



Hope is Here

Intelio Programmer for OPTIMIZER[®] Integra CCM-D System

INSTRUCTIONS FOR USE

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<http://www.impulse-dynamics.com/us/patents>

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

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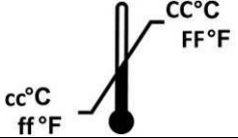











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EXPLANATION OF SYMBOLS ON LABELS

Symbol	Description
	Consult instructions for use
	Do not use if package is damaged
	Storage and transport temperature limits
	Date of manufacture
	Manufacturer
	Catalogue number
	Serial number
	Refer to instruction manual/booklet
	Caution, consult instructions for use
	Item not to be disposed via the municipal waste collection system of any member state of the European Union
	Class II equipment
	Type BF applied part
	Defibrillation-proof type CF applied part
	Non-ionizing electromagnetic radiation

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LIST OF ACRONYMS

Acronym	Description
AC	Alternating Current
AF	Atrial Fibrillation
ALCP	Application Level Communication Protocol
ATP	Antitachycardia Pacing
BF	Body Floating
BOS	Beginning of Service
CCM	Cardiac Contractility Modulation
CF	Cardial Floating
CLI	Coil Lead Impedance
ECG	Electrocardiogram
EGM	Electrogram
EOS	End of Service
EHR	Extended High Rate
ERI	Elective Replacement Indicator
FVT	Fast Ventricular Tachycardia
HR	Heart Rate
HRV	Heart Rate Variability
HV	High Voltage
HVLI	High-Voltage Lead Impedance
ICD	Implantable Cardioverter Defibrillator
IEGM	Intracardiac Electrogram
IPG	Implantable Pulse Generator
LS	Local Sense
PC	Personal Computer
RF	Radio Frequency
RMSSD	Root Mean Square of Successive Differences
RRT	Recommended Replacement Time (synonymous with ERI)
RV	Right Ventricle
SR	Slow Rhythm
USB	Universal Serial Bus
UTC	Coordinated Universal Time
VT	Ventricular Tachycardia
VF	Ventricular Fibrillation
VVE	Ventricle Defibrillation, Ventricle Antitachycardia Pacing, Detection by Electrogram
VVI	Ventricle Paced, Ventricle Sensed, Inhibited by Sensed Signal
Wi-Fi	Wireless Network
WLAN	Wireless Local-Area Network

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1.0 THE INTELIO PROGRAMMER SYSTEM

1.1 Description

The Intelio Programmer System allows the clinician to interrogate and program the OPTIMIZER Integra CCM-D Implantable Pulse Generator (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 Integra CCM-D IPG is accomplished using the Intelio Programming Wand. The Intelio Programming Wand first uses short-range communications to establish a link with the OPTIMIZER Integra CCM-D IPG and then long-range Radio Frequency (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 Integra CCM-D 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 Programming Wand is classified as Class II equipment and a Type BF applied part.

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



Figure 1: Intelio Programmer System

1.2 Programmer Functions

The functions performed by the Intelio Programmer include the following:

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

1.3 Programmer Components

The Intelio Programmer System consists of:

- Intelio Programmer
 - Intelio Programmer Tablet PC installed with the Optimizer Integra CCM-D 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/Vesta Charger)
- Medical-grade Power Supply
- Power Cord

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

1.4 Interconnecting the Programmer Components for Operation

To begin using the Intelio Programmer System with the OPTIMIZER Integra CCM-D IPG, connect the following components:

1. Plug the LEMO connector of the Intelio Programming Wand into the gray-ringed port on the right side of the Intelio Programming Interface.
2. 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 Integra CCM-D 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 Integra CCM-D 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 Integra CCM-D 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 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.

1.7 Indicator Lights and Buttons 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.

1.7.1 Indicator Lights

The Indicator Lights have the following functions (from top to bottom):

- 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

1.7.2 Buttons

The Buttons have the following functions (from top to bottom):

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

1.8 User Profile and Training

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

Physicians and medical personnel can 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.

1.9 Operating the Intelio Programmer

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

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

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

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

1. Press the Power button on the right side of the tablet PC, hold the button down for 2 seconds, and then release it.
2. Verify that the Power indicator light is illuminated blue, indicating the Intelio Programmer has been turned ON.

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

1.10 Using the Intelio Programmer Tablet PC Touch Screen

The Intelio Programmer tablet PC is equipped with a touch screen. Selections on the screen may be made by tapping the screen with one's finger or the attached stylus.

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

1.11 Using the Programming Wand

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

1.11.1 Intelio Programming Wand

The Intelio Programming Wand must be kept directly over the patient's implant site while it is being used to establish a link between the Intelio Programmer and the OPTIMIZER Integra CCM-D IPG. Once the link with the OPTIMIZER Integra CCM-D 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 Routine Cleaning

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

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

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

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

1.13 Maintenance

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

The Intelio Programmer tablet PC contains a battery pack that may need to be replaced if it fails to adequately maintain a charge or is unable to be fully charged. Contact your local Impulse Dynamics representative if a replacement battery pack is needed.

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

Warning: Never puncture or incinerate a used battery.

1.14 Storage and Handling

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

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

Recommended environmental conditions for normal use are the following:

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

2.0 INTELIO PROGRAMMER SYSTEM SOFTWARE APPLICATIONS

The Intelio Programmer System contains various software applications that can be accessed from the Selector Screen.

2.1 Selector Screen

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

- **Optimizer Integra:** Opens the Optimizer Integra Programmer application.
- **System Administration:** (Password-Protected): This selection 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.
- **Data Exporting** (Password-Protected): Opens the application that allows the user to export data to a USB flash drive. It is to be used by Impulse Dynamics technical staff only and is not needed for regular clinical use.

- **Intelio Software Update** (Password-Protected): Opens the application that allows the user to update the software on the Intelio Programmer using a USB flash drive containing the software update files. It is to be used by Impulse Dynamics technical staff only and is not needed for regular clinical use.
- **Charger Firmware Update** (Password-Protected): Opens the application that allows the user to update the firmware of the Guardio/Vesta Charger using the Intelio Programmer, the Charger Bootstrap Cable, and a USB flash drive containing the Guardio/Vesta Charger firmware. It is to be used by Impulse Dynamics technical staff only and is not needed for regular clinical use.
- **Shutdown:** Tapping the red Shutdown button on the Selector screen shuts off the Intelio Programmer.



Figure 2: Intelio Programmer Selector Screen

2.2 Basic Operation of the Optimizer Integra Programmer Application

After the **Optimizer Integra** button has been selected from the Selector screen and has completed the application boot up process, the Optimizer Integra Programmer application is displayed on the Intelio Programmer.

The basic operation of the Optimizer Integra Programmer application includes the following:

2.2.1 Communication with the OPTIMIZER Integra CCM-D IPG

Before the clinician can use the Intelio Programmer to program the OPTIMIZER Integra CCM-D 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 Integra CCM-D IPG 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 Integra Programmer application.

2.2.2 Interrogation and Programming

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

The Optimizer Integra 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 Integra CCM-D IPG. Thereafter, the **Interrogate** command can be issued again, if desired, to update the current status of the OPTIMIZER Integra CCM-D IPG (e.g., rechargeable and ICD battery voltages).

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

The clinician can review and modify the parameter values using the Optimizer Integra Programmer application. The modified parameter values can then be transmitted to the OPTIMIZER Integra CCM-D 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 a **standard** file (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 Integra 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 Integra Programmer application to be used as an editor of standards (see section 3.29).

2.2.3 OPTIset

The Optimizer Integra Programmer application features the OPTIset tool which can be used analyze the patient’s rhythm and propose the best settings for IEGM sensing, CCM timing, and CCM train parameters (see section 3.8)

2.2.4 Data Download

The Optimizer Integra Programmer application can be used to download and view following data stored on the OPTIMIZER Integra CCM-D IPG:

- CCM Statistics (see section 3.18.1)
- ICD Statistics (see section 3.18.7)
- Trends (see section 3.18)

2.2.5 Lead Impedance Measurement

The OPTIMIZER Integra Programmer application can be used to measure the following impedances:

- Ventricular lead impedance (see section 3.16.1)
- Coil lead impedance (see section 3.16.2)
- High voltage lead impedance (see section 3.16.3)

2.2.6 Closing the Programmer Application

Tapping the **Exit** button in the bottom right corner of the Optimizer Integra Programmer application screen will close the application. When the confirmatory pop window appears, tap **Close** to return the Intelio Programmer to the Selector screen.

3.0 OPTIMIZER INTEGRA PROGRAMMER SOFTWARE

The Optimizer Integra Programmer Software is an application used to read and modify the parameters that control the OPTIMIZER Integra CCM-D IPG. This section describes the various features of the Optimizer Integra Programmer application.

Note: Dates displayed by the Optimizer Integra 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 Integra Programmer Application

When the Optimizer Integra Programmer Software is started, the Optimizer Integra Programmer application displays the main screen, which includes the following:

- ECG/IEGM/Marker Pane
 - Surface ECG/Far-Field IEGM Sub-pane
 - IEGM Sub-pane
 - CCM Marker Sub-pane
 - ICD Marker Sub-pane
- CCM Marker Legend
- ICD Marker Legend
- OPTlink Session Pane
- CCM Status Pane
- ICD Status Pane
- Programming Buttons Pane
- Menu Bar
- Status Bar



Figure 3: Optimizer Integra Programmer Application Main Screen

3.1.1 ECG/IEGM/Marker Pane

The ECG/IEGM/Marker pane has four sub-panes and includes features that allow the user to pause the running marker screen, to display a full screen view of the marker screen, to create a report of the marker screen, and to set the sweep speed of the marker screen.

Note: The chart gradient of the ECG/IEGM/Marker screen is not the typical 25 or 50 mm/sec.

3.1.1.1 Surface ECG/Far-Field IEGM Sub-Pane

Warning: The displayed Surface ECG is of monitoring quality and is not diagnostic quality. Do not base clinical diagnostic decisions on the Surface ECG displayed by the Optimizer Integra Programmer application.

The Surface ECG/Far-Field IEGM Sub-pane is displayed at the top of the pane and displays the patient's real-time ECG/IEGM.

The Optimizer Integra Programmer application offers the user the option of selecting which view to display on the ECG/IEGM/Marker pane. To change the view, tap the field indicating the current view (located to the right of the Surface ECG/Far-Field IEGM Sub-pane) and then tap the desired view from the selection.

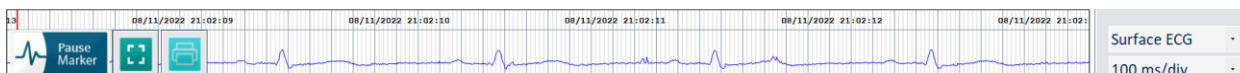


Figure 4: Surface ECG View



Figure 5: Far-Field IEGM View

The Surface ECG/Far-Field IEGM Sub-pane also contains the following buttons:

- Marker (displayed as **Pause Marker** or **Resume Marker**): Pauses or resumes the running marker screen
- Full Screen (see icon image on the right): Toggles the display of the running marker screen between window screen view and full screen view
- Print Screen (see icon image on the right): Creates a report of the marker screen



3.1.1.2 IEGM Sub-Pane

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

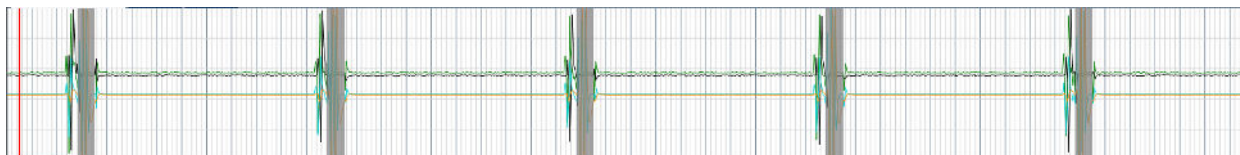


Figure 6: IEGM Sub-Pane

3.1.1.2.1 IEGM Marker Legend

The IEGM Marker legend is located to the right of the IEGM Sub-pane and displays the real-time signal amplitudes of the IEGM signals. The color of each IEGM signal type defined in the legend corresponds to the color of the graph shown in the IEGM Marker Sub-pane. The graph of each IEGM signal may be toggled ON or OFF by tapping on the selector box to the left of the IEGM signal listed in the legend.

Filled-in Box = ON Empty Box = OFF

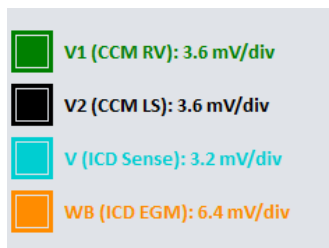


Figure 7: IEGM Marker Legend

3.1.1.3 CCM Marker Sub-Pane

The CCM Marker Sub-pane is displayed below the IEGM Sub-pane. When the OPTIMIZER Integra CCM-D IPG's CCM Therapy 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.

The CCM Marker legend is located to the right of the CCM Marker Sub-pane and identifies the marker row channel.

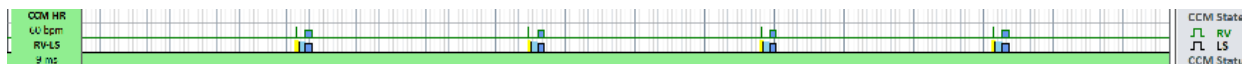


Figure 8: CCM Marker Sub-Pane

3.1.1.4 ICD Marker Sub-Pane

The ICD Marker Sub-pane is displayed below the CCM Marker Sub-pane. When the OPTIMIZER Integra CCM-D IPG ICD mode is enabled, it shows the marker for the ICD EGM and the ICD Status. If any ICD therapies being delivered, that will also be shown on the ICD Marker Sub-pane.

