IMPULSE
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Hope is Here

Intelio Programmer System and Guardio Charger System

INSTRUCTIONS FOR USE

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

Part No.: 13-290-016-US Rev. 00

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

Revision 00, Date of Issue: 2022-03-16

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EXPLANATION OF SYMBOLS ON LABELS

Symbol	Description
$C\epsilon$ 0344	CE Conformity marking, 0344 - Notified Body Number
Rx**Only**	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
(consult IFU symbol)	Consult instructions for use
(do not use if damaged symbol)	Do not use if package is damaged
CC°C FF°F cc°C ff°F (thermometer symbol)	Storage and transport temperature limits
(factory outline symbol)	Date of manufacture
(solid factory symbol)	Manufacturer
EC|REP	Authorized representative in the European Community
REF	Catalogue number
SN	Serial number
(blue refer to manual symbol)	Refer to instruction manual/booklet
⚠ (! in triangle)	Caution, consult instructions for use
(crossed-out wheeled bin symbol)	Item not to be disposed via the municipal waste collection system of any member state of the European Union
☐ (square in square)	Class II equipment
(person in box symbol)	Type BF applied part
(heart symbol)	Defibrillation-proof type CF applied part

Symbol	Description
((•))	Non-ionizing electromagnetic radiation
IP22	Protected against the ingress of solid foreign objects greater than 12.5 mm (0.5 in) in width; Protected against the ingress of vertically falling water drops when the enclosure is tilted at an angle of 15° from its normal position
(power symbol)	Legacy Programming Wand Power Indicator
(interrogation symbol)	Legacy Programming Wand Interrogation
(programming symbol)	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

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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 Guardio 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 Guardio 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 ± 0.05 m (10 ft ± 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 ± 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 ± 0.05 m (10 ft ± 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   User Profile and Training

The operators of the Intelio Programmer system include physicians (and the trained medical personnel who assist them) and Impulse Dynamics representatives. Physicians, medical personnel, and Company representatives who operate the Intelio Programmer system should be familiar with the operation of electronic medical equipment, particularly the operation of implanted medical devices and programmers.

Physicians and medical personnel shall participate in a Company-sponsored training program that will provide theoretical and hands-on training regarding the technology, device features, and detailed operating instructions for the Intelio Programmer. The need for future retraining regarding the Intelio Programmer system is determined by Company personnel based on the user's individual implant history and frequency.

1.10   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.

1.11   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.

1.12   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.

1.12.1   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.

1.12.2   Legacy Programming Wand

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

1.13   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.

1.14   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.

1.15 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*.

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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. When not in OOO (Standby) 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.
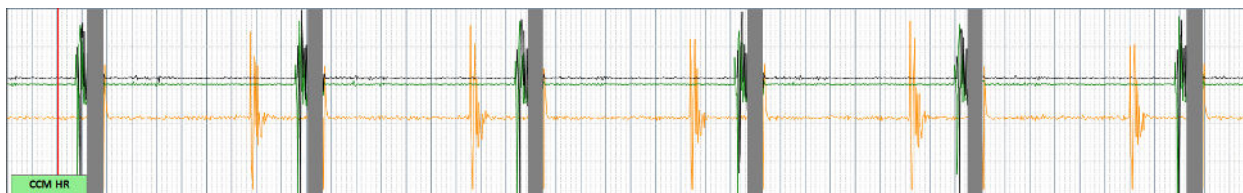
Figure 4: IEGM Sub-Pane

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.
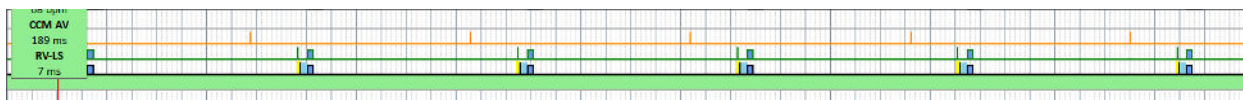
Figure 5: Marker Sub-Pane

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)
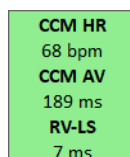
Figure 6: ECG Statistics Bar

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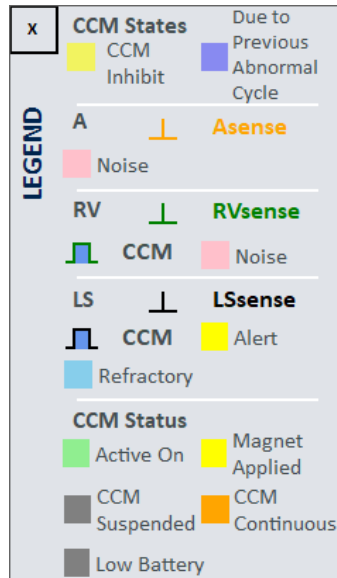
Figure 7: Legend for ECG/IEGM/Marker Pane

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

  - **Short AV:** Sensed 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 OPTIlink Session Pane

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

- **Start OPTIlink:** 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.
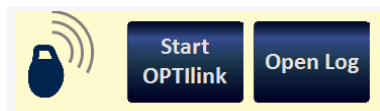
Figure 8: OPTIlink Session Pane (not linked to IPG)

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

- **OPTIlink 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 OPTIlink:** Command button that closes the communication link between the Intelio Programmer and the OPTIMIZER Smart Mini IPG.
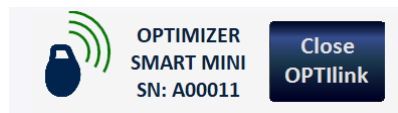
Figure 9: OPTIlink Session Pane (good-quality link to IPG shown)

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".
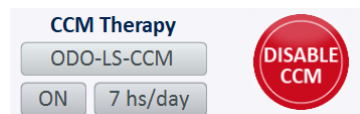
Figure 10: CCM Status Pane

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.
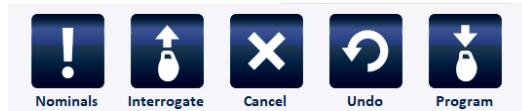
Figure 11: Programming Buttons Pane

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

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- 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
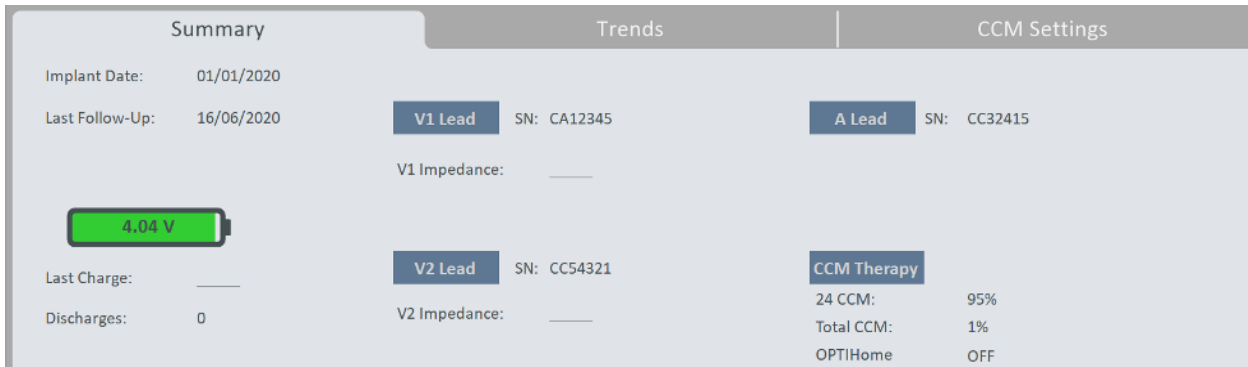
Figure 13: Summary Panel

- **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

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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

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- **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.
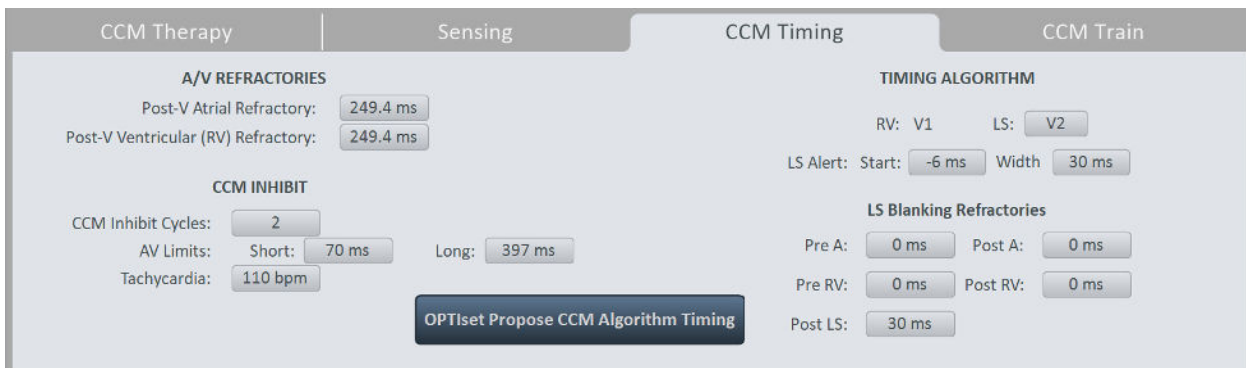
Figure 18: CCM Timing Panel

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

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- **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
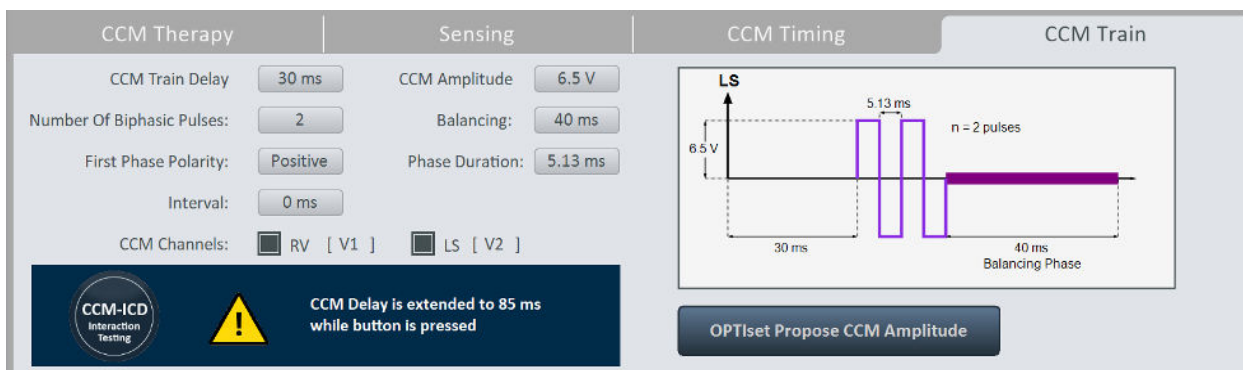
Figure 19: CCM Train Panel

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**
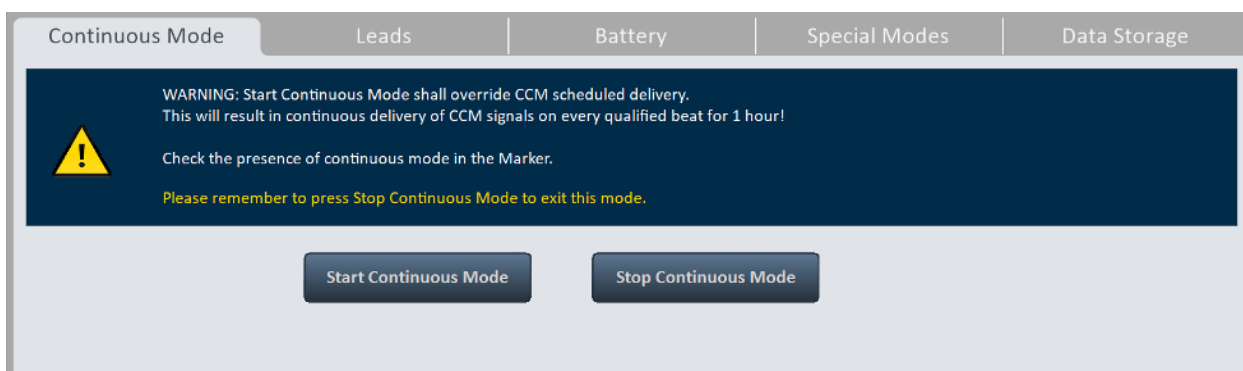
Figure 20: Continuous Mode Panel

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

| Continuous Mode | Leads | Battery | Special Modes | Data Storage |

Atrial Lead SN: CC32415   V1 Lead SN: CA12345   V2 Lead SN: CC54321

V1 lead impedance: 510 Ω   V2 lead impedance: 560 Ω

Measure Leads
Impedance

Figure 21: Leads Panel

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

| Continuous Mode | Leads | Battery | Special Modes | Data Storage |

4.04 V   Last charge: _____

Estimated capacity   100 %   Discharges: 0
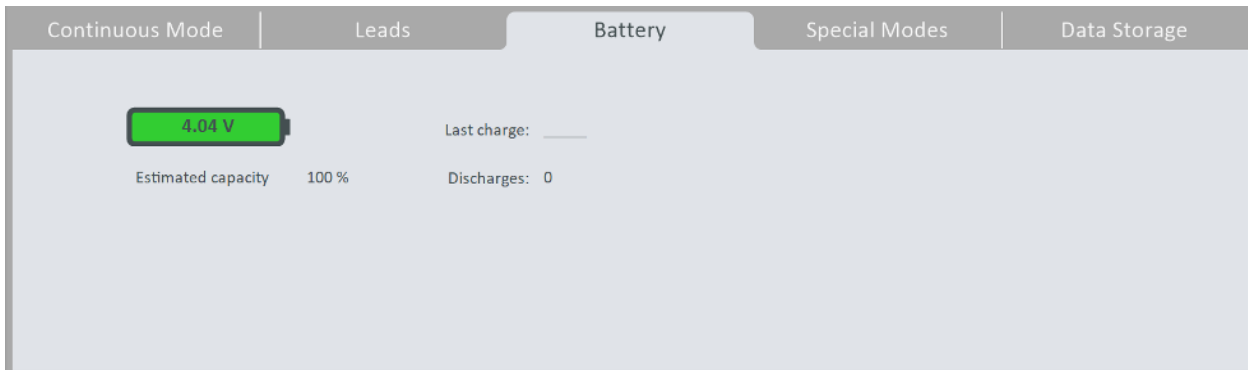
Figure 22: Battery Mode Panel

- **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.

| Continuous Mode | Leads | Battery | Special Modes | Data Storage |

These modes are available only to expert users. Please enter passcode to enable.
Warning: Please consult Physician's Manual prior to using these modes.

OK

Lead Depolarization
This mode temporarily deactivates CCM therapies while all CCM electrodes are connected together to dissipate accumulated charge.

Warning: If the current OPTIlink is interrupted, establishing a new session will not be possible until depolarization ends.

120 v s   Start   Stop

IPG Reset
This action resets the IPG's microcontrollers and programs all the parameters at their nominal settings.

Reset

Rechargeable Battery Disconnect
This action disconnects the rechargeable battery completely. The device must be reactivated with a charger.

