



# **Intelio Programmer System**

## **INSTRUCTIONS FOR USE**



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The Intelio Programmer conform to the essential requirements of the Radio Equipment Directive (RED) 2014/53/EU.

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The OPTIMIZER Smart Mini 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 documentation provided completely before you use the device.**

**NOTICE:** Any serious incident should be reported to the manufacturer Impulse Dynamics by emailing [QualityComplaints@impulse-dynamics.com](mailto:QualityComplaints@impulse-dynamics.com). According to MDR 2017/745, a 'serious incident' means any incident that directly or indirectly led, might have led, or might lead to any of the following:

- a) The death of a patient, user, or other person,
- b) The temporary or permanent serious deterioration of a patient's, users, or other person's state of health. A serious deterioration in the health of the subject, that resulted in any of the following:
  - i. Life-threatening illness or injury,
  - ii. Permanent impairment of a body structure or a body function,
  - iii. Hospitalization or prolongation of patient hospitalization,
  - iv. Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or body function,
  - v. Chronic disease,
- c) A serious public health threat. A public health threat is an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.



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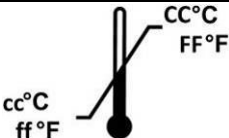











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## EXPLANATION OF SYMBOLS ON LABELS

Symbol	Description
	CE Conformity marking, 0344 - Notified Body Number
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Consult instructions for use
	Do not use if package is damaged
	Storage and transport temperature limits
	Date of manufacture
	Manufacturer
	Authorized representative in the European Community
	Catalogue number
	Serial number
	Refer to instruction manual/booklet
	Caution, consult instructions for use
	Item not to be disposed via the municipal waste collection system of any member state of the European Union
	Class II equipment
	Type BF applied part
	Defibrillation-proof type CF applied part

Symbol	Description
	Non-ionizing electromagnetic radiation
	Legacy Programming Wand Power Indicator
	Legacy Programming Wand Interrogation
	Legacy Programming Wand Programming



# 1.0 THE INTELIO PROGRAMMER SYSTEM

## 1.1 Description

The Intelio Programmer System allows the clinician to interrogate and program the OPTIMIZER Smart Mini IPG. The programmer software runs on a touch screen tablet PC with an attached Intelio Programming Interface. Communication between the Programming Interface and the OPTIMIZER Smart Mini IPG is accomplished using the Intelio Programming Wand. The Intelio Programming Wand first uses short-range communications to establish a link with the OPTIMIZER Smart Mini IPG and then long-range RF communications for all subsequent exchanges of information. Understanding the instructions in this manual on how to operate the Intelio Programmer System is essential to the proper operation of the OPTIMIZER Smart Mini IPG.

The Intelio Programming Interface is classified as Class II equipment. The Programming Wand Port is classified as a Type BF applied part and the ECG Port is classified as a defibrillation-proof Type CF applied part.

The Intelio and Legacy Programming Wands are classified as Class II equipment and a Type BF applied part.

**Warning:** The Intelio Programmer System may be subject to interference from other electrical devices operated in the vicinity. Portable and mobile RF equipment are especially likely to impair the normal function of the programmer. If the Intelio Programmer is not operating as expected, such interference must always be taken into account. Other equipment can also interfere with the Intelio Programmer.



Figure 1: Intelio Programmer System

## 1.2 Programmer Functions

The functions performed by the Intelio Programmer include the following:

- Read (interrogate) OPTIMIZER Smart Mini IPG parameters as currently programmed
- Modify and program OPTIMIZER Smart Mini IPG parameters
- Display the patient's ECG and IEGM and display markers for analysis
- Retrieve statistics accumulated by the OPTIMIZER Smart Mini IPG as it operates
- Log the activity of the OPTIMIZER Smart Mini IPG
- Store standard programs for future use
- Monitor activity level of patient
- Enable Patient Alerts to be displayed by Vesta Charger

## 1.3 Programmer Components

The Intelio Programmer System consists of:

- Intelio Programmer
  - Intelio Programmer Tablet PC installed with the Optimizer SM Software Application
  - Intelio Programming Interface
- Intelio Programming Wand
- Legacy Programming Wand
- Single-lead (3-wire) ECG cable
- Charger Bootstrap Cable (used for updating the firmware of the Vesta Charger)
- Medical-grade Power Supply
- Power Cord

**Warning:** Use of items other than those identified above or in a manner not in accord with these instructions may cause damage to the Intelio Programmer.

## 1.4 Interconnecting the Programmer Components for Operation

To begin using the Intelio Programmer System with the OPTIMIZER Smart Mini IPG, connect the following components:

- Plug the LEMO connector of the Intelio Programming Wand into the gray-ringed port on the right side of the Intelio Programming Interface.
- Plug the LEMO connector of the ECG cable into the blue-ringed port on the left side of the Intelio Programming Interface.

**Warning:** Do not attempt to directly connect any line-powered device (e.g., using a USB cable to connect to a printer) to the Intelio Programmer. This may create an electrical safety hazard for the patient.

## 1.5 Intelio Programming Wand

The Intelio Programming Wand has a 3 m  $\pm$  0.05 m (10 ft  $\pm$  2 in) long cable and is used to communicate with the OPTIMIZER Smart Mini IPG.

### 1.5.1 Short-range Communication

Short-range communication is used when the Intelio Programming Wand first establishes a link between the Intelio Programmer and the OPTIMIZER Smart Mini IPG. This communication includes the exchange of an encryption key.

- Frequency: 13.56 MHz  $\pm$  100 ppm
- Distance: 5 to 40 mm (with the bottom of the wand placed directly over the IPG)

### 1.5.2 Long-range Communication

Long-range communication is used after the Intelio Programming Wand has established a link between the Intelio Programmer and the OPTIMIZER Smart Mini IPG. This communication involves the transfer of encrypted data.

- Frequency: 402 MHz to 405 MHz (MedRadio)
- Distance: 0 to at least 1.5 m (5 ft)

## 1.6 Legacy Programming Wand

The Legacy Programming Wand has a 3 m  $\pm$  0.05 m (10 ft  $\pm$  2 in) long cable and is used to communicate with the OPTIMIZER Smart and OPTIMIZER IVs IPG (when the Intelio Programmer is loaded with the device-specific programmer applications).

### 1.6.1 Legacy Programming Wand Buttons

The Legacy Programming Wand has two buttons:

- Interrogate
- Program

### 1.6.2 Legacy Programming Wand Indicator Lights

The Programming Wand also has two different sets of indicator lights:

- The Power indicator light, located to the left of the power symbol, is illuminated when the Programming Wand is powered.
- The bar graph indicator lights display the strength of the telemetry signal between the Programming Wand and the OPTIMIZER Smart IPG.

## 1.7 Charging the Battery of the Intelio Programmer Tablet PC

**Warning:** Only charge the Intelio Programmer tablet PC battery with the medical-grade power supply provided with the Intelio Programmer System. Do not attempt to recharge the tablet PC's battery with any other power supply.

To charge the battery of the Intelio Programmer Tablet PC, perform the following steps:

1. Flip open the protective cover of the power input connector on the Tablet PC (located at the bottom left of the Tablet PC).
2. Plug the DC output connector of the medical-grade power supply into the power input connector on the Tablet PC.
3. Plug one end of the power cord into the 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 240 VAC, 50/60 Hz and that the receptacle has a properly grounded connection.

## 1.8 Buttons and Symbols on the Intelio Programmer Tablet PC

The Intelio Programmer tablet PC has three illuminated indicator lights and six buttons located on the right side of the tablet PC. They have the following functions (from top to bottom)

### 1.8.1 Indicator Lights

- Power – illuminated when the tablet PC is powered ON
- Battery Charging Status:
  - Not illuminated – tablet PC is operating on battery power
  - Illuminated – has two color states:
    - Amber – when the battery of the tablet PC is being charged
    - Green – when the battery of the tablet PC is fully charged
- WLAN / WI-FI – illuminated when the WI-FI is enabled

### 1.8.2 Buttons

- P1: non-functional
- P2: non-functional
- Windows: non-functional
- Volume +: non-functional
- Volume -: non-functional
- Power (green): used to power up and shut off tablet PC

## 1.9 Operating the Intelio Programmer

**Warning:** The Intelio Programmer shall not be used onboard aircraft without the prior consent of its crew.

The Intelio Programmer is configured to operate using either mains power from its medical-grade power supply or battery power from the Intelio Programmer tablet PC's battery.

**Note:** If the Intelio Programmer is to be used on battery power, fully charge its battery before using it during an implant procedure.

To power up the Intelio Programmer Tablet PC, perform the following steps:

1. Connect the Intelio Programming Wand LEMO-type connector into the gray-ringed port on the right side of the Intelio Programmer Interface.
2. Press the Power button on the right side of the tablet PC, hold the button down for 2 seconds, and then release it.
3. Verify that the Power indicator light is illuminated blue, indicating the Intelio Programmer has been turned ON.

When the Intelio Programmer has completed booting up, the Selector screen will be displayed on the tablet PC screen.

### 1.10 Using the Intelio Programmer Tablet PC Touch Screen

The Intelio 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.

**Warning:** DO NOT use sharp items or regular writing equipment (pen, pencil) on the touch screen of the tablet PC. Damage to the touch screen may result.

## 1.11 Using the Programming Wands

**Caution:** Due to the risk of cross-contamination, placement of a Programming Wand directly onto the patient's skin should be avoided.

### 1.11.1 Intelio Programming Wand

The Intelio Programming Wand must be kept directly over the patient's implant site while it is being used to establish a link between the Intelio Programmer and the OPTIMIZER Smart Mini IPG. Once the link with the OPTIMIZER Smart Mini IPG has been established, the Intelio Programming Wand may be removed from the patient's implant site and placed within 1.5 m (5 ft) away from the IPG.

### 1.11.2 Legacy Programming Wand

The Legacy Programming Wand must be kept directly over the patient's implant site while in use.

## 1.12 Routine Cleaning

**Warning:** **DO NOT** attempt to sterilize the Intelio Programmer or the Programming Wands because any such attempt could severely damage the equipment.

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

**Warning:** Always turn the Intelio Programmer off prior to cleaning.

Following each use, it is recommended that disinfecting wipes be used to clean the exterior of the Intelio Programmer, the ECG cables, and particularly the Programming Wands. Do not use solvents or cleaning cloths impregnated with chemical cleaning agents.

## 1.13 Maintenance

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

The Intelio Programmer tablet PC is powered by a battery that may need to be replaced if the battery fails to adequately maintain a charge or is unable to be fully charged. 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 accordance with local environmental requirements.

**Warning:** Never puncture or incinerate a used battery.

## 1.14 Storage and Handling

The Intelio Programmer and Programming Wands are designed to maintain functionality after they have been exposed to the following environmental extremes:

- Ambient Temperature: -20°C to +60°C (-4°F to 140°F)
- Relative Humidity: 10% to 100% (with or without condensation)
- Atmospheric Pressure: 50 kPa to 156 kPa (14.81 inHg to 46.20 inHg)

Recommended environmental conditions for normal use are the following:

- Ambient Temperature: 0°C to +55°C (32°F to +131°F)
- Relative Humidity: 20% to 75%
- Atmospheric Pressure: 70 kPa to 106 kPa (20.73 inHg to 31.39 inHg)

## 2.0 INTELIO PROGRAMMER SYSTEM SOFTWARE APPLICATION

The Intelio Programmer System includes a software application that is used to read and modify the parameters that control the OPTIMIZER Smart Mini IPG.

### 2.1 Selector Screen

When the Intelio Programmer is turned ON, the following buttons are displayed on the Selector Screen upon completion of the start-up sequence.

- **Optimizer SM:** This button opens the OPTIMIZER Smart Mini Programmer application.
- **System Admin:** This selection is password-protected and allows the user to access the operating system of the Intelio Programmer. It is to be used by Impulse Dynamics technical staff only and is not needed for regular clinical use.
- **Shutdown:** Selecting the red Shutdown button on the Selector screen shuts off the Intelio Programmer.

### 2.2 Basic Operation of the OPTIMIZER Smart Mini Programmer Application

After the **Optimizer SM** button has been selected from the Selector screen, the OPTIMIZER Smart Mini Programmer application is displayed on the Intelio Programmer. This application can be used to establish a communications link, interrogate, and program the OPTIMIZER Smart Mini IPG.

#### 2.2.1 Communication with the OPTIMIZER Smart Mini IPG

Before the clinician can use the Intelio Programmer to program the OPTIMIZER Smart Mini IPG, a communication link must first be established between the Intelio Programmer and the patient's device.

This is accomplished by first placing the Intelio Programming Wand directly over the patient's OPTIMIZER Smart Mini implant site (over the patient's clothes).

After the Intelio Programming Wand is placed over the patient's implant site, a communication link must be established by initiating the **Start OPTILink** command.

Once this communication link is established, the clinician can perform the various commands available in the OPTIMIZER Smart Mini Programmer application.

#### 2.2.2 Interrogation and Programming

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

The OPTIMIZER Smart Mini Programmer application can read the current programmed device values using the **Interrogate** command. This action is carried out automatically when a communication link has been established between the Intelio Programmer and the OPTIMIZER Smart Mini IPG. Thereafter, the **Interrogate** command can be issued again, if desired, to update the current status of the OPTIMIZER Smart Mini IPG (e.g., battery voltage, IPG state).

Whenever the **Interrogate** command is issued, the currently programmed device values are loaded and displayed on the OPTIMIZER Smart Mini Programmer application screen. The values displayed on the OPTIMIZER Smart Mini Programmer application screen are referred to as *parameter values*.

The clinician can review and modify the parameter values using the OPTIMIZER Smart Mini Programmer application. The modified parameter values can then be transmitted to the OPTIMIZER Smart Mini IPG using the **Program** command.

**Note:** The modified parameter values displayed on the programmer screen in blue 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 canceled using the **Undo** command. This command resets the device parameters to the previously programmed values.

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

The **Load Program** command of the OPTIMIZER Smart Mini Programmer application reads data from a standard (.mips) file. The **Save Program** command writes data to a standard (.mips) file. These commands allow the OPTIMIZER Smart Mini Programmer application to be used as an editor of standards (see Section 3.24).

### 2.2.3 Monitoring Tools

The Intelio Programmer System offers a Programming Interface with a built-in electrocardiography channel. The patient’s ECG is displayed in the upper portion of the ECG/IEGM/Marker pane on the OPTIMIZER Smart Mini 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.

When the CCM Therapy Mode of OPTIMIZER Smart Mini IPG is not set to OOO mode (Standby mode), the Intracardiac Electrogram (IEGM) and Event Markers are automatically enabled. “Markers” are flags representing the various states of the device and events detected during its operation. In this mode, all events detected and generated by the OPTIMIZER Smart Mini IPG are displayed in the **ECG/IEGM/Marker Pane** synchronized with the patient’s ECG.

- The OPTIMIZER Smart Mini IPG keeps a record of all the events and conditions that have occurred. These records can be downloaded from the OPTIMIZER Smart Mini IPG to the Intelio Programmer. The number of occurrences of each event can be viewed in the CCM Statistics window of the OPTIMIZER Smart Mini Programmer application (see Section 3.18).
- The OPTIMIZER Smart Mini Programmer application can be used to measure the impedance of the ventricular leads (see Section 3.15).
- The OPTIMIZER Smart Mini Programmer application keeps a log of all interactions with the OPTIMIZER Smart Mini IPG (see Section 3.25).

### 2.2.4 Closing the Programmer Application

Clicking the **Exit** button in the bottom right corner of the OPTIMIZER Smart Mini Programmer application screen will close the application. When the confirmatory pop window appears, click **Close** to return the Intelio Programmer to the Selector screen.

### 3.0 OPTIMIZER SMART MINI PROGRAMMER SOFTWARE

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

**Note:** Dates displayed by the OPTIMIZER Smart Mini Programmer application are in the following format (unless otherwise noted):

DD/MM/YYYY

Where:

- DD = day
- MM = month
- YYYY = year

#### 3.1 Overview of the OPTIMIZER Smart Mini Programmer Application

When the OPTIMIZER Smart Mini Programmer Software is started, the OPTIMIZER Smart Mini Programmer application displays the main screen, which includes the following:

- ECG/IEGM/Marker Pane
  - ECG Sub-pane
  - IEGM Sub-pane
  - Marker Sub-pane
- CCM Marker Legend
- OPTIlink Session Pane
- CCM Status Pane
- Programming Buttons Pane
- Mode Bar
- Status Bar



Figure 2: OPTIMIZER Smart Mini Programmer Application Main Screen



### 3.1.1 ECG/IEGM/Marker Pane

The ECG/IEGM/Marker pane has the following three sub-panes.

#### 3.1.1.1 Surface ECG Sub-Pane

**Warning:** The displayed ECG should not be used for clinical decision-making.

The Surface ECG Sub-pane is displayed at the top of the window. It shows the real-time ECG of the patient. It also contains a Marker button (displayed as **Stop Marker** or **Run Marker**) that allows the user to stop and start the running marker screen.

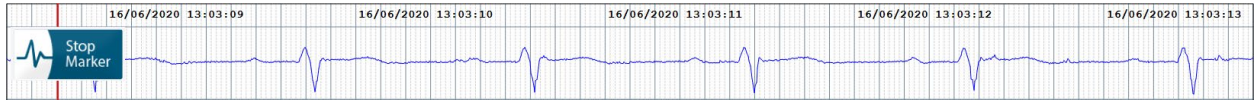


Figure 3: Surface ECG Sub-Pane

#### 3.1.1.2 IEGM Sub-Pane

The IEGM Sub-pane is displayed below the Surface ECG Sub-pane. When the OPTIMIZER Smart Mini IPG is not in OOO mode, it shows the far-field IEGM tracings obtained from the OPTIMIZER Smart Mini IPG, the markers for each active lead, the different events and conditions that may occur, and the CCM Status.