The ICD Marker legend is located to the right of the ICD Marker Sub-pane and defines the type of information displayed in each marker row.

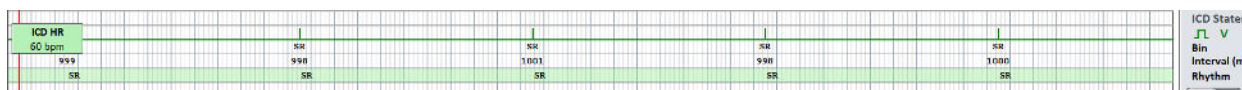


Figure 9: ICD Marker Sub-Pane

3.1.1.5 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 CCM module in beats per minute (bpm)
- **RV-LS:** The interval between the RV and LS sensed event in milliseconds (ms)

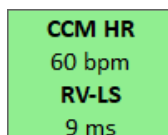


Figure 10: CCM Statistics Bar

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

3.1.1.6 ICD Real-Time Statistics Area

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

- **ICD HR:** Heart rate sensed by the ICD module in beats per minute (bpm)

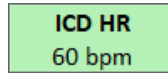


Figure 11: ICD Statistics Bar

The ICD HR interval changes dynamically, showing the current reading for the statistic.

3.1.1.7 Marker Screen Sweep Speed Selector

To the right of the Surface ECG/Far-Field IEGM Sub-Pane is a pull-down menu that allows the user to set the sweep speed of the marker screen.



Figure 12: Marker Screen Sweep Speed Selector

To change the sweep speed of the marker screen, tap the field indicating the current sweep speed (located to the right of the Surface ECG/Far-Field IEGM Sub-pane) and then tap the desired sweep speed from the selection.

3.1.2 Legend for CCM Marker Sub-Pane

The Legend for CCM Marker Sub-pane defines each marker that may appear in the CCM Marker Sub-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):
 - **V Noise:** Noise detected on the ventricular sense channel
 - **VT:** Ventricular rate above the ventricular tracking rate limit
 - **LS Out of Alert:** Local sense (LS) event detected outside of the LS Alert window.
 - **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 CCM IEGM Markers

Each lead has its own CCM IEGM Marker.

- **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.

- **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 Integra CCM-D IPG
- **Dark Gray:** CCM is suspended
- **Orange:** CCM is set to Continuous mode
- **Gray:** The rechargeable battery voltage of the OPTIMIZER Integra CCM-D IPG is low

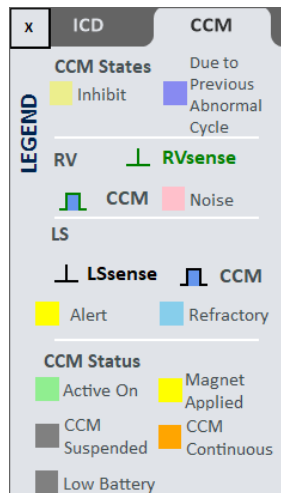


Figure 13: Legend for CCM Marker Sub-Pane

3.1.3 Legend for ICD Marker Sub-Pane

The Legend for ICD Marker Sub-pane defines each marker that may appear in the ICD Marker Sub-pane.

3.1.3.1 ICD States

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

- **Gap:** AF Gap
- **Yellow:** This is displayed when a magnet is applied to the OPTIMIZER Integra CCM-D IPG
- **RS:** Rate stability
- **R On:** Rhythm onset
- **CV:** Conduction velocity
- **Stp:** Stop ICD
- **TD:** Therapy delay
- **M:** Morphology

3.1.3.2 ICD V1

The ICD V1 IEGM Marker is displayed as follows:

- **Green Marker:** Right Ventricular (RV) sensed event
- **Red Marker (I):** Synchronized event
- **Pink:** Noise detected on the V1 channel
- **Light Blue with ↑:** VOO pacing
- **No Color with ↑:** Post-Shock or Rescue Brady pacing
- **Light Gray with ↑:** ATP pulse
- **Yellow with Red Marker (I):** 50 Hz Induction Burst
- **Black:** Prevent Shock
- **Red:** Shock
- **Pink Marker:** Extended High-Rate (EHR) timer start

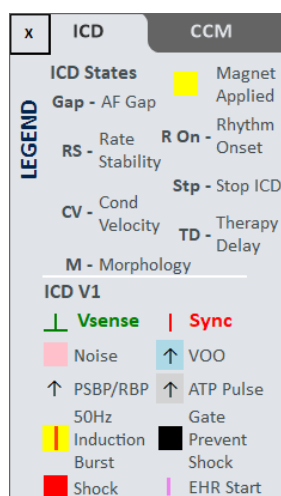


Figure 14: Legend for ICD ECG/IEGM/Marker Pane

3.1.4 OPTlink Session Pane

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

- **Start OPTlink:** Command button that begins the process of establishing a communication link between the Intelio Programmer and the OPTIMIZER Integra CCM-D IPG.
- **Open Log:** Command button that allows the user to open a log file of a previously interrogated OPTIMIZER Integra CCM-D IPG. When tapped, it displays an **Access Log system** window that requires entry of a password. Once the password is entered and **OK** is tapped, a window is displayed showing the list of log files stored on the Intelio Programmer. Once a log file is selected, tap the **Select** button to open the log file for the selected device.

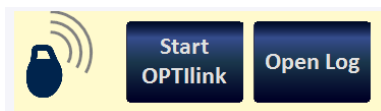


Figure 15: OPTlink Session Pane (not linked to IPG)

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

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

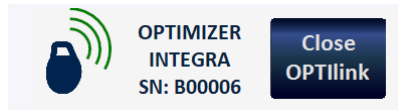


Figure 16: OPTlink Session Pane (good-quality link to IPG shown)

3.1.5 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, tapping it permanently suspends CCM therapy and toggles the button to say “ENABLE CCM”. When the button is in its “ENABLE CCM” state, tapping it unsuspends CCM therapy and toggles the button back to display “DISABLE CCM”.

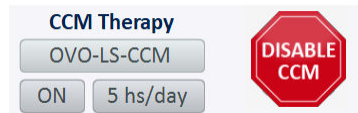


Figure 17: CCM Status Pane

3.1.6 ICD Status Pane

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

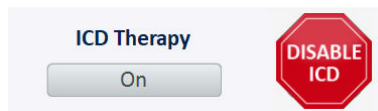


Figure 18: ICD Status Pane

3.1.7 Stat Shock Pane

The Stat Shock Pane has a button that allows the user to command the OPTIMIZER Integra CCM-D IPG to deliver a STAT shock to the patient. When the button is tapped, a confirmatory pop-up message appears, asking the user to confirm if they want a 36J shock to be delivered. If the confirmatory “Yes Deliver 36J Shock button is tapped, a 36J shock will be delivered by OPTIMIZER Integra CCM-D IPG.



Figure 19: Stat Shock Pane

3.1.8 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 Integra CCM-D IPG with nominal values. If **Yes** is chosen, then the nominal values will be programmed into the OPTIMIZER Integra CCM-D IPG. If **No** is chosen, then the pop-up window closes.
- **Interrogate:** Reads the current parameter values of the OPTIMIZER Integra CCM-D IPG. These values become the parameter values displayed by the Optimizer Integra Programmer application.
- **Cancel:** When parameter values have been modified in the Intelio Programmer but not yet programmed into the OPTIMIZER Integra CCM-D 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 Integra CCM-D IPG, it allows the user to reprogram the OPTIMIZER Integra CCM-D IPG with the previously programmed values.
- **Program:** Transmits the current parameter values of the Optimizer Integra Programmer application to the OPTIMIZER Integra CCM-D IPG. This button is disabled when parameter modifications result in a parameter conflict.

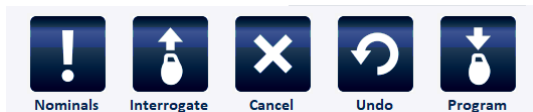


Figure 20: Programming Buttons Pane

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

3.1.9 Menu Bar

The Menu Bar contains the following buttons:

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

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

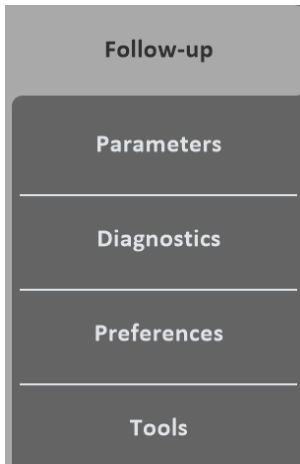


Figure 21: Menu Bar

3.1.9.1 Follow-up Menu

The Follow-up Menu contains the following tabs, each displaying a panel containing information about the current status of the OPTIMIZER Integra CCM-D IPG.

3.1.9.1.1 Summary

The Summary tab displays the following information:

- **Implant Date:** This date is dependent on the implant date information entered on the Implant Data screen
- **Last Follow-Up:** Shows the last time the Optimizer Integra Programmer application established a successful link with the OPTIMIZER Integra CCM-D IPG
- **Battery bar:** Shows the current voltage of the rechargeable battery in the OPTIMIZER Integra CCM-D IPG
- **Discharges:** Indicates the number of discharge episodes experienced by the rechargeable battery in the OPTIMIZER Integra CCM-D IPG
- **ICD Battery**
 - **Status:** Shows the current status of the ICD battery in the OPTIMIZER Integra CCM-D IPG
 - **Voltage:** Shows the current voltage of the ICD battery in the OPTIMIZER Integra CCM-D IPG
- **V1 Lead (Defib)**
 - Serial number (**SN**)
 - **V1 Impedance:** (if measured)
 - **R-Wave Amplitude (CCM):** (if measured)
 - **R-Wave Amplitude (ICD):** (if measured)
 - **Coil Lead Impedance:** (if measured)
 - **HV (High Voltage) Lead Impedance:** (if measured)
- **V2 Lead (CCM)**
 - Serial number (**SN**)
 - **V2 Impedance:** (if measured)
 - **R-Wave Amplitude:** (if measured)

- **ICD Episodes**
- **Reset:** Date and time of when the ICD (VT) episodes were last deleted from the OPTIMIZER Integra CCM-D IPG (if reset)
- **Episodes:** The number of ICD (VT) episodes stored in the OPTIMIZER Integra CCM-D IPG
- **CCM Therapy**
 - **24 CCM:** The percentage of CCM therapy delivered during the previous day
 - **Total CCM:** The total percentage of CCM therapy delivered
- **OPTIHome:** (future capability)

The Summary tab also has the following buttons:

- **Update Measurements:** Allows user to update the ventricular and coil lead impedance measurements
- **Print Summary Report:** Allows the user to print a Summary Report (see section 3.28.1.1).

Figure 22: Summary Panel

3.1.9.1.2 VT Episodes

The VT Episodes tab has the following buttons:

- **Get Episodes:** Used to retrieve the most recent tachy episodes from the OPTIMIZER Integra CCM-D IPG
- **Delete Episodes from IPG:** Used to delete all tachy episodes stored in the OPTIMIZER Integra CCM-D IPG

This tab also has the **Show Episodes from Past Sessions** checkbox, which when selected, displays episodes that were previously downloaded from the OPTIMIZER Integra CCM-D IPG.

	Date	Time	Rhythm	Therapies	HV Ω	Fastest Period	ECG Data
1	08/11/2022	22:15:07	VF	VF Shock 1 - Energy: 33.8 J - Charge Time: 21 s - Impedance: 81.3 Ω Post - Shock Brady	81.3 Ω	132 ms	<input checked="" type="checkbox"/>
2	08/11/2022	20:56:36	VT	ATP VT Shock 1 - Energy: 5.6 J - Charge Time: 3 s - Impedance: 80.1 Ω	80.1 Ω	176 ms	<input checked="" type="checkbox"/>

Figure 23: VT Episodes Panel

3.1.9.1.3 Stats and Trends

The Stats and Trends tab has the following buttons:

- **CCM Statistics:** Used to download and view the CCM statistics data stored in the OPTIMIZER Integra CCM-D IPG.
- **Daily Activity:** Used to view the Daily Activity trends data stored in the OPTIMIZER Integra CCM-D IPG.
- **Activity Per Hour:** Used to view the Activity per Hour trends data stored in the OPTIMIZER Integra CCM-D IPG.
- **Alerts:** Used to view the Alerts trends data stored in the OPTIMIZER Integra CCM-D IPG.
- **Rechargeable Battery:** Used to view the Rechargeable Battery trends data stored in the OPTIMIZER Integra CCM-D IPG.
- **Leads:** Used to view the Lead trends data stored in the OPTIMIZER Integra CCM-D IPG.
- **ICD Statistics:** Used to download and view the ICD statistics data stored in the OPTIMIZER Integra CCM-D IPG.
- **High Voltage Capacitors:** Used to view the High Voltage Capacitors trends data stored in the OPTIMIZER Integra CCM-D IPG.
- **QHR Battery:** Used to view the QHR Battery trends data stored in the OPTIMIZER Integra CCM-D IPG.



Figure 24: Stats and Trends Panel

3.1.9.1.4 CCM Settings

The CCM Settings tab displays an overview of the CCM setting currently programmed into the OPTIMIZER Integra CCM-D IPG. This tab also has the **OPTIset IEGM Sensitivities** button, which allows the user to let the application analyze the patient's heart rhythm and recommend the best sensing parameter setting for each lead.

