IMPULSE
DYNAMICS

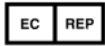# OMNI II Programmer (with OMNI Smart Software) System and OPTIMIZER Mini Charger

INSTRUCTIONS FOR USE

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EC | REP

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OPTIMIZER® is a US registered trademark property of Impulse Dynamics.
OMNI™ is a trademark property of Impulse Dynamics.
CCM™ is a trademark of Impulse Dynamics.

The OMNI II Programmer (with OMNI Smart Software) and OPTIMIZER Mini Charger conform to the essential requirements of the Radio Equipment Directive (RED) 2014/53/EU.

The information provided in this document may change without prior notice.

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.

Please read the complete documentation provided before you use the device.

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[2017]

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EXPLANATION OF SYMBOLS ON LABELS

SYMBOL	DESCRIPTION
	Manufacturer
YYYY-MM	Date of Manufacture
CE 0344	Conformité Européenne 0344 = Notified Body Number for AIMDD
	Consult instructions for use.
	Caution, consult accompanying documents
EC REP	European Representative
CC°C FF°F cc°C ff°F	Transport Temperature Limits
REF XXXX	Part Number
SN XXXX	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)
IOIOI	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) System allows the physician to interrogate and program the OPTIMIZER Smart IPG and OPTIMIZER IVs 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 IPG implanted in the patient. Understanding the instructions contained in this manual on how to operate the OMNI II Programmer (with OMNI Smart Software) System is essential to proper operation of both the OPTIMIZER Smart IPG and OPTIMIZER IVs IPG.

Figure 1: OMNI II Programmer (with OMNI Smart Software) and Programmer Wand

Warning: The OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software).

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1.2   Programmer Functions

The programmer can perform the following:

- Read (interrogate) OPTIMIZER Smart IPG and OPTIMIZER IVs IPG parameters as currently programmed

- Modify OPTIMIZER Smart IPG and OPTIMIZER IVs IPG parameters

- Read ECG signals from patient and display for analysis

- Retrieve statistics accumulated by the OPTIMIZER Smart IPG and OPTIMIZER IVs IPG as it operates

- Log the activity of the OPTIMIZER Smart IPG and OPTIMIZER IVs IPG

- Store standard programs for future use

- Program the OPTIMIZER Smart IPG and OPTIMIZER IVs 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

1.3   Programmer Components

The OMNI II Programmer (with OMNI Smart Software) System consists of:

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

- OMNI II Programmer Wand

- OMNI II Programmer Wand Extension Cable

- Single-lead (3-wire) ECG cable

- Medical-grade Power Supply

- CE marked 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 II Programmer (with OMNI Smart Software).

1.4 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 II 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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) at implant. It is recommended that the Tablet PC battery of the OMNI II Programmer (with OMNI Smart Software) be routinely recharged between uses.

1.7 Operating the OMNI II Programmer (with OMNI Smart Software)

Note: The OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) will not be able to interrogate or program the OPTIMIZER Smart IPG and OPTIMIZER IVs IPG until the Tablet PC of the OMNI II Programmer (with OMNI Smart Software) is disconnected from the mains.

The Tablet PC of the OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) or the Programmer Wand because any such attempt could severely damage the equipment.

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

Warning: Always turn the OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) and Programmer Wand are designed to function normally after they have been exposed (while being packaged for transport) to the following environmental extremes: (1) -20°C to +70°C, (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) 0°C to +55°C, (2) relative humidity between 20% and 75%, and (3) atmospheric pressure between 700 hPa and 1060 hPa.

Warning: The OMNI II Programmer (with OMNI Smart Software) shall not be used on board aircraft unless under the crew's approval.

1.13 Additional Notes

The OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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 II PROGRAMMER (WITH OMNI SMART SOFTWARE) SYSTEM SOFTWARE APPLICATIONS

The OMNI II Programmer (with OMNI Smart Software) System contains software applications that are used to read and modify the parameters that control the OPTIMIZER Smart IPG and OPTIMIZER IVs IPG.

2.1 Selection Screen

When the OMNI II Programmer (with OMNI Smart Software) is turned on, a selection screen is presented upon completion of the start-up sequence. Click on the appropriate button for the desired operation.
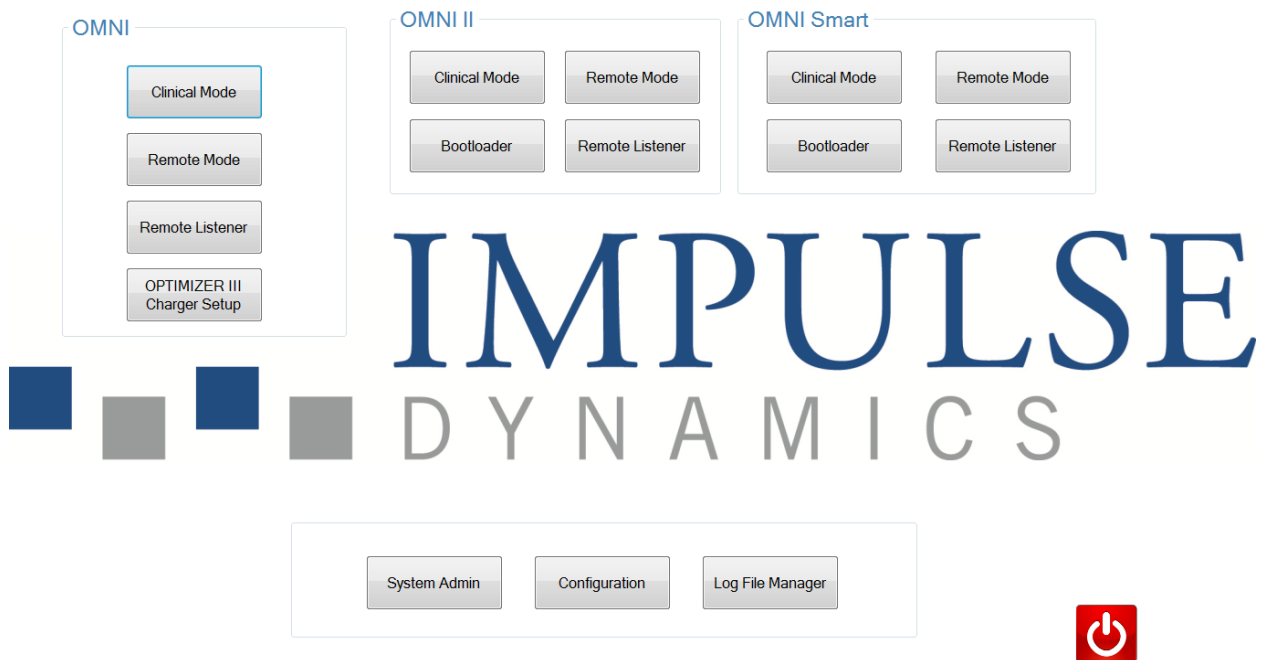
Figure 5: OMNI II Programmer (with OMNI Smart Software) Selection Screen

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 for use with the **OPTIMIZER IVs** IPG.

- **Clinical Mode**: For regular programming of the OPTIMIZER IVs IPG

- **Remote Mode**: For remote control of another OMNI II Programmer using the OMNI II software (see Section 3.20).

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- **Remote Listener**: For remote watching of another OMNI II Programmer using the OMNI II software (see Section 3.20).

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 II Programmer using the OMNI Smart software (see Section 4.21).

- **Remote Listener**: For remote watching of another OMNI II Programmer using the OMNI Smart software (see Section 4.21).

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 II Programmer (with OMNI Smart Software). 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.

  o **Set Bluetooth**: Setup for Bluetooth settings needed for printer connection.

  o **Network Configuration**: Setup for network settings (LAN and WLAN) needed for remote control and remote mode of OMNI II Programmer (with OMNI Smart Software).

  o **Set Default Printer**: Selecting the default printer to be used by the OMNI II Programmer (with OMNI Smart Software).

- **Log File Manager**: This selection allows special settings of OMNI II Programmer (with OMNI Smart Software). 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 II Programmer (with OMNI Smart Software).

2.2 Basic Operation of the OMNI II Programmer Application

After the **Clinical Mode** button has been selected from the OMNI II box on the Selector screen, the OMNI II Programmer application's main screen is displayed.

2.2.1 Communication with the OPTIMIZER IVs IPG

The physician can obtain data from the OPTIMIZER IVs 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 IVs 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 II Programmer application 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 IVs IPG. If the interrogation process is successful, the device values are loaded and displayed on the screen of the OMNI II Programmer application. The values displayed on the screen of the OMNI II Programmer application are referred to as the *programmer (parameter) values*.

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

The physician can review and modify the programmer values using the OMNI II Programmer application. The modified programmer values can then be transmitted to the OPTIMIZER IVs device 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 Programming** command programs the OPTIMIZER IVs IPG with standard safe parameter values (CCM OFF). There is an Urgent Programming icon in the **Programming Bar** and the equivalent icon under **Tools** tab of the **Menu Bar**. There is also an **Emergency Programming** 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 II Programmer application read and write data from and to .tip files. As such, the OMNI II Programmer application can also be used as an editor of standards (see Section 3.6).

2.2.3   Monitoring Tools

The OMNI II Programmer (with OMNI Smart Software) System offers a Programmer Interface has a built-in electrocardiography channel. The patient's ECG is displayed in the lower portion of the OMNI II Programmer application 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 II Programmer application can be used to set the OPTIMIZER IVs device 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 IVs IPG are displayed in the patient's ECG window synchronized with the patient's ECG signal.

- The OMNI II Programmer application keeps a Log of all the interactions that take place with the OPTIMIZER IVs IPG.
- Segments of the (marked) patient's ECG can be recorded, and they can be easily accessed using the Log options.
- The OPTIMIZER IVs IPG keeps a record of all the events and conditions that have occurred. These records can be downloaded from the OPTIMIZER IVs device to the OMNI II Programmer (with OMNI Smart Software), and the number of occurrences of each event can be viewed in a Statistics window of the OMNI II Programmer application.
- The OMNI II Programmer application can be used to measure the impedance of the LS and RV leads.

2.3   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 application is started, which offers various commands for communicating, interrogating, and programming the OPTIMIZER Smart IPG.

2.3.1   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.

2.3.2   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 application 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 application. The values displayed on the screen of the OMNI Smart Programmer application 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 application. 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 application read and write data from and to standard (.tip) files. As such, the OMNI Smart Programmer application can also be used as an editor of standards (see Section 4.5).

2.3.3   Monitoring Tools

The OMNI II Programmer (with OMNI Smart Software) 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 application 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 application 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 application 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 4.1.10).
- 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 II Programmer (with OMNI Smart Software), and the number of occurrences of each event can be viewed on the Statistics bar of the OMNI Smart Programmer application (see Section 4.15).
- The OMNI Smart Programmer application can be used to measure the impedance of the LS and V leads (see Section 4.16).

2.3.4   Closing the Programmer Application

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

3. OMNI II SOFTWARE

The OMNI II software is an application that is used to read and modify the parameters that control the OPTIMIZER IVs IPG. This section describes the various features of the OMNI II software.

3.1 The OMNI II Programmer Application Screen

When the OMNI II software is started, the OMNI II Programmer application displays the main screen, which includes the following:

- Title Bar

- Menu Bar (with the displayed content of the selected tab)

- Parameter Tabs

- Programming Bar

- Log Bar

- ECG Window

- Statistics Bar

- Status Bar
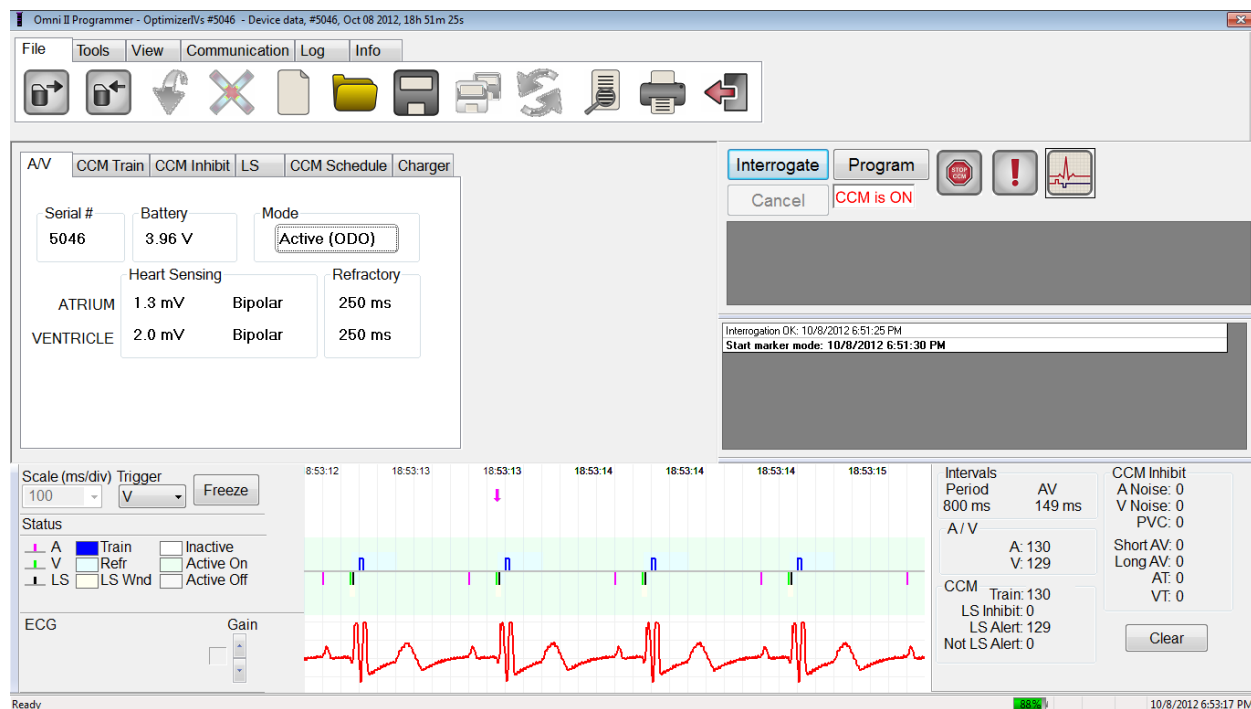
Figure 6: OMNI II Programmer Application Main Screen

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 IVs 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 Menu Bar

The Menu Bar is displayed under the Title Bar. It contains the commands of the OMNI II Programmer application grouped under the following tabs:

- **File**: contains commands to read and set the parameters of the OPTIMIZER IVs IPG, file manipulation commands, and commands for the Standard files.

- **Tools**: contains communication commands used for diagnostics, programming, as well as LS diagnostic tools.

- **View**: contains commands to toggle views.

- **Communication**: contains commands for remote operation and monitoring.

- **Log**: contains tools for log file creation, recording, filtering, and exporting.

- **Info**: contains commands used to display information about the OPTIMIZER IVs IPG and the OMNI II Software version, as well as Interface Battery information, and a Help command.

Select the tab to display the list of options/commands under each tab.

In order to initiate a desired option/command, select its corresponding icon.

If an option or command has a name that is followed by dots, this indicates that a dialog box will be displayed whenever this option or command is selected.

When a command icon appears gray on the menu, this indicates that the command is not currently available.

The content of each Menu Bar tab is displayed in the tables beginning on the next page.

3.1.2.1 File Tab Menu

Command Name	Description
Interrogate	Reads the parameter values of the OPTIMIZER IVs IPG. These values become the programmer values of the OMNI II Programmer application.
Program	Sets the values of the OPTIMIZER IVs IPG with the current programmer values of the OMNI II Programmer application. This command is enabled only if no parameter conflict occurs.
Undo	If the OPTIMIZER IVs IPG has been reprogrammed with a new set of parameter values, the Undo command *resets the OPTIMIZER IVs IPG values to those previously programmed.*
Cancel	If any of the programmer values is modified, the Cancel option becomes available. Selecting this command will *reset the programmer 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.
Open device model	Allows the user to choose the device model being interrogated or programmed.
Open standard…	Reads a standard (.tip) file containing saved OMNI II Programmer application values. Opens a window allowing the user to choose the name and location of the saved standard (.tip) file.
Save current standard…	Writes a standard (.tip) file containing the current OMNI II Programmer application values. A window pops up asking for the name and location of the .tip file.
Backup	Saves session data to removable flash drive.
Restore	Restores session data from removable flash drive.
Print preview	Shows a preview of a list of the current OMNI II Programmer application values to be printed.
Print current standard…	The list of the current OMNI II Programmer application values is sent to the default printer.
Exit	Closes the OMNI II Programmer application.

3.1.2.2 Tools Tab Menu

Command Name	Description
Stop CCM™	Programs the OPTIMIZER IVs IPG to stop delivering cardiac contractility modulation therapy.
Doctor session	Allows the physician to transitorily try cardiac contractility modulation therapy regardless of the programmed schedule for CCM™ delivery.
Marker Mode	Sets the OPTIMIZER IVs IPG in Marker Mode (i.e., Marker Events are displayed in the ECG Window for every sensed and generated event.
Statistics…	Opens the Statistics window.
A sensing threshold	Displays a window through which the user can get and set the Atrial sensing thresholds.
V sensing threshold	Displays a window through which the user can get and set the Ventricular sensing thresholds.
LS diagnostics…	Opens the Local Sense Diagnostics window.
Impedance…	Opens the Impedance window which allows the user to direct the OPTIMIZER IVs IPG to measure the RV and LS lead impedances.
Reset Device	Resets the OPTIMIZER IVs device. This command should be used only if the OMNI II Programmer application reports that the OPTIMIZER IVs IPG being interrogated is in the "DOWN" mode (safe OOO, no CCM™ reversion mode).
Urgent Programming	Programs the OPTIMIZER IVs IPG with safe standard values in case of emergency (OOO, no CCM™ signal delivery).
Time…	Shows the current time settings of the real-time clocks in the OPTIMIZER IVs IPG and the OMNI II Programmer tablet PC. The window opened through this menu option allows the time of the devices to be set. (The time setting of the OPTIMIZER IVs IPG is used by the CCM™ signal delivery scheduling mechanism to turn CCM™ signal delivery on and off on a daily basis).
Set system time…	Allows user to set the OMNI II Programmer (with OMNI Smart Software) system time. This is analogous to setting the PC time.