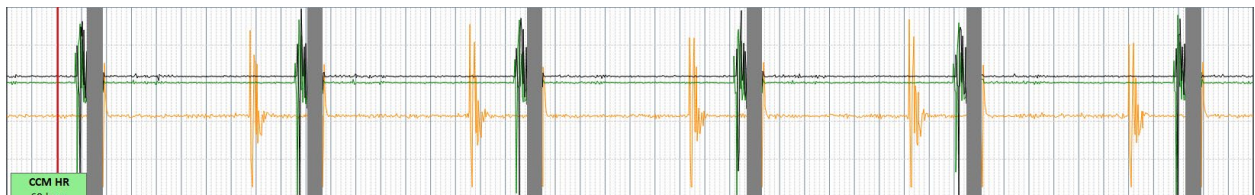


Figure 4: IEGM Sub-Pane

#### 3.1.1.3 Marker Sub-Pane

The Marker Sub-pane is displayed below the IEGM Sub-pane. When the OPTIMIZER Smart Mini IPG is not in OOO mode, it shows the markers for each active lead, the different events and conditions that may occur, and the CCM Status.

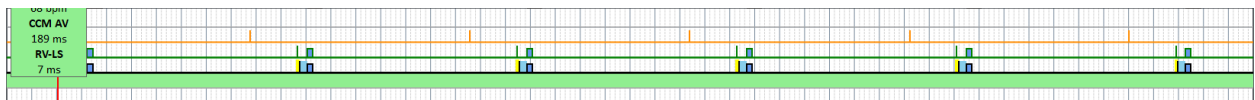


Figure 5: Marker Sub-Pane

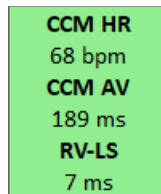
#### 3.1.1.4 CCM Real-Time Statistics Area

Within the ECG/IEGM/Marker pane is the CCM Real-Time Statistics Area. It displays the following real-time values:

- CCM HR: Heart rate sensed by the IPG in beats per minute (bpm)
- CCM AV: The interval between the atrial and RV sensed event in milliseconds (ms)

**Note:** "N/A" is displayed in OVO-LS-CCM mode

- RV-LS: The interval between the RV and LS sensed event in milliseconds (ms)

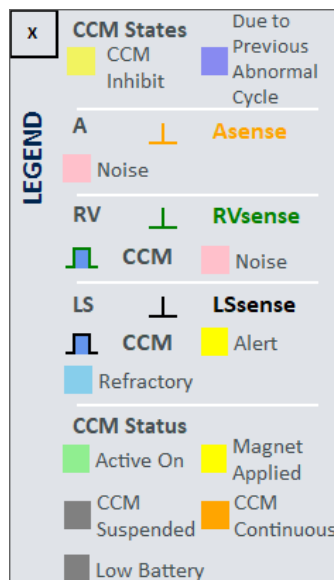


**Figure 6: ECG Statistics Bar**

The CCM HR, CCM AV, and RV-LS intervals change dynamically, showing the current reading for each value.

#### 3.1.2 Legend for ECG/IEGM/Marker Pane

The Legend for ECG/IEGM/Marker pane defines each marker that may appear in the ECG/IEGM/Marker pane.



**Figure 7: Legend for ECG/IEGM/Marker Pane**

### 3.1.2.1 CCM States

In Marker view, the CCM states are displayed as follows:

- **Yellow:** This is displayed when CCM is inhibited due to the following conditions (the specific cause is indicated within the yellow bar):
  - **Long AV:** Sensored AV interval exceeds “Long AV” limit (ODO-LS-CCM mode only).
  - **Short AV:** Sensored AV interval shorter than “Short AV” limit (ODO-LS-CCM mode only).
  - **A Noise:** Noise detected on the atrial sense channel (ODO-LS-CCM mode only).
  - **V Noise:** Noise detected on the ventricular sense channel
  - **AT:** Atrial rate above the atrial tachycardia rate limit (ODO-LS-CCM mode only).
  - **VT:** Ventricular rate above the ventricular tachycardia rate limit (OVO-LS-CCM mode only).
  - **LS Out of Alert:** Local sense (LS) event detected outside of the LS Alert window.
  - **PVC:** Two successive ventricular sensed events without an intervening atrial sensed event (ODO-LS-CCM mode only).
  - **ImpMeas:** If an impedance measurement is taken.
  - **Skipped Pulse:** A CCM therapy pulse could not be delivered due to exceptional timing conditions internal to the IPG
- **Dark Blue:** CCM is inhibited due to previously detected event (if the CCM inhibit cycle parameter is programmed to be greater than 1).

### 3.1.2.2 IEGM Markers

Each lead has its own IEGM Marker.

#### 3.1.2.2.1 A Channel

- **Orange:** Atrial sensed event
- **Pink:** Noise detected on the A channel

#### 3.1.2.2.2 RV Channel

- **Green:** Right Ventricular (RV) sensed event
- **Pink:** Noise detected on the RV channel
- **Blue Rectangle:** CCM pulse train delivered on the RV channel

**Note:** The width of the blue rectangle represents the duration of the CCM pulse train on the RV channel.

#### 3.1.2.2.3 LS Channel

- **Black:** Local Sense (LS) event
- **Yellow:** LS Alert Window
- **Light Blue:** LS Blanking Refractory Periods
- **Blue Rectangle:** CCM pulse train delivered on the LS channel

**Note:** The width of the blue rectangle represents the duration of the CCM pulse train on the LS channel.

### 3.1.2.3 CCM Status

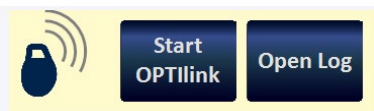
The CCM Status is displayed as follows:

- **Green:** CCM is Active and ON
- **Yellow:** Magnet is actively being applied to the OPTIMIZER Smart Mini IPG
- **Dark Gray:** CCM is suspended
- **Orange:** CCM is set to Continuous mode
- **Gray:** The battery voltage of the OPTIMIZER Smart Mini IPG is low

### 3.1.3 OPTlink Session Pane

When a communication link has not been established with the implanted device, the OPTlink Session Pane displays the following buttons:

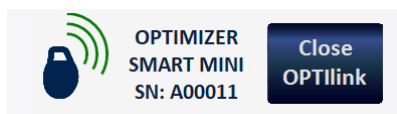
- **Start OPTlink:** Command button that begins the process of establishing a communication link between the Intelio Programmer and the OPTIMIZER Smart Mini IPG.
- **Open Log:** Command button that allows the user to open a log file of a previously interrogated OPTIMIZER Smart Mini IPG. When clicked, it displays a window showing the list of log files stored on the Intelio Programmer. Once a log file is selected, click the **Select** button to open the log file for the selected device.



**Figure 8: OPTlink Session Pane (not linked to IPG)**

Once a link has been established, the appearance of the OPTlink Session Pane changes and displays the following:

- **OPTlink Signal Strength Indicator:** Dynamically displays the quality of the link between the Intelio Programming Wand and the OPTIMIZER Smart Mini IPG. Depending on the quality of the link, waves of the Signal Strength Indicator are displayed in the following manner:
  - Good-quality link – 3 green signal waves
  - Medium-quality link – 2 yellow signal waves
  - Low-quality link – 1 red signal wave
- Device model
- Device serial number
- **Close OPTlink:** Command button that closes the communication link between the Intelio Programmer and the OPTIMIZER Smart Mini IPG.



**Figure 9: OPTlink Session Pane (good-quality link to IPG shown)**

### 3.1.4 CCM Status Pane

The CCM Status Pane shows the current status of the following parameters:

- Device Mode
- CCM Therapy Mode
- CCM Therapy Dosage

The CCM Status Pane also has a button that allows the user to suspend permanently and unsuspend CCM therapy. When the button is in its default “DISABLE CCM” state, clicking it permanently suspends CCM therapy and toggles the button to say “ENABLE CCM”. When the button is in its “ENABLE CCM” state, clicking it unsuspends CCM therapy and toggles the button back to display “DISABLE CCM”.

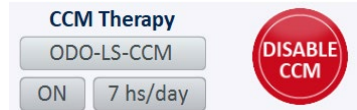


Figure 10: CCM Status Pane

### 3.1.5 Programming Buttons Pane

The Programming Buttons Pane contains the following command buttons:

- **Nominals:** Opens up a pop-up window asking the user to confirm reprogramming of the OPTIMIZER Smart Mini IPG with nominal values. If **Yes** is chosen, then the nominal values will be programmed into the OPTIMIZER Smart Mini IPG. If **No** is chosen, then the pop-up window closes.
- **Interrogate:** Reads the current parameter values of the OPTIMIZER Smart Mini IPG. These values become the parameter values displayed by the OPTIMIZER Smart Mini Programmer application.
- **Cancel:** When parameter values have been modified in the Intelio Programmer but not yet programmed into the OPTIMIZER Smart Mini IPG, it allows the user to discard the changes made to the parameter values. If no device was interrogated and data were loaded from a .mips file, the programmer parameters are set to the values defined in the file.
- **Undo:** When parameter values are modified and then programmed into the OPTIMIZER Smart Mini IPG, it allows the user to reprogram the OPTIMIZER Smart Mini IPG with the previously programmed values.
- **Program:** Transmits the current parameter values of the OPTIMIZER Smart Mini Programmer application to the OPTIMIZER Smart Mini IPG. This button is disabled when parameter modifications result in a parameter conflict.

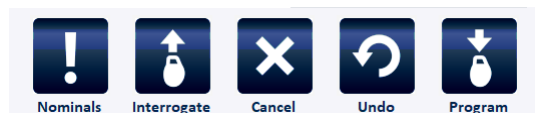


Figure 11: Programming Buttons Pane

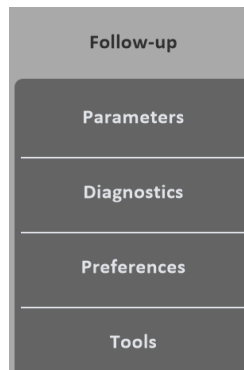
**Note:** When a command button appears grayed out on a **Programming Buttons Pane**, this indicates that the command is not currently available.

### 3.1.6 Mode Bar

The Mode Bar contains the following buttons:

- **Follow-up**
- **Parameters**
- **Diagnostics**
- **Preferences**
- **Tools**

When selected, each button displays a different mode with its own set of tabs

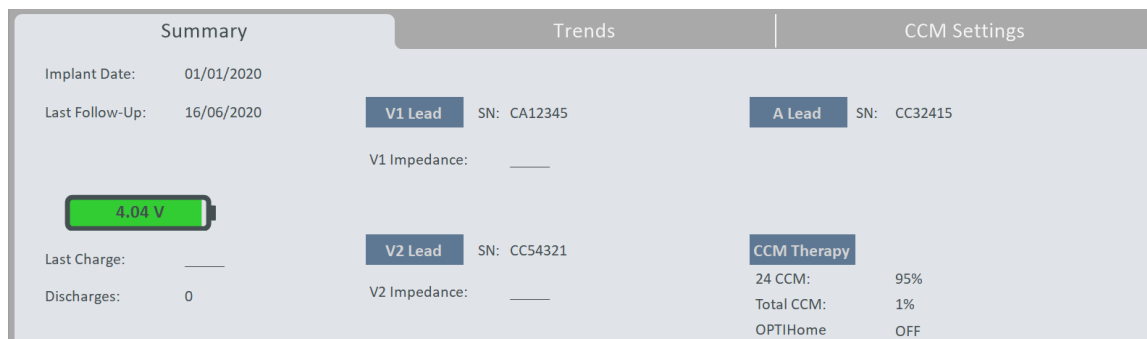


**Figure 12: Mode Bar**

#### 3.1.6.1 Follow-up Mode

The Follow-up Mode contains the following tabs, each displaying a panel containing information about the current status of the OPTIMIZER Smart Mini IPG:

- **Summary:** Displays the following information:
  - Implant date
  - Last Follow-up date
  - IPG Battery information – Voltage, last charge, and number of discharge episodes
  - V1 Lead – Serial number and ventricular lead impedance (if measured) of the V1 lead
  - V2 Lead – Serial number and ventricular lead impedance (if measured) of the V2 lead
  - CCM Therapy – 24 hour CCM % and total CCM %
  - OPTIHome – Status of OPTIHome



**Figure 13: Summary Panel**

- **Trends:** This tab has the following button:
  - **CCM Statistics:** Used to view the CCM statistics downloaded from the OPTIMIZER Smart Mini IPG.



**Figure 14: Trends Panel**

- **CCM Settings:** Displays an overview of the CCM setting currently programmed into the OPTIMIZER Smart Mini IPG. This tab also has the **OPTiset Wizard** button, which allows the user to let the application analyze the patient's heart rhythm and recommend the best settings for the lead sensing, CCM timing, and CCM amplitude parameters.



**Figure 15: CCM Settings Panel**

### 3.1.6.2 Parameters Mode

The Parameters Mode contains the following tabs, each displaying a panel with parameters that can be set for the OPTIMIZER Smart Mini IPG:

- **CCM Therapy:** Contains the following parameters:
  - **CCM Therapy Mode**
  - **Mode**
  - **Start Time**
  - **End Time**
  - **CCM Magnet Mode**
  - **Extend on low CCM %**

**Note:** The **On Time** is set to 01 h : 00 m and cannot be changed.

**Note:** The **Off Time** is calculated based on the following parameter values:

- **CCM Therapy Hours/Day**
- **Start Time**
- **End Time**

**Figure 16: CCM Therapy Panel**

- **Sensing:** Contains the following parameters:
  - **Sensitivity**
  - **Polarity**

This tab also has the **OPTiset Propose IEGM Sensitivities** button, which allows the user to let the application analyze the patient's heart rhythm and recommend the best settings for the sensing parameters.

**Figure 17: Sensing Panel**

- **CCM Timing:** Contains the following parameters categories and their associated parameters:
  - **A/V REFRACTORIES**
    - **Post-V Atrial Refractory**
    - **Post-V Ventricular (RV) Refractory**
  - **CCM INHIBIT**
    - **CCM Inhibit Cycles**
    - **AV Limits**
      - **Short**
      - **Long**
    - **Tachycardia**



- **TIMING ALGORITHM**
  - **LS Channel assignment**
  - **LS Alert Start**
  - **LS Alert Width**
  - **LS Blanking Refractories**
    - **Pre and Post A**
    - **Pre and Post RV**
    - **Post LS**

This tab also has the **OPTiset Propose CCM Algorithm Timing** button, which allows the user to let the application analyze the patient's heart rhythm and recommend the best settings for the CCM timing parameters.

The screenshot shows the 'CCM Timing' tab selected. The interface includes several sections:

- CCM Therapy** (inactive): A/V REFRACTORIES (Post-V Atrial Refractory: 249.4 ms, Post-V Ventricular (RV) Refractory: 249.4 ms), CCM INHIBIT (CCM Inhibit Cycles: 2, AV Limits: Short: 70 ms, Long: 397 ms, Tachycardia: 110 bpm).
- Sensing** (inactive): No visible parameters.
- CCM Timing** (active):
  - TIMING ALGORITHM**: RV: V1, LS: V2, LS Alert: Start: -6 ms, Width: 30 ms.
  - LS Blanking Refractories**: Pre A: 0 ms, Post A: 0 ms, Pre RV: 0 ms, Post RV: 0 ms, Post LS: 30 ms.
  - OPTiset Propose CCM Algorithm Timing** button.
- CCM Train** (inactive): No visible parameters.

**Figure 18: CCM Timing Panel**

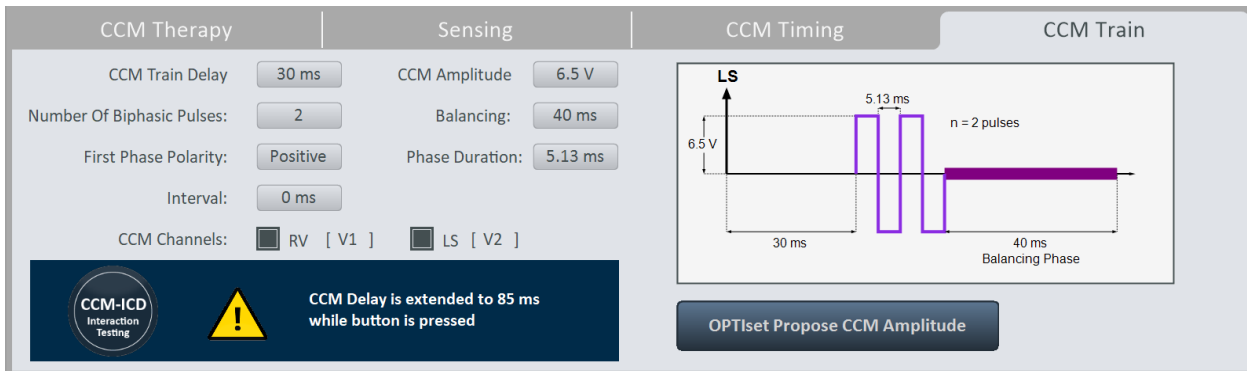
- **CCM Train:** Contains the following parameters:
  - **CCM Train Delay**
  - **CCM Amplitude**
  - **Number of Biphasic Pulses**
  - **Balancing**
  - **First Phase Polarity**
  - **Phase Duration**
  - **Interval**
  - **CCM Channels**
    - **RV**
    - **LS**

This tab includes the CCM Train Graphic Display Window (on the right side of the CCM Train panel) that shows a graphical view of the CCM Train parameters associated with an LS event. Each parameter displayed in the window dynamically changes whenever its parameter value is modified.