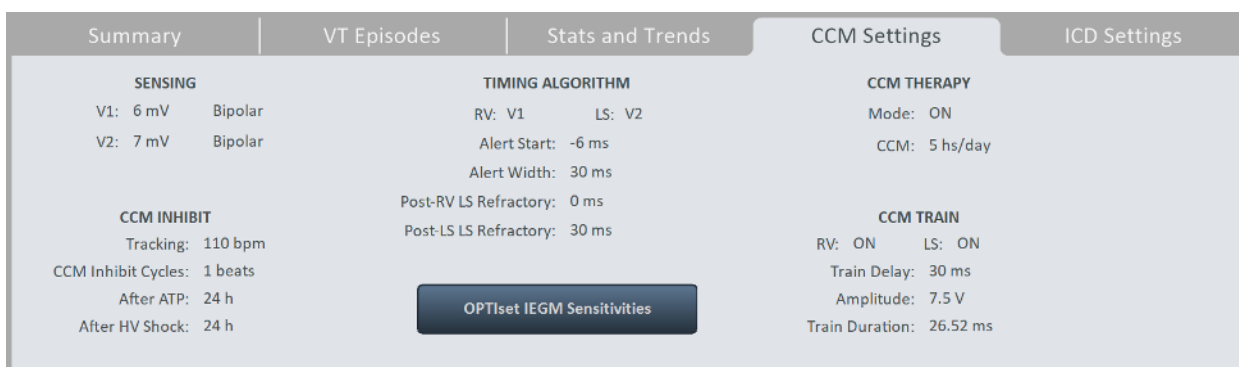


Figure 25: CCM Settings Panel

3.1.9.1.5 ICD Settings

The ICD Settings tab displays an overview of the ICD setting currently programmed into the OPTIMIZER Integra CCM-D IPG.

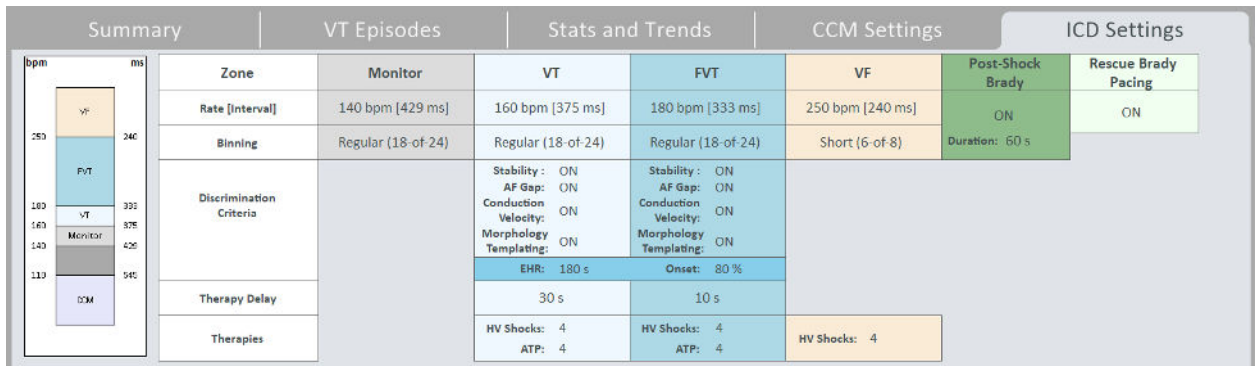


Figure 26: ICD Settings Panel

3.1.9.2 Parameters Menu

The Parameters Menu contains the following tabs, each displaying a panel with parameters that can be set for the OPTIMIZER Integra CCM-D IPG.

3.1.9.2.1 CCM Therapy

The CCM Therapy tab 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**

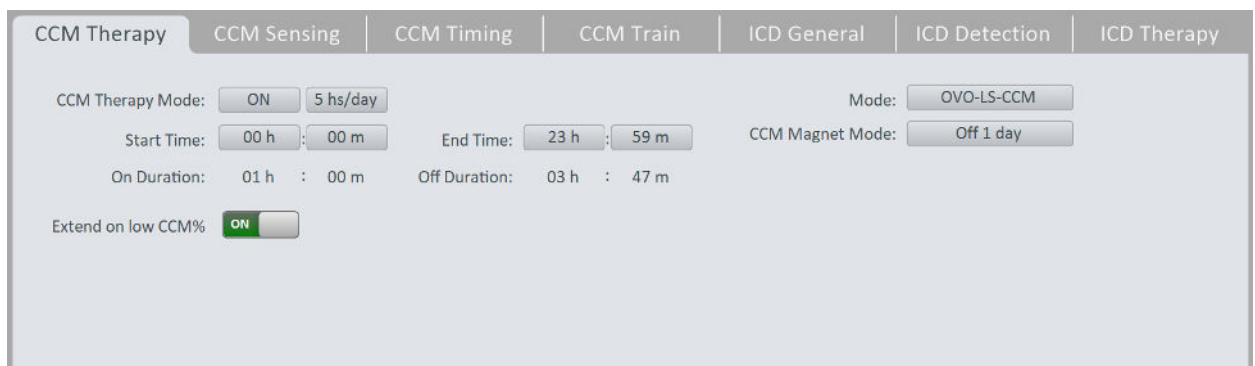


Figure 27: CCM Therapy Panel

3.1.9.2.2 Sensing

The Sensing tab contains the following parameters for each lead:

- **Sensitivity**
- **Polarity**

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

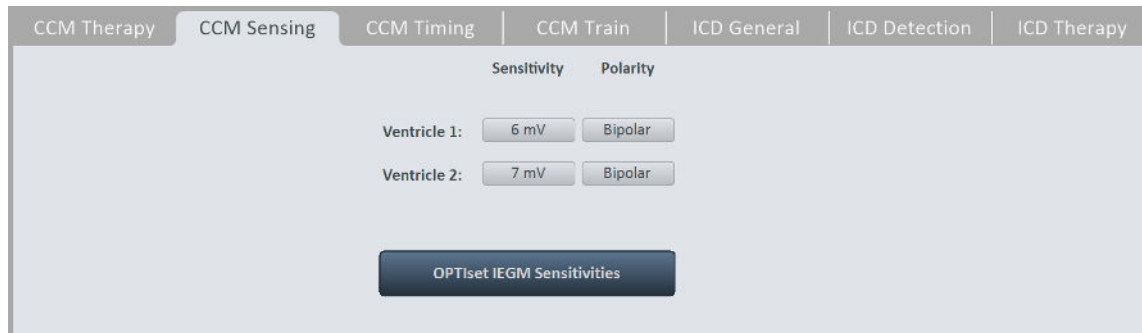


Figure 28: Sensing Panel

3.1.9.2.3 CCM Timing

The CCM Timing tab contains the following parameters categories and their associated parameters:

- **V REFRACTORIES**
 - **Post-V Ventricular (RV) Refractory**
- **CCM INHIBIT**
 - **CCM Inhibit Cycles**
 - **Tracking**
 - **After ATP**
 - **After HV Shock**
- **TIMING ALGORITHM**
 - **LS Channel assignment**
 - **LS Alert Start**
 - **LS Alert Width**
 - **LS Blanking Refractories**
 - **Pre and Post RV**
 - **Post LS**

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



Figure 29: CCM Timing Panel

3.1.9.2.4 CCM Train

The CCM Train tab contains the following parameters:

- **CCM Train Delay**
- **CCM Amplitude**
- **Number of Biphasic Pulses**
- **Balancing**
- **First Phase Polarity**
- **Phase Duration**
- **Interval**
- **CCM Channels**
 - **RV**
 - **LS**

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

This tab also has the following button:

- **OPTiset CCM Amplitude**: allows the user to let the application analyze the CCM lead impedance of the ventricular lead(s) and recommend the best CCM amplitude setting for the measured total lead impedance.

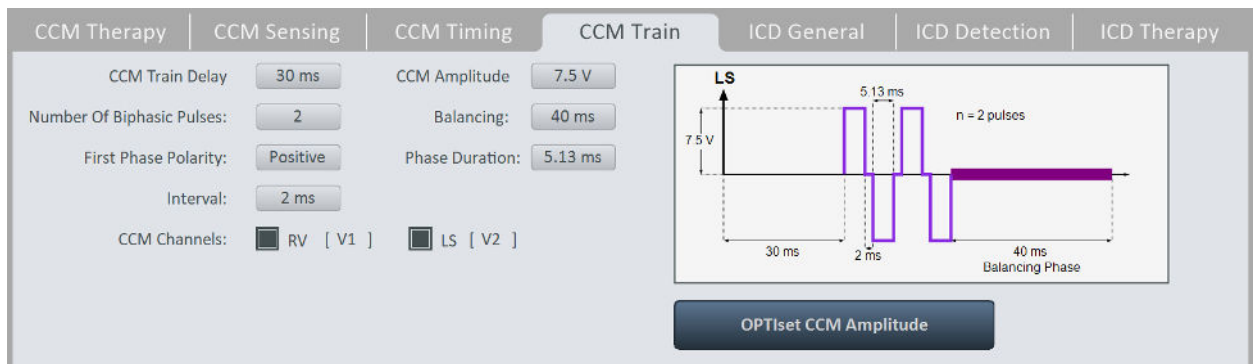


Figure 30: CCM Train Panel

3.1.9.2.5 ICD General

The ICD General tab contains the following parameters:

- **ICD Mode**
- **Sense Slope Filter**
- **Long/Short Filter**
- **Onset**
- **Onset (Δ rate)**
- **Morphology Threshold Percentage**
- **ICD Highest Sensitivity**
- **Conduction Velocity History**
- **EHR (Timeout)**
- **Pre-trigger EGM Recording**
- **Stored EGM Waveform Source**

This tab also has the **Morphology Templating** button which allows the user to create, load, and read IEGM templates of the patient's cardiac rhythm.

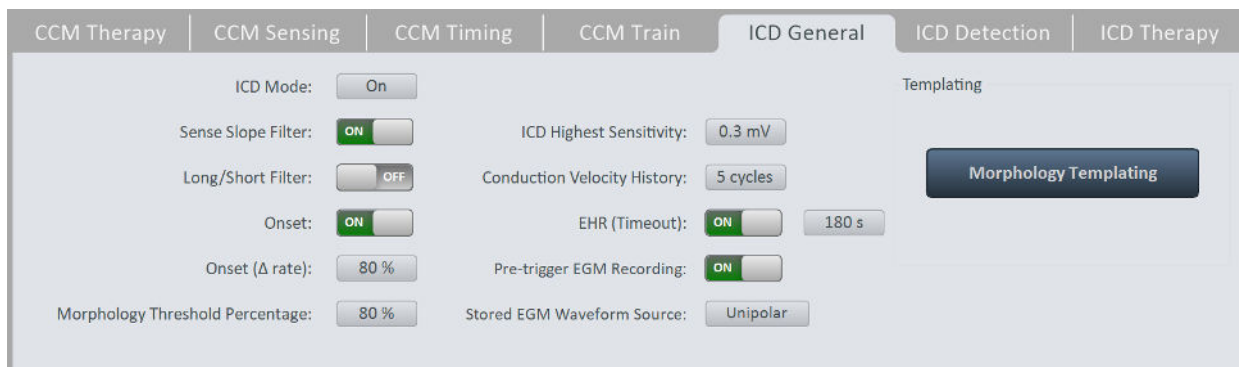


Figure 31: ICD General Panel

3.1.9.2.6 ICD Detection

The ICD Detection tab contains the following parameters:

- **Zone**
 - **Monitor**
 - **VT**
 - **FVT**
 - **VF**
- **Rate [Interval]**
- **Binning**
- **Stability (Δ variability)**
- **AF Gap**
- **AF-Gap Persistence Interval**
- **Conduction Velocity**
- **Morphology Binning**

This tab includes the Rate Zone Graphic Display Window (on the left side of the ICD Detection panel) that shows a graphical view of the CCM and ICD detection zones. The CCM and ICD detection zones displayed in the window dynamically change whenever the rate parameter value for each zone is modified.

