (some of which may be life-threatening, such as ventricular fibrillation and tachycardia). For this reason, it is imperative that CCM™ signal delivery parameters be chosen carefully. Most importantly, the various settings related to conditions that inhibit CCM™ signal delivery (e.g. Long AV Delay, Short AV Delay, LS Alert Window, refractory periods, and IEGM sensitivities) must be selected to allow delivery of CCM™ signals only on normally conducted (e.g. non-arrhythmic) beats, but inhibit them on beats of suspected ectopic or premature origin.

In addition, CCM™ signals may cause changes in the electrical conduction of tissue. For this reason, the delivery of CCM™ signals to the ventricular septum has the potential of causing bundle branch block that could lead to bradycardia. Through similar mechanisms, CCM™-induced changes in the electrical conduction of the myocardium have the potential of inducing tissue refractoriness that may facilitate the induction of reentrant tachyrrhythmias. It is recommended that the patient's rhythm be monitored carefully for changes in rhythm when

CCM™ signals are delivered during lead implantation, as well as during first activation of the OPTIMIZER Smart IPG and subsequent follow-up visits. Changes in ventricular rhythm caused by the delivery of CCM™ signals may require relocating the leads, as well as reprogramming the CCM™ delay and amplitude to settings that do not cause changes in the patient's ventricular rhythm.

4.1.3 Atrial Arrhythmias Potentially Caused by CCM™ Signals

Atrial and supraventricular arrhythmias could theoretically be initiated when CCM™-induced ventricular activity is conducted retrograde to the atria, resulting in premature atrial depolarization. The OPTIMIZER Smart IPG may sense the ventricular activation resulting from the retrograde-induced atrial event and deliver CCM™ as programmed. In addition, strong CCM™ signals delivered through leads implanted in basal position close to the atria have the potential of directly stimulating the atria. If CCM™ delivery causes atrial activation through either of these mechanisms, and the atrial signal is then conducted to the ventricles, the cycle may develop into a condition similar to pacemaker-mediated tachycardia (PMT).

The main variables that may have an impact on CCM™ events leading to atrial activation are the location of lead placement on the right ventricular septum, CCM™ amplitude, and CCM™ delay. To prevent the occurrence of atrial arrhythmias due to CCM™ signal delivery, it is recommended that basal lead implant locations be avoided. The potential for direct atrial activation by CCM™ signals can be tested during the implant by delivering the strongest possible CCM™ signal 20 to 30 ms longer than the LS-CCM delay with which the IPG will be ultimately programmed, as long as this delay places the CCM™ signal, including its 40 ms balancing phase, completely within the ventricular absolute refractory period, and monitoring for atrial activations. In such a case, the delay should be programmed to a longer value and lack of atrial activation confirmed. Besides proper lead location and CCM™ parameter programming, the “Atrial Tachycardia Rate” must be programmed to a sufficiently low value as a protective measure against atrial arrhythmias that could be induced by CCM™ signal delivery.

4.2 Handling

Do not implant the OPTIMIZER Smart IPG if the package is damaged or if the device has been dropped onto a hard surface from a height of 30 cm (12 in) or more while still in the shipping box. Do not implant the device if it has been dropped onto a hard surface after unpacking. Damaged packages or dropped devices need to be returned to Impulse Dynamics.

4.3 Storage and Handling

The recommended storage temperature range for the OPTIMIZER Smart IPG is 32°F to 104°F. Atmospheric pressure and relative humidity have no impact on the OPTIMIZER Smart IPG.

4.4 Packaging Information

The OPTIMIZER Smart IPG is supplied in a shelf box containing a literature pack and the sterile package. The sterile pack has been sterilized with ethylene oxide gas and comprises an outer TYVEK/PET blister pack containing an inner TYVEK/PET blister.

The following items are included in the shelf box:

- OPTIMIZER Smart System Insert Card
- Peel-off labels for use with implantation documents
- Sterile pack

The inner blister pack contains:

- One (1) OPTIMIZER Smart IPG
- One (1) Allen #2 torque wrench (11 oz-in = 77.68 mNm)
- One (1) Port Plug

Before opening the sterile package, check for any signs of damage suggesting that the sterility of the package or its contents might have been compromised. Damaged packages need to be returned to Impulse Dynamics. Do not attempt resterilize the contents of the sterile package that has been damaged or in any way compromised.

4.5 Resterilization and Reuse

Do not resterilize the OPTIMIZER Smart IPG, Port Plug, or the Allen wrench provided with the device. An OPTIMIZER Smart IPG that has been explanted for any reason may not be reimplanted in another patient.

4.6 Cremation

The OPTIMIZER Smart IPG contains a sealed chemical battery and therefore must not be incinerated. Make absolutely sure to explant the device before a deceased patient is cremated.

5. CAUTIONS

5.1 Environmental Conditions

The following discussion on potential hazards from the environment focuses on maintaining the utmost patient safety. Although the OPTIMIZER Smart IPG was designed to provide the highest possible protection against such hazards, complete immunity against these risks cannot be guaranteed.

Note: The OPTIMIZER Smart IPG should not be used in the vicinity of other electrical equipment. If proper separation is not feasible, the OPTIMIZER Smart IPG has to be monitored to ensure normal function.

Just like any other IPG, the OPTIMIZER Smart IPG can be affected by interference from magnetic, electrical, and electromagnetic signals, provided these are sufficiently strong or have characteristics resembling cardiac activity. Most interference will lead to inhibition of CCM™ signal delivery. In rare cases, an interfering signal could trigger inappropriate CCM™ signal delivery. In addition, interfering signals exceeding a certain threshold may couple enough energy into the IPG to damage the IPG circuits and/or the myocardial tissue in the vicinity of the leads. The patient manual also covers these factors, and these risks should be disclosed in the discussion with the patient.

The susceptibility of a particular device is dependent on the location of the IPG pocket, the type of interfering signal, and on the programmed operating parameters.

Because of the diversity of the potential causes of electromagnetic interference, Impulse Dynamics cannot characterize and describe all sources of interference and their effects in this manual.

Warning: Patients should be instructed to be cautious in the vicinity of equipment that generates electrical or electromagnetic fields and to seek medical advice before entering an area with posted warnings advising pacemaker patients (or patients with other types of implantable devices) not to approach.

5.2 Electrocautery

Use of surgical electrocautery devices can induce CCM™ signal inhibition or can make the OPTIMIZER Smart IPG revert to its “DOWN” mode [Standby (OOO) mode, with no delivery of CCM™] with the possible loss of statistical data. The device can be damaged if high energies are coupled into the system.

Use of electrocautery in close proximity to an implanted OPTIMIZER Smart IPG can also couple radio frequency energy directly through the leads and lead tips into the cardiac muscle tissue, producing burns or possibly cardiac arrhythmias. If electrocautery is used, only brief signal bursts may be delivered and the neutral electrode has to be positioned such that the current affecting the OPTIMIZER Smart IPG and the attached leads is minimized. The risk of adverse effects can be decreased by reprogramming the OPTIMIZER Smart IPG into Standby (OOO) mode. The patient’s peripheral pulse should be monitored throughout the procedure and correct operation of the OPTIMIZER Smart IPG should be verified immediately after the procedure. If the device has gone into its “DOWN” mode, it needs to be reset.

5.3 RF Ablation

RF ablation can cause the OPTIMIZER Smart IPG to inhibit CCM™ signal delivery or to revert to its “DOWN” mode [Standby (OOO) mode, with no delivery of CCM™] with the possible loss of statistical data. Depending on the amount of energy coupled into the system, the device could also be damaged. If an RF ablation procedure is performed in close proximity to the leads, the leads can couple radio frequency energy via the lead tips into the myocardium, producing burns or possibly cardiac arrhythmias.

If an RF ablation procedure has to be performed, the neutral electrode should be positioned such that the current flowing through the OPTIMIZER Smart IPG and the leads is minimized. Avoid direct contact between the ablation catheter and the OPTIMIZER Smart IPG or its leads. The risk of adverse effects can be decreased by reprogramming the OPTIMIZER Smart IPG into Standby (OOO) mode. The patient’s peripheral pulse should be monitored throughout the procedure and correct operation of the OPTIMIZER Smart IPG should be verified immediately after the procedure. If the device has gone into its “DOWN” mode, it needs to be reset.

5.4 Diathermy (Medical “Short Wave” Induction Heating)

Medical diathermy is generally contraindicated in patients with implanted devices. The effects of such intense energies on the OPTIMIZER Smart IPG cannot be predicted. Although damage to the circuitry of the IPG and/or the myocardium appears unlikely, it nevertheless could occur.

If diathermy is to be used notwithstanding the contraindication, it may not be applied in proximity of the OPTIMIZER Smart IPG and its leads. The risk of adverse effects can be decreased by reprogramming the OPTIMIZER Smart IPG into Standby (OOO) mode.

The patient's peripheral pulse should be monitored throughout the procedure and correct operation of the OPTIMIZER Smart IPG should be verified immediately after the procedure. If the device has gone into its "DOWN" mode, it needs to be reset.

5.5 Defibrillation and Cardioversion

Any implanted device can be damaged by external cardioversion or defibrillation. In addition, the myocardium adjacent to the lead tips and/or the tissue in the area of the device may be damaged. Altered signal thresholds could also be one of the consequences. The defibrillation current can also make the OPTIMIZER Smart IPG revert to its "DOWN" mode [Standby (OOO) mode, with no delivery of CCM™] with the possible loss of statistical data. The system can be damaged by exposure of high energies.

No particular paddle placement can avoid such damage. To decrease the risk, it is recommended to position the paddles as far away from the OPTIMIZER Smart IPG as possible. In addition, paddle positions that would bring the OPTIMIZER Smart IPG into the direct path of the defibrillation current should be avoided.

After defibrillation, the function of the OPTIMIZER Smart IPG should be closely monitored. In the unlikely event of abnormal function, lead repositioning (or replacement), reprogramming of the IPG may be required. If the device is found to have reverted to its "DOWN" mode, it needs to be reset.

Internal defibrillation will not damage the device.

5.6 Radiation Therapy

Warning: Therapeutic equipment generating ionizing radiation, such as linear accelerators and cobalt machines employed for treating malignant diseases, can damage the circuits used in most active implantable devices. Because the effect is cumulative, both dose rate and total dose determine if damage will occur and its possible extent. Please be aware of the fact that certain types of damage may not be immediately obvious. In addition, the electromagnetic fields generated by some types of radiation equipment for beam "steering" purposes can affect the function of the OPTIMIZER Smart IPG.

Radiation therapy can lead to a wide spectrum of effects, reaching from transient interference to permanent damage. It is therefore advisable to locally shield the OPTIMIZER Smart IPG against radiation if radiation therapy is to be used. During a radiation treatment and thereafter, the function of the IPG needs to be monitored. If tissue in the vicinity of the implant has to be irradiated, it may be advisable to relocate the IPG.

5.7 Nuclear Magnetic Resonance (NMR), Magnetic Resonance Imaging (MRI)

Exposure of the OPTIMIZER Smart system to strong magnetic and electromagnetic fields encountered within MRI systems has not been investigated. Even though programming the IPG into Standby (OOO) mode reduces the risk of adverse events, exposure of the patient to an MRI scan could result in:

- Unintended cardiac stimulation (induced tachycardia)
- Tissue damage near the IPG and lead electrodes with the result of inability to deliver CCM therapy
- Device malfunction (discharge of battery, damage to device electronics)

Exposure of patients with the OPTIMIZER Smart system to MRI scans should therefore not be allowed.

5.8 Lithotripsy

Warning: Direct exposure of the OPTIMIZER Smart IPG to shock waves can damage the device. A device implanted outside the shock wave path presents no clear-cut contraindication to lithotripsy. Precautionary programming of the OPTIMIZER Smart IPG to Standby (OOO) mode reduces the risk of adverse effects. The patient's peripheral pulse should be monitored during the procedure. Immediately after the treatment, the OPTIMIZER Smart IPG has to be checked for proper function. If the device is found to have reverted to its "DOWN" mode, it needs to be reset.

5.9 Therapeutic Ultrasound

Warning: Direct exposure of the OPTIMIZER Smart IPG to therapeutic ultrasound can damage the device. In addition, unexpected focusing of the ultrasound beam may harm the patient.

Therapeutic ultrasound can be used provided the implant is located far away from the ultrasound field and clearly outside the field. Precautionary programming the OPTIMIZER Smart IPG to Standby (OOO) mode reduces the risk of adverse effects. The patient's peripheral pulse should be monitored during the procedure. Immediately after the treatment, the OPTIMIZER Smart IPG should be checked for proper function. If the device is found to have reverted to its "DOWN" mode, it needs to be reset.

5.10 Transcutaneous Electrical Nerve Stimulation (TENS)

TENS is generally contraindicated in patients with implanted electrical devices. The high-voltage impulse delivered into the body by the TENS unit can impair the operation of the OPTIMIZER Smart IPG.

If a TENS unit is used nonetheless, the TENS electrodes have to be attached as far as possible from the OPTIMIZER Smart IPG and its leads. In addition, aiming for a limited current path, the TENS electrodes should be placed as close to each other as possible. The patient's peripheral pulse should be closely monitored while TENS is applied. Precautionary programming the OPTIMIZER Smart IPG to Standby (OOO) mode reduces the risk of adverse effects.

5.11 Home Appliances

Home and commercial microwave ovens do not affect the operation of the OPTIMIZER Smart IPG, provided they are in good condition and used as intended. Even microwave energy from a severely defective microwave oven directly radiating onto the IPG does not damage the device, although the sensing function may be impaired, which could eventually impact CCM™ signal delivery.

Patients with an implanted OPTIMIZER Smart IPG should be advised that some electric razors, electric power tools, and electric ignition systems, including those of gasoline powered engines, could cause interference. Generally, patients implanted with an OPTIMIZER Smart IPG may use gasoline powered engines, provided that protective hoods, shrouds, and other shielding devices have not been removed.

5.12 Store Anti-Theft Systems/Airport Security Screening Systems

Certain types of anti-theft systems, such as those installed at entrances/exits of stores, libraries and other facilities, as well as airport security systems can interfere with the OPTIMIZER Smart IPG. Such interference would most often inhibit CCM™ signal delivery. Patients should be advised to walk through such systems at a normal pace, i.e. not to slow down while passing through. Prior to passing through airport security systems, patients should notify the attendant security personnel that they carry an implant and should present their implant ID card.

5.13 Industrial Machinery

High voltage power lines, electric and arc welders, electric smelters, and power-generating equipment can interfere with the operation of the OPTIMIZER Smart IPG. For that reason, one needs to take into account the field strengths and modulation characteristics of all electromagnetic fields patients are exposed to in their workplaces or due to their lifestyle. Patients need to be specifically warned about these risks, or the OPTIMIZER Smart IPG should be programmed to minimize its susceptibility.

5.14 Transmitting Devices

Communication equipment such as radio and TV transmitters (including amateur [“ham radio”] transmitters, microwave, and CB radio transmitters with power amplifiers) as well as radar transmitters can interfere with the operation of the OPTIMIZER Smart IPG. For that reason, one needs to take into account the field strengths and modulation characteristics of all electromagnetic fields patients are exposed to in their workplaces or due to their lifestyle. Patients need to be specifically warned about these risks, or the OPTIMIZER Smart IPG should be programmed to minimize its susceptibility.

5.15 Cellular and Mobile Phones

Cell phones and other mobile phones can affect the operation of the OPTIMIZER Smart IPG. These effects can be caused by the radio frequencies emitted by the phones or by the phones’ speaker magnets. Potential effects include inhibition of or inappropriate CCM™ signal delivery if the phone is in very close proximity (within 25 cm / 10 in) of an OPTIMIZER Smart IPG and the corresponding leads. Because of the great variety of mobile phones as well as the significant physiologic differences between patients, it is impossible make generally applicable recommendations.

As a general guideline, patients implanted with an OPTIMIZER Smart IPG who would like to use a mobile phone are advised to hold the phone to the ear that is contralateral to the implant site. Patients should not carry the phone in a breast pocket or on a belt closer than 25 cm (10 in) from the implanted IPG because some phones emit signals even when they are turned on but not in use.

Compared to smaller cell phones, portable (handbag) and mobile (permanent car or boat installation) phones will generally transmit at higher power levels. For phones with higher transmission power levels, it is recommended to maintain a minimum separation of 50 cm (20 in) between the antenna and the implanted IPG.

6. POTENTIAL ADVERSE EFFECTS

Examples of adverse effects that may occur as the result of the surgical procedure are listed below in the order of their clinical severity:

1. Death
2. Arrhythmias (brady- or tachyarrhythmias including fibrillation)
3. Stroke or TIA (“transient ischemic attack”)
4. Respiratory/ventilatory failure
5. RA/RV perforation
6. Hemorrhage
7. Infection
8. Pleura or pericardial effusion
9. Pneumothorax

Examples of additional adverse effects potentially occurring secondary to CCM™ signal delivery are listed in the table below in the order of their clinical severity:

1. Abnormal cardiac function
2. Atrial and Ventricular Tachyarrhythmias
3. Atrial and Ventricular Bradyarrhythmias
4. Worsening heart failure
5. Myocardial tissue damage
6. Chest pain

7. DEVICE IMPLANTATION

7.1 General Considerations

Generally, the OPTIMIZER Smart IPG is implanted in the right pectoral region. Subclavian venous access is preferred over access via the axillary or cephalic vein, because a total of three intracardiac leads have to be inserted. The atrial lead is typically positioned in the right atrial appendage (RAA). Two right ventricular leads are placed for CCM™ signal delivery, one of these preferably in an anterior septal and the other in a posterior septal location, approximately half way between base and apex. Placing both leads in an anterior or posterior septal location is an acceptable alternative, provided the leads are separated by at least 2 cm. In patients who carry an ICD, one needs to ensure that there is adequate separation between CCM™ leads and ICD lead.

Warning: Avoid Subclavian crush by proper lead placement. Patients need to be monitored closely after the implantation procedure.

Warning: Exercise care while placing the leads to avoid swelling of the steroid plug or formation of a blood clot, which could prevent retraction of the corkscrew.

Warning: It is important to avoid prolonged manipulation of the leads and catheters in the venous system, which could lead to venous thrombosis.

Warning: During implantation, leads and catheters need to be manipulated with extra caution in order to avoid perforation of the right ventricular wall. Obtain X-rays, perform echocardiography, and device interrogation after implantation to detect perforations even in the absence of corresponding symptoms.

Warning: In order to prevent vascular injury and hemorrhage, be extremely cautious when introducing catheters and leads into arteries and veins.

7.2 Opening the Lead Sterile Package(s)

Visually inspect the lead packages before opening them for implantation. Follow the instructions provided by the lead manufacturer. Unless otherwise indicated by the lead manufacturer, proceed as follows with each sterile package:

- Open the shelf box outside the sterile field and remove the TYVEK/PET molded tray.
- Using the provided tab, peel back the TYVEK from the outer PET molded tray, taking care not to touch the inner sterile package.
- Using strict sterile technique, open the inner sterile blister pack and make it accessible to the scrub nurse. At the recess adjacent to the molded tab, the inner TYVEK/PET container can be removed from the outer tray with a pair of forceps.
- Peel back the inner cover starting at the provided peel tab.
- Remove the lead from the inner package and place it on a sterile and lint-free surface.

7.3 Opening the OPTIMIZER Smart Sterile Package

The OPTIMIZER Smart IPG is supplied in a shelf box that contains a literature pack and the sterile package sterilized with ethylene oxide gas. The sterile package comprises an outer TYVEK/PET blister pack containing an inner TYVEK/PET blister. Visually inspect the package before opening it for the implantation procedure. Please contact your Impulse Dynamics representative if package or seal is damaged. The inner blister pack contains:

- One (1) OPTIMIZER Smart IPG
- One (1) Allen #2 torque wrench (11 oz-in = 77.68 mNm)
- One (1) Port Plug

Open the shelf box outside the sterile field and remove the TYVEK/PET molded insert. To open the sterile package, proceed as follows:

- Starting at the provided tab, peel back the TYVEK from the outer PET molded insert, taking care not to touch the sterile inner package.
- Maintaining strict sterile technique, make the inner sterile blister pack accessible to the scrub nurse. The inner TYVEK/PET container can be removed from the outer tray with a pair of forceps inserted at the recess next to the molded tab.
- Peel back the inner cover starting at the provided tab.
- Remove the OPTIMIZER Smart IPG and the accessories.

7.4 Verifying Lead Placement

Note: The Programmer Wand of the OMNI Smart Programmer is not sterile and cannot be sterilized. The Programmer Wand needs to be placed in a sterile cover before it can be brought into the sterile field.

Place the Programmer Wand over the IPG. Ask the person operating the Programmer (outside the sterile field) to measure the lead impedances and make sure they are adequate.

Note: Any significant lead impedance deviation at a subsequent check-up may be a sign of lead displacement or indicative of another problem requiring further investigation.

Once the leads are in place, secure each lead to its respective lead anchor sleeve. Clean the lead body with sterile saline before you secure the anchoring sleeve to the lead. Secure the anchoring sleeve with two non-absorbable ligatures and tighten gently -- **Do Not Over-Tighten**.

7.5 Connecting the Implanted Leads to the OPTIMIZER Smart IPG

Important considerations:

- When tightening or loosening the set screws, always insert the tip of the torque wrench fully and in line with the set screw. Do not insert the wrench into the set screw at an angle.
- Prior to inserting the IS-1-BI lead connectors, verify visually that none of the set screws protrude into any of the IPG header cavities (please refer to the diagram on the IPG). Back off any set screw found protruding beyond the wall into the header cavity by turning it back with the Allen wrench in a counter-clockwise direction. Turn the set screw just enough so that its tip is no longer inside the header cavity. Do not back the set screw completely out of the terminal block.
- Under no circumstances may items other than the implantable lead connectors be introduced into the port of the IPG connector terminal.

Note: Provided the connectors are correctly installed, the connector retention force in the terminals is at least 10 N.

Clean the lead plugs with sterile distilled water (if using saline, wipe the plugs dry with a surgical sponge afterwards) and fully insert each plug into the respective connector terminal at the IPG. Observe that the male ends of the lead plugs are inserted beyond the respective lead tip terminals. Tighten the set screws using the sterile #2 Allen torque wrench included in the IPG package. Turn the torque wrench clockwise until there is a distinct clicking sound/feel. This feature prevents over-tightening of the set screw. Carefully apply traction on the strain relief of each lead to make sure that the leads are securely anchored in the terminal. Finally, tighten the set screws securing the contact between the rings of the plugs and the corresponding parts of the terminal block.

7.6 Dissection of the IPG Pocket

Blunt dissection directly on top of the fascia is the preferred method for creating the pocket, which should be just large enough to accommodate the IPG and any loops of excess lead.

Note: When dissecting the pocket, please bear in mind that for charging to be possible, the distance between charging wand and OPTIMIZER Smart IPG must not exceed 4 cm (1.5 in).

Before tightening the set screws, please ensure that the connector pin of each lead is completely inserted into the corresponding connector terminal of the OPTIMIZER Smart IPG.

7.7 Inserting the OPTIMIZER Smart IPG and Closing the Pocket

Insert the OPTIMIZER Smart IPG into the subcutaneous pocket. Although the OPTIMIZER Smart IPG can theoretically be interrogated and charged in any position, the preferred placement is such that the lettering points to the front, which provides the best link between the charging coil inside the header and the OPTIMIZER Mini Charger.

The recommended maximum depth of implant for proper device interrogation and charging is not more than 2.5 cm. Coil any excess lead and place these coils around the IPG or in the pocket inferior to the device. Ensure that the leads form not more than a gentle curve where they exit the IPG connector terminal and that they are not under traction or strain. Secure the IPG to the fascia with a non-absorbable suture and close the pocket.

Radiographs should be obtained after device implantation to rule out pneumothorax, even if there are no symptoms. In addition, proper device function should be verified by device interrogation, which can also detect lead displacement. Thereafter, patients should receive standard post-operative care for a minimum of 24 hours prior to discharge. The use of narcotics for pain relief should be minimized.

Remark: If the patient is also implanted with an ICD, concomitant device interaction testing should be performed (see Appendix III).

8. DEVICE EXPLANTATION / REPLACEMENT

Special care should be exercised when opening the IPG pocket so as to not damage the leads implanted with the OPTIMIZER Smart IPG. Once the IPG is lifted out of the pocket, the set screws can be loosened with a sterile #2 Allen wrench. While holding the IPG in one hand, grasp each silicone lead connector between thumb and forefinger. Pull the lead connectors from the terminal by cautious application of constant traction. Grasping the plugs with a sterile pad can help improve traction. Never apply traction to the actual lead body, which could damage the leads and cause lead failure.

Note:

- When tightening or loosening a set screw, always insert the tip of the torque wrench fully into and in line with the set screw. Do not insert the torque wrench into the set screw at an angle.

- Prior to inserting the IS-1-BI lead connectors, verify visually that none of the set screws protrudes into any of the IPG header cavities. Back off any set screw found protruding beyond the wall into the header cavity by turning it back in a counter-clockwise direction with the Allen wrench. Turn the set screw just enough so that its tip is no longer inside the header cavity. Do not back the set screw completely out of the terminal block.

Clean the lead plugs with sterile distilled water (if using saline, wipe the plugs dry with a surgical sponge afterwards) and fully insert the plug into the respective connector terminal of the OPTIMIZER Smart IPG. Observe that the tips of the lead plugs are inserted beyond the respective lead tip terminals. Tighten the set screws using the sterile #2 torque wrench included in the OPTIMIZER Smart package. Turn the Allen wrench clockwise until you can clearly hear and feel the clicking that limits excessive torque on the set screw. Carefully apply traction to the strain relief of each lead to make sure that the leads are securely anchored in the terminal. Finally, tighten the set screws securing the contact between the rings of the plugs and the corresponding parts of the terminal block.

Make sure to visually verify that the lead insulation is intact when replacing an OPTIMIZER Smart IPG. At this time, the impedances and sensing thresholds should also be assessed with a PSA.

When the OPTIMIZER Smart IPG is being explanted and not replaced, the remaining implanted leads need to be capped after they are disconnected from the IPG.

All explanted OPTIMIZER Smart IPGs should be returned to Impulse Dynamics for testing and analysis, which can provide valuable information on how to further improve device quality and reliability.

Warning: Never incinerate an OPTIMIZER Smart IPG. The IPG must be explanted before a deceased patient is cremated.

Warning: Implantable parts are not to be reused if they have previously been implanted in another patient.

9. OPTIMIZER SMART IPG: FUNCTIONS AND PROGRAMMING OPTIONS

9.1 Operating Modes

The implantable OPTIMIZER Smart IPG features three operating modes:

- Standby (OOO): The device is in standby; no events are sensed and no CCM™ signal trains are delivered.
- Active ODO-LS-CCM: The device senses atrial, ventricular, and local sense events and is capable of CCM™ signal delivery.
- Active OVO-LS-CCM: The device senses ventricular and local sense events and is capable of CCM™ signal delivery without the need for the detection of atrial sense events.

Note: Active OVO-LS-CCM mode is only available for the 2-lead clinical study.

9.2 CCM™ Off Status

Under certain conditions, which are listed below, the OPTIMIZER Smart IPG is set to a special “Off” status:

- **Permanent Off:** In this state, the OPTIMIZER Smart IPG does not deliver CCM™ signals, although it senses and classifies cardiac events. This status can only be changed by using the OMNI Smart Programmer software to reprogram the OPTIMIZER Smart IPG under supervision of a physician. The patient or a physician can force the OPTIMIZER Smart IPG into the **Permanent Off** state by placing a magnet over the implant site of the OPTIMIZER Smart IPG and by maintaining it in close proximity to the device for at least two cardiac cycles (2 - 3 seconds).

Note: This **Permanent Off** state is maintained even after the magnet is removed from the implant site.

- **DOWN:** In this state, the OPTIMIZER Smart IPG does not deliver CCM™ signals, and it may not sense cardiac events. Reversal of this state can only be accomplished by resetting the OPTIMIZER Smart IPG with the OMNI Smart Programmer software under physician supervision. In the unlikely event of inconsistent operation of the system’s logic circuits, the OPTIMIZER Smart IPG will automatically assume the “**DOWN**” state.

9.3 A/V Sensing

Through leads implanted in the heart, the OPTIMIZER Smart IPG can sense, detect, and analyze activity in the form of electrical signals generated by the heart, for example, electrical depolarization events which occur during the cardiac cycle. The controller and signal generation circuitry of the OPTIMIZER Smart IPG are programmed to receive the signals detected by electrodes and sensing circuitry and, based on the detected signal, analyze their characteristics (including, for example, magnitude and timing), and to determine whether or not to trigger the delivery of the CCM™ signal, as well as when to deliver the CCM™ signal.

9.3.1 A/V Sensing Leads

Right heart events are detected through two sensing leads:

- **A lead:** lead positioned in the right atrium (A)
- **V lead:** lead positioned in the right ventricle (V)

9.3.2 A/V Sensing Parameters

A and V polarity and sensitivity are the parameters determining how right heart events are sensed.

- **Sensitivity:** With the OMNI Smart Programmer software, the Atrium sensitivity can be set to any one of 13 values between 0.1 mV and 5.0 mV, and the Ventricle sensitivity to set to any one of 18 values between 0.1 mV and 10.0 mV.

- **Polarity:** To configure A and V sensing, the OPTIMIZER Smart IPG provides the following options:
 - **Bipolar:** The signal between lead “tip” (distal electrode) and “ring” (proximal electrode) of a bipolar lead is sensed.
 - **Unipolar:** The signal between lead tip (distal electrode) and the case of the OPTIMIZER Smart IPG is sensed.

9.3.3 Refractory Period

The Refractory period is the time interval when the OPTIMIZER Smart IPG does not detect input events. The refractory period is applicable to the right heart sensing:

- **Refractory:** Signals sensed within this period after an atrial or ventricular event do not register as atrial or ventricular events. With the OMNI Smart Programmer software, the A/V refractory period can be set to values between 148 ms and 453 ms, in 8 ms increments.

9.4 CCM™ Delivery Options

The implantable OPTIMIZER Smart IPG features three CCM™ delivery scheduling options:

- **CCM OFF:** No CCM™ signal delivery
- **Timed:** The device is programmed to deliver cardiac contractility modulation therapy within the time frame between Start Time (default: 0:00) and End Time (default: 23:59). The default configuration in the USA is for 1 hour ON Time followed by 3:48 hours OFF Time, repeatedly, to produce 5 hours of programmed cardiac contractility modulation therapy per day.

Note: An ON phase is started after each charging process. The timer will resume the normal program on the following midnight.

- **Continuous:** Continuous CCM™ signal delivery (for testing purposes only)

9.5 CCM™ Signal Delivery

This section describes how the implantable OPTIMIZER Smart IPG delivers CCM™ signals to the cardiac tissue during the absolute refractory period.