3.1.2.3 View Tab Menu

Command Name	Description
Toggle graph view	Toggles between Parameter view and Static/Dynamic Graph View in the OMNI II Programmer application. Some of the programmer parameter values are displayed in a graphical mode. See Section 3.1.2.
Toggle dynamic view	Toggles between Static and Dynamic Graph View in the OMNI II Programmer application. In the **Dynamic View,** the ECG for each beat is displayed in the Graphic View together with Marker Events. This view is available only if the Marker Mode is on. In the **Static View,** only the parameter values are shown in the Graphic View and they can be modified by dragging-and-dropping. No Marker Events are shown in this mode.
Marker detail	Opens an expanded Marker Window.

3.1.2.4 Communication Tab Menu

Command Name	Description
Connect	Opens the OMNI II Programmer Client window which allows the user to initiate a remote session.
Send message…	Opens Chat message window, which allows the user to exchange chat messages with the remote pair.
Master	Puts the OMNI II Programmer application in Master mode, which allows the user to control the device.
Slave	Puts the OMNI II Programmer application in Slave mode and allows the Remote user to control the local programmer.
Show Client Window	Displays the OMNI II Programmer Client window (if a remote session was initiated).

3.1.2.5 Log Tab Menu

Command Name	Description
Log browser	Opens the Marker window for viewing.
Open log file…	Opens a window allowing the user to choose from the list of the saved marker files.
Compare programs…	Opens a window displaying the differences in Parameters found between the Old value and the Current value.
Log filter…	Opens a window whereby the user can filter a log on desired recorded session events.
Add log bookmark	Adds a bookmark to the Log while it is recording to annotate a desired event.
Start Recording	Starts recording the patient's ECG.
Export programs	Writes a text file containing the values of the current parameters.
Export statistics	Writes a text file containing the values of the statistics counters.
Export marker	Writes a text file containing the values of the markers.
Upload/Download log	Opens a window which allows the user to transfer log files between the OMNI II Programmer and the Remote server.

3.1.2.6 Info Tab Menu

Command Name	Description
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.
Help…	Opens the help window.
About…	Displays information about the OMNI II Software version.

3.1.3 Parameter Tabs

The set of parameters of the OPTIMIZER IVs IPG are displayed by six Parameter screens placed under six tabs. Each one of these screens displays a different set of parameter values, grouped by the following tabs:

- **A/V**: displays the serial number and battery voltage of the interrogated device, the operating mode, as well as the atrial and ventricular heart sensing and timing parameters.

- **CCM™ Train**: contains the parameters that define the CCM™ signal.

- **CCM™ Inhibit**: contains the parameters to configure the CCM™ inhibition mechanism.

- **LS**: contains the parameters for the Local Sense mechanism.

- **CCM™ Schedule**: contains the parameters to configure the CCM™ signal delivery schedule.

- **Charger**: contains the parameters related to the alarms to be reported to the charger.

The available actions are:

- Interrogate (i.e. read the device parameters' current values)

- Modify the parameters' values through the editing features at hand

- Program (i.e. transmit to the device a set of compatible parameter values)

Figure 7: A/V Parameter Tab

Figure 8: CCM™ Train Parameter Tab

Figure 9: CCM™ Inhibit Parameter Tab

Figure 10: LS Parameter Tab

Figure 11: CCM™ Schedule Parameter Tab

Figure 12: Charger Parameter 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 IVs IPG is 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 **Programming Bar** (See Section 3.1.4 for more information). As long as there is a parameter conflict, the OMNI II Programmer application will not allow the OPTIMIZER IVs IPG to be programmed with new parameter values. This ensures that only compatible parameter configurations can be downloaded to the OPTIMIZER IVs 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 3.4.1.

3.1.4   Programming Bar

The **Programming** Bar is located to the right of the **Parameter Tabs**. It contains seven buttons; some of which correspond to menu commands:
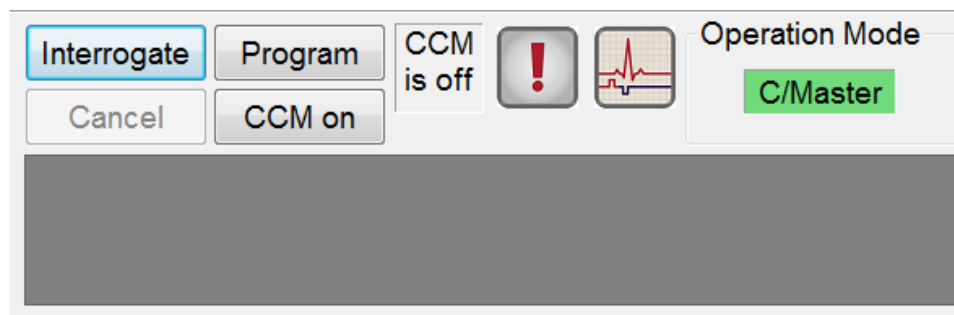
Figure 13: Programming Bar

The Programming Bar has two purposes:

1. Provides a fast access method to OMNI II Programmer application essential commands, through a programming bar with the following buttons:

    a. **Interrogate**: For obtaining the implanted device actual parameter values.

    b. **Program**: For transmitting a compatible set of parameter values to the active device. This button blinks in blue whenever a programmer value has been modified and there is no parameter conflict. This indicates that the values of the OPTIMIZER IVs device are different from the programmer values. If there is a parameter conflict, this button is disabled until the conflict is resolved.

    c. **Cancel/Undo**: Depending on the context- canceling the modifications not transmitted yet, or restores the last programming action previous values.

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d.   **CCM™ On**: (displayed when CCM is OFF) Activates CCM™ signal delivery by programming the CCM Mode parameter to Timed.

e.   **CCM™ is On**: Displayed when CCM™ signal delivery is ON.

f.   **Stop CCM™**: (displayed when CCM™ is ON) Deactivates CCM™ signal delivery by programming the CCM Mode parameter to CCM OFF.

g.   **CCM™ is Off**: Displayed when CCM™ signal delivery is OFF.

h.   **Urgent programming**: Programs the OPTIMIZER IVs IPG with a safe parameter set (OOO Mode, CCM OFF).

i.   **Marker Mode**: Toggles the initiation and termination of the Marker Mode.

2.   The window under the buttons displays the parameter conflict messages. 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. When an error message is selected, a list of the parameters that are in conflict appears. When a parameter in this list is selected, a window with all its possible values pops up, allowing the value of the conflicting parameter to be directly modified. See Section 3.4.2 for ways in which to resolve parameter conflicts.

Figure 14: Example of Parameter Conflict Message

3.1.5   Log Bar

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

Figure 15: Log Bar

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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 II Programmer application 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 (Bookmarks, begin/end of Marker Mode, etc.), a message appears indicating that the event has no more associated data to display.

3.1.6 ECG Window

This window is displayed at the bottom of the screen. It scrolls the real-time ECG of the patient.

When the OPTIMIZER IVs device is in **Marker Mode**, markers are shown along the ECG for the different events and conditions that may occur.
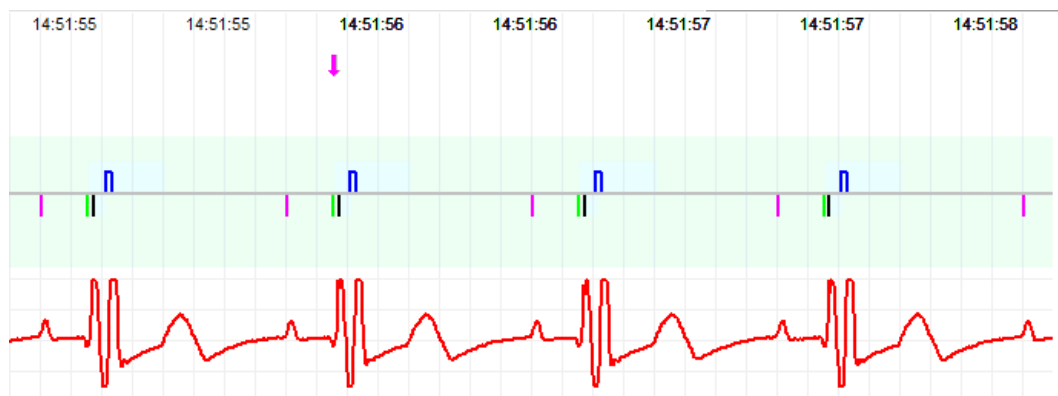
Figure 16: ECG Window in Marker Mode

The trace and color references are shown in a small window.

Figure 17: References Window

The Marker events are displayed as follows:

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

  o **Magenta**: Atrial sensed event

  o **Green**: Ventricular sensed event

  o **Black**: Local Sense event

These color references are displayed in the ECG window of the OMNI II Programmer application screen.

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- 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:

  o **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.

  o **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.

  o **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.

3.1.7   Statistics Bar

The OPTIMIZER IVs IPG accrues a statistical record of events and conditions that occur as it functions. This record appears in the Statistics Bar, indicating the number of occurrences of each event type. Events considered are as follows:

Figure 18: Statistics Bar

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- **Intervals**
  - **Period**: R-R interval in milliseconds.
  - **AV**: AV interval in milliseconds.
- **A / V**
  - **A**: the number of sensed atrial events.
  - **V**: the number of sensed right-ventricular events.
- **CCM™**
  - **Train**: the number of delivered CCM™ signals.
  - **LS Inhibit**: the number of CCM™ signal delivery inhibitions due to Local Sense events detected outside of the LS Alert Window.
  - **LS Alert**: the number of beats in which Local Sense events occurred inside the LS Alert Window.
  - **Not LS Alert**: the number of beats in which Local Sense events occurred, but not inside the LS Alert Window.
- **CCM™ Inhibit**
  - **A Noise**: the number of times Atrial Noise was detected.
  - **V Noise**: the number of times Ventricular Noise was detected.
  - **PVC**: the number of times a Premature Ventricular Contraction 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.
  - **AT**: the number of times the instantaneous atrial rate exceeded the Atrial Tachycardia rate limit.
  - **VT**: the number of times the instantaneous ventricular rate exceeded the Ventricular Tachycardia rate limit.

When the OPTIMIZER IVs device is in **Marker Mode** and within communications range of the OMNI II Programmer (with OMNI Smart Software), the contents of the **Statistics** counters change dynamically, showing the current number of occurrences of each event type.

3.1.8 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.

3.2 Graphic View

A graphical view is available on the OMNI II Programmer application to display some of the OPTIMIZER IVs device 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.

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- 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.

The graphic view can be set to be **Dynamic** or **Static**.

3.2.1   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 19: Graphic View (Dynamic)

3.2.2   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 20: 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.

3.3   Interrogation

3.3.1   Communicating with the Implanted OPTIMIZER IVs 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 IVs 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 IVs IPG are completely out of communication range or that the battery of the OPTIMIZER IVs IPG is completely discharged and thus incapable of communicating with the Programmer Wand.

3.3.2   Interrogating the OPTIMIZER IVs IPG

To read the parameter values of the OPTIMIZER IVs IPG, perform one of the following:

- Press the **Interrogate** button on the Programmer Wand, or

- Select the **Interrogate** icon under the **File** tab of the **Menu Bar**, or

- Select the **Interrogate** button on the **Programming Bar**

If the interrogation is successful, the OMNI II Programmer application will display the message "**Interrogation OK**". The serial number and the battery voltage of the OPTIMIZER IVs IPG being interrogated will appear under the A/V parameter tab 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 Erro**r" 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.

3.4   Modifying Parameter Values

The OPTIMIZER IVs device parameters are organized under six categories:

- **A/V:**   Display of IPG serial number, battery voltage, mode of operation, right heart sensing, and timing parameters.

- **CCM™ Train:** Parameters that define the CCM™ signal,

- **CCM™ inhibit:** Parameters that cause cardiac contractility modulation therapy inhibition

- **LS:** Sensing and timing parameters for Local Sense.

- **CCM™ Schedule:** Parameters that control the scheduled delivery of CCM™ signals.

- **Charger:** Parameter limits measured by the Mini Charger that, if exceeded, cause the Mini Charger to display a numerical code corresponding to the limit that has been exceeded.

There is a Programming Tab in the OMNI II Programmer application for each one of these groups. Parameter values can be viewed and modified on the screens marked by these tabs.

In order to modify a parameter value, perform the following steps:

- 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 that the parameter values displayed on the programmer screen are **not** transferred to the IPG until the **Program** command is issued. Note also that it is not necessary to keep the Programmer Wand over the OPTIMIZER IVs 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 issue the **Program** command.

3.4.1 Parameter Color Convention

The following color convention is used to represent programmer values and conflicts:

- **Black:** for the current parameter values of the OPTIMIZER IVs 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 unallowed 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.

3.4.2 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 II Programmer application will not allow the OPTIMIZER IVs 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.

- The name of the Programming Tabs in which the conflicting parameters appear.

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 Programming Tabs, since these values appear in red. Look for the names of the error related tabs in the error message displayed in the Programming 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.

3.5   Programming

3.5.1   Programming the OPTIMIZER IVs IPG

Programming the OPTIMIZER IVs 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, follow these steps:

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

- Transmit the OMNI II Programmer application parameter values to the OPTIMIZER IVs IPG using the **Program** command. To issue this command, perform one of the following options (these options will be enabled only if *there is no parameter conflict*):

  o Press the **Program** button on the Programmer Wand or

  o Select the **Program** icon under the **File** tab of the **Menu Bar**, or

  o Select the **Program** button on the **Programming Bar**

If the programming is successful, the OMNI II Programmer application 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 a **Program** command, the modified parameter values on the OMNI II Programmer application screen will become black, indicating that they are now the programmed parameter values of the OPTIMIZER IVs IPG.

3.5.2 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 IVs IPG.

3.5.2.1 Cancel

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

You may cancel modifications by:

- Selecting the **Cancel** button on the **Programming Bar**. This button is enabled only if a parameter value has been modified, or

- Selecting the **Cancel** icon under the **File** tab of the **Menu Bar.**

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

3.5.2.2 Undo

If the OPTIMIZER IVs 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*.

You can undo the most recent programming by:

- Selecting the **Undo** button on the **Programming Bar**. This button is enabled only after the execution of a **Program** command, or

- Selecting the **Undo** icon under the **File** tab of the **Menu Bar**

If the **Undo** operation is successful, the OMNI II Programmer application 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.

3.6 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 II Programmer application can interpret. The file extension used for them is "**.**tip". The **Open** and **Save** commands of the OMNI II Programmer application read and write data from and to **.**tip files. As such, the OMNI II Programmer application can also be used as an editor of standards.

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

3.6.1 Opening a Standard File

A standard (**.**tip) file can be loaded by:

- Selecting the **Open standard…** icon under the **File** tab of the **Menu Bar**.

- An **Open (OptimizerIVs)** 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 programmer values. This implies that:

- If an OPTIMIZER IVs 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 **.**tip 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**.

3.6.2 Saving a Standard File

A parameter value set can be saved in standard (**.**tip) file by:

- Selecting the **Save current standard…** icon under the **File** tab of the **Menu Bar**

- A **Save (OptimizerIVs)** window will pop up. Enter the file name of the standard to be saved and then click **Save**.

3.7 Loading And Exporting Information

3.7.1 Loading Log Files

A **Log** file can be loaded by:

- Selecting the **Open log file…** icon under the **Log** tab of the **Menu Bar.**

- An **Open (OptimizerIVs)** 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.

3.7.2 Exporting Data

The current parameter values, statistics counters, and log bar markers can be saved in text files by:

- Selecting the **Export programs** icon under the **Log** tab of the **Menu Bar** to export the parameter values**.**

- Selecting the **Export statistics** icon under the **Log** tab of the **Menu Bar** to export the device statistics.

- Selecting the **Export marker** icon under the **Log** tab of the **Menu Bar** to export the contents of the log bar.

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

Then, a **Save (OptimizerIVs)** 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.

3.8 Log And ECG Recording

3.8.1 Log

The OMNI II Programmer application keeps a log of all the interactions that take place between it and an OPTIMIZER IVs 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 for a particular OPTIMIZER IVs IPG is **created** when the device is interrogated for the first time.

- Each communications event that takes place between the OMNI II Programmer application and the OPTIMIZER IVs IPG appears in the Log 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:

  o If an **Interrogation** or **Programming** event is chosen, the parameter values displayed by the OMNI II Programmer application are the set of values present at the moment the selected event occurred.

  o 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 (bookmarks, begin/end of Marker Mode, etc.), a message appears indicating that the event has no more associated data to display.

3.8.2 ECG Recording

The patient's ECG can be recorded by:

- Selecting the **Start Recording** icon under the **Log** tab of the **Menu Bar**

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

When the OPTIMIZER IVs 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 3.13 for more information on Markers.)

The recorded ECG segments are displayed in the **Marker Window**.