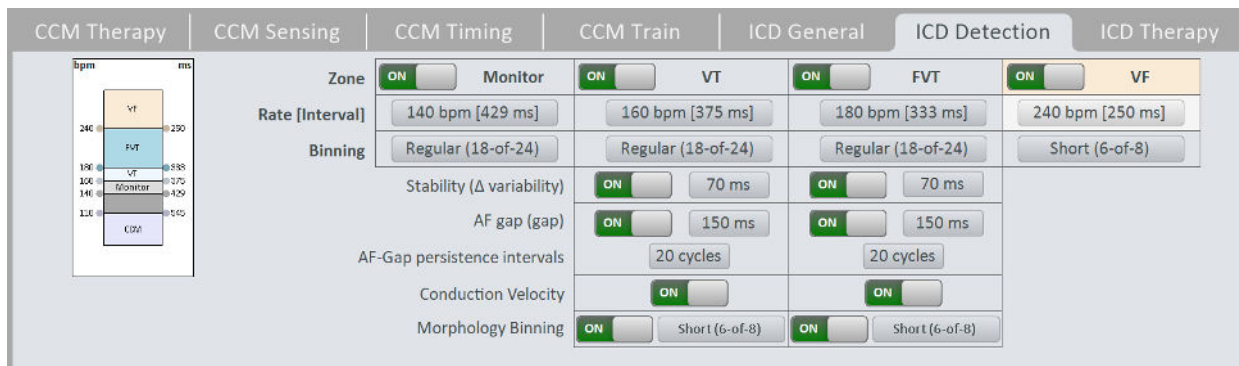


Figure 32: ICD Detection Panel

3.1.9.2.7 ICD Therapy

The ICD Therapy tab contains the following parameters:

- **Magnet Mode**
- **Shock Waveform**
- **Shock Waveform Polarity**
- **Inverting Shock Polarity**
- **Rescue Brady Pacing**
- **Zone**
 - VT
 - FVT
 - VF
- **HV Shock**
- **Therapy Delay**
- **ATP Bursts**
 - Initial train
 - R-S1 (%RR)
 - Start from last successful
- **Post-Shock Brady**
 - Duration

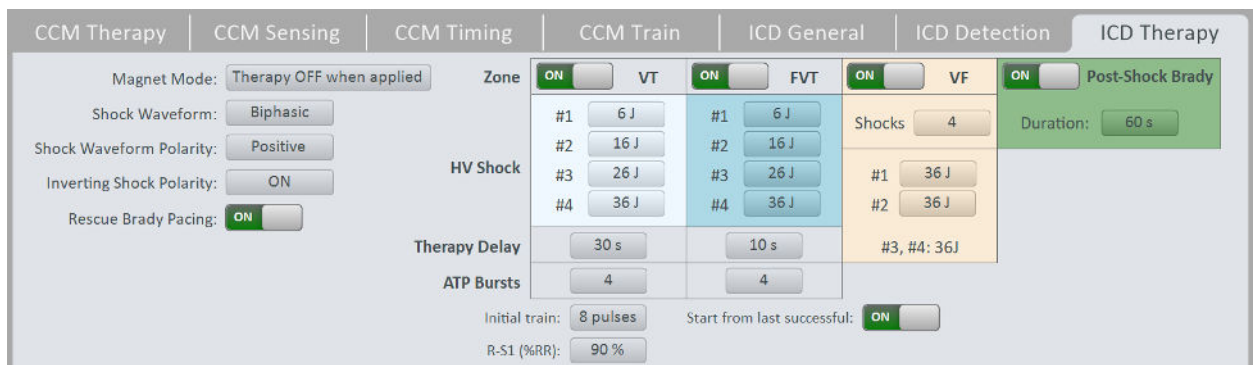


Figure 33: ICD Therapy Panel

3.1.9.3 Diagnostics Menu

The Diagnostics Menu contains the following tabs, each displaying a panel with diagnostic tools and settings for use in assessing the status of the implanted OPTIMIZER Integra CCM-D system.

3.1.9.3.1 Leads

The Leads tab displays the following information:

- **Coil Lead Impedance** (if measured)
- **HV Lead Impedance** (if measured)
- **V1 Lead (Defib)** Serial number (SN)
- **V1 Lead Impedance** (if measured)
- **V1 Lead R-Wave Amplitude (CCM)** (if measured)
- **V1 Lead R-Wave Amplitude (ICD)** (if measured)
- **V2 Lead (CCM)** Serial number (SN)
- **V2 Lead Impedance** (if measured)
- **V2 Lead R-Wave Amplitude** (if measured)

The Leads tab also has the following buttons:

- **Measure HV Lead Impedance**
- **Measure Coil Lead Impedance**
- **Measure CCM Leads Impedance**
- **Retrieve Last Measured HV Lead Impedance**
- **Measure V1 R-Wave Amplitude (ICD)**

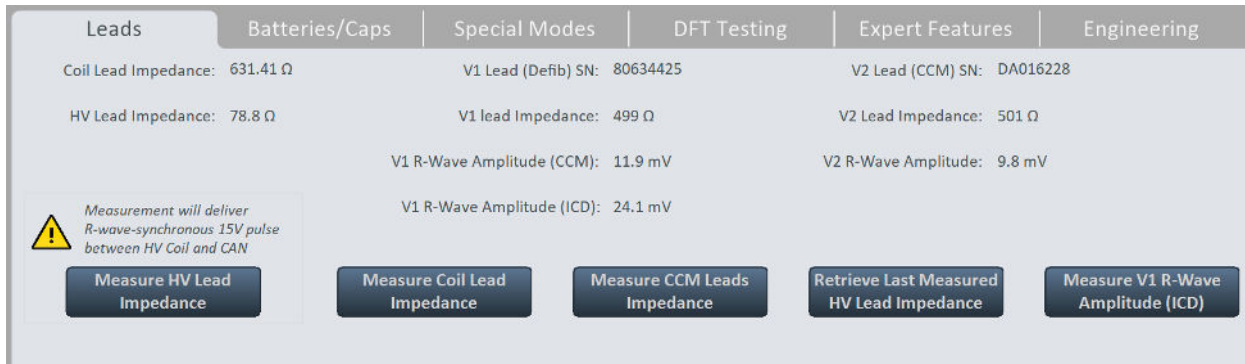


Figure 34: Leads Panel

3.1.9.3.2 Batteries/Caps

The Batteries/Caps tab displays the following information:

- **Rechargeable Battery**
 - **Estimated capacity:** Shows the current estimated charge capacity of the rechargeable battery in the OPTIMIZER Integra CCM-D IPG
 - **Battery bar:** Shows the current voltage of the rechargeable battery in the OPTIMIZER Integra CCM-D IPG
 - **Discharges:** Indicates the number of discharge episodes experienced by the rechargeable battery in the OPTIMIZER Integra CCM-D IPG
- **ICD Battery**
 - **Status:** Shows the current status of the ICD battery in the OPTIMIZER Integra CCM-D IPG
 - **Voltage:** Shows the current voltage of the ICD battery in the OPTIMIZER Integra CCM-D IPG
- **ICD Capacitors**
 - **Last time to charge to 36J or reform:** Shows the date and time when the last 36J charge or reform occurred.
 - **Duration:** Indicates the length of time it took the capacitors to charge to 36J

This tab also has the **Get Last time to charge to 36J or reform** button, which allows the user to retrieve information from the OPTIMIZER Integra CCM-D IPG about the last time its ICD capacitors were charged to 36J or reformed.

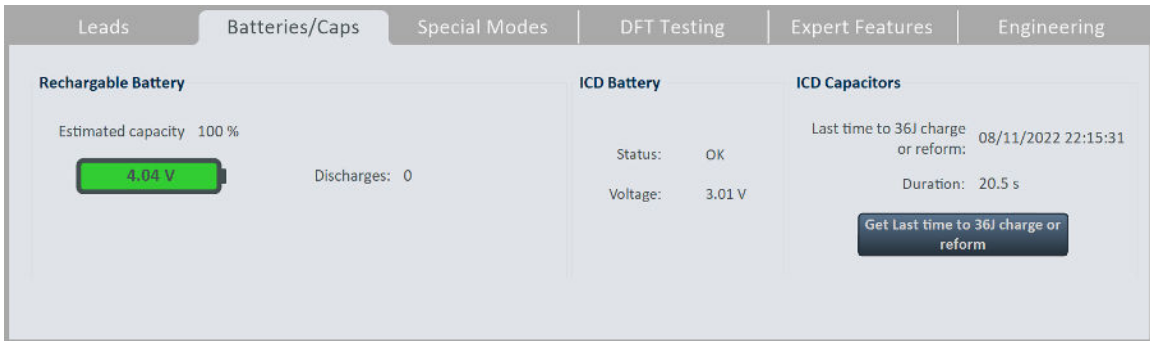


Figure 35: Battery/Caps Panel

3.1.9.3.3 Special Modes

The Special Modes tab has the following modes:

- **Continuous Mode:** When initiated, this programs the OPTIMIZER Integra CCM-D IPG to deliver continuous CCM therapy delivery.
 - **Start Continuous Mode**
 - **Stop Continuous Mode**
- **Medical Procedure:** When initiated, this mode turns OFF all ICD and CCM therapies.
 - **Start Medical Procedure Mode**
 - **Stop Medical Procedure Mode**

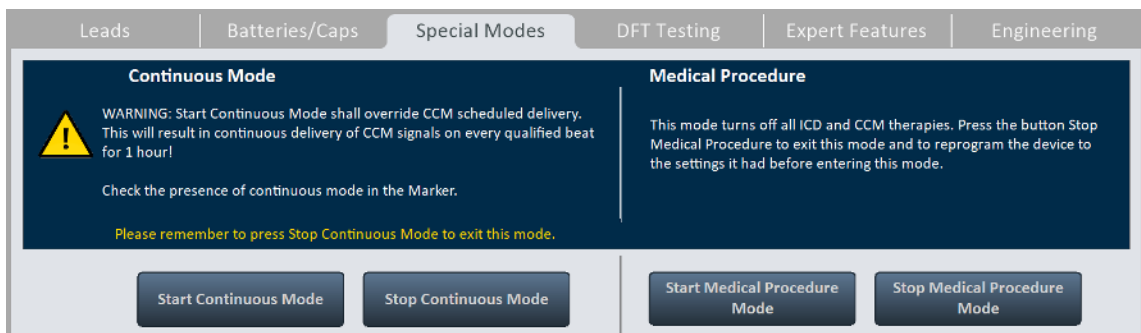


Figure 36: Special Modes Panel

3.1.9.3.4 DFT Testing

The DFT Testing tab has the following buttons and associated parameters:

- **Induce Arrhythmia**
 - **Duration:** Sets the duration of the 50 Hz, 8 V biphasic pulses to be delivered by the **Induce Arrhythmia** command
 - **Induce Arrhythmia:** Induces ventricular arrhythmia
- **Deliver Pacing**
 - **Rate:** Sets the pulse rate of the VOO pacing
 - **Number of Pulses:** Sets the number of VOO pacing pulses to be delivered by the **Deliver Pacing** command
 - **Deliver Pacing:** Delivers VOO pacing pulses
- **Stat Shock**
 - **Energy Shock:** Sets the energy level of the STAT shock to be by the **Stat Shock** command
 - **Stat Shock :** Delivers 36 J shock

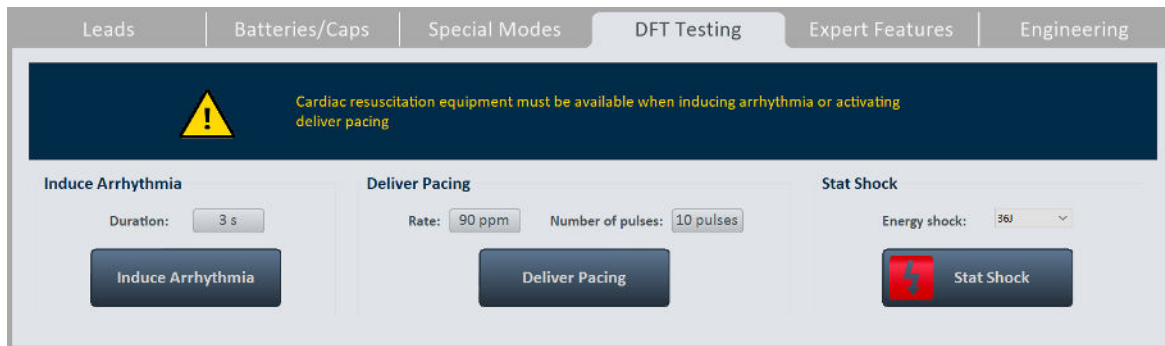


Figure 37: DFT Testing Panel

3.1.9.3.5 Expert Features

The Expert Features tab has the following features that are enabled only after entering the correct passcode:

- **Blind Charge Mode**

Note: Blind Charge Mode is only to be used for blinded clinical investigation protocols

 - **Set Blind Mode:** Enables Blind Charge Mode
 - **Minimum Charge Time:** Sets the minimum charge duration for the Guardio/Vesta Charger to charge the OPTIMIZER Integra CCM-D IPG
 - **Current Status:** Indicates the current Blind Charge Mode status of the OPTIMIZER Integra CCM-D IPG (OFF or ON)
 - **Clear Blind Mode:** Disables Blind Charge Mode
- **Lead Depolarization:** Electronically connects V1 and V2 electrodes together to dissipate accumulated charge.

Caution: The ICD Mode must be programmed to OFF prior to starting the Lead Depolarization.

 - Lead Depolarization Time: Sets the length of time the V1 and V2 electrodes are connected together
 - **Start:** Starts Lead Depolarization
 - **Stop:** Stops Lead Depolarization
- **IPG Reset:** Resets the OPTIMIZER Integra CCM-D IPG's microcontrollers and programs all its parameter values to their nominal settings.
- **Rechargeable Battery Disconnect:** Temporarily disconnects the rechargeable battery in the OPTIMIZER Integra CCM-D IPG from its internal circuitry.

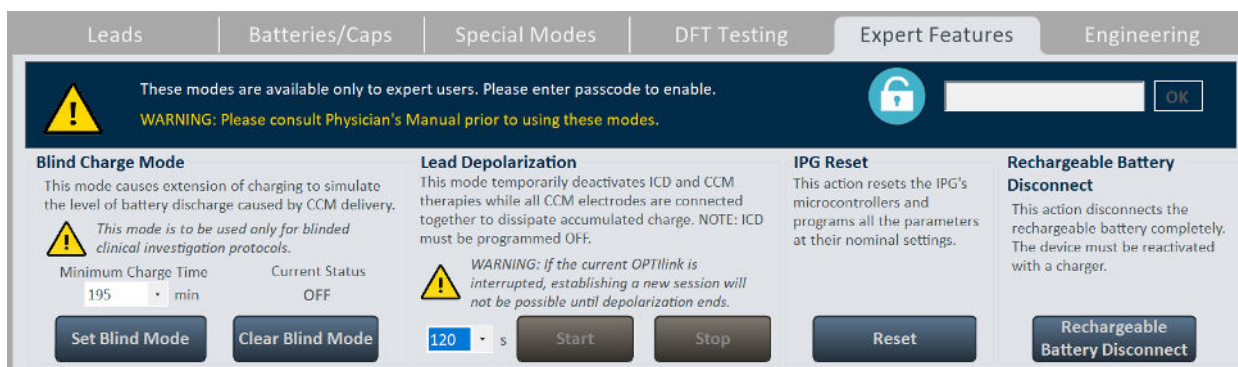


Figure 38: Expert Features Panel

3.1.9.3.6 Engineering (for expert use only)

The Engineering tab has the following buttons that are enabled only after entering the correct passcode.