9.5.1 Channels

CCM™ signals that are generated by the signal generation circuitry of the OPTIMIZER Smart IPG can either be delivered through one of the following channels or through a combination of these channels:

- **V lead**
- **LS lead**

9.5.2 CCM™ Signal Parameters

The CCM™ signal is a pulse train comprising a programmable number of consecutive pulses, each with two phases of opposite polarity and programmable duration. Accordingly, the common practical configuration is given by programming cardiac contractility modulation to be delivered for one hour every few hours, for example 1 hour ON followed by 3:48 hours OFF, repeatedly, to produce 5 hours of cardiac contractility modulation therapy per day.

- **Number of Pulses:** With the OMNI Smart Programmer software, the number of pulses can be set to 1, 2, or 3.
- **Delay:** CCM™ signal delivery is triggered by the Local Sense event. The delay parameter (coupling interval) is the time interval between the leading edge of the Local Sense triggering event and the start of CCM™ pulse train delivery. With the OMNI Smart Programmer software, the delay parameter can be set to values between 3 ms and 140 ms, in 1 ms increments. This delay range is designed to ensure that the delivery is only within the absolute refractory period, and to avoid potential excitatory behavior of the CCM™ signal.
- **Amplitude (Magnitude):** This is the initial voltage of the CCM™ signal. With the OMNI Smart Programmer software, the amplitude can be set to values between 4.0 V and 7.5 V, in 0.5 V increments.
- **Phase Duration:** The phase duration of the pulses comprising the CCM™ signal can be programmed with the OMNI Smart Programmer software to one of 4 possible values between 5.14 ms and 6.60 ms. The duration of both phases are automatically set to identical values.
- **Phase Polarity:** The phase polarity of the pulses comprising the CCM™ signal can be programmed with the OMNI Smart Programmer software to “Positive” or “Negative”. When the polarity of PHASE 1 is set to one value, the polarity of PHASE 2 is automatically set to the opposite value

9.5.3 Balancing Phase

Delivery of each CCM™ pulse train is completed by a Balancing Phase, which discharges any residual polarization at the electrode/tissue interface. Balancing is accomplished by short-circuiting the channels used to deliver the CCM™ signal for a period of 40 ms.

9.5.4 Parameter Interaction

In order to avoid false event detections, the CCM™ signal has to be delivered entirely within the right atrial and right ventricular refractory period. Prior to the end of these refractory periods, an 86 ms long noise window is activated to detect external interference. Therefore, CCM™ signal delivery has to be completed before the noise window is opened. This is accomplished with the following constraint:

- *The sum of the values Alert Start, Alert Width, CCM™ Delay, and CCM™ Train Total Duration must be smaller than the lower of the following two values: right atrial refractory period, right ventricular refractory period minus 86 ms.*

If the V channel is used for CCM™ signal delivery, the balancing phase also needs to be completed before the noise window starts. This can be guaranteed by the following constraint:

- *If the V channel is used for CCM™ signal delivery, the sum of the values Alert Start, Alert Width, CCM™ Delay, CCM™ Train Total Duration, and Balancing Phase (40 ms) needs to be smaller than the lower of the following two values: right atrial refractory period, right ventricular refractory period minus 86 ms.*

The Alert Start time relates to the right ventricular event. Thus, if the Alert Start value is negative and if a local sense event is detected during the AV interval, a right ventricular event will have to occur and be detected before the device can determine if the event fell inside the alert window. That implies that the OPTIMIZER Smart IPG cannot deliver a CCM™ signal prior to the right ventricular event occurring. This is asserted by the following constraint:

- *The sum of Alert Start and CCM™ Delay must be equal to or greater than 3 ms*

9.6 CCM™ Inhibit Parameters

By analyzing the train of sensed cardiac events based on their succession and their temporal order, the OPTIMIZER Smart IPG “decides” for each heart action whether to deliver CCM™ signals or not.

9.6.1 Number of Beats for CCM Inhibition

For the period when CCM™ signal delivery is inhibited, one can program the number of beats for which CCM™ signal delivery will continue to be inhibited after the initial inhibiting event. With the OMNI Smart Programmer software, the total number of inhibited beats can be set to any value between 1 and 16. This means that CCM™ delivery can be inhibited from to none to 15 additional beats beyond the beat leading to the initial inhibiting event.

Please note that this number of inhibited cycles applies to the most current event leading to signal inhibition, i.e. a new inhibiting condition occurring during a period of already inhibited CCM™ signal delivery will start a new inhibition period.

9.6.2 Conditions Causing Inhibition

The following cardiac activities or events are sensed and detected by the OPTIMIZER Smart IPG while it is in its **Active** state. These events are also entered into the statistical data set, and they pertain to transmitted marker events. When CCM™ train delivery is on, such events inhibit CCM™ signal delivery. An event that occurs outside the configurable time window(s) could indicate, for example, suspected cardiac arrhythmia, and, in response to detecting the suspected arrhythmia, or other abnormal event, the CCM™ signal would not be delivered.

- **Short AV:** Intervals between an atrial and a ventricular event are considered “Short AV” if they fall below a programmed threshold. Using the OMNI Smart Programmer software, the Short AV threshold can be set to one of 49 possible values between 23 ms and 398 ms. CCM™ signal delivery is *always inhibited* if a Short AV condition is detected.

- **Long AV:** Intervals between an atrial and a ventricular event are considered “Long AV” if they exceed a programmed threshold. Using the OMNI Smart Programmer software, the Long AV threshold can be set to one of 49 possible values between 23 ms and 398 ms. CCM™ signal delivery is *always inhibited* if a Long AV condition is detected.
- **Atrial Tachycardia:** Any atrial rate exceeding a certain threshold is considered atrial tachycardia. Using the OMNI Smart Programmer software, the atrial tachycardia threshold rate can be set to one of 51 possible values between 62 bpm and 179 bpm. CCM™ signal delivery is *always inhibited* when atrial tachycardia is detected.
- **Premature Ventricular Contractions (PVC):** A sensed right ventricular event is considered a PVC if it was preceded by another right ventricular sensing event without an interposing atrial sense event. CCM™ signal delivery is *inhibited each time* a PVC condition is detected.
- **LS Out of Alert:** A local sense event detected after the end of the Local Sense Alert Window triggers an LS Out of Alert condition. The Local Sense Alert Window is the time interval during which the leading edge of valid LS events triggers CCM™ signal delivery. How this is programmed is detailed in Section 9.8.1.
- **Atrial and ventricular noise:** Despite various methods for detecting and filtering noisy signals implemented in the OPTIMIZER Smart IPG, noise from powerful electromagnetic sources (e.g. from portable telephones, radio transmitters, etc.) as well as noise from physiological events (e.g. myopotentials, etc.) can interfere with the detection of cardiac events.

Any time higher rate signals (greater than 11.6 Hz) are detected on the atrial or ventricular channel, the control logic of the OPTIMIZER Smart IPG assumes the presence of noise and declares an A/V noise condition. CCM™ signal delivery is *always inhibited* if atrial or ventricular noise is detected.

9.7 Local Sensing

The local electrical activity of the ventricular myocardium is detected via the Local Sense (LS) lead. LS channel sensitivity can be set with the OMNI Smart Programmer software to one of 18 values between 0.1 mV and 10.0 mV.

9.8 CCM™ Triggering Based on Local-Sense Events

Delivery of CCM™ signal trains is synchronized with the intrinsic myocardial electrical activity in the vicinity of the Local Sense (LS) electrode. The LS channel is configured to sense the electrical activity of a small, localized area of the heart (near the fixation site of the LS electrode). In response to this sensed activity, the OPTIMIZER Smart IPG evaluates the myocardial electrical signal to determine whether it meets the criteria defined by the set of LS parameter values programmed into the device. If the criteria are met, then the device delivers the CCM™ stimulus. The timing of the signal detected through the LS channel within a cardiac cycle, especially with regard to the R wave, is the main criterion for the OPTIMIZER Smart IPG to classify the cycle as normal or abnormal. CCM™ signals are *not delivered* during cycles classified as abnormal.

Provided that the CCM™ signal delivery is not prohibited by detecting a Local Sense event inconsistent with the Alert Window, the OPTIMIZER Smart IPG may deliver CCM pulses to thousands of heart beats over the course of a day. For example, it may deliver CCM™ to several thousand beats out of 50,000 consecutive beats, taking into account any conditions causing inhibition (as noted in Section 9.6.2) that result in CCM™ pulses not being delivered.

9.8.1 Local Sense Alert Window

When the internal logic of the device detects ventricular events corresponding to cardiac cycles not classified as abnormal because of noise, atrial tachycardia, or suspected PVCs, it will open a Local Sense Alert Window. The Alert Window can be inside the AV interval, inside the VA interval, or partially inside the AV and partially inside the VA interval.

The first event detected within the window serves as a trigger for CCM™ signal delivery.

Valid Local Sense events detected outside the Alert Window are considered to be PVCs and inhibit CCM™ signal delivery for a programmable number of cycles. Inhibiting Local Sense events can be detected even between a triggering Local Sense event and the start of the corresponding CCM™ signal, which in this case will not be delivered.

The Local Sense Alert Window is the time interval during which the leading-edge of valid LS events is used to trigger CCM™ signal delivery.

The position in time of this window is determined by two programmable parameters:

- **Alert Start:** Begins with the right ventricular event. Using the OMNI Smart Programmer software, Alert Start can be set to values between -100 ms and 100 ms, in 2 ms increments. Please note that the Alert Window starts inside the AV interval if this value is negative.
- **Alert Width:** Equivalent to the duration of the Alert Window. Using the OMNI Smart Programmer software, Alert Width can be set to values between 1 ms and 40 ms, in 1 ms increments. If the sum of **Alert Start** and **Alert Width** is negative, the Alert Window ends inside the AV interval.

The leading edge of the first event detected within this window is used to trigger CCM™ signal delivery. When an event is detected, the Local Sense Alert Window is immediately closed. Any Local Sense events detected after the window closes are considered to lie outside the Alert Window and lead to the **LS Out of Alert Status**.

If a Local Sense event is detected outside the Alert Window, CCM™ signal delivery is *always inhibited*.

9.8.2 Local Sense Refractory Periods

With the exception of events occurring during the Local Sense Refractory Periods, any event detected through the LS channel is considered a valid Local Sense event.

Local Sense Refractory Periods include:

- **Pre A Refractory Period:** Ends with the atrial event. With the OMNI Smart Programmer software, the duration can be set to values between 0 ms and 55 ms, in 5 ms increments.
- **Post A Refractory Period:** Begins with the atrial event. With the OMNI Smart Programmer software, the duration can be set to values between 0 ms and 55 ms, in 5 ms increments.
- **Pre V Refractory Period:** Ends with the ventricular event. With the OMNI Smart Programmer software, the duration can be set to values between 0 ms and 55 ms, in 5 ms increments.
- **Post V Refractory Period:** Begins with the ventricular event. With the OMNI Smart Programmer software, the duration can be set to values between 0 ms and 39 ms, in 1 ms increments.
- **Post LS Refractory Period:** Begins with a valid LS event. With the OMNI Smart Programmer software, the duration can be set to one of 56 possible values between 15 ms and 250 ms.
- **Post CCM Refractory Period:** Begins with the start of the CCM™ signal train and ends with the end of the **Right V Refractory Period**.

9.8.3 Remarks

If the Pre- and Post-ventricular LS Refractory Periods are inside the Local Sense Alert Window (i.e. if the Alert Start is negative and the sum of Alert Start and Alert Width is longer than the Post-Ventricular Refractory Period), only Local Sense events falling inside the Alert Window and outside the Ventricular LS Refractory Periods will trigger CCM™ signal delivery.

If a Local Sense event is detected after the window closes and before CCM™ signal train delivery commences, the new event is considered to be outside the Alert Window and CCM™ signal delivery will be inhibited.

In Active ODO-LS-CCM mode, the Local Sense Alert Window cannot start prior to the atrial event. Therefore, if the Alert Start occurs before the end of the post-atrial refractory period (Alert Start is negative and the AV interval minus the Post-Atrial Refractory Period is smaller than the absolute value of Alert Start), the Local Sense Alert Window will start at the end of the Post-Atrial Refractory Period.

9.8.4 Parameter Interaction

Local Sense signals are ignored during Local Sense refractory periods. Therefore, the OMNI Smart Programmer software will not permit the *Alert Window to start or end inside the pre- and/or post-ventricular refractory period*.

APPENDIX I

As a convenience to the user, the following overview provides a brief and succinct summary of the characteristics of the OPTIMIZER Smart IPG. Some of these data are also presented in the manual in text form.

Physical Characteristics

Model	OPTIMIZER Smart IPG
Height (mm)	69.4 ± 2.0
Width (mm)	47.5 ± 0.5
Thickness (mm)	11.5 ± 0.5
Volume (cm ³)	30.5 ± 0.5
Mass (g)	46 ± 3.0
Area of exposed metal can (cm ²)	58.1
Radiopaque ID	ID OS y¹
Materials in contact with human tissue	Titanium Epoxy resin Silicone rubber
Lead connectors	3.2 mm; IS-1/VS-1
¹ The manufacturer code stands for Impulse Dynamics; the model ID code for the OPTIMIZER is "OS"; y corresponds to the year code: A for 2015, B for 2016, C for 2017, D for 2018 etc...	

Battery

Model and IEC type	QL02001, rechargeable
Manufacturer	Quallion
Chemistry	Lithium-ion
Low battery indicator	3.3 V
Battery life to elective replacement indication	6 years
Battery life to end of service	7 years
Approximate capacity after recharging to LBI	200 mAh

Current Consumption

Mode	Current
OOO	Less than 40 μ A
ODO-LS - CCM OFF	Less than 45 μ A
ODO-LS - CCM ON	Less than 1200 μ A ¹

¹Current consumption of the OPTIMIZER Smart IPG is strongly dependent on the energy delivered by the CCM™ pulse train.

Safe Mode

Mode	Description
DOWN mode	When the device encounters conditions considered to be the result of faulty device circuitry or software, it will switch to DOWN mode. In DOWN mode, the device is completely quiescent; CCM signals are not delivered and cardiac events are not sensed. To take the device out of this mode, a device reset must be performed under physician supervision.

Programmable Parameters

OPERATING MODES

Mode	Characteristics
OOO	Standby mode: no events are sensed and no CCM™ impulse trains are delivered
ODO-LS-CCM	Active mode where the device senses atrial, ventricular and Local Sense events and is capable of CCM™ signal delivery

A / V SENSING PARAMETERS

Parameter Name	Values
Atrium sense amplifier sensitivity	13 possible between 0.1 mV to 5.0 mV ¹
Ventricle sense amplifier sensitivity	18 possible between 0.1 mV to 10.0 mV
Atrium sensing polarity ¹	Unipolar, Bipolar
Ventricle sensing polarity	Unipolar, Bipolar
Atrium refractory period	Between 148 ms to 453 ms in 8 ms increments
Ventricle refractory period	Between 148 ms to 453 ms in 8 ms increments

CCM™ TRAIN PARAMETERS

Parameters Name	Values	
CCM Mode	CCM OFF	No pulse train enabled
	Timed	As defined by the parameter values programmed under the CCM Scheduling Tab.
	Continuous	The pulse train is enabled for the entire day.
Number of Pulses	1, 2, or 3	
CCM™ Train Delay	Between 3 ms and 140 ms in 1 ms increments	
CCM™ Pulse Amplitude	Between 4.0 V and 7.5 V in 0.5 V increments	
CCM™ Delivery Channels	LS and/or V	
Phase 1 Duration	4 possible between 5.14 ms and 6.60 ms.	
Phase 1 Polarity	“Positive” or “Negative”.	

CCM™ INHIBIT PARAMETERS

Parameter Name	Values
Count	Between 1 and 16 in increments of 1
Short AV	49 possible between 23 ms and 398 ms
Long AV	49 possible between 23 ms and 398 ms
Atrial Tachycardia Rate	51 possible between 62 bpm and 179 bpm

LOCAL SENSE PARAMETER

Parameter Name	Values
Local Sense Sensitivity	18 possible between 0.1 mV to 10.0 mV
Local Sense Alert Start	Between –100 ms to 100 ms in 2 ms increments
Local Sense Alert Width	Between 1 ms to 40 ms in 1 ms increments
Local Sense Pre-Atrial refractory period	Between 0 ms to 55 ms in 5 ms increments
Local Sense Post-Atrial refractory period	Between 0 ms to 55 ms in 5 ms increments
Local Sense Pre-Ventricular refractory period	Between 0 ms to 55 ms in 5 ms increments
Local Sense Post-Ventricular refractory period	Between 0 ms to 39 ms in 1 ms increments
Local Sense Post-LS refractory period	Between 15 ms to 250 ms in 1 ms increments

Factory Settings

PARAMETERS RELATED TO CONTROLLING RIGHT HEART SENSING

Mode	OOO
Atrial Sense Amplifier Sensitivity	1.3 mV
Ventricular Sense Amplifier Sensitivity	2.0 mV
Ventricular Sensing Polarity	Bipolar
Atrial Sensing Polarity	Bipolar
Ventricular Refractory Period	250 ms
Post-Ventricular Atrial Refractory Period	250 ms

CCM™ PULSE TRAIN ACTIVATION

CCM™ Pulse train enable	OFF
-------------------------	-----

CCM™ PULSE TRAIN TIMING

Number of pulses	2
Train delay	35 ms
Phase 1 duration	5.14 ms
Phase 2 duration	5.14 ms
Phase 1 polarity	Positive
Phase 2 polarity	Negative
CCM™ Pulse Amplitude	7.5 V
CCM™ signal delivery channel	LS, V
Interval	0 ms

CCM™ INHIBIT ALGORITHM

CCM™ Inhibit Count	2 beats
Short AV Delay	70 ms
Long AV Delay	398 ms
Atrial tachycardia rate	154 bpm

LS CHANNEL PROGRAMMABLE PARAMETERS

LS Sensitivity	2.0 mV
LS Alert Window Start	-10 ms
LS Alert Window Width	30 ms
LS Pre-Atrial LS Refractory Period	5 ms
LS Post-Atrial LS Refractory Period	5 ms
LS Pre-Ventricular LS Refractory Period	0 ms
LS Post-Ventricular LS Refractory Period	0 ms
LS Post-LS Refractory Period	20 ms

CCM™ SCHEDULE PARAMETERS

Start time	00:00
End time	23:59
On Time	01:00
Off Time	02:25

CHARGER ALARM PARAMETERS

Minimum Target % for CCM™ Delivery	30%
Maximum Lead Displacement	20%

Emergency Programming**PARAMETERS RELATED TO CONTROLLING RIGHT HEART SENSING**

Mode	OOO
Atrial Sense Amplifier Sensitivity	1.3 mV
Ventricular Sense Amplifier Sensitivity	2.0 mV
Ventricular Sensing Polarity	Bipolar
Atrial Sensing Polarity	Bipolar
Ventricular Refractory Period	250 ms
Post-Ventricular Atrial Refractory Period	250 ms

CCM™ PULSE TRAIN ACTIVATION

CCM™ Pulse train enable	OFF
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CCM™ PULSE TRAIN TIMING

Number of pulses	2
Train delay	35 ms
Phase 1 duration	5.14 ms
Phase 2 duration	5.14 ms

Phase 1 polarity	Positive
Phase 2 polarity	Negative
CCM™ Pulse Amplitude	7.5 V
CCM™ signal delivery channel	LS, V
Interval	0 ms

CCM™ INHIBIT ALGORITHM

Programmable parameters to inhibit CCM™ signal delivery	
CCM™ Inhibit Count	2 beats
Short AV Delay	70 ms
Long AV Delay	398 ms
Atrial tachycardia rate	154 bpm

LS CHANNEL PROGRAMMABLE PARAMETERS

LS Sensitivity	2.0 mV
LS Alert Window Start	-10 ms
LS Alert Window Width	30 ms
LS Pre-Atrial LS Refractory Period	5 ms
LS Post-Atrial LS Refractory Period	5 ms
LS Pre-Ventricular LS Refractory Period	0 ms
LS Post-Ventricular LS Refractory Period	0 ms
LS Post-LS Refractory Period	20 ms

CCM™ SCHEDULE PARAMETERS

Start time	00:00
End time	23:59
On Time	01:00
Off Time	02:25

CHARGER ALARM PARAMETERS

Minimum Target % for CCM™ Delivery	30%
Maximum Lead Displacement	20%

APPENDIX II

Communications/Telemetry

Between the OPTIMIZER Smart IPG and the OMNI Smart Programmer:

- **OPTIMIZER Smart IPG to OMNI Smart Programmer:**
 - PPM: “0” = 180 μ s, “1” = 270 μ s
 - 14.5 kHz LC excited by pulse
 - 1 cycle per pulse until dampened to 10%
 - Energy invested per pulse 0.36 μ J \rightarrow 5.14 mW_{peak} per pulse; 1.8 mW_{average}
- **OMNI Smart Programmer to OPTIMIZER Smart IPG:**
 - AM: “0” = no carrier, “1” = carrier for 305 μ s
 - 23 kHz carrier frequency
 - Power: 0.56 W_{peak}; 0.27 W_{average}

APPENDIX III

Testing procedure for device/device interaction:

Patients with a concomitant device (e.g. ICD, pacemaker) require additional testing at the end of the implant procedure to ensure appropriate function of both the OPTIMIZER Smart IPG and the concomitant device. The steps of the required testing procedure are as follows:

1. Program the ICD so that it does not deliver antitachycardic therapy during this test.
2. Program the sensing windows of the OPTIMIZER Smart IPG and verify that it can be programmed to consistently delivery cardiac contractility modulation therapy in the presence of the concomitant device.
3. Activate cardiac contractility modulation therapy and analyze the real-time intracardiac electrograms and marker channels to ensure that the cardiac contractility modulation therapy does not cause inappropriate oversensing during normal sinus rhythm which cannot be resolved by reprogramming or lead repositioning.
4. Activate cardiac contractility modulation therapy and analyze the real-time intracardiac electrograms and marker channels to ensure that the cardiac contractility modulation therapy does not cause inappropriate undersensing during normal sinus rhythm which cannot be resolved by reprogramming or lead repositioning.
5. Activate cardiac contractility modulation therapy in patients requiring antibradycardic pacing and analyze the intracardiac electrograms and marker channels to ensure that the cardiac contractility modulation therapy does not cause inappropriate inhibition of antibradycardic pacing which cannot be resolved by reprogramming or lead repositioning.

APPENDIX IV

Extrapolated Battery Life of the OPTIMIZER SMART IPG

The expected life of the Optimizer Smart IPG is limited by the expected service life of its rechargeable battery. The rechargeable battery inside the Optimizer Smart IPG should provide at least six years of service. Over time and with repeated charging, the battery in the Optimizer Smart IPG will lose its ability to recover its full capacity.

Once the implant reaches its sixth year of service, it will have entered its elective replacement period. The Optimizer Smart IPG will need replacement when stimulation can no longer be maintained for a full week with routine weekly charging. In the sixth year of service, it is thus important that the patient will be instructed to fully charge the Optimizer Smart IPG seven days prior to routine checkup visits so that the physician may determine if the Optimizer Smart IPG is still able to deliver a full week of cardiac contractility modulation therapy when recharged weekly.

The Optimizer Smart IPG is estimated to reach the end of its useful service at seven years after implant, and replacement of the Optimizer Smart IPG is recommended at this point.

Extrapolated Battery Charge Longevity

The FDA approved dosage is 5 hours/day at 7V stimulation amplitude. Battery charge longevity can be estimated from the following tables. This is a conservative estimate of charge longevity for OPTIMIZER Smart IPG at 5 and 7 V.

For CCM™ delivery of 7 hours per day as a function of parallel lead impedance:

Channels impedance (OHM)	Stimulation amplitude (V)	Charge longevity (days)
220	5	20
220	7	11
300	5	26
300	7	15
600	5	46
600	7	28
900	5	60
900	7	38
1200	5	65
1200	7	44

This is the same but at 5 hours per day. The FDA approved dosage is 5 hours per day.

Channels impedance (OHM)	Stimulation amplitude (V)	Charge longevity (days)
220	5	28
220	7	15
300	5	36
300	7	21
600	5	65
600	7	39

Channels impedance (OHM)	Stimulation amplitude (V)	Charge longevity (days)
900	5	84
900	7	53
1200	5	90
1200	7	62

These are for the following conditions:

- Number of pulses per CCM™ train: 2
- Phase duration: 5.14 ms
- Heart rate: 85 bpm

Under these conditions, the average current drain from the battery during CCM™ delivery is approximately as follows:

VBAT (V)	Impedance (OHM)	Stimulation amplitude (V)	Average Measured Current Drain (uA)
3.4	220	5	1,420
3.4	220	7	2,603
3.4	300	5	1,094
3.4	300	7	1,848
3.4	600	5	613
3.4	600	7	1,015
3.4	900	5	468
3.4	900	7	734
3.4	1200	5	412
3.4	1200	7	596
4.1	220	5	1,159
4.1	220	7	2,124
4.1	300	5	909
4.1	300	7	1,652
4.1	600	5	511
4.1	600	7	879
4.1	900	5	402
4.1	900	7	652
4.1	1200	5	394
4.1	1200	7	582

Failure to recharge the OPTIMIZER Smart IPG in a timely manner may cause the device to revert to Standby (OOO) mode and to suspend CCM™ signal delivery. In this mode, the device has to be recharged first before it resumes therapy delivery.

APPENDIX V

Scientific Background About Heart Failure and Cardiac Contractility Modulation

Heart failure is a condition wherein the heart muscle does not pump blood as well as it should, generally resulting in reduced cardiac output, possibly due to reduced contraction force or impaired relaxation or other deficiencies. Chronic heart failure is associated with cardiac muscle remodeling, which is the result of abnormal genomic, molecular, cellular, and structural changes that typically manifest clinically as changes in size, shape, and function of the heart's ventricles. The reduced cardiac function is associated with multiple symptoms, such as fatigue, shortness of breath (dyspnea), co-morbidities, and limited ability to walk, exercise or tolerate effort. The severity of symptoms is often classified by the physician in accordance with New York Heart Association (NYHA) classification (for example, NYHA class II represents moderate symptoms and class IV represents severe symptoms). Over time, chronic heart failure is a leading cause for hospitalizations and mortality. There are several medications that are used for treating heart failure according to the guidelines. In patients that are symptomatic despite appropriate medication, further evaluation of left ventricular ejection fraction (usually valuated by echocardiography) and QRS duration (evaluated by ECG) are useful in determining the possible need for an ICD, in cases having low ejection fraction, or a CRT, in cases with wide QRS, respectively.

Cardiac Contractility Modulation therapy is based on the delivery of non-excitatory electrical signals to the ventricles during the ventricular absolute refractory period. Published scientific research on cardiac contractility modulation therapy in animals and in humans explored various properties and effects. Some data suggests that cardiac contractility modulation has immediate effects on heart failure tissue, including potentially increasing the contraction force (contractility) of the muscle, possibly by immediate (i.e. less than a minute) improvement in the activity of the intracellular proteins that are associated with calcium cycling, for example by increased phosphorylation of the phospholamban protein, which is believed to modify the activity level of SERCA-2a, a protein responsible for intracellular calcium handling. Other data in heart failure animals and in humans suggest that after treating with cardiac contractility modulation for several hours, there may be normalization of mRNA expression levels of plurality of cardiac genes that are associated with heart failure (e.g. SERCA-2a, ANP, BNP, α -MHC, and others). Some data suggest that these changes and improvements in contraction are not associated with increase in myocardial oxygen consumption. Other data in animals over a period of a few months of cardiac contractility modulation delivery suggest the potential for improvements in the expression levels of several proteins that are associated with heart failure. In addition, some data suggest that with a few months of cardiac contractility modulation delivery, cardiac dimensions, structure, function (e.g. LVEDD, LVESD, and LVEF), cellular function, and/or tissue behavior may improve, providing the potential for reverse remodeling. Other studies explored clinical benefits with cardiac contractility modulation therapy in chronic heart failure patients, typically with a narrow QRS and New York Heart Association (NYHA) class of at least II, and suggest that several months (e.g. at least 3 months) of treatment potentially result in improvements in exercise tolerance (e.g. by six minute walk tests or by peak oxygen consumption in cardio pulmonary tests) and in quality of life (e.g. by NYHA

classification or by questionnaire), which could be indicative of clinically significant improvements in cardiac function. Various studies explored effects of cardiac contractility modulation in patients with NYHA classes II, III and IV, some with EF up to 35%, some with higher EF (e.g. 40%, 45%). The studies usually included population with a range of age, gender, etiology (e.g. ischemic, idiopathic) and other characteristics.

With regard to use of cardiac contractility modulation outside the United States, the 2016 European Society of Cardiology practice guidelines has reviewed clinical studies of cardiac contractility modulation in heart failure patients and mentioned cardiac contractility modulation as a treatment option that may be considered in selected patient population. Summaries of some of these studies are available on Impulse Dynamics' website (<http://www.impulse-dynamics.com/int/for-physicians/clinical-data/>).

Over the years of evaluation of cardiac contractility modulation therapy and use of the therapy outside the USA in countries that accept the CE Mark, CCM™ was delivered using various models of the OPTIMIZER® System, which includes an implantable pulse generator (IPG) that is programmable and has a rechargeable battery. In principle, the OPTIMIZER® System is implanted in a procedure which is similar to a pacemaker implantation. Unlike pacemakers or defibrillators, the OPTIMIZER® System does not have integrated pacing or defibrillation capabilities, and is only used for delivering cardiac contractility modulation therapy. Often a patient may have concomitant implantable devices, as may be indicated per patient. The OPTIMIZER® is connected to the heart's ventricles using leads, typically with the electrodes fixated to the right ventricular septum. For example, the ventricular leads may be spaced apart by a few centimeters and positioned on the septum, at or adjacent to an intersection of the septum and right ventricular free wall. The electrodes are used for sensing electrical activity of the heart and for delivery of CCM™ signals to the ventricular muscle at the proper timing and signal configuration. The OPTIMIZER can be programmed to deliver cardiac contractility modulation therapy for several hours every day: typically 5 hours per day in the US studies, and 7 or more hours per day in other countries. As part of the OPTIMIZER algorithm, the circuitry records one or more local electrical activity (i.e. activity in the vicinity of the electrode measured using the bipolar electrode configuration) or non-local electrical activity (i.e. wide-field electrogram using unipolar sensing between the electrode and the distant IPG can). The timing of the CCM™ delivery is determined to be at a certain delay and duration from the sensing, designed to deliver the CCM™ during the absolute refractory period of the muscle within the current beat cycle; this may maintain the CCM™ signal non-excitatory. If the patient has a concomitant pacing or defibrillation device, the OPTIMIZER can be configured to apply the CCM™ signals during a paced cardiac cycle, within the refractory period which follows the pacing. The OPTIMIZER can also be configured to apply the CCM™ signal during a non-paced cardiac cycle. The algorithm also applies criteria for delivery of the CCM™ signal or inhibiting the delivery of the CCM™ signal according to the relative timing of events, for example using criteria for minimum and maximum acceptable heart rate (R-R intervals), minimum and maximum acceptable time between sensed events in two locations on the RV septum, inhibition if signals are detected at an unexpected timing, and/or the use of an alert window in order to detect unexpected events and potentially block CCM™ delivery. Thus, the OPTIMIZER may deliver the non-excitatory CCM™ signal during the absolute

refractory period of hundreds or thousands of beats out of 50,000 consecutive beats, taking into account the detection of any conditions that inhibit the CCM™ signal delivery (such as, for example, a detected arrhythmia). The parameters of the algorithm are configured per patient, with the purpose of enabling the normal delivery of the contractility modulating signal when the trace of events is indicative of an expected activation sequence of the heart.