This tab also has the following buttons:

- **CCM-ICD Interaction Testing:** allows the user to temporarily extend the CCM Delay to 85 ms to determine the maximum amount of CCM Train Delay allowed before the ICD begins to inappropriately sense CCM therapy pulses as R waves

- **OPTiset Propose CCM Amplitude:** allows the user to let the application analyze the lead impedance of the ventricular leads and recommend the best setting for the CCM amplitude

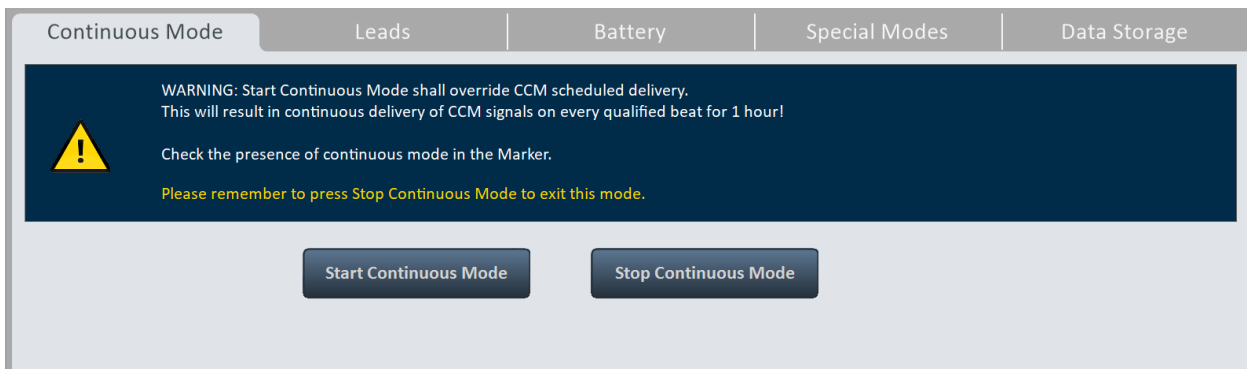


**Figure 19: CCM Train Panel**

### 3.1.6.3 Diagnostics Mode

The Diagnostics Mode contains the following tabs, each displaying a panel with diagnostic tools and settings for use in assessing the status of the implanted OPTIMIZER Smart Mini system:

- **Continuous Mode:** This tab has the following buttons:
  - **Start Continuous Mode**
  - **Stop Continuous Mode**



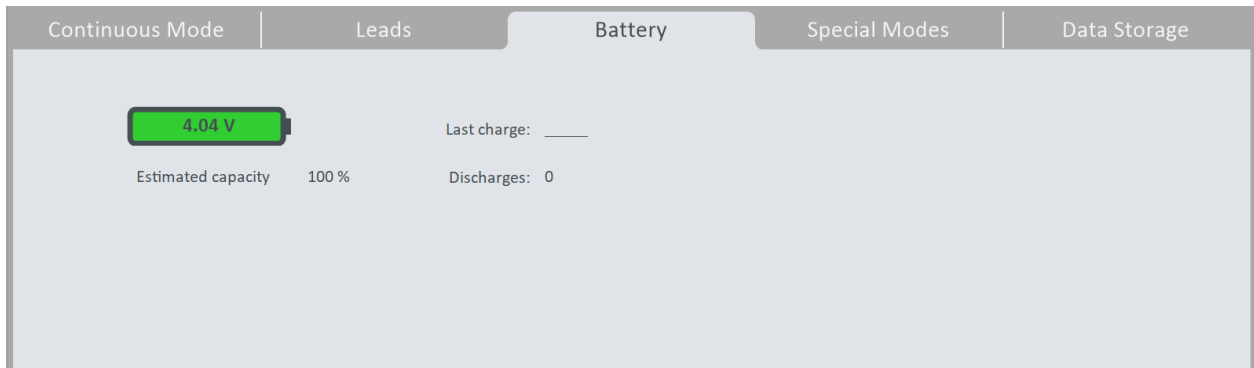
**Figure 20: Continuous Mode Panel**

- **Leads:** This tab has the following button:
  - **Measure Lead Impedance**



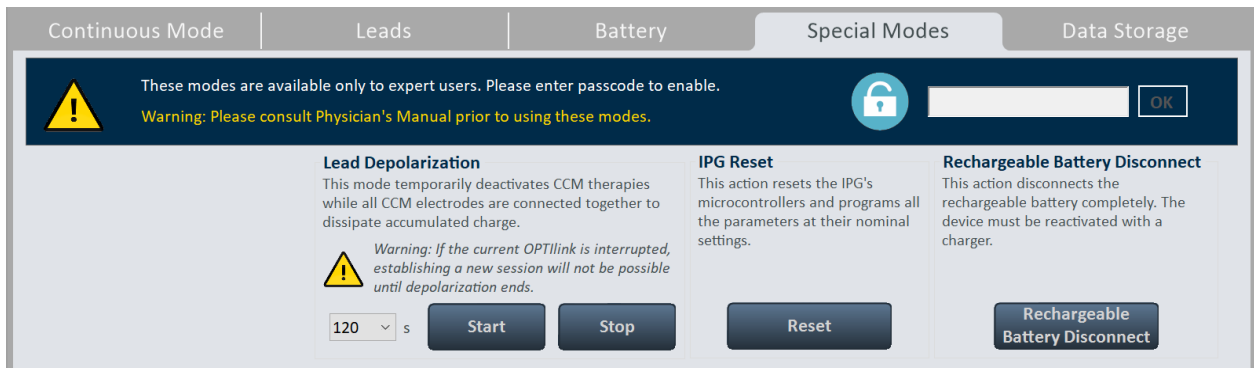
**Figure 21: Leads Panel**

- **Battery:** Displays the IPG Battery information – voltage, estimated capacity, last charge, and number of discharge episodes.



**Figure 22: Battery Mode Panel**

- **Special Modes** (for expert use only): These buttons are enabled only after entering the correct passcode.
  - **Lead Depolarization:** Connects V1 and V2 electrodes together to dissipate accumulated charge.
  - **IPG Reset:** Resets the IPG's microcontrollers and reset and programs all parameter values to their nominal settings.
  - **Rechargeable Battery Disconnect:** Disconnects IPG battery from device circuitry.



**Figure 23: Special Modes Panel**

- **Data Storage:** Displays the following implant information
  - **Implant Date**
  - **V1 Lead**
    - **Model**
    - **SN** – Serial number of V1 lead
  - **V2 Lead**
    - **Model**
    - **SN** – Serial number of V2 lead
  - **A Lead**
    - **Model**
    - **SN** – Serial number of atrial lead
  - **Paced Rhythm (co-implanted CRM device)** – Indicates whether the Paced Rhythm flag has been enabled.

- **CCM delay/CCM start limit measure during OPTIMIZER/ICD Interaction Testing** – Shows limit (in milliseconds) of this value.
- **Minimum R-R interval in ICD VT Zone** – Shows limit (in milliseconds) of this value.

**Data Storage** also contains the following parameters:

- **Activity Tracking**
  - **Accelerometer**
  - **Posture**
  - **HRV**

**Figure 24: Data Storage Panel**

### 3.1.6.4 Preferences Mode

The Preferences Mode contains the following tabs, each with its own separate panel:

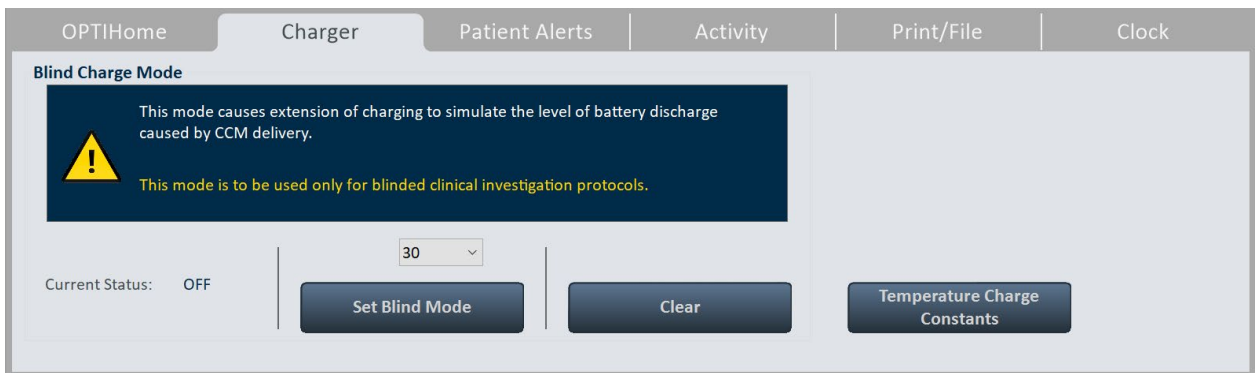
- **OPTIhome** (future capability)

**Figure 25: OPTIhome Panel**

- **Charger:** This tab has the following buttons:

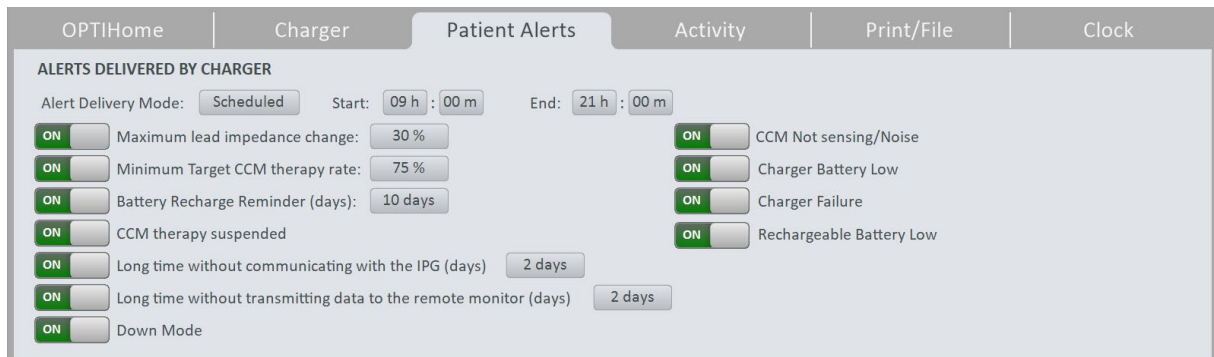
**Note:** This mode is to be used only for blinded clinical investigation protocols

- **Set Blind Mode**
- **Clear**
- **Temperature Charge Constants**



**Figure 26: Charger Panel**

- **Patient Alerts:** This tab has the following parameters:
  - **Alert Delivery Mode**
    - **Start**
    - **End**
  - **Maximum lead impedance change**
    - **%**
  - **Minimum Target CCM therapy rate**
    - **%**
  - **Battery Recharge Reminder**
    - **Days**
  - **CCM therapy suspended**
  - **Long time without communication with the IPG**
    - **Days**
  - **Long time without transmitting to the remote monitor**
    - **Days**
  - **Down Mode**
  - **CCM Not sensing/Noise**
  - **Charger Battery Low**
  - **Charger Failure**
  - **Rechargeable Battery Low**



**Figure 27: Patient Alert Panel**

- **Activity:** This tab has the **Activity Sensor Setup** button



**Figure 28: Activity Panel**

- **Print/File:** This tab has the following buttons:
  - **Parameters Report:** Creates a report (that can be saved in PDF file format) of the current parameters settings programmed into the OPTIMIZER Smart Mini IPG.
  - **Database Backup:** Backs up log files stored on the Intelio Programmer.
  - **Database Restore:** Loads backed up log files onto the Intelio Programmer.



**Figure 29: Print/File Panel**

- **Clock:** This tab has the following buttons:
  - **Read IPG Clock:** Reads the current date and time from the OPTIMIZER Smart Mini IPG.
  - **Set IPG Clock:** (inactive until Read IPG Clock command is executed): Manual setting of the clock in the OPTIMIZER Smart Mini IPG.
  - **Synchronize IPG clock to programmer clock:** Sets the clock in the OPTIMIZER Smart Mini IPG to the current date and time of the Intelio Programmer.



**Figure 30: Clock Panel**

### 3.1.6.5 Tools Mode

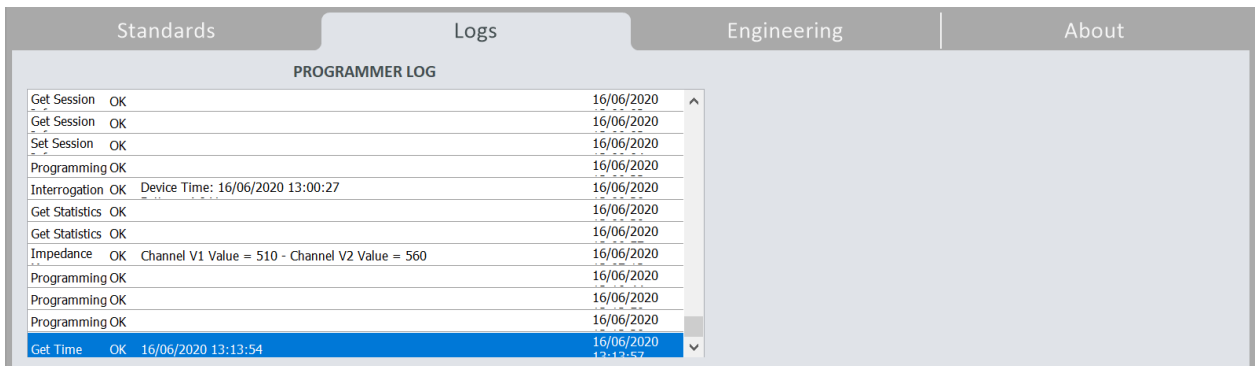
The Tools Mode contains the following tabs, each with its own separate panel:

- **Standards:** This tab has the following buttons:
  - **Load Program:** Loads the saved standard file onto the OPTIMIZER Smart Mini Programmer application.
  - **Save Program:** Saves the current parameter values as a standard file.



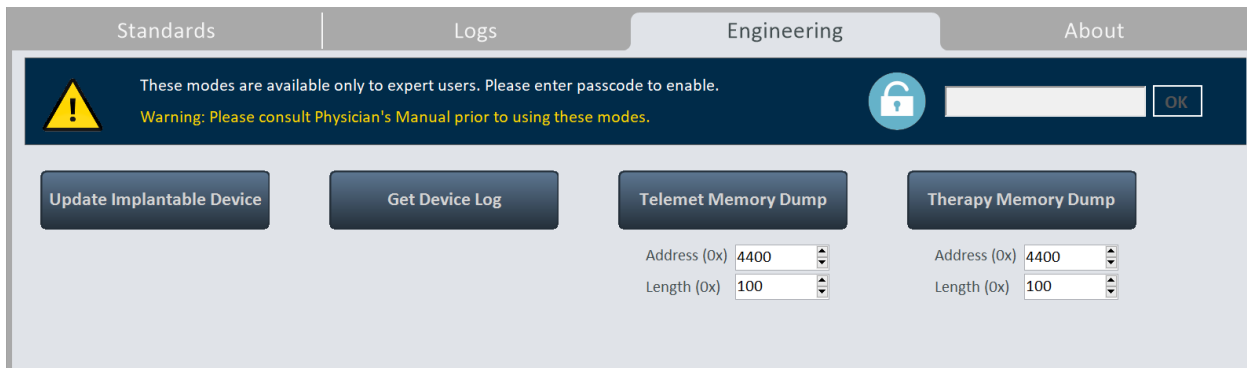
**Figure 31: Standards Panel**

- **Logs:** This tab displays the Programmer Log.



**Figure 32: Logs Panel**

- **Engineering** (for expert use only): These buttons are enabled only after entering the correct passcode.
  - **Update Implantable IPG:** Updates the firmware of the OPTIMIZER Smart Mini IPG using a bootloader file loaded from a separate USB flash drive.
  - **Get Device Log:** Downloads the activities log from the OPTIMIZER Smart Mini IPG.
  - **Telemet Memory Dump**
  - **Therapy Memory Dump**



**Figure 33: Engineering Panel**

- **About:** This tab displays the following information regarding the firmware or software listed items:
  - **IPG**
    - **Telemetry Version:** Firmware version of the OPTIMIZER Smart Mini IPG's telemetry module.
    - **Therapy Version:** Firmware version of the OPTIMIZER Smart Mini IPG's therapy module.
    - **ALCP Version:** Application Level Communication Protocol (ALCP) version of the OPTIMIZER Smart Mini IPG.
  - **Programmer Application**
    - **Version:** Software version of the OPTIMIZER Smart Mini Programmer application.
    - **ALCP Version:** Application Level Communication Protocol (ALCP) version of the Optimizer SM Programmer application.
  - **Programming Interface**
    - **Version:** Firmware version of Intelio Programming Wand





Figure 34: About Panel

### 3.1.7 Status Bar

The Impulse Dynamics log is displayed at the screen's last line along with the laptop's battery charge percentage and the following buttons:

- **Restrictions and Warnings:** (becomes active when a parameter conflict, restriction, or warning is present): When clicked, opens the Error Message window, which displays the restriction or warning message. When clicked again, it closes the Error Message window.
- **Exit:** When clicked, a pop-up window appears, asking the user to confirm the closure of the Programmer Software. If **Close** is chosen, the Programmer application will close. If **Cancel** is selected, then the pop-up window closes.