Rechargeable
Battery Disconnect

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**
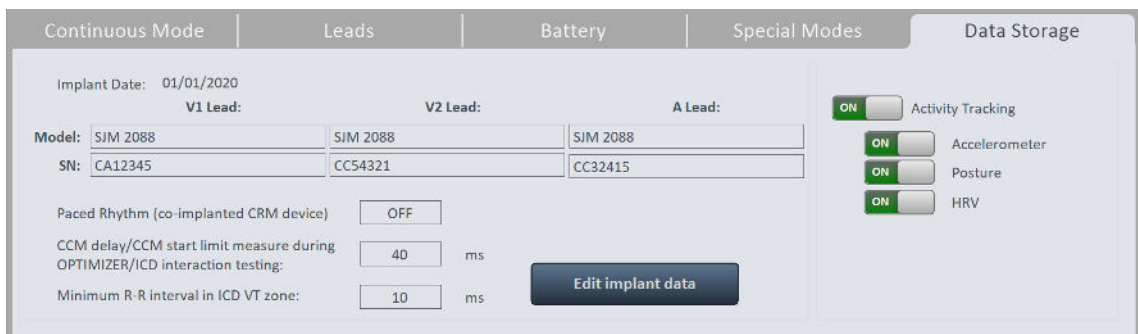
Figure 24: Data Storage Panel

3.1.6.4   Preferences Mode

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

- **OPTIhome** Contains the following parameters:
  - **OPTIhome remote monitoring**
    - **Patient Alerts**
    - **Activity Data**
    - **CCM Statistics**
    - **Lead impedance IEGM amplitudes**
    - **Battery Data**
    - **CCM settings**

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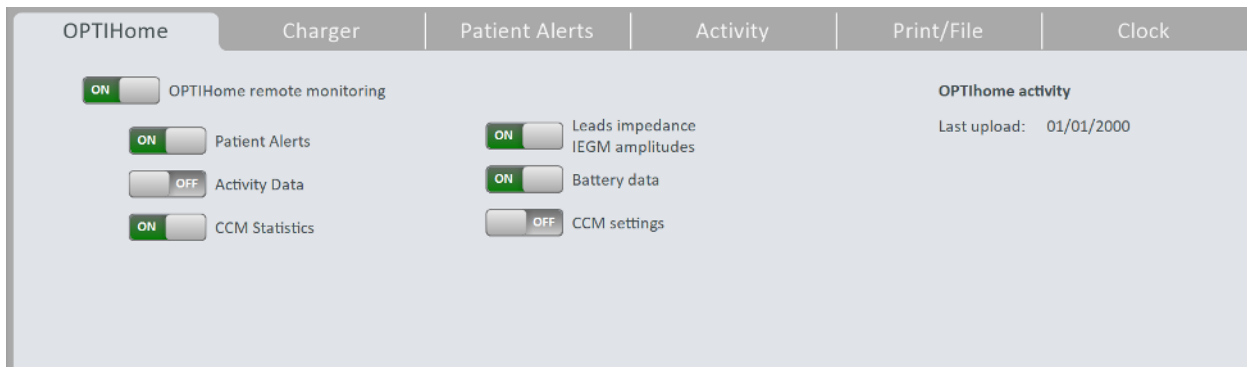
Figure 25: OPTIhome Panel

- **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**
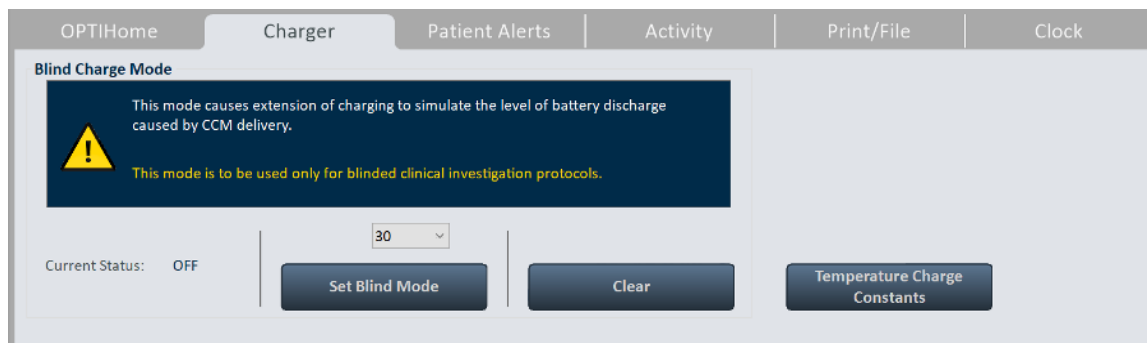
Figure 26: Charger Panel

- **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**

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- o **CCM Not sensing/Noise**
- o **Charger Battery Low**
- o **Charger Failure**
- o **Rechargeable Battery Low**
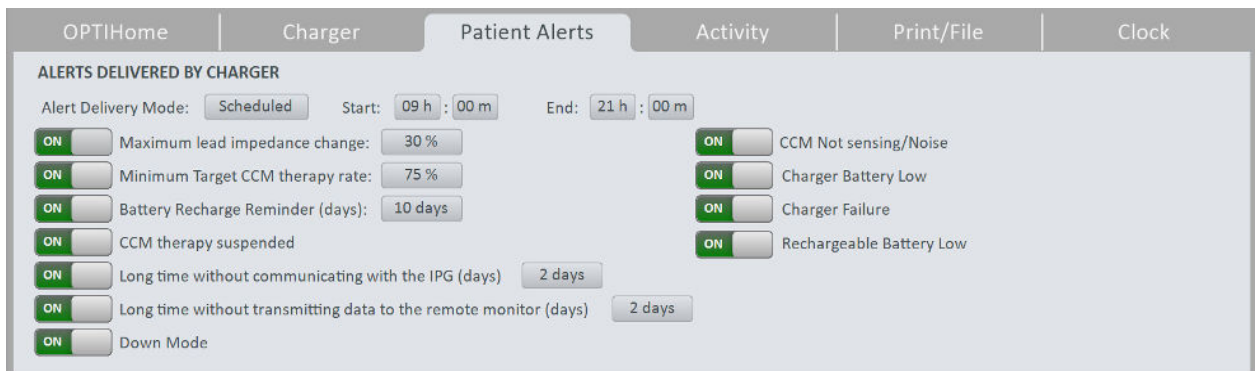
Figure 27: Patient Alert Panel

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

Figure 28: Activity Panel

- **Print/File:** This tab has the following buttons:
  - o **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.
  - o **Database Backup:** Backs up log files stored on the Intelio Programmer.
  - o **Database Restore:** Loads backed up log files onto the Intelio Programmer.

Figure 29: Print/File Panel

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- **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

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- **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.

- o **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.
- o **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.
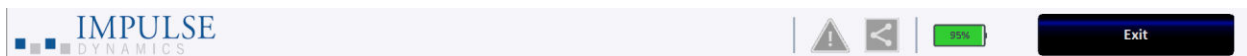
Figure 35: Status Bar

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 after the user makes a selection. Clicking the red pin changes its color back to green and allows the parameter window to close after the user selects 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 vise 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 <u>not</u> 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.
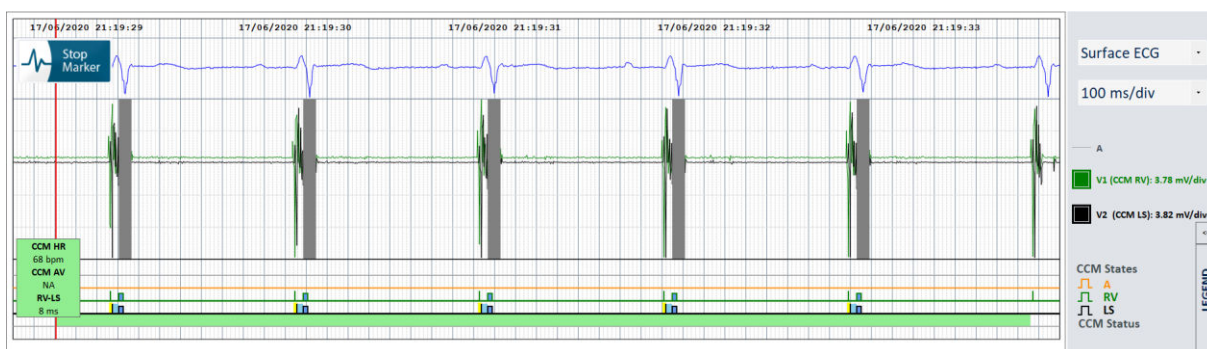
Figure 36: ECG/IEGM/Marker Pane in OVO-LS-CCM Mode

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
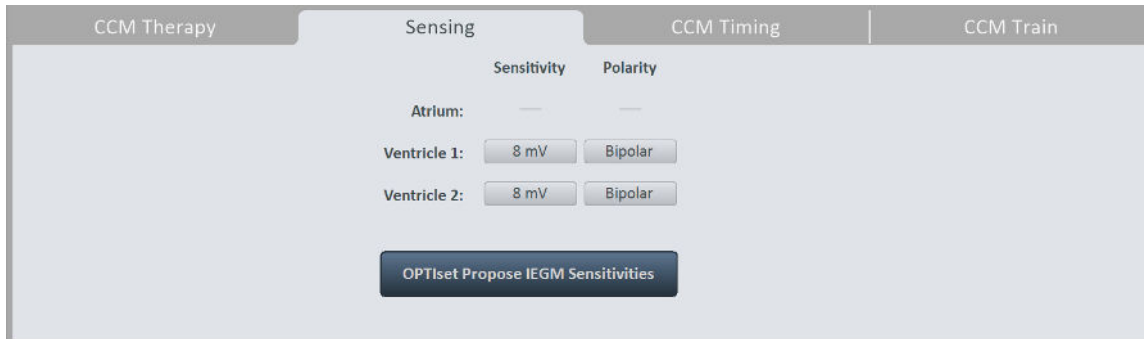
Figure 37: Sensing Panel in OVO-LS-CCM Mode
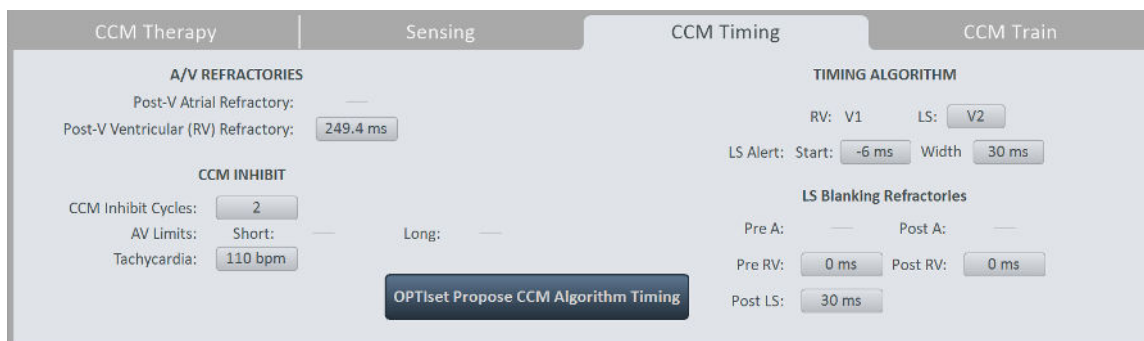
Figure 38: CCM Timing Panel in OVO-LS-CCM Mode

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 <u>not</u> 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:

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

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
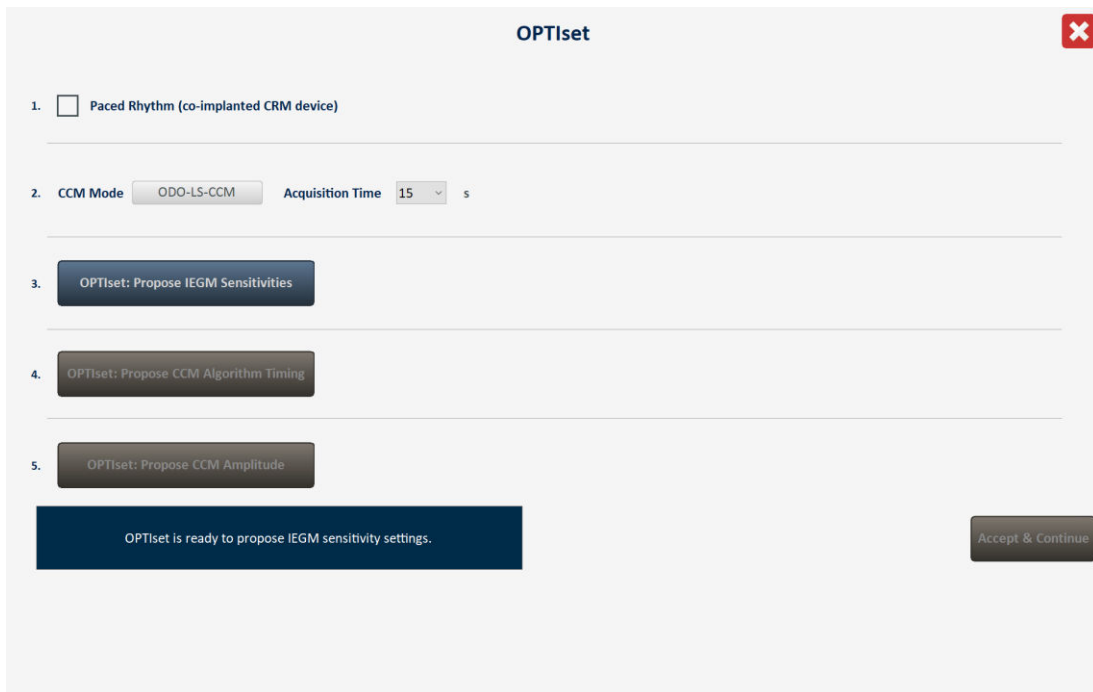
Figure 39: OPTIset Window (Initial)

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.

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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.
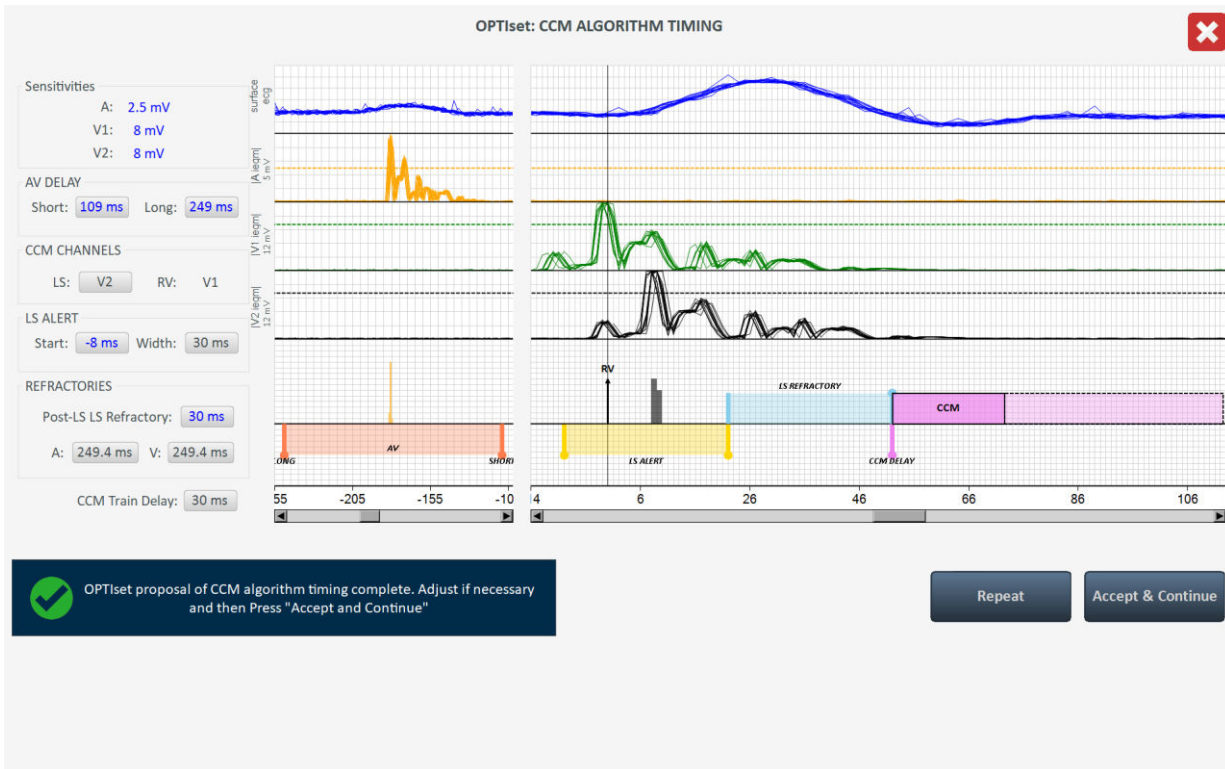
Figure 41: OPTIset: CCM ALGORITHM TIMING Window

- 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.