APPENDIX VI

Current Clinical Summary: FIX-HF-5C

1.0 Study Design

FIX-HF-5C was a prospective, randomized, third-party blinded, multicenter study involving 160 patients. Key inclusion criteria included $EF \geq 25\%$ and $\leq 45\%$, normal sinus rhythm, QRS duration < 130 ms and NYHA Class III or ambulatory IV heart failure despite GDMT (including ICD when indicated). Main exclusion criteria included baseline peak $VO_2 < 9$ or > 20 mL/min/kg, hospitalization for heart failure 30 days before enrollment, clinically significant ambient ectopy ($> 8,900$ premature ventricular contractions [PVCs] / 24 hours), PR interval > 375 ms, and chronic atrial fibrillation or atrial flutter within 30 days of enrollment.

A device implant date was scheduled for all eligible patients, which served as the study start date (SSD) for all patients. Patients were then randomized 1:1 to either continued OMT alone (control group) or OMT plus CCM (CCM group). Patients randomized to the CCM group were implanted with the device and the implant date was canceled for patients randomized to the control group. Patients returned to the clinic for evaluation at 2 weeks, 12 weeks, and 24 weeks. Follow-up visits included 2 CPX tests, a blinded NYHA assessment, MLWHFQ quality of life assessment, and an assessment of adverse events (AEs).

Blinding of NYHA and CPX

NYHA was assessed by a blinded on-site clinician according to their standard clinical practice.

CPX tests were assessed by an independent core laboratory blinded to the randomization assignment of individual patients.

Primary Effectiveness Endpoint

The primary effectiveness endpoint was defined as the change in peak VO_2 from baseline at 24-weeks between the control and CCM groups as evaluated by the blinded core laboratory. The primary effectiveness analysis employed a Bayesian repeated measures linear model to estimate group differences in mean peak VO_2 at 24 weeks from baseline, with fixed 30% borrowing of information (70% down-weighting) from the corresponding treatment group difference observed in the FIX-HF-5 study subgroup defined as $EF \geq 25\%$.

Secondary Effectiveness Endpoints

Because there were multiple secondary hypotheses being tested, the method of alpha control was the closed form hierarchical method. For these analyses, if the one-sided p-value for the secondary endpoint was ≤ 0.025 , the null hypothesis was rejected, and the next secondary endpoint was tested. The hierarchy for testing the secondary endpoints is the following:

- Minnesota Living with Heart Failure Questionnaire
- NYHA classification
- Peak VO_2 with a peak respiratory equivalent ratio (RER) ≥ 1.05

Safety Endpoints

The primary safety endpoint was the proportion of patients experiencing an OPTIMIZER device- or procedure-related complication through the 24-week follow up period as determined by the events adjudication committee (EAC). The primary safety endpoint was evaluated against a prespecified performance goal of 70% which was derived from several prior studies involving CRT (PMAs P010012: Contak CD CRT D, P030005: Contak Renewal TR, P030035: St. Jude Frontier, and P010012/S37: Contak Renewal 3AVT; Van Rees, 2011).

Other safety endpoints included all-cause death, cardiovascular death, composite rate of all-cause death or all-cause hospitalizations, composite rate of cardiovascular death or worsening heart failure-related hospitalizations, and overall rate of AEs and SAEs.

2.0 Demographics and Baseline Characteristics

Of the 160 eligible patients, 74 were randomized to the CCM group and 86 were randomized to the control group. In the CCM group, 6 patients did not receive the device and 2 patients died prior to the 24-week visit (including 1 patient who died prior to randomization). In the control group, 4 patients died, and 3 patients withdrew prior to the 24-week visit.

The groups were well-balanced with regards to demographic and baseline characteristics (Table 1). Overall, the mean age was approximately 63 years. The majority of patients were white and male, and the etiology was predominantly ischemic cardiomyopathy, characteristics which are typical of recent heart failure studies. Average peak VO_2 at baseline was approximately 15 mL/kg/min, which is moderately reduced compared to the normal population. Characteristics of the prospectively enrolled FIX-HF-5C patients were similar to those of the FIX-HF-5 subgroup used for Bayesian analysis (Table 1).

Table 1. Demographic and Baseline Characteristics

	FIX-HF-5C		FIX-HF-5 Subgroup (25% \leq EF \leq 35%)	
	CCM (N=74)	Control (N=86)	CCM (N=117)	Control (N=112)
Mean Age (years)	63	63	59	60
Male	73%	79%	71%	74%
White	74%	71%	75%	72%

	FIX-HF-5C		FIX-HF-5 Subgroup (25% ≤ EF ≤ 35%)	
	CCM (N=74)	Control (N=86)	CCM (N=117)	Control (N=112)
Ischemic Heart Failure	62%	59%	72%	69%
Prior MI	49%	59%	67%	59%
Prior PM/ICD System	88%	85%	80%	79%
Diabetes	51%	49%	49%	52%
NYHA				
Class III	87%	91%	93%	87%
Class IV	14%	9%	7%	13%
QRS Duration (ms)	103	104	99	101
LVEF (%)	33	33	31	32
LVEDD (mm)	58	60	57	56
Peak VO ₂ (mL/kg/min)	15.5	15.4	14.6	14.8
Exercise Time (minutes)	11.4	10.6	11.3	11.7
6MHW (meters)	317	324	326	324
MLWHFQ (total score)	56	57	60	56

Mean or % (n/N)

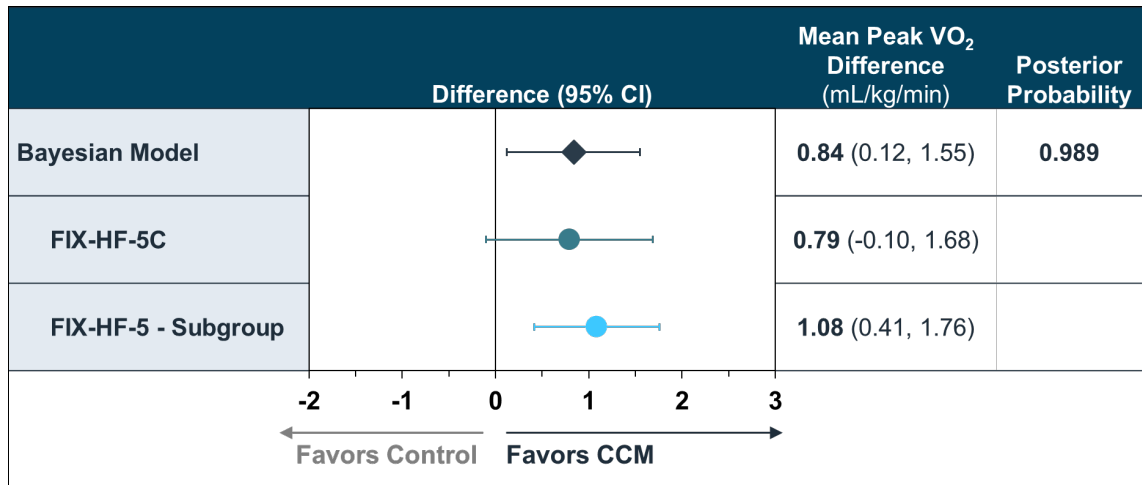
3.0 Effectiveness Results

a. Primary Effectiveness Endpoint

The primary effectiveness endpoint was met. The model-based estimated mean difference in peak VO₂ at 24 weeks between CCM and control groups was 0.84 mL/kg/min with a 95% Bayesian credible interval of (0.12, 1.55) mL/kg/min. The probability that CCM is superior to control was 0.989, which exceeds the 0.975 criterion required for statistical significance of the primary endpoint.

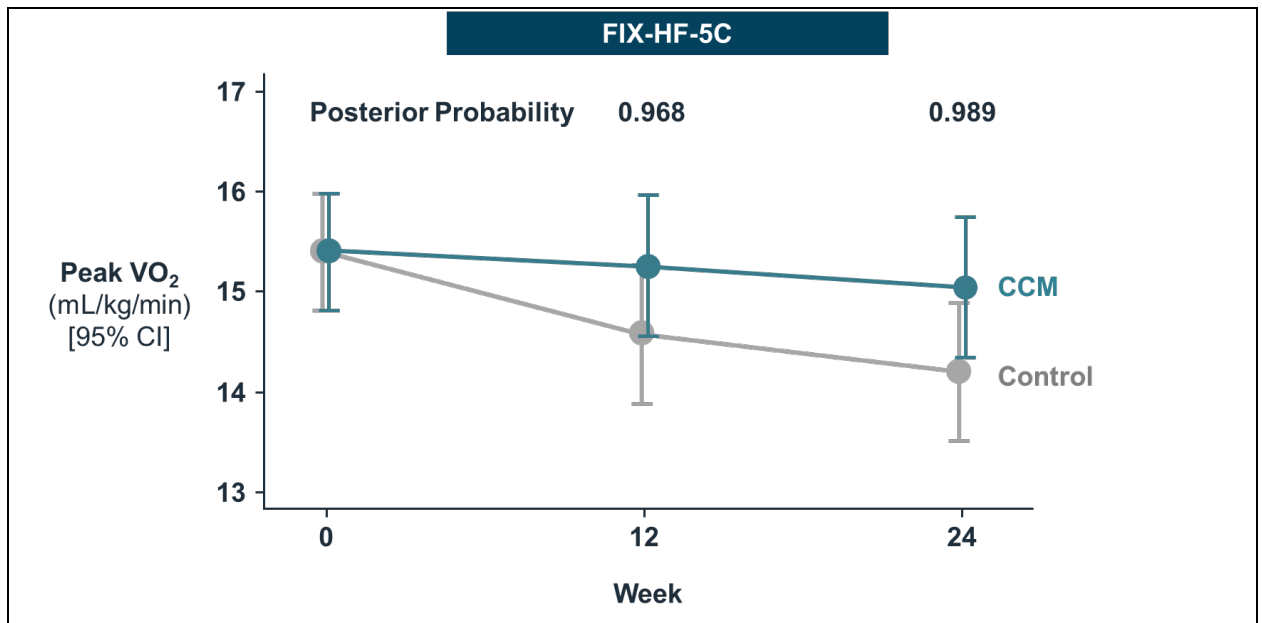
Figure 1 shows that the Bayesian model's point estimate is very similar to the estimate from just the FIX-HF-5C study. However, the model further incorporates the high quality data from the previous randomized, blinded trial which increases the precision of the estimate. If FIX-HF-5C were a standalone trial, the middle CI would be appropriate. However, the Bayesian model allows us to incorporate the totality of the clinical experience which is an increased precision in the effect size estimate and is shown by the narrower 95% CI with the Bayesian estimate.

Figure 1. Peak VO₂ by Study



The improvement in peak VO₂ built up over time, from 3 to 6 months (Figure 2). The treatment effect can be seen in this graph to be a result of a significant decrease in VO₂ for the control group with relatively little increase in VO₂ for the treatment group.

Figure 2. Time Course of Treatment Effect on Peak VO₂ (FIX-HF-5C)



Sensitivity analyses involving the primary effectiveness endpoint were conducted in which missing data were handled with different mechanisms or modifications (Table 2). Method of imputation affected the results and the VO₂ estimate varied from 0.48 to 0.84 depending on method. The conclusion of CCM superiority with respect to mean peak VO₂ was consistent across all sensitivity analyses. In addition, the primary analysis would achieve statistical significance with any borrowing weight of 0.11 or larger (as noted above, 0.30 was pre-specified in the analysis plan).

Table 2. Peak VO₂ Treatment Effect Across Studies

Study	Population	Bayesian VO ₂ Estimate	Bayesian Posterior Probability
Primary Analysis with Borrowing FIX-HF-5C & FIX-HF-5	Imputation (Death = 0)	0.836	0.989
	Imputation (Death = lowest peak VO ₂)	0.693	0.988
	Completed Cases (No Imputation)	0.603	0.978
Pooled FIX-HF-5C & FIX-HF-5	Completed Cases (No Imputation)	0.749	0.999
FIX-HF-5C Alone	Imputation (Death = 0)	0.799	0.960
	Imputation (Death = lowest peak VO ₂)	0.611	0.957
	Completed Cases (No Imputation)	0.480	0.916
FIX-HF-5 Alone	Imputation (Death = 0)	1.074	1.00
	Completed Case (No Imputation)	1.080	1.00

b. Secondary Effectiveness Endpoints

MLWHFQ results at 24 weeks are presented in Table 3 and show that the CCM group was statistically significantly superior over the control group ($p < 0.001$) in each study.

Table 3. Change in MLWHFQ at 24 Weeks by Study

	Difference (95% CI) in MLWHFQ Total Score Between Groups	p-value (1-sided)
Pooled data	-10.9 (-14.6, -7.2)	< 0.001
FIX-HF-5C	-11.7 (-17.6, -5.9)	< 0.001
FIX-HF-5 Subgroup	-10.8 (-15.6, -6.1)	< 0.001

The percentage of patients improving by 1 or more NYHA class by study was statistically significantly superior in the CCM group compared to the control group ($p < 0.001$ in each study; Table 4).

Table 4. Patients Achieving ≥ 1 Class Improvement in NYHA at 24 Weeks by Study

Change in ≥ 1 Class in NYHA Class	CCM	Control	p-value (1-sided)
Pooled data	104/173 (60.1%)	59/169 (34.9%)	< 0.001
FIX-HF-5C	57/70 (81.4%)	32/75 (42.7%)	< 0.001
FIX-HF-5 Subgroup	47/103 (45.6%)	27/94 (28.7%)	< 0.001

In the FIX-HF-5C study, the p-value for the comparison of mean peak VO₂ at 24 weeks for CCM compared to control among observations with RER > 1.05 was 0.1100. Therefore, this secondary effectiveness endpoint was not met with FIX-HF-5C data alone. When data were pooled from the FIX-HF-5 and FIX-HF-5C studies, the treatment effect was estimated as 0.62 mL/kg/min with a p-value of 0.009. In addition, the endpoint was met in the FIX-HF-5 subgroup (Table 5).

Table 5. Change in Peak VO₂ in Tests with RER ≥ 1.05 at 24 Weeks by Study

	Difference (95% CI) in Peak VO₂ (mL/kg/min) Between Groups	p-value (1-sided)
Pooled data	0.62 (0.11, 1.14)	0.009
FIX-HF-5C	0.43 (-0.25, 1.11)	0.1100
FIX-HF-5 - Subgroup	0.83 (0.06, 1.61)	0.017

A significant treatment effect was observed in 6 exploratory outcomes. There was no significant effect on change in VE/VCO₂ at 24 weeks.

4.0 Safety Results

The incidence of AEs in this study was relatively low. Comparisons between the groups did not show any statistical differences between CCM and control groups with respect to any AE tabulated for the analysis.

a. Primary Safety Endpoint

The primary safety endpoint was met as shown in Table 6. The complication-free proportion in the CCM group cohort was 89.7% (61/68) with lower confidence limit of 79.9% (one-sided alpha=0.025), which was greater than the pre-defined threshold of 70%. The majority of complications (5/7, 71.4%) were lead dislodgements.

Table 6. Primary Safety Endpoint (FIX-HF-5C, As Treated CCM Group Only)

Complication Free Rate n/N (%)	95% LCL (%)	95% UCL (%)
61/68 (89.7%)	79.9%	95.8%

b. Secondary Safety Endpoints (FIX-HF-5C)

As shown in Table 7, the freedom from death, freedom from cardiovascular death, and freedom from all-cause death or all-cause hospitalization at 24 weeks were similar in both groups.

Table 7. Secondary Safety Endpoints at 24 Weeks (FIX-HF-5C)

Freedom from	CCM	Control	p-value
All-cause death	98.3%	95.3%	0.2549
Cardiovascular death	100%	96.5%	0.1198
All-cause death or all-cause hospitalization	78.1%	77.7%	0.9437



**OMNI II Programmer (with
OMNI Smart Software)
System and OPTIMIZER
Mini Charger**

INSTRUCTIONS FOR USE

Federal (US) law restricts this device to sale by or on the order of a physician

Impulse Dynamics (USA), Inc
30 Ramland Road South, Suite 204
Orangeburg, NY 10962-2698
U.S.A.

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The OPTIMIZER® Smart system and the CCM™ technology are protected by several U.S. Patents. For an up-to-date list of relevant patents and patent applications, visit our patents page: <http://www.impulse-dynamics.com/us/patents>.

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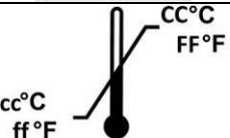








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EXPLANATION OF SYMBOLS ON LABELS

SYMBOL	DESCRIPTION
	Manufacturer
	Date of Manufacture
	Conformité Européenne 0344 = Notified Body Number for AIMDD
	Consult instructions for use.
	Caution, consult accompanying documents
	European Representative
	Transport Temperature Limits
	Part Number
	Serial Number
	Do Not Use if Package is Damaged
	Class II
	Type BF Applied Part
	Defibrillation-Proof Type BF Applied Part
	Produces Non-ionizing Electromagnetic Radiation
	Wand Power Indicator

SYMBOL	DESCRIPTION
	Emergency Programming
	Programming
	Interrogation
	Wand Signal Strength Indicator
	DC Power Input (charger connection)
	Serial data I/O port (for use only by Impulse Dynamics technical personnel)
	IPG-Charger Coupling Signal Strength Indicator
	"Call Doctor" Indicator
	Charger Start Button
	Battery Status Indicator
	OPTIMIZER Mini Charger

SYMBOL	DESCRIPTION
	OPTIMIZER Smart IPG

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1. OVERVIEW OF THE OMNI II PROGRAMMER (WITH OMNI SMART SOFTWARE) SYSTEM

1.1 Description

The OMNI II Programmer (with OMNI Smart Software) allows the physician to interrogate and program the OPTIMIZER Smart IPG. The programmer software runs on a Lenovo Touch screen Laptop connected to a Programmer Interface box. Communication between the Programmer Interface and the IPG is accomplished with a Programmer Wand placed directly over the implant site. The Programmer Wand communicates via magnetic induction telemetry with the OPTIMIZER Smart IPG implanted in the patient. Understanding the instructions contained in this manual on how to operate the OMNI Smart Programmer System is essential to proper operation of the OPTIMIZER Smart IPG. (Refer to the OPTIMIZER SMART IPG Instructions for Use-13-290-008-US for more information)



Figure 1: OMNI Smart Programmer and Programmer Wand

Warning: The OMNI Smart Programmer may be subject to interference from other electrical devices operated in the vicinity. Portable and mobile RF equipment is especially likely to impair the normal function of the programmer. If the OMNI Smart Programmer is not operating as expected, such interference has to be always taken into account. Other equipment, even if it outperforms the CISPR emission limits, can also interfere with the OMNI Smart Programmer.

1.2 Indications¹

The OPTIMIZER Smart System, which delivers CCM™ therapy, is indicated to improve 6-minute hall walk distance, quality of life and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for CRT, and have an LVEF ranging from 25% to 45%.

The OPTIMIZER Smart system delivers non-excitatory CCM™ signals to the heart and has no pacemaker or ICD functions.

1.3 Programmer Functions

The programmer can perform the following:

- Read (interrogate) OPTIMIZER Smart IPG parameters as currently programmed
- Modify OPTIMIZER Smart IPG parameters
- Read ECG signals from patient and display for analysis
- Retrieve statistics accumulated by the OPTIMIZER Smart IPG as it operates
- Log the activity of the OPTIMIZER Smart IPG
- Store standard programs for future use
- Program the OPTIMIZER Smart IPG to safe parameter values in emergency situations

Additionally, the Programmer can also perform the following:

- Be remotely controlled by another Programmer
- Remotely control another Programmer
- Upload and download log files to/from a remote, dedicated server

1.4 Programmer Components

The OMNI Smart Programmer System consists of:

- OMNI II Programmer (with OMNI Smart Software)
 - OMNI II Programmer Tablet PC installed with OMNI Smart Programmer Software
 - OMNI II Programmer Interface Box
 - OMNI II Programmer Interface Box Cable
 - Medical-grade Ethernet isolator with Ethernet patch cable
- OMNI II Programmer Wand
- OMNI II Programmer Wand Extension Cable

¹ The safety and performance of the OPTIMIZER Smart System is based on clinical investigations conducted with the prior generation device, the OPTIMIZER IVs and III Systems given the similarities between the Systems with regard to function, intended use, design characteristics, and the CCM™ signals. Summaries of these studies are available on Impulse Dynamics' website.

(<http://www.impulse-dynamics.com/int/for-physicians/clinical-data/>)

- Single-lead (3-wire) ECG cable
- Medical-grade Power Supply
- Hospital-grade Power Cord
- Bluetooth printer with AC Adapter

Warning: Use of items other than those identified above or in a manner not in accord with these instructions may cause damage to the OMNI Smart Programmer. Interconnecting the Programmer Components for Operation

- Plug the USB end of the Interface Box Cable into the USB port on the side of the Tablet PC. Plug the other end (fitted with a LEMO®-type connector) into the port labeled **USB** on the back panel of the Programmer Interface Box.
- Plug the OMNI II Programmer Wand cable connector into port labeled **WAND** on the back panel of the Programmer Interface Box.

Note: If required, the Wand Extension cable may be used to extend the reach of the Programmer Wand. Connect one end of the Extension cable to the Programmer Wand cable connector and the other end to the port labeled **WAND** on the back panel of the Programmer Interface Box.

- Plug the ECG cable (3-wire with a Type LGH connector) into the port labeled **ECG** on the back panel of the Programmer Interface Box.

Warning: Do not attempt to connect any line-powered device (such as a cable-connection printer) to the OMNI Smart Programmer. This may create an electrical safety hazard for the patient.



Figure 2: OMNI II Programmer Interface Box

1.5 Programmer Wand

The Programmer Wand has three buttons:

- **Interrogate**
- **Program**
- **Emergency program with a safe parameter set**

The Programmer Wand also has three different sets of indicator lights:

- The Power indicator light, located to the left of the power symbol, is illuminated when the Programmer Wand is powered.
- The bar graph indicator lights display the strength of the telemetry signal between the Programmer Wand and the OPTIMIZER Smart IPG.
- The Emergency Programming indicator light, located above the Emergency Programming button, flashes a few times after Emergency Programming has been successfully completed.



Figure 3: OMNI II Programmer Wand

1.6 Charging the Battery of the OMNI II Programmer Tablet PC

Warning: Only charge the OMNI II Programmer Tablet PC battery with the medical-grade power supply provided with the OMNI Smart Programmer system. Do not attempt to recharge the Tablet PC's battery with any other power supply.

Note: Power cord used with medical-grade power supply must be CE marked.

To charge the battery of the OMNI II Programmer Tablet PC:

- Plug the DC output connector of the medical-grade power supply into the power input connector of the Tablet PC (located at the bottom right of the Tablet PC and identified by a yellow socket).
- Plug one end of the CE marked power cord into AC input connector of the medical-grade power supply and then plug the other end into a hospital-grade mains power receptacle. Be sure that the mains voltage is in the range 100 to 240VAC, 50/60Hz and that the receptacle has a properly grounded connection.
- When the charging the battery of the OMNI II Programmer Tablet PC, allow the internal battery to charge for a full 24 hours before attempting to use the OMNI Smart Programmer at implant. It is recommended that the Tablet PC battery of the OMNI II Programmer be routinely recharged between uses.

1.7 Operating the OMNI Smart Programmer

Warning: The OMNI Smart Programmer shall not be used on board aircraft without prior consent from the aircraft's crew.

Note: Consult local regulations if using the OMNI Smart Programmer outside of the country where it was obtained.

Note: The OMNI Smart Programmer must be operated as a battery-powered device. Connect it to the mains only when charging of the Tablet PC battery is required. The OMNI Smart Programmer will not be able to interrogate or program the OPTIMIZER Smart IPG until the Tablet PC of the OMNI II Programmer is disconnected from the mains.

The Tablet PC of the OMNI II Programmer must be disconnected from the line-powered power supply before use. Disconnect the DC output connector of the medical-grade power supply from the power input connector located in back of the Tablet PC.

Note: Position the OMNI Smart Programmer such that disconnecting it from the mains is not impeded.

1.8 Using the OMNI II Programmer Tablet PC Touch Screen

The OMNI II Programmer Tablet PC is equipped with a touch screen. Selections on the screen may be made by touching the screen with one's finger or the attached stylus.

Caution: Using sharp items or regular writing equipment (pen, pencil) may damage the touch screen.

1.9 Buttons and Symbols on the OMNI II Programmer Tablet PC

The OMNI II Programmer Tablet PC has 3 buttons and 3 illuminated indicator symbols located on the left side below the touchpad. Those have the following functions (from left to right)

Buttons (top row from left to right):

- Main switch
- Change user (disabled)
- Screen rotating function (disabled)

Illuminated Indicator Symbols (bottom row from left to right):

- Indicates WLAN / WIFI is active
- Indicates Bluetooth is active (not shown on all Tablet PC models)
- Indicates hard drive operation



Figure 4: Example of Buttons and Illuminated Symbols on OMNI II Programmer Tablet PC

1.10 OMNI II Programmer Tablet PC Battery Replacement

The OMNI II Programmer Tablet PC is powered by a battery that may need to be replaced if it fails to properly recharge. Contact your local Impulse Dynamics representative if a replacement battery is needed.

Warning: Proper disposal of the used battery is essential. Dispose of the used battery in accord with local environmental requirements.

Warning: Never puncture or incinerate a used battery.

1.11 Routine Cleaning

Warning: DO NOT attempt to sterilize an OMNI Smart Programmer or the Programmer Wand because any such attempt could severely damage the equipment.

Warning: DO NOT submerge any part of the OMNI Smart Programmer in water. Damage to the unit may result. The OMNI Smart Programmer System is not protected against ingress of water or humidity (ingress protection rating IPX0).

Warning: Always turn the OMNI Smart Programmer off prior to cleaning.

Following each use, it is recommended that a soft cloth dampened with a germicidal cleaning solution be used to wipe the exterior case of the programmer, the ECG cables and, particularly the Programmer Wand. Do not use solvents or cleaning cloths impregnated with chemical cleaning agents.

1.12 Storage and Handling

The OMNI Smart Programmer and Programmer Wand are designed to function normally after they have been exposed (while being packaged for transport) to the following environmental extremes: (1) -4°F to +158°F, (2) relative humidity 10% to 100% (with or without condensation), (3) atmospheric pressure 500 hPa to 1060 hPa.

Recommended conditions for normal use are: (1) 32°F to +131°F, (2) relative humidity between 20% and 75%, and (3) atmospheric pressure between 700 hPa and 1060 hPa.

1.13 Additional Notes

The OMNI Smart Programmer has an isolated patient connection with defibrillation protection.

In general, contact between the Programmer Wand and the patient's skin should be avoided due to the risk of cross-contamination.

OMNI II Programmer Interface Box has a battery for back-up safe mode programming. This battery is not intended to be replaced by the operator. It can only be replaced by designated Impulse Dynamics service personnel.

Note: The OMNI Smart Programmer System does not contain any user serviceable parts. It must be replaced if it fails to operate in accordance with its specifications.

Warning: DO NOT discard the OMNI II Programmer Interface Box or Programmer Wand in the trash. The OMNI II Programmer Interface Box contains a Lithium battery as well as non-RoHS components. The Programmer Wand contains non-RoHS components. If disposal of the OMNI II Programmer Interface Box or Programmer Wand is necessary, properly dispose of the OMNI II Programmer Interface Box or Programmer Wand in accordance with local regulations governing the disposal of such material.

The OMNI Smart Programmer is classified as Class II equipment when connected to the supply mains, Internally Powered ME equipment when laptop power supply not connected to mains.

The Programmer Wand is classified as a Type BF applied part and ECG channel is classified as a defibrillation-proof Type BF applied part.

2. OMNI SMART PROGRAMMER SYSTEM SOFTWARE

The OMNI Smart Programmer System software contains applications that are used to read and modify the parameters that control the OPTIMIZER Smart IPG.

2.1 Selection Screen

When the OMNI Smart Programmer is turned on, a selection screen is presented upon completion of the start-up sequence. Click on the appropriate button for the desired operation.

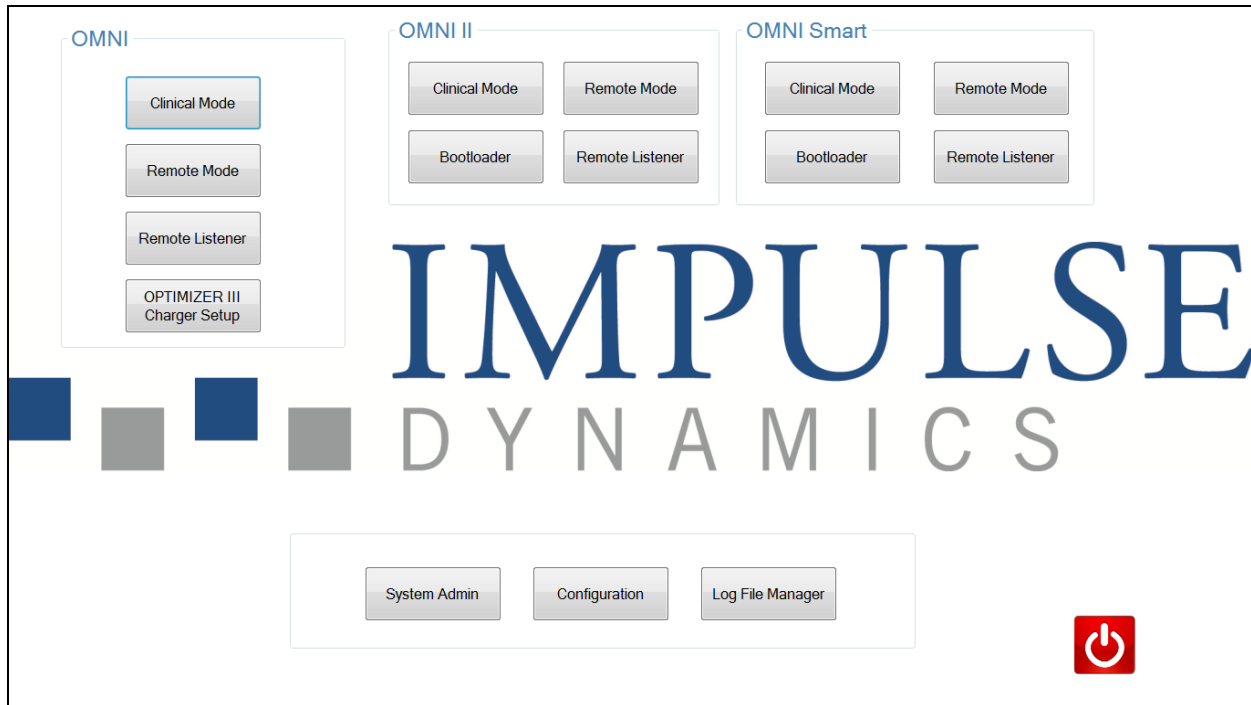


Figure 5: OMNI Smart Programmer Selection Screen

2.1.1 OMNI

The buttons contained within the **OMNI** box are disabled and cannot be used with the **OPTIMIZER III** system.