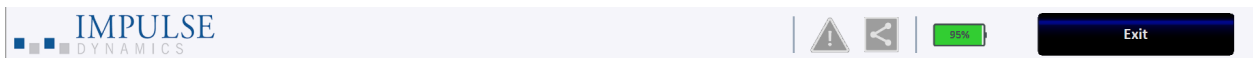


Figure 35: Status Bar

## 3.2 Linking and Interrogation

### 3.2.1 Initiating a Link with the OPTIMIZER Smart Mini IPG

To initiate a link with the OPTIMIZER Smart Mini IPG:

- Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
- Click the **Start OPTIlink** button on the **OPTIlink Session Pane**

The message "Place OPTIlink Wand over IPG" will first be displayed, followed by the message "IPG identified Keep Wand over IPG", and then finally the message "OPTIlink downloading IPG data".

If the link is successful, the **OPTIlink Session Pane** will display the device model, serial number, and the **Close OPTIlink** button. In addition, the **CCM Status Pane** will display the current CCM therapy status.

However, if the Intelio Programming Wand is not well-positioned over the implant site, the interrogation operation may fail. If a failure in communication occurs, the **OPTIlink Session Pane** will display the message "Failed to establish OPTIlink session".

If this occurs, reposition the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site and click the **Start OPTIlink** button again.

Upon the successful completion of the link, the OPTIMIZER Smart Mini Programmer application automatically performs an interrogation of the OPTIMIZER Smart Mini IPG and reads the latest statistics from the device.

**Note:** Once the link with the OPTIMIZER Smart Mini IPG has been established, the Intelio Programming Wand may be removed from its position directly over the implant site and placed within 1.5 m (5 ft) away from the IPG.

### 3.2.2 Interrogating the OPTIMIZER Smart Mini IPG

The Interrogation command may be used to update the information about the OPTIMIZER Smart Mini IPG displayed by the OPTIMIZER Smart Mini Programmer application (e.g., battery voltage of the IPG).

To interrogate the OPTIMIZER Smart Mini IPG:

- Click the **Interrogate** button on the **Programming Buttons Pane**

## 3.3 Modifying Parameter Values

Parameter values can be viewed and modified by selecting the **Parameters** or **Preferences** button on the **Mode Bar**, selecting one of the tabs associated with each mode, then choosing one of the parameters on the panel.

Parameter values are displayed in three different ways:

- A sliding toggle switch is used for parameters that can only be enabled or disabled (except CCM Channels). Sliding the switch right turns the parameter **ON**. Sliding the switch left turns the parameter **OFF**.
- For the CCM Channels, checkboxes are used to enable or disable this parameter. To toggle the options for each CCM channel, click the checkbox to the left of the CCM channel. If clicking on a CCM channel checkbox causes it to become filled in, this action enables the channel. If clicking on a CCM channel checkbox causes it to become empty, this action disables the channel.
- For parameters with a set of possible values, the parameter value is outlined by a small rectangular box. To modify its value, select the parameter value shown. A window with all the possible values for the selected parameter will then appear. To modify the value of the parameter, select the new value in the list. When the selection is made, the parameter window automatically closes and the selected parameter value is shown. In addition, the parameter window has a green pin on the top right corner that, when clicked, changes the pin color to red, keeping the window open and preventing the user from making a selection. Clicking the red pin changes its color back to green and allows the user to select a parameter value.

To modify a parameter value:

- Select the tab where the parameter to be modified appears
- Select the parameter value to be modified. If the parameter is a switch, it will change from one state to another (e.g., OFF to ON or vice versa). If the parameter is not a switch, 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.

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

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

There also are parameters for which values are valid only when certain other parameters are enabled or are set to certain values (for instance, if the device mode of the OPTIMIZER Smart Mini IPG is set to 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.

### 3.3.1 Parameter Color Convention

When viewing a set of parameter values in a parameter window, the following color convention is used to represent the different parameter choices:

- **Black:** For the current parameter value programmed into the OPTIMIZER Smart Mini IPG.
- **Blue:** For parameter values that are different from the current programmed value which, if selected, will not result in a parameter conflict.
- **Yellow:** For parameter values that are different from the current programmed value which, if selected, will result in a parameter warning.
- **Red:** For prohibited values which, if selected, will result in a parameter conflict.

**Note:** Not all parameter windows will include all four types of parameter choices.

The black/blue/yellow/red (programmed, pending, warning, conflict) color convention is also used when viewing the parameter values displayed on the various panels. Thus the user can identify which parameters are currently programmed into the OPTIMIZER Smart Mini IPG, which parameters have been modified but not yet programmed, and which parameters will generate a parameter conflict or warning.

### 3.3.2 Parameter Conflicts and Warnings

#### 3.3.2.1 Parameter Conflict

When a parameter value that is incompatible with other parameter values is selected, a *parameter conflict* occurs. When such situations arise, an error message is displayed in the **Error Message Window**.

To view the **Error Message Window**:

- Click the Restrictions and Warnings button on the Status Bar

The parameter conflict error messages displayed in the **Error Message Window** include:

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

When a parameter conflict occurs, the parameter values that are in conflict are all displayed in red.

As long as there is a parameter conflict, the OPTIMIZER Smart Mini Programmer application will not allow the OPTIMIZER Smart Mini IPG to be programmed with new parameter values. This ensures that only compatible parameter configurations can be downloaded to the OPTIMIZER Smart Mini IPG.

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

- Viewing the list of available values for the parameter(s) in conflict and selecting a new “blue” parameter value for each parameter setting.

**Note:** It is permissible to select a parameter that causes a conflict provided that the values of the other parameters involved in the conflict are changed to new “blue” values that resolve the conflict.

### 3.3.2.2 Parameter Warning

When a parameter value that violates a logical condition is selected, a *parameter warning* occurs. When such situations arise, a warning message is displayed in the **Error Message Window**.

To view the **Warning Message Window**:

- Click the **Restrictions and Warnings** button on the Status Bar

The parameter conflict warning messages displayed in the **Error Message Window** include:

- Which parameter values are violating a logical condition
- An explanation of the logical condition being violated

When a parameter warning occurs, the parameter values that are violating a logical condition are all displayed in yellow.

Though there is a logical condition being violated, the OPTIMIZER Smart Mini Programmer application still allows the OPTIMIZER Smart Mini IPG to be programmed with new parameter values.

To resolve a parameter warning, new values must be selected for the parameters causing the issue. Resolving the parameter warning may be rapidly achieved by:

- Viewing the list of available values for the parameter(s) violating the logical condition and selecting a new “blue” parameter value for each parameter setting.

**Note:** It is permissible to select a parameter that causes a warning provided that the values of the other parameters involved in the warning are changed to new “blue” values that resolve the warning.

## 3.4 Programming

### 3.4.1 Programming the OPTIMIZER Smart Mini IPG

Programming the OPTIMIZER Smart Mini 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 amber, if parameter values have been modified, and there is no parameter conflict.

To program the modified parameter values:

- Click the **Program** button on the **Programming Buttons Pane**

If the programming is successful, the **Program** button will change from blinking amber to blue, and the modified parameter values on the OPTIMIZER Smart Mini Programmer application screen will become black, indicating that they are now the programmed parameter values of the OPTIMIZER Smart Mini IPG.

### 3.4.2 Cancel and Undo Commands

The OPTIMIZER Smart Mini Programmer application has two separate commands for resetting modified parameter values to the previous values.

#### 3.4.2.1 Cancel

If any parameter values have been modified but not yet programmed into the OPTIMIZER Smart Mini IPG (**Program** button is blinking amber), the **Cancel** command will reset the parameter values to the last set of interrogated / programmed values.

To cancel modifications:

- Click the **Cancel** button on the **Programming Buttons Pane**

Please note that after executing a **Cancel** command, the parameter values displayed on the OPTIMIZER Smart Mini Programmer application screens are all shown in black, since they are the parameter values currently programmed into the OPTIMIZER Smart Mini IPG. If an OPTIMIZER Smart Mini IPG is not linked with the programmer and parameter data were loaded from a standard (.mips file), the parameter values displayed are the values stored in the standard file.

#### 3.4.2.2 Undo

If the OPTIMIZER Smart Mini IPG has been programmed with a new set of parameter values, the **Undo** command resets the parameter values to the previous set of programmed values.

To undo the most recent programming:

- Click the **Undo** button on the **Programming Buttons Pane**

### 3.5 Device and CCM Therapy Modes

The **Mode** parameter sets the device mode of the OPTIMIZER Smart Mini IPG.

To set the device mode of the OPTIMIZER Smart Mini IPG:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Parameters** button on the **Mode Bar**
- Select the **CCM Therapy** tab
- On the **CCM Therapy** panel, click the **Mode** parameter
- The **Mode** parameter window will display the following options for this parameter:
  - **OOO**: The device is placed in safe mode with no CCM therapy delivery.
  - **ODO-LS-CCM**: The device uses atrial, ventricular (RV), and local sense (LS) events as inputs in determining if CCM therapy should be delivered.
  - **OVO-LS-CCM**: The device uses only RV and LS events as inputs in determining if CCM therapy should be delivered.
- Select one of the parameter choices shown in the **Mode** parameter window

**Note:** If **ODO-LS-CCM** or **OVO-LS-CCM** is selected, the **CCM Therapy Mode** parameter, **Sensing** parameters, and **CCM Timing** parameters become enabled, allowing the user to set these parameters.

To set the **CCM Therapy Mode** parameter:

- On the **CCM Therapy** panel, click the **CCM Therapy Mode** parameter
- The **CCM Therapy Mode** parameter window will display the following options for this parameter:
  - **OFF** – Turns OFF the delivery of CCM therapy.
  - **ON** – Enables the OPTIMIZER Smart Mini IPG to deliver CCM therapy a set number of hours per day within the timeframe set by the **Start Time** and **End Time** parameters (see Section 3.7).
- Select one of the parameter choices shown in the **CCM Therapy Mode** parameter window

**Note:** If **ON** is selected, the **CCM Train** parameters, as well as the remaining **CCM Therapy** parameters, become enabled, allowing the user to set these parameters.

**Note:** If the parameter value **ON** is red after it is selected, at least one **CCM Channel** under the **CCM Train** tab must be enabled before continuing.

- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter settings

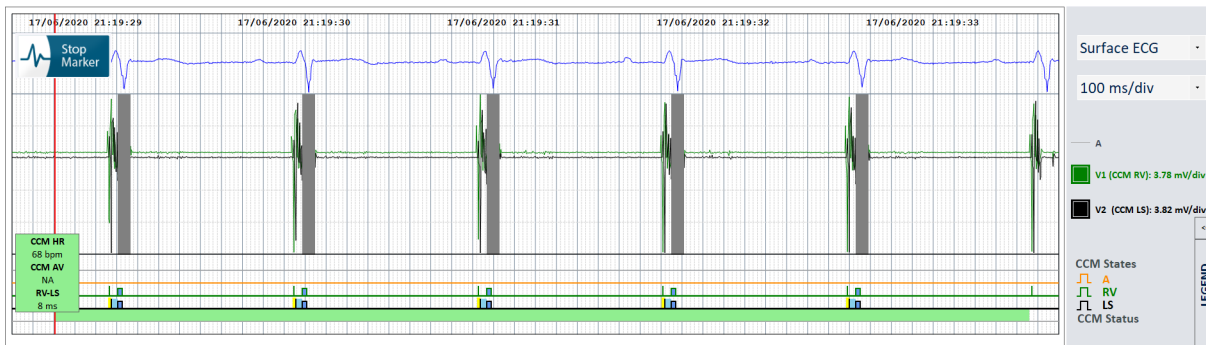
**Note:** The Device and CCM Therapy modes can also be set using the **CCM Status Pane**.

### 3.6 OVO-LS-CCM Mode

When the OPTIMIZER Smart Mini IPG is set to OVO-LS-CCM mode, the device no longer detects the presence of atrial events. Accordingly, all markers associated with atrial events are ignored and all parameters associated with atrial events are disabled. In addition, limitations are placed on certain parameters in order to ensure that CCM therapy is delivered appropriately.

#### 3.6.1 ECG/IEGM/Marker Pane in OVO-LS-CCM Mode

Since atrial signals and events are ignored in OVO-LS-CCM mode, the atrial IEGM, CCM AV interval, and atrial event markers are not displayed in the ECG/IEGM/Marker Pane.



**Figure 36: ECG/IEGM/Marker Pane in OVO-LS-CCM Mode**

#### 3.6.2 Disabled or Limited Parameters in OVO-LS-CCM Mode

Below is a list of parameters that are disabled or limited when the OPTIMIZER Smart Mini IPG is set to OVO-LS-CCM mode:

- The Sensitivity and Polarity parameters for the Atrium are disabled
- The display of PVC, AT, Long AV, and Short AV markers are disabled
- The minimum V1 and V2 sensitivity setting is limited to 1.0 mV
- 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 of 62 bpm to 110 bpm
- The maximum LS Alert Window Width is limited to 30 ms
- The maximum CCM Train Delay is limited to 45 ms

CCM Therapy | Sensing | CCM Timing | CCM Train

Sensitivity      Polarity

Atrium:      —      —

Ventricle 1:      8 mV      Bipolar

Ventricle 2:      8 mV      Bipolar

OPTiset Propose IEGM Sensitivities

**Figure 37: Sensing Panel in OVO-LS-CCM Mode**

CCM Therapy | Sensing | CCM Timing | CCM Train

**A/V REFRACTORIES**

Post-V Atrial Refractory:      —

Post-V Ventricular (RV) Refractory:      249.4 ms

**CCM INHIBIT**

CCM Inhibit Cycles:      2

AV Limits:      Short:      —      Long:      —

Tachycardia:      110 bpm

**TIMING ALGORITHM**

RV: V1      LS: V2

LS Alert: Start:      -6 ms      Width:      30 ms

**LS Blanking Refractories**

Pre A:      —      Post A:      —

Pre RV:      0 ms      Post RV:      0 ms

Post LS:      30 ms

OPTiset Propose CCM Algorithm Timing

**Figure 38: CCM Timing Panel in OVO-LS-CCM Mode**

## 3.7 CCM Schedule

The **CCM Therapy** panel also contains the parameters that set the CCM therapy schedule.

### 3.7.1 CCM Therapy Hours/Day

The **CCM hs/day** parameter sets the total number of hours per day the OPTIMIZER Smart Mini IPG is scheduled to deliver CCM therapy. By default, the **CCM hs/day** parameter is set to 7 hs/day.

To access the **CCM hs/day** parameters:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Parameters** button on the **Mode Bar**
- Select the **CCM Therapy** tab
- On the **CCM Therapy** panel, click the **CCM hs/day** parameter (next to CCM Therapy Mode)
- Select one of the parameter choices shown in the **CCM hs/day** parameter window
- Click the blinking Program button on the Programming Buttons Pane to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.7.2 Start Time and End Time

The **Start Time** and **End Time** parameters set the start and end time for each day's CCM therapy delivery intervals. By default, the CCM therapy delivery intervals are set to be distributed over a 24-hour period each day.

To set the parameters for **Start Time** and **End Time**:

- On the **CCM Therapy** panel, select the **Start Time Hour** parameter
- Select one of the parameter choices shown in the **Start Time Hour (h)** parameter window
- On the **CCM Therapy** panel, select the **Start Time Minute** parameter
- Select one of the parameter choices shown in the **Start Time Minute (m)** parameter window
- On the **CCM Therapy** panel, select the **End Time Hour** parameter
- Select one of the parameter choices shown in the **End Time Hour (h)** parameter window
- On the **CCM Therapy** panel, select the **End Time Minute** parameter
- Select one of the parameter choices shown in the **End Time Minute (m)** parameter window
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter settings.

Below the **Start Time** and **End Time** parameters are the **On Time** and **Off Time** intervals. The **On Time** is the interval when the OPTIMIZER Smart Mini IPG is scheduled to deliver CCM therapy. It always has the value **01 h : 00 m**. The **Off Time** is the period of time between each one-hour **On Time** interval when the OPTIMIZER Smart Mini IPG is not scheduled to deliver CCM therapy. The OPTIMIZER Smart Mini Programmer application calculates the **Off time** interval using the parameter values chosen for **CCM hs/day**, **Start Time**, and **End Time**.

**Note:** When the parameter **CCM hs/day** is set to a specific value, the OPTIMIZER Smart Mini Programmer application automatically calculates and sets the exact times for the **Off Time** parameters using the default parameter settings for the **Start Time** and **End Time**.

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

<b>CCM Therapy Mode:</b>	<b>ON</b>	<b>7 hs/day</b>			
<b>Start Time:</b>	<b>00 h</b>	<b>00 m</b>	<b>End Time:</b>	<b>23 h</b>	<b>59 m</b>
<b>On Time:</b>	<b>01 h</b>	<b>00 m</b>	<b>Off Time:</b>	<b>02 h</b>	<b>25 m</b>

### 3.7.3 Extend on Low CCM%

The OPTIMIZER Smart Mini Programmer application features the **Extend on Low CCM%** function, which when enabled, allows the OPTIMIZER Smart Mini IPG to extend the **On Time** interval for CCM therapy delivery based on the percentage of CCM therapy delivered during the initial one-hour **On Time** interval. The amount in which the **On Time** interval is extended is as follows:

- If the CCM% is 80% to 90%, the **On Time** interval is extended 11%
- If the CCM% is 70% to 79%, the **On Time** interval is extended 26%
- If the CCM% is 60% to 69%, the **On Time** interval is extended 46%
- If the CCM% is less than 60%, the **On Time** interval is extended 72%

In all cases, the Off Time is correspondingly reduced by the same amount.