3.9 Emergency Programming

The OMNI II Programmer (with OMNI Smart Software) can program the OPTIMIZER IVs IPG to emergency mode (OOO mode, CCM OFF) even if the Programmer is turned OFF (either the Tablet PC is OFF or is not functioning).

3.9.1 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.

Emergency Programming when the OMNI II Programmer (with OMNI Smart Software) is OFF can be achieved by placing the Programmer Wand over the implant site and pressing 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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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** icon under the **Info** tab of the OMNI II Programmer application. 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 II Programmer (with OMNI Smart Software) System.

3.9.2 Emergency Programming When the Programmer is ON

The **Urgent Programming** command can be used to program the OPTIMIZER IVs IPG with a safe parameter set (OOO Mode, CCM OFF).

The **Urgent Programming** command can be issued by positioning the Programmer Wand over the implant and doing one of the following:

- Selecting the **Urgent Programming** icon from the **Programming Bar**, or
- Selecting the **Urgent Programming** icon under the **Tools** tab of the **Menu Bar**, or
- Pressing the **F4** button on the keyboard of the tablet PC, or
- Pressing the **Emergency Programming** button on the Programmer Wand (see Section 1.5).

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 Programmin**g 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 IVs IPG is set in Standby (OOO Mode, CCM OFF).

3.10   Magnet Mode

Placing a pacemaker magnet over the implant site of the OPTIMIZER IVs IPG and maintaining it in close proximity to the device for at least two cardiac cycles (2–3 seconds), sets the OPTIMIZER IVs IPG in **Permanent Off** status.

Note: This feature is useful for turning off CCM™ signal delivery when an OMNI II Programmer (with OMNI Smart Software) 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 II Programmer with OMNI Smart Software).

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

3.11   Resetting the OPTIMIZER IVs IPG

The OPTIMIZER IVs 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 IVs IPG will place itself into a safe state referred to as "DOWN" mode. In "DOWN" mode, the OPTIMIZER IVs 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 IVs IPG using the OMNI II Programmer application under physician supervision.

To reset the OPTIMIZER IVs IPG:

- Place the Programmer Wand over the OPTIMIZER IVs IPG implant site.

- Issue the **Reset** command to the OPTIMIZER IVs IPG by selecting the **Reset device** icon under the **Tools** tab of the **Menu Bar.**

If the OPTIMIZER IVs 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 II Programmer application, 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.

3.12 Initiating CCM™ Delivery

3.12.1 Operating Mode Options

The operational status of the OPTIMIZER IVs IPG is set by the **Mode** button under the **A/V** tab. Selecting the **Mode** button will cause the **Mode A/V** pop-up menu to appear.
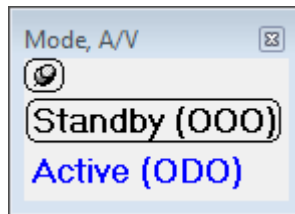
Figure 21: Mode A/V Pop-up Menu

The Operating Mode choices are:

- **Standby (OOO):** The device is placed in safe mode with no CCM™ signal delivery.

- **Active (ODO):** The device uses atrial, ventricular, and local sense events as triggers for CCM™ signal delivery.

To program the Operating Mode into the OPTIMIZER IVs IPG:

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

- Select the Operating Mode from the **Mode A/V** pop-up menu

- Issue the **Program** command using one of the following options:
  - Press the **Program** button on the Programmer Wand or
  - Select the **Program** icon under the **File** tab of the **Menu Bar**, or
  - Select the **Program** button on the **Programming Bar**

If the programming is successful, the OMNI II Programmer application will display the message "**Programming OK**".

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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.

3.12.2 CCM™ Signal Delivery Options

CCM™ signal delivery by the OPTIMIZER IVs IPG is set by the **CCM OFF** button under the **CCM™ Train** tab.

Selecting the **CCM OFF** button will cause the **CCM Mode** pop-up menu to appear.
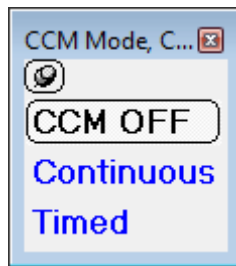
Figure 22: CCM Mode Pop-up Menu

The CCM Mode choices are:

- **CCM OFF**

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

Warning: The OPTIMIZER IVs 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 **Continuous** mode is for testing purposes only. Inadvertent extended use of **Continuous** mode will cause the battery of the OPTIMIZER IVs IPG to prematurely run-down, necessitating frequent recharging sessions.

Figure 23: Continuous CCM™ Delivery Warning

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To program the CCM Mode into the OPTIMIZER IVs IPG:

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

- Select the CCM Mode from the **CCM Mode** pop-up menu

- Issue the **Program** command using one of the following options:

  o Press the **Program** button on the Programmer Wand or

  o Select the **Program** icon under the **File** tab of the **Menu Bar**, or

  o Select the **Program** button on the **Programming Bar**

If the programming is successful, the OMNI II Programmer application 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.

3.13 Marker Events

The OMNI II Programmer application can be used to set the OPTIMIZER IVs 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 IVs IPG are displayed in the patient's ECG window synchronized with the patient's ECG signal. The markers are useful for analyzing the behavior of the IPG with different programmed parameters.

3.13.1 Turning Markers On

To set the OPTIMIZER IVs IPG in Marker Mode:

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

  o Select the **Marker Mode** icon under the **Tools** tab of the **Menu Bar**, or

  o Select the **Marker mode** button of the **Programming Bar**

If the programming is successful, the Programmer reports "**Start marker mode**". In the **ECG Window** of the OMNI II Programmer application, 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 IVs 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.

3.13.2 Turning Markers Off

Marker Mode may be turned off by:

- Selecting the **Marker Mode** icon under the **Tools** tab of the **Menu Bar**, or

- Selecting the **Marker mode** button of the **Programming Bar**, or

- Removing the Programmer Wand from the implant zone. *If the Programmer Wand cannot communicate with the OPTIMIZER IVs IPG, the Marker Mode is automatically terminated.*

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

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

3.13.3 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

3.13.4 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.

3.13.5 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.

- **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.

3.13.6 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 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 on 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 on the top left of the ECG window as long as the CCM™ delivery is **Active** but **Off**. The background color of the ECG window is **gray** in this case.

3.13.7 Log Browser Window

When the **Log Browser** icon under the **Log** tab is selected, the corresponding window titled Marker Window is displayed.
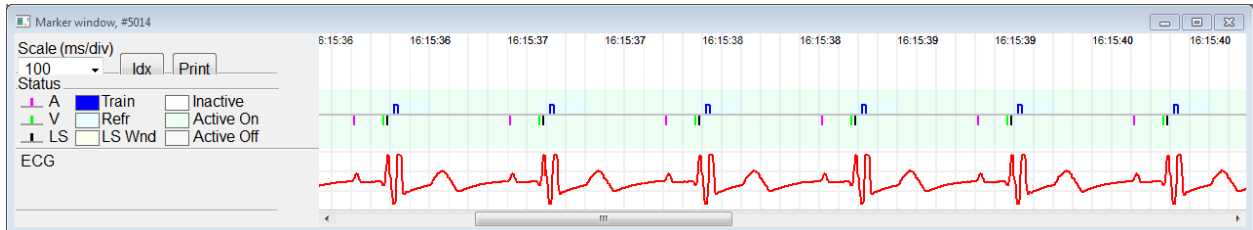
Figure 24: Marker Window

For the OPTIMIZER IVs 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.

- Xdx button that opens up a Marker index log window containing log items that can be used for navigation purposes.

- Markers and ECG labeled display.

- Inserted bookmark indicators and associated text when selected.

- 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 bookmark item or 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.

3.14 CCM™ Schedule

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

The upper 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

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schedule is set to be distributed over a 24 hour period each day. The standard programming for these parameters is

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

The lower half of this tab contains the parameters **On Time** and **Off time**. The **On Time** parameter sets the amount of time the OPTIMIZER IVs 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 IVs IPG is scheduled <u>not</u> to deliver cardiac contractility modulation therapy within the time frame set by the **Start time** and **End time**.

On the right side of this tab is the parameter **Scheduled.** The **Scheduled** parameter sets the total number of hours per day the OPTIMIZER IVs 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 II Programmer application 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 7h per day distributed over 24h, it sets the following standard scheduling parameters:

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

3.15   Statistics

The OPTIMIZER IVs IPG accrues a statistical record of events and conditions that occur as it functions. This record can be loaded into the OMNI II Programmer (with OMNI Smart Software), and appears in the Statistics window of the OMNI II Programmer application, 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.

- **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.

3.15.1 Loading Statistics

To obtain the Statistics from the OPTIMIZER IVs IPG:

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

- Select the **Statistics** icon under the **Tools** tab of the **Menu Bar**.

- When the Statistics window appears, select the **Read** button.
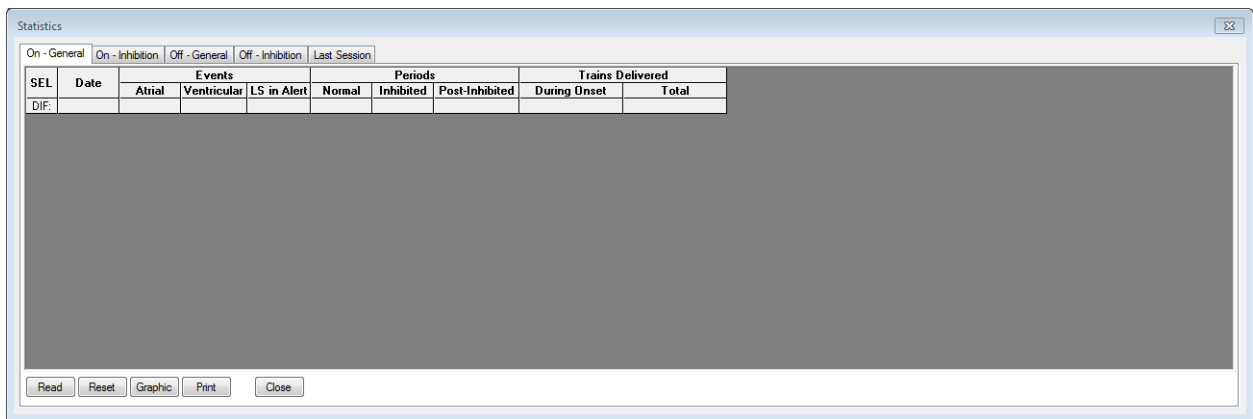
Figure 25: Statistics Window

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 IVs 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.

3.15.1.1 Statistics Window Tabs

- **On – General**
  - **Events**
    - **Atrial**: number of atrial events sensed during scheduled CCM™ delivery

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- **Ventricular**: number of ventricular events sensed during scheduled CCM™ delivery

- **LS in Alert**: number of local sense events sensed during scheduled CCM™ delivery

  - o **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

  - o **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**

  - o **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

  - o **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 IVs IPG is scheduled <u>not</u> 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 IVs IPG is scheduled <u>not</u> to deliver cardiac contractility modulation therapy

- **Last Session**: Statistics for Last Delivery V, Last Delivery Trains, Percentage, and Battery Discharge Episodes.

3.15.1.2   Statistics Window Buttons

- **Read:** Reads statistics from IPG.

- **Reset:** Resets statistics inside IPG.

- **Graphic:** Displays histogram of statistics from active tab – see Figure 26.

- **Print:** Prints the statistics

- **Close:** Closes Statistics Window.
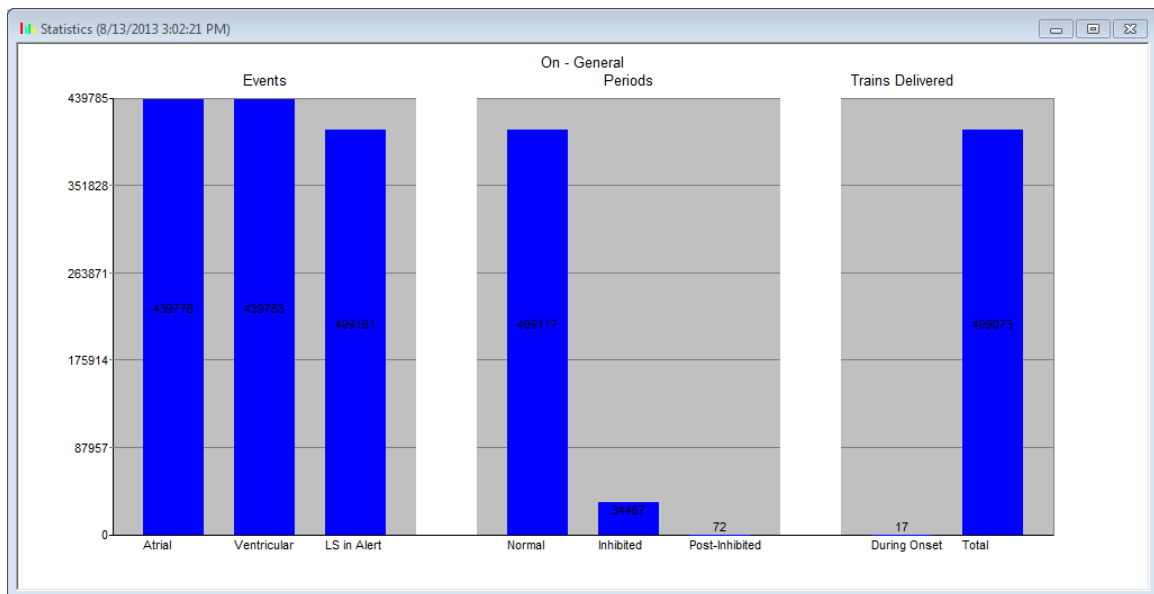
Figure 26: Statistics Histogram

3.15.2 Resetting Device Counters

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

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

- Select the **Statistics** icon under the **Tools** tab of the **Menu Bar**.

- When the Statistics window appears, select the **Reset** button.

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.

3.16 Measuring Lead Impedances

The impedance of the LS and RV leads can be measured by the OPTIMIZER IVs IPG and displayed by the OMNI II Programmer application. A CCM™ signal is delivered through the selected channel by the OPTIMIZER IVs 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 IVs 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 IVs IPG.

- Verify that the CCM™ Train Delivery parameter is set to **Timed** or **Continuous**.

- Select the **Impedance** icon under the **Tools** tab of the **Menu Bar**

- When the Impedance window appears, select the LS or RV 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.
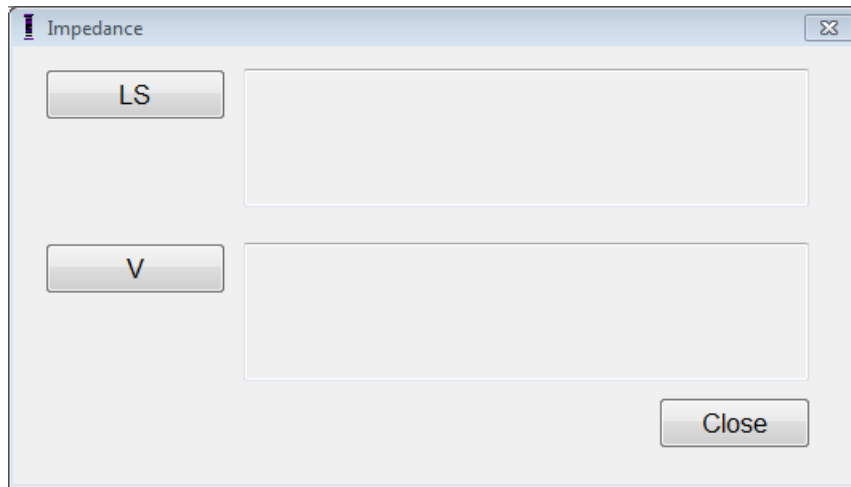
Figure 27: Impedance Window

3.17 Setting the OPTIMIZER IVs IPG and OMNI II Clocks

The time of day is maintained by an internal clock within the OPTIMIZER IVs 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 interrogating 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

3.17.1 Reading the OPTIMIZER IVs Device Time

The real-time clock in the OPTIMIZER IVs device 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 IVs IPG:

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

- Select the **Time…** icon under the **Tools** tab of the **Menu Bar**

- When the Time window appears, select the **Get Time** button**.**

Caution: Be certain that you are selecting the correct button
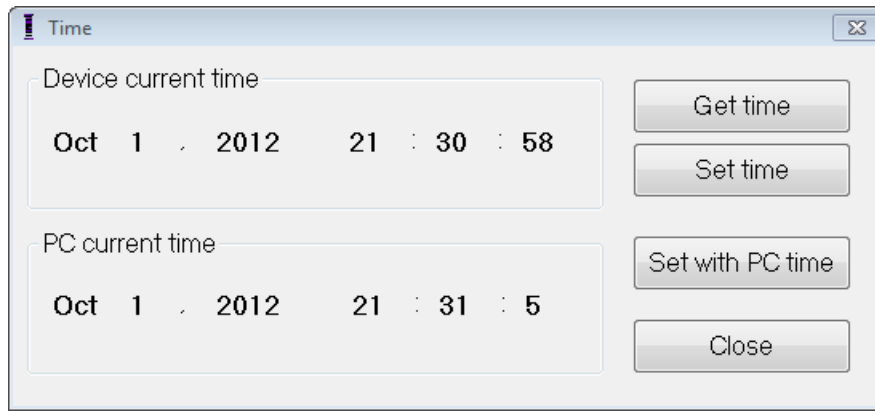
Figure 28: Time Window

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.

3.17.2 Setting the OPTIMIZER IVs Device Real Time Clock

You can set the OPTIMIZER IVs device 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 IVs IPG.