2.1.2 OMNI II

The buttons contained within the **OMNI II** box are disabled and cannot be used with the **OPTIMIZER IVs** IPG.

2.1.3 OMNI Smart

The buttons contained within the **OMNI Smart** box are for use with the **OPTIMIZER Smart** IPG.

- **Clinical Mode:** For regular programming of the OPTIMIZER Smart IPG
- **Remote Mode:** For remote control of another OMNI Smart Programmer using the OMNI Smart Programmer software (see Section 4.20).

- **Remote Listener:** For remote watching of another OMNI Smart Programmer using the OMNI Smart Programmer software (see Section 4.20).

2.1.4 Miscellaneous

The buttons displayed at the bottom of the Selection screen are for miscellaneous system functions.

- **System Admin:** This selection allows special settings of OMNI Smart Programmer. It is to be used by Impulse Dynamics technical staff only and is not needed for regular clinical use.
- **Configuration:** Selection of the **Configuration** button opens a pop-up window for additional settings.
 - **Set Bluetooth:** Setup for Bluetooth settings needed for printer connection.
 - **Network Configuration:** Setup for network settings (LAN and WLAN) needed for remote control and remote mode of OMNI Smart Programmer.
 - **Set Default Printer:** Selecting the default printer to be used by the OMNI Smart Programmer.
- **Log File Manager:** This selection allows special settings of OMNI Smart Programmer. It is to be used by Impulse Dynamics technical staff only and is not needed for regular clinical use.
- **Shutdown:** Selecting the red Shutdown button on the Selection screen turns OFF the OMNI Smart Programmer.

2.2 Basic Operation of the OMNI Smart Programmer Application

After the **Clinical Mode** button has been selected from the OMNI Smart box on the Selector screen, the OMNI Smart Programmer software is started, which offers various commands for communicating, interrogating, and programming the OPTIMIZER Smart IPG.

2.2.1 Communication with the OPTIMIZER Smart IPG

The physician can obtain data from the OPTIMIZER Smart IPG by means of the Programmer Wand, which must be placed over the patient's implant site.

Caution: The Programmer Wand must be thoroughly cleaned between uses, and draped when necessary, to prevent patient skin irritation or contamination.

2.2.2 Interrogation and Programming

The OPTIMIZER Smart IPG has a set of parameters that control its operation. The values of these parameters are referred to as the *device (parameter) values*.

The OMNI Smart Programmer software can read the device values by means of the **Interrogate** command. This must be the first action carried out by the physician in order to access information from the OPTIMIZER Smart IPG. If the interrogation process is successful, the device values are loaded and displayed on the screen of the OMNI Smart Programmer. The values displayed on the screen of the OMNI Smart Programmer are referred to as the *parameter values*.

The physician can also view some of these values in a graphical representation.

The physician can review and modify the parameter values using the OMNI Smart Programmer software. The modified parameter values can then be transmitted to the OPTIMIZER Smart IPG by means of the **Program** command.

Note that the modified parameter values displayed on the programmer screen are NOT transferred to the IPG until the **Program** command is performed.

If the new parameter values do not yield the desired clinical effect, they can be cancelled using the **Undo** command. This command resets the device parameters to those previously programmed.

The **Urgent** command programs the OPTIMIZER Smart IPG with standard safe parameter values (CCM OFF). The **Urgent** command may be initiated by clicking the **Urgent** button in the Tool Bar or pressing the **Emergency** button on the Programmer Wand.

Useful parameter combinations can be stored as *standard* files (these are also, sometimes, called “user presets”). The file extension for a standard file is “.tip”. After the creation of a particular standard, the standard can be loaded for patients who require a similar set of programmed values.

The **Open** and **Save** commands of the OMNI Smart Programmer software read and write data from and to standard (.tip) files. As such, the OMNI Smart Programmer software can also be used as an editor of standards (see Section 16).

2.2.3 Monitoring Tools

The OMNI Smart Programmer System offers a Programmer Interface with a built-in electrocardiography channel. The patient’s ECG is displayed in the upper portion of the OMNI Smart Programmer screen.

Warning: The displayed ECG is of monitoring quality and is not diagnostic quality. Do not base clinical diagnostic decisions on the displayed ECG. In particular, it is important to note that the chart gradient is not the typical 25 or 50 mm/sec.

The OMNI Smart Programmer software can be used to set the OPTIMIZER Smart IPG to **Marker** mode. “Markers” are flags that represent the various states of the device and events detected during its operation. In this mode, all events detected and generated by the OPTIMIZER Smart IPG are displayed in the ECG window synchronized with the patient’s ECG signal.

- The OMNI Smart Programmer software keeps a log of all the interactions that take place with the OPTIMIZER Smart IPG.
- Segments of the (marked) patient’s ECG can be recorded, and then easily accessed using the **Browse** button (see Section 4.1.4).
- The OPTIMIZER Smart IPG keeps a record of all the events and conditions that have occurred. These records can be downloaded from the OPTIMIZER Smart IPG to the OMNI Smart Programmer, and the number of occurrences of each event can be viewed on the Statistics bar of the OMNI Smart Programmer software (see Section 4.15).
- The OMNI Smart Programmer software can be used to measure the impedance of the LS and V leads (see Section 4.16).

2.2.4 Closing the Programmer Application

Clicking the “X” in the top right-hand corner of the OMNI Smart Programmer software screen will close the application and return the programmer to the selection screen.

3. OMNI SMART PROGRAMMER SOFTWARE

3.1 The OMNI Smart Programmer Screen

When the OMNI Smart Programmer software is started, it displays the main screen, which includes the following:

- Title Bar
- ECG Window
- View Bar
- ECG Statistics Bar
- Tool Bar
- Device Bar
- Log Bar
- Programming Bar
- Parameter Conflict Bar
- Task Bar
- Status Bar

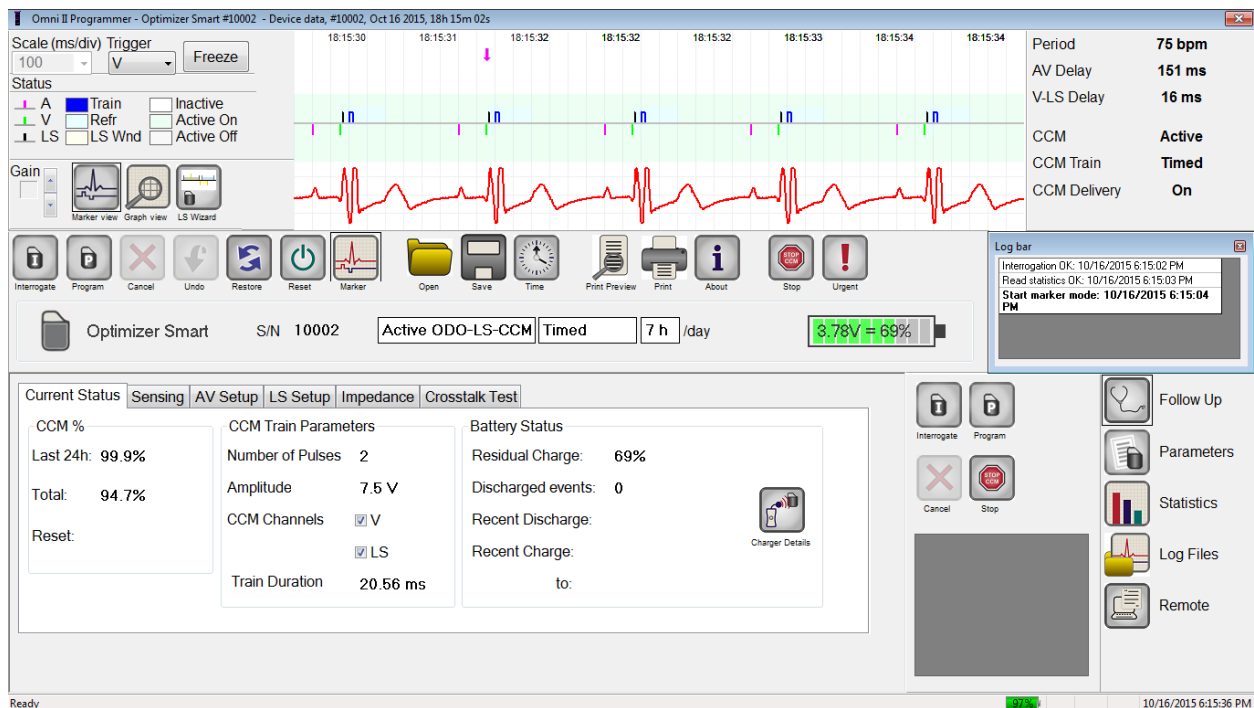


Figure 6: OMNI Smart Programmer Main Screen

3.1.1 Title Bar

The Title Bar is displayed at the top of the window. It identifies the software currently running, and the source of the data, which can be either:

- A OPTIMIZER Smart IPG, in which case the serial number of the device, and the date and time of the last interrogation are shown, or
- A file containing the nominal values of certain model, in which case its name is displayed, or
- A file containing a set of parameter values already used and saved, in which case its name is displayed.

3.1.2 ECG Window

This window is displayed at the top of the screen. It scrolls the real-time ECG of the patient. When the OPTIMIZER Smart IPG is in **Marker Mode**, markers are shown along the ECG for the different events and conditions that may occur.

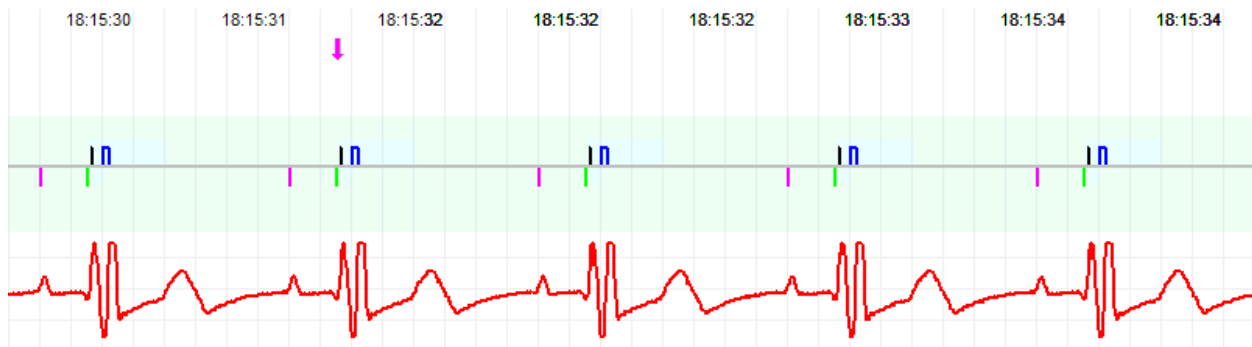


Figure 7: Window in Marker Mode – Active ODO-LS-CCM Mode shown

The trace and color references are shown in the **ECG Reference Bar**.

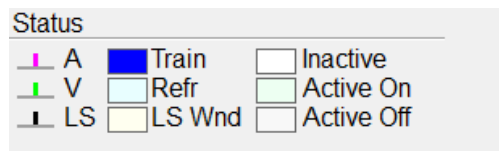


Figure 8: ECG Reference Bar

3.2 View Bar

The View Bar contains the buttons for following commands:

- **Marker view:** displays the ECG window in Marker view
- **Graph view:** displays the ECG window in Graph view
- **LS Wizard:** displays the ECG window in LS Wizard view

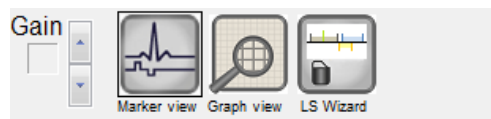


Figure 9: View Bar

3.2.1 Marker View

In Marker view, the Marker events are displayed as follows:

- Sensed events, below the baseline, are represented by colored line markers which use the following color conventions:
 - **Magenta:** Atrial sensed event
 - **Green:** Ventricular sensed event
 - **Black:** Local Sense event

These color references are displayed in the ECG window of the OMNI Smart Programmer Software screen.

- CCM™ signal delivery is represented by a marker in the shape of a blue rectangle above the baseline whose length represents the duration of the CCM™ signal.

In addition, labels are shown indicating when the following conditions occur:

- **PVC:** two successive ventricular sensed events without an intervening atrial sensed event
- **AT:** atrial rate above the atrial tachycardia rate limit
- **VT:** ventricular rate above the ventricular tachycardia rate limit
- **A Noise:** noise detected on the atrial sense channel
- **V Noise:** noise detected on the ventricular sense channel
- **Long AV:** sensed AV interval exceeds “Long AV” limit
- **Short AV:** sensed AV interval shorter than “Short AV” limit

Warning: The displayed ECG should not be used for clinical decision making. Medical decisions should only be based on an independent ECG measurement device.

- CCM™ signal delivery state is indicated by labels as well as by the background color of the ECG window as follows:
 - **Inactive:** this label appears at the top left of the ECG window as long as the CCM™ delivery is **not Active**. The background color of the ECG window is **white** in this case.
 - **Active-On:** this label appears at the top left of the ECG window as long as the CCM™ delivery is **Active** and **On**. The background color of the ECG window is **green** in this case.
 - **Active-Off:** this label appears at the top left of the ECG window as long as CCM™ delivery is **Active** but **Off**. The background color of the ECG window is **gray** in this case.

3.2.2 Graph View

A graphical view is available on the OMNI Smart Programmer software to display some of the OPTIMIZER Smart IPG parameters in an easy-to-understand graph.

This window displays the following parameter values:

- Right Heart Sensing
 - Atrial Sensitivity
 - Ventricular Sensitivity
 - Atrial Refractory Period (PVARP)
 - Ventricular Refractory Period
 - Short AV Limit
 - Long AV Limit
- Local Sense
 - LS Sensitivity
 - LS Alert Window Start
 - LS Alert Window Width
 - Pre Atrial LS Refractory Period
 - Post Atrial LS Refractory Period
 - Pre Ventricular LS Refractory Period
 - Post Ventricular LS Refractory Period
 - Post LS Refractory Period
- CCM™ Signal
 - Number of pulses in CCM™ pulse train
 - Trigger-to-CCM™ signal delay (coupling interval)
 - CCM™ signal initial amplitude
 - Phase duration of individual phases in each CCM™ pulse in CCM™ pulse train

This window also displays a marker at the top left of the display indicating cursor position in msec. It also places the text 'Modified' alongside the marker when a parameter has been changed while in this window.

The conventions for this graph are:

- Atrial, Ventricular and LS events are displayed as vertical lines under the horizontal axis of the graph.
- Sensing thresholds are displayed as small rectangles below the sensed events. The distance to the axis is proportional to their values.
- LS Refractory periods are displayed as light blue rectangles of the corresponding width with a dotted line edge.
- LS Alert Window is displayed as a light yellow rectangle of the corresponding width with a dotted line edge.
- The CCM™ Pulse Train is displayed as a square wave.
- The balance phase is displayed as a green zone.
- The noise window is displayed as a light red zone.
- For LS events that fall outside the graph, their time of occurrence is indicated in a gray zone located on the left of the graph.

3.2.2.1 Dynamic View

In the Dynamic View, one period of the current ECG is shown alongside the (graphic) parameters appearing as described above, together with Marker Events. The Dynamic View is available only if the Marker Mode is on. No modification of parameter values is allowed in this view. If an attempt to modify a parameter value is made, the graph mode automatically switches to Static View.

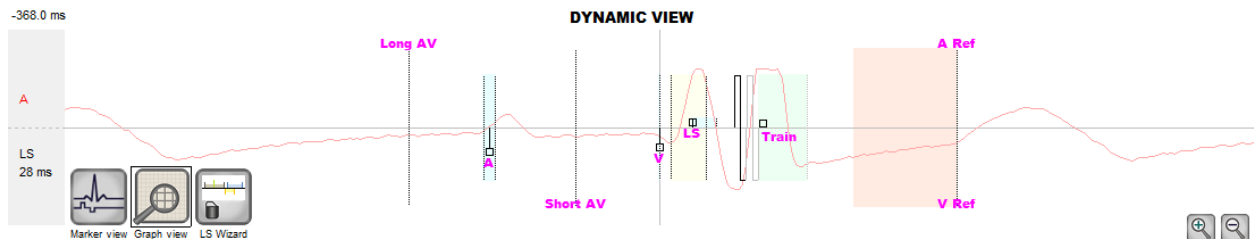


Figure 10: Graphic View (Dynamic)

3.2.2.2 Static View

In the Static View the ECG is not displayed, only the parameter values are shown and can be modified. To modify a parameter value, drag it with the cursor inside the graph to the desired position (the numeric value of the parameter is shown as you point to it or move it). To have access to the list of possible values for a parameter, select it with the cursor.

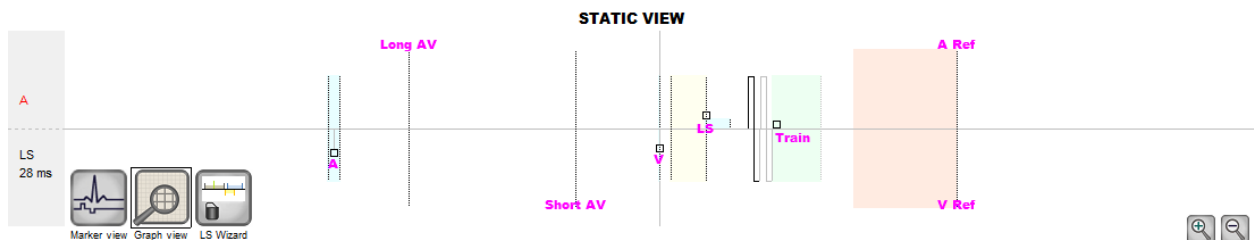


Figure 11: Graphic View (Static)

Left-clicking the keyboard mouse button or touching the screen with the stylus causes the graph to zoom in. Right-clicking the keyboard mouse button or touching the screen with the stylus' button depressed causes the graph to zoom out. A scrollbar appears in the bottom of the graph when it is zoomed in.

Additionally, the position of the cursor with respect to the ventricular event is indicated in the top left of the graph.

The black/blue/red (programmed, pending, conflict) color convention is also used for the parameter values in the graphic view.

3.2.3 LS Wizard

In the LS Wizard the ECG is not displayed, only the LS parameter values are shown and can be modified. To modify a parameter value, drag it with the cursor inside the graph to the desired position (the numeric value of the parameter is shown as you point to it or move it). To have access to the list of possible values for a parameter, select it with the cursor.

3.3 ECG Statistics Bar

The ECG Statistics Bar displays the following values:

- **Period:** Heart rate in beats per minute (bpm)
- **AV Delay:** AV interval in milliseconds
- **V-LS Delay:** V-L interval in milliseconds
- **CCM:** CCM mode status
- **CCM Train:** CCM delivery mode
- **CCM Delivery:** CCM delivery status

Period	75 bpm
AV Delay	151 ms
V-LS Delay	16 ms
CCM	Active
CCM Train	Timed
CCM Delivery	On

Figure 12: ECG Statistics Bar

When the OPTIMIZER Smart IPG is in **Marker Mode** and within communications range of the OMNI II Programmer Wand, the Period, AV Delay, and V-LS Delay intervals change dynamically, showing the current reading for each value.

3.4 Main Tool Bar

The Main Tool Bar is displayed under the **ECG Window**. It contains the buttons of the following OMNI Smart Programmer commands (Whenever a shortcut alternative exists for a command, it is denoted next to the command name in parentheses):

- **Interrogate (Ctrl+I)**: Reads the current parameter values of the OPTIMIZER Smart IPG. These values become the parameter values of the OMNI Smart Programmer.
- **Program (Ctrl+P)**: Sets the parameter values of the OPTIMIZER Smart IPG with the current parameter values of the OMNI Smart Programmer. This command is enabled only if no parameter conflict occurs.
- **Cancel (Esc)**: When any parameter value of the Programmer is modified, the Cancel command becomes available. Selecting this command will *reset the parameter values to the last interrogated/programmed ones*. If no device was interrogated and data were loaded from a .tip file, the programmer parameters are set to the values defined in the file.
- **Undo (Ctrl+U)**: If the OPTIMIZER Smart IPG has been reprogrammed with a new set of parameter values, this command *resets the OPTIMIZER Smart IPG to the previously programmed set of values*.
- **Restore**: If the OPTIMIZER Smart IPG has been reprogrammed to a new mode, this command *restores the OPTIMIZER Smart IPG to the values of the session's first interrogation*.
- **Reset**: Resets the OPTIMIZER Smart IPG. This command should be used only if the OMNI Smart Programmer reports that the OPTIMIZER Smart IPG being interrogated is in the "DOWN" mode [Standby (OOO), no CCM™ reversion mode].
- **Marker (Ctrl+M)**: Sets the OPTIMIZER Smart IPG in Marker Mode (i.e., Marker Events are displayed in the ECG Window for every sensed and generated event).
- **Open (Ctrl+O)**: Reads a standard (.tip) file containing saved parameter values stored on the Programmer's tablet PC. Opens a window allowing the user to choose the name and location of the saved standard (.tip) file. Reads device data from a .tip file.
- **Save**: Writes a standard (.tip) file containing the current parameter values to the Programmer's tablet PC. A window pops up asking for the name and location of the standard (.tip) file.
- **Time**: Opens the **Time** window which shows the current time settings of the real-time clocks in the OPTIMIZER Smart IPG and the OMNI II Programmer Tablet PC. This window also allows the time of the IPG to be set with PC time. (The time setting of the OPTIMIZER Smart IPG is used by the CCM™ signal delivery scheduling mechanism to turn CCM™ signal delivery on and off on a daily basis).

- **Print Preview:** Opens up the **Print Preview** window containing following buttons that can be selected for previewing their associated print functions:
 - **Print Parameters:** The list of the current OMNI Smart Programmer values to be printed is previewed.
 - **Print Statistics:** The list of the current statistics to be printed is previewed.
 - **Print Follow Up:** The list of the current Follow Up measurements to be printed is previewed.
 - **Print Screen:** A snapshot of the current screen is created as a bmp file.
- **Print:** Opens up the **Print** window containing following buttons that can be selected for printing:
 - **Print Parameters:** The list of the current OMNI Smart Programmer values is sent to the default printer.
 - **Print Statistics:** The list of the current statistics is sent to the default printer.
 - **Print Follow Up:** The list of the current Follow Up measurements is sent to the default printer.
 - **Print Screen:** A snapshot of the current screen is created as a bmp file.
- **About:** Displays information about the OMNI Smart Programmer software version.
- **Start/Stop:** Activates CCM™ signal delivery (if CCM™ is OFF) or deactivates CCM™ signal delivery (if CCM is ON).
- **Urgent (F4):** Programs the OPTIMIZER Smart IPG with safe standard values in case of emergency [Standby (OOO) mode, CCM OFF].



Figure 13: Tool Bar

Note: When a command button appears grayed out on a **Tool Bar**, this indicates that the command is not currently available.

3.5 Device Bar

The Device Bar displays the device model, serial number, current cardiac contractility modulation therapy status, and current battery level of the interrogated device.

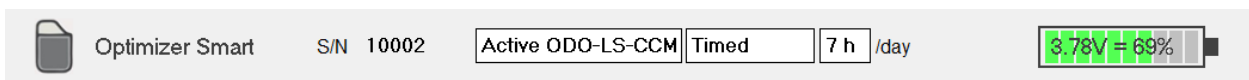


Figure 14: Device Bar

3.6 Log Bar

A special file in the OMNI Smart Programmer Software contains a record (**log**) of all the interactions between the OPTIMIZER Smart IPG and the OMNI Smart Programmer, including the date and time when these interactions occurred.

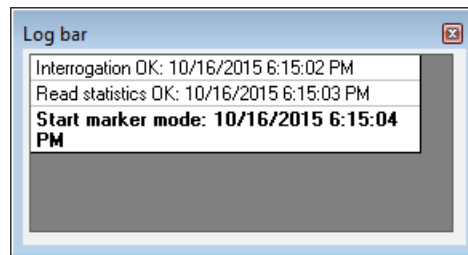


Figure 15: Log Bar

More information regarding an event in the log may be obtained by double-clicking on the event in the Log Bar. If there are data associated with the selected event, the following occurs:

- If an **Interrogation** or **Programming** event is chosen, the parameter values displayed by the OMNI Smart Programmer are the set of values present at the moment the selected event occurred.
- For all other recorded events (Bookmarks, begin/end of Marker Mode, etc.), a message appears indicating that the event has no more associated data to display.

3.7 Programming Bar

The Programming Bar provides fast access to the OMNI Smart Programmer's essential commands with the following buttons:

- **Interrogate:** For obtaining the implanted device actual parameter values.
- **Program:** For transmitting a compatible set of parameter values to the IPG. This button blinks in blue whenever a parameter value has been modified and there is no parameter conflict. This indicates that the programmed parameter values of the OPTIMIZER Smart IPG are different from the displayed parameter values. If there is a parameter conflict, this button is disabled until the conflict is resolved.
- **Cancel/Undo:** Depending on the context – cancels the modifications not transmitted yet, or restores the last programming action values.
- **Stop/Start:** Depending on the context – deactivates CCM™ signal delivery by programming the CCM™ Mode parameter to CCM OFF, or activates CCM™ signal delivery by programming the CCM™ Mode parameter to CCM ON.

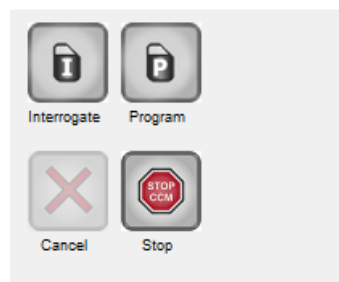


Figure 16: Programming Bar

3.8 Parameter Conflict Bar

In the bar under the Programming Bar, parameter conflict messages are displayed. These messages indicate which parameter values are in conflict, why the parameters are in conflict and the name of the parameter tab in which the conflicting parameters appear. By clicking on an error message, a list of the parameters that are in conflict appears. By selecting a parameter in this list, a window with all its possible values pops up, allowing the value of the conflicting parameter to be directly modified. See Section 14.2 for ways in which to resolve parameter conflicts.

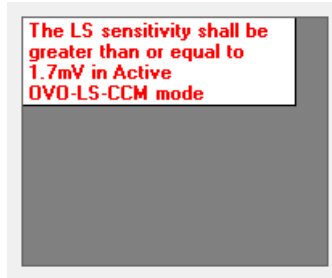


Figure 17: Example of Parameter Conflict Message in Parameter Conflict Bar

3.9 Task Bar

The Task Bar is displayed next to the Programming Bar. The various commands of the OMNI Smart Programmer software are grouped under the following buttons:

- **Follow Up**
- **Parameters**
- **Statistics**
- **Log Files**
- **Remote**

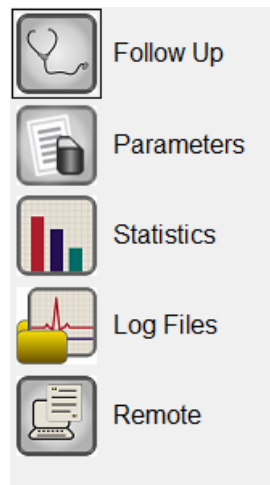


Figure 18: Task Bar

3.9.1 Follow Up

The Follow Up bar contains the following tabs, each with their own panel:

- **Current Status:** displays the current IPG status.
- **Sensing:** contains the atrium, ventricle, and LS sensing threshold buttons which allows the user to measure the atrium and ventricle sensing thresholds.
- **AV Setup:** contains the Propose AV button which allows the user to determine the best AV Window Setting values.
- **LS Setup:** contains the LS Scan and Propose AV buttons which allows the user to determine the best LS Window Setting values.
- **Impedance:** contains the V and LS impedance buttons which allows the user to measure the V and LS lead impedances.
- **Crosstalk Test:** contains the Crosstalk Start button which allows the user to perform interaction testing between the OPTIMIZER Smart IPG and an implanted concomitant device.

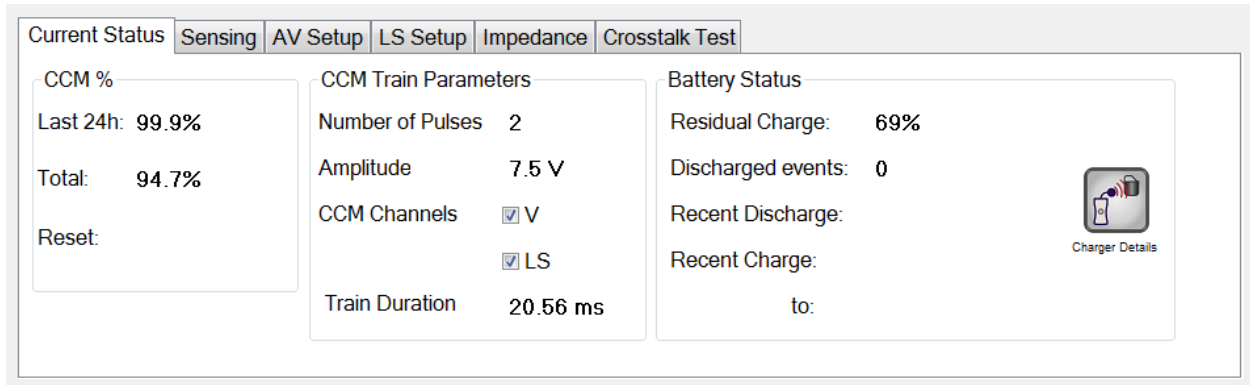


Figure 19: Current Status Tab

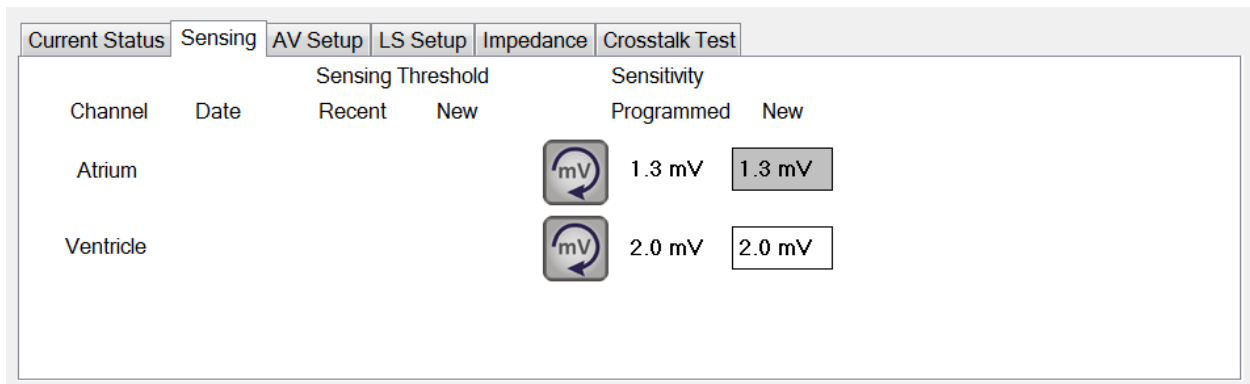


Figure 20: Sensing Tab

Current Status Sensing AV Setup LS Setup Impedance Crosstalk Test

GUIDED ALERT SETUP
AV Window

Which Heart rhythm?