To enable the Extend on low CCM% feature:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Parameters** button on the **Mode Bar**
- Select the **CCM Therapy** tab
- On the **CCM Therapy** panel, toggle the **Extend on Low CCM%** button to **ON**
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.8 CCM Magnet Mode

Placing a pacemaker magnet over the implant site of the OPTIMIZER Smart Mini IPG and keeping it over the implant site for at least two cardiac cycles (3 seconds) and then removing it from the implant site sets the OPTIMIZER Smart Mini IPG into CCM Magnet Mode (indicated by a yellow bar in **CCM Status** row of the **Marker Sub-pane**), suspending CCM therapy.

When the magnet is removed from the implant site, this suspension of CCM therapy is maintained.

In this state, the OPTIMIZER Smart Mini IPG still senses and classifies cardiac events.

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

To set the parameter associated with this Magnet Mode suspension:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Parameters** button on the **Mode Bar**
- Select the **CCM Therapy** tab
- On the **CCM Therapy** panel, click the **CCM Magnet Mode** button
- The **Magnet Mode** parameter window will display the following options for this parameter:
  - **Off 1 day:** Suspends CCM therapy delivery for 24-hours after a pacemaker magnet is temporarily applied over the implant site of the OPTIMIZER Smart Mini IPG (unless the Program command is sent to the IPG after the magnet application)

**Note:** If a pacemaker magnet is temporarily reapplied over the implant site of the OPTIMIZER Smart Mini IPG for at least two cardiac cycles (3 seconds) at any time during this 24-hour period, the 24-hour period is restarted.
  - **Off:** Permanently suspends CCM therapy delivery after a pacemaker magnet is temporarily applied over the implant site of the OPTIMIZER Smart Mini IPG (unless the Program command is sent to the IPG after the magnet application)
- Select one of the parameter choices and then click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.9 OPTIset

**Note:** If the parameter **Paced Rhythm** is set to **ON** (see **Data Storage** section), the **OPTIset** tool cannot be used.

The OPTIMIZER Smart Mini Programmer application features the **OPTIset** tool, which can be used to propose new values for the following parameters:

- IEGM Sensitivities
- CCM Algorithm Timing
- CCM Amplitude

The **OPTIset** tool is offered collectively as the **OPTIset Wizard** or as the following individual tools:

- **OPTIset: Propose IEGM Sensitivities** (located on Sensing panel)
- **OPTIset: Propose CCM Algorithm Timing** (located on CCM Timing panel)
- **OPTIset: Propose CCM Amplitude** (located on CCM Train panel)

To use the **OPTIset Wizard** tool:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Follow-up** button on the **Mode Bar**
- Select the **CCM Setting** tab
- On the **CCM Setting** panel, click the **OPTIset Wizard** button

The **OPTIset** window will appear.

**Note:** If the parameter **Paced Rhythm** is set to **ON** (as indicated by a filled-in checkbox, the buttons on the **OPTIset** will all be disabled.

**Note:** The CCM Mode used by the **OPTIset** tool during its analysis can be changed by modifying the **CCM Mode** parameter on the **OPTIset** window.

The **Acquisition Time** parameter allows the user to adjust the time allotted the **OPTIset** to analyze the patient's IEGM and determine the best settings for each parameter.

- If desired, adjust the **Acquisition Time**
  - Click the Acquisition Time parameter
  - When the pull-down menu appears, select the desired Acquisition Time from the list of choices
- Click the **OPTIset: Propose IEGM Sensitivities** button

**OPTiset**

1. ☐ Paced Rhythm (co-implanted CRM device)

2. CCM Mode **ODO-LS-CCM** Acquisition Time **15** s

3. **OPTiset: Propose IEGM Sensitivities**

4. **OPTiset: Propose CCM Algorithm Timing**

5. **OPTiset: Propose CCM Amplitude**

**OPTiset is ready to propose IEGM sensitivity settings.**

**Accept & Continue**

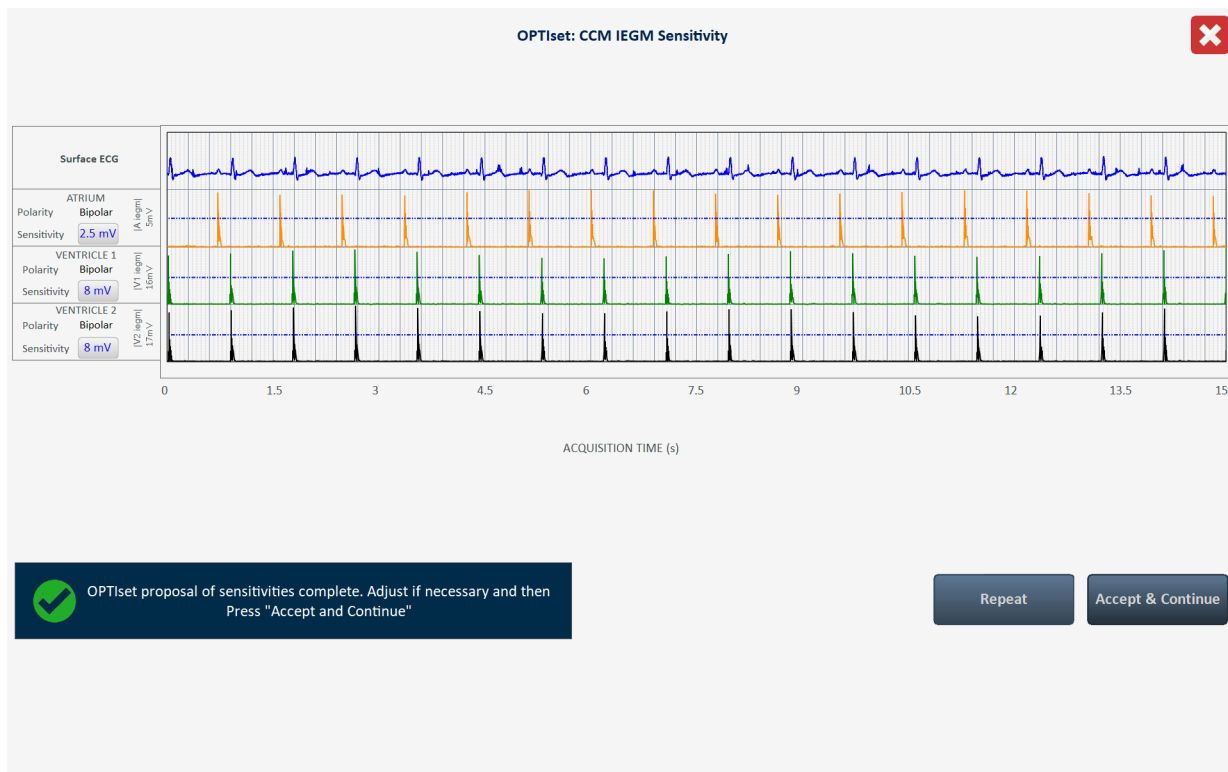
**Figure 39: OPTiset Window (Initial)**

When the **OPTiset: CCM IEGM SENSITIVITIES** window appears, the analysis will begin automatically. If successful, a green checkmark will be shown along with a message indicating that the OPTiset proposal of sensitivities is complete. If any proposed parameter value is different from the currently programmed value, it will be shown in blue.

**Note:** The proposed parameter values can be modified by clicking on the specific parameter and choosing a new value.

**Note:** If **OPTiset** cannot successfully find a set of proposed values, click the **Repeat** button to repeat the analysis. If **OPTiset** still cannot successfully find a set of proposed values after the second attempt, click the red X at the top right corner of the window to close the **OPTiset** application and set the **IEGM Sensitivity** parameters on the **Sensitivity** panel manually.

- When **OPTiset** has successfully completed its analysis and displayed its recommended settings for the IEGM sensitivity, the **Accept & Continue** button will become enabled.
- Click the **Accept & Continue** button on the **OPTiset: CCM IEGM SENSITIVITIES** window.



**Figure 40: OPTiset: CCM IEGM SENSITIVITIES Window**

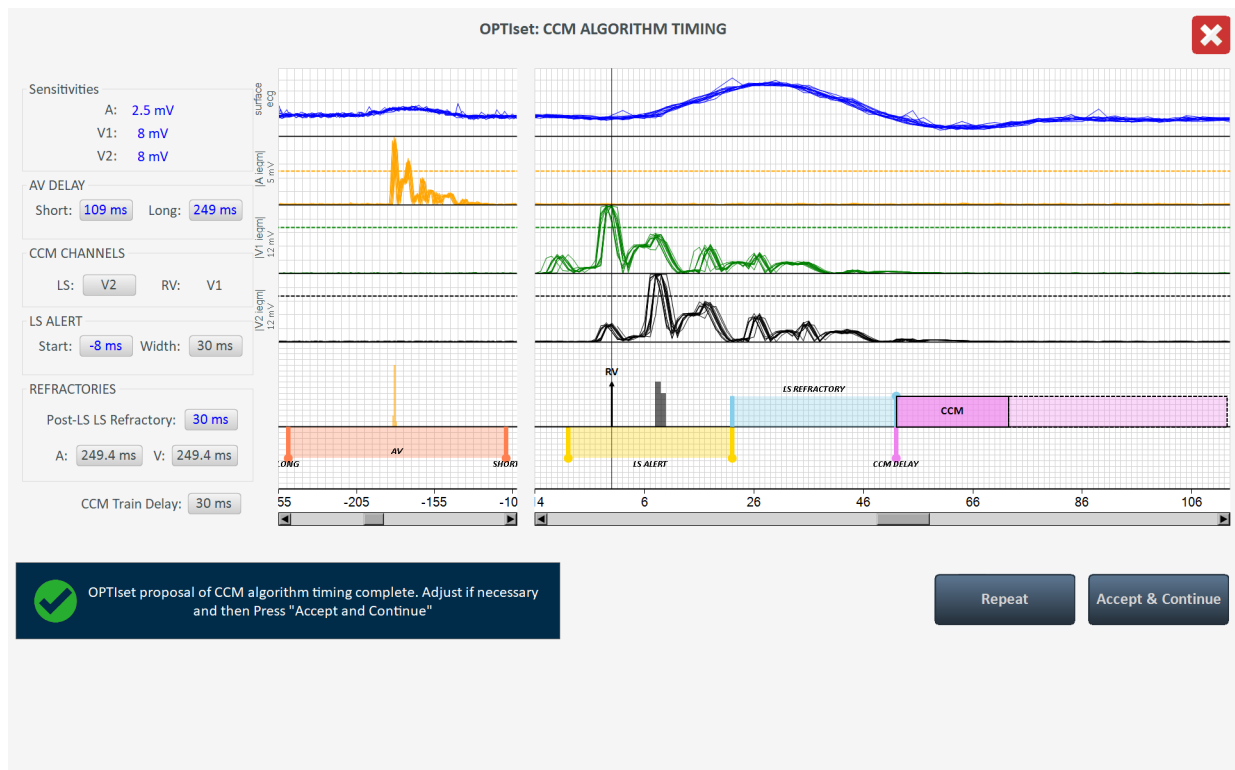
- When the **OPTiset** window appears again, click the **OPTiset: Propose CCM Algorithm Timing** button

When the **OPTiset: CCM ALGORITHM TIMING** window appears, the analysis will begin automatically. If successful, a green checkmark will be shown along with a message indicating that the OPTiset proposal of CCM algorithm timing is complete. If any proposed parameter value is different from the currently programmed value, it will be shown in blue.

**Note:** The proposed parameter values can be modified by clicking on the specific parameter and choosing a new value.

**Note:** If **OPTiset** cannot successfully find a set of proposed values, click the **Repeat** button to repeat the analysis. If **OPTiset** still cannot successfully find a set of proposed values after the second attempt, click the red X at the top right corner of the window to close the **OPTiset** application and set the CCM Timing parameters on the **CCM Timing** panel manually. This will also cause any proposed changes to the **IEGM Sensitivity** parameters to be discarded.

- When **OPTiset** has successfully completed its analysis and displayed its recommended settings for the CCM algorithm timing, the **Accept & Continue** button will become enabled.
- Click the **Accept & Continue** button on the **OPTiset: CCM ALGORITHM TIMING** window.



**Figure 41: OPTiset: CCM ALGORITHM TIMING Window**

- When the **OPTiset** window appears again, click the **OPTiset: Propose CCM Amplitude** button

When the **OPTiset: CCM AMPLITUDE** window appears, the analysis will begin automatically if at least one CCM Delivery Channel has been enabled.

**Note:** If no CCM Delivery channels have been enabled, enable one CCM Delivery channel, wait for OPTiset to complete its analysis, and then enable the second CCM Delivery channel.



If successful, a green checkmark will be shown along with a message indicating that the OPTiset proposal of CCM algorithm amplitude is complete. If the proposed CCM Amplitude parameter value is different from the currently programmed value, it will be shown in blue.

**Note:** The proposed CCM Amplitude parameter value can be modified by clicking on the parameter and choosing a new value.

**Note:** If **OPTiset** cannot successfully find a proposed CCM Amplitude parameter, click the **Repeat** button to repeat the analysis. If **OPTiset** still cannot successfully find a proposed CCM Amplitude parameter after the second attempt, click the red X at the top right corner of the window to close the **OPTiset** application and set the CCM Amplitude parameter on the **CCM Train** panel manually. This will also cause any proposed changes to the **CCM Algorithm Timing** and **CCM IEGM Sensitivity** parameters to be discarded.

- When **OPTiset** has successfully completed its analysis and displayed its recommended setting for the CCM algorithm amplitude, the **Accept & Continue** button will become enabled.
- Click the **Accept & Continue** button on the **OPTiset: CCM AMPLITUDE** window.

OPTiset: CCM AMPLITUDE ✕

Lead	CCM Delivery	Impedance	CCM Current
V1		475 $\Omega$	14.74 mA
V2		518 $\Omega$	13.51 mA
<b>CCM TOTAL</b>		248 $\Omega$	28.25 mA

CCM Amplitude: 7 V

✓

OPTiset proposal of CCM algorithm amplitude complete. Adjust if necessary and then Press "Accept and Continue"

Repeat

Accept & Continue

**Figure 42: OPTiset: CCM AMPLITUDE Window**

- When the **OPTiset** window appears again, click the **Accept & Continue** button

OPTiset ✕

1. ☐ Paced Rhythm (co-implanted CRM device)

---

2. CCM Mode ODO-LS-CCM    Acquisition Time 15 s

---

3. OPTiset: Propose IEGM Sensitivities    **A:** 2.5 mV    **V1:** 8 mV    **V2:** 8 mV

---

4. OPTiset: Propose CCM Algorithm Timing

**LEAD ASSIGNMENT:**    **RV:** V1    **LS:** V2

**Refractories:**    **A:** 249.4 ms    **V:** 249.4 ms

**LS: Alert Start:** -8 ms    **Alert Width:** 30 ms

**Post-LS LS Refractory:** 30 ms

**AV Delay:**    **Long:** 249 ms    **Short:** 109 ms

**CCM Train Delay:** 30 ms

---

5. OPTiset: Propose CCM Amplitude    **CCM Amplitude:** 7 mV

✓

OPTiset parameter proposal complete. Press "Accept and Continue".

Accept & Continue

**Figure 43: OPTiset Window (Final)**

- When the OPTIMIZER Smart Mini Programmer application returns to its main application screen, click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter settings.

### 3.10 Sensing

The **Sensing** panel contains the following parameters:

- **Sensitivity:** This parameter is used to determine the sensitivity threshold and set the final sensitivity setting for the lead. After the sensitivity threshold for a lead has been determined, the final sensitivity setting is typically set to the closest parameter value representing 50% of the lead's sensitivity threshold value.
- **Polarity:** This parameter offers the following options:
  - **Bipolar:** The signal is sensed between the lead "tip" (distal electrode) and "ring" (proximal electrode) of a bipolar lead.
  - **Unipolar:** The signal is sensed between the lead tip (distal electrode) and the case of the OPTIMIZER Smart Mini IPG.

To modify the Sensing parameters:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG.
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site.
  - Click the **Start OPTILink** button on the **OPTILink Session Pane**.
- Click the **Parameters** button on the **Mode Bar**.
- Select the **Sensing** tab.
- On the **Sensing** panel, click the **Sensitivity** parameter for each lead and modify as needed to determine the sensitivity threshold and the final sensitivity setting for the lead.
- Click the **Polarity** parameter for each lead and modify as needed.
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting.