- Select the **Time…** icon under the **Tools** tab of the **Menu Bar.**

To manually set the current time of the OPTIMIZER IVs device:

- 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 IVs IPG to the computer's time:

- Select the **Set with PC Time** button**.**

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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.

3.17.3 Setting the OMNI II Programmer (with OMNI Smart Software) Clock

To set the system time of the OMNI II Programmer (with OMNI Smart Software):

- Select the **Set system time…** icon under the **Tools** tab of the **Menu Bar.**

- A **Set system time** window will appear which has a calendar and also the current OMNI II Programmer (with OMNI Smart Software) time. The current system date is highlighted.
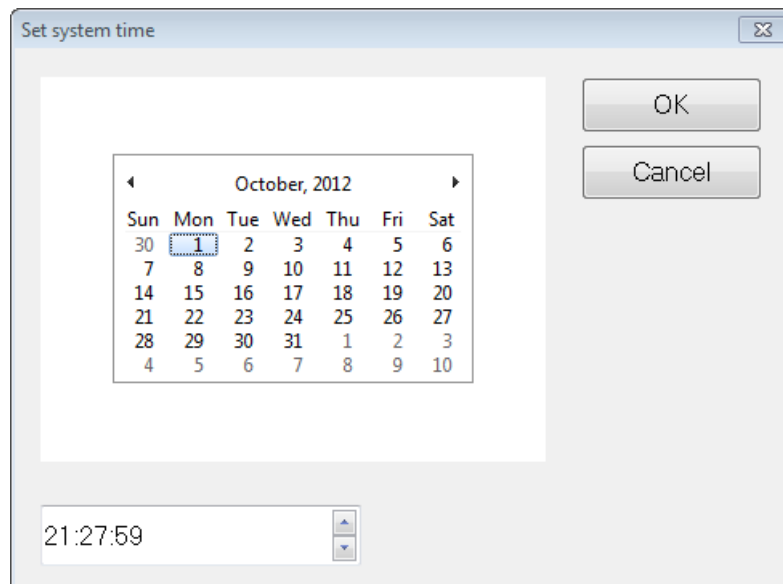
Figure 29: Set system time Window

- 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**

- You may cancel the operation by selecting **Cancel**.

3.18 Error Messages of OPTIMIZER IVs IPG Delivered by the OPTIMIZER Mini Charger

3.18.1 Minimum Target Percentage for CCM™ Delivery

The OPTIMIZER IVs 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 7.6.5).

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

- Find the **Minimum Target % for CCM™ Delivery** under the **Charger** tab of the **Menu Bar.**

- Activate this function by setting the check (✔) symbol in the checkbox next to **Enable**.

Currently programmed value for this parameter will appear

To see/modify the current value of the minimum target percentage for CCM™ delivery, perform the following:

- Verify that the **Minimum Target % for CCM™ Delivery** parameter is enabled.

- If necessary, select new value for **Minimum Target % for CCM™ Delivery.**

- Program the new parameter value to OPTIMIZER IVs IPG.

3.18.2 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 RV and LS lead impedance by either the OMNI II Programmer application or OPTIMIZER Mini Charger are stored in the OPTIMIZER IVs IPG.

Measurement of RV 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 7.6.2).

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

- Find **Maximum lead displacement** under the **Charger** tab of the **Menu Bar.**

- Activate this function by setting the check (✔) symbol in the checkbox next to **Enable**.

Currently programmed value for this parameter will appear

To see/modify the current value of the minimum target percentage for CCM™ delivery, do the following:

- Verify that the **Maximum lead displacement** parameter is enabled.

- If necessary, select new value for **Maximum lead displacement**.

- Program new parameter value to OPTIMIZER IVs IPG.

3.19 Local Sense (LS) Diagnostics

CCM™ trains are delivered in synchronism with intrinsic ventricular events detected by the Local Sense channel through the LS Lead. The OMNI II Programmer application has a **LS Diagnostic** tool which can be used to select appropriate operating parameters for the LS channel. This section describes the LS Diagnostic tool.

To open the LS Diagnostic Tool select:

- the **LS Diagnostics** icon of the **LS parameter tab** on the Programmer's screen, or

- the **LS Diagnostics** icon under the **Tools** tab in the **Menu Bar**

The Local Sense Diagnostic window will appear. Parameters related to Local Sensing appear on the right pane of this window:

- **LS Sensitivity** ("Sensitivity")

- **Pre Right-Ventricular Refractory** ("Pre V Ref") - applied to the LS channel

- **Post Right-Ventricular Refractory** ("Post V Ref") - applied to the LS channel

- **LS Alert Window Start** ("Alert Start")

- **LS Alert Window Width** ("Alert Width")

- **Post LS Refractory** ("Post LS Ref")

When running LS diagnostics, the OPTIMIZER IVs 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 II Programmer application to be displayed in the Local Sense Diagnostic Window as histograms.

Local Sense scans can be performed either manually or automatically:

- Use the **Manual** button to acquire a LS histogram for the specific LS sensitivity selected through the **LS Sensitivity** parameter. The **Clear** button can be used to clear out the graph.

- The **Automatic** button is used to start a process that scans through the LS Sensitivity values. In this mode, the OMNI II Programmer application automatically collects data at a number of different LS sensitivities. The automatic mode limits its search to histograms for LS sensitivities that yield LS events, but which avoid excessive sensing of noise. To do so, two parameters are needed:

o **Noise Threshold -** if the number of intervals where a LS signal is sensed is greater than this value, the corresponding LS Sensitivity will be considered too high and a new histogram will be collected using a lower sensitivity (i.e. higher sensing threshold).

o **Sense Threshold -** if the number of intervals where a LS signal is sensed is less than this value, the corresponding LS Sensitivity will be considered too low, and a new histogram will be collected using a higher sensitivity (i.e. lower sensing threshold).

When the automatic process is completed, all collected histograms appear in the Local Sense Diagnostic window. 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. The **Times** parameter indicates the number of cycles this sampling will be performed to accrue the histogram.

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 Diagnostic 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 35**, an appropriate value for the LS Sensitivity parameter would be 1.7 mV.
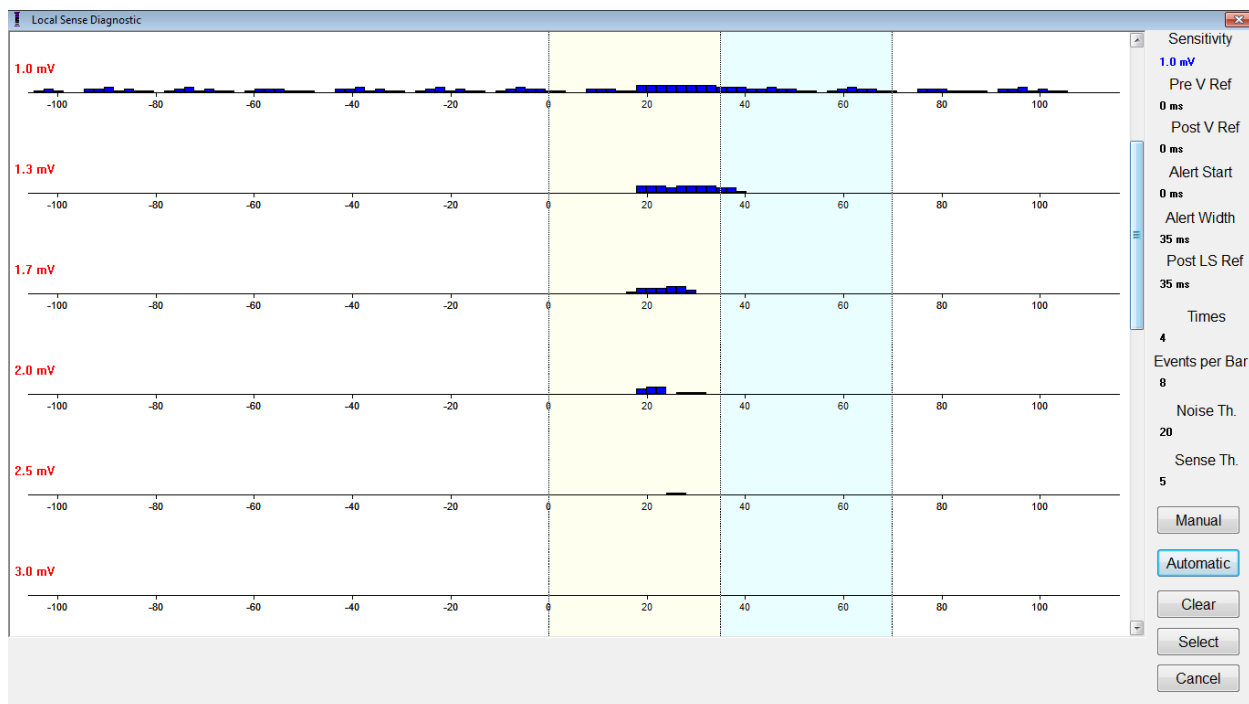
Figure 30: Local Sense Diagnostic Window after an Automatic Scan

Once the LS signal is located, the LS Refractory periods and the Alert Window can be set either in the graph (by dragging-and-dropping, in the same way as done in the Graph View Window) or by changing the values shown at the right of the LS Diagnostic window.

To exit the LS Diagnostic Window:

- Select the **Select** button. This command sets the LS parameter values of the OMNI II Programmer application with the ones of this window (please note that this operation changes the Programmer values only. The selected parameters must be programmed into the OPTIMIZER IVs IPG using the **Program** command), or

- Select the **Cancel** button. This command resets the parameters of the OMNI II Programmer application to the last interrogated/programmed values.

3.20 Remote Operation

The OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) must be connected to the Internet. The OMNI II Programmer (with OMNI Smart Software) 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 (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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

3.20.1 Connecting the OMNI II Programmer (with OMNI Smart Software) to a Wired Ethernet Network

Note: The connection of the OMNI II Programmer's 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 II Programmer (with OMNI Smart Software) 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 Programmer's Tablet PC.

3.20.2 Connecting the OMNI II Programmer (with OMNI Smart Software) to a Wireless Network

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

3.20.2.1 OMNI II Wireless Network Configuration

At the Selector screen, click the "Configuration" button. The Configuration Dialog window will appear.
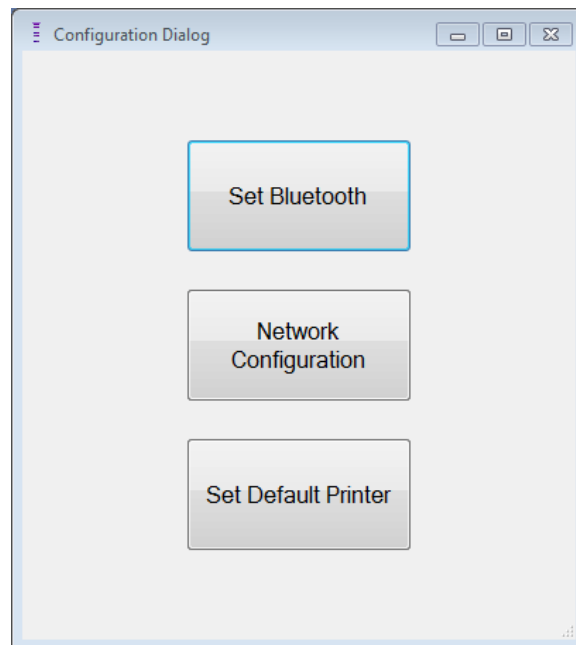
Figure 31: Configuration Dialog Window

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 II Programmer (with OMNI Smart Software).

Figure 32: 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:

  o Network name.

  o Signal strength percentage.

  o Connection status ("Connected" will appear next to the signal strength percentage if the OMNI II Programmer (with OMNI Smart Software) is connected to that network).

- Status: status of the connection. A red circle with the message "The system is connected to the internet but cannot reach the server IP address (40.114.12.242)." will be displayed if the OMNI II Programmer (with OMNI Smart Software) is connected to the internet, while a red circle with the message "The system is not connected to any network." indicates that some problem is preventing the programmer from connecting to the internet.

Figure 33: OMNI II Network Status Indicators

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3.20.2.2 OMNI II Wireless Network Configuration Commands

The OMNI II 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.

3.20.3 OMNI II Software Operation Modes

3.20.3.1 OMNI II Startup Modes

The OMNI II 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 II Programmer application 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 II Programmer application in a clinical setting
    - A particular case of Remote Mode in which the OMNI II Programmer application 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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software).

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 II – Remote Mode' button is selected:

"This OMNI II Programmer cannot be used to interrogate or program local OPTIMIZER IVs 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 IVs 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 3.20.3.2) 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.

3.20.3.2   OMNI II Master/Slave Modes

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

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

3.20.4 OMNI II Programmer Client Window

Note: In order to connect the OMNI II Programmer application to the OMNI Remote Server, the OMNI II Programmer (with OMNI Smart Software) must first be connected to Internet. See Sections 3.20.1 and 3.20.2 on ways to connect the OMNI II Programmer (with OMNI Smart Software) to the Internet.

The Programmer Client Window is used to log in to the Client Server. To open the OMNI II Programmer Client window, select the **Connect** icon under the **Communication** tab of the **Menu Bar**.
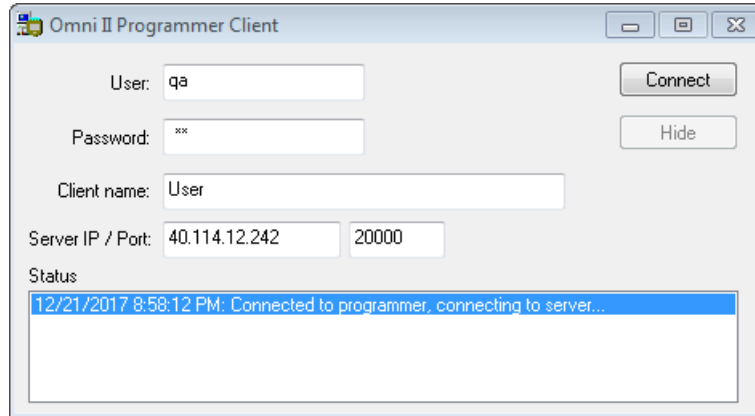
Figure 34: OMNI II Programmer Client Window

3.20.4.1 Connecting the OMNI II to the Remote Server

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

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

Note: When connecting to the Remote Server for the first time, delete the existing User, Password, and Client Name and type in the User, Password, and Client Name assigned to you by Impulse Dynamics.

- **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 II Programmer (with OMNI Smart Software). 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 to the current IP address when the OMNI II Programmer

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(with OMNI Smart Software) is shipped but is subject to change after you receive your programmer. When this change occurs, you will be notified by Impulse Dynamics and be given information regarding the new IP address to be used to connect to the OMNI Remote Server.)

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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) connected to the Internet can initiate pairing with the Clinical OMNI II Programmer (with OMNI Smart Software) at the requesting clinic.

- If internet connectivity is interrupted during the remote session, the Local (Slave) OMNI II Programmer application will display a warning screen, and CCM™ delivery by the OPTIMIZER IVs IPG being followed-up will be turned 'OFF'. The Local (Slave) OMNI II Programmer application will automatically revert to master mode after 5 consecutive failed retry attempts on any communication order.

- The local (Slave) OMNI II Programmer application will also revert to master mode after pressing the 'Urgent' Programming button on the OMNI II Programmer Wand.

3.20.4.2   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 **Show Client Window** icon under the **Communication** tab of the **Menu Bar**.

3.20.5 Starting a Remote Session with the OMNI II Programmer (with OMNI Smart Software)

To start an OMNI II remote session, 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 II Programmer (with OMNI Smart Software) to the Internet via an Ethernet or wireless network connection.

To start a remote session, perform the following steps:

- Start the Clinical Programmer in **Clinical Mode**

- o Select the **Connect** icon under the **Communication** tab of the **Menu Bar**.

- o 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, **"Operation Mode"** is displayed in the Programming Bar along with the current mode of operation, "==C/Master=="".

- • Start the Remote Programmer in **Remote Mode**

  - o Select the **Connect** icon under the **Communication** tab of the **Menu Bar**.

  - o When the Omni II Client window appears, enter the User name, password, and Client name in the appropriate spaces and then select **Connect**.

  - o When the Select Local Programmer window pops up, select the desired OMNI II Programmer, and then select **OK**.

After a connection has been established with the Client server, **"Operation Mode"** is displayed in the Programming Bar along with the current mode of operation, "==R/Slave=="".

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** icon under the **Communication** tab of the **Menu Bar** on the Clinical Programmer

The following message will be displayed when the Clinical mode OMNI II Programmer application 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.

The **"Operation Mode"** in the Programming Bar of the Clinical Programmer will change to ==C/Slave==.

Meanwhile, the **"Operation Mode"** in the Programming Bar of the Remote Programmer will change to ==R/Master==.

3.20.6 Ending an OMNI II Remote Session

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

In order to terminate an OMNI II remote session:

- Select the **Connect** icon under the **Communication** tab of the **Menu Bar** again after a session has been initiated.