- **Update Implantable Device:** Updates the firmware of the OPTIMIZER Integra CCM-D IPG using a bootloader file loaded from a separate USB flash drive.
- **Get CCM Log:** Downloads the CCM log from the OPTIMIZER Integra CCM-D IPG.
- **Get ICD Anomaly Information:** Downloads the ICD Anomaly log from the OPTIMIZER Integra CCM-D IPG.
- **Temperature Charge Constants**
- **Telemet Memory Dump**
- **Therapy Memory Dump**

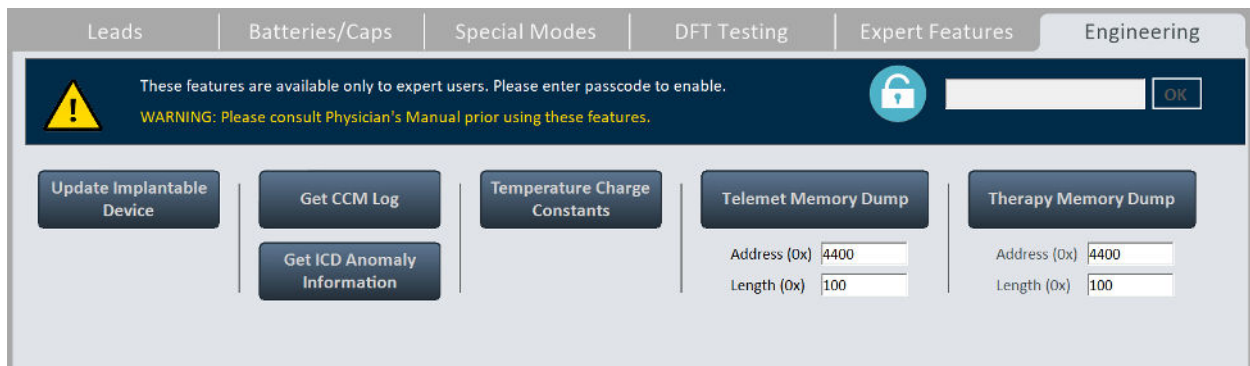


Figure 39: Engineering Panel

3.1.9.4 Preferences Menu

The Preferences Menu contains the following tabs, each with its own separate panel.

3.1.9.4.1 Implant Data

The Implant Data tab displays the following implant information:

- **Implant Date**
- **V1 Lead (Defib)**
 - **Model**
 - **SN:** Serial number of V1 lead
- **V2 Lead (CCM)**
 - **Model**
 - **SN:** Serial number of V2 lead
- **Co-implanted:** Indicates whether the Co-implanted 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.

This tab also has the **Edit implant data** button, which allows the user to add or edit information about the implant date, lead model and serial number, as well as measurement values obtained for the CCM delay/CCM start limit measure during OPTIMIZER/ICD Interaction testing and Minimum R-R interval in ICD VT Zone.

Implant Data	Patient Alerts	OPTIHome	Activity	Clock
Implant Date: 07/05/2020				
V1 Lead (Defib):		V2 Lead (CCM):		
Model:	Biotronik Plexa S 65	SJM 2088TC 65		
SN:	80634425	DA016228		
Co-Implanted	<input type="checkbox"/> OFF			
CCM delay/CCM start limit measure during OPTIMIZER/ICD interaction testing:	<input type="text" value="0"/>	ms		
Minimum R-R interval in ICD VT zone:	<input type="text" value="40"/>	ms	<input type="button" value="Edit implant data"/>	

Figure 40: Implant Data Panel

3.1.9.4.2 Patient Alerts

The Patient Alerts tab has the following parameters:

- **Alert Delivery Mode**
 - **Start**
 - **End**
- **Low-Priority Alert Delivered by Charger**
 - **Charger Battery Low**
 - **Charger Failure**
 - **Rechargeable Battery Low**
 - **Battery Recharge Reminder**
 - **Days**
 - **Long time without communicating with the IPG**
 - **Days**
 - **Long time without transmitting data to the remote monitor**
 - **Days**
 - **Minimum CCM%**
 - **%**
 - **Maximum lead impedance change**
 - **%**
 - **CCM Not sensing/Noise**
 - **CCM therapy suspended**
 - **CCM Safe Mode**
 - **ICD battery RRT**
 - **ICD Not Sensing**
 - **ICD battery EOS**
 - **HV lead impedance not OK**
 - **ICD Safe Mode**
 - **ICD Anomaly**
- **High-Priority Alert Delivered by Charger**
 - **Detected VF Event**
 - **Detected FVT Event**
 - **Detected VT Event**

- **Detected Monitor Event**
- **Delivered HV Shock**
- **Delivered ATP**
- **Delivered Rescue Brady Pacing**



Figure 41: Patient Alert Panel

3.1.9.4.3 OPTIHome (future capability)

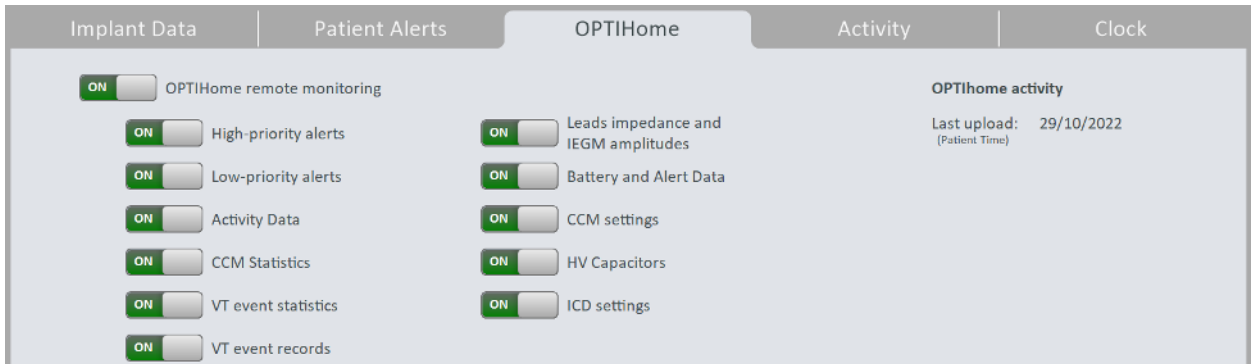


Figure 42: OPTIHome

3.1.9.4.4 Activity

The Activity tab has the **Activity Sensor Setup** button and contains the following parameters:

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

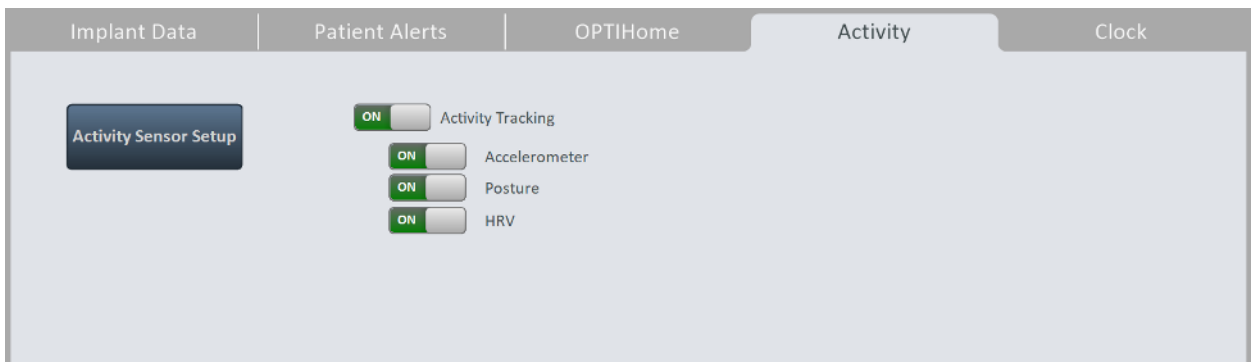


Figure 43: Activity Panel

3.1.9.4.5 Clock

The Clock tab displays the following information:

- **IPG's Date and Time**
 - **Local:** Shows the current date and time of the OPTIMIZER Integra CCM-D IPG
 - **Time Zone:** Indicates the current time zone of the OPTIMIZER Integra CCM-D IPG with respect to UTC
- **Programmer's Date and Time**
 - **Local:** Shows the current date and time of the Intelio Programmer
 - **Time Zone:** Sets and displays the current time zone of the Intelio Programmer and if the time zone is currently in Daylight Saving Time or Standard Time (see **Figures 44 and 45**)

The Clock tab also has the following buttons:

- **Read IPG Clock:** Reads the current date and time from the OPTIMIZER Integra CCM-D IPG.
- **Set IPG Clock:** (inactive until Read IPG Clock command is executed): Manual setting of the clock in the OPTIMIZER Integra CCM-D IPG.
- **Synchronize IPG clock to programmer clock:** Automatically sets the clock in the OPTIMIZER Integra CCM-D IPG to the current date and time of the Intelio Programmer.
- **Set programmer clock:** Manual setting of the Intelio Programmer's

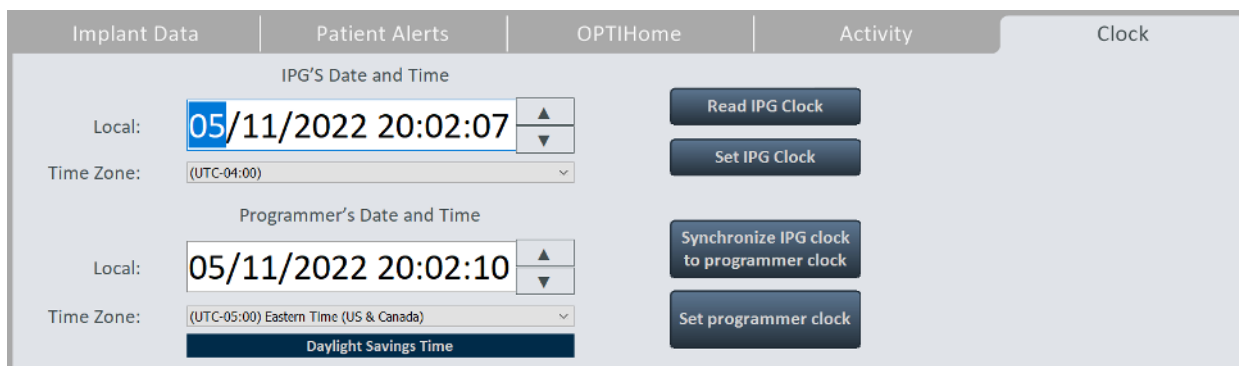


Figure 44: Clock Panel (Time Zone in Daylight Savings Time)

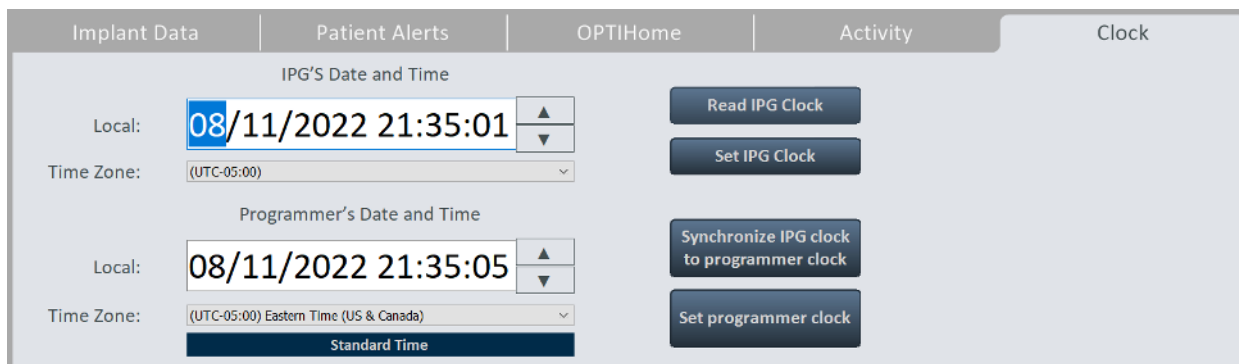


Figure 45: Clock Panel (Time Zone in Standard Time)

3.1.9.5 Tools Menu

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

3.1.9.5.1 Print/File

The Print/File tab has the following buttons:

- **Complete Report:** Creates a report (that can be saved in PDF file format) containing various information obtained from the OPTIMIZER Integra CCM-D IPG (see section 3.28.1.2).
- **Parameters Report:** Creates a report (that can be saved in PDF file format) of the current parameter settings programmed into the OPTIMIZER Integra CCM-D IPG (see section 3.28.1.3).
- **Export Statistics:** Creates and saves a CSV file containing the CCM statistics downloaded from the OPTIMIZER Integra CCM-D IPG.
- **DB Log Backup:** Backs up OPTIMIZER Integra CCM-D IPG log files stored on the Intelio Programmer.
- **DB Log Restore:** Loads the backed-up OPTIMIZER Integra CCM-D IPG log files onto the Intelio Programmer.



Figure 46: Print/File Panel

3.1.9.5.2 Standards

The Standards tab has the following buttons:

- **Load Program:** Loads the saved standard file onto the Optimizer Integra Programmer application.
- **Save Program:** Saves the current parameter values as a standard file.



Figure 47: Standards Panel

3.1.9.5.3 Logs

The Logs tab displays the Programmer Log.