### 3.11 CCM Timing

The **CCM Timing** panel contains the parameters for setting the following parameter categories:

- **A/V Refractories** – Consist of the following set of parameters:
  - **Post-V Atrial Refractory Period:** Sets the time interval after a ventricular (RV) event when signals sensed on the atrial lead are not acknowledged as atrial events.  
**Note:** This parameter is active only when the OPTIMIZER Smart Mini IPG is in ODO-LS-CCM mode.
  - **Post-V Ventricular (RV) Refractory Period:** Sets the time interval after a ventricular (RV) event when signals sensed on the RV channel are not acknowledged as ventricular (RV) events.
- **CCM Inhibit** – Consist of the following set of parameters that control CCM inhibition:
  - **CCM Inhibit Cycles:** Sets the number of cycles for which CCM therapy delivery will continue to be inhibited after the initial inhibiting event.  
**Note:** The number of inhibited cycles applies to the most recent detected event that caused CCM therapy inhibition. If a new inhibiting event is detected during CCM therapy inhibition, this will trigger a new inhibition period.
  - **Short AV Limit:** Sets the minimum permissible interval between an atrial and a ventricular event.  
**Note:** This parameter is active only when the OPTIMIZER Smart Mini IPG is in ODO-LS-CCM mode.

- **Long AV Limit:** Sets the maximum permissible interval between an atrial and a ventricular event.  
**Note:** This parameter is active only when the OPTIMIZER Smart Mini IPG is in ODO-LS-CCM mode.
- **Tachycardia:** This parameter is dependent on the CCM Mode of the device.
  - **ODO-LS-CCM mode:** When operating in this mode, sets the maximum limit for the number of detected atrial events per minute.
  - **OVO-LS-CCM mode:** When operating in this mode, sets the maximum limit for the number of detected ventricular (RV) events per minute.
- **Timing Algorithm** – Consist of the following set of parameters that control events that control CCM timing:
  - **LS:** Assigns the V1 or V2 lead as the LS channel.
  - **LS Alert Start:** Sets the start of the time interval during which a valid LS event must be sensed in order to trigger the delivery of CCM therapy.  
**Note:** The Alert Window starts inside the AV interval if the parameter value is negative.
  - **LS Alert Width:** Sets the time interval duration in which a valid LS event must be sensed in order to trigger the delivery of CCM therapy.  
**Note:** If the sum of Alert Start and Alert Width is negative, the Alert Window ends inside the AV interval.  
**Note:** If a Local Sense event is detected outside the Alert Window, CCM therapy delivery is *always inhibited*.  
**Note:** When the OPTIMIZER Smart Mini IPG is in OVO-LS-CCM mode, the maximum allowable setting for this parameter is 30 ms.
- **LS Blanking Refractories** – Consist of the following set of parameters that allow for the masking of unwelcome signals (e.g., noise) that may be detected before or after an atrial, RV, or LS event:
  - **Pre A Refractory Period:** Sets the time interval before an atrial event when LS signals are masked from detection.  
**Note:** This parameter is active only when the OPTIMIZER Smart Mini IPG is in ODO-LS-CCM mode.
  - **Post A Refractory Period:** Sets the time interval after an atrial event when LS signals are masked from detection.  
**Note:** This parameter is active only when the OPTIMIZER Smart Mini IPG is in ODO-LS-CCM mode.
  - **Pre RV Refractory Period:** Sets the time interval before an RV event when LS signals are masked from detection.
  - **Post RV Refractory Period:** Sets the time interval after an RV event when LS signals are masked from detection.
  - **Post LS Refractory Period:** Sets the time interval after an LS event when LS signals are masked from detection.

To modify the CCM Timing parameters:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**



- Click the **Parameters** button on the **Mode Bar**
- Select the **CCM Timing** tab
- On the **CCM Timing** panel, modify the CCM Timing parameters as needed
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.12 CCM Train

The **CCM Train** panel contains the following parameters:

- **CCM Train Delay:** Sets the time interval between the leading edge of the Local Sense triggering event and the start of CCM pulse train delivery.  
**Note:** When the OPTIMIZER Smart Mini IPG is in OVO-LS-CCM mode, the maximum allowable setting for this parameter is 45 ms.
- **CCM Amplitude:** Sets the voltage of the CCM therapy pulse.
- **Number of Biphasic Pulses:** Sets the number of biphasic CCM therapy pulses.
- **Balancing:** Sets the amount of time used by the OPTIMIZER Smart Mini IPG to discharge any residual polarization at the electrode/tissue interface after the delivery of the CCM pulse train has been completed.
- **First Phase Polarity:** Sets the first phase polarity of the CCM therapy pulse and offers the following options:
  - **Positive:** The first phase of the CCM pulse has a positive deflection (e.g., 7.5 V) followed by a corresponding negative deflection (e.g., -7.5 V).
  - **Negative:** The first phase of the CCM pulse has a negative deflection followed by a corresponding positive deflection.**Note:** If a patient expresses discomfort when the OPTIMIZER Smart Mini IPG is delivering CCM therapy, setting the first phase polarity to “Negative” may help alleviate this discomfort.
- **Phase Duration:** Sets the width of each CCM therapy pulse phase.  
**Note:** Do not change the Phase Duration from the default setting of 5.13 ms unless directed by a physician.
- **Interval:** Sets the time delay between each CCM therapy pulse.  
**Note:** If a patient expresses discomfort when the OPTIMIZER Smart Mini IPG is delivering CCM therapy, setting the Interval to a value > 1 ms may help alleviate this discomfort.
- **CCM Channels:** Assigns the channel to be used to deliver CCM therapy.

To modify the CCM Train parameters:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Parameters** button on the **Mode Bar**
- Select the **CCM Train** tab
- On the **CCM Train** panel, modify the CCM Train parameters as needed

**Note:** The CCM Train Graphic Display Window (on the right side of the CCM Train panel) shows a graphical view of the CCM Train parameters with respect to a valid LS event. Each parameter displayed in the window dynamically changes whenever its parameter value is modified.

- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.13 CCM-ICD Interaction Testing

The OPTIMIZER Smart Mini Programmer application has a **CCM-ICD Interaction Testing** tool that may be used whenever device/device interaction testing (see Appendix III) is performed between the OPTIMIZER Smart Mini IPG and an implanted ICD.

To begin CCM-ICD Interaction Testing:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Parameters** button on the **Mode Bar**
- Program the **Post-V Atrial Refractory Period** and **Post-V Ventricular (RV) Refractory Period** to 389.8 ms (see Section 3.11)
- Select the **CCM Train** tab
- On the **CCM Train** panel, press and hold the **CCM-ICD Interaction Testing** button

The **CCM Train Delay** parameter will be temporarily set to 85 ms.

To stop the CCM-ICD Interaction Testing:

- Release the **CCM-ICD Interaction Testing** button

The **CCM Train Delay** parameter will be returned to its pre-test programmed value.

When testing has been completed, click the Undo button to set the **Post-V Atrial Refractory Period** and **Post-V Ventricular (RV) Refractory Period** to their previous programmed values.

### 3.14 Continuous Mode

Continuous Mode allows the user to override scheduled CCM therapy delivery and initiate continuous CCM therapy delivery.

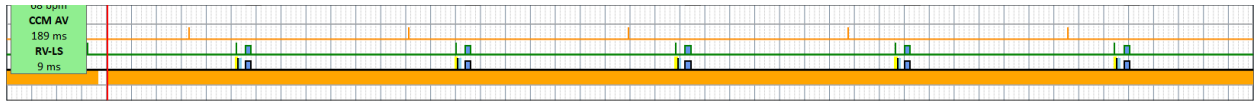
**Note:** The Continuous Mode option is only available when the OPTIMIZER Smart Mini IPG is not in **OOO** mode and **CCM Therapy Mode** is set to **ON**.

To start continuous CCM therapy delivery:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Diagnostics** button on the **Mode Bar**
- Select the **Continuous Mode** tab
- On the **Continuous Mode** panel, click the **Start Continuous Mode** button

The OPTIMIZER Smart Mini IPG will begin delivering continuous CCM therapy delivery for up to one hour.

**Note:** The **CCM Status** in the **Marker Sub-Pane** will be orange, indicating that CCM therapy is in Continuous Mode.



**Figure 44: Marker Sub-Pane with CCM Therapy in Continuous Mode**

To stop continuous CCM therapy delivery:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Diagnostics** button on the **Mode Bar**
- Select the **Continuous Mode** tab
- Click the **Stop Continuous Mode** button

### 3.15 Measuring Lead Impedances

The OPTIMIZER Smart Mini IPG measures the impedance of the ventricular leads by delivering of a biphasic pulse through each lead with the following parameters:

- **Number of Biphasic Pulses:** 1
- **Amplitude:** 4.5 V  $\pm$  10%
- **Phase Duration:** 0.5 ms  $\pm$  0.031 ms
- **Interval:** 60  $\mu$ s  $\pm$  10  $\mu$ s
- **Balancing:** 40 ms  $\pm$  5%

The ventricular lead impedance can be measured by the OPTIMIZER Smart Mini IPG, with a tolerance of 20%, if it is within the range of 75  $\Omega$  to 2000  $\Omega$ .

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

To measure the lead impedances:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Diagnostics** button on the **Mode Bar**
- Select the **Leads** tab
- On the **Leads** panel, click the **Measure Leads Impedance** button

When completed, the **V1 Lead Impedance:** and **V2 Lead Impedance:** fields will become populated with the lead impedance of each ventricular lead.

## 3.16 Special Modes

**Note:** Contact Impulse Dynamics technical support to obtain the passcode prior to attempting to reset the OPTIMIZER Smart Mini IPG.

### 3.16.1 Resetting the OPTIMIZER Smart Mini IPG

The OPTIMIZER Smart Mini 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 Mini IPG will place itself into a safe state referred to as “DOWN” Mode. In “DOWN” Mode, the OPTIMIZER Smart Mini IPG does not deliver CCM therapy and does not sense cardiac events. This status can be changed only by resetting the OPTIMIZER Smart Mini IPG using the OPTIMIZER Smart Mini Programmer application under physician supervision.

To reset the OPTIMIZER Smart Mini IPG:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTlink** button on the **OPTlink Session Pane**
- Click the **Diagnostic** button on the **Mode Bar**
- Select the **Special Modes** tab
- On the **Special Modes** panel, click the passcode box, enter the passcode obtained from Impulse Dynamics and then click **OK**
- When the **Special Modes** buttons become enabled, click the **Reset** button

If the OPTIMIZER Smart Mini IPG is successfully reset, the **CCM Status Pane** will show that the CCM Therapy setting for the OPTIMIZER Smart Mini IPG is “OOO”, indicating that the device has been set to Standby mode.

**IMPORTANT:** If a device is found to be in DOWN Mode, please document the contents of the DOWN Mode pop-up message, displayed whenever the IPG is interrogated, before resetting the device. After documenting the contents of the DOWN Mode message, contact your Impulse Dynamics representative. Also, please provide details regarding the device mode and the occurrence of any events that may have caused the device to revert to DOWN Mode.

## 3.17 Data Storage

### 3.17.1 Implant Data

Information pertaining to the implant of the system can be entered and stored in the OPTIMIZER Smart Mini. This information is displayed by the OPTIMIZER Smart Mini Programmer application whenever the Intelio Programmer is used to interrogate the OPTIMIZER Smart Mini IPG.

To edit the implant data:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTlink** button on the **OPTlink Session Pane**
- Click the **Diagnostic** button on the **Mode Bar**
- Select the **Data Storage** tab
- On the **Data Storage** panel, click the **Edit implant data** button

- When the **Data Storage** window appears, proceed with setting the implant date and entering the implant data in the fields provided.

The screenshot shows a 'Data Storage' window with the following fields and controls:

- Implant Date:** A date picker set to 01/01/2020.
- V1 Lead Model:** An empty text field.
- V2 Lead Model:** An empty text field.
- A Lead Model:** An empty text field.
- V1 Lead SN:** An empty text field.
- V2 Lead SN:** An empty text field.
- A Lead SN:** An empty text field.
- Paced Rhythm (Co-Implanted CRM Device):** A toggle switch currently set to OFF.
- CCM Delay/CCM Start Limit Measure During Optimizer/ICD Interaction Testing:** A numeric input field set to 40, followed by 'ms'.
- Minimum R-R Interval in ICD VT Zone:** A numeric input field set to 10, followed by 'ms'.
- Buttons:** 'Set Implant Data in IPG' and 'Cancel'.

**Figure 45: Data Storage Window**

- When the data entry has been completed, click the **Set Implant Data in IPG** button

The fields on the **Data Storage** panel should now be populated with the implant information.

### 3.17.2 Activity Tracking

Information about a patient's activity level can be obtained by using the Activity Tracking data collected and stored by the OPTIMIZER Smart Mini IPG.

The **Activity Tracking** setting controls the availability of the data collection methods used to obtain information about the patient's level of activity.

To set Activity Tracking:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTlink** button on the **OPTlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Data Storage** tab
- On the **Data Storage** panel, toggle the **Activity Tracking** button to enable (**ON**) or disable (**OFF**) the setting

**Note:** If **ON** is selected, the data collection methods for obtaining information about the patient's level of activity can subsequently be set, allowing the user to enable or disable each parameter.

### 3.17.2.1 Accelerometer

The **Accelerometer** setting controls the use of the built-in accelerometer in the OPTIMIZER Smart Mini IPG to collect information about the patient's level of activity with regards to movement (i.e., stationary vs. walking or running).

To set the Accelerometer:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Data Storage** tab
- On the **Data Storage** panel, toggle the **Accelerometer** button to enable (**ON**) or disable (**OFF**) the setting
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.17.2.2 Posture

The Posture setting controls the use of the built-in accelerometer in the OPTIMIZER Smart Mini IPG to collect information about the patient's posture (i.e., lying vs. standing).

To set the Posture:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Data Storage** tab
- On the **Data Storage** panel, toggle the **Posture** button to enable (**ON**) or disable (**OFF**) the setting
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.17.2.3 HRV

The **HRV** setting controls the use of the OPTIMIZER Smart Mini IPG to collect information about the patient's heart rate variability (HRV).

To set the HRV:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Data Storage** tab
- On the **Data Storage** panel, toggle the **HRV** button to enable (**ON**) or disable (**OFF**) the setting

- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.18 CCM Statistics

The OPTIMIZER Smart Mini IPG continuously monitors the patient's heart rhythm, collecting a statistical record of events and conditions that occur throughout the day. This record can be loaded into the OPTIMIZER Smart Mini Programmer application and viewed using the CCM Statistics window of the OPTIMIZER Smart Mini Programmer application.

#### 3.18.1 Viewing CCM Statistics

To view the CCM Statistics from the OPTIMIZER Smart Mini IPG:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Follow-up** button on the **Mode Bar**
- Select the **Trends** tab
- On the **Trends** panel, click the **CCM Statistics** button

If successful, the Programmer will display the CCM Statistics table. To view each statistical category, select its **CCM Statistics** tab.

Summary

Trends

CCM Settings

CCM Statistics

On - General

On - Inhibition

Off - General

Off - Inhibition

Other

Date	Events		Periods			Trains Delivered	
	Atrial	Ventricular	LS in Alert	Normal	Inhibited	Post-Inhibited	Total
17/06/2020 19:41:49	14845	25147	24248	24189	513	24	24195
17/06/2020 19:42:50	14906	25208	24274	24215	513	24	24220
17/06/2020 19:45:37	14923	25225	24282	24223	513	24	24229
17/06/2020 20:46:23	19004	29306	28363	28304	513	24	28310

Read

Reset

Figure 46: CCM Statistics

##### 3.18.1.1 CCM Statistics Tabs

- On - General:** Events occurring when the OPTIMIZER Smart Mini IPG is scheduled to deliver CCM therapy (On Time).
  - Events**
    - Atrial:** The number of atrial events sensed during scheduled CCM delivery (ODO-LS-CCM mode only).
    - Ventricular:** The number of ventricular (RV) events sensed during scheduled CCM delivery.
    - LS in Alert:** The number of local sense (LS) events sensed during scheduled CCM delivery.
  - Periods**
    - Normal:** The number of normal event cycles (i.e., detected ventricular and LS in Alert events) during scheduled CCM delivery.
    - Inhibited:** The number of inhibited event cycles during scheduled CCM delivery.

- **Post-Inhibited:** The number of post-inhibited event cycles during scheduled CCM delivery.
- **Trains Delivered**
  - **Total:** The total number of CCM trains delivered during scheduled CCM delivery.
- **On – Inhibition:** Inhibitions occurring when the OPTIMIZER Smart Mini IPG is scheduled to deliver CCM therapy (On Time).
  - **Causes**
    - **AT:** The number of atrial events exceeding the tachycardia rate during scheduled CCM delivery (ODO-LS-CCM mode only).
    - **PVC:** The number of PVCs detected during scheduled CCM delivery (ODO-LS-CCM mode only).
    - **Long AV:** The number of times Long AV condition detected during scheduled CCM delivery (ODO-LS-CCM mode only).
    - **Short AV:** The number of times Short AV condition detected during scheduled CCM delivery (ODO-LS-CCM mode only).
    - **LS Alert:** The number of Local Sense events outside the LS Alert Window during scheduled CCM delivery.
    - **LS Absence:** The number of Local Sense events not detected during scheduled CCM delivery.
    - **VT:** The number of ventricular events exceeding the tachycardia rate during scheduled CCM delivery (OVO-LS-CCM mode only).
    - **Charger:** The number of beats inhibited during scheduled CCM delivery due to the IPG being subjected to a charging session.
  - **Noise Episodes**
    - **A Noise:** The number of atrial noise episodes detected during scheduled CCM delivery (ODO-LS-CCM mode only).
    - **V Noise:** The number of ventricular noise episodes detected during scheduled CCM delivery.
- **Off – General:** Events occurring when the OPTIMIZER Smart Mini IPG is not scheduled to deliver CCM therapy (Off Time). Displays the same list of CCM statistical counters as detailed under **On – General** (except for **Trains Delivered**).
- **Off – Inhibition:** Inhibitions occurring when the OPTIMIZER Smart Mini IPG is not scheduled to deliver CCM therapy (Off Time). Displays the same list of CCM statistical counters as detailed under **On – Inhibition**.