3.20.7 OMNI II Chat

In order to send a chat message, open the Chat message window by selecting the **Send message…** icon under the **Communication** tab of the **Menu 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.
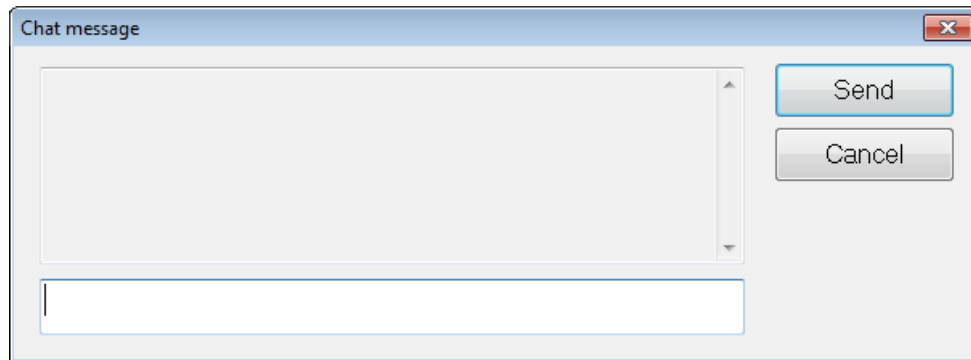
Figure 35: Chat message Window

3.20.8 OMNI II Log Upload/Download

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

3.20.8.1 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 application Upload/Download Log window, select the **Upload/Download log** icon under the **Log** tab of the **Menu Bar**.
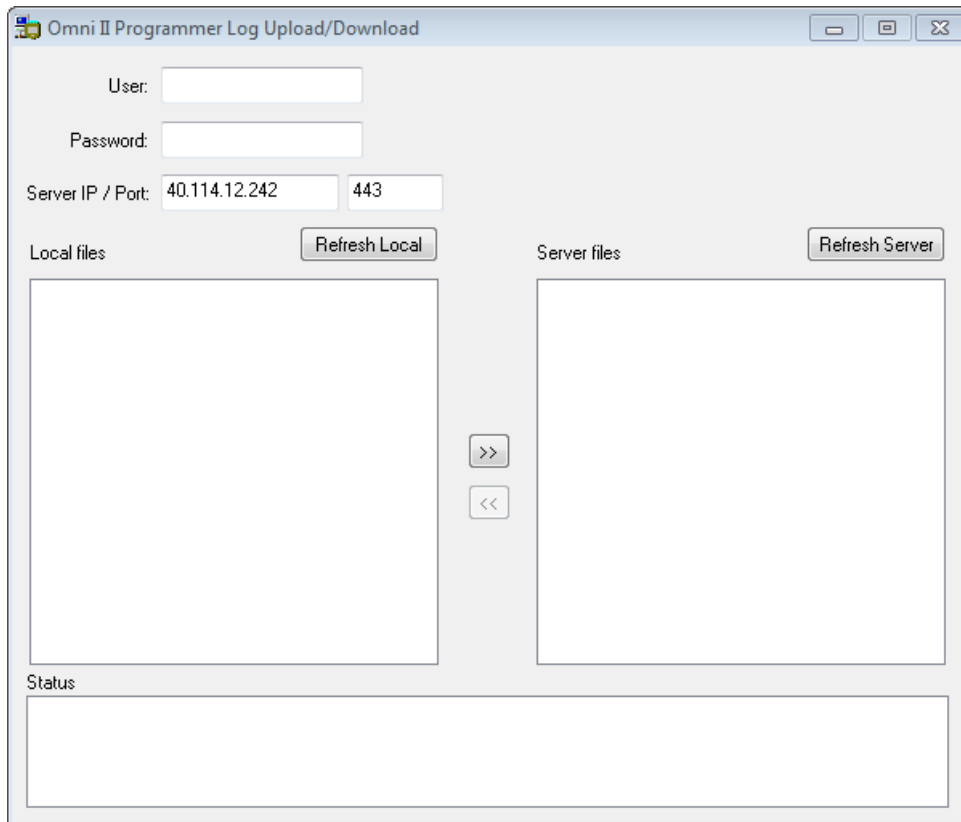
Figure 36: OMNI II Programmer Log Upload/Download Window

3.20.8.2 OMNI II Refresh Local

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

3.20.8.3 OMNI II Refresh Server

In order to display the log files stored on the server, the OMNI II Programmer (with OMNI Smart Software) must first be connected to Internet. See Sections 3.20.1 and 3.20.2 on ways to connect the OMNI II Programmer (with OMNI Smart Software) 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 to the current IP address when the OMNI II Programmer (with OMNI Smart Software) is shipped but is subject to change after you receive your programmer. When this change occurs, you will be notified by Impulse Dynamics and be given information regarding the new IP address to be used to connect to the OMNI Remote Server.)

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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.

3.20.8.4   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 II software is operating in Clinical Mode.

3.20.8.5   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 II software is operating in Remote Mode.

4.   OMNI SMART SOFTWARE

The OMNI Smart software is an application that is used to read and modify the parameters that control the OPTIMIZER Smart IPG. This section describes the various features of the OMNI Smart software.

4.1   The OMNI Smart Programmer Application Screen

When the OMNI Smart software is started, the OMNI Smart Programmer application 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
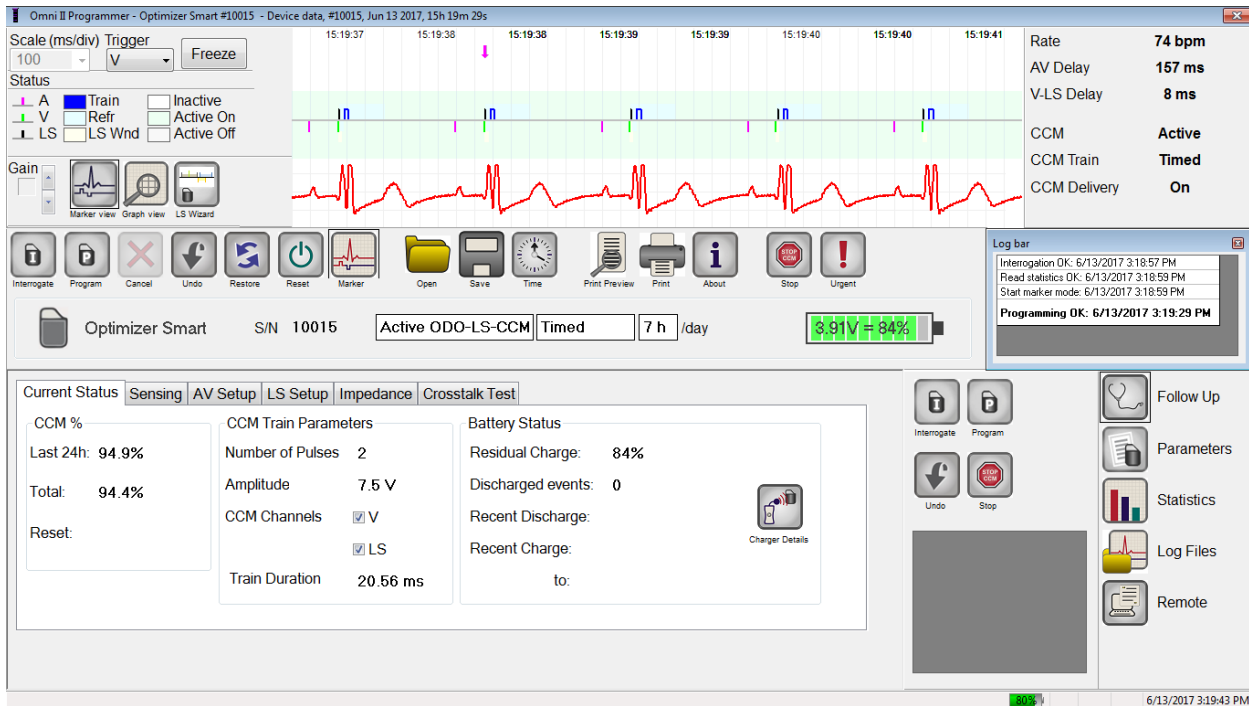
Figure 37: OMNI Smart Programmer Application Main Screen

4.1.1 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.

4.1.2 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.
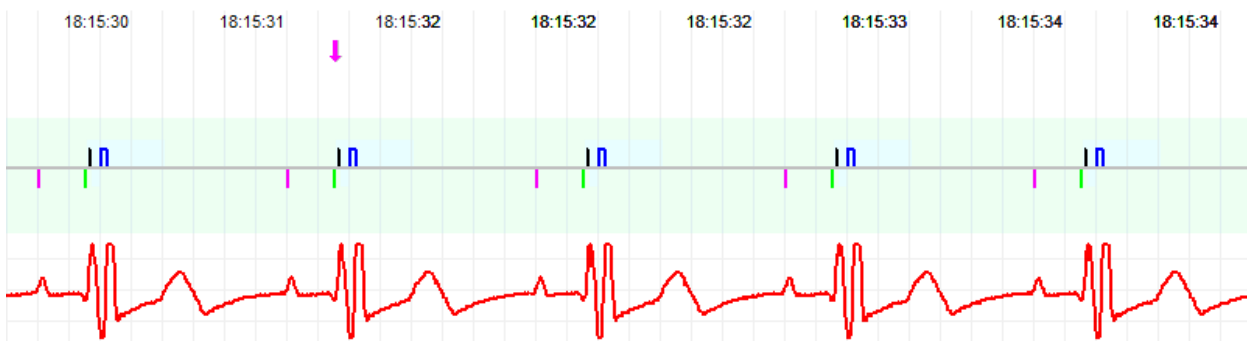
Figure 38: ECG Window in Marker Mode – Active ODO-LS-CCM Mode shown

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The trace and color references are shown in the **ECG Reference Bar**.
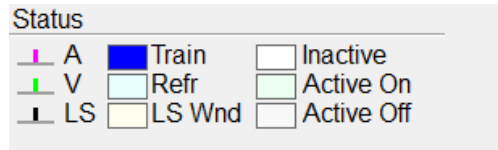
Figure 39: ECG Reference Bar

4.1.3   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
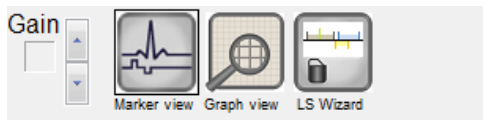
Figure 40: View Bar

4.1.3.1 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:

  o **Magenta**: Atrial sensed event

  o **Green**: Ventricular sensed event

  o **Black**: Local Sense event

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

4.1.3.2 Graph View

A graphical view is available on the OMNI Smart Programmer application 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)

- o CCM™ signal initial amplitude
- o 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.

4.1.3.2.1 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.
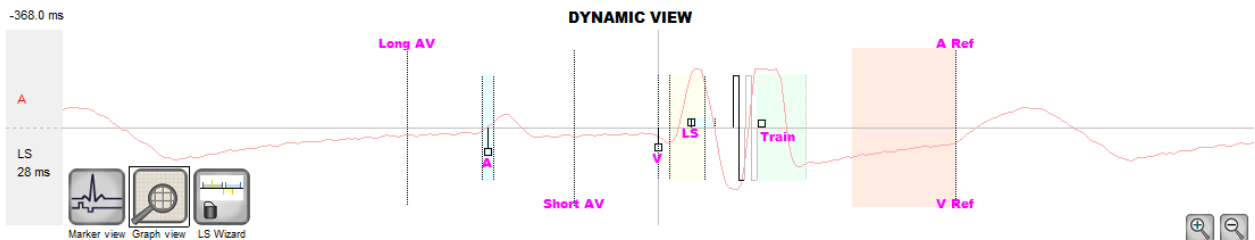
Figure 41: Graphic View (Dynamic)

4.1.3.2.2 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.
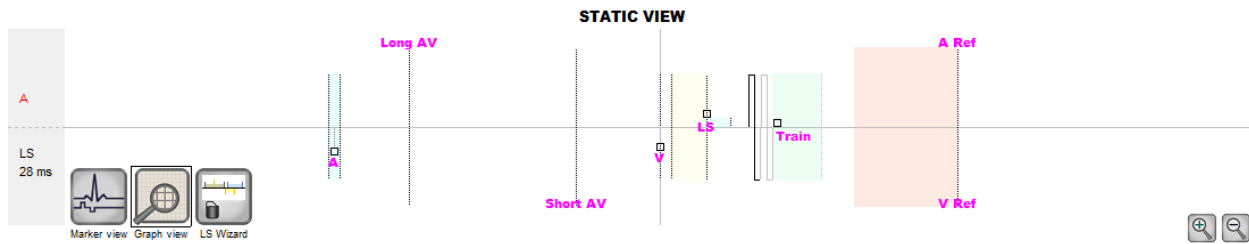
Figure 42: Graphic View (Static)

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.

4.1.3.3 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.

4.1.4   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

Figure 43: ECG Statistics Bar

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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.

4.1.5   Main Tool Bar

The Main Tool Bar is displayed under the **ECG Window**. It contains the buttons of the following OMNI Smart Programmer application 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 application.

- **Program (Ctrl+P)**: Sets the parameter values of the OPTIMIZER Smart IPG with the current parameter values of the OMNI Smart Programmer application. 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 application 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:

    o **Print Parameters**: The list of the current OMNI Smart Programmer application values to be printed is previewed.

    o **Print Statistics**: The list of the current statistics to be printed is previewed.

    o **Print Follow Up**: The list of the current Follow Up measurements to be printed is previewed.

    o **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:

    o **Print Parameters**: The list of the current OMNI Smart Programmer application values is sent to the default printer.

    o **Print Statistics**: The list of the current statistics is sent to the default printer.

    o **Print Follow Up**: The list of the current Follow Up measurements is sent to the default printer.

    o **Print Screen**: A snapshot of the current screen is created as a bmp file.

- **About**: Displays information about the OMNI Smart 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].
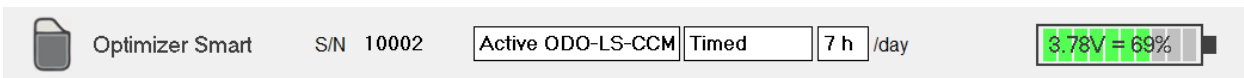

Figure 44: Tool Bar

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

4.1.6 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 45: Device Bar

4.1.7 Log Bar

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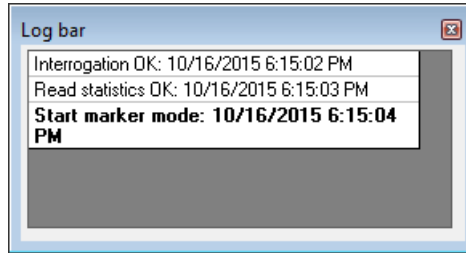

Figure 46: Log Bar

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 application 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.

4.1.8 Programming Bar

The Programming Bar provides fast access to the OMNI Smart Programmer application'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.
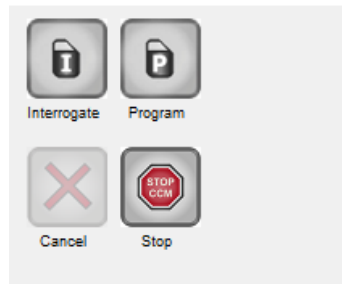
Figure 47: Programming Bar

4.1.9 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 4.3.2 for ways in which to resolve parameter conflicts.
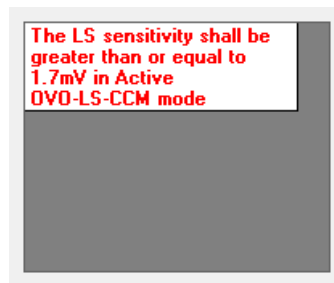
Figure 48: Example of Parameter Conflict Message in Parameter Conflict Bar

4.1.10 Task Bar

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

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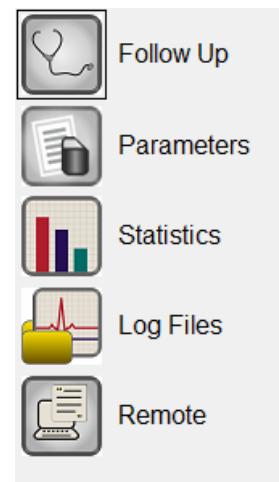- **Statistics**
- **Log Files**
- **Remote**

Figure 49: Task Bar

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4.1.10.1   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.

| Current Status | Sensing | AV Setup | LS Setup | Impedance | Crosstalk Test |

CCM %
Last 24h: 99.9%
Total: 94.7%
Reset:

CCM Train Parameters
Number of Pulses   2
Amplitude   7.5 V
CCM Channels   ☑ V
                              ☑ LS
Train Duration   20.56 ms

Battery Status
Residual Charge: 69%
Discharged events: 0
Recent Discharge:
Recent Charge:
                              to:

Charger Details

Figure 50: Current Status Tab

| Current Status | Sensing | AV Setup | LS Setup | Impedance | Crosstalk Test |

		Sensing Threshold		Sensitivity	
Channel	Date	Recent	New	Programmed	New
Atrium			mV	1.3 mV	1.3 mV
Ventricle			mV	2.0 mV	2.0 mV

Figure 51: Sensing Tab

Figure 52: AV Setup 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 53: LS 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   ☐   ☐   ☐

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 54: Impedance Tab

Current Status | Sensing | AV Setup | LS Setup | Impedance | Crosstalk Test

	Date	Recent	Current
V			467 Ohms
LS			405 Ohms

Figure 55: Crosstalk Test 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 inappropiate shocks.
* Document the value maximum CCM delay with no Crosstalk in the ICD-EGM.
* Reprogramm the appropiate 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

4.1.10.2 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:

  o **Set system time…:** Allows the user to set the OMNI II Programmer (with OMNI Smart Software) system time. This is analogous to setting the PC time.

  o **IPG Version:** Displays the firmware version of the interrogated IPG.

  o **Interface battery:** Reads the battery voltage of the lithium battery inside the OMNI II Programmer Interface Box.

  o **Interface version:** Displays the firmware version of the OMNI II Programmer Interface Box.