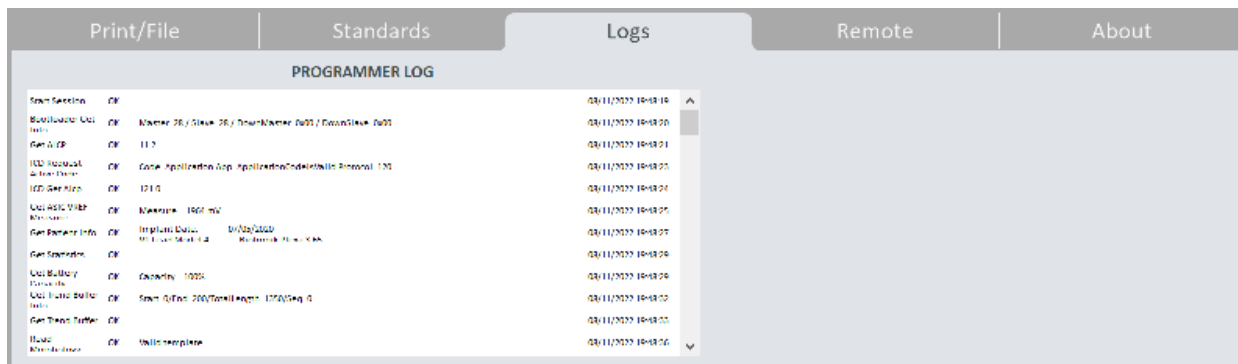


Figure 48: Logs Panel

3.1.9.5.4 Remote (Future capability)

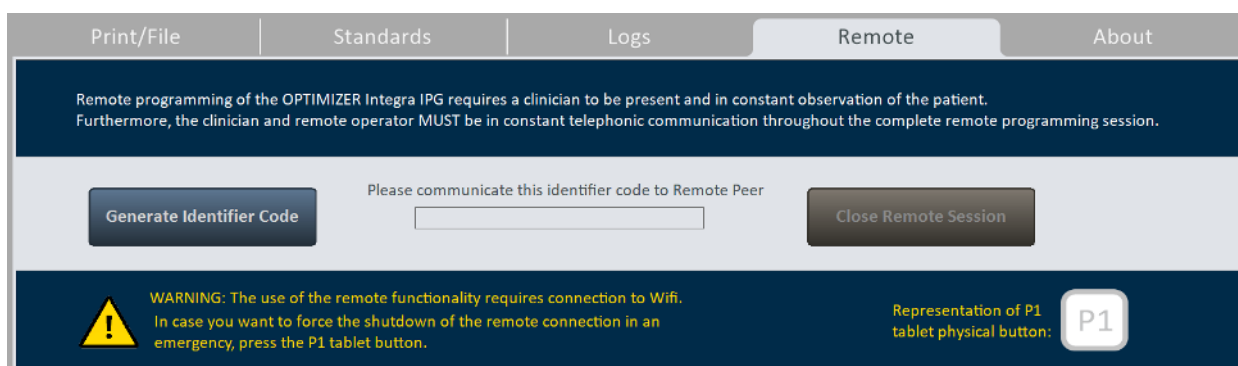


Figure 49: Remote Panel

3.1.9.5.5 About

The About tab displays the following information regarding the firmware or software listed items:

- **CCM**
 - **Telemetry Version:** Firmware version of the OPTIMIZER Integra CCM-D IPG's CCM telemetry module.
 - **Therapy Version:** Firmware version of the OPTIMIZER Integra CCM-D IPG's CCM therapy module.
 - **ALCP Version:** Application Level Communication Protocol (ALCP) version of the OPTIMIZER Integra CCM-D IPG's CCM module.
- **Programmer Application**
 - **Version:** Software version of the Optimizer Integra Programmer application.
 - **CCM ALCP Version:** CCM Application Level Communication Protocol (ALCP) version of the Optimizer Integra Programmer application.
 - **ICD ALCP Version:** ICD Application Level Communication Protocol (ALCP) version of the Optimizer Integra Programmer application.
- **Programming Interface**
 - **Version:** Firmware version of Intelio Programming Wand

- **ICD**
 - **Serial:** Serial number of the OPTIMIZER Integra CCM-D IPG's ICD module.
 - **Model:** Model number of the OPTIMIZER Integra CCM-D IPG's ICD module.
 - **Hardware Version:** Hardware version of the OPTIMIZER Integra CCM-D IPG's ICD module.
 - **Software Version:** Firmware version of the OPTIMIZER Integra CCM-D IPG's ICD module.
 - **ALCP Version:** Application Level Communication Protocol (ALCP) version of the OPTIMIZER Integra CCM-D IPG's ICD module.

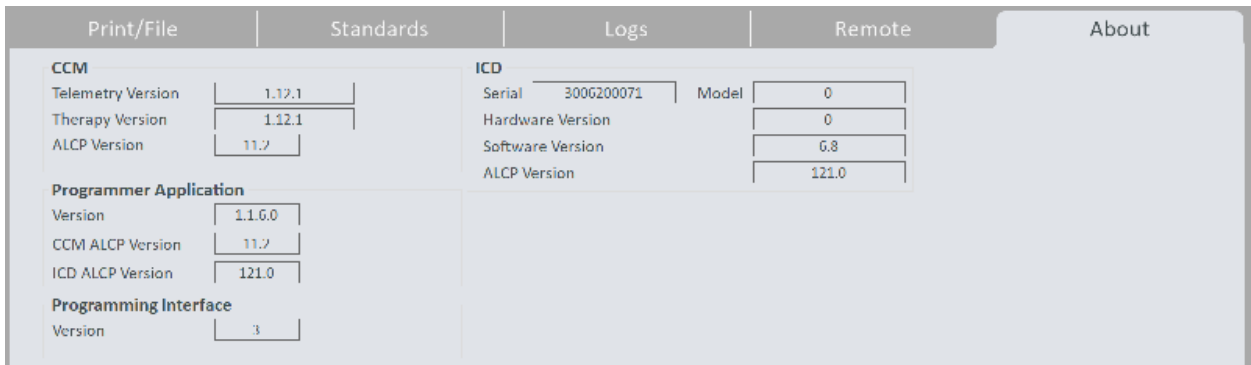


Figure 50: About Panel

3.1.10 Status Bar

The Status Bar displays the Impulse Dynamics logo along with the tablet PC's battery charge percentage and the following information:

- **Restrictions and Warnings** (becomes active when a parameter conflict, restriction, or warning is present – see image on the right): When tapped, opens the Error Message window, which displays the restriction or warning message. When tapped again, it closes the Error Message window.



The Status Bar also has the following button:

- **Exit:** When tapped, 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.

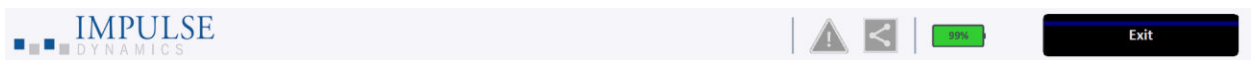


Figure 51: Status Bar

3.2 Linking and Interrogation

3.2.1 Initiating a Link with the OPTIMIZER Integra CCM-D IPG

To initiate a link with the OPTIMIZER Integra CCM-D IPG:

1. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
2. Tap 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 Integra CCM-D IPG implant site and tap the **Start OPTIlink** button again.

Upon the successful completion of the link, the Optimizer Integra Programmer application automatically performs an interrogation of the OPTIMIZER Integra CCM-D IPG and reads the latest CCM statistics from the device.

Note: Once the link with the OPTIMIZER Integra CCM-D 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.

Note: If the OPTIMIZER Integra CCM-D IPG does not have any stored implant data, a pop-up **Patient Data** window may appear indicating that the Patient Data is empty. If this occurs, tap **Ok** to continue.

Note: If an internal discrepancy has occurred with the OPTIMIZER Integra CCM-D IPG, a pop-up **Safe Mode** message may appear indicating that the device is in Safe Mode

3.2.1.1 Safe Mode

The OPTIMIZER Integra CCM-D 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 Integra CCM-D IPG will place itself into a safe state referred to as Safe Mode.

If the Safe Mode state is confined to only the CCM module of the OPTIMIZER Integra CCM-D IPG, the device will no longer deliver CCM therapy, but it will still be able to sense cardiac events and deliver ICD therapy if necessary.

If the Safe Mode originated in the ICD module of the OPTIMIZER Integra CCM-D IPG, the device will no longer deliver CCM or ICD therapies.

IMPORTANT: If an OPTIMIZER Integra CCM-D IPG is found to be in Safe Mode, please document the contents of the Safe Mode pop-up message before resetting the device. After documenting the contents of the Safe Mode message, please call the 24-hour Support Hotline (866-312-5370). Make sure to provide details regarding the device mode and the occurrence of any events that may have caused the device to revert to Safe Mode.

After documenting the contents of the Safe Mode pop-up message, tap **Close**.

The Safe Mode status of the OPTIMIZER Integra CCM-D IPG can only be changed by resetting the IPG using the Optimizer Integra Programmer application under physician supervision (see section 3.21.2).

3.2.2 Interrogating the OPTIMIZER Integra CCM-D IPG

The Interrogation command may be used to update the information about the OPTIMIZER Integra CCM-D IPG displayed by the Optimizer Integra Programmer application (e.g., rechargeable battery voltage of the IPG).

To interrogate the OPTIMIZER Integra CCM-D IPG:

1. Tap 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 Menu Bar, selecting one of the tabs associated with each menu, then choosing one of the parameters on the panel.

Parameter values are displayed in three different ways:

1. A sliding toggle switch is used for parameters that can only be enabled or disabled (except CCM Channels). Depending on its initial state, tapping the switch will either cause it to slide right, turning the parameter **ON**, or to slide left, turning the parameter **OFF**.
2. For the CCM Channels, checkboxes are used to enable or disable this parameter. To toggle the options for each CCM channel, tap the checkbox to the left of the CCM channel. If tapping on a CCM channel checkbox causes it to become filled in, this action enables the channel. If tapping on a CCM channel checkbox causes it to become empty, this action disables the channel.
3. 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 tapped, changes the pin color to red, keeping the window open after the user makes a selection. Tapping 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:

1. Select the tab where the parameter to be modified appears
2. Tap the parameter value to be modified. If the parameter is a switch, it will change from one state to another (e.g., OFF to ON or vice versa). If the parameter is not a switch, a window with all of its possible values will appear.
3. 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 parameter settings that become visible or for which certain setting values are allowed only when certain other parameters are enabled or are set to certain values (for instance, if the CCM Therapy Mode of the OPTIMIZER Integra CCM-D IPG is set to ON, only then the parameters settings associated with CCM train delivery are displayed). As such, when a parameter setting is meaningless in the context of other parameter settings, it is not displayed by the programmer application.

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 Integra CCM-D IPG.
- **Blue:** For parameter values that are different from the current programmed value which, if selected, will not result in a parameter conflict.
- **Yellow:** For parameter values that are different from the current programmed value which, if selected, will result in a parameter warning.
- **Red:** For prohibited values which, if selected, will result in a parameter conflict.

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

The black/blue/yellow/red (programmed, pending, warning, conflict) color convention is also used when viewing the parameter values displayed on the various panels. Thus, the user can identify which parameters are currently programmed into the OPTIMIZER Integra CCM-D 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**:

1. Tap 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 Integra Programmer application will not allow the OPTIMIZER Integra CCM-D IPG to be programmed with new parameter values. This ensures that only compatible parameter configurations are programmed into the OPTIMIZER Integra CCM-D 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 performing the following:

- 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**:

1. Tap 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 Integra Programmer application still allows the OPTIMIZER Integra CCM-D 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 performing the following:

- 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 Integra CCM-D IPG

Programming the OPTIMIZER Integra CCM-D 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:

1. Tap 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 Integra Programmer application screen will become black, indicating that they are now the programmed parameter values of the OPTIMIZER Integra CCM-D IPG.

3.4.2 Cancel and Undo Commands

The Optimizer Integra 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 Integra CCM-D IPG (**Program** button is blinking amber), the **Cancel** command will reset the modified parameter values to the last set of interrogated / programmed values.

To cancel modifications:

1. Tap the **Cancel** button on the Programming Buttons Pane

Please note that after executing a **Cancel** command, the parameter values displayed on the Optimizer Integra Programmer application screens are all shown in black, since they are the parameter values currently programmed into the OPTIMIZER Integra CCM-D IPG. If an OPTIMIZER Integra CCM-D 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 Integra CCM-D 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:

1. Tap 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 Integra CCM-D IPG.

To set the device mode of the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTILink** button on the OPTILink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **CCM Therapy** tab
4. On the **CCM Therapy** panel, tap the **Mode** parameter
5. The **Mode** parameter window will display the following options for this parameter:
 - a. **OOO**: The device is placed in safe mode with no CCM therapy delivery.
 - b. **OVO-LS-CCM**: The device uses ventricular (RV) and local sense (LS) events as inputs in determining if CCM therapy should be delivered.
6. Select one of the parameter choices shown in the **Mode** parameter window

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

To set the CCM Therapy Mode parameter:

1. On the **CCM Therapy** panel, tap the **CCM Therapy Mode** parameter
2. The **CCM Therapy Mode** parameter window will display the following options for this parameter:
 - a. **OFF**: Disables CCM therapy delivery
 - b. **ON**: Enables the OPTIMIZER Integra CCM-D 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 3.6).
3. Select one of the parameter choices shown in the **CCM Therapy Mode** parameter window

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

1. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter settings

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

3.6 CCM Schedule

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

3.6.1 CCM Therapy Hours/Day

The **CCM hs/day** parameter sets the total number of hours per day the OPTIMIZER Integra CCM-D IPG is scheduled to deliver CCM therapy. By default, the **CCM hs/day** parameter is set to 5 hs/day.