- **Other**
  - **Last Session:** The period between the current day's CCM Therapy Start Time and End Time.
    - **Last Delivery V:** The number of ventricular events sensed during the current day's CCM scheduled delivery session.
    - **Last Delivery Trains:** The number of CCM trains delivered during the current day's CCM scheduled delivery session.
    - **Percentage:** CCM delivery percentage during the current day's CCM scheduled delivery session.
    - **Max Lead Impedance Change Alert:** Indicates whether the Max Impedance Change alert was triggered at the start of the day's CCM therapy session.
    - **Min Target CCM Therapy % Alert:** Indicates whether the Min Target CCM Therapy % alert was triggered at the start of the day's CCM therapy session.
  - **General**
    - **Lead Displacement:** The number of lead displacement detections.
    - **Battery Discharge Episodes:** The number of times the device reverted to OOO mode due to the battery voltage dropping below 3.5 V.

#### 3.18.1.2 CCM Statistics Buttons

- **Read:** Reads the latest CCM statistics from OPTIMIZER Smart Mini IPG.
- **Reset:** Resets the CCM statistics stored in OPTIMIZER Smart Mini IPG.

#### 3.18.2 Resetting CCM Statistics Counters

To reset the OPTIMIZER Smart Mini IPG CCM Statistics counters to zero:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTILink** button on the **OPTILink Session Pane**
- Click the **Follow-up** button on the **Mode Bar**
- Select the **Trends** tab
- On the **Trends** panel, click the **CCM Statistics** button
- Select the **Reset** button at the bottom of the **CCM Statistics** window

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

### 3.19 Blinded Mode

When the OPTIMIZER Smart Mini IPG is used for a blinded clinical investigation, the study protocol may stipulate that the OPTIMIZER Smart Mini IPG implanted in one group of patients be programmed not to deliver CCM therapy. Since the battery discharge rate of an OPTIMIZER Smart Mini IPG programmed to not deliver CCM therapy is significantly less than an OPTIMIZER Smart Mini IPG programmed to deliver CCM therapy, this disparity in battery discharge rates may lead to the unblinding of the patient's device configuration.

The blinded mode feature allows the charging behavior of an OPTIMIZER Smart Mini IPG that is not programmed to deliver CCM therapy to mimic the behavior of an OPTIMIZER Smart Mini IPG that is programmed to deliver CCM therapy.

### 3.20 Temperature Charge Constants

**Note:** The Temperature Charge Constants do not typically require modification and should only be changed by or at the direction of a physician.

To ensure patient safety while charging the OPTIMIZER Smart Mini IPG, the temperature of the IPG is monitored during the charging process. The temperature limits used by the OPTIMIZER Smart Mini IPG when monitoring its temperature are referred to as the Temperature Charge Constants.

To read and set the Temperature Charge Constants:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the Start **OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the **Mode Bar**
- Select the **Charger** tab
- Click the **Temperature Charge Constants** button
- When the **Temperature Charge Constants** window appears, click the **Read** button
- Click the up/down arrows next to any listed charge constant parameter to change its value
- Click the **Set** button to program the changes into the OPTIMIZER Smart Mini IPG
- Click the X at the top right corner of the **Temperature Charge Constants** window to close it

Parameter	Value
Low Integrity Temperature Threshold (°C)	10
High Integrity Temperature Threshold (°C)	45
Maximum Allowed Initial Temperature (°C)	39.00
Maximum Allowed Temperature During Charge (°C)	42.00
Restart Temperature (°C)	2.50

**Figure 47: Temperature Charge Constants Window**

## 3.21 Patient Alerts

Patient Alerts are specific Direct Action Alerts or Alert Codes displayed by the Vesta Charger that notify the patient of a condition they need to address.

### 3.21.1 Alert Delivery Mode

The Alert Delivery Mode allows the user to set if and when audible tones are emitted by the Vesta Charger whenever it displays a Patient Alert received from the OPTIMIZER Smart Mini IPG.

To set the Alert Delivery Mode:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, click the **Alert Delivery Mode** button
- The **Alert Delivery Mode** parameter window will display the following options for this parameter:
  - **Never** – Audible tones are never emitted by the Vesta Charger when it displays a Patient Alert received from the OPTIMIZER Smart Mini IPG
  - **Always** – Audible tones are always emitted by the Vesta Charger when it displays a Patient Alert received from the OPTIMIZER Smart Mini IPG
  - **Scheduled** – Audible tones are emitted by the Vesta Charger only when it displays a Patient Alert received from the OPTIMIZER Smart Mini IPG during the period specified by the Alert Delivery Mode Start and End parameter settings

**Note:** If **Scheduled** is selected, the **Start** and **End** parameters become enabled, allowing the user to set these parameters.

To set the parameters for Patient Alert Start Time and End Time:

- On the **Patient Alerts** panel, select the **Patient Alert Start Time Hour** parameter
- Select one of the parameter choices shown in the **Patient Alert Start Time Hour (h)** parameter window
- On the **Patient Alerts** panel, select the **Patient Alert Start Time Minute** parameter
- Select one of the parameter choices shown in the **Patient Alert Start Time Minute (m)** parameter window
- On the **Patient Alerts** panel, select the **Patient Alert End Time Hour** parameter
- Select one of the parameter choices shown in the **Patient Alert End Time Hour (h)** parameter window
- On the **Patient Alerts** panel, select the **Patient Alert End Time Minute** parameter
- Select one of the parameter choices shown in the **Patient Alert End Time Minute (m)** parameter window

- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.2 Maximum Lead Impedance Change Alert

The OPTIMIZER Smart Mini IPG is programmed to conduct lead impedance measurements each day automatically. These daily lead impedance measurements are collected and used by the OPTIMIZER Smart Mini IPG to monitor the leads for changes in impedance.

The following conditions trigger the Maximum Lead Impedance Change alert:

- The difference in percentage between the average of the last three daily impedance measurements and the average of the last 30 daily impedance measurements is greater than the maximum lead impedance change %.
- The last impedance measurement was lower than 50Ω or greater than 2000Ω.

To set the Maximum Lead Impedance Change alert and set its % value:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTlink** button on the **OPTlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **Maximum Lead Impedance Change** button to enable (**ON**) or disable (**OFF**) the alert
- If enabled, the default (or previously programmed) value for the Maximum Lead Impedance Change Percentage parameter will now appear next to the **Maximum Lead Impedance Change**
- If required, change the Maximum Lead Impedance Change Percentage parameter
  - Click the numerical parameter value
  - Select a value from the **Maximum Lead Impedance Change Percentage** parameter window
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.3 Minimum Target CCM Therapy Rate Alert

The OPTIMIZER Smart Mini IPG maintains a record of the events and conditions that occurred during the last active scheduled CCM delivery period. This record is used to determine the percentage of CCM therapy pulses delivered during this period.

The Minimum Target CCM Therapy Rate alert is triggered if the averaged percentage of CCM therapy pulses delivered in the last three days is below the Minimum Target CCM Therapy Rate %.

To set the Minimum Target CCM Therapy Rate alert and set its % value:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTlink** button on the **OPTlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab

- On the **Patient Alerts** panel, toggle the **Minimum Target CCM Therapy Rate** button to enable (**ON**) or disable (**OFF**) the alert
- If enabled, the default (or previously programmed) value for the Minimum Target CCM Therapy Rate Percentage parameter will now appear next to the **Minimum Target CCM Therapy Rate**
- If required, change the Minimum Target CCM Therapy Rate Percentage parameter
  - Click the numerical parameter value
  - Select a value from the **Minimum Target CCM Therapy Rate %** parameter window
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

#### 3.21.4 Battery Recharge Reminder Alert

The OPTIMIZER Smart Mini IPG maintains a record of charging events. This record is used to determine the number of days since it was last charged.

The Battery Recharge Reminder alert is triggered if the number of days since the Vesta Charger last charged the OPTIMIZER Smart Mini IPG exceeds the programmed value of the Battery Recharge Reminder days set by the OPTIMIZER Smart Mini Programmer application.

To set the Battery Recharge Reminder alert and set its days value:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **Battery Recharge Reminder** button to enable (**ON**) or disable (**OFF**) the alert
- If enabled, the default (or previously programmed) value for the Battery Recharge Reminder Days parameter will now appear next to the **Battery Recharge Reminder**
- If required, change the Battery Recharge Reminder Days parameter
  - Click the numerical parameter value
  - Select a value from the **Battery Recharge Reminder Days** parameter window
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.5 CCM Therapy Suspended Alert

The CCM Therapy Suspended alert is triggered whenever CCM therapy is suspended in the OPTIMIZER Smart Mini IPG for any reason.

To set the CCM Therapy Suspended alert:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **CCM Therapy Suspended** button to enable (**ON**) or disable (**OFF**) the alert
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.6 Long Time Without Communication With The IPG Alert

The Vesta Charger keeps a record of the communication events with the OPTIMIZER Smart Mini IPG. This record is used to determine the number of days since its last successful communication event with the OPTIMIZER Smart Mini IPG.

The Long time without communication with the IPG alert is triggered if the number of days since the Vesta Charger successfully communicated with the OPTIMIZER Smart Mini IPG exceeds the Long time without communication with the IPG days parameter value set by the OPTIMIZER Smart Mini Programmer application.

To set the Long time without communication with the IPG alert and set its days value:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **Long time without communication with the IPG** button to enable (**ON**) or disable (**OFF**) the alert
- If enabled, the default (or previously programmed) value for the Long time without communication with the IPG days parameter will now appear next to the **Long time without communication with the IPG**
- If required, change the Long time without communication with the IPG days parameter
  - Click the numerical value
  - Select a value from the **Long time without communication with the IPG days** parameter window
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.7 Down Mode Alert

The **Down Mode** alert is triggered whenever when the OPTIMIZER Smart Mini IPG has been placed into “DOWN” Mode for any reason.

To set the Down Mode alert:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **Down Mode** button to enable (**ON**) or disable (**OFF**) the alert
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.8 CCM Not Sensing/Noise Alert

The **CCM Not Sensing/Noise** alert is triggered by the following conditions:

- The OPTIMIZER Smart Mini IPG did not sense an RV event for 17 consecutive cycles (minimum of 30 seconds)
- 1000 cycles of either A or RV noise detected in 1 day (minimum of 30 minutes of noisy cycles)

To set the CCM Not Sensing/Noise alert:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **CCM Not Sensing/Noise** button to enable (**ON**) or disable (**OFF**) the alert
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.9 Charger Battery Low Alert

The **Charger Battery Low** alert is triggered whenever the charge level of the battery in the Vesta Charger drops below 10%.

To set the Charger Battery Low alert:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **Charger Battery Low** button to enable (**ON**) or disable (**OFF**) the alert
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.10 Charger Failure Alert

The **Charger Failure** alert is triggered when the Vesta Charger detects an internal failure.

To set the Charger Failure alert:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **Charger Failure** button to enable (**ON**) or disable (**OFF**) the alert
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting

### 3.21.11 Rechargeable Battery Low Alert

The **Rechargeable Battery Low** alert is triggered whenever the OPTIMIZER Smart Mini IPG's battery voltage drops to 3.5 V or lower.

To set the Rechargeable Battery Low alert:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Patient Alerts** tab
- On the **Patient Alerts** panel, toggle the **Rechargeable Battery Low** button to enable (**ON**) or disable (**OFF**) the alert
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new parameter setting



### 3.22 Activity Sensor

The OPTIMIZER Smart Mini IPG includes a built-in accelerometer, which it utilizes as an “Activity Sensor”, allowing it to monitor the activity level of the patient.

To complete the initial setup of the Activity Sensor:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the Mode Bar
- Select the **Activity** tab
- On the **Activity** panel, click the **Activity Sensor Setup** button
- When the Activity Sensor Setup window appears, have the patient stand upright and then click the **Vertical** button
- Have the patient assume a supine position and then click the **Horizontal** button
- Click the Save button to save the calibration
- Click the red “X” at the top right of the Activity Sensor Setup window

To enable the collection of data using the activity sensor, see Section 3.17.2.

### 3.23 Clock Settings for the OPTIMIZER Smart Mini IPG

The date and time of the OPTIMIZER Smart Mini IPG is maintained by an internal clock and is used by the following IPG functions:

- The CCM Therapy Delivery scheduling mechanism to turn the CCM Therapy ON and OFF in accordance with the programmed CCM Therapy scheduling parameters
- The performance of daily lead measurements (lead impedance, IEGM amplitudes, etc...)
- The assignment of a date and time to logged events
- Updating of the date and time in the Vesta Charger

#### 3.23.1 Reading the OPTIMIZER Smart Mini IPG Time

The real-time clock in the OPTIMIZER Smart Mini 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.

To read the current device time of the OPTIMIZER Smart Mini IPG:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the **Mode Bar**
- Select the **Clock** tab
- On the **Clock** panel, click the **Read IPG Clock** button

### 3.23.2 Setting the OPTIMIZER Smart Mini IPG Real Time Clock

The real-time clock of the OPTIMIZER Smart Mini IPG can be set manually or synchronized to the programmer's clock.

To set the current device time of the OPTIMIZER Smart Mini IPG:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG
  - Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - Click the **Start OPTIlink** button on the **OPTIlink Session Pane**
- Click the **Preferences** button on the **Mode Bar**
- Select the **Clock** tab
- On the **Clock** panel, click the **Read IPG Clock** button

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

- When the IPG's Local time window appears, change the date and time as needed and then click the **Set IPG Clock** button

To synchronize the clock of the OPTIMIZER Smart Mini IPG to the programmer's clock:

- Click the **Synchronize IPG Clock To Programmer Clock** button

## 3.24 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 OPTIMIZER Smart Mini Programmer application can interpret. The file extension used for them is ".mips". The OPTIMIZER Smart Mini Programmer application's **Open** command reads data from a .mips file and the **Save** command writes data to a .mips file.

### 3.24.1 Saving a Standard File

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

- Click the **Tools** button on the **Mode Bar**
- Select the **Standards** tab
- On the **Standards** panel, click the **Save Program** button
- When the **Save Standard** window appears, enter a file name for the standard to be saved and then click **Save**

### 3.24.2 Opening a Standard File

To open a standard (.mips) file:

- Click the **Tools** button on the **Mode Bar**
- Select the **Standards** tab
- On the **Standards** panel, click the **Load Program** button
- When the **Load Standard** window appears, select the file to be loaded, and then click **Open**
- Click the blinking **Program** button on the **Programming Buttons Pane** to load the OPTIMIZER Smart Mini IPG with the new CCM parameters from the standard file

When parameter values are loaded from a standard file but not yet programmed into the OPTIMIZER Smart Mini IPG, they become the current parameter values displayed by the Programmer. If any of the standard's parameter values are different from the current programmed parameter values, they are displayed in blue.

### 3.25 Programmer Log

The OPTIMIZER Smart Mini Programmer application keeps a log of all the interactions that occur between the programmer and an OPTIMIZER Smart Mini IPG. This record can be used as an index to provide quick access to specific data retrieved from the OPTIMIZER Smart Mini IPG during device communications.

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

- The log file for a particular OPTIMIZER Smart Mini IPG is created when the device is interrogated for the first time.
- Each communications event that occurs between the OPTIMIZER Smart Mini Programmer application and the OPTIMIZER Smart Mini IPG appears in the **Programmer Log**, together with the date and time of each interaction.
- More information regarding a communication event in the log may be obtained by double-clicking on the communication event in the Programmer Log. If there is data associated with the selected communication event, the following occurs:
  - If an Interrogation or Programming event is chosen, the parameter values displayed by the OPTIMIZER Smart Mini Programmer application are the set of values present at the moment the selected communication event occurred.
  - If an event such as Get Battery Capacity is chosen, the data shown is the value detected when the selected communication event occurred.
- For all other recorded events (Get Session Info, etc.), no additional information regarding the communication event is shown in the Programmer Log.
- To view the entire log, double-click on the gray bar to the right of the Programmer Log, keeping the stylus in contact with the gray bar with the second click. When the bar's color turns dark gray, move the stylus up or down the screen along the right of the Programmer Log to scroll the length of the log.

# APPENDIX I

## Statement of FCC Compliance

### FCC Compliance of the Intelio Programming Interface

THE INTELIO PROGRAMMER INTERFACE IS EXEMPT FROM FCC CERTIFICATION  
SEE 15.103(e)

### FCC Compliance of the Intelio Programming Wand

The Intelio Programming Wand has been tested to the following FCC rules:

- 47 CFR Part 15 – Radio Frequency Devices
- 47 CFR Part 95 Subpart I - Medical Device Radio Communications Service

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration "Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

Changes or modifications to the Intelio Programming Wand not approved by Impulse Dynamics could void the user's authority to operate the equipment under FCC rules.

### FCC Compliance of the Legacy Programming Wand

The Legacy Programming Wand has been tested to the following FCC rule:

- 47 CFR Part 15 – Radio Frequency Devices

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:


- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications to the Legacy Programming Wand not approved by Impulse Dynamics could void the user's authority to operate the equipment under FCC rules.