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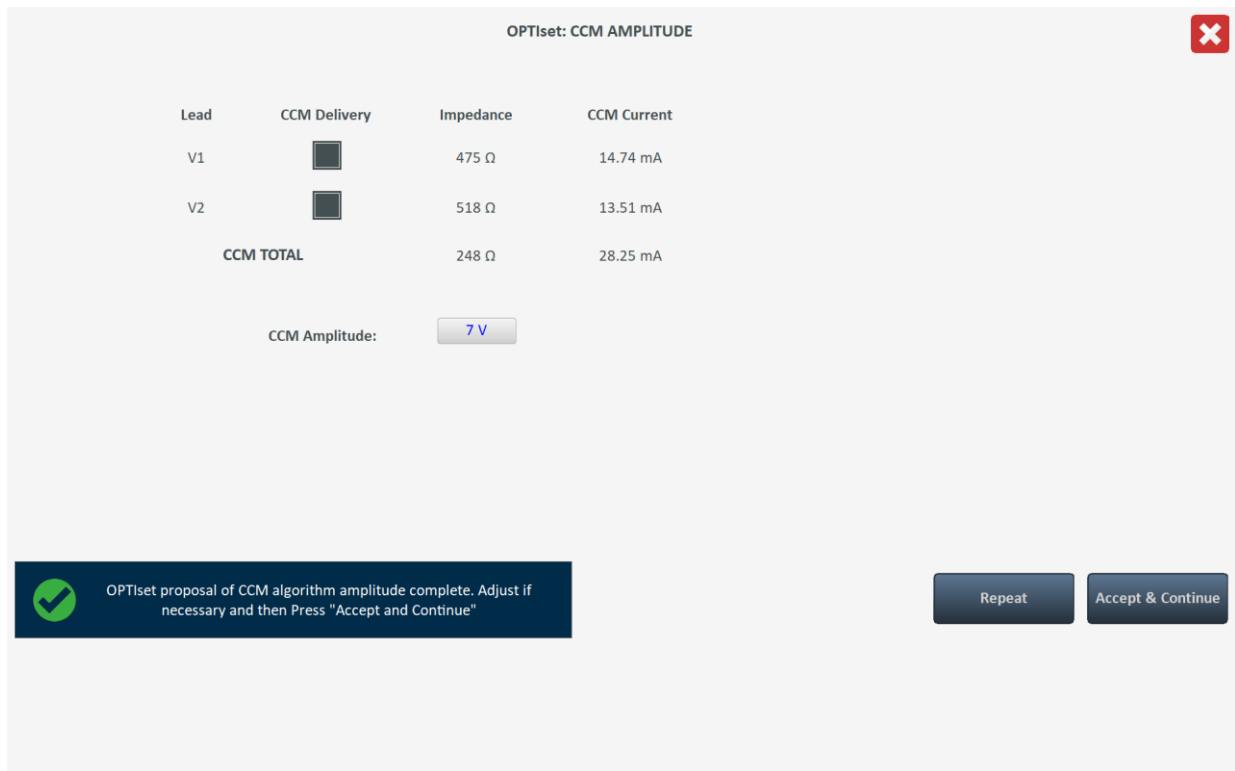
Figure 42: OPTIset: CCM AMPLITUDE Window

- When the **OPTIset** window appears again, click the **Accept & Continue** button
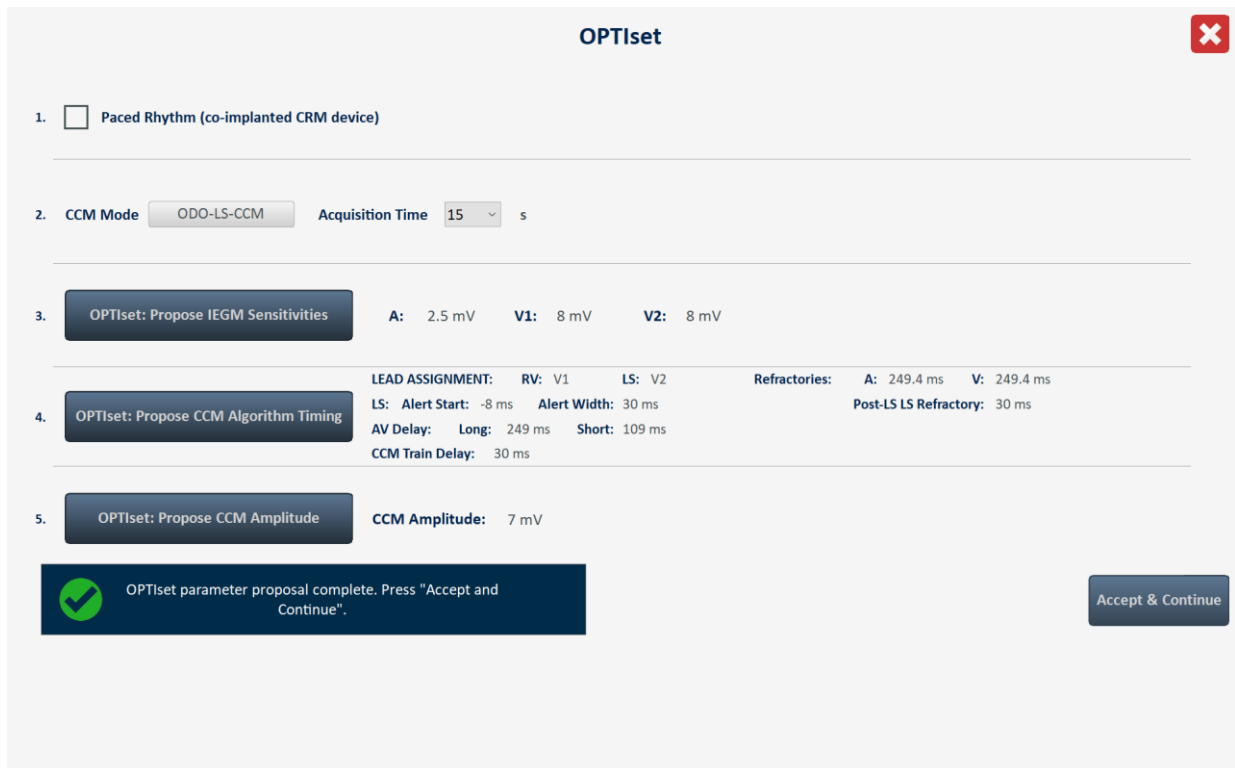
Figure 43: OPTIset Window (Final)

- 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.

- o **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.

  - o **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:

  - o **LS**: Assigns the V1 or V2 lead as the LS channel.

  - o **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.

  - o **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:

  - o **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.

  - o **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.

  - o **Pre RV Refractory Period**: Sets the time interval before an RV event when LS signals are masked from detection.

  - o **Post RV Refractory Period**: Sets the time interval after an RV event when LS signals are masked from detection.

  - o **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

  - o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  - o 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:

  o **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).

  o **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

  o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  o 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

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o 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

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

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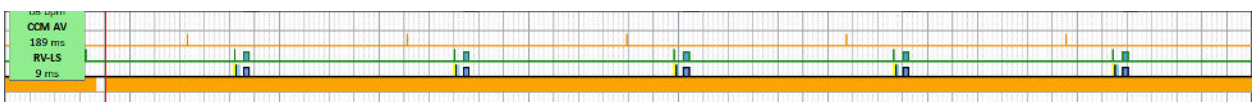
Figure 44: Marker Sub-Pane with CCM Therapy in Continuous Mode

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 ± 10%

- **Phase Duration:** 0.5 ms ± 0.031 ms

- **Interval:** 60 µs ± 10 µs

- **Balancing:** 40 ms ± 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 Ω to 2000 Ω.

Warning: Lead impedance measurements above 1000 Ω 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

    o   Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o   Click the **Start OPTIlink** button on the **OPTIlink 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

    o   Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o   Click the **Start OPTIlink** button on the **OPTIlink 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.

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 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 **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.

| | | Events | | | Periods | | | Trains Delivered |
| Summary | | Trends | | | CCM Settings | | | |

				Events			Periods			Trains Delivered
Date	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	

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 <u>and</u> 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.

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- o **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).

  - o **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.

  - o **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**
  - o **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.
  - o **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
  - o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site
  - o 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.

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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 <u>not</u> 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 <u>not</u> 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

    o   Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o   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
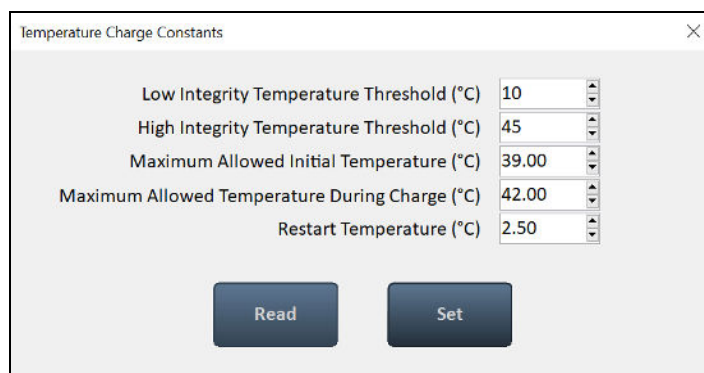
Figure 47: Temperature Charge Constants Window

3.21   Patient Alerts

Patient Alerts are specific Direct Action Alerts or Alert Codes displayed by the Guardio 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 Guardio 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

     o   Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

     o   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:

     o   **Never** – Audible tones are <u>never</u> emitted by the Guardio Charger when it displays a Patient Alert received from the OPTIMIZER Smart Mini IPG

     o   **Always** – Audible tones are <u>always</u> emitted by the Guardio Charger when it displays a Patient Alert received from the OPTIMIZER Smart Mini IPG

     o   **Scheduled** – Audible tones are emitted by the Guardio 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 every day at midnight whenever it is set to ODO or OVO mode. 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 last impedance measurement was lower than 50Ω or greater than 2000Ω, or

- If there are more than three lead impedance measurements in the buffer, 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 %.

  Note: When the OPTIMIZER Smart Mini IPG is first programmed to ODO or OVO mode, the lead impedance buffer is empty. When the number of lead impedance measurements in the buffer are three or less, no comparison is made that would lead to this alert being triggered for this cause.

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 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 **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 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 **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 Guardio Charger lasted 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

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o 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 Guardio 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 Guardio 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

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o 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

    o Click the numerical value

    o 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 Long Time Without Transmitting Data To The Remote Monitor

The Guardio Charger keeps a record of the transmission events with the remote monitoring server. This record is used by the Guardio Charger to determine the number of days since its last successful data transmission to the Remote Patient Monitoring Server (RPMS).

The Long Time without transmitting data to the remote monitor alert is triggered if the number of days since the Guardio Charger transmitted data to the remote monitor exceeds the Long time without transmitting data to the remote monitor days set by the OPTIMIZER SM Programmer application.

To set the Long time without transmitting data to the remote monitor alert and set its days value:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG

  o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  o 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 transmitting data to the remote monitor** button to enable (**ON**) or disable (**OFF**) the alert

- If enabled, the default (or previously programmed) value for the Long time without transmitting data to the remote monitor days parameter will now appear next to **Long time without transmitting data to the remote monitor**

- If required, change the Long time without communication with the IPG days parameter

  o Click the numerical value

  o Select a value from the **Long time without transmitting data to the remote monitor 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

3.21.8 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

  o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  o 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

3.21.9 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

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o 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

3.21.10 Charger Battery Low Alert

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

To set the Charger Battery Low alert:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o 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

3.21.11 Charger Failure Alert

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

To set the Charger Failure alert:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o 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

3.21.12 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

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o 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 OPTIhome

The OPTIhome Remote Patient Monitoring System transmits information about the status of the patient's health as well as the status of the OPTIMIZER Smart Mini IPG and Guardio Charger to the patient's healthcare provider.

3.22.1 OPTIhome Remote Monitoring

The **OPTIhome Remote Monitoring** setting allows the user to enable the transmission of information by the Guardio Charger to the Remote Patient Monitoring Server.

Once enabled, the date of the last successful upload of information by the Guardio Charger will be displayed on the **OPTIHome** panel under **OPTIhome activity**.

To set OPTIhome Remote Monitoring:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG

    o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

    o Click the **Start OPTIlink** button on the **OPTIlink Session Pane**

- Click the **Preferences** button on the Mode Bar

- Select the **OPTIHome** tab

- On the **OPTIHome** panel, toggle the **OPTIhome Remote Monitoring** button to enable (**ON**) or disable (**OFF**) the setting

Note: If **ON** is selected, the list of information categories for the OPTIhome Remote Monitoring can subsequently be set, allowing the user to enable or disable each parameter.

3.22.2 Patient Alerts

The **Patient Alerts** setting controls whether the information transmitted by the Guardio Charger includes any triggered Low-Priority alerts.

To set the OPTIhome Patient Alerts:

- 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 **OPTIHome** tab

- On the **OPTIHome** panel, toggle the **Patient Alerts** 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

3.22.3 Activity Data

The **Activity Data** setting controls whether the information transmitted by the Guardio Charger includes the compilation of Activity Data stored by the OPTIMIZER Smart Mini IPG.

Note: In order for the OPTIMIZER Smart Mini IPG to collect Activity Data, the Activity Sensor Setup must first be completed and the Activity Tracking must be enabled (see Sections 3.23 and 3.17.2).

To set the OPTIhome Activity 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 OPTIlink** button on the **OPTIlink Session Pane**

- Click the **Preferences** button on the Mode Bar

- Select the **OPTIHome** tab

- On the **OPTIHome** panel, toggle the **Activity Data** 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

3.22.4 CCM Statistics

The **CCM Statistics** setting controls whether the information transmitted to the Remote Monitoring Server includes the compilation of CCM statistics stored by the OPTIMIZER Smart Mini IPG.