Atrial paced

Ventricular Paced

AV Window Setting

AV Delay 158 ms

Long AV 219 ms

Short AV 78 ms

LS Refractories

Pre A 0 ms

Post A 0 ms

LS Scan

Propose AV

Figure 21: AV Setup Tab

Current Status Sensing AV Setup LS Setup Impedance Crosstalk Test

LS Sensitivity 1.7 mV

LS Refractories for artifact blanking

Pre V: 0 ms Post V: 0 ms

Post LS: 24 ms

Alert Start to V: 0 ms Alert Width: 30 ms

CCM Train Delay: 35 ms

Measurement

LS data	LS 1	LS 2	LS 3
V/LS delay			
LS duration			
Intrinsic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Advice:

Alert Start = Intrinsic V/LS delay - 15ms

Post LS Ref >= Duration Intrinsic LS

Post LS Ref <= CCM Train Delay

LS Scan

Propose LS

Figure 22: LS Setup Tab

Current Status Sensing AV Setup LS Setup Impedance Crosstalk Test

Date	Recent	Current
V		467 Ohms
LS		405 Ohms

Refresh icons for V and LS rows.

Figure 23: Impedance Tab

Current Status Sensing AV Setup LS Setup Impedance Crosstalk Test

Attention!

- * Perform this test only in combination and use of the programmer of the implanted ICD and monitoring of the ICD-EGM.
- * During the test deactivate the ICD-Tachy Therapy to avoid inappropriate shocks.
- * Document the value maximum CCM delay with no Crosstalk in the ICD-EGM.
- * Reprogramm the appropriate CCM delay after the test.
- * Reactivate the ICD Tachy Therapy, document this with a parameter printout.

CCM Train Parameters

Num of Pulses 2

Amplitude 7.5 V

CCM Channels RV LS

Chronic Test

CCM delay to LS 35 ms 85 ms

V Refractory 250 ms 336 ms

Test button

Refresh icon

Figure 24: Crosstalk Test Tab

3.9.2 Parameters

The Parameters Bar contains the following tabs, each with their own panel:

- **Overview:** contains the most important parameters found under the A/V, LS, and CCM™ Train & Schedule tabs.
- **A/V:** displays the operating mode, as well as the atrial and ventricular heart sensing and timing parameters.
- **LS:** contains the parameters for the Local Sense mechanism.
- **CCM™ Train & Schedule:** contains the parameters that define the CCM™ signal and the parameters to configure the CCM™ signal delivery schedule.
- **Alarms:** contains the parameters related to the alarms to be reported to the charger.
- **Settings:** contains buttons for following commands:
 - **Set system time...:** Allows the user to set the OMNI Smart Programmer system time. This is analogous to setting the PC time.
 - **IPG Version:** Displays the firmware version of the interrogated IPG.
 - **Interface battery:** Reads the battery voltage of the lithium battery inside the OMNI II Programmer Interface Box.
 - **Interface version:** Displays the firmware version of the OMNI II Programmer Interface Box.

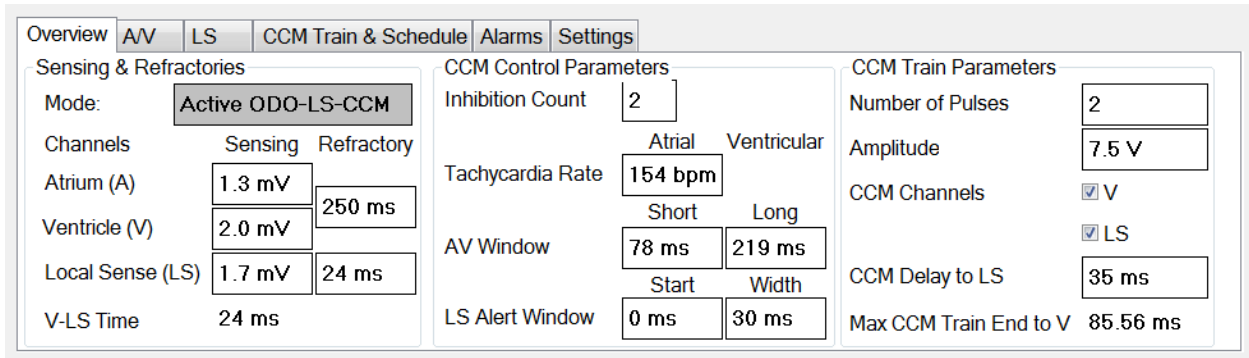


Figure 25: Overview Tab

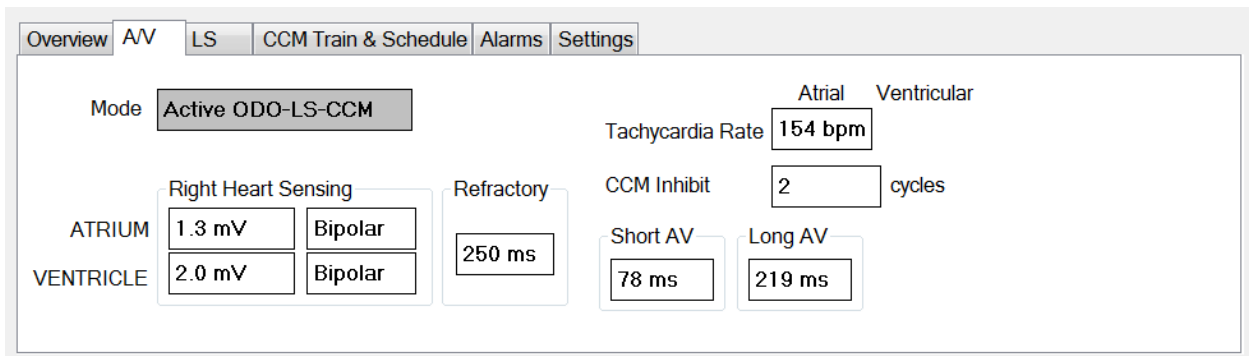


Figure 26: A/V Tab

Overview | AV | **LS** | CCM Train & Schedule | Alarms | Settings

LS Alert Sensing Window

LS Sensitivity:

LS Alert Start to V:

Alert Width:

Post LS Refractory:


LS-CCM Delay:

LS Blanking Refractories

Pre A: Post A:

Pre V: Post V:

Info:
Lastest Start of CCM Train:
65 ms after V



LS Scan

Figure 27: LS Tab

Overview | AV | **LS** | CCM Train & Schedule | Alarms | Settings

CCM /day

Start Time:

End Time:

On Time:

Off Time:

LS-CCM Delay:

N Pulses/Train:

Train Duration:

CCM Pulse Parameters

Phase	Polarity	Duration	Interval	Amplitude	Channels
1	Positive	5.14 ms	0 ms	7.5 V	<input checked="" type="checkbox"/> V
2	Negative	5.14 ms			<input checked="" type="checkbox"/> LS

Figure 28: CCM™ Train & Schedule

Overview | AV | **LS** | CCM Train & Schedule | Alarms | Settings

Minimum Target % for CCM Delivery

Enable

Maximum Lead Displacement

Enable

Figure 29: Alarms Tab

Overview | AV | **LS** | CCM Train & Schedule | Alarms | Settings







Figure 30: Settings Tab

Parameter values are displayed in two different ways:

- For enabling/disabling parameters (such as **CCM™ Channels**), checkboxes are used, and a ✓ symbol indicates that the option is selected. To change the option, select the box to the left of the parameter name.
- For parameters that have a set of possible values, the parameter value is displayed in a box. In order to modify the (programmer) value of such parameters, select the value in the box and a window with all the possible values for the selected parameter will appear. To modify the value of the parameter, select the new value in the list. In addition, the value list windows have a “pin” on their top left corner. Selecting this pin keeps the window open (otherwise, the window will close automatically after a value is selected). Selecting the **X** box at the top right corner to close a value list window that has the pin activated.

Some parameters directly depend on others (such as rates and periods). In such cases, modifying the value of a parameter will automatically modify the value of parameters that directly depend on it.

There also are parameters for which values are valid only when some other parameters are enabled or have certain values [for instance, if the operating mode of the OPTIMIZER Smart IPG is set to Standby (OOO), then no parameters are valid]. When the setting of a parameter is meaningless in the context of other parameters, its value is not displayed.

When a parameter value is selected that is incompatible with other parameter values, a *parameter conflict* occurs. When such situations arise, an error message is displayed in the **Parameter Conflict Bar** (See Section 12.9 for more information). As long as there is a parameter conflict, the OMNI Smart Programmer will not allow the OPTIMIZER Smart IPG to be programmed with new parameter values. This ensures that only compatible parameter configurations can be downloaded to the OPTIMIZER Smart IPG. To resolve the conflict, new values must be selected for the parameters in conflict.

Please recall that parameter values seen on the screen are the *programmer values*, which can be different from the current *device values*. For information on the color convention employed, see Section 14.1.

3.9.3 Statistics

The Statistics Bar contains the following tabs, each with their own panel:

- **On - General:** displays the number of sensed events, periods, and trains during scheduled CCM delivery.
- **On - Inhibition:** displays the number of sensed events that inhibited CCM during scheduled CCM delivery.
- **Off - General:** displays the number of sensed events and periods when CCM is not scheduled for delivery.
- **Off - Inhibition:** displays the number of sensed events that would have inhibited CCM when CCM is not scheduled for delivery.
- **Last Session:** displays the number of ventricular events and trains delivered during the last scheduled CCM delivery session, the percentage of CCM delivered during the last scheduled CCM delivery session, and the number of battery discharge episodes.

The panel of each tab can be viewed in Numeric Mode or Graph Mode

On - General							
On - Inhibition							
Off - General							
Off - Inhibition							
Last Session							
	Date	Events			Periods		
		Atrial	Ventricular	LS in Alert	Normal	Inhibited	Post-Inhibited
	0 0:12:26	931	932	932	930	1	1
»	10/16/2015 6:15:03 PM	77266	144983	138842	137625	20311	1222
»»	10/16/2015 6:27:29 PM	78197	145915	139774	138555	20312	1223

Figure 31: Statistics On - General Tab (Numeric View)

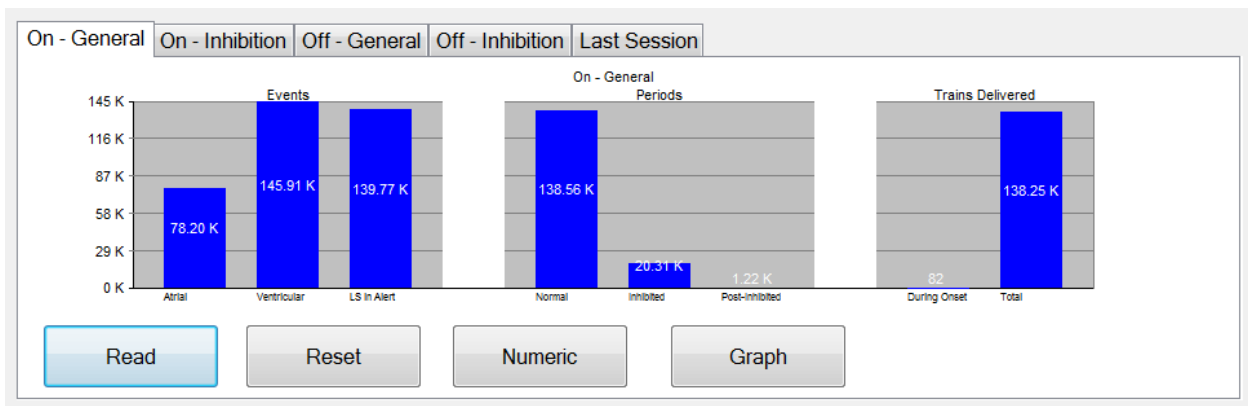


Figure 32: Statistics On - General Tab (Graph View)

3.9.4 Log Files

When the Log Files button is selected, the programming commands on the Main Tool Bar are changed to the following Log File commands:

- **Browse:** opens the Marker window for viewing.
- **Open Log:** opens a window allowing the user to choose from the list of the saved marker files.
- **Recording:** starts recording the patient's ECG.
- **Export Prog:** writes a text file containing the values of the current parameters.
- **Export Stats:** writes a text file containing the values of the statistics counters.
- **Export Marker:** writes a text file containing the values of the markers.
- **Up/Down:** opens a window which allows the user to transfer log files between the OMNI Smart Programmer and the Remote server.
- **Compare:** opens a window displaying the differences in parameters found between the old values and the current values.

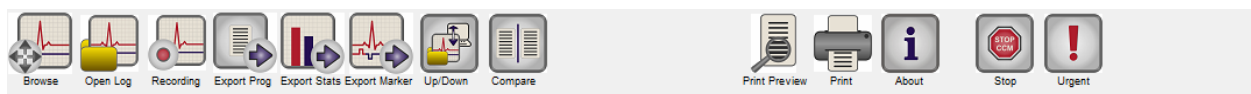


Figure 33: Tool Bar with Log File Commands

3.9.5 Remote

When the Remote button is selected, the programming commands on the Main Log Bar are changed to the following Remote commands:

- **Connect:** opens the OMNI II Programmer Client window which allows the user to initiate a remote session.
- **Send Msg:** opens Chat message window, which allows the user to exchange chat messages with the remote pair.
- **Master:** puts the local OMNI Smart Programmer in Master mode, which allows the user to control the programmer.
- **Slave:** puts the local OMNI Smart Programmer in Slave mode and allows the Remote user to control the local programmer.
- **Client:** displays the OMNI II Programmer Client window (if a remote session was initiated).

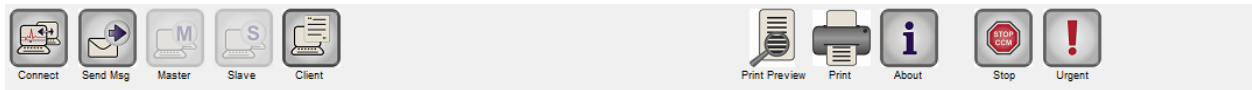


Figure 34: Tool Bar with Remote Commands

3.10 Status Bar

The current communication event (for example: interrogation, programming, ready) is displayed at the screen's last line along with the laptop's battery charge percentage and the system's date and time.



Figure 35: Status Bar

4. INTERROGATION

4.1 Communicating with the Implanted OPTIMIZER Smart IPG

Place the Programmer Wand over the implant site, at a distance of no more than 3.5 cm (1.4 in) from the implanted OPTIMIZER Smart IPG. A blinking green or yellow light on the signal strength indicator indicates that the IPG is within communications range of the Programmer Wand. A blinking red light indicates that the distance is excessive and communications may be difficult. No light at all means that the Programmer Wand and OPTIMIZER Smart IPG are completely out of communication range or that the battery of the OPTIMIZER Smart IPG is completely discharged and thus incapable of communicating with the Programmer Wand.

4.2 Interrogating the OPTIMIZER Smart IPG

To read the parameter values of the OPTIMIZER Smart IPG:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Perform one of the following actions:
 - Press the **Interrogate** button on the Programmer Wand, or
 - Select the **Interrogate** button on the **Tool Bar**, or
 - Select the **Interrogate** button on the **Programming Bar**, or
 - Press the keyboard shortcut <Ctrl+I>

If the interrogation is successful, the OMNI Smart Programmer will display the message “**Interrogation OK**”. The device model, serial number, current CCM therapy status, and current battery level of the OPTIMIZER Smart IPG being interrogated will appear on the Device Bar of the Programmer’s screen.

However if the Programmer Wand is not well positioned over the implant site, the interrogation operation may fail. If a failure in communication occurs, the Programmer will display the message “**Interrogation Error**” along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button or by pressing the **Interrogate** button located on the Programmer Wand.

5. MODIFYING PARAMETER VALUES

Parameter values are found on the Parameters and Follow Up bars and can be viewed and modified by selecting one of the tabs on these bars and then choosing one of the parameters on the panel.

To modify a parameter value:

- Select the tab where the parameter to be modified appears.
- Select the parameter value to be modified. A window with all of its possible values will appear.
- Select the new value from the list. This value will become the new parameter value.
- Checkboxes are used for enabling/disabling parameters. A check (✓) symbol indicates that the option is selected. In order to change the option, select the box to the left of the parameter name.

If the setting of a parameter value is not applicable in the context of other selected parameters, its value is not displayed.

Note: Parameter values displayed on the programmer screen are **not** transferred to the IPG until the **Program** command is issued.

Note: It is not necessary to keep the Programmer Wand over the OPTIMIZER Smart IPG while the parameters are being modified on the programmer screen. Once the modified parameter is ready to be programmed into the device, ensure correct placement of the Programmer Wand over the implant site and then issue the **Program** command.

5.1 Parameter Color Convention

The following color convention is used to represent the programmer's parameter values and conflicts:

- **Black:** for the current parameter values of the OPTIMIZER Smart IPG; i.e. the last interrogated/programmed parameter values.
- **Blue:** for modified allowed values; i.e. parameter values that are different from the programmed values which if selected, *will not* result in a parameter conflict.
- **Red:** for modified prohibited values; i.e. parameter values that are different from the programmed values which if selected, *will* result in a parameter conflict.

The black/blue/red (programmed, pending, conflict) color convention is also used in the list of possible values for a particular parameter. Thus the user can see all three types of parameter values displayed in the list of parameter choices and know in advance whether choosing a particular parameter value will or will not result in a parameter conflict.

5.2 Parameter Conflicts

When parameter values that are incompatible with each other are selected, a *parameter conflict* occurs. Typical conflicts arise from trying to program timing intervals that should add up to less than another programmed parameter. The OMNI Smart Programmer will not allow the OPTIMIZER Smart IPG to be programmed with parameter values that will result in a parameter conflict.

When a parameter conflict occurs, the parameter values that are in conflict are displayed in red. In addition, an error message is displayed in the Programming Bar for each parameter in conflict.

Parameter conflict error messages include:

- Which parameter values are in conflict
- An explanation of why the conflict arose

To resolve a parameter conflict, new values must be selected for the parameters that are causing the conflict. Viewing the conflicting parameters may be rapidly achieved by:

- Select the error message. A list of the parameters in conflict appears.
- Select a parameter name from this list to display a table of all its possible values.
- Select a new "blue" value for the parameter from the list of parameter values.

Conflicting parameters can also be found directly under the **Follow Up** or **Parameters** bars, since these values appear in red. Look for the names of the conflict related tabs in the parameter conflict message displayed in the **Parameter Conflict Bar**.

Please note that it is permissible to select a parameter that causes a conflict provided that another parameter value is changed that resolves the conflict.

6. PROGRAMMING

6.1 Programming the OPTIMIZER Smart IPG

Programming the OPTIMIZER Smart IPG with the modified parameter values is allowed only *if no parameter conflict occurs*.

The **Program** button will indicate whether a modified parameter value is allowed in the following manner:

- Disabled, if there is a parameter conflict,
- Blinking blue, if parameter values have been modified, and there is no parameter conflict.

To program the modified parameter values:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Perform one of the following actions (these actions will be enabled only if *there is no parameter conflict*):
 - Press the **Program** button on the Programmer Wand or
 - Select the **Program** button on the **Tool Bar**, or
 - Select the **Program** button on the **Programming Bar**,
 - Press the keyboard shortcut <Ctrl+P>

If the programming is successful, the OMNI Smart Programmer will display the message “**Programming OK**”.

However if the Programmer Wand is not well positioned over the implant site, the programming operation may fail. If a failure in communication occurs, the Programmer will display the message “**Programming Error**” along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button or by pressing the **Program** button located on the Programmer Wand.

Please note that after executing the **Program** command, the modified parameter values on the OMNI Smart Programmer Software screen will become black, indicating that they are now the programmed parameter values of the OPTIMIZER Smart IPG.

6.2 Cancel and Undo Functions

Modifications to the parameter values can be reset to the previous values in two different ways. The method used to reset the modified parameters depends on whether or not the modified parameters have been programmed into the OPTIMIZER Smart IPG.

6.2.1 Cancel

If any parameter values have been modified but not yet programmed into the OPTIMIZER Smart IPG, the **Cancel** command will *reset the parameter values to the last interrogated/programmed set*.

To cancel modifications, perform one of the following actions:

- Select the **Cancel** button on the **Programming Bar**. This button is enabled only if a parameter value has been modified, or
- Select the **Cancel** button on the **Tool Bar**, or
- Press the keyboard shortcut <Esc>

Please note that after executing a **Cancel** command, the parameter values in the OMNI Smart Programmer Software screens become black, since they are the same as the parameter values in the OPTIMIZER Smart IPG. If no device was interrogated and parameter data were loaded from a .tip file, the displayed parameter values are the values stored in the standard (.tip file).

6.2.2 Undo

If the OPTIMIZER Smart IPG has been reprogrammed with a new set of parameter values, the **Undo** button *resets the parameter values to the prior set of programmed values*.

To undo the most recent programming, perform one of the following actions:

- Select the **Undo** button on the **Programming Bar**. This button is enabled only after the execution of a **Program** command, or
- Select the **Undo** button on the **Tool Bar**. This button is enabled only after the execution of a **Program** command, or
- Press the keyboard shortcut <Ctrl+U>

If the **Undo** operation is successful, the OMNI Smart Programmer will display the message “**Programming OK**”.

However, if the Programmer Wand is not well positioned over the implant site, the Undo operation may fail. If a failure in communication occurs, the Programmer will display the message “**Programming Error**” along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button.

7. USING STANDARDS

Some standard parameter combinations are useful in certain clinical situations. Specific programs can be stored as *standards* (also known as *user presets*). Files containing a standard have a special format that the OMNI Smart Programmer Software can interpret. The file extension used for them is “.tip”. The **Open** and **Save** commands of the OMNI Smart Programmer read and write data from and to .tip files. As such, the OMNI Smart Programmer Software can also be used as an editor of standards.

This section includes information on the use and storage of parameter value configurations.

7.1 Opening a Standard File

To open a standard (.tip) file, perform one of the following actions:

- Select the **Open** button on the **Tool Bar**, or
- Press the keyboard shortcut <Ctrl+O>
- An **Open** window will pop up containing the names and locations of the standard files that can be loaded. Choose a standard file and then click **Open**.

When parameter values are loaded from a standard file, these become the current parameter values displayed by the Programmer. This implies that:

- If an OPTIMIZER Smart IPG has been interrogated before opening a standard file, the values of the standard that are different from the corresponding parameter values of the device will be displayed in blue and the name of the standard file appears in the **Title Bar**.
- If no device has been interrogated, the values of the standard are displayed in black, and the name of the standard file appears in the **Title Bar**.

7.2 Saving a Standard File

To save a parameter value set in a standard (.tip) file:

- Select the **Save** button on the **Tool Bar**
- A **Save As** window will pop up. Enter the file name of the standard to be saved and then click **Save**.

8. LOADING AND EXPORTING INFORMATION

8.1 Loading Log Files

To load a Log file:

- Select the **Log Files** button on the **Task Bar**
- Select the **Open Log** button on the **Tool Bar**
- An **Open** window will pop up containing the names of the marker files that can be loaded. Choose a marker file and then click **Open**.

A Marker window will open up and the color of the text in the Log Window will become blue to indicate that the log does not correspond to the interrogated device.

8.2 Exporting Data

To save current parameter values, statistics counters, and log bar markers as text files:

- Select the **Log Files** button on the **Task Bar**
- Select the **Export Prog** button on the **Tool Bar** to export the parameter values.
- Select the **Export Stats** button on the **Tool Bar** to export the device statistics.
- Select the **Export Marker** button on the **Tool Bar** to export the contents of the log bar.

In all cases, an **Open** window will first pop up where the name of the marker file associated with the device will need to be selected.

Then, a **Save** window will appear which will allow the user to enter the name and, if desired, create a new folder for the file that is to be exported.

9. LOG AND ECG RECORDING

9.1 Log

The OMNI Smart Programmer keeps a log of all the interactions that take place between it and an OPTIMIZER Smart IPG. This record can be used as an index to provide fast access to specific data associated with the communications. *Bookmarks* can also be set in order to have fast access to specific events and conditions that deserve special attention in the patient's ECG.

The following is a description of the basic features of the log:

- The log file for a particular OPTIMIZER Smart IPG is **created** when the device is interrogated for the first time.
- Each communications event that takes place between the OMNI Smart Programmer and the OPTIMIZER Smart IPG appears in the Log Bar window, together with the date and time of each interaction.
- More information regarding an event in the log may be obtained by double-clicking on the event in the Log Bar. If there are data associated with the selected event, the following occurs:
 - If an **Interrogation** or **Programming** event is chosen, the parameter values displayed by the OMNI Smart Programmer are the set of values present at the moment the selected event occurred.
 - If an event involving **Statistics** (clear/load/reset) is chosen, the Statistics Bar values are set to the values present at the moment the selected event occurred.
- For all other recorded events (begin/end of Marker Mode, etc.), a message appears indicating that the event has no more associated data to display.

9.2 ECG Recording

To record a patient's ECG:

- Select the **Log Files** button on the **Task Bar**
- Select the **Recording** button on the **Tool Bar**

The same procedure must be used to stop recording the ECG.

When the OPTIMIZER Smart IPG is set to Marker Mode, the ECG starts recording automatically. When Marker Mode is stopped, the ECG stops recording.

In the recorded ECG, Markers are displayed in the same way as in the Marker Window. (See Section 23 for more information on Markers.)

The recorded ECG segments are displayed in the Marker Window.

10. EMERGENCY PROGRAMMING

In an emergency, the OMNI Smart Programmer can program the OPTIMIZER Smart IPG with a safe parameter set [Standby (OOO) mode, CCM OFF]. This Emergency Programming can be performed even if the Programmer is turned OFF (either the Tablet PC is OFF or is not functioning).

10.1 Emergency Programming When the Programmer is OFF

Note: Even if the Programmer is OFF, the Programmer Wand must still be plugged into the OMNI II Programmer Interface Box before using the Emergency Programming function.

To program the OPTIMIZER Smart IPG with a safe parameter set when the OMNI Smart Programmer is OFF:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Press the **Emergency Programming** button on the Programmer Wand.

If the Emergency Programming is successful, the Emergency Programming Indicator Light on the Programmer Wand will flash for a few seconds.

Warning: When the Emergency Programming function is used with the OMNI Smart Programmer OFF, the Programmer Wand uses a long-life lithium battery inside the OMNI II Programmer Interface Box. The charge of this battery is consumed only if the Programmer Interface is unplugged from the Tablet PC or if the OMNI Smart Programmer is OFF when performing Emergency Programming. Though the estimated average longevity for the lithium battery inside the OMNI II Programmer Interface Box is 54 months, the voltage of the lithium battery inside the OMNI II Programmer Interface Box should be periodically checked to ensure that the battery is not depleted. The voltage of this battery can be read by selecting the **Interface battery** button under the **Settings** tab of the Parameters Bar on the OMNI Smart Programmer software screen. If the battery voltage reading is less than 2.5 V, the battery inside the OMNI II Programmer Interface Box must be replaced. If battery replacement is required, please contact your Impulse Dynamics representative. This battery is not intended to be replaced by the operator.

To perform any other operation, it is necessary to turn ON the OMNI Smart Programmer System.

10.2 Emergency Programming When the Programmer is ON

The **Urgent Programming** command can be used to program the OPTIMIZER Smart IPG with a safe parameter set [Standby (OOO) mode, CCM OFF].

To program the OPTIMIZER Smart IPG with a safe parameter set:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Perform one of the following actions:
 - Pressing the **Emergency Programming** button on the Programmer Wand, or
 - Selecting the **Urgent** button on the **Tool Bar**, or
 - Pressing the **F4** button on the keyboard of the tablet PC,

If the **Urgent Programming** operation is successful, the Programmer reports “**Urgent Programming OK**”.

However if the Programmer Wand is not well positioned over the implant site, the **Urgent Programming** operation may fail. If a failure in communication occurs, the Programmer will display the message “**Urgent Programming Error**” along with 3 short warning beeps and the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button or by pressing the **Emergency Programming** button located on the Programmer Wand.

After a successful **Urgent Programming** operation, the OPTIMIZER Smart IPG is placed in Standby (OOO) mode, CCM OFF.

The emergency programming mode may be used to turn off CCM therapy in the event that side effects such as pectoral stimulation or interaction with co-implanted ICDs develop. CCM would be left off until the patient can follow-up with a specialist. The emergency programming mode may also be used by clinicians who are not experienced with CCM therapy to evaluate ECG tracings without adding the complication of CCM signal artifacts.

11. MAGNET MODE

Placing a pacemaker magnet over the implant site of the OPTIMIZER Smart IPG and maintaining it in close proximity to the device for at least two cardiac cycles (2–3 seconds), sets the OPTIMIZER Smart IPG into a **Permanent Off** state. This **Permanent Off** state is maintained even after the magnet is removed from the implant site.

In this state, the OPTIMIZER Smart IPG does not deliver CCM™ signals, although it senses and classifies cardiac events. This **Permanent Off** state can be changed only by reprogramming the OPTIMIZER Smart IPG using the OMNI Smart Programmer software under physician supervision.

Note: This feature is useful for turning off CCM™ signal delivery when an OMNI Smart Programmer is not available (for example, when a STAT ECG needs to be performed on a patient in an Emergency Room not equipped with an OMNI Smart Programmer).