## Electromagnetic Immunity

### Electromagnetic Immunity of the Intelio Programmer

<b>GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE INTELIO PROGRAMMER</b>			
The Intelio Programmer, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.			
<p>Essential Performance of the Intelio Programmer:</p> <ul style="list-style-type: none"> <li>The Programming System shall be able to program the IPG with a safe program. It is allowable that this may require an occasional reattempt.</li> <li>The Programming System shall be able to reprogram the IPG with a desired program. It is allowable that this may require an occasional retrying of the programming operation, or restarting the computer.</li> <li>The Programming System shall only program the intended program and show as retrieved critical data the current set stored in the IPG.</li> </ul> <p><b>NOTE:</b> In case of emergency, placing a pacemaker magnet over the implant site of the OPTIMIZER Smart Mini IPG and maintaining it in close proximity to the device for at least two cardiac cycles (2–3 seconds), sets the OPTIMIZER Smart Mini IPG into Magnet Mode, suspending CCM therapy.</p>			
<b>Immunity test</b>	<b>IEC 60601-1-2:2014 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidelines</b>
Electrostatic discharge as defined in IEC 61000-4-2	Contact Discharge: $\pm 8$ kV Air Discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, and $\pm 15$ kV	Contact Discharge: $\pm 8$ kV Air Discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, and $\pm 15$ kV	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	$\pm 2$ kV for mains power supply $\pm 1$ kV for in-/output lines	$\pm 2$ kV for mains power supply $\pm 1$ kV for in-/output lines	Mains power quality should be that of a typical professional healthcare or hospital environment.  Do not operate motors or other noisy electrical equipment on the same mains circuit as the Intelio Programmer.
AC line voltage surges as defined in IEC 61000-4-5	Line-to-Earth $\pm 2$ kV; Line-to-Line $\pm 1$ kV	Line-to-Earth $\pm 2$ kV; Line-to-Line $\pm 1$ kV	Mains power quality should be that of a typical professional healthcare or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines as defined in IEC 61000-4-11	Dips: 100% reduction for 0.5/1 cycles 30% reduction for 25/30 cycles Interruptions: 100% reduction for 250/300 cycles	Dips: 100% reduction for 0.5/1 cycles 30% reduction for 25 cycles Interruptions: 100% reduction for 250 cycles	Mains power quality should be that of a typical professional healthcare or hospital environment.  <b>Note:</b> If the user of the Intelio Programmer requires uninterrupted operation during power mains interruptions, it is recommended to power the Intelio Programmer from an uninterruptible power supply.

Power line frequency magnetic fields (50/60 Hz) as defined in IEC 61000-4-8	3 A/m	3 A/m	Power line frequency magnetic fields (50/60 Hz) should be at levels expected in a typical professional healthcare or hospital environment.
Conducted RF as defined in IEC 61000-4-6:2013	3 V r.m.s outside industrial, scientific, and medical (ISM) and amateur radio bands between 0.15 MHz and 80 MHz, 6 V r.m.s. in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V r.m.s outside industrial, scientific, and medical (ISM) and amateur radio bands between 0.15 MHz and 80 MHz, 6 V r.m.s. in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b>  $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz  Where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m).  Field strengths from fixed 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:  
Radiated RF as defined in IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010	10 V/m: 80 MHz to 2.7 GHz and wireless frequencies	10 V/m: 80 MHz to 2.7 GHz and wireless frequencies	

**NOTES:**

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 Intelio Programmer is used exceeds the applicable RF compliance level above, the Intelio Programmer should be monitored to ensure normal operation. If an abnormal function is observed, additional measures may be necessary, such as relocating the Intelio Programmer.

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

**Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Intelio Programmer**

<b>Recommended separation distances between portable and mobile RF communications equipment and the Intelio Programmer</b>			
The Intelio Programmer should be used in an electromagnetic environment with limited radiated RF noise. The customer or user of the Intelio Programmer can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the Intelio Programmer recommended below, which is determined by the maximum output power of the communications equipment.			
<b>Rated maximum output power of transmitter (W)</b>	<b>Separation distance broken down by transmitter frequency(m)</b>		
	<b>150 kHz to 80 MHz<sup>1</sup> <math>d = 1.17\sqrt{P}</math></b>	<b>80 MHz to 800 MHz<sup>1</sup> <math>d = 1.17\sqrt{P}</math></b>	<b>800 MHz to 2.5 GHz <math>d = 2.33\sqrt{P}</math></b>
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.75
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.70	11.70	23.30
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.			
<sup>1</sup> At 80 MHz and 800 MHz, the higher frequency range applies.			
<b>Note:</b> These guidelines may not apply to all settings. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and people.			

## Electromagnetic Emissions

### Electromagnetic Emissions from the Intelio Programmer with Intelio Programming Wand

The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

**Warning:** The Intelio Programmer with Intelio Programming Wand must not be used onboard an aircraft.

**Warning:** Permission must be requested from a ship's crew prior to using the Intelio Programmer with Intelio Programming Wand onboard a ship.

### FCC 47 CFR 95 Subpart I - Medical Device Radio Communications Service

#### GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:

#### FCC - 47 CFR 95 Subpart I - Medical Device Radio Communications Service

The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.

Emissions Test	Compliance	Electromagnetic environment - guidelines
Duration of Transmissions	Complies with clause 95.2557	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Frequency Monitoring	Complies with clause 95.2559	
Frequency Accuracy	Complies with clause 95.2565	
EIRP	Complies with clause 95.2567(a)	
Field Strength	Complies with clause 95.2569	
Bandwidth	Complies with clause 95.2573	
Unwanted Emissions	Complies with clause 95.2579	
Permissible Exposure Evaluation	Complies with clause 95.2585	



**GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:**

**ETSI EN 301 839 V2.1.1 - Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU**

The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidelines</b>
Frequency Error	Complies with clause 5.3.1	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Occupied Bandwidth	Complies with clause 5.3.2	
Power Output	Complies with clause 5.3.3	
Transmitter Spurious Emissions (30 MHz to 6 GHz)	Complies with clause 5.3.4	
Frequency Stability Under Low Voltage Conditions	Complies with clause 5.3.5	
Spurious Radiation of Receivers	Complies with clause 5.3.6	

**GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:**

**ETSI EN 301 489-1 V2.2.3 - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility**

**ETSI EN 301 489-27 - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P) operating in the 402 MHz to 405 MHz bands; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU**

The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.

There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidelines</b>
Radiated Emissions EN 55032:2012/AC:2013	Class B	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions EN 55032:2012/AC:2013	Class B	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.  Class A equipment is equipment suitable for use in all establishments other than domestic buildings, and Class B equipment is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
AC Harmonic Emissions IEC 61000-3-2:2014	Class A	
Voltage Flicker IEC 61000-3-3:2013	Pass for all parameters	

**GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:**

**IEC 60601-1-2 2014, Edition 4.0 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests**

The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.

There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidelines</b>
Radiated Emissions CISPR 11: 2009 + A1:2010	Group 2, Class A	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions CISPR 11: 2009 + A1:2010; FCC 18	Group 1, Class B	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.  Class A equipment is equipment suitable for use in all establishments other than domestic buildings, and Class B equipment is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
AC Harmonic Emissions IEC 61000-3-2:2014	Class A	
Voltage Flicker IEC 61000-3-3:2013	Pass for all parameters	

## Electromagnetic Emissions from the Intelio Programmer with Legacy Programming Wand

The Intelio Programmer with Legacy Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

**Warning:** The Intelio Programmer with Legacy Programming Wand must not be used onboard an aircraft.

**Warning:** Permission must be requested from a ship's crew prior to using the Intelio Programmer with Legacy Programming Wand onboard a ship.

### FCC - 47 CFR Part 15 – Intentional Radiators

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH LEGACY PROGRAMMING WAND PURSUANT TO:		
FCC - 47 CFR Part 15 – Intentional Radiators		
The Intelio Programmer with Legacy Programming Wand, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.		
Emissions Test	Compliance	Electromagnetic environment - guidelines
Fundamental Radiated 15.209	Complies with clause 15.209	The Intelio Programmer with Legacy Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions 15.207	Complies with clause 15.207	
Spurious Emissions	Complies with clause 15.209	
Permissible Exposure Evaluation	1.1307(b) and 2.1093 exposure limit satisfied	

### ETSI EN 302 195

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH LEGACY PROGRAMMING WAND PURSUANT TO:		
ETSI EN 302 195 V2.1.1 - Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU		
The Intelio Programmer with Legacy Programming Wand, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.		
Emissions Test	Compliance	Electromagnetic environment - guidelines
Radiated Field Strength	Complies with clause 4.2.1	The Intelio Programmer with Legacy Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Modulation Bandwidth	Complies with clause 4.2.2	
Transmitter Spurious Emissions (9 kHz to 30 MHz)	Complies with clause 4.2.3	
Duty Cycle	Complies with clause 4.2.4	
Receiver Blocking	Complies with clause 4.3.2	
Receiver Spurious Emissions (9 kHz to 30 MHz)	Complies with clause 4.3.3	

**GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH LEGACY PROGRAMMING WAND PURSUANT TO:**

**ETSI EN 301 489-1 V2.2.3 - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility**

**EN 301 489-31 - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonised Standard covering the essential requirements of article 3.1(b) of the Directive 2014/53/EU**

The Intelio Programmer with Legacy Programming Wand, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.

There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidelines</b>
Radiated Emissions CISPR 11:2009 + A1:2010	Group 2, Class A	The Intelio Programmer with Legacy Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions EN 55032:2012/AC:2013	Class B	The Intelio Programmer with Legacy Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.  Class A equipment is suitable for use in all establishments other than domestic buildings, and Class B equipment is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
AC Harmonic Emissions IEC 61000-3-2:2014	Class A	
Voltage Flicker IEC 61000-3-3:2013	Pass for all parameters	

# IEC 60601-1-2

## GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH LEGACY PROGRAMMING WAND PURSUANT TO:

**IEC 60601-1-2 2014, Edition 4.0 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests**

The Intelio Programmer with Legacy Programming Wand, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.

There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidelines</b>
Radiated Emissions CISPR 11:2009 + A1:2010	Group 2, Class A	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions CISPR 11: 2009 + A1:2010	Group 2, Class B	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.  Class A equipment is equipment suitable for use in all establishments other than domestic buildings, and Class B equipment is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
AC Harmonic Emissions IEC 61000-3-2:2014	Class A	
Voltage Flicker IEC 61000-3-3:2013	Pass for all parameters	

## APPENDIX II

### Wireless Technology

RF wireless technology is used in the communication between an OPTIMIZER Smart Mini Implantable Pulse Generator (IPG) and an Intelio Programmer. It occurs through an encrypted channel over an RF link that complies with the requirements of the Medical Implant Communication System (MICS) (range specified to 2 m, 402–405 MHz) of the MedRadio Band. The “OPTIlink” encrypted MICS channel is established after the IPG is positively identified and encryption keys are exchanged via a very-short-range (< 4 cm) communication over the 13.56 MHz recharge channel.

Lastly, the Legacy Programming Wand, which is part of the Intelio Programming System, is capable of communicating with the OPTIMIZER SMART IPG using short-range (< 5 cm) magnetic-coupling telemetry.

#### Intelio Programmer with Intelio Programming Wand Wireless Nominal Specifications

Characteristic	Nominal
<b>OPTIlink MICS MedRadio</b>	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	< 145 kHz
Modulation	FSK
Radiated Power	< 25 $\mu$ W E.I.R.P.
Range	0 to at least 1.5 m
<b>Recharge Channel Communication</b>	
Frequency Band	13.56 MHz $\pm$ 100 ppm Industrial, Scientific, and Medical radio band (ISM)
Bandwidth	<0.014 MHz
Modulation	PPM
Radiated Power	<7 mW
Range	5 mm to 40 mm

### Intelio Programmer with Legacy Wand Wireless Nominal Specifications

**Note:** Programming Application Software is not currently available for the Intelio Programmer to program the OPTIMIZER Smart IPG

Characteristic	Nominal
<b>Legacy Programming Wand to OPTIMIZER Smart IPG</b>	
Frequency Band	23 kHz
Modulation	100% AM: "0" = no carrier, "1" = carrier for 305 $\mu$ s
Radiated Power	0.56 W <sub>peak</sub> ; 0.27 W <sub>average</sub>
Range	5 mm to 50 mm
<b>OPTIMIZER Smart IPG to Legacy Wand</b>	
Frequency Band	14.5 kHz LC excited by pulse; 1 cycle per pulse until dampened to 10%
Modulation	PPM: "0" = 180 $\mu$ s, "1" = 270 $\mu$ s
Radiated Power	5.14 mW <sub>peak</sub> per pulse; 1.8 mW <sub>average</sub>
Range	5 mm to 50 mm



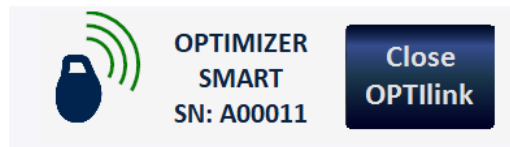
## Quality of Service (QoS) for Wireless Technology

### QoS for Communications between the Intelio Programmer and the OPTIMIZER Smart Mini IPG

MedRadio in the MICS sub-band (402 to 405 MHz) wireless technology enables communication between the OPTIMIZER Smart Mini IPG and the Intelio Programmer.

Before the Intelio Programmer can be used to program the OPTIMIZER Smart Mini IPG, an OPTIlink communication session must first be established between the Intelio Programmer and the IPG. This is accomplished by means of the Intelio Programming Wand, which must be placed over the implant site and within 4 cm of the IPG. Once the Intelio Programming Wand is over the patient's implant site, the communication link is established by initiating the Start OPTIlink command. Encryption keys are exchanged through a proprietary process using the 13.56 MHz Recharge Channel, after which the Intelio Programming Wand can be placed within 1.5 m (5 ft) away from the implant site, with communications taking place over MedRadio.

The OPTIlink Signal Strength Indicator dynamically displays the Quality of Service (QoS) for the link between the Intelio Programming Wand and the OPTIMIZER Smart Mini IPG. Depending on the quality of the link, the curved “waves” of the Signal Strength Indicator are displayed in the following manner:



- Good quality link – 3 green signal waves
- Medium quality link – 2 yellow signal waves
- Low quality link – 1 red signal wave

## Wireless Security Measures

### Wireless Security Measures in OPTIlink Communications between OPTIMIZER Smart Mini IPG and Intelio Programmer

OPTIlink wireless signals are secured through device system design that includes the following:

- Establishing an OPTIlink communications channel requires the Intelio Programming Wand to be placed within 4 cm of the OPTIMIZER Smart Mini IPG. The 13.56 MHz short-range channel is used as part of a proprietary process to authenticate the devices and securely exchange encryption keys.
- The OPTIMIZER Smart Mini IPG and the Intelio Programmer encrypt their wireless communications using encryption keys that are randomly generated for each OPTIlink session.
- Only one Intelio Programmer may communicate with the IPG at the same time.

## Troubleshooting for Wireless Coexistence Issues

### Troubleshooting OPTIlink Connection between the OPTIMIZER Smart Mini IPG and the Intelio Programmer

If you experience issues with establishing an OPTIlink session between the OPTIMIZER Smart Mini IPG and the Intelio Programmer, try the following:

- Reposition the Intelio Programming Wand so that it lays parallel to the IPG's plane and its center is coaxial with the center of the IPG's header.
- Decrease the distance between the devices.
- Move the devices away from other devices that may be causing interference.
- Do not operate other wireless devices (i.e., programmers for other devices, laptop, tablet, mobile phone, or cordless phone) at the same time.

If you experience issues with maintaining an OPTIlink session between the OPTIMIZER Smart Mini IPG and the Intelio Programmer, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Do not operate other wireless devices (i.e., programmers for other devices, laptop, tablet, mobile phone, or cordless phone) at the same time.
- Wait a few minutes and try connecting again

**NOTE:** Wireless communications equipment, such as wireless home network devices, mobile and cordless telephones, and tablets, could affect the quality of the OPTIlink connection.

## APPENDIX III

### Security of the Intelio Programmer Unit

#### How the Programmer Promotes Security

All installed software in the Intelio Programmer Unit has been approved by Impulse Dynamics.

It is not possible to install general-purpose software on the programmer.

Controlling installed software minimizes the potential for vulnerabilities.

Internal software that runs the programmer is locked from change. Every time the programmer is started, a clean version of the installed software is used.

The disk drive is encrypted.

#### What Hospitals and Clinics Can Do To Promote the Security of Programmers

It is very important to maintain good physical controls over the Intelio Programmer. Having a secure physical environment prevents access to the internals of the Programmer and its components. USB devices connected to the Programmer should be strictly controlled to limit the potential introduction of malware.

Information regarding programmed IPGs and programming sessions may be stored in the Intelio Programmer, and thus appropriate precautions should be taken to secure the Programmer from unauthorized access.

## APPENDIX IV

### Procedure for IPG-ICD Interaction Testing:

Patients with a concomitantly-implanted defibrillator (ICD) require additional testing at the end of the implant procedure to ensure the appropriate function of both the OPTIMIZER Smart Mini 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. Enable CCM therapy and program the sensing windows of the OPTIMIZER Mini IPG to consistently deliver CCM therapy in the presence of the concomitant device.
3. Extend the CCM Train Delay by a minimum of 40 ms up to 50 ms beyond the chronic CCM Train Delay setting 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 CCM therapy pulses as R waves.
4. Document the maximum CCM Train Delay and enter the information as part of the Implant data.
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. Obtain the minimum R-R interval ICD VT zone from the ICD programmer or printout and enter the information as part of the Implant data.
9. Document reactivation of the antitachycardic therapy with a parameter printout of the ICD setting.