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

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **CCM Therapy** tab
4. On the **CCM Therapy** panel, tap the **CCM hs/day** parameter (next to CCM Therapy Mode)
5. Select one of the parameter choices shown in the **CCM hs/day** parameter window
6. Tap the blinking Program button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.6.2 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**:

1. On the **CCM Therapy** panel, select the **Start Time Hour** parameter
2. Select one of the parameter choices shown in the **Start Time Hour (h)** parameter window
3. On the **CCM Therapy** panel, select the **Start Time Minute** parameter
4. Select one of the parameter choices shown in the **Start Time Minute (m)** parameter window

5. On the **CCM Therapy** panel, select the **End Time Hour** parameter
6. Select one of the parameter choices shown in the **End Time Hour (h)** parameter window
7. On the **CCM Therapy** panel, select the **End Time Minute** parameter
8. Select one of the parameter choices shown in the **End Time Minute (m)** parameter window
9. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D 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 Integra CCM-D 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 Integra CCM-D IPG is not scheduled to deliver CCM therapy. The Optimizer Integra 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 Integra 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 5 hours per day distributed over 24 hours, it sets the following standard scheduling parameters:

CCM Therapy Mode:	ON	5 hs/day			
Start Time:	00 h	00 m	End Time:	23 h	59 m
On Time:	01 h	00 m	Off Time:	03 h	47 m

3.6.3 Extend on Low CCM%

The Optimizer Integra Programmer application features the **Extend on Low CCM%** function, which when enabled, allows the OPTIMIZER Integra CCM-D 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 of time in which the **On Time** interval is extended is as follows:

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

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **CCM Therapy** tab
4. On the **CCM Therapy** panel, tap the **Extend on Low CCM%** toggle switch to enable it (set to **ON**)
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.7 CCM Magnet Mode

Note: To find out how the placement of a magnet over the implant site of the OPTIMIZER Integra CCM-D IPG affects ICD Therapy delivery, see section 3.15.

Placing a pacemaker magnet over the implant site of the OPTIMIZER Integra CCM-D IPG, 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 Integra CCM-D IPG into CCM Magnet Mode (indicated by a gray 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 Integra CCM-D 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 CCM Magnet Mode parameter:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTILink** button on the OPTILink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **CCM Therapy** tab
4. On the **CCM Therapy** panel, tap the **CCM Magnet Mode** button

The **CCM 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 Integra CCM-D 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 Integra CCM-D 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 Integra CCM-D IPG (unless the Program command is sent to the IPG after the magnet application)
5. Select one of the parameter choices and then tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.8 OPTIset

Note: If the parameter **Co-implanted** is set to **ON** (see Implant Data, section 3.23), the OPTIset tool cannot be used.

The Optimizer Integra 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 as the following individual tools:

- **OPTIset IEGM Sensitivities** (located on the **CCM Settings** and **Sensing** panels)
- **OPTIset CCM Algorithm Timing** (located on the **CCM Timing** panel)
- **OPTIset CCM Amplitude** (located on the **CCM Train** panel)

To use the OPTIset IEGM Sensitivities tool:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **CCM Setting** tab
4. On the **CCM Setting** panel, tap the **OPTIset IEGM Sensitivities** button
5. The **Acquisition Time** window will appear.

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

6. If desired, adjust the **Acquisition Time**
 - a. Tap the Acquisition Time parameter
 - b. When the pull-down menu appears, select the desired Acquisition Time from the list of choices
7. Tap the **Accept** button

When the **OPTIset: IEGM SENSITIVITIES** window appears, the analysis will begin automatically. When the analysis is done, the buttons at the bottom right of the screen will become enabled (turn blue).

8. Tap the **Propose** button

If the analysis was 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 tapping on the specific parameter and choosing a new value.

Note: If OPTIset cannot successfully find a set of proposed values, tap the **Repeat Acquisition** button to repeat the analysis. If OPTIset still cannot successfully find a set of proposed values after the second attempt, tap the **Accept & Exit Optiset** button to close the OPTIset application and set the **IEGM Sensitivity** parameters on the **Sensitivity** panel manually.

9. Tap the **Accept & Continue to Optiset Timing** button.

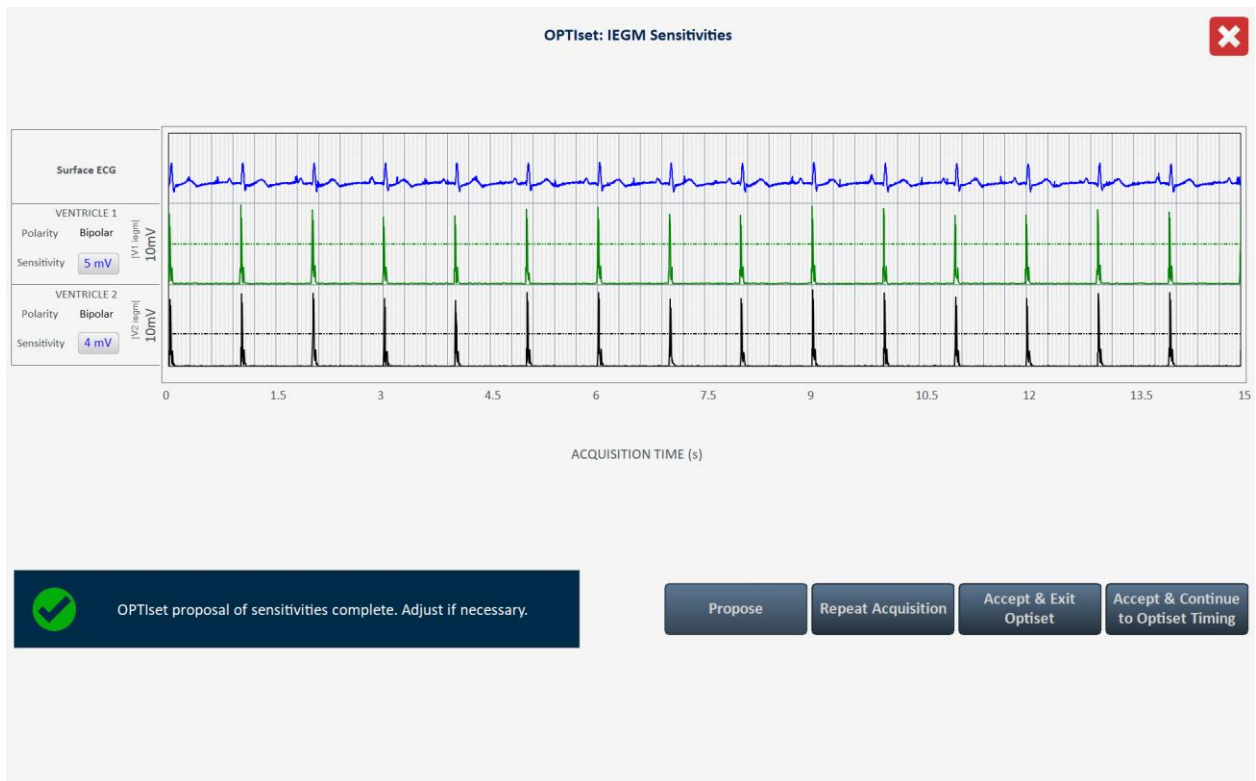


Figure 52: OPTiset: IEGM SENSITIVITIES Window

When the **OPTiset: CCM ALGORITHM TIMING** window appears, the analysis will begin automatically. When the analysis is done, the buttons at the bottom right of the screen will become enabled (turn blue).

10. Tap the **Propose** button

If the analysis was 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 tapping on the specific parameter and choosing a new value.

Note: If OPTiset cannot successfully find a set of proposed values, tap the **Repeat** button to repeat the analysis. If OPTiset still cannot successfully find a set of proposed values after the second attempt, tap the **Accept & Exit Optiset** button to close the OPTiset application and set the CCM Timing parameters on the **CCM Timing** panel manually.

11. Tap the **Accept & Continue to Optiset Amplitude** button.

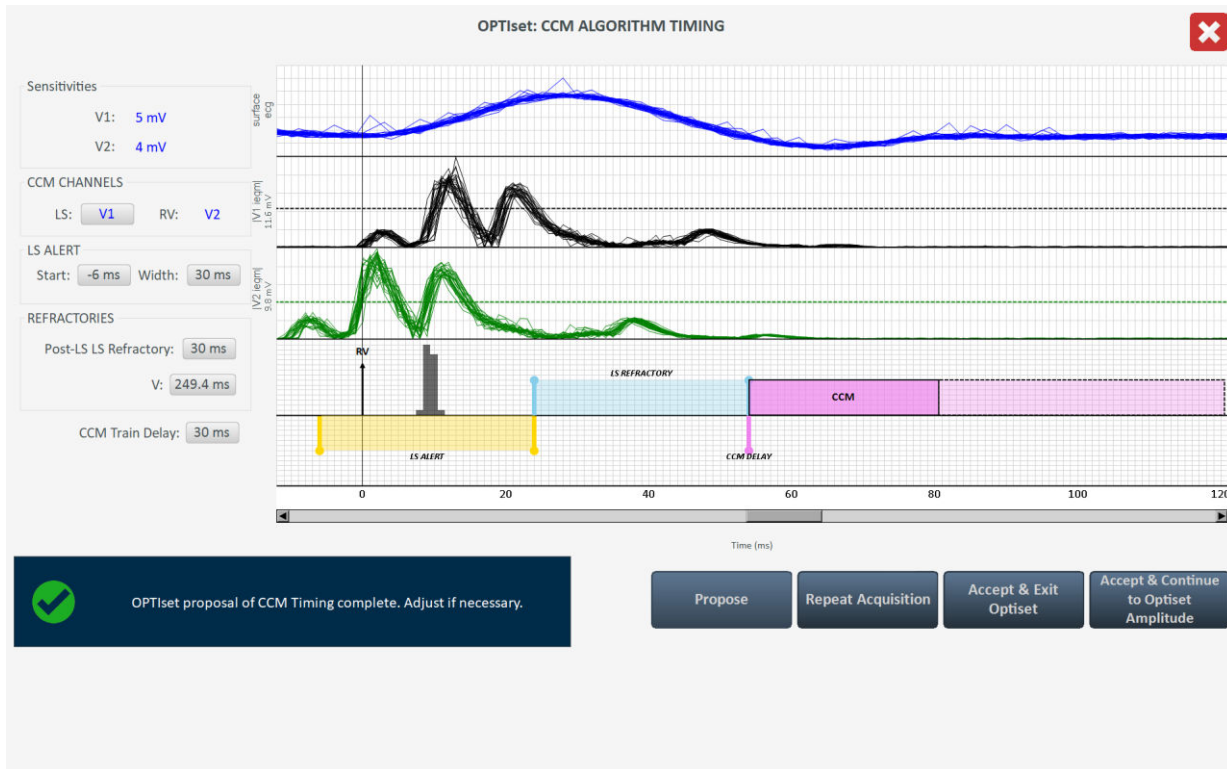


Figure 53: OPTiset: CCM ALGORITHM TIMING Window

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.

Note: As long as at least one CCM Delivery channel is enabled, enabling or disabling a CCM Delivery channel will cause OPTiset to automatically begin the analysis of the CCM amplitude again.

When the analysis is done, the buttons at the bottom right of the screen will become enabled (turn blue).

12. Tap the **Propose** button

If the analysis was successful, a green checkmark will be shown along with a message indicating that the OPTiset proposal of CCM 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 tapping on the parameter and choosing a new value.

Note: If OPTiset cannot successfully find a proposed CCM Amplitude parameter, tap the **Repeat** button to repeat the analysis. If OPTiset still cannot successfully find a proposed CCM Amplitude parameter after the second attempt, tap the **Accept & Continue** button to close the OPTiset application and set the CCM Amplitude parameter on the **CCM Train** panel manually.

13. Tap the **Accept & Continue** button on the **OPTiset: CCM AMPLITUDE** window.

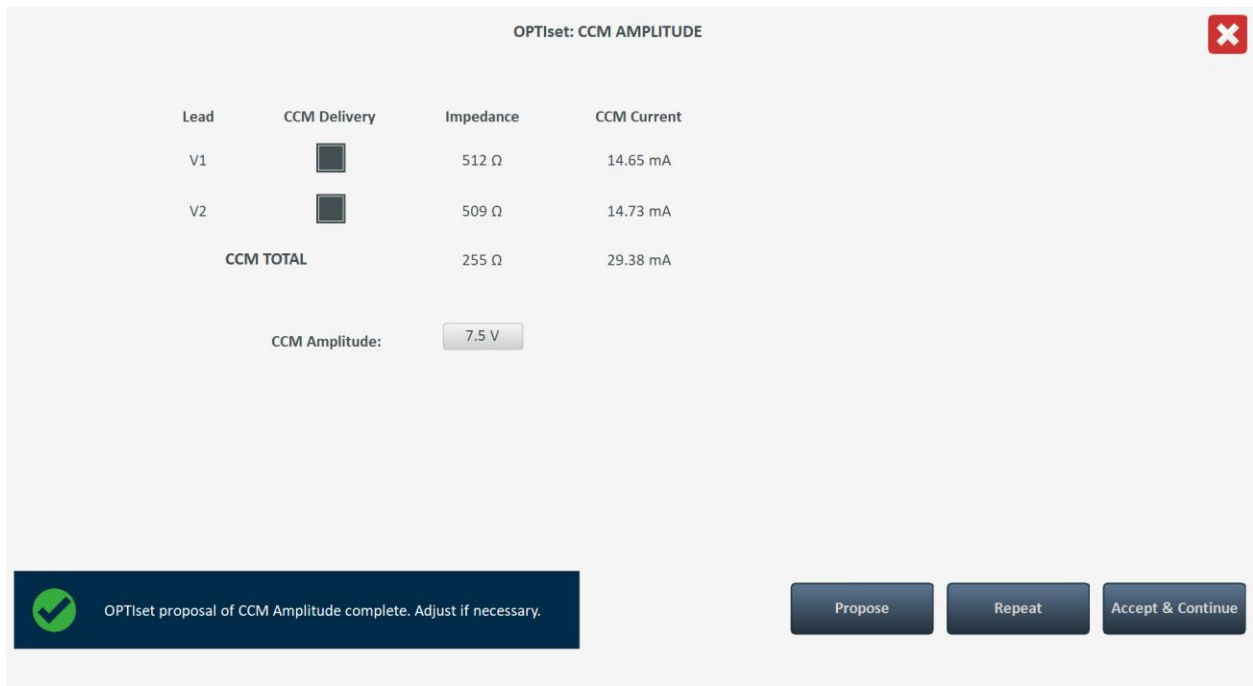


Figure 54: OPTiset: CCM AMPLITUDE Window

- When the Optimizer Integra Programmer application returns to its main application screen, tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter settings.