12. RESETTING THE OPTIMIZER SMART IPG

The OPTIMIZER Smart IPG has protective mechanisms that maintain the internal consistency of the system. These mechanisms detect when an internal discrepancy (for instance, clocks not oscillating at the expected frequency) occurs.

If in the unlikely event a malfunction of this type occurs, the OPTIMIZER Smart IPG will place itself into a safe state referred to as “DOWN” mode. In “DOWN” mode, the OPTIMIZER Smart IPG does not deliver CCM™ signals, and in some cases it does not even sense cardiac events. This status can be changed only by resetting the OPTIMIZER Smart IPG using the OMNI Smart Programmer under physician supervision.

If an OPTIMIZER Smart IPG device reverts to the DOWN Mode, when attempting recharge, the OPTIMIZER Mini Charger will turn on the “Call Doctor” indicator and will display Numerical Code “0”.

To reset the OPTIMIZER Smart IPG:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Select the **Reset** button on the **Tool Bar**.

If the OPTIMIZER Smart IPG is successfully reset, the Programmer will display the message “**Reset Device OK**”.

However if the Programmer Wand is not well positioned over the implant site, the resetting operation may fail. If a failure in communication occurs, the Programmer will display the message “**Reset Device Error**” along with and the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button.

IMPORTANT: If a unit is found in “DOWN” mode, please document the event before resetting the device. After recording the cause of the reversion displayed by the OMNI Smart Programmer, contact your Impulse Dynamics representative. Also, please provide details of the programmed mode in which the reversion occurred, and any conditions that may have caused the device to revert to “DOWN” mode.

The conditions that would cause the IPG to revert to DOWN Mode are as follows:

Safe Mode

Mode	Description
DOWN mode	When the device encounters conditions considered to be the result of faulty device circuitry or software, it will switch to DOWN mode. In DOWN mode, the device is completely quiescent; CCM signals are not delivered and cardiac events are not sensed. To take the device out of this mode, a device reset must be performed under physician supervision.

13. INITIATING CCM DELIVERY

13.1 Operating Mode Options

The operational status of the OPTIMIZER Smart IPG is set by the **Mode** parameter on the **Device Bar**. Selecting the **Mode** parameter will cause the **Mode** pop-up menu to appear.

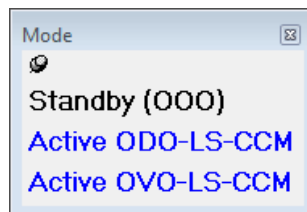


Figure 36: Mode Pop-up Menu

The Operating Mode choices are:

- **Standby (000):** The device is placed in safe mode with no CCM™ signal delivery.
- **Active ODO-LS-CCM:** The device uses atrial, ventricular, and local sense events as triggers for CCM signal delivery.
- **Active OVO-LS-CCM:** The device uses only ventricular and local sense events as triggers for CCM signal delivery.

Note: Active OVO-LS-CCM mode is not supported by this version of programmer.

To program the Operating Mode into the OPTIMIZER Smart IPG:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.

- Select the **Mode** parameter on the **Device Bar**.
- Select the operating mode from the **Mode** pop-up menu.
- Perform one of the following actions to issue the **Program** command:
 - Press the **Program** button on the Programmer Wand or
 - Select the **Program** button on the **Tool Bar**, or
 - Select the **Program** button on the **Programming Bar**

If the programming is successful, the OMNI Smart Programmer will display the message “**Programming OK**”.

However if the Programmer Wand is not well positioned over the implant site, the programming operation may fail. If a failure in communication occurs, the Programmer will display the message “**Programming Error**” along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button or by pressing the **Program** button located on the Programmer Wand.

13.2 CCM™ Signal Delivery Options

CCM™ signal delivery by the OPTIMIZER Smart IPG is set by the **CCM Mode** parameter on the **Device Bar**.

Selecting the **CCM Mode** parameter will cause the **CCM Mode** pop-up menu to appear.



Figure 37: CCM Mode Pop-up Menu

The CCM Mode choices are:

- **CCM OFF**
- **Continuous:** For testing purposes only.

Warning: The OPTIMIZER Smart IPG **MUST NEVER** be left in **Continuous** mode.

- **Timed:** CCM™ signals will be delivered as scheduled by the **CCM Schedule** tab.

Selecting **Continuous** will cause a warning window to appear. This window will reappear every time a programming command is issued to remind the operator that the OPTIMIZER Smart IPG is still set to **Continuous** mode. Inadvertent extended use of **Continuous** mode will cause the battery of the OPTIMIZER Smart IPG to prematurely run-down, necessitating frequent recharging sessions.

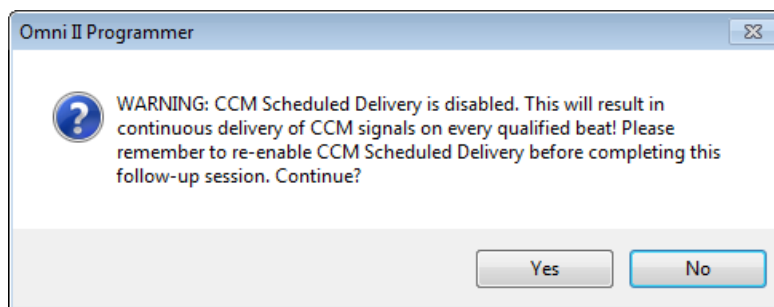


Figure 38: Continuous CCM Delivery Warning

To program the CCM™ Mode into the OPTIMIZER Smart IPG:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Select the **CCM Mode** parameter on the **Device Bar**.
- Select the CCM Mode from the **CCM Mode** pop-up menu.
- Perform one of the following actions to issue the **Program** command:
 - Press the **Program** button on the Programmer Wand or
 - Select the **Program** button on the **Tool Bar**, or
 - Select the **Program** button on the **Programming Bar**.

If the programming is successful, the OMNI Smart Programmer will display the message “**Programming OK**”.

However if the Programmer Wand is not well positioned over the implant site, the programming operation may fail. If a failure in communication occurs, the Programmer will display the message “**Programming Error**” along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button or by pressing the **Program** button located on the Programmer Wand.

14. MARKER EVENTS

The OMNI Smart Programmer can be used to set the OPTIMIZER Smart IPG into **Marker Mode**. Markers are flags that represent the various states of the device and events detected during its operation. In this mode, all events detected and generated by the OPTIMIZER Smart IPG are displayed in the ECG window synchronized with the patient’s ECG signal. The markers are useful for analyzing the behavior of the IPG with different programmed parameters.

14.1 Turning Markers On

To set the OPTIMIZER Smart IPG in Marker Mode:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Select the **Marker** button on the **Tool Bar**.

If the programming is successful, the Programmer reports “**Start marker mode**”. In the **ECG Window** of the OMNI Smart Programmer Software, a bar will appear and Marker Events will be displayed as they occur.

However if the Programmer Wand is not well positioned over the implant site, setting the OPTIMIZER Smart IPG in Marker mode will fail, and the Programmer will display the message “**Marker mode error**” along with the options **Retry** and **Cancel**

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button.

14.2 Turning Markers Off

To turn off Marker Mode:

- Select the **Marker** button the **Tool Bar**, or
- Remove the Programmer Wand from the implant zone. *If the Programmer Wand cannot communicate with the OPTIMIZER Smart IPG, the Marker Mode is automatically terminated.*

In all cases, the Programmer reports “**Marker mode end OK**”.

Whenever a communication command between the OPTIMIZER Smart IPG and the OMNI Smart Programmer takes place (programming, reading statistics, measuring impedances, etc.), the Marker Mode automatically ends and is re-established when the communication has finished.

14.3 Sensed Events

Sensed events are represented by colored line markers below the baseline, which use the following color conventions:

- **Magenta:** Atrial sensed event
- **Green:** Ventricular sensed event
- **Black:** Local Sense event

14.4 CCM™ Train Delivery

CCM™ signal delivery is represented by a marker in the shape of a blue rectangle whose width is in proportion to the duration of the CCM™ signal.

14.5 CCM™ Inhibit Conditions

Labels for the following events are displayed:

- **PVC:** two adjacent ventricular sensed events without an intervening atrial sensed event.
- **AT:** Atrial rate above the atrial tachycardia rate limit. *Any atrial rate exceeding a certain threshold is considered atrial tachycardia. Using the OMNI Smart Programmer software, the atrial tachycardia threshold rate can be set to one of 51 possible values between 62 bpm and 179 bpm. CCM signal delivery is always inhibited when atrial tachycardia is detected.*
- **A Noise:** Noise detected on the atrial sense channel.
- **V Noise:** Noise detected on the ventricular sense channel.
- **Long AV:** Sensed AV interval exceeds “Long AV” limit.
- **Short AV:** Sensed AV interval shorter than “Short AV” limit.

14.6 CCM™ Signal Delivery State

CCM signal delivery state is indicated by labels as well as by the background color of the ECG window as follows:

- **Inactive:** this label appears on the ECG window when CCM™ delivery first becomes **not Active**. The background color of the ECG window is **white** in this case.
- **Active-On:** this label appears on the ECG window when CCM™ delivery first becomes **Active** and **On**. The background color of the ECG window is **green** in this case.
- **Active-Off:** this label appears on the ECG window when CCM™ delivery first becomes **Active** but **Off**. The background color of the ECG window is **gray** in this case.

14.7 Log Browser Window

When **Log Files** button from the **Task Bar** is selected and then the **Browse** button is selected from the **Tool Bar**, the corresponding window titled Marker Window is displayed.

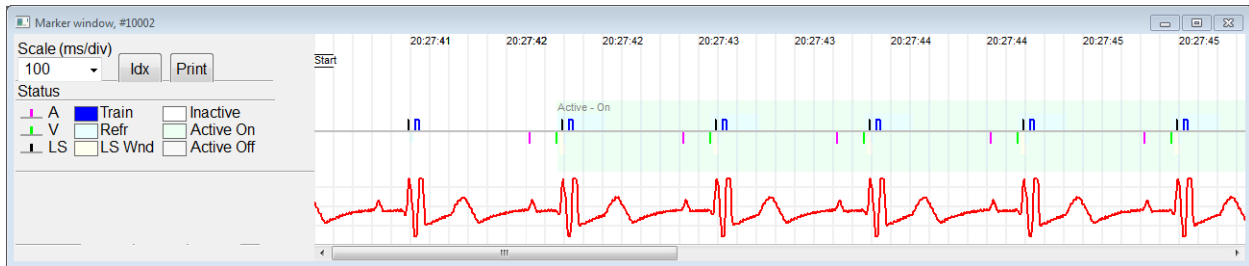


Figure 39: Marker Window

For the OPTIMIZER Smart IPG the log browser window is composed of the following elements:

- Time scale that can be modified with the available options or typing a scale value.
- Idx button that opens up a Marker index log window containing log items that can be used for navigation purposes.
- Markers and ECG labeled display.
- Horizontal scrollbar to allow browsing in time.
- Vertical scrollbar whenever the signals do not fit in the defined window.
- Print button.

When an event in the Marker index log window is double-clicked, the Marker Window screen automatically displays the information associated to the event time stamp. Analogous behavior occurs when a command in the log window or the associated indicator in the screen is selected.

The distance between two available cursors, one principal to be fixed and another to be moved along the window, allow direct measurements of several dimensions as time intervals or voltage.

15. CCM™ Schedule

When the OPTIMIZER Smart IPG is programmed to deliver **Timed** cardiac contractility modulation therapy, the CCM Schedule parameters become enabled.

To access the CCM™ Schedule parameters:

- Select the **Parameters** button on the **Task Bar**
- Select the **CCM Train & Schedule** tab on the **Parameters** bar.

The upper middle half of this tab contains the parameters **Start Time** and **End Time**. The parameters set the general start and end time of cardiac contractility modulation therapy delivery during each day. By default, the cardiac contractility modulation therapy schedule is set to be distributed over a 24 hour period each day. The standard programming for these parameters is:

- **Start Time:** 0 h 0 m
- **End Time:** 23 h 59 m

The upper right half of this tab contains the parameters **On Time** and **Off time**. The **On Time** parameter sets the amount of time the OPTIMIZER Smart IPG is scheduled to deliver cardiac contractility modulation therapy within the time frame set by the **Start time** and **End time**. The **Off Time** parameter sets the amount of time the OPTIMIZER Smart IPG is scheduled not to deliver cardiac contractility modulation therapy within the time frame set by the **Start time** and **End time**.

The upper left half of this tab is the parameter **Scheduled**. The **Scheduled** parameter sets the total number of hours per day the OPTIMIZER Smart IPG is scheduled to deliver cardiac contractility modulation therapy within the time frame set by the **Start time** and **End time**. This parameter is calculated depending on settings for **On Time** and **Off time**.

Note: When the parameter **Scheduled** is set to a specific value, the OMNI Smart Programmer software automatically calculates and sets the exact times for the **On Time** and **Off time** parameters using the default parameters for the **Start Time** and **End Time**.

For instance, if cardiac contractility modulation therapy rate is set to 7 hours per day distributed over 24 hours, it sets the following standard scheduling parameters:

- **Start Time** 0 h 0 m
- **End Time** 23 h 59 m
- **On Time** 1 h 0 m
- **Off Time** 2 h 25 m
- **Scheduled** 7 h

16. STATISTICS

The OPTIMIZER Smart IPG accrues a statistical record of events and conditions that occur as it functions. This record can be loaded into the OMNI Smart Programmer, and appears in the Statistics window of the OMNI Smart Programmer software, indicating the number of occurrences of each event type.

Events considered are as follows:

- **Atrial:** the number of sensed atrial events.
- **Ventricular:** the number of sensed right-ventricular events.
- **A Noise:** the number of times atrial noise was detected.
- **V Noise:** the number of times ventricular noise was detected.
- **Short AV:** the number of times a Short AV condition was detected.
- **Long AV:** the number of times a Long AV condition was detected.
- **PVC:** the number of times a PVC was detected.

- **AT:** the number times the instantaneous atrial rate exceeded the Atrial Tachycardia rate limit.
- **VT:** the number times the instantaneous ventricular rate exceeded the Ventricular Tachycardia rate limit.
- **Trains Delivered:** the number of delivered CCM™ signals.
- **LS Inhibit:** the number of CCM™ signal delivery inhibitions due to Local Sense events detected outside the LS Alert Window.
- **LS Absence:** the number of CCM™ signal delivery inhibitions because Local Sense events were not detected.
- **LS in Alert:** the number of Local Sense events inside the LS Alert Window.

16.1 Loading Statistics

To obtain the Statistics from the OPTIMIZER Smart IPG:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Select the **Statistics** button on the **Task Bar**.
- Select the **Read** button at the bottom of the **Statistics** bar.

If the loading is successful, the Programmer will display the message “**Read Statistics OK**”.

However if the Programmer Wand is not well positioned over the implant site, the transfer of data may fail. If a failure in communication occurs, the Programmer will display the message “**Read Statistics Error**” along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button.

When the OPTIMIZER Smart IPG is in **Marker Mode** and within communications range of the OMNI II Programmer Wand, the contents of the Statistics counters change dynamically, showing the current number of occurrences of each event type.

16.1.1 Statistics Tabs

- **On – General**
 - **Events**
 - **Atrial:** number of atrial events sensed during scheduled CCM™ delivery
 - **Ventricular:** number of ventricular events sensed during scheduled CCM™ delivery
 - **LS in Alert:** number of local sense events sensed during scheduled CCM™ delivery
 - **Periods**
 - **Normal:** number of normal periods during scheduled CCM™ delivery
 - **Inhibited:** number of inhibited periods during scheduled CCM™ delivery
 - **Post-Inhibited:** number of post-inhibited periods during scheduled CCM™ delivery
 - **Trains Delivered**

- **During Onset:** number of CCM™ trains delivered during the onset of scheduled CCM delivery
- **Total:** total number of CCM™ trains delivered during scheduled CCM™ delivery
- **On – Inhibition**
 - **Causes**
 - **AT:** number of atrial tachycardia beats detected during scheduled CCM™ delivery
 - **PVC:** number of PVCs detected during scheduled CCM™ delivery
 - **Long AV:** number of times Long AV condition detected during scheduled CCM™ delivery
 - **Short AV:** number of times Short AV condition detected during scheduled CCM™ delivery
 - **LS:** number of Local Sense events outside the LS Alert Window during scheduled CCM™ delivery
 - **LS Absence:** number of Local Sense events not detected during scheduled CCM™ delivery
 - **VT:** number of ventricular tachycardia beats detected during scheduled CCM™ delivery
 - **Noise Episodes**
 - **A Noise:** number of times atrial noise detected during scheduled CCM™ delivery
 - **V Noise:** number of times ventricular noise detected during scheduled CCM™ delivery
- **Off – General:** Displays the same list of statistical counters as detailed under **On – General** (except for **Trains Delivered**). Statistics for when the OPTIMIZER Smart IPG is scheduled not to deliver cardiac contractility modulation therapy
- **Off – Inhibition:** Displays the same list of statistical counters as detailed under **On – Inhibition**. Statistics for when the OPTIMIZER Smart IPG is scheduled not to deliver cardiac contractility modulation therapy
- **Last Session:** Statistics for Last Delivery V, Last Delivery Trains, Percentage, and Battery Discharge Episodes.

16.1.2 Statistics Buttons

- **Read:** Reads statistics from IPG.
- **Reset:** Resets statistics stored in IPG.
- **Numeric:** Displays a table of the numerical statistics from the active tab.
- **Graphic:** Displays a histogram of the statistics from the active tab.

16.2 Resetting Device Counters

In order to reset the OPTIMIZER Smart IPG Statistics counters to zero:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Select the **Statistics** button on the **Task Bar**.
- Select the **Reset** button at the bottom of the **Statistics** bar.

As this operation resets the internal counters of the device, a confirmation message will pop up. If the reset request is confirmed, the reset operation is performed.

If the statistical counters are successful reset, the Programmer reports “**Reset statistics OK**”.

However if the Programmer Wand is not well positioned over the implant site, the resetting operation may fail. If a failure in communication occurs, the Programmer will display the message “**Reset Statistics Error**” along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button.

17. MEASURING LEAD IMPEDANCES

The impedance of the LS and V leads can be measured by the OPTIMIZER Smart IPG and displayed by the OMNI Smart Programmer. A CCM™ signal is delivered through the selected channel by the OPTIMIZER Smart IPG in order to measure the lead impedance. A pulse train with the following parameters is used for impedance measurement:

- Number of Pulses: 1
- Amplitude: 5.0
- Phase Duration: 0.5 ms

The impedance of the selected channel can be measured by the OPTIMIZER Smart IPG within the range 50Ω to 2000Ω to within a precision of 20% or 10Ω, whichever is greater.

Warning: Lead impedance measurements above 1000Ω are very imprecise and must be construed only as an indication of electrical continuity through the lead.

During the impedance measurement, all programmed parameters remain the same, except for the ones described above, which are transitorily changed. However, impedance measurement cannot be performed if a triggering event does not occur, or if an inhibiting event occurs, for the parameter values programmed in the device.

To measure the lead impedances:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Verify that the CCM™ Train Delivery parameter is set to **Timed** or **Continuous**.
- Select the **Follow Up** button on the **Task Bar**.
- Select the **Impedance** tab on the **Follow Up** bar.
- Select the **V** or **LS** button to measure the desired lead impedance.

Warning: After performing the lead impedance measurement, the operator should perform an interrogation to verify that the programmed values are set as intended.

18. SETTING THE CLOCKS ON THE OPTIMIZER SMART IPG AND OMNI SMART PROGRAMMER

The time of day is maintained by an internal clock within the OPTIMIZER Smart IPG and is used by the cardiac contractility modulation Therapy Delivery Scheduling mechanism to turn the CCM™ Signal on and off in accordance with the programmed CCM Schedule parameters.

There are three buttons that are used to manage the internal clock functions:

- **Get time:** Button for reading the current IPG time.
- **Set time:** Button for manually setting the IPG time.
- **Set with PC time:** Button for synchronizing the IPG time with the PC time.

18.1 Reading the OPTIMIZER Smart IPG Time

The real-time clock in the OPTIMIZER Smart IPG is very precise. Nevertheless over the successive months and years, the current device time of the IPG may lose its synchronicity with the current local time. In order to read the current device time of the OPTIMIZER Smart IPG:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Select the **Time** button on the **Tool Bar**.
- When the Time window appears, select the **Get Time** button.

Caution: Be certain that you are selecting the correct button.

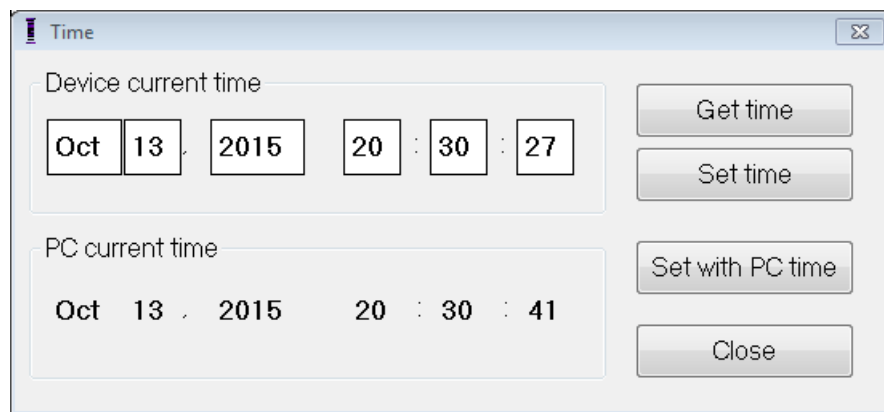


Figure 40: Time Window

If Interrogation is successful, the current time in the device will be displayed under “Device current time” in the Time window.

If the Programmer Wand is not well positioned over the implant site, the interrogation operation may fail. If a failure in communication occurs, the Programmer will display the message “**Get Time Error**” along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button.

18.2 Setting the OPTIMIZER Smart IPG Real Time Clock

You can set the OPTIMIZER Smart IPG real-time clock either manually or by using the computer’s clock. In both cases:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Select the **Time** button on the **Tool Bar**.
- When the Time window appears, select the **Get Time** button.

To manually set the current time of the OPTIMIZER Smart IPG:

- Select the new time in the **Device current time** box. The **Set Time** button will start to blink, indicating that the current device time is different from the one displayed in the screen.
- Select the **Set Time** button.

Caution: Be certain that you are selecting the correct button.

If the time change is successful, the Programmer will display the message “**Set time OK**”.

If the Programmer Wand is not well positioned over the implant site, the interrogation operation may fail. If a failure in communication occurs, the Programmer will display the message “**Set Time Error**”, along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button.

To set the current time of the OPTIMIZER Smart IPG to the computer’s time:

- Place (or replace, if necessary) the Programmer Wand over the OPTIMIZER Smart IPG implant site.
- Select the **Time** button on the **Tool Bar**.
- When the **Time** window appears, select the **Set with PC time** button.

Caution: Be certain that you are selecting the correct button.

If the time change is successful, the Programmer will display the message “**Set time OK**”.

If the Programmer Wand is not well positioned over the implant site, the interrogation may fail. If a failure in communication occurs, the Programmer will display the message “**Set Time Error**”, along with the options **Retry** and **Cancel**.

Retry can be performed by repositioning the Programmer Wand and selecting the **Retry** button.

18.3 Setting the OMNI Smart Programmer Clock

To set the system time of the OMNI Smart Programmer:

- Select the **Parameters** button on the **Task Bar**.
- Select the **Settings** tab on the **Parameters** bar.
- Select the **Set system time...** button on the **Settings** panel
- A **Set system time** window will appear which has a calendar and the current OMNI Smart Programmer time. The current system date is highlighted.

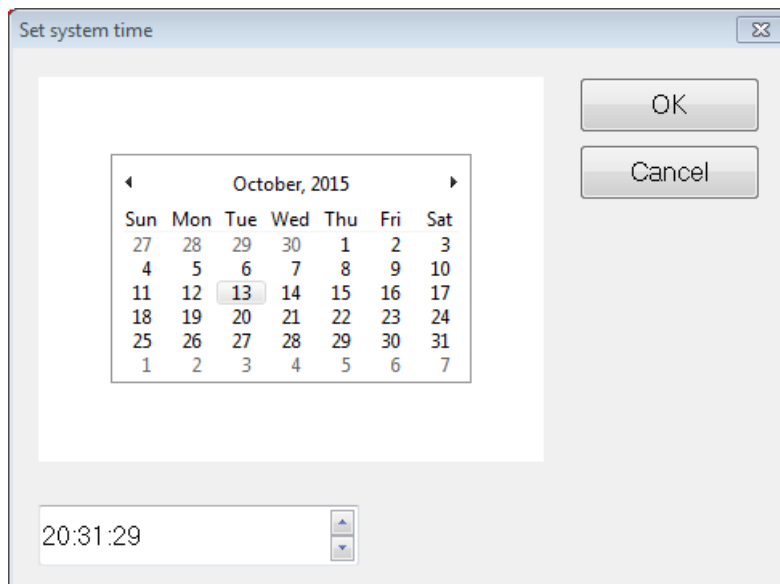


Figure 41: Set system time Window

- Using the cursor, select a new date, if required. To adjust the time, select the hour, minute or seconds and then change the value using the up or down arrows to the right of the time display.
- When you are done, select **OK** or cancel the operation by selecting **Cancel**.

19. OPTIMIZER SMART IPG ALARMS REPORTED TO THE OPTIMIZER MINI CHARGER

19.1 Minimum Target Percentage for CCM™ Delivery

The OPTIMIZER Smart IPG keeps a record of the events and conditions that occurred during the last Active Period of the CCM™ scheduled delivery. This record can be used to calculate the percentage of CCM™ signals delivered compared to the number of right ventricular events sensed during the period.

The minimum target percentage for CCM™ delivery parameter is the expected minimum CCM™ train delivery ratio.

The OPTIMIZER Mini Charger can be programmed to display a Numerical Code whenever that cardiac contractility modulation therapy rate falls short of programmed minimum target percentage (Numerical Code 4 – see Section 33.6.5).

To activate the Numerical Code 4 alarm in the OPTIMIZER Mini Charger:

- Select the **Parameters** button on the **Task Bar**.
- Select the **Alarms** tab on the **Parameters** bar.
- Find the **Minimum Target % for CCM Delivery** on the **Alarms** panel.
- Activate this function by setting the check (✓) symbol in the checkbox next to **Enable**.

Currently programmed value for this parameter will appear

To modify the current value of the Minimum Target % for CCM Delivery, perform the following:

- Select current value for **Minimum Target % for CCM Delivery**.
- When the **Min Target for CCM Deliv. (%)** window appears, select a new parameter value.
- Program the new parameter value to OPTIMIZER Smart IPG.

19.2 Maximum Lead Displacement

Possible damage or displacement of a ventricular lead could be identified by a change in the lead impedance compared to previous measured values.

Measurement of V and LS lead impedance by either the OMNI Smart Programmer or OPTIMIZER Mini Charger are stored in the OPTIMIZER Smart IPG.

Measurement of V and LS lead impedance by the OPTIMIZER Mini Charger is done automatically at beginning of every charge procedure. The latest measured impedance value for each lead is then compared to previous stored impedance values for each lead.

The OPTIMIZER Mini Charger can be programmed to display a Numerical Code whenever the lead impedance exceeds the maximum tolerated difference to latest stored lead impedance (Numerical Code 1 – see Section 33.6.2).

To activate the Numerical Code 1 alarm in the OPTIMIZER Mini Charger:

- Select the **Parameters** button on the **Task Bar**.
- Select the **Alarms** tab on the **Parameters** bar.
- Find **Maximum Lead Displacement** on the **Alarms** panel.
- Activate this function by setting the check (✓) symbol in the checkbox next to **Enable**.

Currently programmed value for this parameter will appear

To modify the current value of the Maximum Lead Displacement, perform the following:

- Select current value for **Maximum Lead Displacement**.
- When the **Max Lead Displac...** window appears, select new parameter value.
- Program new parameter value to OPTIMIZER Smart IPG.

20. LOCAL SENSE (LS) SCAN

The OMNI Smart Programmer software has a **LS Scan** tool which can be used to select appropriate operating parameters for the LS channel.

To open the LS Scan tool:

- Select the **Follow Up** button on the **Task Bar**.
- Select the **LS Setup** tab on the **Follow Up** bar.
- Select the **LS Scan** button on the **LS Setup** panel.

The Local Sense Scan screen will appear. The Graph view is shown at the top of the screen and the **Sensitivity** parameter related to Local Sensing appear on the right pane of the screen.



Figure 42: LS Scan Screen

When running an LS Scan, the OPTIMIZER Smart IPG is set to a special mode in which LS signals are sampled every 2 ms throughout a 200 ms interval centered at the right-ventricular event. These signals are sent to the OMNI Smart Programmer to be displayed in the Local Sense Scan window as histograms.

Local Sense scans can be performed either manually or automatically:

- Use the **Manual** button to acquire a LS histogram for a specific LS sensitivity selected through the **Sensitivity** parameter.
- Use the **Automatic** button to start a process that scans through various LS Sensitivity values.

When the automatic scans are completed, all collected histograms appear in the Local Sense Scan screen. The operator can then select the most appropriate sensing threshold.

The sensitivity used to accrue sensing data for one histogram is the **LS Sensitivity** parameter that appears on the right-part of the window.

By acquiring these samples for different LS Sensitivity values, the timing of the LS event relative to the right-ventricular event is clearly demonstrated. The LS Scan results should be interpreted as follows:

- Blue bars in the histogram indicate that the LS signal was sensed more than the number of times indicated by the **Events per Bar** parameter.

Note: For lower values of LS sensing threshold (higher sensitivity), signals other than the LS may be detected. For example, using **Figure 45**, an appropriate value for the LS Sensitivity parameter would be 1.7 mV.