Figure 56: Overview Tab

Figure 57: A/V Tab

Figure 58: LS Tab

Figure 59: CCM™ Train & Schedule

Figure 60: Alarms Tab

Figure 61: 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 4.1.9 for more information). As long as there is a parameter conflict, the OMNI Smart Programmer application 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 4.3.1.

4.1.10.3 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
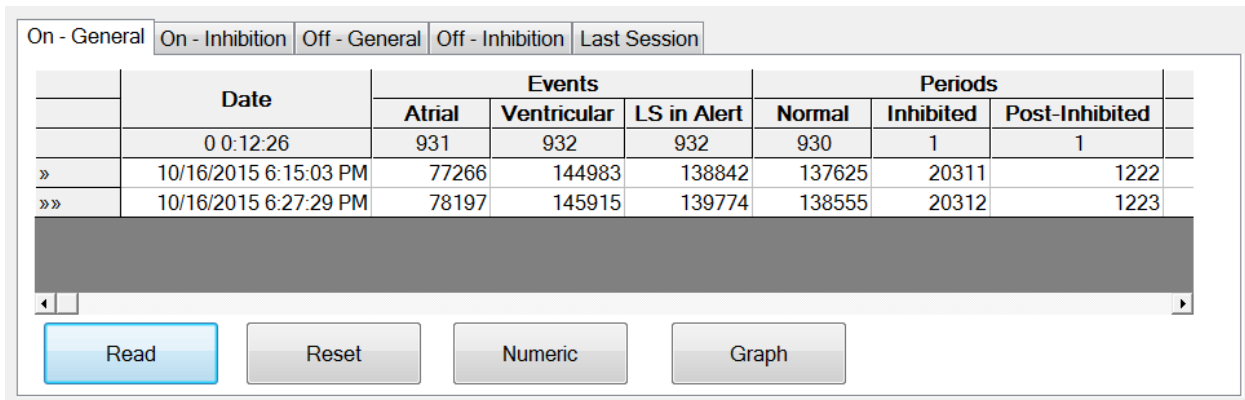
Figure 62: Statistics On - General Tab (Numeric View)
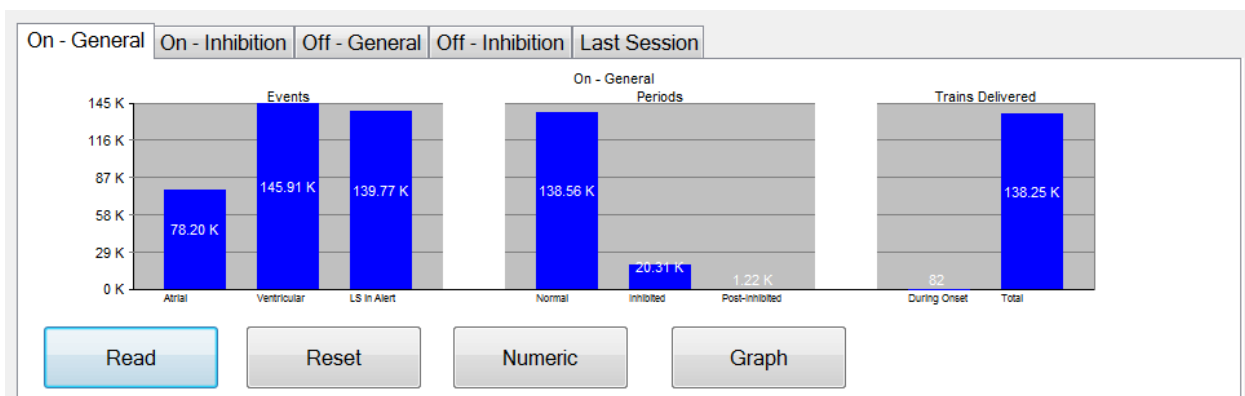
Figure 63: Statistics On - General Tab (Graph View)

4.1.10.4 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.

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- **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 application and the Remote server.

- **Compare**: opens a window displaying the differences in parameters found between the old values and the current values.
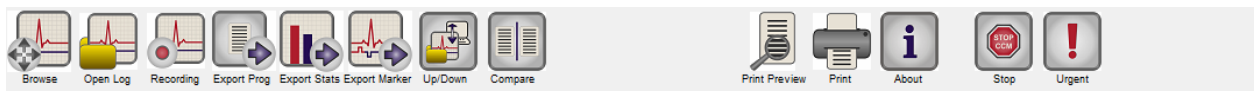
Figure 64: Tool Bar with Log File Commands

4.1.10.5 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 application in Master mode, which allows the user to control the programmer.

- **Slave**: puts the local OMNI Smart Programmer application 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).
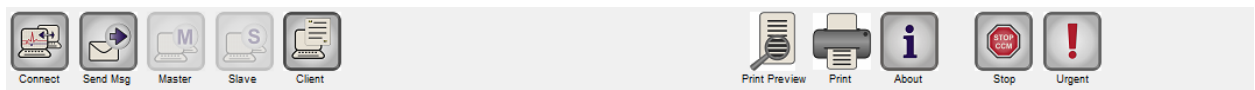
Figure 65: Tool Bar with Remote Commands

4.1.11 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 66: Status Bar

4.2   Interrogation

4.2.1   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.

4.2.2   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:

    o Press the **Interrogate** button on the Programmer Wand, or

    o Select the **Interrogate** button on the **Tool Bar**, or

    o Select the **Interrogate** button on the **Programming Bar, or**

    o Press the keyboard shortcut **<Ctrl+I>**

If the interrogation is successful, the OMNI Smart Programmer application will display the message "**Interrogation OK**". The device model, serial number, current cardiac contractility modulation 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 Erro**r" 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.

4.3   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.

4.3.1 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 unallowed 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.

4.3.2 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 application 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.

4.4   Programming

4.4.1   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*):
  o Press the **Program** button on the Programmer Wand or
  o Select the **Program** button on the **Tool Bar**, or
  o Select the **Program** button on the **Programming Bar**,
  o Press the keyboard shortcut **<Ctrl+P>**

If the programming is successful, the OMNI Smart Programmer application 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 a **Program** command, the modified parameter values on the OMNI Smart Programmer application screen will become black, indicating that they are now the programmed parameter values of the OPTIMIZER Smart IPG.

4.4.2   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.

4.4.2.1 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 application 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).

4.4.2.2 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 application 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.

4.5   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 application can interpret. The file extension used for them is "**.**tip". The **Open** and **Save** commands of the OMNI Smart Programmer application read and write data from and to **.**tip files. As such, the OMNI Smart Programmer application can also be used as an editor of standards.

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

4.5.1   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 <u>blue</u> 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 <u>black</u>, and the name of the standard file appears in the **Title Bar**.

4.5.2   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**.

4.6   Loading And Exporting Information

4.6.1   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.

4.6.2 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.

4.7 Log And ECG Recording

4.7.1 Log

The OMNI Smart Programmer application 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 application 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:

  o If an **Interrogation** or **Programming** event is chosen, the parameter values displayed by the OMNI Smart Programmer application are the set of values present at the moment the selected event occurred.

  o 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.

4.7.2 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 4.12 for more information on Markers.)

The recorded ECG segments are displayed in the Marker Window.

4.8 Emergency Programming

In an emergency, the OMNI II Programmer (with OMNI Smart Software) 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).

4.8.1 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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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 application 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 II Programmer (with OMNI Smart Software) System.

4.8.2   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:

   o Pressing the **Emergency Programming** button on the Programmer Wand, or

   o Selecting the **Urgent** button on the **Tool Bar**, or

   o 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 Programmin**g 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.

4.9   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 application under physician supervision.

Note: This feature is useful for turning off CCM™ signal delivery when an OMNI II Programmer (with OMNI Smart Software) 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 II Programmer with OMNI Smart Software).

4.10 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 application under physician supervision.

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 application, 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.

4.11 Initiating CCM™ Delivery

4.11.1 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.
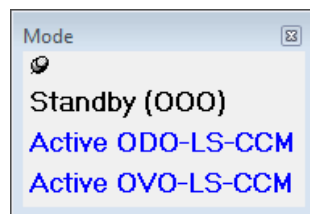
Figure 67: Mode Pop-up Menu

The Operating Mode choices are:

- **Standby (OOO):** 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.

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- **Active OVO-LS-CCM:** The device uses only ventricular and local sense events as triggers for CCM™ signal delivery.

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:

  o Press the **Program** button on the Programmer Wand or

  o Select the **Program** button on the **Tool Bar**, or

  o Select the **Program** button on the **Programming Bar**

If the programming is successful, the OMNI Smart Programmer application 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.

4.11.2 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 68: 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.
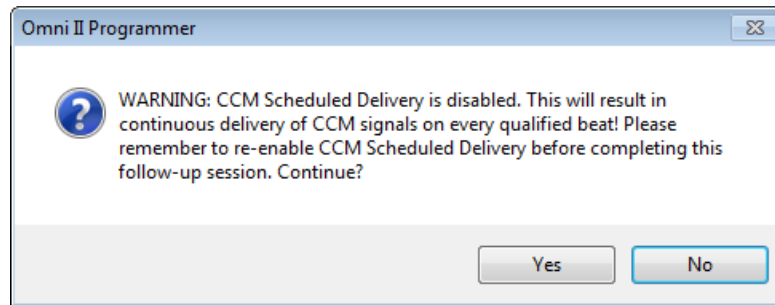
Figure 69: Continuous CCM™ Delivery Warning

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:

  o Press the **Program** button on the Programmer Wand or

  o Select the **Program** button on the **Tool Bar**, or

  o Select the **Program** button on the **Programming Bar**.

If the programming is successful, the OMNI Smart Programmer application 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.

4.12 Marker Events

The OMNI Smart Programmer application 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.

4.12.1 Turning Markers On

To set the OPTIMIZER Smart IPG in Marker Mode:

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- 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 application, 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.

4.12.2 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 application takes place (programming, reading statistics, measuring impedances, etc), the Marker Mode automatically ends and is re-established when the communication has finished.

4.12.3 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

4.12.4 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.

4.12.5 CCM™ Inhibit Conditions

Labels for the following events are displayed:

- **PVC**: two adjacent ventricular sensed events without an intervening atrial sensed event. (Active ODO-LS-CCM mode only)

- **AT**: Atrial rate above the atrial tachycardia rate limit. (Active ODO-LS-CCM mode only)

- **VT**: Ventricular rate above the ventricular tachycardia rate limit. (Active OVO-LS-CCM mode only)

- **A Noise**: Noise detected on the atrial sense channel. (Active ODO-LS-CCM mode only)

- **V Noise**: Noise detected on the ventricular sense channel.

- **Long AV**: Sensed AV interval exceeds "Long AV" limit. (Active ODO-LS-CCM mode only)

- **Short AV**: Sensed AV interval shorter than "Short AV" limit. (Active ODO-LS-CCM mode only)

4.12.6 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.

4.12.7 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.
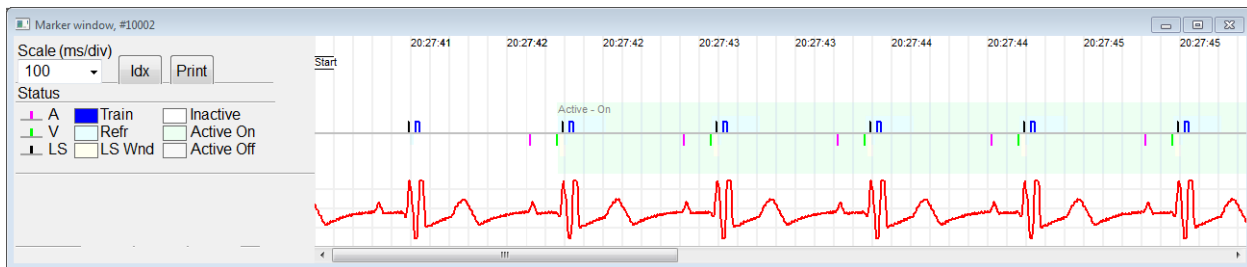
Figure 70: Marker Window

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.

4.13   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 <u>not</u> 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 application 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:
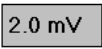
- **Start Time   0 h   0 m**

- **End Time   23 h   59 m**

- **On Time   1 h   0 m**

- **Off Time**   **2 h**   **25 m**
- **Scheduled**   **7 h**

4.14   Active OVO-LS-CCM Mode

4.14.1 Deactivated Parameters in Active OVO-LS-CCM Mode

When the OPTIMIZER Smart IPG is set to Active OVO-LS-CCM mode, the device no longer requires the detection of an atrial event in order to deliver cardiac contractility modulation therapy. Thus the parameters associated with atrium heart sensing and atrial events are deactivated.

Figure 71: Sensing Tab in Active OVO-LS-CCM Mode

Figure 72: A/V Setup Tab in Active OVO-LS-CCM Mode

Figure 73: Overview Tab in Active OVO-LS-CCM Mode

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Figure 74: A/V Tab in Active OVO-LS-CCM Mode

4.14.2 Parameter Modifications in Active OVO-LS-CCM Mode

Below is a list of parameters that are modified when the OPTIMIZER Smart IPG is set to Active OVO-LS-CCM:

- The display of PVC, AT, Long and Short AV flags in Marker Mode are disabled

- CCM Inhibit on PVC is disabled

- CCM Inhibit on Long AV is disabled

- CCM Inhibit on Short AV is disabled

- CCM Inhibit on Atrial Tachycardia is disabled

- CCM Inhibit on Ventricular Tachycardia is enabled, with a programmable range, but a maximum of 110 bpm

- The minimum right ventricle (V) sensitivity is limited to 1.0 mV

- The maximum CCM™ delay is limited to 45 ms

- The minimum LS sensitivity is limited to 1.0 mV

- The maximum LS Alert Window Width is limited to 30 ms

4.14.3 Marker Events in Active OVO-LS-CCM Mode

With the OPTIMIZER Smart IPG is set to Active OVO-LS-CCM in Marker mode, atrial events are ignored. As such, atrial event markers are not displayed in the ECG Window.
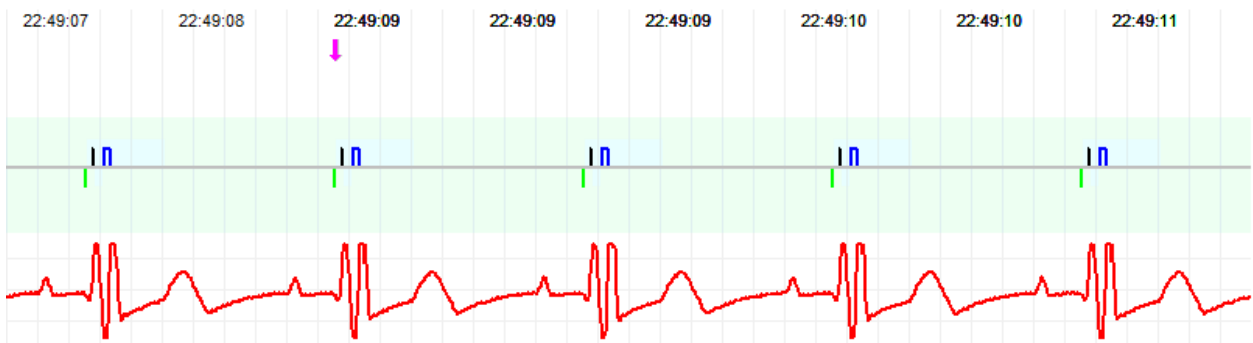
Figure 75: ECG Window in Marker Mode – Active OVO-LS-CCM Mode shown

4.15 Statistics

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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 application, and appears in the Statistics window of the OMNI Smart Programmer application, 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.

4.15.1 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.

4.15.1.1 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**
    - o **A Noise**: number of times atrial noise detected during scheduled CCM™ delivery
    - o **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 <u>not</u> 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 <u>not</u> to deliver cardiac contractility modulation therapy
- **Last Session**: Statistics for Last Delivery V, Last Delivery Trains, Percentage, and Battery Discharge Episodes.

4.15.1.2   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.

4.15.2 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.

4.16 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 application. 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.

4.17 Setting the Clocks On the OPTIMIZER Smart IPG and OMNI II Programmer (with OMNI Smart Software)

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.

4.17.1 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.
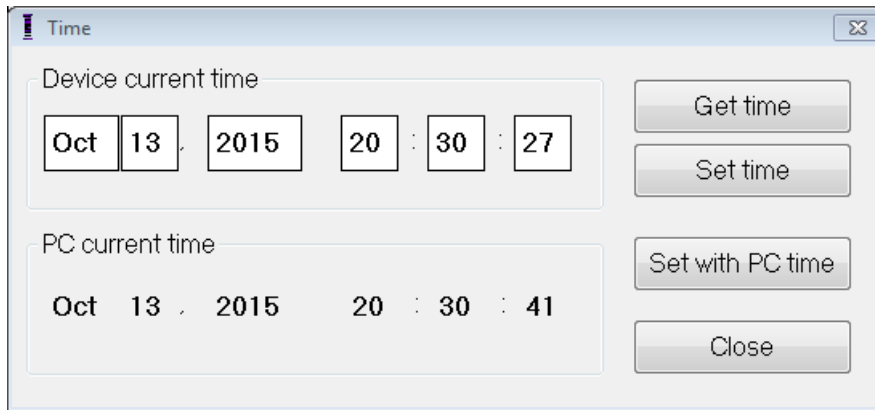
Figure 76: Time Window

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.

4.17.2 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.

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- 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.