To set the OPTIhome CCM Statistics:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG

  o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  o Click the **Start OPTIlink** button on the **OPTIlink Session Pane**

- Click the **Preferences** button on the Mode Bar

- Select the **OPTIHome** tab

- On the **OPTIHome** panel, toggle the **CCM Statistics** 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

3.22.5 Lead Impedance and IEGM Amplitudes

The **Lead Impedance and IEGM Amplitudes** setting controls whether the information transmitted to the Remote Monitoring Server includes the compilation of lead impedance measurements and IEGM R-wave amplitude measurements stored by the OPTIMIZER Smart Mini IPG.

To set the OPTIhome Lead Impedance and IEGM Amplitudes:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG

  o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  o Click the **Start OPTIlink** button on the **OPTIlink Session Pane**

- Click the **Preferences** button on the Mode Bar

- Select the **OPTIHome** tab

- On the **OPTIHome** panel, toggle the **Lead Impedance and IEGM Amplitudes** 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

3.22.6 Battery Data

The **Battery Data** setting controls whether the information transmitted to the Remote Monitoring Server includes the compilation of rechargeable battery voltage measurements stored by the OPTIMIZER Smart Mini IPG.

To set the OPTIhome Battery Data:

- If necessary, initiate a link with OPTIMIZER Smart Mini IPG

  o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  o Click the **Start OPTIlink** button on the **OPTIlink Session Pane**

- Click the **Preferences** button on the Mode Bar

- Select the **OPTIHome** tab

- On the **OPTIHome** panel, toggle the **Battery Data** 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

3.22.7 CCM Settings

The **CCM Settings** setting controls whether the information transmitted to the Remote Monitoring Server includes the current CCM settings programmed into the OPTIMIZER Smart Mini IPG.

To set the OPTIhome CCM Settings:

- 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 **OPTIHome** tab

- On the **OPTIHome** panel, toggle the **CCM Settings** 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

3.23 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.

3.24 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 Guardio Charger

3.24.1 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

  o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  o 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

3.24.2 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

  o Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Smart Mini IPG implant site

  o 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

3.25 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.

3.25.1 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**

3.25.2 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.

3.26   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.

4.0   THE GUARDIO CHARGER SYSTEM

4.1   Description

The Guardio Charger is designed to charge the battery of the OPTIMIZER Smart Mini IPG with only minimal patient intervention while ensuring patient safety and maintaining proper operation of the IPG during the charging process.

In addition, the Guardio Charger is programmed to display alerts and other messages that may require action by the patient (e.g., Call Doctor Alert Codes that require the patient to contact the doctor, reminders to charge your implanted device, etc…).

The Guardio Charger has a permanently attached charging wand and is powered by a rechargeable battery. To recharge this battery, the Guardio Charger System includes a Cell-Con AC Adapter (Input: 100–240 VAC, 50-60 Hz, 0.2 A; Output: 4.2 V, 1.3 A).

The Guardio Charger is a Class I, Type BF device, classified as ordinary equipment suitable for continuous operation, with short-time loading, within the patient environment.

Caution: The Guardio Charger is subject to interference from other electrical devices operated in the vicinity. Portable and mobile Radio Frequency (RF) equipment are especially prone to impair the normal function of the charger. If Guardio Charger is not operating as expected, such interference has to be taken into account.

The Guardio Charger communicates with the OPTIMIZER Smart Mini IPG at a frequency range of 402 MHz to 405 MHz (MedRadio frequency band). The communication range of the Guardio Charger is between zero and at least 1.5 m (5 ft).

The Guardio Charger charges the OPTIMIZER Smart Mini IPG at a frequency range of 13.56 MHz.

When the distance between the Charging Wand and the OPTIMIZER Smart Mini IPG is between 0.5 cm and 2.0 cm, the Guardio Charger should be able to recharge the OPTIMIZER Smart Mini IPG with a battery charge of 10% to 90% battery charge in less than 2.5 hours with the Guardio Charger's charging current fixed at 90 mA ± 10%.

When the distance between the Charging Wand and the OPTIMIZER Smart Mini IPG is > 2.0 cm, the Guardio Charger should be able to recharge the OPTIMIZER Smart Mini IPG in less than 4 hours with starting and ending IPG battery charge levels shown in the **Table 1**. In such an instance, the Guardio Charger's battery may become depleted before the rechargeable battery in the OPTIMIZER Smart Mini IPG is fully charged

Table 1: IPG Charge Levels Attained with Fully Charged Guardio Charger

Charging Wand and IPG Distance	Starting IPG Battery Charge Level	Ending IPG Battery Charge Level
> 2.0 cm, ≤ 3.5 cm	10%	80%
> 3.5 cm, ≤ 4.0 cm	10%	70%

When fully charged, the Guardio Charger should be able to perform two IPG charging cycles, charging the IPG battery from 10% to 90% each time, when the distance between the Charging Wand and the OPTIMIZER Smart Mini IPG is between 0.5 cm and 2.0 cm.

4.2   User Profile and Training

The operators of the Guardio Charger system include patients, physicians (and the trained medical personnel who assist them), and Impulse Dynamics representatives. Physicians, medical personnel, and Company representatives who operate the Guardio Charger system should be familiar with the operation of electronic medical equipment, particularly the operation of implanted medical devices.

Physicians and medical personnel shall participate in a Company-sponsored training program that will provide theoretical and hands-on training regarding the technology, device features, and detailed operating instructions for the Guardio Charger.

Patient training on the use of the Guardio Charger will be provided by Impulse Dynamics Representatives post-implant.

4.3 Charging Method

The charging method utilized by the Guardio Charger to charge the battery of the OPTIMIZER Smart Mini IPG is called inductive energy transfer. Since magnetic fields can penetrate human tissues with nearly no attenuation, inductive energy transfer is the only practical transcutaneous recharging method.

The manner in which inductive energy transfer is used to charge the battery of the OPTIMIZER Smart Mini IPG is as follows:

1. Electrical energy from the battery of the Guardio Charger passes through a primary coil connected to the electronic circuitry of the charger that converts it into an oscillating electromagnetic field.

2. When a primary coil is placed in close proximity to a secondary coil, the oscillating electromagnetic field generated by a primary coil is picked up by a secondary coil.

3. The secondary coil that picks up the oscillating electromagnetic field is connected to the electronic circuitry of the implant that converts it back into electrical energy. That electrical energy is used to charge the battery of the OPTIMIZER Smart Mini IPG.

4.4 System Components

The Guardio Charger System consists of the following components:

Figure 48: Guardio Charger System Components

- **Guardio Charger** (with attached charging wand and charging wand cable clip) – used to charge the OPTIMIZER Smart Mini IPG.

- **AC Adapter** – used to charge the internal battery of the Guardio Charger.

- **EU/US Plug Adapters** – plug adapters for the AC Adapter, allowing the AC Adapter to be connected to wall outlets in the EU and US.

- **Carrying Case** – used to store and transport the Guardio Charger System.

4.5 Features

The Guardio Charger has the following features:

- **Graphical Display:** Display screen used by the Guardio Charger to communicate information to the patient

- **Power Button:** Press-button switch used to initiate and terminate charging of the OPTIMIZER Smart Mini IPG and to silence alerts displayed by the Guardio Charger

- **Buzzer:** An internal buzzer that produces beeping tones to inform the patient of a condition that requires action

- **Charging Wand:** Wand containing a coil and circuitry used by the Guardio Charger for charging as well as short-range communications with the OPTIMIZER Smart Mini IPG

- **Radio Transceiver:** Device used by the Guardio Charger for long-range communications [between zero and at least 1.5 m (5 ft)] with the OPTIMIZER Smart Mini IPG

- **Cellular Modem:** Modem is used to send data downloaded from the OPTIMIZER Smart Mini IPG to the OPTIhome Remote Patient Monitoring Service (RPMS)

4.6 Overview of the Screens Displayed by the Guardio Charger

The Guardio Charger displays a different screen for each operational state. This section presents an overview of each screen displayed by the Guardio Charger.

4.6.1 Screens Displayed When Connected to the AC Adapter

4.6.1.1 Charger Self-Charge Status Screen

This screen is displayed whenever the AC Adapter is connected to the Guardio Charger. The number of bars shown on the battery icon will vary depending on the current level of charge in the Guardio Charger battery (see **Table 2**).

Table 2: Guardio Charger Battery Charge Levels

Charger Battery Icon (When Not Charging or Charge Complete)	Charger Battery Icon (When Charging)	Charger Battery Charge Level
1 bar	1 flashing bar	Below 25%
2 bars	2 bars, last one flashing	Between 25% and 50%
3 bars	3 bars, last one flashing	Between 50% and 75%
4 bars	4 bars, last one flashing	Above 75%

Figure 49: Charger Self-Charge Status Screen

4.6.1.2 Charger Self-Charge Success Screen

This screen is displayed either when the AC Adapter has successfully completed charging the internal battery of the Guardio Charger, when the AC Adapter is connected to the Guardio Charger and the battery charge level of the Guardio Charger is above 75%, or when the AC Adapter is charging the Guardio Charger and the AC Adapter current is less than 50 mA.
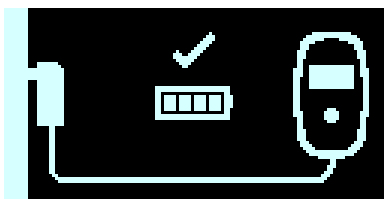
Figure 50: Charger Self-Charge Success Screen

4.6.1.3 IPG Data Download Screen

This screen is displayed whenever the Guardio Charger is actively attempting to download data from the OPTIMIZER Smart Mini IPG. The encrypted data downloaded from the device includes information regarding the current status of your IPG, statistical information regarding its operation, and any active alerts that require action.

This is the first screen displayed after the AC Adapter is connected to the Guardio Charger and then plugged into the wall outlet.
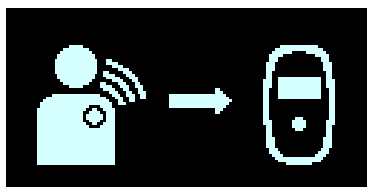
Figure 51: IPG Data Download Screen

4.6.1.4 IPG Data Download Success Screen

This screen is displayed whenever the Guardio Charger has successfully completed downloading data from the OPTIMIZER Smart Mini IPG.

This is the second screen displayed after the AC Adapter is connected to the Guardio Charger and then plugged into the wall outlet.

Figure 52: IPG Data Download Success Screen

4.6.1.5 IPG Data Download Error Screen

This screen is displayed whenever the Guardio Charger has not successfully completed downloading data from the OPTIMIZER Smart Mini IPG.

Figure 53: IPG Data Download Error Screen

4.6.1.6 Data Upload Status Screen

This screen is displayed whenever the Guardio Charger is transmitting data to the OPTIHome Remote Patient Monitoring Service (RPMS).

Depending on the circumstances, this may be displayed after the Battery Charger is connected to the Guardio Charger and then plugged into the wall outlet.
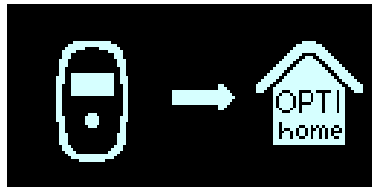
Figure 54: Data Upload Status Screen

4.6.1.7 Data Upload Success Screen

This screen is displayed whenever the Guardio Charger has successfully transmitted data to the OPTIHome Remote Patient Monitoring Service (RPMS).

Depending on the circumstances, this may be displayed after Data Upload Status Screen when the Battery Charger is connected to the Guardio Charger and then plugged into the wall outlet.

Figure 55: Data Upload Success Screen

4.6.1.8 Data Upload Error Screen

This screen is displayed whenever the Guardio Charger has <u>not</u> successfully transmitted data to the OPTIhome Remote Patient Monitoring Service (RPMS).

Figure 56: Data Upload Error Screen

4.6.2 Screens Displayed When Paring with the OPTIMIZER Smart Mini IPG

4.6.2.1 Charger/IPG Pairing Screen

This screen is displayed whenever the Guardio Charger is actively pairing with the OPTIMIZER Smart Mini IPG.

Figure 57: Charger/IPG Pairing Screen

4.6.2.2 Charger/IPG Pairing Success Screen

This screen is displayed whenever the Guardio Charger has successfully paired with the OPTIMIZER Smart Mini IPG. The display of this screen is accompanied by 3 short beeping tones.

Figure 58: Charger/IPG Pairing Success Screen

4.6.2.3 Charger/IPG Pairing Error Screen

This screen is displayed whenever an error has occurred during the pairing of the Guardio Charger and the OPTIMIZER Smart Mini IPG.

Figure 59: Charger/IPG Pairing Error Screen

4.6.3 Screens Displayed When Charging the OPTIMIZER Smart Mini IPG

4.6.3.1 IPG Data Download Screen

This screen is displayed whenever the Guardio Charger is actively downloading data from the OPTIMIZER Smart Mini IPG.

This is the first screen displayed after pressing the Power Button on the Guardio Charger to begin a charging session.
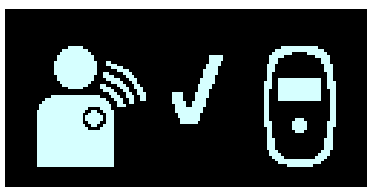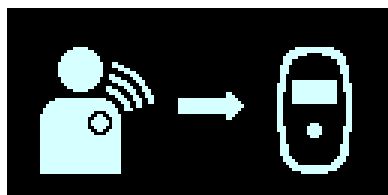

Figure 60: IPG Data Download Screen

4.6.3.2 IPG Data Download Success Screen

This screen is displayed whenever the Guardio Charger has successfully completed downloading data from the OPTIMIZER Smart Mini IPG. The display of this screen is accompanied by 3 short beeping tones.

If the Guardio Charger has successfully completed downloading data from the OPTIMIZER Smart Mini IPG, this is the second screen that is displayed after pressing the Power Button on the Guardio Charger to begin a charging session.
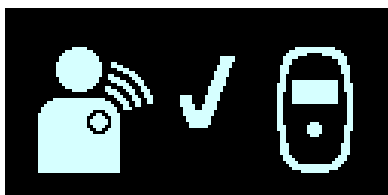
Figure 61: IPG Data Download Success Screen

4.6.3.3   IPG Data Download Error Screen

This screen is displayed whenever the Guardio Charger has <u>not</u> successfully completed downloading data from the OPTIMIZER Smart Mini IPG. The display of this screen is accompanied by 3 long beeping tones.

If the Guardio Charger is unable to establish coupling with the OPTIMIZER Smart Mini IPG, this is the second screen that is displayed after pressing the Power Button on the Guardio Charger to begin a charging session.

Figure 62: IPG Data Download Error Screen

4.6.3.4   Charging IPG Status Screen

This screen is displayed whenever the Guardio Charger has successfully coupled with the OPTIMIZER Smart Mini IPG and is charging the implanted device.

If the Guardio Charger has successfully coupled with the OPTIMIZER Smart Mini IPG, this is the third screen displayed after pressing the Power Button on the Guardio Charger.

The number of bars shown on the Guardio Charger Battery icon (on the left) and the IPG Battery icon (on the right) will vary depending on the current level of charge in each battery (see **Tables 3 and 4**).