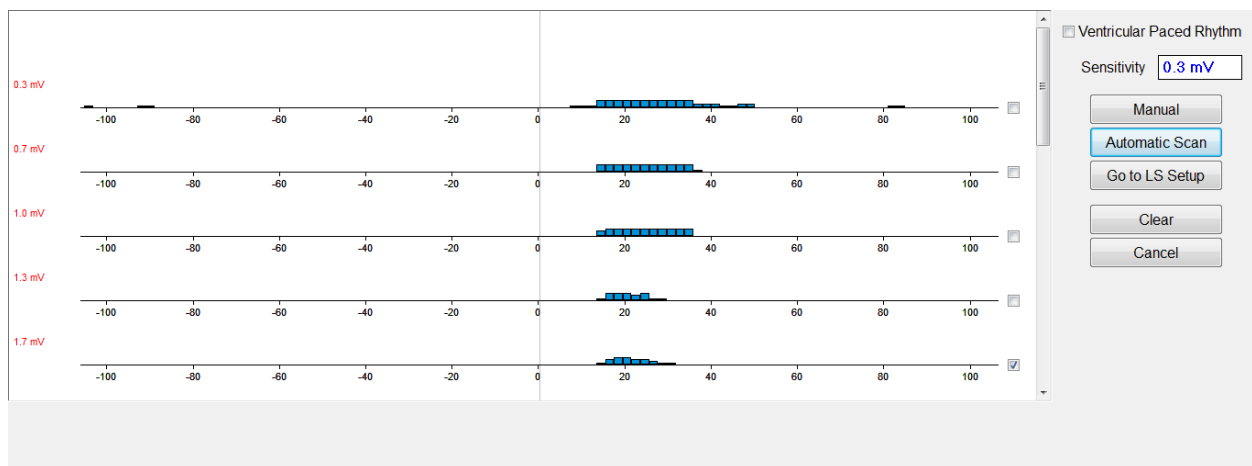


Figure 43: Local Sense Scan Screen after Automatic Scan

To use the results of the LS Scan:

- Select the check box next to the desired sensitivity values.
- Select the **Go to LS Setup** button.
- Once the application returns to the **LS Setup** panel, select the check box under **LS 1** column of the **Measurement** box.
- Select the **Propose LS** button. This command changes the LS parameters of the OMNI Smart Programmer to the optimum settings based on the selected LS Sensitivity.

Note: This operation only changes the parameter values of the Programmer. The selected parameters must still be programmed into the OPTIMIZER Smart IPG using the **Program** command.

- Observe the LS Wizard screen. It shows the LS parameters in graph form. The brown markers represent the Pre and Post V Refractories, the yellow markers represent the Alert Start and Alert Width, and the blue markers represent the Post LS Refractory interval.
- If the proposed LS parameters are acceptable, issue the **Program** command to program the new LS parameters into the OPTIMIZER Smart IPG.

If the proposed LS parameters are not desired, select the **Cancel** button. This command resets the LS parameters of the OMNI Smart Programmer to the last interrogated/programmed values.

If necessary, the **LS Scan** command may be used again to scan and select another LS Sensitivity value.

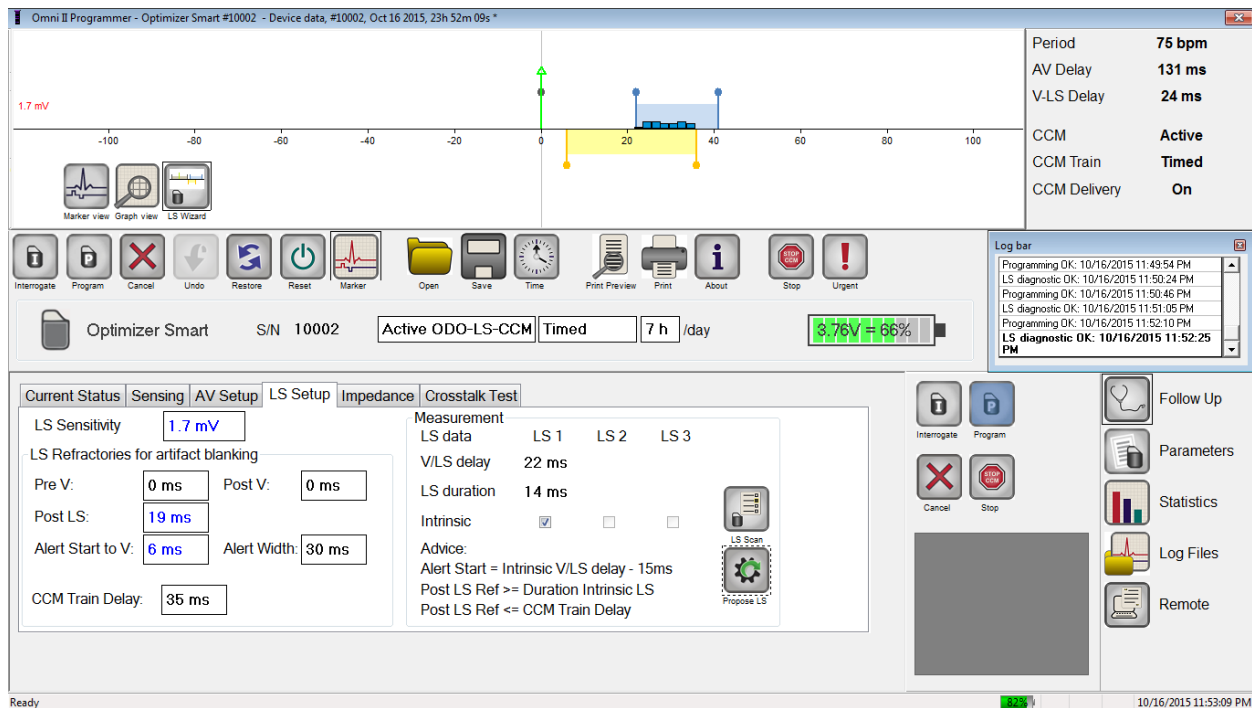


Figure 44: LS Setup Screen after Selection of Propose LS Button

20.1 Crosstalk Test

The OMNI Smart Programmer software has a **Crosstalk Test** tool which may be used whenever device/device interaction testing (see Appendix III) is performed between the OPTIMIZER Smart IPG and an implanted concomitant device.

To start the Crosstalk Test:

- Select the **Follow Up** button on the **Task Bar**.
- Select the **Crosstalk Test** tab on the **Follow Up** bar.

Note: Read the instructions on the left side of the **Crosstalk Test** panel under the heading “Attention!” before performing the test.

- Select the **Crosstalk Start** button on the **Crosstalk Test** panel.

The **CCM delay to LS** parameter will be temporarily set to a default test value of 85 ms and **V Refractory** parameter will be temporarily set to a default test value of 336 ms.

To stop the Crosstalk Test:

- Select the **Crosstalk Undo** button on the **Crosstalk Test** panel.

The **CCM delay to LS** and **V Refractory** parameters will be returned to their pre-test chronic values.

21. REMOTE OPERATION

The OMNI Smart Programmer allows remotely monitoring and controlling of the device via the Internet. Once connected, the operation is identical to the normal (local) operation, except that some commands may be disabled depending on the operating mode.

In order to initiate a remote operation session, the OMNI Smart Programmer must be connected to the Internet. The OMNI Smart Programmer supports wireless networks and Ethernet cable connections. If connecting to a wired Ethernet network, the network cable must be connected to the OMNI II Programmer Tablet PC through the medical-grade Ethernet isolator that is attached to each Programmer.

Note: As with any other device that is connected to the Internet, there may occasionally be technical issues which prevent operation of the remote feature, and thus not allow an implant follow up to be performed by remote operation. In such cases, an in-person follow-up with a Company Representative needs to be scheduled.

Warning: Connection of the OMNI Smart Programmer to a network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. In such cases, the responsible organization should identify, analyze, evaluate, and control these risks. In addition, subsequent changes to the network/data coupling could introduce new risks and require additional analysis. Changes to the network/data coupling include:

- changes in network/data coupling configuration
- connection of additional items to the network/data coupling
- disconnecting items from the network/data coupling
- update of equipment connected to the network/data coupling
- upgrade of equipment connected to the network/data coupling

21.1 Connecting the OMNI Smart Programmer to a Wired Ethernet Network

Note: The connection of the OMNI II Programmer Tablet PC to a wired internet network must only be done through the medical-grade Ethernet isolator.

If use of the Remote Operation Mode is desired, and connection to the Internet is via wired network, the OMNI Smart Programmer must be connected to a standard 10/100 Ethernet network via the unused RJ-45 Ethernet port on the medical-grade Ethernet isolator attached to the bottom of the OMNI II Programmer Tablet PC.

21.2 Connecting the OMNI Smart Programmer to a Wireless Network

If use of the Remote Operation Mode is desired and connection to the Internet is via wireless network, the OMNI Smart Programmer must first be configured to connect to a wireless network.

21.2.1 OMNI Smart Wireless Network Configuration

At the Selector screen, click the “Configuration” button. The Configuration Dialog window will appear.

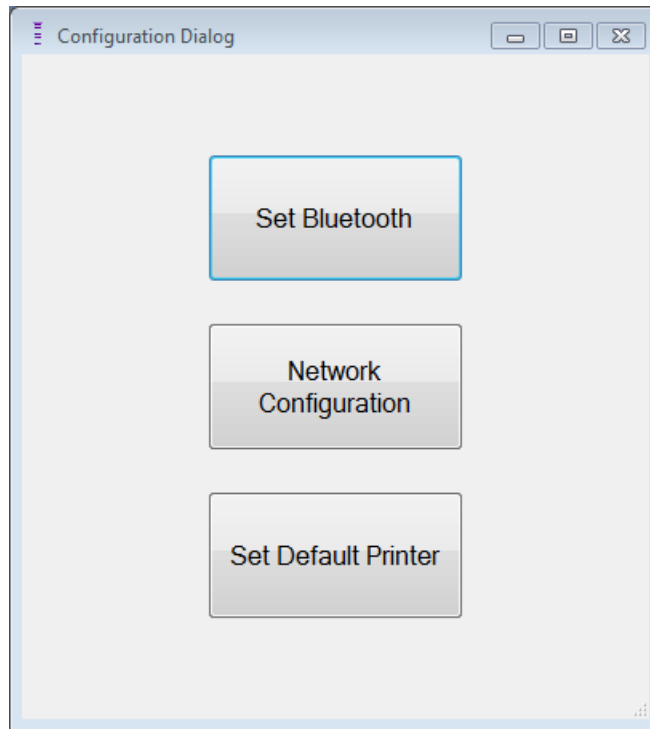


Figure 45: Configuration Dialog Window

Click the “Network Configuration” button to setup the connection with the server or change network settings. The Network configuration window will appear.

Note: If no wireless networks appear, click on the “Refresh” button to view the available wireless networks within range of the OMNI Smart Programmer.

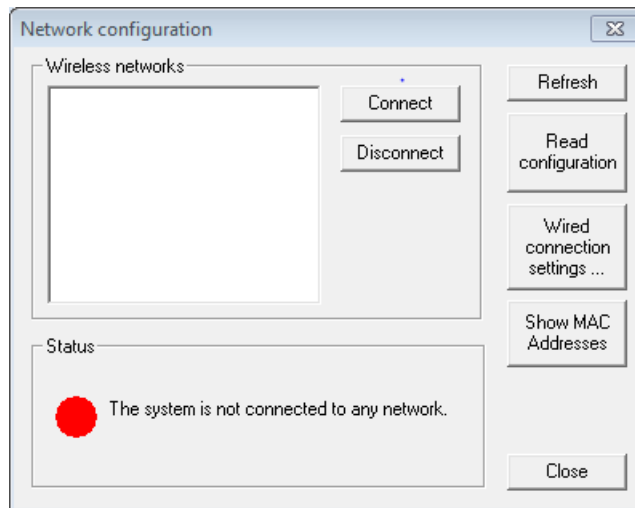


Figure 46: Network Configuration Window

The Network configuration window displays the following information:

- Wireless networks: a list of the available supported wireless networks with the following information:
 - Network name.
 - Signal strength percentage.

- Connection status (“Connected” will appear next to the signal strength percentage if the OMNI Smart Programmer is connected to that network).
- Status: status of the connection. A green circle will indicate that the OMNI Smart Programmer can connect with the server, while a red circle will indicate that some problem is preventing the programmer from connecting with the server.

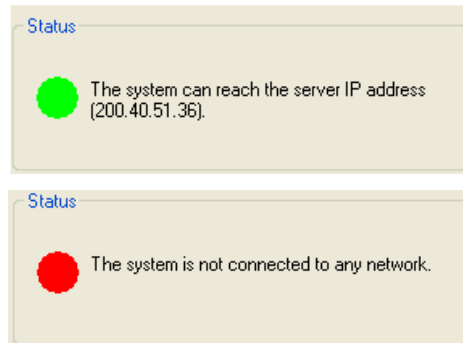


Figure 47: OMNI Smart Network Status Indicators

21.2.2 OMNI Smart Wireless Network Configuration Commands

The OMNI Smart Network configuration window provides the following command buttons:

- **Connect:** connect to the selected wireless network. A password dialog will appear in which you must enter the network key (ask the network administrator for the key).
- **Disconnect:** disconnect from the selected wireless network.
- **Refresh:** refresh the connection status.
- **Read configuration:** read network configuration settings from a USB drive. The USB drive must be provided by you network administrator or Impulse Dynamics.
- **Wired connection settings ...:** A TCP/IP Settings dialog window will appear in which you must enter the TCP/IP settings (ask the network administrator)
- **Show MAC Addresses:** A Network adapters MACs’ addresses dialog window will appear detailing the MAC address of each network adapter installed in the OMNI II Programmer Tablet PC.
- **Close:** closes the window.

21.3 OMNI Smart Operation Modes

21.3.1 OMNI Smart Startup Modes

The OMNI Smart Programmer software can be opened in one of the following modes:

- **Clinical Mode:** for local operation in a clinical setting
 - The OMNI II Programmer Tablet PC must be connected to the OMNI II Programmer Interface Box using the Interface Box cable.
- **Remote Mode:** for remote operation of an OMNI Smart Programmer in a clinical setting

- The OMNI II Programmer Tablet PC does not require an attached interface. It still can monitor or control the device remotely via the Internet (remote programmer, far from the patient).
- **Remote Listener Mode:** for remotely monitoring an OMNI Smart Programmer in a clinical setting
 - A particular case of Remote Mode in which the OMNI Smart Programmer is not able to control the device (just monitoring operations are allowed).

To open the desired startup mode, select the appropriate button on the OMNI Smart Programmer Selection screen. Once the Programmer's mode is selected, it cannot be changed until the mode's application is closed and the Selection screen is again displayed by the OMNI Smart Programmer.

The following rules apply to the various startup modes:

- A Programmer in Clinical Mode can connect to one Programmer in Remote Mode and several Programmers in Remote Listener Mode, but not with another Programmer in Clinical Mode.
- A Programmer in Remote Mode can only connect to one Programmer in Clinical Mode. The following message will be displayed when the 'OMNI Smart Programmer – Remote Mode' button is selected:

“This OMNI II Programmer cannot be used to interrogate or program local OPTIMIZER Mini IPGs while logged on as a Remote Programmer. The remote programming session must be terminated and this OMNI II Programmer rebooted prior to using this programmer to interrogate or program an OPTIMIZER Mini IPG through this programmer's wand.”

- A Programmer in Remote Listener Mode can only connect to one Programmer in Clinical Mode.
- All the Programmers connected to a Clinical Mode Programmer (Remote and Remote Listener) can receive chat messages and monitoring information (markers, programming values, statistics readings, etc).
- Only the Programmer in Clinical or Remote modes can send chat messages.
- Only the Programmer in Master Mode (see Section 30.5) is able to initiate communication operations with the device (interrogate, programming, etc.). The Programmer in Master Mode can be either a Remote or Clinical Programmer.

21.3.2 OMNI Smart Master/Slave Modes

An OMNI Smart programmer opened in Remote or Clinical mode can become Master or Slave during the remote session. The OMNI Smart Programmer can be changed between Master and Slave modes only when the Programmer is in Clinical Mode.

When the OMNI Smart Programmer is in Master mode (Remote or Clinical), it has total control of the OPTIMIZER Smart IPG, whereas when the OMNI Smart Programmer is in Slave mode, the commands that interact with the OPTIMIZER Smart IPG have been disabled (interrogation, programming, initiate marker mode, reading statistics etc.)

21.4 OMNI II Programmer Client Window

Note: In order to connect the OMNI Smart Programmer to the OMNI Remote Server, the OMNI Smart Programmer must first be connected to Internet. See Sections 30.1 and 30.2 on ways to connect the OMNI Smart Programmer to the Internet.

The Omni II Programmer Client window is used to log in to the Client Server.

To open the OMNI II Programmer Client window:

- Select the **Remote** button on the **Task Bar**
- Select the **Connect** button on the **Tool Bar**.

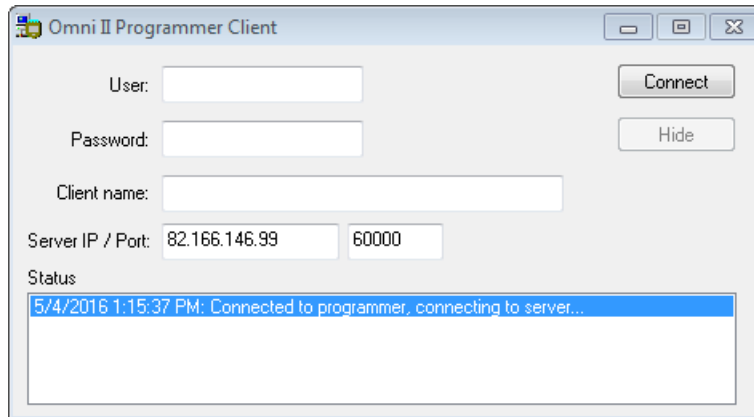


Figure 48: OMNI II Programmer Client Window

21.4.1 Connecting the OMNI Smart Programmer to the Remote Server

When the OMNI II Programmer Client window appears, enter the following information:

- **User:** a user name compatible with the current Programmer's startup mode. If the user name is not registered with the server to operate in the current startup mode (Clinical, Remote, or Remote Listener), the connection will be rejected.
- **Password:** a password corresponding to the user name that is stored in the server.
- **Client name:** a name (different than the User name) that uniquely identifies the OMNI Smart Programmer. This field is not checked by the server but it is important in order to identify the Client Programmer when connecting to it remotely or when sending a chat message (the Client name appears in the chat window).
- **Server IP / Port:** IP address of the server. (This is set by Impulse Dynamics before the OMNI Smart Programmer is shipped and does not need to be changed.)

Note: To use the remote operation feature of the OMNI Smart Programmer, a user must receive a unique user name and password from Impulse Dynamics. An appropriate Client Name must also be registered with Impulse Dynamics.

Once all of the above information has been entered, press Enter or click on the **Connect** button. The status of the connection will appear in the white space on the lower part of the window (Status). If the connection is successful, the OMNI II Programmer Client window will disappear (the remote session started). If an error occurs (incorrect password or connectivity issues for instance) the OMNI II Programmer Client window will remain open, and the appropriate error message will appear in the Status space, requiring the user to retry the connection.

A remote linkup can then be requested from an OMNI Smart Programmer in Remote mode:

- A Clinical Engineer at the Remote Follow-up Center (or any other location, as long as the Clinical Engineer has reliable internet access and telephone connection) who has a Remote OMNI Smart Programmer connected to the Internet can initiate pairing with the Clinical OMNI Smart Programmer at the requesting clinic.
- If internet connectivity is interrupted during the remote session, the Local (Slave) OMNI Smart Programmer will display a warning screen, and CCM™ delivery by the OPTIMIZER Smart IPG being followed-up will be turned ‘OFF’. The Local (Slave) OMNI Smart Programmer will automatically revert to Master mode after 5 consecutive failed retry attempts on any communication order.
- The local (Slave) OMNI Smart Programmer will also revert to Master mode after pressing the ‘Urgent’ Programming button on the OMNI II Programmer Wand.

21.4.2 Show OMNI II Programmer Client Window

In order to show the OMNI II Programmer Client window after the Programmer has logged on to the Remote Server:

- Select the **Remote** button on the **Task Bar**.
- Select the **Client** button on the **Tool Bar**.

21.5 Starting a Remote Session with the OMNI Smart Programmer

To start a remote session with the OMNI Smart Programmer, the clinician at the clinic has to first call the Remote Follow-up Center via the telephone to request a remote follow-up session. Then the clinician has to connect their OMNI Smart Programmer to the Internet via an Ethernet or wireless network connection.

To start a remote session:

- Start the Clinical Programmer in **Clinical Mode**
 - Select the **Remote** button on the **Task Bar**.
 - Select the **Connect** button on the **Tool Bar**.
 - When the Omni II Client window appears, enter the User name, password, and Client name in the appropriate spaces and then select **Connect**.

After a connection has been established with the Client server, “**Network event (Master mode)**” is displayed in the Log Bar.

- Start the Remote Programmer in **Remote Mode**
 - Select the **Remote** button on the **Task Bar**.
 - Select the **Connect** button on the **Tool Bar**.
 - When the Omni II Client window appears, enter the User name, password, and Client name in the appropriate spaces and then select **Connect**.
 - When the Select Local Programmer window pops up, select the desired OMNI Smart Programmer, and then select **OK**.

After a connection has been established with the Client server, “**Network event (Connected to Clinical programmer)**” is displayed in the Log Bar of the Remote Programmer.

Meanwhile, the message “**Network event (Remote pair connected)**” is displayed in the Log Bar of the Clinical Programmer.

The switch from Master to Slave mode is controlled by the Clinical Programmer.

In order to place the Clinical Programmer into Slave mode and the remote Programmer into Master mode, perform the following steps:

- Select the **Slave** button on the **Tool Bar** on the Clinical Programmer.

The following message will be displayed when the master mode of the Clinical OMNI Smart Programmer is about to be set in slave mode:

“Remote programming of the OPTIMIZER Mini IPG requires a clinician to be present and in constant observation of the patient. The programming wand MUST be held by the clinician over the implant site at all times during a remote programming session. Furthermore, the clinician and remote operator MUST be in constant telephonic communication throughout the complete remote programming session.”

- Select **OK** to continue.

If the switch from Master to Slave mode is successful, the following messages will be displayed in the Log Bars of the respective programmers:

- Clinical Programmer – “**Network event (Slave mode)**”
- Remote Programmer – “**Network event (Master mode)**”

21.6 Ending an OMNI Smart Programmer Remote Session

An OMNI Smart Programmer remote session can be terminated from either the Clinical or Remote Programmer.

In order to terminate an OMNI Smart Programmer remote session:

- Select the **Connect** button on the **Tool Bar** again after a session has been initiated.

21.7 Sending a Chat Message Using the OMNI Smart Programmer

In order to send a chat message, open the Chat message window by selecting the **Send Msg** button on the **Tool Bar**. When the Chat message window appears, write the message in the white space and

press Enter or click the **Send** button. Any previously sent and received messages will appear in the Chat message window above the white space where the message is entered.

If you receive a chat message while the Chat message window is closed, the window will pop up automatically.

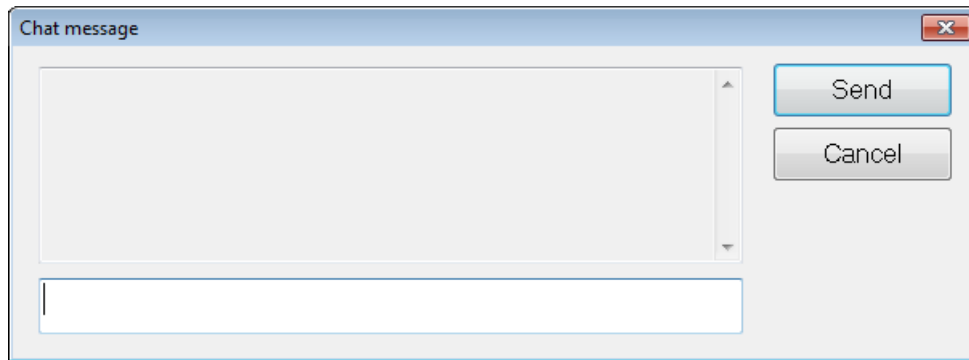


Figure 49: Chat message Window

21.8 OMNI II Log Upload/Download

The OMNI Smart Programmer allows uploading and downloading of log files to and from the OMNI Remote Server.

21.8.1 OMNI II Upload/Download Log Window

The Upload/Download Log window allows you to send log files to the server, receive log files from the server, refresh the server log files, and change network settings. To open the Omni II Programmer Upload/Download Log window:

- select the **Log Files** button on the **Task Bar**
- select the **Up/Down** button on the **Tool Bar**

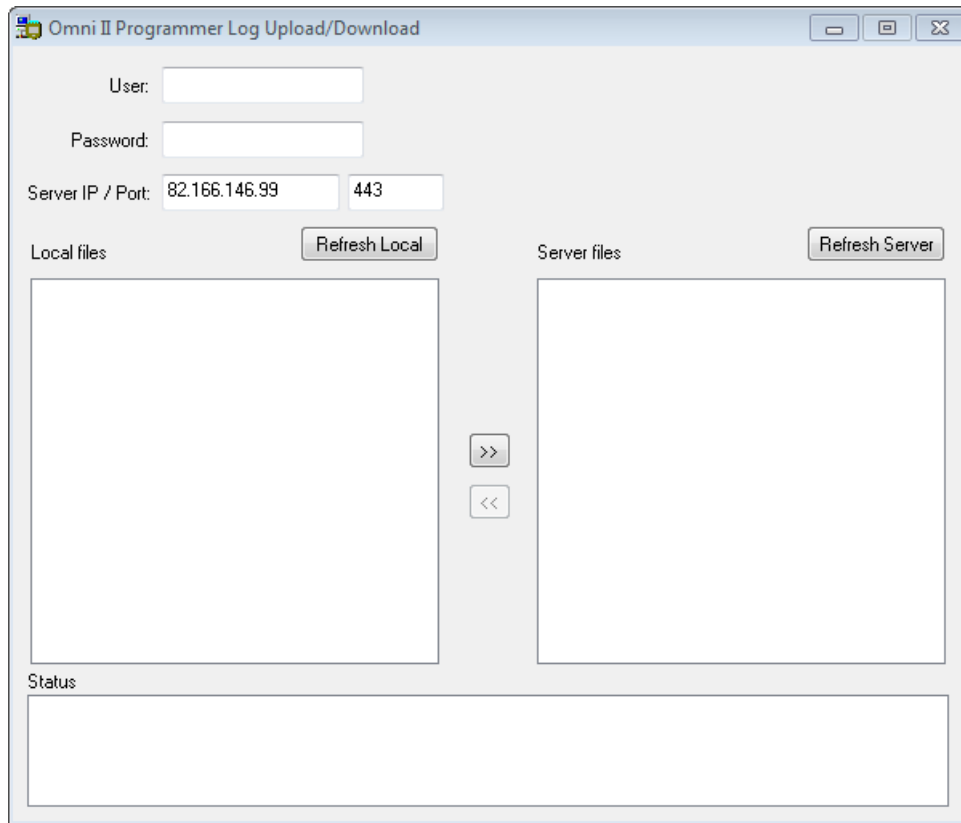


Figure 50: Omni II Programmer Log Upload/Download Window

21.8.2 OMNI II Refresh Local

In order to display the local log files stored on the OMNI Smart Programmer, click the **Refresh Local** button.

21.8.3 OMNI II Refresh Server

In order to display the log files stored on the server, the OMNI Smart Programmer must first be connected to Internet. See Sections 30.1 and 30.2 on ways to connect the OMNI Smart Programmer to the Internet. The user must enter the following information:

- **User:** a user name compatible with the current Programmer's startup mode. If the user name is not registered with the server, the connection will be rejected.
- **Password:** a password corresponding to the user name that is stored in the server.
- **Server IP / Port:** IP address of the server. (This is set by Impulse Dynamics before the OMNI Smart Programmer is shipped and does not need to be changed.)

Once all the information above has been entered, the user must press <Enter> or click the **Refresh Server** button. If the connection is successful, the Server files list will be updated. If an error occurs the error message will appear in the Status space, requiring the user to retry the connection.

21.8.4 OMNI II Log Files Upload

In order to send log files to the server you must be connected to Internet and provide same information as above.

This operation shall be performed only when the OMNI Smart Programmer is operating in Clinical Mode.

21.8.5 OMNI II Log Files Download

In order to receive log files from the server you must be connected to Internet and provide same information as above

This operation shall be performed only when the OMNI Smart Programmer is operating in Remote Mode.

22. BLUETOOTH PRINTER

22.1 Description

The Zebra Bluetooth printer (optional accessory) consists of the following components:

- Zebra Printer (with installed rechargeable battery)
- Printer paper roll
- AC Adapter

22.2 Printer Charging

The Zebra printer may need to be charged before use.

To charge the battery in the Zebra printer:

Note: The Printer should only be charged (connected to its mains-powered charging power supply) when outside of the patient environment.

- Open the port cover on the right side of the printer and plug in the DC output connector of the AC Adapter into the power input connector of the printer.
- Plug in the printer's AC Adapter to the mains to begin charging the internal battery of the printer.
- When the printer's battery is charging, the light on top of the printer (to the left of the power button) will glow amber. When the printer's battery is fully charged, the light will turn green.
- When charging of the printer battery has been completed, unplug the DC output connector of the AC Adapter from the power input connector of the printer.

22.3 Set Bluetooth

The pairing of the Zebra Bluetooth printer provided with the OMNI Smart Programmer has already been done prior to shipment. However if a replacement Zebra Bluetooth printer must be paired with the OMNI Smart Programmer, perform the following steps:

- Press the Power button on top of the Zebra printer to power up the printer.
- On the Selector screen, click the **Configuration** button. The Configuration Dialog window will appear.
- Then click the **Set Bluetooth** button. The Bluetooth Settings window will appear.

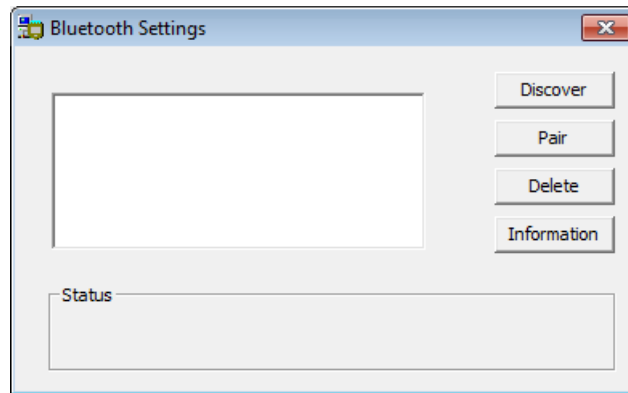


Figure 51: Bluetooth Settings Window

- Click on the **Discover** button to search for Bluetooth devices.
- If “Zebra Printer (Authenticated)” appears, select it and then click the **Delete** button.
- Click on the **Discover** button again to search for Bluetooth devices.
- Select “Zebra Printer” from the list of Bluetooth devices discovered and then click the **Pair** button.
- When the Bluetooth Authentication Code window pops up, enter the pair code “0000”, and then click **OK**.
- When the Set Bluetooth pop-up window appears stating that “The pairing operation was done correctly”, click **OK**.
- Click on the X to close the Bluetooth Settings window.

22.4 Set Default Printer

To set the default printer for the OMNI Smart Programmer:

- At the Selector screen, click the **Configuration** button. The Configuration Dialog window will appear.
- Click the **Set Default Printer** button. The Set Printer window will appear.