4.17.3 Setting the OMNI II Programmer (with OMNI Smart Software) Clock

To set the system time of the OMNI II Programmer (with OMNI Smart Software):

- 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 II Programmer (with OMNI Smart Software) time. The current system date is highlighted.
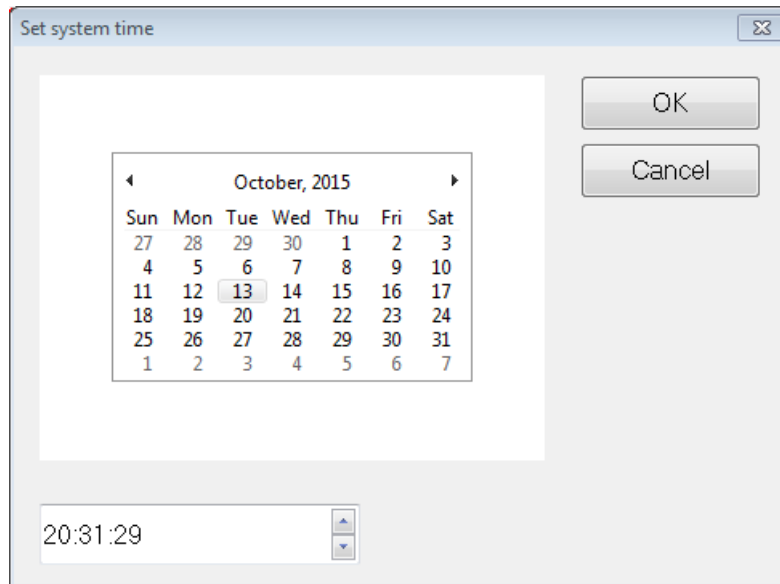
Figure 77: Set system time Window

- 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**.

4.18 OPTIMIZER Smart IPG Alarms Reported to the OPTIMIZER Mini Charger

4.18.1 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 7.6.5).

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:

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- 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.

4.18.2 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 application 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 7.6.2).

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.

4.19 Local Sense (LS) Scan

The OMNI Smart Programmer application 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.
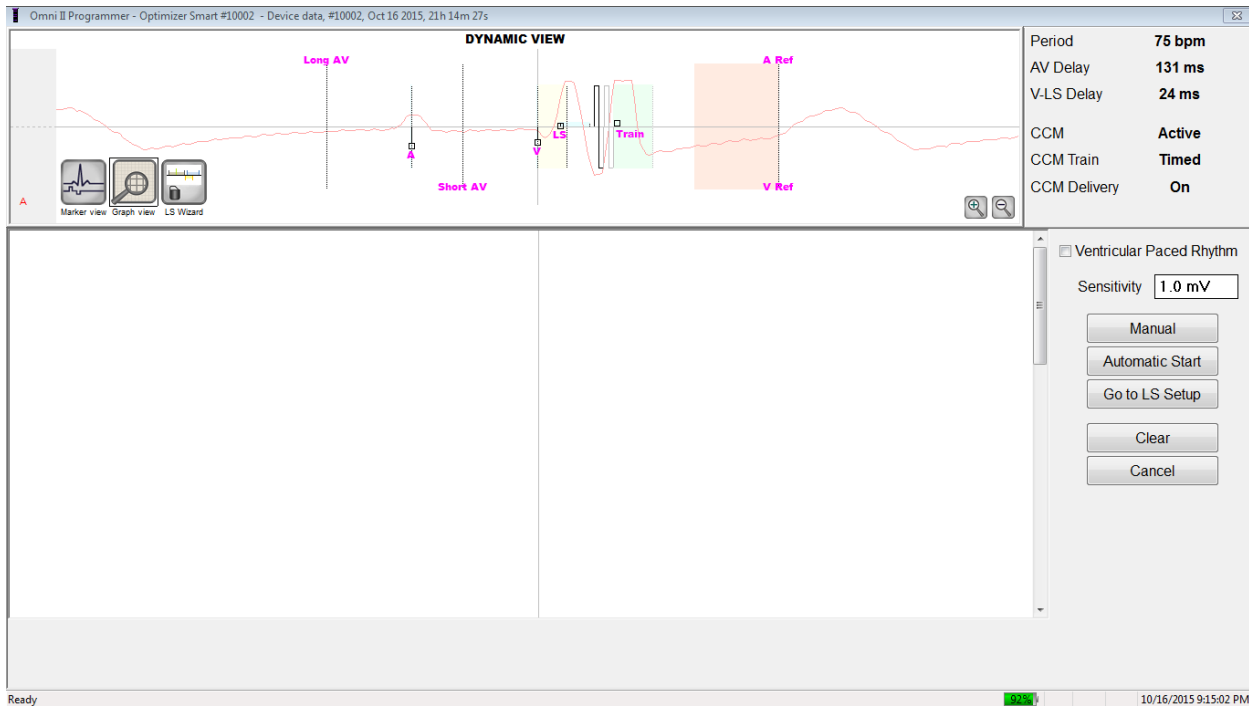
Figure 78: LS Scan Screen

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 application 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 50**, an appropriate value for the LS Sensitivity parameter would be 1.7 mV.

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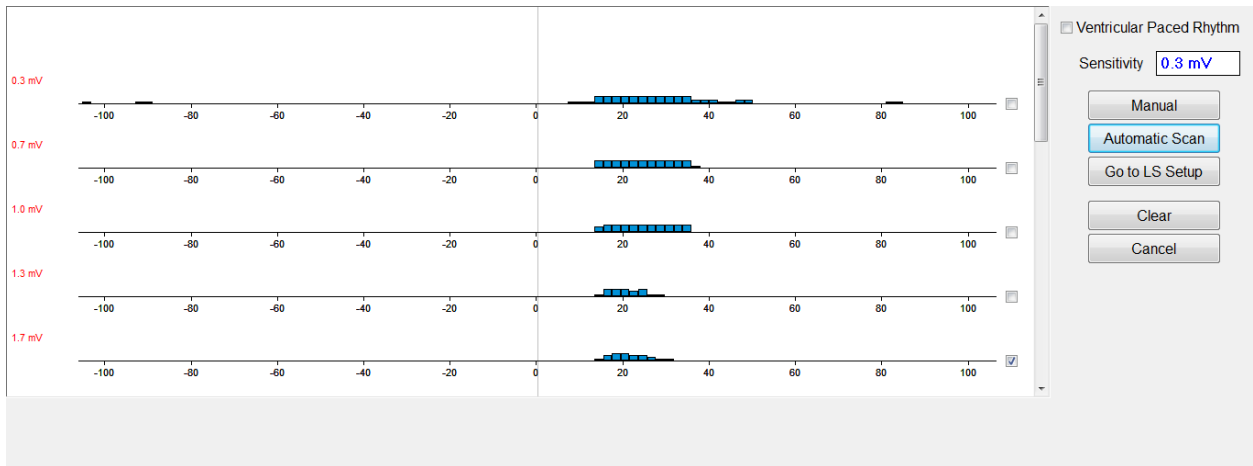
Figure 79: Local Sense Scan Screen after Automatic Scan

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 application 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 application 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 80: LS Setup Screen after Selection of Propose LS Button

4.20   Crosstalk Test

The OMNI Smart Programmer application 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.

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4.21   Remote Operation

The OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) must be connected to the Internet. The OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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

4.21.1   Connecting the OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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.

4.21.2   Connecting the OMNI II Programmer (with OMNI Smart Software) to a Wireless Network

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

4.21.2.1 OMNI II Wireless Network Configuration

At the Selector screen, click the "Configuration" button. The Configuration Dialog window will appear.
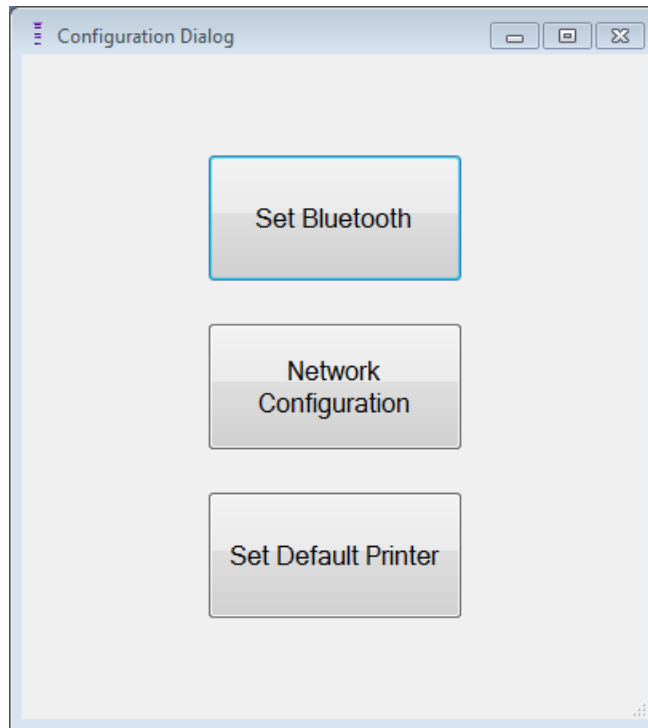
Figure 81: Configuration Dialog Window

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 II Programmer (with OMNI Smart Software).
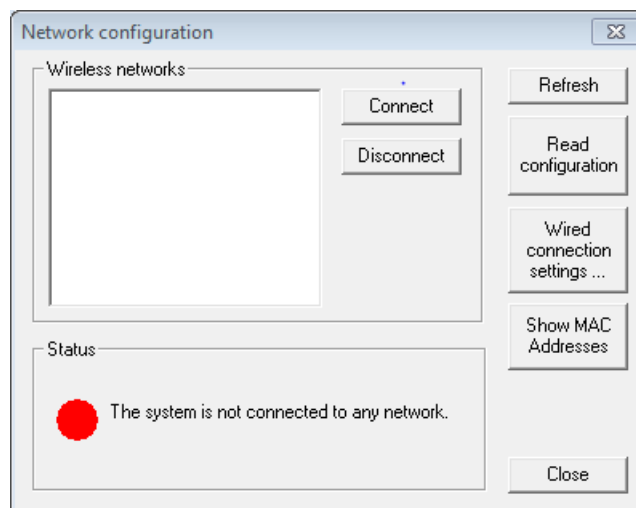
Figure 82: Network Configuration Window

The Network configuration window displays the following information:

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- 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 II Programmer (with OMNI Smart Software) is connected to that network).
- Status: status of the connection. A red circle with the message "The system is connected to the internet but cannot reach the server IP address (40.114.12.242)." will be displayed if the OMNI II Programmer (with OMNI Smart Software) is connected to the internet, while a red circle with the message "The system is not connected to any network." indicates that some problem is preventing the programmer from connecting to the internet.
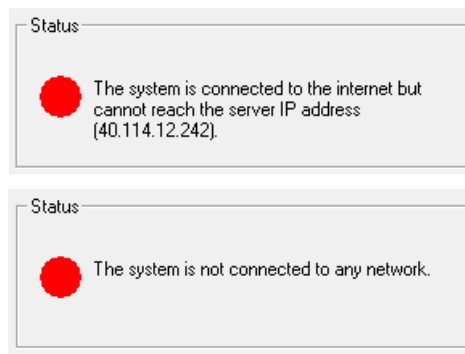
Figure 83: OMNI II Network Status Indicators

4.21.2.2   OMNI II 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.

4.21.3 OMNI Smart Software Operation Modes

4.21.3.1   OMNI Smart Startup Modes

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

- **Clinical Mode:** for local operation in a clinical setting
  - o 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 application in a clinical setting
  - o 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 application in a clinical setting
  - o A particular case of Remote Mode in which the OMNI Smart Programmer application 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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software).

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– 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 4.21.5) 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.

4.21.3.2   OMNI Smart Master/Slave Modes

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

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

4.21.4 OMNI II Programmer Client Window

Note: In order to connect the OMNI Smart Programmer application to the OMNI Remote Server, the OMNI Smart Programmer application must first be connected to Internet. See Sections 4.21.1 and 4.21.2 on ways to connect the OMNI II Programmer (with OMNI Smart Software) 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**.
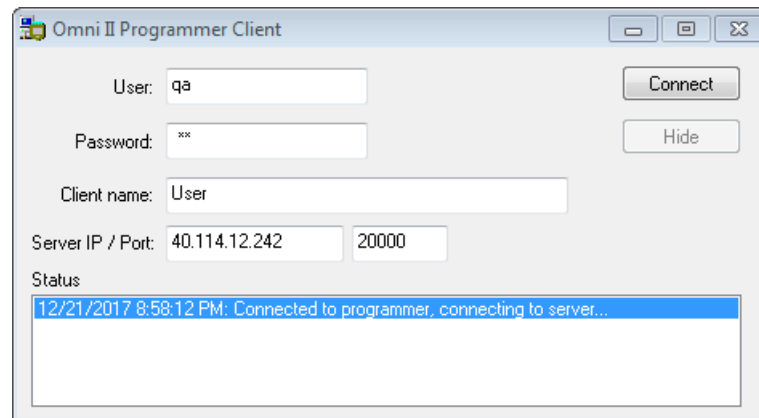
Figure 84: OMNI II Programmer Client Window

4.21.4.1   Connecting the OMNI II Programmer (with OMNI Smart Software) to the Remote Server

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

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

Note: When connecting to the Remote Server for the first time, delete the existing User, Password, and Client Name and type in the User, Password, and Client Name assigned to you by Impulse Dynamics.

- **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 II Programmer (with OMNI Smart Software). 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 to the current IP address when the OMNI II Programmer (with OMNI Smart Software) is shipped but is subject to change after you receive your programmer. When this change occurs, you will be notified by Impulse Dynamics and be given information regarding the new IP address to be used to connect to the OMNI Remote Server.)

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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) connected to the Internet can initiate pairing with the Clinical OMNI II Programmer (with OMNI Smart Software) at the requesting clinic.

- If internet connectivity is interrupted during the remote session, the Local (Slave) OMNI Smart Programmer application 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 application will automatically revert to Master mode after 5 consecutive failed retry attempts on any communication order.

- The local (Slave) OMNI Smart Programmer application will also revert to Master mode after pressing the 'Urgent' Programming button on the OMNI II Programmer Wand.

4.21.4.2   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**.

4.21.5 Starting a Remote Session with the OMNI Smart Programmer Application

To start a remote session with the OMNI Smart Programmer application, 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 II Programmer (with OMNI Smart Software) to the Internet via an Ethernet or wireless network connection.

To start a remote session:

- Start the Clinical Programmer in **Clinical Mode**

  o Select the **Remote** button on the **Task Bar.**

  o Select the **Connect** button on the **Tool Bar**.

  o 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**

  o Select the **Remote** button on the **Task Bar.**

  o Select the **Connect** button on the **Tool Bar**.

  o When the Omni II Client window appears, enter the User name, password, and Client name in the appropriate spaces and then select **Connect**.

  o 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 application 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)"**

4.21.6 Ending an OMNI Smart Programmer Application's Remote Session

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

In order to terminate an OMNI Smart Programmer application's remote session:

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

4.21.7 Sending a Chat Message Using the OMNI Smart Programmer Application

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.
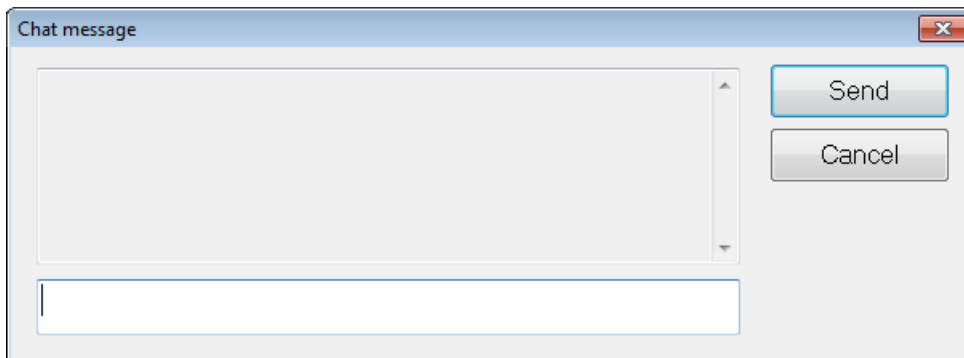
Figure 85: Chat message Window

4.21.8 OMNI II Log Upload/Download

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

4.21.8.1 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**.
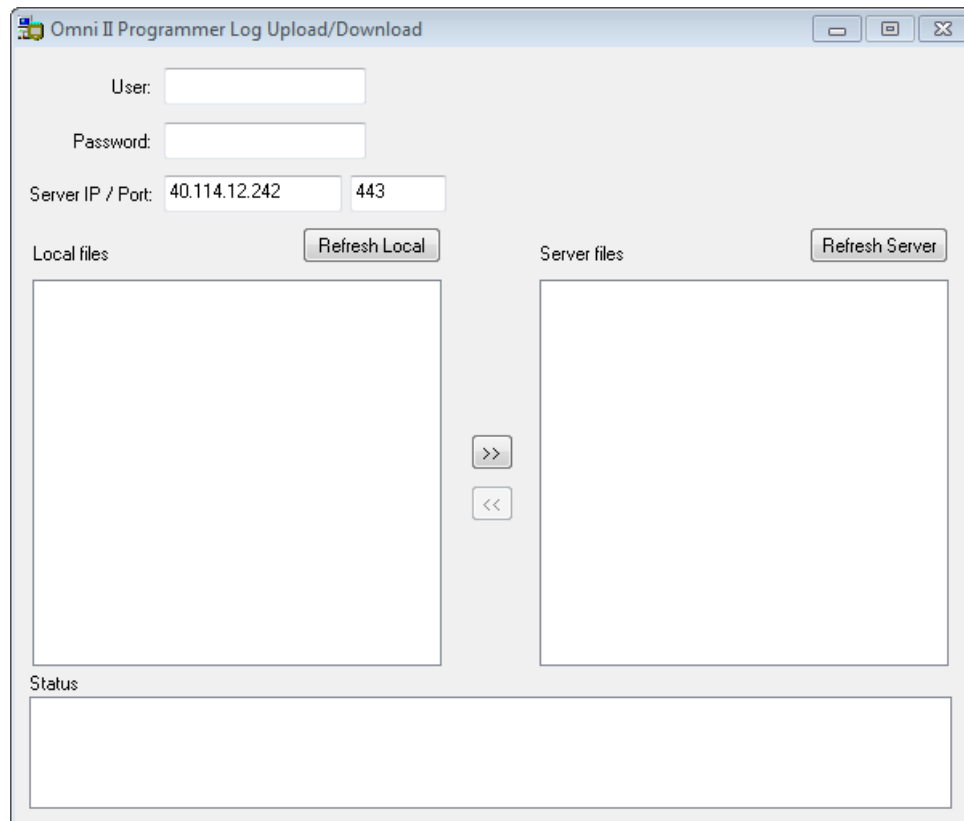
Figure 86: Omni II Programmer Log Upload/Download Window

4.21.8.2 OMNI II Refresh Local

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

4.21.8.3 OMNI II Refresh Server

In order to display the log files stored on the server, the OMNI II Programmer (with OMNI Smart Software) must first be connected to Internet. See Sections 4.21.1 and 4.21.2 on ways to connect the OMNI II Programmer (with OMNI Smart Software) 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 to the current IP address when the OMNI II Programmer (with OMNI Smart Software) is shipped but is subject to change after you receive your programmer. When this change occurs, you will be notified by Impulse Dynamics and be given information regarding the new IP address to be used to connect to the OMNI Remote Server..)