Table 3: Guardio Charger Battery Charge Levels

Guardio Charger Battery Icon	Charger Battery Charge Level
1 bar	Below 25%
2 bars	Between 25% and 50%
3 bars	Between 50% and 75%
4 bars	Above 75%

Table 4: OPTIMIZER Smart Mini IPG Battery Charge Levels

IPG Battery Icon	IPG Battery Charge Level
1 flashing bar	Below 25%
2 bars, last one flashing	Between 25% and 50%
3 bars, last one flashing	Between 50% and 75%
4 bars, last one flashing	Above 75%
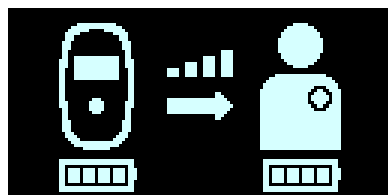
Figure 63: Charging IPG Status Screen

4.6.3.5   Charging IPG Coupling Error Screen

This screen is displayed whenever the Guardio Charger is unable to establish coupling with the OPTIMIZER Smart Mini IPG. The display of this screen is accompanied by 3 long beeping tones.

If your Guardio Charger is unable to establish coupling with the OPTIMIZER Smart Mini IPG, this is the third screen that is displayed after pressing the Power Button on the Guardio Charger.

Figure 64: Charging IPG Coupling Error Screen

4.6.3.6   IPG Charging Successfully Completed Screen

This screen is displayed whenever the Guardio Charger has successfully completed charging the battery of the OPTIMIZER Smart Mini IPG.
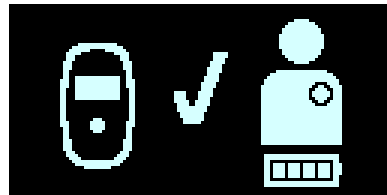
Figure 65: IPG Charging Successfully Completed Screen

4.6.3.7   Charging IPG Timeout Error Screen

This screen is displayed by the Guardio Charger whenever the charging duration of the OPTIMIZER Smart Mini IPG exceeds 5 hours ± 5 minutes.
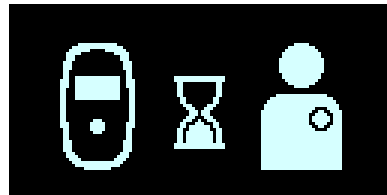
Figure 66: Charging IPG Timeout Error Screen

4.6.3.8   Charging IPG Temperature Error Screen

This screen is displayed by the Guardio Charger whenever one of the following conditions occurs:

- The reported temperature of the OPTIMIZER Smart Mini IPG at the beginning of the charging session is outside the accepted range.

- The charging session is suspended due to the temperature of the OPTIMIZER Smart Mini IPG remaining consistently high for more than 10 minutes.
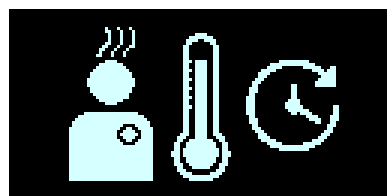
Figure 67: Charging IPG Temperature Error Screen

4.6.3.9 Power Supply Error Screen

This screen is displayed whenever the AC Adapter is connected to the Guardio Charger while it is charging the OPTIMIZER Smart Mini IPG.
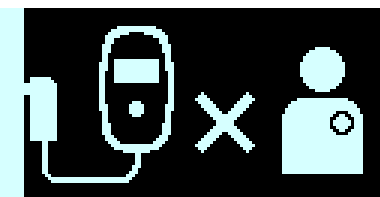
Figure 68: Power Supply Error Screen

4.6.3.10 Charge Session Cancelation Screen

This screen is displayed whenever the button on the Guardio Charger is pressed while it is charging the OPTIMIZER Smart Mini IPG. The display of this screen is accompanied by 3 short beeping tones.

This screen is displayed just before the Guardio Charger shuts off.

Figure 69: Charge Session Cancelation Screen

4.6.4 Screens Displayed After the Detection of an Alert Condition

4.6.4.1 Low Charger Battery Alert Screen

This screen is displayed whenever the Guardio Charger's battery charge level drops below 10%. The display of this screen is accompanied by short beeping tones.
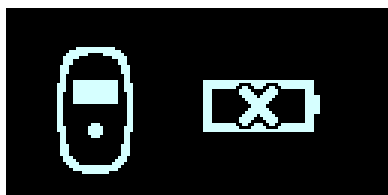
Figure 70: Low Charger Battery Alert Screen

4.6.4.2 Long Time Without Charging IPG Alert Screen

This screen is displayed whenever the Patient Alert "Battery Recharge Reminder" is enabled using the OPTIMIZER Smart Mini Programmer application and the number of days since the OPTIMIZER Smart Mini IPG was last charged has exceeded the number of days set for this Patient Alert. The display of this screen is accompanied by short beeping tones.

Figure 71: Long Time Without Charging IPG Alert Screen

4.6.4.3 Long Time Without Downloading Data From IPG Alert Screen

This screen is displayed whenever the Patient Alert "Long Time Without Communicating with the IPG" is enabled using the OPTIMIZER Smart Mini Programmer application and the number of days since the last successful communication between the Guardio Charger and the OPTIMIZER Smart Mini IPG has exceeded the number of days set for this Patient Alert. The display of this screen is accompanied by short beeping tones.
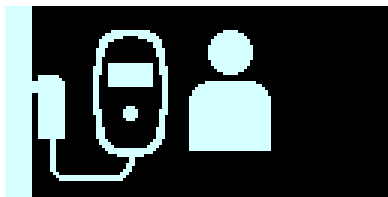
Figure 72: Long Time Without Downloading Data From IPG Alert Screen

4.6.4.4 Long Time Without Uploading Data To RPMS Alert Screen

This screen is displayed whenever the Patient Alert "Long time without transmitting data to the remote monitor" is enabled using the Smart Mini application and the number of days since the last successful data upload from your Guardio Charger to the OPTIHome Remote Patient Monitoring Service (RPMS) has exceeded the number of days set for this Patient Alert.
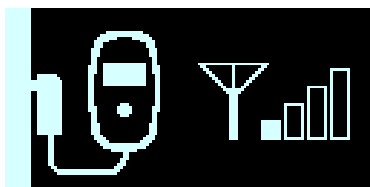
Figure 73: Long Time Without Uploading Data To RPMS Alert Screen

4.6.4.5 Abnormal Condition Error Screen

This screen is displayed whenever an abnormal condition is detected in the OPTIMIZER Smart Mini IPG or the Guardio Charger. The display of this screen is accompanied by 3 long beeping tones.

Figure 74: Abnormal Condition Error Screen

4.6.4.6 Call Doctor Alert Screen

This screen is displayed whenever a Call Doctor Patient Alert that is enabled by the OPTIMIZER Smart Mini Programmer application has been activated. The letter displayed is specific to the model of the implanted IPG. The display of this screen is accompanied by short beeping tones.

Figure 75: Call Doctor Alert Screen

4.6.4.7 Snooze Buzzer Alert Screen

This screen instructs the patient to press the button on the Guardio Charger to silence the beeping tone associated with the activated alert.

It is the screen that is displayed after the alert screen of a newly activated alert.
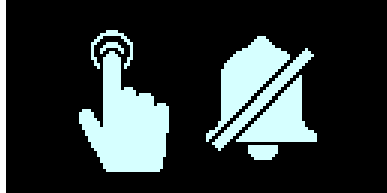
Figure 76: Snooze Buzzer Alert Screen

4.6.4.8 Snooze Alert Screen

This screen instructs the patient to press the button on the Guardio Charger to snooze an alert.

This screen is displayed after the alert screen if the Guardio Charger is used outside the scheduled Patient Alert Delivery period set by the OPTIMIZER Smart Mini Programmer application (usually between 08:00 and 21:00) or when an alert that was previously activated is retriggered.
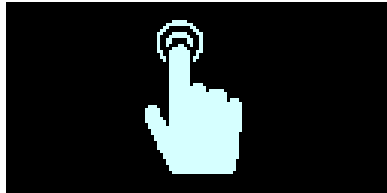
Figure 77: Snooze Alert Screen

4.6.5 Info Screens

The Guardio Charger displays the Info Screens when the following conditions are met:

- The AC Adapter is connected to the Guardio Charger.

- The **Power Button** is continuously pressed until a beeping tone is heard and then released (usually more than 5 seconds and less than 10 seconds).

4.6.5.1 First Info Screen

When the **Power Button** is released, the First Info screen displays the following information:

- The list of active and snoozed Call Doctor Alert Codes

- The IPG model code

- The battery charge level of the IPG after the completion of its last charge session

- The date and time of the last successful charge of the IPG

  Note: The date format is (DD/MM/YY) and the time format is 24 hours.
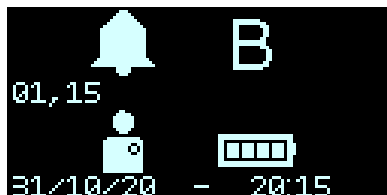
Figure 78: First Info Screen

4.6.5.2   Second Info Screen

After the display of the First Info screen, the Second Info screen displays the following information:

- The signal strength level during the last successful IPG data download session

- The date and time of the last successful IPG data download session

  Note: The date format is (DD/MM/YY) and the time format is 24 hours.

- The signal strength level during the last successful data upload session to the OPTIhome Remote Patient Monitoring Service (RPMS)

- The date and time of the last successful IPG data upload session to the OPTIhome Remote Patient Monitoring Service (RPMS)

  Note: The date format is (DD/MM/YY) and the time format is 24 hours.
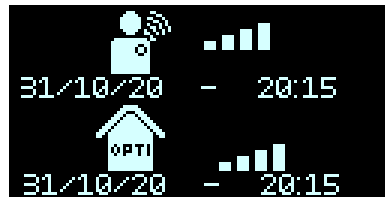
Figure 79: Second Info Screen

4.7   Pairing the Guardio Charger with the OPTIMIZER Smart Mini IPG

The pairing of the Guardio Charger with the OPTIMIZER Smart Mini IPG ensures that the communication and charging information received by the Guardio Charger is securely encrypted and unique to a specific implanted device.

During the pairing process, the Guardio Charger uses short-range communication to search for a device to pair with and creates an encryption key once a compatible device model has been found. This encryption key is stored and used by the Guardio Charger for all its subsequent communications sessions with the paired device.

To pair the Guardio Charger with the OPTIMIZER Smart Mini IPG, perform the following steps:

1. Determine the location of the OPTIMIZER Smart Mini IPG (typically right upper chest area) and then place the charging wand directly over the OPTIMIZER Smart Mini implant site (over the patient's clothes).

2. Place a pairing magnet (or a standard pacemaker magnet) to the left of the **Power Button** on the Guardio Charger. **See Figure 80**.

Note: A Guardio Charger being used for the first time does not require the use of a magnet during the pairing process.

Figure 80: Pairing Magnet on Guardio Charger

3. Begin the pairing process by pressing the **Power Button**, holding the button down for 1-2 seconds, and then releasing it.

4. The Charger/IPG Pairing screen is displayed while the Guardio Charger is actively attempting to pair with the OPTIMIZER Smart Mini IPG. **See Figure 81**.
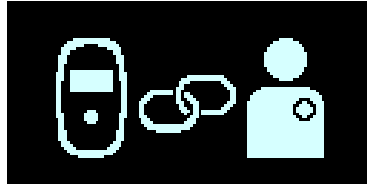
Figure 81: Charger/IPG Pairing Screen

5. When the pairing process has been completed, the Guardio Charger will emit 3 short beeping tones and display the Charger/IPG Pairing Success screen. **See Figure 82**.

Figure 82: Charger/IPG Pairing Success Screen

6. Remove the pairing magnet from the Guardio Charger.

4.8 Charging the Guardio Charger

Note: When the Guardio Charger is not being used to charge their implanted device, advise patients to always keep it connected to its AC Adapter and the AC Adapter plugged into the wall outlet. This keeps the battery of the Guardio Charger fully charged and ready to be used the next time they need to charge their implanted OPTIMIZER Smart Mini IPG.

Note: Charging the Guardio Charger and charging the OPTIMIZER Smart Mini IPG CANNOT be done simultaneously. Always charge the internal battery of the Guardio Charger before attempting to charge the battery of the OPTIMIZER Smart Mini IPG.

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

Warning: Only use the AC Adapter provided with the Guardio Charger to charge the battery in the Guardio Charger. Otherwise, damage to the Guardio Charger may result.

To connect the AC Adapter to the Guardio Charger and begin charging its internal battery, perform the following steps:

1. Turn the Guardio Charger around so that the back of the charger is facing up.

2. Remove the protective cover flap from the power input connector located next to the base of the charging wand cable.

3. Obtain the AC Adapter from the Carrying Case and rotate its DC output connector until the red dot on its connector is visible.

4. Line up the red dot on the DC output connector of the AC Adapter with the red line on the power input connector of the Guardio Charger and then insert in the DC output connector into the power input connector. **See Figure 83.**
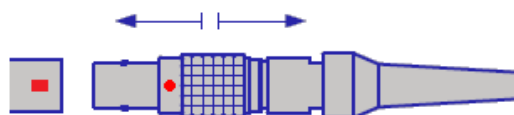
Figure 83: Connection of DC Connectors

5. Attach the location-specific Plug Adapter to the AC Adapter and then plug the AC Adapter into the wall outlet to begin charging the internal battery of the Guardio Charger.

When the Charging Self-Charge Success screen is displayed on the Guardio Charger screen, the battery in the Guardio Charger is fully charged. **See Figure 84**.
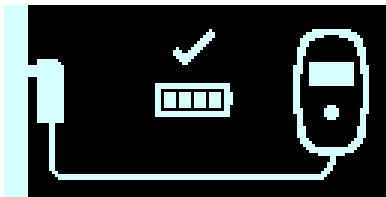
Figure 84: Charger Self-Charge Success Screen

To disconnect the AC Adapter from the Guardio Charger, perform the following steps:

1. Unplug the AC Adapter from the wall outlet.

2. Hold and pull back on the metal sleeve of the DC output connector to disconnect it from the Guardio Charger.

3. Replace the protective cover flap over the power input connector of the Guardio Charger.

4.9   Charging the OPTIMIZER Smart Mini IPG

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

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

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

Warning: The Guardio Charger must not be used onboard an aircraft.

Warning: Request permission from the ship's crew prior to using your Guardio Charger onboard a ship.

To charge the battery of the OPTIMIZER Smart Mini IPG, perform the following steps:

1. Place the patient in a stationary, comfortable sitting position, ideally reclining at a 45° angle (e.g., on a sofa or armchair).

2. Determine the location of the OPTIMIZER Smart Mini IPG (typically right upper chest area) and then place the flat side of the Guardio charging wand (the side with the four blue rubber screw covers) directly over the OPTIMIZER Smart Mini implant site (over the patient's clothes). To prevent the charging wand from becoming displaced while charging, the charging wand cable may be draped around the patient's neck or the clip on the charging wand cable may be attached to the patient's clothing.

3. Start the charging process by pressing the **Power Button**, holding the button down for 1-2 seconds, and then releasing it.