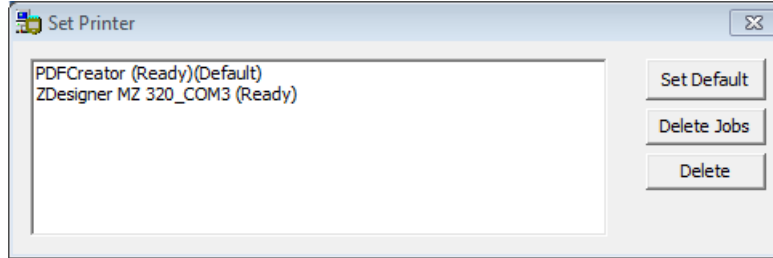


Figure 52: Set Printer Window

- Select the ZDesigner printer and then click on the **Set Default** button.
- Click on the X to close the Set Printer window.
- Click on the X to close Configuration Dialog window.

23. LOG FILE MANAGER

The Log File Manager allows the user to copy and delete log files stored on the OMNI Smart Programmer.

To copy and delete the stored log files:

- At the Selector screen, click the **Log File Manager** button. The Insert Password window will appear.

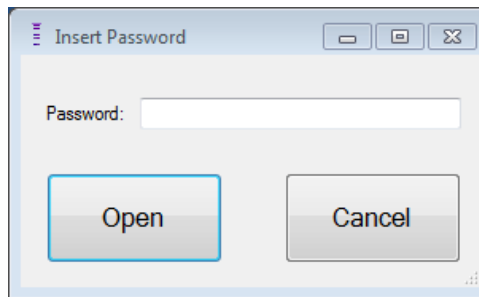


Figure 53: Log File Manager Window

- Enter the password *MountLaurel*.
- Click the **Open** button. The Log File Manager 2.0 window will appear.

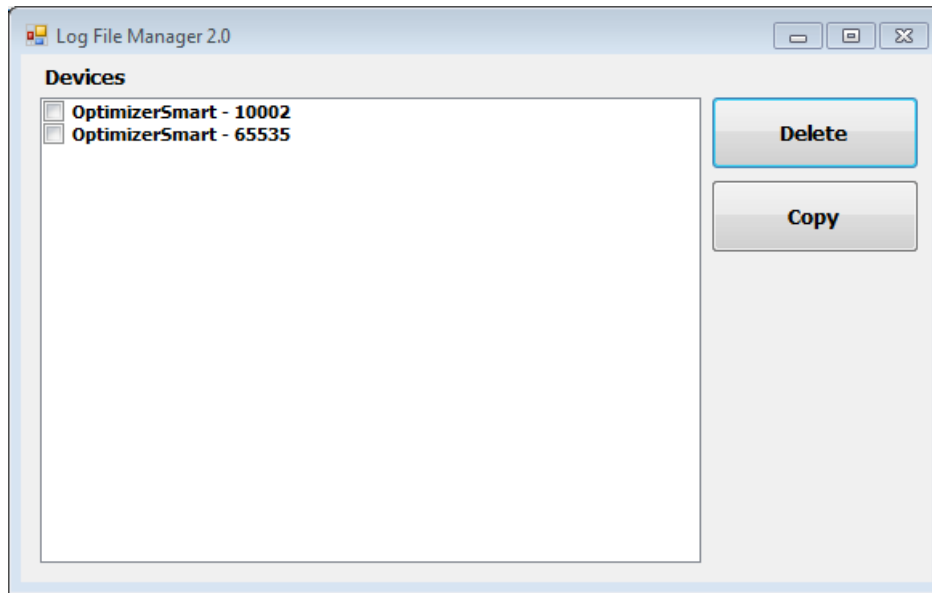


Figure 54: Log File Manager 2.0 Window

- To Delete files:
 - Select the check box to the left of the file name of each file to be deleted.
 - Click the **Delete** button.
 - When the Warning window appears, click **Yes** to confirm the file deletion.
 - Click on the X to close the Log File Manager 2.0 window.
- To Copy files:
 - Select the check box to the left of the file name of each file to be copied.
 - Insert a USB Flash drive into the USB port of the OMNI Smart Programmer
 - Click the **Copy** button.
 - Wait for the pop-up Information window to appear stating **Copy completed** and then click **OK**.
 - Click on the X to close the Log File Manager 2.0 window.

24. OPTIMIZER MINI CHARGER

24.1 Description

The OPTIMIZER Mini Charger is a charger powered by a rechargeable battery. The system includes a permanently attached charging wand. The OPTIMIZER Mini Charger is supplied with an AC Adapter (Cell Con Battery Charger; Input: 100–240VAC, 50-60Hz, 0.3A; Output: 8.4V, 1.3A) to recharge the internal battery. The charger is a Class I, Type BF device, classified as ordinary equipment suitable for continuous operation, with short-time loading, within the patient environment. The charger is designed to permit recharging with only minimal patient interaction.

Warning: Failure to recharge the OPTIMIZER Smart IPG as required may cause it to shut down when the battery is depleted, suspending cardiac contractility modulation therapy.



Figure 55: OPTIMIZER Mini Charger with AC Adapter

24.1.1 Charger System Components

The OPTIMIZER Mini Charger System consists of following components:

- OPTIMIZER Mini Charger (with attached charging wand) – used to charge the OPTIMIZER Smart IPG.
- AC Adapter – used to charge the internal battery of the OPTIMIZER Mini Charger and isolate it from the mains.
- Carrying Case – used to transport the OPTIMIZER Mini Charger
- Patient belt – (optional accessory) used to hold the charger in its pocket while the OPTIMIZER Smart IPG is being charged. (Manufacturer: Spider Black Widow Holster)

24.2 Charger Features

The following explains the features of the OPTIMIZER Mini Charger.

- **IPG-Charger Coupling Signal Strength Indicator:** Bar graph display depicting connection between the charger and the OPTIMIZER Smart IPG
- **“Call Doctor” Indicator:** 7-segment LED display for numerical codes
- **Charger Battery Status Indicator:** Bar graph display depicting the state-of-charge of the OPTIMIZER Mini Charger battery
- **Start Button:** Start button for the OPTIMIZER Mini Charger
- **IPG Battery Status Indicator:** Bar graph display depicting the current state-of-charge of the OPTIMIZER Smart IPG battery

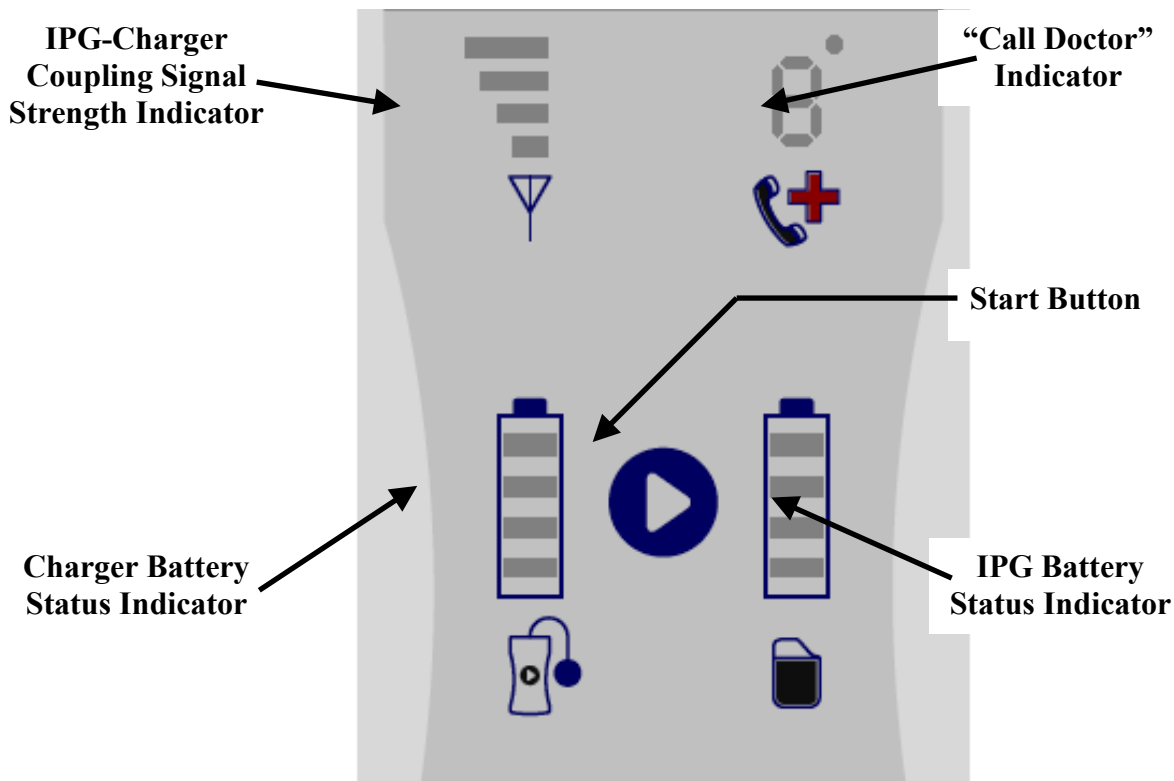


Figure 56: OPTIMIZER Mini Charger Features

24.3 Charging Method: Transcutaneous Energy Transfer

Inductive energy transfer is the only practicable transcutaneous recharging method. Inductive energy transfer is based on an oscillating electromagnetic field generated by a primary coil. Magnetic fields can penetrate human tissues with nearly no attenuation. Therefore, the field energy can be picked up by a secondary coil which is connected to the electronic circuitry of the implant and be converted back into electrical energy.

The charging current of the OPTIMIZER Mini Charger is fixed at 90mA.

The OPTIMIZER Mini Charger operates at a frequency range of 410 kHz – 490 kHz.

Note: The OPTIMIZER Mini Charger is subject to interference from other electrical devices operated in the vicinity. Portable and mobile radio frequency equipment is especially prone to impair the normal function of the charger. If OPTIMIZER Mini Charger is not operating as expected, such interference has to always be taken into account.

24.4 Charger Operation

The battery of the OPTIMIZER Smart IPG is charged with the OPTIMIZER Mini Charger, which was designed to control the charging process precisely so that correct operation of the IPG and patient safety are ensured. The following describes the operation of the OPTIMIZER Mini Charger:

Warning: The OPTIMIZER Mini Charger shall not be used on board aircraft. The OPTIMIZER Mini Charger shall not be used on board a ship without prior consent from the ship's crew.

Note: Consult local regulations if using the Mini Charger outside of the country where it was purchased.

Warning: Do not attempt to connect any equipment to the I/O port of the OPTIMIZER Mini Charger. This port is solely for factory or service personnel use.

- Plug the DC output connector of the AC Adapter into the power input connector located on the top left of the charger and then plug in the AC Adapter to the mains to begin charging the internal battery of the charger.

Note: Inspect the AC Adapter for any damage before each use. Contact your Impulse Dynamics representative if a replacement AC Adapter is needed.

Warning: Only use the AC Adapter provided with the OPTIMIZER Mini Charger to charge the battery in the OPTIMIZER Mini Charger.

Caution: Do not touch the DC contacts of the AC Adapter. However it poses no significant risk if inadvertent contact is made.

- When all 4 bars of the **Charger Battery Status Indicator** are continuously illuminated, the battery in the OPTIMIZER Mini Charger is fully charged.
- Disconnect the AC Adapter from the OPTIMIZER Mini Charger. The OPTIMIZER Mini Charger can now be used to charge OPTIMIZER Smart IPG.

Note: The OPTIMIZER Mini Charger cannot be used to charge the OPTIMIZER Smart IPG until the AC Adapter is disconnected from the charger.

- Place the charging wand over the OPTIMIZER Smart implant site. The charging wand cable may be draped around the patient's neck with the charging wand lying on the chest over the patient's clothes.

Note: The charger should not be operated close to other electronic equipment. If sufficient spatial separation cannot be maintained, the charger needs to be monitored to ensure normal function.

- Start the charging process by pressing the **Start Button** and holding it down for about 3-4 seconds.

- Slowly move the charging wand over the implant site and observe **IPG-Charger Coupling Signal Strength Indicator** for an indication that the OPTIMIZER Smart IPG and the charging wand are communicating. Reposition the charging wand until the most number of bars are illuminated on **IPG-Charger Coupling Signal Strength Indicator**.
- Once the charging wand has established a link with the OPTIMIZER Smart IPG, the OPTIMIZER Mini Charger will begin the charging process.

Note: Improper positioning or displacement of the charging wand is indicated by the corresponding a low signal strength on **IPG-Charger Coupling Signal Strength Indicator** on the charger and by an audible signal sounding approximately once per second.

Note: The charger will automatically discontinue the charging process if the charging wand is not repositioned onto the OPTIMIZER Smart implant site. When this occurs, a new charging process has to be initiated by pressing the **Start Button** again.

- The **IPG Battery Status Indicator** depicts the charging status of the OPTIMIZER Smart IPG.

Note: Try to fully charge the device during the charging session. If the device cannot be completely charged in one session, repeat the charging process, if needed in daily stages, until the device is fully charged.

Note: Charging the OPTIMIZER Smart IPG can take longer than one hour if the battery is severely discharged. The patient should be in a comfortable position while recharging the OPTIMIZER Smart IPG, ensuring that the wand will be properly located over the implanted IPG. This may be accomplished by draping the wand cable around the patient's neck so that the wand rests over the implant site. It is recommended that the patient remain stationary during the charging process.

- When the battery of the OPTIMIZER Smart IPG is completely charged, a long audible signal will sound and all 4 bars of the **IPG Battery Status Indicator** will be illuminated. The charging process will then be automatically terminated and the charger will shut off.
- To discontinue or suspend the charging process of the OPTIMIZER Smart IPG, the patient can remove the charging wand of the OPTIMIZER Mini Charger from the implant site, causing the interruption of the charging process. Alternatively, the charger can be turned off by pressing the Start Button once again.

24.5 Frequency of Charging Sessions

Optimal performance of the rechargeable battery in the OPTIMIZER Smart IPG is only ensured if the battery is fully recharged on a weekly basis. The day or time chosen to charge the OPTIMIZER Smart IPG is not important, however it is recommended that the patient not let more than one week pass between the charge sessions.

If the charge level of the OPTIMIZER Smart IPG battery drops below a certain threshold, therapy delivery is automatically suspended. If this occurs, the OPTIMIZER Smart IPG battery will need to be recharged before it resumes delivering therapy. Once the charging session has been completed, the OPTIMIZER Smart IPG will automatically resume therapy delivery with its previously programmed parameters.

24.6 Numerical Codes

The OPTIMIZER Mini Charger was designed to provide the patient with certain data and warnings appropriate to the situation. If the charger detects a situation that requires action, a code digit will appear on the “**Call Doctor**” **Indicator**. The following table gives a description of each numerical code:

Numerical Code	Description	Will Charging Process Be Discontinued?
0	IPG deactivated (see Section 33.6.1)	YES (see Note1,2)
1	Markedly changed lead impedance (see Section 33.6.2)	NO
2	Therapy suspended (see Section 33.6.3)	NO
3	No cardiac contractility modulation therapy delivery programmed (see Section 33.6.4)	NO
4	cardiac contractility modulation therapy rate low (see Section 33.6.5)	NO
5	High initial IPG temperature (see Section 33.6.6)	YES (see Note1,2)
6	Internal charger fault (see Section 33.6.7)	YES (see Note1)
7	Implant is not an OPTIMIZER Smart IPG (see Section 33.6.8)	YES (see Note1)
8	Problem related to profoundly discharged battery (see Section 33.6.9)	YES (see Note1)

24.6.1 Numerical Code 0

When Numerical Code 0 is displayed, it means that the OPTIMIZER Smart IPG has been deactivated and placed in Down mode. If this Numerical Code is displayed by the charger, please contact your Impulse Dynamics representative.

24.6.2 Numerical Code 1

When Numerical Code 1 is displayed, it means that the OPTIMIZER Smart IPG has detected a significant change in the impedance in one or both ventricular leads. If this Numerical Code is displayed by the charger, please contact your Impulse Dynamics representative.

24.6.3 Numerical Code 2

When Numerical Code 2 is displayed, it means that cardiac contractility modulation therapy in the OPTIMIZER Smart IPG has been suspended. If this Numerical Code is displayed by the charger, please contact your Impulse Dynamics representative.

24.6.4 Numerical Code 3

When Numerical Code 3 is displayed, it means that cardiac contractility modulation therapy has not been programmed. If this Numerical Code is displayed by the charger, please contact your Impulse Dynamics representative.

24.6.5 Numerical Code 4

When Numerical Code 4 is displayed, it means that the OPTIMIZER Smart IPG has detected that the amount of cardiac contractility modulation therapy delivered is below the alarm level

parameter programmed in the implanted device. If this Numerical Code is displayed by the charger, please contact your Impulse Dynamics representative.

24.6.6 Numerical Code 5

When Numerical Code 5 is displayed, it means that the temperature of the OPTIMIZER Smart IPG at the beginning of a charging session is greater than 102.2°F. This Numerical Code may also be displayed if the temperature of the OPTIMIZER Smart IPG during charging increases by more than 3° for over 10 minutes. If this Numerical Code is displayed repeatedly by the charger over the course of several days, please contact your Impulse Dynamics representative.

24.6.7 Numerical Code 6

When Numerical Code 6 is displayed, it means that the OPTIMIZER Mini Charger has detected a fault within the charger itself. If this Numerical Code is displayed by the charger, please contact your Impulse Dynamics representative.

24.6.8 Numerical Code 7

When Numerical Code 7 is displayed, it means that the OPTIMIZER Mini Charger has determined that it is attempting to be used on an unrecognized device. If this Numerical Code is displayed by the charger, please verify the charging wand is placed over the implanted OPTIMIZER Smart IPG. If this code is still displayed after the charging wand is placed over the implanted OPTIMIZER Smart IPG, please contact your Impulse Dynamics representative.

24.6.9 Numerical Code 8

When Numerical Code 8 is displayed, it means that the OPTIMIZER Mini Charger has detected that even after attempting to charge a deeply discharged battery in the OPTIMIZER Smart IPG, the level of the battery's charge remains low. If this Numerical Code is displayed by the charger, please contact your Impulse Dynamics representative.

Note 1: Whenever Numerical Code 0 or 5-8 is displayed, the charger automatically terminates the charging process.

Note 2: When Numerical Code 0 or 5 occurs, the charger can be set to a special state to conduct a charging session. However, this option is only accessible to Impulse Dynamics service technicians.

24.7 Cleaning

The OPTIMIZER Mini Charger should only be cleaned with disinfectant wipes as needed.

Warning: DO NOT submerge any part of the OPTIMIZER Mini Charger in water. Damage to the unit may result. The OPTIMIZER Mini Charger has limited protection against ingress of water or humidity (ingress protection rating IP22).

Warning: DO NOT sterilize any part of the OPTIMIZER Mini Charger because any such attempt could severely damage the equipment.

24.8 Maintenance

The OPTIMIZER Mini Charger does not contain any user serviceable parts. If the OPTIMIZER Mini Charger is not operational, please contact your Impulse Dynamics representative to obtain a replacement charger.

Warning: No modification of this equipment is allowed.

The battery inside the OPTIMIZER Mini Charger is expected to have a service life of 5 years. If the OPTIMIZER Mini Charger is unable to fully charge an OPTIMIZER Smart IPG or OPTIMIZER IVs IPG after the charger battery has been fully charged, please contact your Impulse Dynamics representative to obtain a replacement charger.

24.9 Storage and Handling

The OPTIMIZER Mini Charger is designed to function normally after it has been exposed (while being packaged for transport) to the following environmental extremes: (1) -4°F to +140°F, (2) relative humidity 10% to 100% (with or without condensation), (3) atmospheric pressure 500 hPa to 1060 hPa.

The OPTIMIZER Mini Charger should not be exposed to excessively hot or cold conditions. Patients should be instructed not to leave the devices in their car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat. For proper operation, the Charger should not be used if the ambient temperature is above 80°F. In addition, the recommended conditions for use are relative humidity between 20% and 75%, and atmospheric pressure between 700 hPa and 1060 hPa.

24.10 Disposal

If the OPTIMIZER Mini Charger is no longer needed by the patient and is returned, please notify your Impulse Dynamics representative of its return.

Warning: DO NOT discard the OPTIMIZER Mini Charger in the trash. The OPTIMIZER Mini Charger contains Lithium batteries as well as non-RoHS components. If disposal of the OPTIMIZER Mini Charger is necessary, properly dispose of the OPTIMIZER Mini Charger in accordance with local regulations governing the disposal of such material.

25. SERVICE AND WARRANTY

For emergency assistance, Impulse Dynamics has professional technical staff on call around the clock. If you require assistance, please contact your local Impulse Dynamics representative.

25.1 Limited Warranty Information

Impulse Dynamics warrants that all IPGs (including the respective firmware and software) will be free from defects in workmanship and materials for a period of 24 months after the original implantation of the IPG, unless a longer period is required pursuant to applicable law (the “Warranty Period”).

If it appears that any IPG or part thereof appears to be defective in workmanship or materials, or fails to conform to applicable specifications, Impulse Dynamics shall either replace defective or non-conforming implantable components or repair or replace defective or non-conforming non-implantable components. The warranty period for a replaced or repaired IPG shall be the time remaining on the original warranty period or nine months from delivery of the repaired or replaced IPG, whichever is longer.

In the event of complete failure of an IPG within 72 hours after implantation, Impulse Dynamics shall replace the failed IPG with a new one.

Under this warranty, Impulse Dynamics shall not be liable if tests and analyses reveal that the alleged defect or non-conformity of the IPG is not present or was caused by improper use, neglect, improper implantation, or follow-up, unauthorized repair attempts by the user, or due to accident, fire, lightning, or other hazards.

25.2 Mandatory Battery Charging

The rechargeable battery in the OPTIMIZER Smart IPG is designed to provide optimal performance if it is completely recharged on a weekly basis. While letting more than one week lapse between full charging cycles is acceptable if it occurs infrequently, regular weekly recharging sessions are required to prevent battery deterioration, which would ultimately decrease device longevity.

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APPENDIX I


Electromagnetic interference information (Table 1 of 4):

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The OPTIMIZER Smart System (the OMNI Smart Programmer and the OPTIMIZER Mini Charger) is intended for use in an electromagnetic environment as specified below. The customer or user of the OPTIMIZER Smart System has to ensure that it is used in such an environment. (Note: Not applicable for the OMNI Smart Programmer.)			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge as defined in 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, relative humidity should be 30% or greater.
Electrical fast transient / burst as defined in IEC 61000-4-4	±2 kV for mains power supply ±1 kV for in-/output lines	±0.5 kV for mains power line ±1 kV for in-/output lines	Mains power should be that of a typical hospital environment. Do not operate motors or other noisy electrical equipment on the same mains circuit as the OMNI Smart Programmer or OPTIMIZER Mini Charger.
Voltage surges as defined in IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines as defined in IEC 61000-4-11	<5% U_T (>95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	100% dip in U_T for ½ cycle 60% dip in U_T for 5 cycles 30% dip in U_T for 30 cycles 100% dip in U_T for 5 s	Mains power quality should be that of a typical business or hospital environment. Note: If the user of the OMNI Smart Programmer or OPTIMIZER Mini Charger requires uninterrupted operation during power mains interruptions, it is recommended to power the OMNI Smart Programmer or OPTIMIZER Mini Charger from an uninterruptible power supply or battery.
Power line frequency magnetic fields (50/60 Hz) as defined in IEC 61000-4-8	3 A/m	30 A/m	Power line frequency magnetic fields (50/60 Hz) should be at levels expected in a typical business or hospital environment.

Electromagnetic interference information (Table 2 of 4):

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE OMNI Smart PROGRAMMER			
The OMNI Smart Programmer is intended for use in an electromagnetic environment as specified below. The customer or user of the OMNI Smart Programmer has to ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) as defined in IEC 61000-4-2	Indirect application: ± 2 kV, ± 4 kV, and ± 6 kV; contact discharge: ± 2 kV, ± 4 kV, and ± 6 kV; air discharge: ± 2 kV, ± 4 kV, and ± 8 kV	Indirect application: ± 2 kV, ± 4 kV, and ± 6 kV; contact discharge: ± 2 kV, ± 4 kV, and ± 6 kV; air discharge: ± 2 kV, ± 4 kV, and ± 8 kV Note: Allowable degradation or loss of function or performance requiring a system reset or operator intervention when the interfering signal is removed, but no inappropriate reprogramming of the IPG.	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be 30% or higher. The operator may have to reset the system if the communication between the OMNI II Interface Box and the Tablet PC is interrupted.
Electrical fast transients / bursts as defined in IEC 61000-4-4	±1 kV for in- and output lines (Ethernet)	±1 kV for in- and output lines Note: Allowable degradation or loss of function or performance requiring a system reset or operator intervention when the interfering signal is removed, but no inappropriate reprogramming of the IPG.	Ethernet network routing should be that of a typical hospital environment. Do not operate motors or other electrically noisy equipment in the proximity of the Ethernet line.
Power line frequency magnetic fields (50/60 Hz) as defined in IEC 61000-4-8	3 A/m	30 A/m	Power line frequency magnetic fields (50/60 Hz) should be at levels expected in a typical business or hospital environment.

Electromagnetic interference information (Table 3 of 4):

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (133)			
The OMNI Smart Programmer and the OPTIMIZER Mini Charger are intended for use in an electromagnetic environment as specified below. The customer or user of the OPTIMIZER Smart system has to ensure that the equipment is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF as defined in IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should not be used any closer to any part or cable of the OMNI Smart Programmer or OPTIMIZER Mini Charger than the recommended separation distance calculated from the equation for the respective transmitter frequency.</p> <p>Recommended separation distance</p> $d = 1.17 \sqrt{P}$
Radiated RF as defined in IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 0.35 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}^1$ $d = 0.70 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ MHz}$ <p>“P” refers to the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer. “d” is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply to all settings. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and people.</p>			
<p>^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 theoretically predicted with accuracy. An electromagnetic site survey should be taken into consideration to assess the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location where the OMNI Smart Programmer is used exceeds the applicable RF compliance level above, the OMNI Smart Programmer should be monitored to ensure normal operation. If abnormal function is observed, additional measures may be necessary, such as relocating the OMNI Smart Programmer.</p>			
<p>^b For frequencies in the range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.</p>			

Electromagnetic interference information (Table 4 of 4):

Recommended separation distances between portable and mobile RF communications equipment and the OMNI Smart Programmer or OPTIMIZER Mini Charger			
Both the OMNI Smart Programmer and the OPTIMIZER Mini Charger should be used in an electromagnetic environment with limited radiated RF noise. The customer or user of the OMNI Smart Programmer or OPTIMIZER Mini Charger can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the OMNI Smart Programmer or OPTIMIZER Mini Charger recommended below, which is determined by the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance broken down by transmitter frequency (m)		
	150 kHz to 80 MHz ¹ $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz ¹ $d = 0.35 \sqrt{P}$	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
For transmitters with a maximum rated 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 rated output power of the transmitter in watts (W) specified by the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
Note 2: These guidelines may not apply to all settings. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and people.			

APPENDIX II

Communications/Telemetry

Between the OPTIMIZER Smart IPG and the OMNI Smart Programmer:

- **OPTIMIZER Smart IPG to OMNI Smart Programmer:**
 - PPM: “0” = 180 μ s, “1” = 270 μ s
 - 14.5 kHz LC excited by pulse
 - 1 cycle per pulse until dampened to 10%
 - Energy invested per pulse 0.36 μ J \rightarrow 5.14 mW_{peak} per pulse; 1.8 mW_{average}
- **OMNI Smart Programmer to OPTIMIZER Smart IPG:**
 - AM: “0” = no carrier, “1” = carrier for 305 μ s
 - 23 kHz carrier frequency
 - Power: 0.56 W_{peak}; 0.27 W_{average}

APPENDIX III

Testing procedure for device/device interaction:

Patients with a concomitant device (e.g. ICD, pacemaker) require additional testing at the end of the implant procedure to ensure appropriate function of both the OPTIMIZER Smart IPG and the concomitant device. The steps of the required testing procedure are as follows:

1. Program the ICD so that it does not deliver antitachycardic therapy during this test.
2. Program the sensing windows of the OPTIMIZER Smart IPG and verify that it can be programmed to consistently delivery cardiac contractility modulation therapy in the presence of the concomitant device.
3. Activate cardiac contractility modulation therapy and analyze the real-time intracardiac electrograms and marker channels to ensure that the cardiac contractility modulation therapy does not cause inappropriate oversensing during normal sinus rhythm which cannot be resolved by reprogramming or lead repositioning.
4. Activate cardiac contractility modulation therapy and analyze the real-time intracardiac electrograms and marker channels to ensure that the cardiac contractility modulation therapy does not cause inappropriate undersensing during normal sinus rhythm which cannot be resolved by reprogramming or lead repositioning.
5. Activate cardiac contractility modulation therapy in patients requiring antibradycardic pacing and analyze the intracardiac electrograms and marker channels to ensure that the cardiac contractility modulation therapy does not cause inappropriate inhibition of antibradycardic pacing which cannot be resolved by reprogramming or lead repositioning.

APPENDIX IV

Factory Settings

PARAMETERS RELATED TO CONTROLLING RIGHT HEART SENSING

Mode	OOO
Atrial Sense Amplifier Sensitivity	1.3 mV
Ventricular Sense Amplifier Sensitivity	2.0 mV
Ventricular Sensing Polarity	Bipolar
Atrial Sensing Polarity	Bipolar
Ventricular Refractory Period	250 ms
Post-Ventricular Atrial Refractory Period	250 ms

CCM PULSE TRAIN ACTIVATION

CCM Pulse train enable	OFF
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CCM PULSE TRAIN TIMING

Number of pulses	2
Train delay	35 ms
Phase 1 duration	5.14 ms
Phase 2 duration	5.14 ms
Phase 1 polarity	Positive
Phase 2 polarity	Negative
CCM Pulse Amplitude	7.5 V
CCM signal delivery channel	LS, V
Interval	0 ms

CCM INHIBIT ALGORITHM

CCM Inhibit Count	2 beats
Short AV Delay	70 ms
Long AV Delay	398 ms
Atrial tachycardia rate	154 bpm

LS CHANNEL PROGRAMMABLE PARAMETERS

LS Sensitivity	2.0 mV
LS Alert Window Start	-10 ms
LS Alert Window Width	30 ms
LS Pre-Atrial LS Refractory Period	5 ms
LS Post-Atrial LS Refractory Period	5 ms
LS Pre-Ventricular LS Refractory Period	0 ms
LS Post-Ventricular LS Refractory Period	0 ms
LS Post-LS Refractory Period	20 ms

CCM SCHEDULE PARAMETERS

Start time	00:00
End time	23:59
On Time	01:00
Off Time	02:25

CHARGER ALARM PARAMETERS

Minimum Target % for CCM Delivery	30%
Maximum Lead Displacement	20%