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.

4.21.8.4   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 software is operating in Clinical Mode.

4.21.8.5   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 software is operating in Remote Mode.

5.   BLUETOOTH PRINTER

5.1   Description

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

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

5.2   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.

5.3   Set Bluetooth

Note: The steps for pairing of a replacement Zebra Bluetooth printer is applicable for model MZ 320 Zebra Bluetooth printers only. It <u>does not</u> apply to model iMZ320 Zebra Bluetooth printers.

The pairing of the Zebra Bluetooth printer provided with the OMNI II Programmer (with OMNI Smart Software) has already been done prior to shipment. However if a replacement Zebra Bluetooth printer must be paired with the OMNI II Programmer (with OMNI Smart Software), 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.
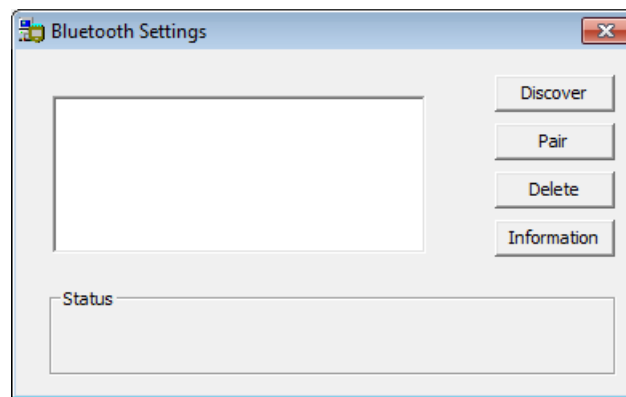
Figure 87: Bluetooth Settings Window

- 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.

5.4   Set Default Printer

To set the default printer for the OMNI II Programmer (with OMNI Smart Software):

- 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.
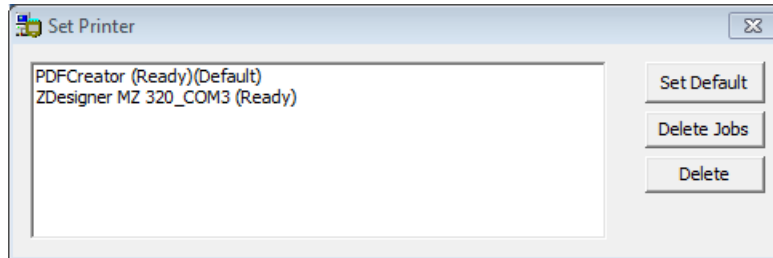
Figure 88: Set Printer Window

- 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.

6.   LOG FILE MANAGER

The Log File Manager allows the user to copy and delete log files stored on the OMNI II Programmer (with OMNI Smart Software).

To copy and delete the stored log files:

- At the Selector screen, click the **Log File Manager** button. The Insert Password window will appear.
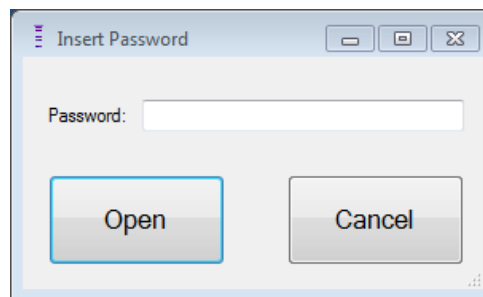
Figure 89: Log File Manager Window

- Enter the password *MountLaurel*.

- Click the **Open** button. The Log File Manager 2.0 window will appear.
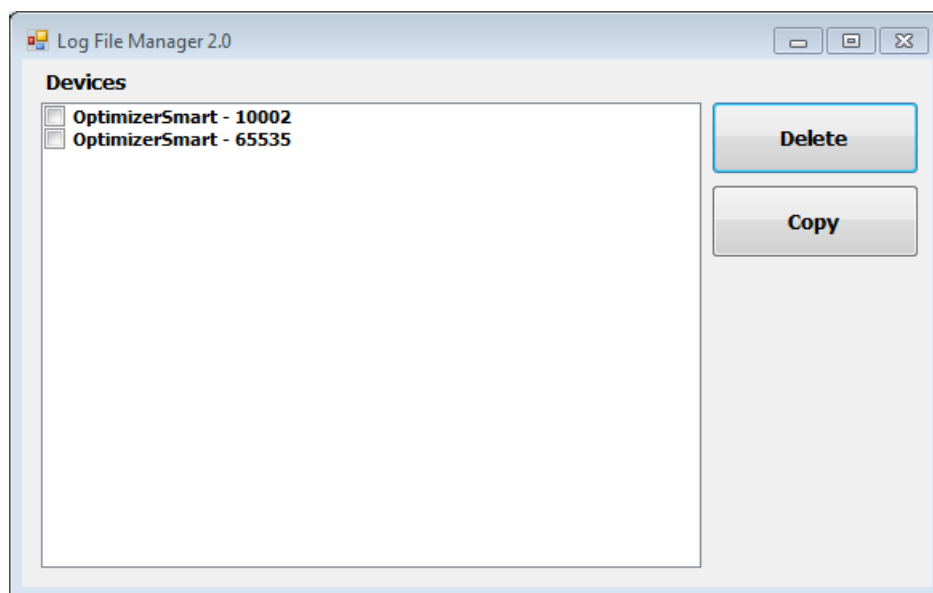
Figure 90: Log File Manager 2.0 Window

- To Delete files:

  o Select the check box to the left of the file name of each file to be deleted.

  o Click the **Delete** button.

  o When the Warning window appears, click **Yes** to confirm the file deletion.

  o Click on the X to close the Log File Manager 2.0 window.

- To Copy files:

  o Select the check box to the left of the file name of each file to be copied.

  o Insert a USB Flash drive into the USB port of the OMNI II Programmer (with OMNI Smart Software)

  o Click the **Copy** button.

  o Wait for the pop-up Information window to appear stating **Copy completed** and then click **OK**.

  o Click on the X to close the Log File Manager 2.0 window.

7. OPTIMIZER MINI CHARGER

7.1 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 (Mascot or 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 91: OPTIMIZER Mini Charger with AC Adapter

7.1.1 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)

7.2 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
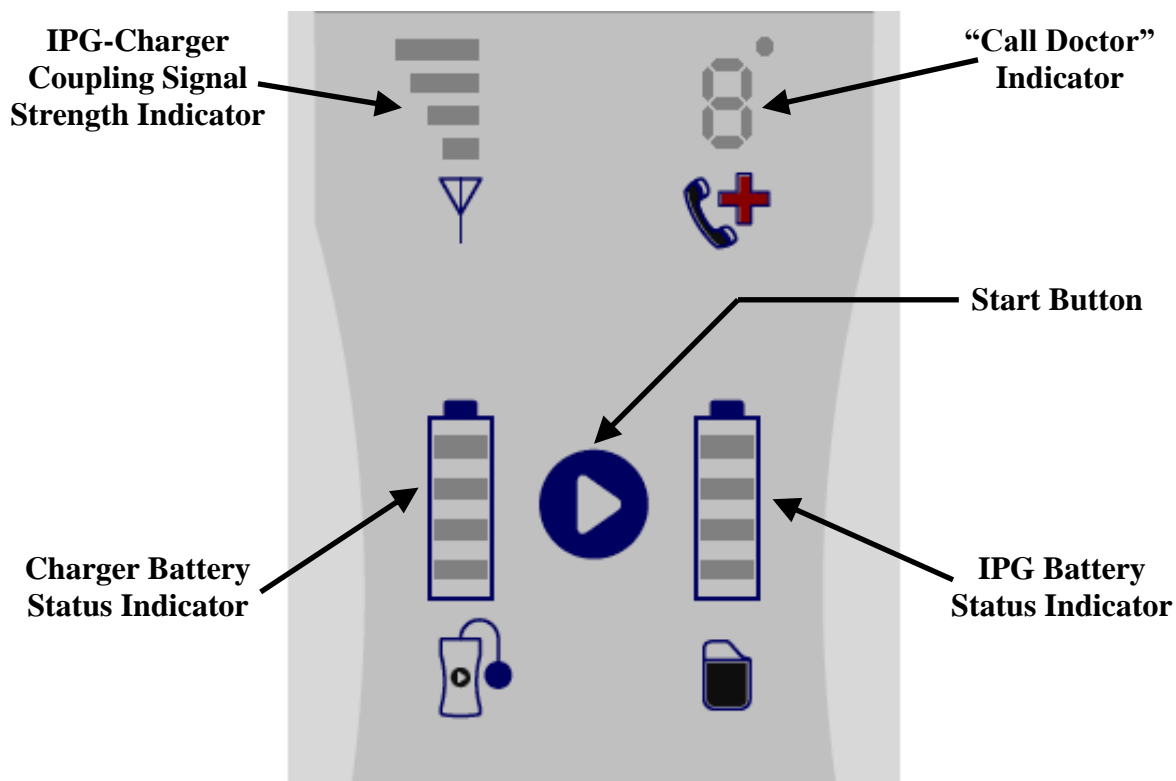
Figure 92: OPTIMIZER Mini Charger Features

7.3 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.

7.4 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: 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.

7.5   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.

7.6   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 7.6.1)	YES (see Note1,2)
1	Markedly changed lead impedance (see Section 7.6.2)	NO
2	Therapy suspended (see Section 7.6.3)	NO
3	No cardiac contractility modulation therapy delivery programmed (see Section 7.6.4)	NO
4	cardiac contractility modulation therapy rate low (see Section 7.6.5)	NO
5	High initial IPG temperature (see Section 7.6.6)	YES (see Note1,2)
6	Internal charger fault (see Section 7.6.7)	YES (see Note1)
7	Implant is not an OPTIMIZER IVs or OPTIMIZER Smart IPG (see Section 7.6.8)	YES (see Note1)
8	Problem related to profoundly discharged battery (see Section 7.6.9)	YES (see Note1)

7.6.1 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.

7.6.2 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.

7.6.3 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.

7.6.4 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.

7.6.5 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.

7.6.6 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 39°C. 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.

7.6.7 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.

7.6.8 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.

7.6.9 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.

7.7 Cleaning

The OPTIMIZER Mini Charger should <u>only</u> 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.

7.8   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.

7.9   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) -20°C to +60°C, (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 27°C. In addition, the recommended conditions for use are relative humidity between 20% and 75%, and atmospheric pressure between 700 hPa and 1060 hPa.

Warning: The OPTIMIZER Mini Charger shall not be used on board an airplane, and that the crew be asked prior to being used on a ship.

7.10   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.

APPENDIX I

Electromagnetic interference information (Table 1 of 5):

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The OPTIMIZER Smart System (the OMNI II Programmer with OMNI Smart Software 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 II Programmer with OMNI Smart Software.)			
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 II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) or OPTIMIZER Mini Charger requires uninterrupted operation during power mains interruptions, it is recommended to power the OMNI II Programmer (with OMNI Smart Software) 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 5):

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE OMNI II PROGRAMMER (WITH OMNI SMART SOFTWARE)			
The OMNI II Programmer (with OMNI Smart Software) is intended for use in an electromagnetic environment as specified below. The customer or user of the OMNI II Programmer (with OMNI Smart Software) 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: $\pm$ 2 kV, $\pm$ 4 kV, and $\pm$ 6 kV; contact discharge: $\pm$ 2 kV, $\pm$ 4 kV, and $\pm$ 6 kV; air discharge: $\pm$ 2 kV, $\pm$ 4 kV, and $\pm$ 8 kV	Indirect application: $\pm$ 2 kV, $\pm$ 4 kV, and $\pm$ 6 kV; contact discharge: $\pm$ 2 kV, $\pm$ 4 kV, and $\pm$ 6 kV; air discharge: $\pm$ 2 kV, $\pm$ 4 kV, and $\pm$ 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	$\pm$1 kV for in- and output lines (Ethernet)	$\pm$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 5):

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (133)			
The OMNI II Programmer (with OMNI Smart Software) 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	Portable and mobile RF communications equipment should not be used any closer to any part or cable of the OMNI II Programmer (with OMNI Smart Software) or OPTIMIZER Mini Charger than the recommended separation distance calculated from the equation for the respective transmitter frequency. **Recommended separation distance** $d = 1.17 \sqrt{P}$
Radiated RF as defined in IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz[1] $d = 0.70 \sqrt{P}$ 800 MHz to 2.5 MHz "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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:

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.

[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 II Programmer (with OMNI Smart Software) is used exceeds the applicable RF compliance level above, the OMNI II Programmer (with OMNI Smart Software) should be monitored to ensure normal operation. If abnormal function is observed, additional measures may be necessary, such as relocating the OMNI II Programmer (with OMNI Smart Software).

[b] For frequencies in the range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Electromagnetic interference information (Table 4 of 5):

Recommended separation distances between portable and mobile RF communications equipment and the OMNI II Programmer (with OMNI Smart Software) or OPTIMIZER Mini Charger			
Both the OMNI II Programmer (with OMNI Smart Software) and the OPTIMIZER Mini Charger should be used in an electromagnetic environment with limited radiated RF noise. The customer or user of the OMNI II Programmer (with OMNI Smart Software) 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 II Programmer (with OMNI Smart Software) 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.

Electromagnetic interference information (Table 5 of 5):

Compliance with the Radio Equipment Directive (RED) (2014/53/EU)	
The OMNI II Programmer (with OMNI Smart Software) complies with the Radio Equipment Directive (RED) (2014/53/EU).	
Applicable standard	**Compliance requirements**
ETSI EN 302 195 v2.1.1 (2016-06) EN 60601-1-2[1]	Radiated H Field (normal and extreme conditions)
	Spurious emissions (radiated), (transmitter)
	Frequency range of the modulation (normal and extreme conditions)
	Spurious Radiation (receiver)

[1]Compliance is claimed to EN 60601-1-2 rather than the two harmonized standards (ETSI EN 301 489-1 and ETSI EN 301 489-31). This is due to the fact that not all sections of the ETSI standards are applicable and those that are applicable are covered by testing performed in EN 60601-1-2 which uses equivalent test methods and performance criteria which are as restrictive as or even more restrictive than those in ETSI EN 301 489-1 and ETSI EN 301 489-31.

APPENDIX II

Communications/Telemetry

Between the OPTIMIZER Mini IPG and the OMNI II Programmer:

- **OPTIMIZER Mini IPG to OMNI II Programmer:**
  - PPM: "0" = 180 μs, "1" = 270 μs
  - 14.5 kHz LC excited by pulse
  - 1 cycle per pulse until dampened to 10%
  - Energy invested per pulse 0.36 μJ → 5.14 mW$_{peak}$ per pulse; 1.8 mW$_{average}$
- **OMNI II Programmer to OPTIMIZER Mini IPG:**
  - AM: "0" = no carrier, "1" = carrier for 305 μs
  - 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 Mini IPG (i.e. OPTIMIZER Smart IPG or OPTIMIZER IVs 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. Activate cardiac contractility modulation therapy and program the sensing windows of the OPTIMIZER Mini IPG to consistently delivery cardiac contractility modulation therapy in the presence of the concomitant device.

3. Extend the CCM™ Train Delay repeatedly and observe the real-time intracardiac electrograms (ICD-EGM) to determine the maximum amount of CCM™ Train Delay allowed before the ICD begins to inappropriately sense the cardiac contractility modulation therapy pulses as R waves.

4. Document the maximum CCM™ Train Delay.

5. Reprogram the CCM™ Train Delay to the pre-test value.

6. Document reprogramming of the CCM™ Train Delay with a parameter printout of the IPG setting.

7. Reprogram the ICD so that it is able to deliver antitachycardic therapy.

8. Document reactivation of the antitachycardic therapy with a parameter printout of the ICD setting.