4. The charging process begins with a display of the IPG Data Download and IPG Data Download Success screens. **See Figures 85 and 86**.
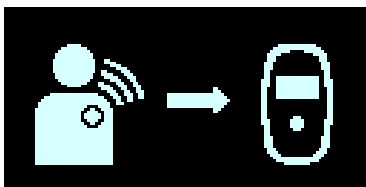
Figure 85: IPG Data Download Screen
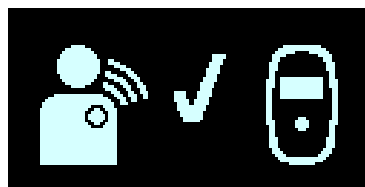
Figure 86: IPG Data Download Success Screen

5. After the data download has been completed, the Charging IPG Status screen is displayed by the Guardio Charger. **See Figure 87**.

The Coupling Level icon (), at the center of the Charging IPG Status screen will show anywhere from zero to four illuminated bars. Reposition the charging wand until at least 2 bars of the Coupling Level icon are illuminated.
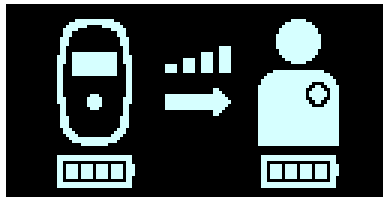
Figure 87: Charging IPG Status Screen

Note: Zero illuminated bars on the Coupling Level icon accompanied by an audible beeping tone indicates poor placement of the charging wand. If the charging wand is not repositioned onto the implant site within 20 seconds, the Guardio Charger will emit 3 long beeping tones, display the Charging IPG Coupling Error screen, and then shut off. If this occurs, press the **Power Button** again to initiate a new charging session.

6. The number of bars on the Charging IPG Battery icon (see icon image on the right) depicts the current charge level of the OPTIMIZER Smart Mini IPG.

7. The Charging IPG Status screen (see **Figure 87**) will continue to be displayed as the OPTIMIZER Smart Mini IPG is being charged.

Note: It is recommended that the patient remain stationary during the charging process. If the charging wand becomes displaced during charging, the Coupling Level icon will show zero illuminated bars and the Guardio Charger will begin to emit an audible beeping tone. If this occurs, please reposition the charging wand until at least 2 bars are illuminated on the Coupling Level icon.

Note: Instruct the patient to try to fully charge their OPTIMIZER Smart Mini IPG during the charging session. Also, inform the patient that charging their implanted device may take longer than one hour if its battery is significantly depleted. If the recharging of the OPTIMIZER Smart Mini IPG cannot be completed in one session, instruct the patient to repeat charging sessions (at least daily) until their implanted device is fully charged.

8. When the battery of the OPTIMIZER Smart Mini IPG is fully charged, the Guardio Charger will emit three short beeping tones and display the IPG Charging Successfully Completed screen (see **Figure 88**). The Guardio Charger will then shut off automatically.
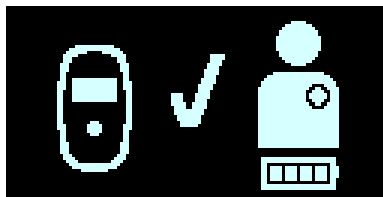
Figure 88: IPG Charging Successfully Completed Screen

9. Detach the charging wand cable clip from the patient's clothing (if necessary), then remove the Guardio charging wand from the patient's implant site and undrape the wand cable from around the patient's neck.

10. Reconnect the AC Adapter to the Guardio Charger as described in Section 4.10.

4.9.1 Early Termination of Charging Session

To terminate a charging session before it has been completed, instruct the patient to press and hold the **Power Button** down for one second and then release it. The Guardio Charger will emit 3 short beeping tones and display the Charge Session Cancelation screen. **See Figure 89**.

Figure 89: Charge Session Cancelation Screen

Alternatively, the patient can remove the charging wand of the Guardio Charger from the implant site, which will cause the Guardio Charger to time out and shut off automatically.

Note: During the charging process, the Guardio Charger monitors the temperature of the OPTIMIZER Smart Mini IPG. To resume charging the OPTIMIZER Smart Mini IPG after terminating a charging session, please wait for approximately 10 minutes before initiating a new charging session to allow the temperature of the implanted device to return to its baseline temperature.

4.10 Guardio Charger Placement When Not Being Used for Device Charging

Whenever the Guardio Charger is not being used to charge the OPTIMIZER Smart Mini IPG, instruct the patient to place it in an area frequented by the patient (e.g., bedside table in the bedroom), connected to its AC Adapter, and the AC Adapter plugged into the wall outlet. This will keep the battery of the Guardio Charger fully charged as well as ensure regular communications between the OPTIMIZER Smart Mini IPG and the Guardio Charger.

4.11 Frequency of Charging Sessions

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

If the Guardio Charger is not used to perform a charging session on the OPTIMIZER Smart Mini IPG within the time period set by the OPTIMIZER Smart Mini Programmer application, the patient may see the Long Time Without Charging IPG alert screen (see **Figure 90**) displayed by the Guardio Charger.

Figure 90: Long Time Without Charging IPG Alert Screen

If a patient reports seeing this screen displayed by the Guardio Charger, instruct the patient to use their Guardio Charger to charge their OPTIMIZER Smart Mini IPG. If the patient reports that their attempt to charge their OPTIMIZER Smart Mini IPG with their Guardio Charger was unsuccessful, please contact your Impulse Dynamics representative.

If the battery voltage of the OPTIMIZER Smart Mini IPG battery drops below 3.5 V, CCM therapy delivery is automatically suspended. If this occurs, the OPTIMIZER Smart Mini IPG will need to be recharged before it resumes delivering CCM therapy. Once the OPTIMIZER Smart Mini IPG has been recharged, it will automatically resume CCM therapy delivery with its previously programmed parameters.

4.12 Communications

4.12.1 Communications with the OPTIMIZER Smart Mini IPG

The Guardio Charger is configured to communicate with the OPTIMIZER Smart Mini IPG at least once a day. This communication occurs whenever the IPG is within 1.5 m (5 ft) of the Guardio Charger for a few minutes.

If the Guardio Charger and the OPTIMIZER Smart Mini IPG do not communicate within the time period set by the OPTIMIZER Smart Mini Programmer application, the patient may see the Long Time Without Downloading Data From IPG alert screen (see **Figure 91**) displayed by the Guardio Charger.
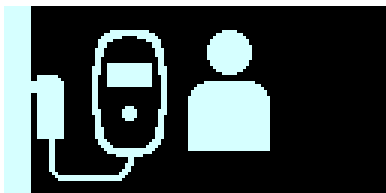
Figure 91: Long Time Without Downloading Data From IPG Alert Screen

If a patient reports seeing this screen displayed by the Guardio Charger, instruct the patient to attempt to charge their OPTIMIZER Smart Mini IPG with their Guardio Charger. If the patient is able to charge their implanted device successfully, then the alert screen should no longer be displayed by the Guardio Charger. If the patient reports that their attempt to charge their OPTIMIZER Smart Mini IPG with their Guardio Charger was unsuccessful, please contact your Impulse Dynamics representative.

4.12.2 Communications with the Remote Server

The Guardio Charger is configured to communicate with the OPTIHome Remote Patient Monitoring Service (RPMS) server once a day. This communication occurs whenever the Battery Charger is connected to the Guardio Charger and the Battery Charger is plugged into the wall outlet.

One part of this communication involves uploading data to the OPTIHome Remote Patient Monitoring Service (RPMS) server. If the Guardio Charger is unable to upload data to the OPTIHome Remote Patient Monitoring Service (RPMS) server, the patient may see the "Long Time Without Uploading Data To Server" alert screen (see **Figure 92**) displayed by your Guardio Charger.
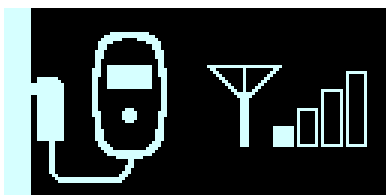
Figure 92: Long Time Without Uploading Data To RPMS Alert Screen

If a patient reports seeing this screen displayed by the Guardio Charger, instruct the patient to unplug the Battery Charger from the wall outlet and then take the Guardio Charger and the Battery Charger to a room more conducive to cellular phone service and then plug the Battery Charger into the nearest wall outlet.

4.13   Call Doctor Alert Codes

In addition to charging the OPTIMIZER Smart Mini IPG, the Guardio Charger is also able to notify the patient of an alert condition in the OPTIMIZER Smart Mini IPG that requires action.

If a detected alert condition is associated with a Direct Action Alert, an alert screen such as Long Time Without Downloading Data from IPG (see **Figure 91**) will be displayed by the Guardio Charger.

If the detected condition is associated with a Call Doctor Alert, the Guardio Charger will display a Call Doctor Alert Code (preceded by a letter denoting the IPG model code) on its screen. The display of a Call Doctor Alert Code (with the exception of code 32) is dependent on whether the specific Patient Alert associated with the Call Doctor Alert Code has been enabled using the OPTIMIZER Smart Mini Programmer application.

Table 5: Call Doctor Alert Codes for the OPTIMIZER Smart Mini IPG

Alert Code	Alert Description	Prevents Charge	Persistent	Auto Refresh
9	IPG Deactivated (see Section 4.13.2.1)	Yes	No	Yes
19	Lead Impedance Change (see Section 4.13.2.2)	No	Yes	Yes
21	CCM Therapy Suspended (see Section 4.13.2.3)	No	No	No
23	Low IPG Battery Voltage (see Section 4.13.2.4)	No	No	Yes
25	CCM Not Sensing/Noise (see Section 4.13.2.5)	No	Yes	Yes
27	Low CCM Therapy Rate (see Section 4.13.2.6)	No	Yes	Yes
31	Charger Failure (see Section 4.13.2.7)	Yes	N/A	N/A
32	IPG has not been paired with Charger (see Section 4.13.2.8)	Yes	N/A	N/A

4.13.1   Call Doctor Alert Code Attributes

Each Alert has the following attributes:

- **Prevents Charge:** An alert that forces the Guardio Charger to terminate the charging process.

- **Persistent:** An alert that will be displayed even if the alert condition that triggered the event is no longer present.

- **Auto Refresh:** An alert that will be displayed again after 24 hours if the alert condition is still present.

4.13.2   Call Doctor Alert Code Definitions

The OPTIMIZER Smart Mini IPG supports the following Call Doctor Alert Codes.

4.13.2.1   Alert Code 9

When Alert Code 9 is displayed, it means that the OPTIMIZER Smart Mini IPG has been deactivated and placed in "DOWN" Mode. If the Guardio Charger displays this Alert Code, please contact your Impulse Dynamics representative.

4.13.2.2   Alert Code 19

When Alert Code 19 is displayed, it means that the OPTIMIZER Smart Mini IPG has detected a significant change in the impedance in one or both ventricular leads. If the Guardio Charger displays this Alert Code, please contact your Impulse Dynamics representative.

4.13.2.3 Alert Code 21

When Alert Code 21 is displayed, it means that CCM therapy in the OPTIMIZER Smart Mini IPG has been suspended. If the Guardio Charger displays this Alert Code, please contact your Impulse Dynamics representative.

4.13.2.4 Alert Code 23

When Alert Code 23 is displayed, it means that the battery voltage level in the OPTIMIZER Smart Mini IPG is less than 3.6 V. If the Guardio Charger displays this Alert Code, please charge the OPTIMIZER Smart Mini IPG battery as soon as possible to prevent CCM therapy from becoming suspended.

4.13.2.5 Alert Code 25

When Alert Code 25 is displayed, it means that the OPTIMIZER Smart Mini IPG has detected that an implanted lead is not sensing or sensing an excessive amount of noise. If the Guardio Charger displays this Alert Code, please contact your Impulse Dynamics representative.

4.13.2.6 Alert Code 27

When Alert Code 27 is displayed, it means that the OPTIMIZER Smart Mini IPG has detected that the amount of CCM therapy delivered is below the alert level programmed into the implanted device by the Intelio Programmer. If the Guardio Charger displays this Alert Code, please contact your Impulse Dynamics representative.

4.13.2.7 Alert Code 31

When Alert Code 31 is displayed, it means that the Guardio Charger has detected repeated internal errors during its operation. If the Guardio Charger displays this Alert Code, please contact your Impulse Dynamics representative.

4.13.2.8 Alert Code 32

When Alert Code 32 is displayed, it means that the Guardio Charger has determined that it is attempting to be used on an unrecognized device. If this Alert Code is displayed by the Guardio Charger, please pair the implanted OPTIMIZER Smart Mini IPG with the Guardio Charger and then restart the charging process. If the Guardio Charger still displays this code after it has been successfully paired with the implanted OPTIMIZER Smart Mini IPG, please contact your Impulse Dynamics representative.

4.14   FCE Guardio Charger

The FCE Guardio Charger allows the field clinical engineer (FCE) or clinical staff to charge a patient's implanted OPTIMIZER Smart Mini IPG in a clinical setting without disrupting its pairing with the patient's assigned Guardio Charger.

Note: FCE Guardio Chargers are for clinical use only and are not to be assigned to patients. To obtain an FCE Guardio Charger, please contact your Impulse Dynamics representative.

The FCE Guardio Charger is intended to be used in a clinical setting to charge a patient's implanted OPTIMIZER Smart Mini IPG whose battery charge level is found to be too low to allow for device interrogation / programming or when the implanted IPG is found to be in DOWN Mode and the battery charge level is too low to allow for an IPG reset.

Using the Unpaired Charge Mode, the FCE Guardio Charger can be used in a clinical setting to recharge a deeply discharged OPTIMIZER Smart Mini IPG that cannot be paired and charged with a standard Guardio Charger.

4.14.1 Screens Displayed When FCE Guardio Charger is Connected to AC Adapter

4.14.1.1 FCE Guardio Charger Self-Charge Status Screen

This screen is displayed whenever the AC Adapter is connected to the FCE Guardio Charger. The number of bars shown on the battery icon will vary depending on the current level of charge in the Guardio Charger battery (see **Table 2** in section 4.6.1.1).

Figure 93: FCE Charger Self-Charge Status Screen

4.14.1.2 FCE Guardio Charger Self-Charge Success Screen

This screen is displayed either when the AC Adapter has successfully completed charging the internal battery of the FCE Guardio Charger, when the AC Adapter is connected to the FCE Guardio Charger and the battery charge level of the FCE Guardio Charger is above 75%, or when the AC Adapter is charging the FCE Guardio Charger and the AC Adapter current is less than 50 mA.

Figure 94: FCE Charger Self-Charge Success Screen

4.14.2 Charging the OPTIMIZER Smart Mini IPG using the FCE Guardio Charger

To charge an OPTIMIZER Smart Mini IPG using the FCE Guardio Charger, perform the following steps:

1. Place the patient in a stationary, comfortable sitting position.

2. Determine the location of the OPTIMIZER Smart Mini IPG (typically right upper chest area) and then place the flat side of the Guardio charging wand (the side with the four blue rubber screw covers) directly over the OPTIMIZER Smart Mini implant site (over the patient's clothes).

3. Start the charging process by pressing the **Power Button**, holding the button down for 1-2 seconds, and then releasing it.

4. Using the FCE Guardio Charger, the charging process begins by displaying the FCE Charger/IPG Pairing screen as the FCE Guardio Charger attempts to pair with the OPTIMIZER Smart Mini IPG. **See Figure 93**.

    Note: If the FCE Guardio Charger is unable to successfully pair with the patient's implanted OPTIMIZER Smart Mini IPG, reposition the charging wand, and repeat Step 3. If pairing is still unsuccessful, proceed to section 4.14.3.

Figure 95: FCE Charger/IPG Pairing Screen

5. When the pairing process has been successfully completed, the FCE Guardio Charger will emit 3 short beeping tones and display the Charger/IPG Pairing Success screen. **See Figure 96**.
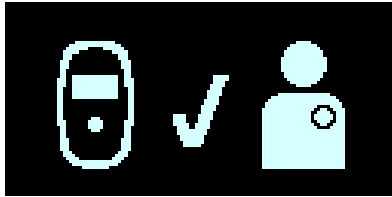
Figure 96: Charger/IPG Pairing Success Screen

6. After the pairing has been successfully completed, the FCE Guardio Charger will display the FCE Charging IPG Status screen. **See Figure 97**.

The Coupling Level icon (), at the center of the Charging IPG Status screen will show anywhere from zero to four illuminated bars. Reposition the charging wand until at least 2 bars of the Coupling Level icon are illuminated.

Figure 97: FCE Charging IPG Status Screen

Note: Zero illuminated bars on the Coupling Level icon accompanied by an audible beeping tone indicates poor placement of the charging wand. If the charging wand is not repositioned onto the implant site within 20 seconds, the Guardio Charger will emit 3 long beeping tones, display the Charging IPG Coupling Error screen, and then shut off. If this occurs, press the **Power Button** again to initiate a new charging session.

7. The FCE Charging IPG Status screen (see **Figure 97**) will continue to be displayed as the OPTIMIZER Smart Mini IPG is being charged.

Note: It is recommended that the patient remain stationary during the charging process.

Note: If the intended use of the FCE Guardio Charger is only to charge the battery of the OPTIMIZER Smart Mini IPG enough to allow for the interrogation / programming of the device, the charging session may be terminated once the IPG Battery icon (see icon on the right in **Figure 97**) displays 2 bars, with the last one flashing. To terminate the charge session, press the **Power Button**, hold it down for 1-2 seconds, and then release it.

8. When the battery of the OPTIMIZER Smart Mini IPG is fully charged, the Guardio Charger will emit three short beeping tones and display the IPG Charging Successfully Completed screen (see **Figure 98**). The Guardio Charger will then shut off automatically.

Figure 98: IPG Charging Successfully Completed Screen

9. Remove the Guardio charging wand from the patient's implant site and undrape the wand cable from around the patient's neck.

4.14.2.1 Charging the OPTIMIZER Smart Mini IPG in DOWN Mode

When charging an OPTIMIZER Smart Mini IPG that is in DOWN Mode, the FCE Charging IPG Status screen shown in **Figure 99** will be displayed during the charging session.

Figure 99: FCE Charging IPG Status Screen When Charging IPG in DOWN Mode

4.14.3 Charging the OPTIMIZER Smart Mini IPG in Unpaired Charge Mode

To charge an OPTIMIZER Smart Mini IPG using the FCE Guardio Charger in Unpaired Charge Mode, perform the following steps:

1. Place the patient in a stationary, comfortable sitting position.

2. Determine the location of the OPTIMIZER Smart Mini IPG (typically right upper chest area) and then place the flat side of the Guardio charging wand (the side with the four blue rubber screw covers) directly over the OPTIMIZER Smart Mini implant site (over the patient's clothes).

3. Place a pairing magnet (or a standard pacemaker magnet) to the left of the **Power Button** on the Guardio Charger. **See Figure 100**.

Figure 100: Pairing Magnet on Guardio Charger

4. Start the unpaired charging process by pressing and holding down the **Power Button** (> 5 seconds) until the Guardio Charger emits a single beeping tone, and then releasing it.

5. When using the FCE Guardio Charger in Unpaired Charge Mode, the charging process begins by displaying the FCE Charging IPG Status screen. **See Figure 101**.
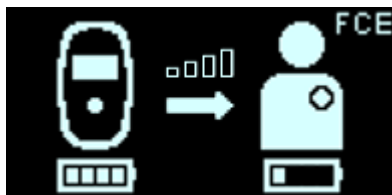
Figure 101: FCE Charging IPG Status Screen in Unpaired Charge Mode

6. If the FCE Guardio Charger is able to reestablish communications with the OPTIMIZER Smart Mini IPG within 5 minutes of charging in Unpaired Charge Mode, the FCE Guardio Charger will emit three short beeping tones, display the Charge Session Cancelation screen (see **Figure 102**), and then automatically terminate the Unpaired Charge Mode charging session. When this occurs, remove the Pairing Magnet from atop the FCE Guardio Charger and then proceed Step 3 in section 4.14.2.

Note: If the FCE Guardio Charger is not able to reestablish communications with the OPTIMIZER Smart Mini IPG after 5 minutes of charging in Unpaired Charge Mode, it will emit three short beeping tones, display the Charge Session Cancelation screen (see **Figure 102**), and then terminate the Unpaired Charge Mode charging session. If this occurs, repeat Step 4 to initiate another charge session in Unpaired Charge Mode.
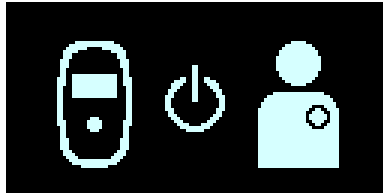
Figure 102: Charge Session Cancelation Screen

4.15   Cleaning

Warning: Always unplug the AC Adapter from the Guardio Charger prior to cleaning.

The exterior surface of the Guardio Charger should only be cleaned with disinfectant wipes as needed.

Caution: DO NOT use solvents or cleaning cloths impregnated with chemical cleaning agents.

Warning: DO NOT attempt to clean the electrical connector of your Guardio Charger.

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

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

4.16   Maintenance

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

Warning: No modification of this equipment is allowed.

The battery inside the Guardio Charger is expected to have a service life of at least 5 years. If the Guardio Charger cannot fully charge an OPTIMIZER Smart Mini IPG after the charger battery has been fully charged, please contact your Impulse Dynamics representative to obtain a replacement charger.

4.17 Storage and Handling

The Guardio Charger System is designed to maintain functionality after it has 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)

The Guardio Charger System should not be exposed to excessively hot or cold storage conditions. Patients should be instructed not to leave the Guardio Charger System in their car or outdoors for extended periods of time. Temperature extremes, particularly high heat can damage the sensitive electronics of the Guardio Charger System.

For proper operation, the Guardio Charger should be used <u>only</u> under the following environmental conditions:

- **Ambient Temperature:** 10°C to 27°C (50°F and 81°F)

- **Relative Humidity:** 20% to 75%

- **Atmospheric Pressure:** 70 kPa to 106 kPa (20.73 inHg to 31.39 inHg)

Note: When not being used to charge the OPTIMIZER Smart Mini IPG, the Guardio Charger should always be connected to its AC Adapter, and the AC Adapter plugged into the wall outlet

4.18 Disposal

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

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

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APPENDIX I

Statement of FCC Compliance

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.

The Intelio Programming Wand is marketed under FCC ID: 2AY43-INPW0

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.

FCC Compliance of the Guardio Charger

The Guardio Charger has been tested to the following FCC rules:

- 47 CFR Part 15 – Radio Frequency Devices
- 47 CFR Part 18 – Industrial, Scientific, and Medical Equipment
- 47 CFR Part 95 Subpart I - Medical Device Radio Communications Service

This device complies with part 18 of the FCC Rules.

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.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

— Reorient or relocate the receiving antenna.

— Increase the separation between the equipment and receiver.

— Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

— Consult the dealer or an experienced radio/TV technician for help.

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 Guardio Charger not approved by Impulse Dynamics could void the user's authority to operate the equipment under FCC rules.

The Guardio Charger is marketed under FCC ID: 2AY43-GDCH1. Additionally, the Guardio Charger contains a certified LTE module filed under FCC ID: 2AY43-EG25G.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

Note: The Guardio Charger can interrupt RFIDs or other communications systems that utilize the 13.56MHz ISM band.

Electromagnetic Immunity

Electromagnetic Immunity of the Intelio Programmer

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE INTELIO PROGRAMMER			
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.			
Essential Performance of the Intelio Programmer: • The Programming System shall be able to program the IPG with a safe program. It is allowable that this may require an occasional reattempt. • 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. • The Programming System shall only program the intended program and show as retrieved critical data the current set stored in the IPG. • If essential performance is lost due to electromagnetic disturbances, operators will be unable to program or reprogram the IPG as desired.			
Note: 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.			

Immunity test	IEC 60601-1-2:2014 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge as defined in IEC 61000-4-2	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 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	± 2 kV for mains power supply ± 1 kV for in-/output lines	± 2 kV for mains power supply ± 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 Guardio Charger.
AC line voltage surges as defined in IEC 61000-4-5	± 2 kV Common Mode ± 1 kV Differential Mode 1.2/50 µs	± 2 kV Common Mode ± 1 kV Differential Mode 1.2/50 µs	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	0%, 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles	0%, 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles	Mains power quality should be that of a typical professional healthcare or hospital environment. **Note:** If the user of the Intelio Programmer requires uninterrupted operation during power mains interruptions, it is recommended to power the Guardio Charger from an uninterruptible power supply.

Power line frequency magnetic fields (50/60 Hz) as defined in IEC 61000-4-8	30 A/m	30 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. **Recommended separation distance:** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 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	3 V/m: 80 MHz to 2.7 GHz, 80% 1kHz AM	3 V/m: 80 MHz to 2.7 GHz, 80% 1kHz AM	
Proximity fields from RF communications equipment as defined in IEC 61000-4-3	Various per table 9	Various per table 9	

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.

Electromagnetic Immunity of the Guardio Charger

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE GUARDIO CHARGER			
Essential Performance of the Guardio Charger: • The Guardio Charger shall not charge any IPG inappropriately. • The Guardio Charger shall only charge a paired IPG appropriately. • The patient shall be made aware of inappropriate charging either by an explicit message, or by the absence of an expected message from the Guardio Charger. • If essential performance is lost due to electromagnetic disturbances, the Guardio Charger shall not be able to charge any IPG.			
The Guardio Charger, part of the OPTIMIZER Smart Mini System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.			
The test levels follow FDA recommendations for the home environment per "Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff", November 24, 2014			
Immunity test	**IEC 60601-1-2:2014 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge as defined in IEC 61000-4-2	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 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	± 2 kV for mains power supply ± 1 kV for in-/output lines	± 2 kV for mains power supply ± 1 kV for in-/output lines	Mains power quality should be that of a typical home healthcare, business, or hospital environment. Do not operate motors or other noisy electrical equipment on the same mains circuit as the Guardio Charger.
AC line voltage surges as defined in IEC 61000-4-5	± 2 kV Common Mode ± 1 kV Differential Mode 1.2/50 µs	± 2 kV Common Mode ± 1 kV Differential Mode 1.2/50 µs	Mains power quality should be that of a typical home healthcare, business, or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines as defined in IEC 61000-4-11	0%, 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles	0%, 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles	Mains power quality should be that of a typical home healthcare, business, or hospital environment. **Note:** If the user of the Guardio Charger requires uninterrupted operation during power mains interruptions, it is recommended to power the Guardio Charger from an uninterruptible power supply.
Power line frequency magnetic fields (50/60 Hz) as defined in IEC 61000-4-8	30 A/m	30 A/m	Power line frequency magnetic fields (50/60 Hz) should be at levels expected in a typical home healthcare, business, 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.
Radiated RF as defined in IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010	10 V/m: 80 MHz to 2.7 GHz, 80% 1kHz AM	10 V/m: 80 MHz to 2.7 GHz, 80% 1kHz AM	**Recommended separation distance:** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 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).
Proximity fields from RF communications equipment as defined in IEC 61000-4-3	Various per table 9	Various per table 9	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:

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

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 or Guardio Charger**

Recommended separation distances between portable and mobile RF communications equipment and the Intelio Programmer or Guardio Charger			
The Intelio Programmer or the Guardio Charger should be used in an electromagnetic environment with limited radiated RF noise. The customer or user of the Intelio Programmer or the Guardio Charger can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the Intelio Programmer or the Guardio Charger recommended below, which is determined by the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance broken down by transmitter frequency(m)**		
	150 kHz to 80 MHz[1] $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz[1]** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
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.			
[1] At 80 MHz and 800 MHz, the higher frequency range applies.			
Note: 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 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.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Intelio Programmer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

FCC 47 CFR Part 15 – Radio Frequency Devices

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:		
FCC 47 CFR Part 15 – Radio Frequency Devices		
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**
Radiated and Spurious Emissions	Complies with clause 15.109(a), 15.209, and 15.225	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	Complies with clause 15.107(a) and 15.207	
Frequency Stability	Complies with clause 15.225	
RF Connector	Complies with clause 15.203	
Permissible Exposure Evaluation	1.1307(b) and 2.1093 exposure limit satisfied	

FCC 47 CFR 95 Subpart I – Medical Device Radio Communications Service

<table>
<tr><td colspan="3">GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:
FCC 47 CFR 95 Subpart I – Medical Device Radio Communications Service</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic environment – guidelines</th></tr>
<tr><td>Duration of Transmissions</td><td>Complies with clause 95.2557</td><td rowspan="9">The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>Frequency Monitoring</td><td>Complies with clause 95.2559</td></tr>
<tr><td>Frequency Range</td><td>Complies with clause 95.2563(a) and 2.1033(c)(5)</td></tr>
<tr><td>Frequency Stability</td><td>Complies with clause 95.2565 and 2.1055</td></tr>
<tr><td>EIRP</td><td>Complies with clause 95.2567(a)(1), 2.1033(c)(6), 2.1033(c)(7), and 2.1046</td></tr>
<tr><td>Field Strength</td><td>Complies with clause 95.2569, 95.2579(a), 2.1053, and 2.1057</td></tr>
<tr><td>Authorized Bandwidth</td><td>Complies with clause 95.2573(a) and 2.1049</td></tr>
<tr><td>Unwanted Emissions</td><td>Complies with clause 95.2579(c), 2.1033(c)(4), and 2.1047</td></tr>
<tr><td>Permissible Exposure Evaluation</td><td>Complies with clause 95.2585 and 2.1093</td></tr>
</table>

ETSI EN 300 330

<table>
<tr><td colspan="3">GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:
ETSI EN 300 330 V2.1.1 – Short Range Devices (SRD); Radio equipment in the frequency range 9kHz to 25MHz and inductive loop systems in the frequency range 9kHz to 30MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic environment – guidelines</th></tr>
<tr><td>Permitted range of operating frequencies</td><td>Complies with clause 4.3.2.3</td><td rowspan="6">The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>Modulation bandwidth</td><td>Complies with clause 4.3.3.3</td></tr>
<tr><td>Radiated H Field</td><td>Complies with clause 4.3.4.3</td></tr>
<tr><td>Transmitter Spurious Emissions below 30MHz – Operating and Stand-By Mode</td><td>Complies with clause 4.3.8.3</td></tr>
<tr><td>Transmitter Spurious Emissions 30-1000MHz – Operating and Stand-By Mode</td><td>Complies with clause 4.3.9.3</td></tr>
<tr><td>Receiver Spurious Emissions up to 1000MHz</td><td>Complies with clause 4.4.2.3</td></tr>
</table>

ETSI EN 301 839

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS 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.		

Emissions Test	Compliance	Electromagnetic environment – guidelines
Frequency Error	Complies with clause 4.2.1.1	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Emission Bandwidth	Complies with clause 4.2.1.2	
Effective radiated power of the fundamental emission	Complies with clause 4.2.1.3	
Spurious Emissions	Complies with clause 4.2.1.4	
Frequency Stability Under Low Voltage Conditions	Complies with clause 4.2.1.5	
Spurious Radiation of Receivers	Complies with clause 4.2.2.1	
Spectrum Access	Complies with clause 4.2.3.1	
Receiver Blocking	Complies with clause 4.2.3.2	

ETSI EN 301 489-1 and ETSI EN 301 489-27

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS 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 V2.2.1 – 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.		

Emissions Test	Basic Standard	Compliance	Electromagnetic environment – guidelines
Radiated Emissions	EN 55032	N/A – covered by relevant radio standards	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	Pass	
Harmonic Current Emissions	IEC 61000-3-2	Pass	
Voltage Fluctuations	IEC 6100-3-3	Pass	

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS 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.

Caution: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Emissions Test	Standard/Section	Compliance	Electromagnetic environment – guidelines
Radiated Emissions 30-1000MHz	CISPR11, Section 6, Table 4 (Rated input power < kVA)	Group 1, 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 0.15-30MHz, 230V 50Hz and 120V, 60Hz	CISPR11, Section 6, Table 2 (Rated input power < kVA)	Group 1, Class A	
AC Harmonic Emissions	IEC 61000-3-2	Class A	
Voltage Fluctuations	IEC 61000-3-3	Pass	

Electromagnetic Emissions from 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.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Intelio Programmer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

FCC 47 CFR Part 15 – Radio Frequency Devices

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE INTELIO PROGRAMMER WITH LEGACY PROGRAMMING WAND PURSUANT TO:		
FCC 47 CFR Part 15 – Radio Frequency Devices		
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 and Spurious Emissions	Complies with clause 15.109(a), 15.209, and 15.225	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	Complies with clause 15.107(a) and 15.207	
Permissible Exposure Evaluation	1.1307(b) and 2.1093 exposure limit satisfied	

ETSI EN 302 195

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS 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	

ETSI EN 301 489-1 and EN 301 489-31

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS 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.			
Emissions Test	**Basic Standard**	**Compliance**	**Electromagnetic environment – guidelines**
Radiated Emissions	EN 55032	Pass	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	Pass	
Harmonic Current Emissions	IEC 61000-3-2	Pass	
Voltage Fluctuations	IEC 6100-3-3	Pass	

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS 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.

Caution: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Emissions Test	Standard/Section	Compliance	Electromagnetic environment – guidelines
Radiated Emissions 30-1000MHz	CISPR11, Section 6, Table 4 (Rated input power < kVA)	Group 1, 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 0.15-30MHz, 230V 50Hz and 120V, 60Hz	CISPR11, Section 6, Table 2 (Rated input power < kVA)	Group 2, Class B	
AC Harmonic Emissions	IEC 61000-3-2	Class A	
Voltage Fluctuations	IEC 61000-3-3	Pass	

Electromagnetic Emissions from the Guardio Charger

The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

Warning: The Guardio Charger must not be used onboard an aircraft.

Warning: Permission must be requested from a ship's crew prior to using the Guardio Charger onboard a ship.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Intelio Programmer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

FCC 47 CFR Part 15 – Radio Frequency Devices

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO:		
FCC 47 CFR Part 15 – Radio Frequency Devices		
The Guardio Charger, part of the OPTIMIZER Smart Mini System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidelines**
Radiated and Spurious Emissions	Complies with clause 15.109(a), 15.209, and 15.225	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions	Complies with clause 15.107(a) and 15.207	
Frequency Stability	Complies with clause 15.225	
RF Connector	Complies with clause 15.203	
Permissible Exposure Evaluation	Complies with clause 1.1307(b) and 2.1093	

FCC 47 CFR Part 18 – Industrial, Scientific, and Medical Equipment

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO:		
FCC 47 CFR Part 18 – Industrial, Scientific, and Medical Equipment		
The Guardio Charger, part of the OPTIMIZER Smart Mini System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidelines**
Conducted Emissions	Complies with clause 18.307(b)	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Radiated Emissions	Complies with clause 18.305(b)	
Permissible Exposure Evaluation	Complies with clause 1.1307(b), 2.1093 and 18.313	

FCC 47 CFR 95 Subpart I – Medical Device Radio Communications Service

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO:		
FCC 47 CFR 95 Subpart I – Medical Device Radio Communications Service		
The Guardio Charger, part of the OPTIMIZER Smart Mini System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger 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 Guardio Charger 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 Range	Complies with clause 95.2563(a) and 2.1033(c)(5)	
Frequency Stability	Complies with clause 95.2565 and 2.1055	
EIRP	Complies with clause 95.2567(a)(1), 2.1033(c)(6), 2.1033(c)(7), and 2.1046	
Field Strength	Complies with clause 95.2569, 95.2579(a), 2.1053, and 2.1057	
Authorized Bandwidth	Complies with clause 95.2573(a) and 2.1049	
Unwanted Emissions	Complies with clause 95.2579(c), 2.1033(c)(4), and 2.1047	
Permissible Exposure Evaluation	Complies with clause 95.2585 and 2.1093	

ETSI EN 300 330

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO:		
ETSI EN 300 330 V2.1.1 – Short Range Devices (SRD); Radio equipment in the frequency range 9kHz to 25MHz and inductive loop systems in the frequency range 9kHz to 30MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU		
The Guardio Charger, part of the OPTIMIZER Smart Mini System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidelines**
Permitted range of operating frequencies	Complies with clause 4.3.2.3	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Modulation bandwidth	Complies with clause 4.3.3.3	
Radiated H Field	Complies with clause 4.3.4.3	
Transmitter Spurious Emissions below 30MHz – Operating and Stand-By Mode	Complies with clause 4.3.8.3	
Transmitter Spurious Emissions 30-1000MHz – Operating and Stand-By Mode	Complies with clause 4.3.9.3	
Receiver Spurious Emissions up to 1000MHz	Complies with clause 4.4.2.3	

ETSI EN 301 839

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER 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 Guardio Charger, part of the OPTIMIZER Smart Mini System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidelines**
Frequency Error	Complies with clause 4.2.1.1	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Emission Bandwidth	Complies with clause 4.2.1.2	
EIRP	Complies with clause 4.2.1.3	
Transmitter Spurious Emissions (30 MHz to 6 GHz)	Complies with clause 5.3.4	
Frequency Stability Under Low Voltage Conditions	Complies with clause 4.2.1.5	
Receiver Spurious Emissions	Complies with clause 4.2.2.1	
Spectrum Access	Complies with clause 4.2.3.1	
Receiver Blocking	Complies with clause 4.2.3.2	

ETSI EN 301 489-1 and ETSI EN 301 489-27

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER 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 Guardio Charger, part of the OPTIMIZER Smart Mini System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger 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.

Emissions Test	Basic Standard	Compliance	Electromagnetic environment – guidelines
Radiated Emissions	EN 55032	N/A – covered by relevant radio standards	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions	EN 55032	Pass	
Harmonic Current Emissions	IEC 61000-3-2	Pass	
Voltage Fluctuations	IEC 6100-3-3	Pass	

IEC 60601-1-2 2014

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER 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 Guardio Charger, part of the OPTIMIZER Smart Mini System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger 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.

Emissions Test	Standard/Section	Compliance	Electromagnetic environment – guidelines
Radiated Emissions 30-1000MHz	CISPR11, Section 6, Table 11 (Class B, Group 2)	Group 2, Class B	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions 0.15-30MHz, 230V 50Hz and 120V, 60Hz	CISPR11, Section 6, Table 6 (Class B, Group 2)	Group 2, Class B	
AC Harmonic Emissions	IEC 61000-3-2	Class A	
Voltage Fluctuations	IEC 61000-3-3	Pass	

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 "OPTI*link*" 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.

RF wireless technology is also used to transcutaneously transmit energy from the Guardio Charger to recharge the OPTIMIZER Smart Mini IPG at the 13.56 MHz ISM frequency. The transmission range is specified at a maximum of 4 cm (1.5 in) between the Charger's coil and the IPG's receiving coil. Control over the recharge process, as well as the communications of alert messages from the IPG to the Charger take place over an encrypted MICS 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
OPTI*link* MICS MedRadio	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	253 kHz
Modulation	FSK
Radiated Power	-24.4 dBm EIRP
Range	0 to at least 1.5 m
Recharge Channel Communication	
Frequency Band	13.56 MHz ± 9.2 ppm Industrial, Scientific, and Medical radio band (ISM)
Bandwidth	<0.014 MHz
Modulation	PPM
Radiated Power	-11.73 dBm EIRP
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
Legacy Programming Wand to OPTIMIZER Smart IPG	
Frequency Band	23 kHz
Modulation	100% AM: "0" = no carrier, "1" = carrier for 305 µs
Radiated Power	0.56 W_{peak}; 0.27 $W_{average}$
Range	5 mm to 50 mm
OPTIMIZER Smart IPG to Legacy Wand	
Frequency Band	14.5 kHz LC excited by pulse; 1 cycle per pulse until dampened to 10%
Modulation	PPM: "0" = 180 µs, "1" = 270 µs
Radiated Power	5.14 mW_{peak} per pulse; 1.8 $mW_{average}$
Range	5 mm to 50 mm

Guardio Charger Wireless Nominal Specifications

| Characteristic	Nominal
MICS MedRadio	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	240 kHz
Modulation	FSK
Radiated Power	-20.6 dBm EIRP
Range	0 to at least 1.5 m
Transcutaneous Energy Transfer	
Frequency Band	13.56 MHz Industrial, Scientific, and Medical radio band (ISM)
Modulation	Amplitude (slow to optimize coupling)
Radiated Power	< 0.6 W reactive near-field
Range	5 mm to 40 mm
Recharge Channel Communication	
Frequency Band	13.56 MHz ± 9.2 ppm Industrial, Scientific, and Medical radio band (ISM)
Bandwidth	<0.014 MHz
Modulation	PPM
Radiated Power	-6.93 dBm EIRP
Range	5 mm to 40 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 OPTI*link* 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 (1.5 in) of the IPG. Once the Intelio Programming Wand is over the patient's implant site, the communication link is established by initiating the Start OPTI*link* 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 OPTI*link* 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:
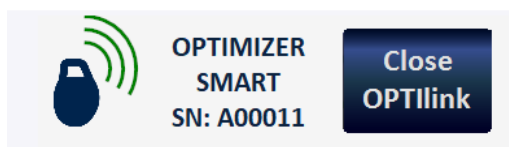
- Good quality link – 3 green signal waves
- Medium quality link – 2 yellow signal waves
- Low quality link – 1 red signal wave

QoS for Communications between the Guardio Charger 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 Guardio Charger. The requirements for the Quality of Service (QoS) vary depending on the use environment (operating room, recovery room, clinic, and home environment).

The Guardio Charger will begin by displaying the IPG Data Download and IPG Data Download Success screens:
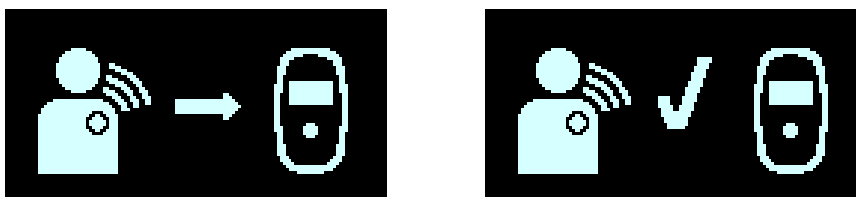
After the data download has been completed, the Charging IPG Status screen is displayed by the Guardio Charger:

The Coupling Level icon (), whose number of illuminated bars is proportional to the proximity of the charging wand to the implanted OPTIMIZER Smart Mini IPG, is indicative of the Quality of Service (QoS) for the transcutaneous energy transmission wireless link. The charging wand should be repositioned until at least 2 bars of the Coupling Level icon are illuminated, indicating sufficient QoS for charging the OPTIMIZER Smart Mini IPG.

One illuminated bar indicates degraded QoS which may require a longer charging time. Zero illuminated bars on the Coupling Level icon accompanied by an audible beeping tone indicates poor placement of the charging wand. If the charging wand is not repositioned onto the implant site within 20 seconds, the Guardio Charger will emit 3 long beeping tones, display the Charging IPG Coupling Error screen, and then shut off.

Besides charging the OPTIMIZER Smart Mini, the Guardio Charger also serves as a way of messaging the patient about alerts and other conditions. The Guardio Charger is configured to communicate with the OPTIMIZER Smart Mini IPG at least once a day. This communication occurs whenever the IPG is within 1.5 m (5 ft) of the Guardio Charger for a few minutes.

If the Guardio Charger and the OPTIMIZER Smart Mini IPG do not communicate within a programmable time period, the patient may see the "Long Time Without Downloading Data From IPG" alert screen displayed by the Guardio Charger:

In this case, instruct the patient to attempt to charge their OPTIMIZER Smart Mini IPG with their Guardio Charger. If the patient is able to charge their implanted device successfully, then the alert screen should no longer be displayed by the Guardio Charger. If the attempt to charge the OPTIMIZER Smart Mini IPG with the Guardio Charger is unsuccessful, the Impulse Dynamics representative should be contacted.

Wireless Security Measures

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

OPTI*link* 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 (1.5 in) 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.
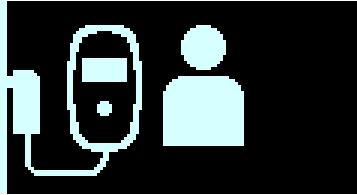
Wireless Security Measures in Communications between OPTIMIZER Smart Mini IPG and Guardio Charger

Pairing of the Guardio Charger with the OPTIMIZER Smart Mini IPG ensures that the communication and charging information received by the Guardio Charger is securely encrypted and unique to a specific implanted device.

During the pairing process, the Guardio Charger uses short-range communication to search for a device to pair with and creates an encryption key once a compatible device model has been found. This encryption key is stored and used by the Guardio Charger for all its subsequent communications sessions with the paired device.

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

- Pairing of a Guardio Charger and an OPTIMIZER Smart Mini IPG requires the placing of a pairing magnet on the Guardio Charger, and locating the Charge Wand within 4 cm (1.5 in) of the OPTIMIZER Smart Mini IPG. The 13.56 MHz short-range channel is used as part of a proprietary process to pair the devices and exchange encryption keys.

- The OPTIMIZER Smart Mini IPG and the Guardio Charger encrypt their wireless communications using encryption keys that are generated during the pairing process.

- Only one Guardio Charger can be paired with the IPG at any one 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 OPTI*link* 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 OPTI*link* 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 OPTI*link* connection.

Troubleshooting Wireless Connection between OPTIMIZER Smart Mini IPG and Guardio Charger

If you experience issues with establishing a wireless connection between the OPTIMIZER Smart Mini IPG and the Guardio Charger, try the following:

- Whenever the Guardio Charger is not being used to charge the OPTIMIZER Smart Mini IPG, place it in an area that is frequented by the patient (e.g., bedside table in the bedroom), connected to its AC Adapter, and the AC Adapter plugged into the wall outlet. This will ensure regular communications between the OPTIMIZER Smart Mini IPG and the Guardio Charger.

- Remain stationary during the charging or data transfer process.

- 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 wireless 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.