3.9 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 can only be set to the following option:
 - **Bipolar:** The signal is sensed between the lead “tip” (distal electrode) and “ring” (proximal electrode) of a bipolar lead.

To modify the Sensing parameters:

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

3.10 CCM Timing

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

3.10.1 V Refractories

V Refractories consist of the following parameter:

- **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.

3.10.2 CCM Inhibit

CCM Inhibit consists 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.
- **Tracking:** Sets the maximum limit for the number of detected ventricular (RV) events per minute.
- **After ATP:** Sets the number of hours to suspend CCM therapy after the delivery of antitachycardia pacing (ATP).
- **After HV Shock:** Sets the number of hours to suspend CCM therapy after the delivery of a high voltage (HV) shock.

3.10.3 Timing Algorithm

Timing Algorithm consists of the following set of parameters that control events that control CCM timing:

- **LS:** Assigns the V1 or V2 lead as the LS channel.
- **LS Alert:**
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*.
 - **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.
 - **Width:** Sets the time interval duration in which a valid LS event must be sensed in order to trigger the delivery of CCM therapy.

3.10.4 LS Blanking Refractories

The 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 RV or LS event:

- **Pre RV:** Sets the time interval before an RV event when signals falsely identified as LS events are masked from detection.
- **Post RV:** Sets the time interval after an RV event when signals falsely identified as LS events are masked from detection.
- **Post LS:** Sets the time interval after an LS event when signals falsely identified as LS events are masked from detection.

3.10.5 CCM Timing Parameter Modification

To modify the CCM Timing parameters:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **CCM Timing** tab
4. On the **CCM Timing** panel, modify the CCM Timing parameters as needed
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.11 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.
- **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 Integra CCM-D IPG to discharge any residual polarization at the electrode/tissue interface after the delivery of the CCM pulse train has been completed.
- **First Phase Polarity:** Sets the first phase polarity of the CCM therapy pulse and offers the following options:
 - **Positive:** The first phase of the CCM pulse has a positive deflection (e.g., 7.5 V) followed by a corresponding negative deflection (e.g., -7.5 V).
 - **Negative:** The first phase of the CCM pulse has a negative deflection followed by a corresponding positive deflection.

Note: If a patient expresses discomfort when the OPTIMIZER Integra CCM-D 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 Integra CCM-D 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:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **CCM Train** tab
4. 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.

5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.12 ICD General

The **ICD General** panel contains the following parameters:

- **ICD Mode:** Enables the ICD module of the OPTIMIZER Integra CCM-D IPG
- **Sense Slope Filter:** Enables the filtering of the sensed signal by the ICD to reject waves with lower slopes (e.g., T-waves). This filter is beneficial for T-wave rejection in cases where large T-waves are misidentified as R-waves.
- **Long/Short Filter:** Enables the filtering of R-waves that occur too close to a previous R-wave. This filter is used to reject T-waves and slow R-waves.
- **Onset:** Enables the ICD to discriminate between slow acceleration due to exercise and sudden acceleration that is typically associated with tachyarrhythmias.
- **Onset (Δ rate):** If the Onset is set to ON, this parameter is enabled and sets the rhythm onset discrimination threshold.
- **Morphology Threshold Percentage:** Sets the threshold the ICD will use when classifying each R-wave for template matching.
- **ICD Highest Sensitivity:** Sets the sensitivity threshold the ICD will use to recognize and classify ventricular events.
- **Conduction Velocity History:** Sets the number of intervals to be surveyed by the ICD when using conduction delay for arrhythmia discrimination.
- **EHR (Timeout):** Enables the extended high rate (EHR) timer. The timer continues to run until slow rhythm (SR) is reestablished or it expires. EHR time expiration sets the prevailing rhythm to VF and the appropriate therapy sequence is started.
- **Pre-trigger EGM Recording:** Enables the OPTIMIZER Integra CCM-D IPG to record 15 seconds of the EGM waveform that precedes a tachyarrhythmia episode.
- **Stored EGM Waveform Source:** Sets the source of the EGM waveform used by the OPTIMIZER Integra CCM-D IPG when recording a tachyarrhythmia episode.
 - **Bipolar:** EGM waveform source is tip to ring
 - **Unipolar:** EGM waveform source is tip to can

To modify the ICD General parameters:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **ICD General** tab
4. On the **ICD General** panel, set the ICD General parameters as instructed by the physician.
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting.

3.12.1 Morphology Templating

The Optimizer Integra Programmer application allows for the creation of sample R-wave of the patient's rhythm as well as the creation of a morphology template file and loading it into the OPTIMIZER Integra CCM-D IPG.

To use the Morphology Templating tool:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **ICD General** tab
4. On the **ICD General** panel, tap the **Morphology Templating** button

The **Morphology Templating** window will appear. The Morphology Templating tool has the following commands:

- **Get R-Waves:** Retrieves sample R-waves of the patient's rhythm.
 - **R-Wave Samples:** Sets the number of R-waves to be sampled when obtaining the sample R-wave.
- **Calculate template:** Removes any abnormal waves from the R-wave samples and creates a template file.
- **Load Template to IPG:** Loads the template file onto the OPTIMIZER Integra CCM-D IPG.
- **Show Current Template:** Shows the current template stored in the OPTIMIZER Integra CCM-D IPG.
- **Clear IPG Template:** Deletes the template stored in the OPTIMIZER Integra CCM-D IPG.
- **Recall Last Saved Template:** Retrieves and displays the last template stored in the OPTIMIZER Integra CCM-D IPG.

To create an R-wave template and load it onto the OPTIMIZER Integra CCM-D IPG:

1. If necessary, change the number of R-Wave samples parameter
 - a. Tap the numerical value
 - b. Select a value from the **Morphology Sample Quantity** parameter window
2. Tap the **Get R-Waves** button

Once the set number of R-wave samples has been retrieved, a graph of the R-Wave samples will be displayed.

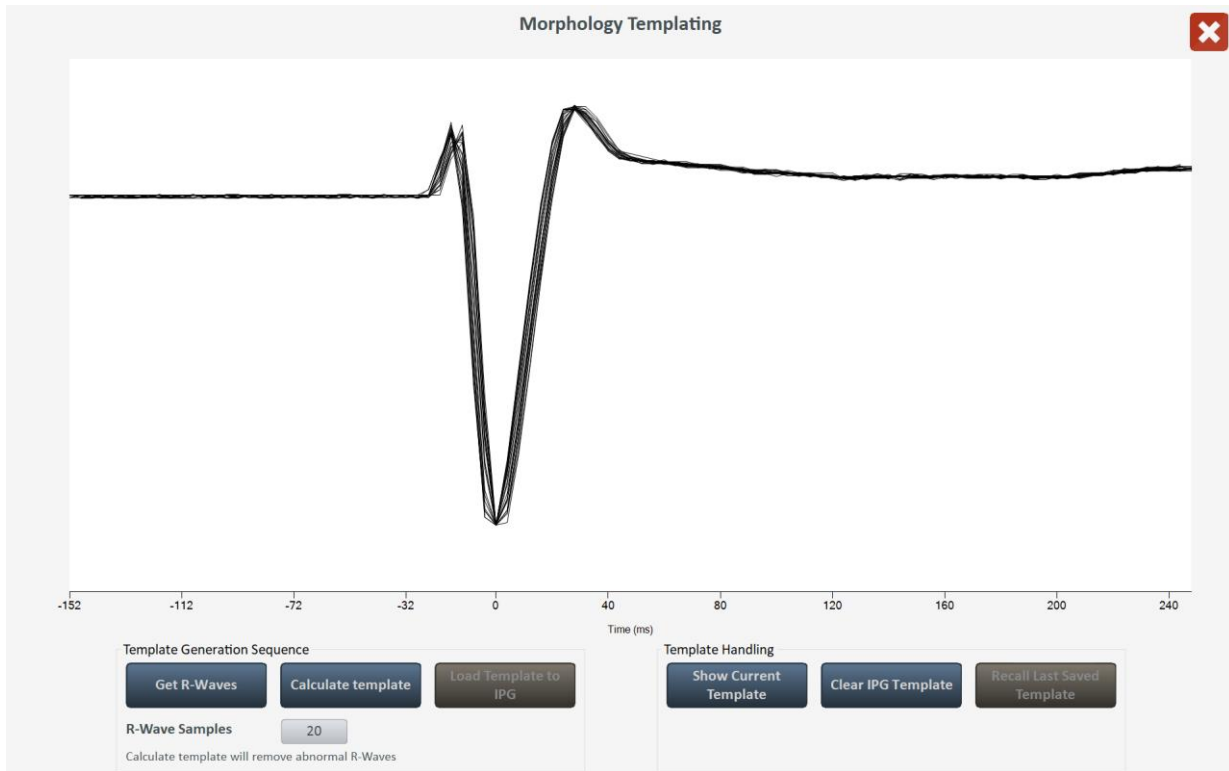


Figure 55: Example of Sampled SR R-Wave

3. Tap the **Calculate template** button

A red line will appear over the sample waveform depicting the calculated waveform template.

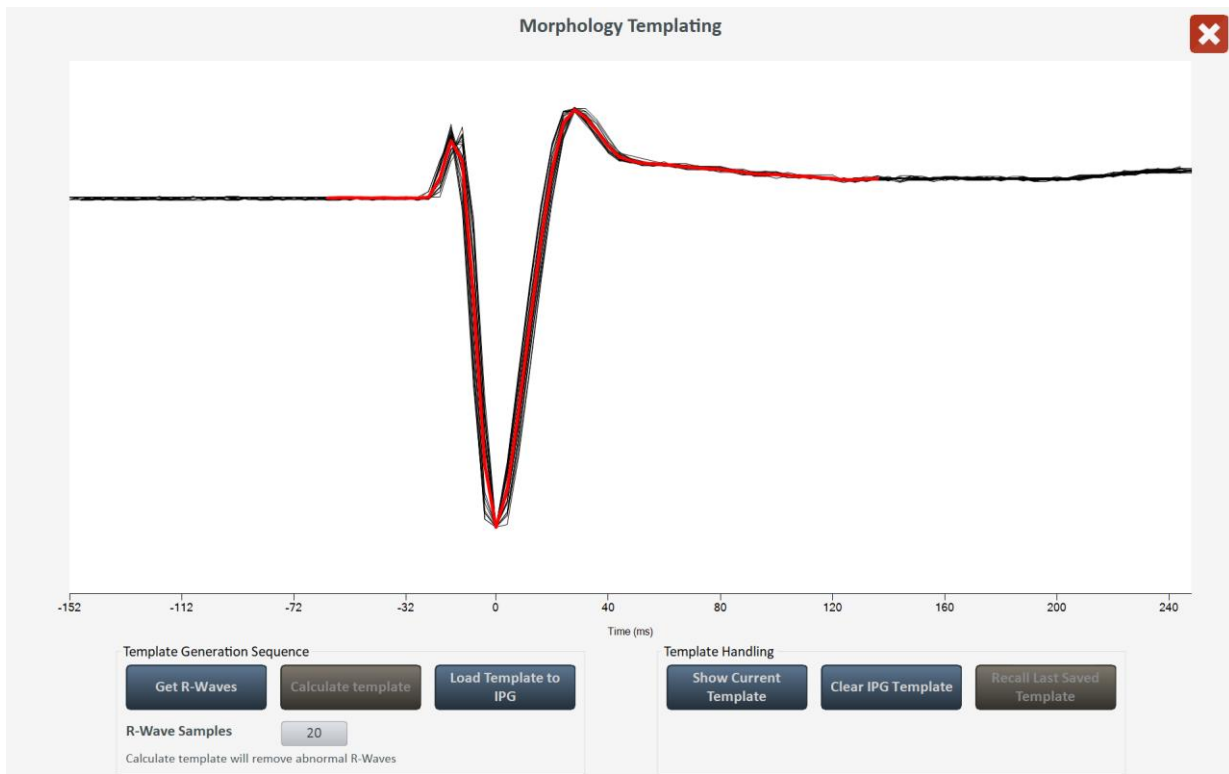


Figure 56: Example of Waveform after Template Calculation

4. Tap the **Load Template to IPG** button

A pop-up window will appear indicating that the Template was written to the ICD. Tap **Close** to close the window.

To read a template file stored in the OPTIMIZER Integra CCM-D IPG:

1. Tap the **Show Current Template** button

The graph of the waveform template in the OPTIMIZER Integra CCM-D IPG will be displayed on the screen.

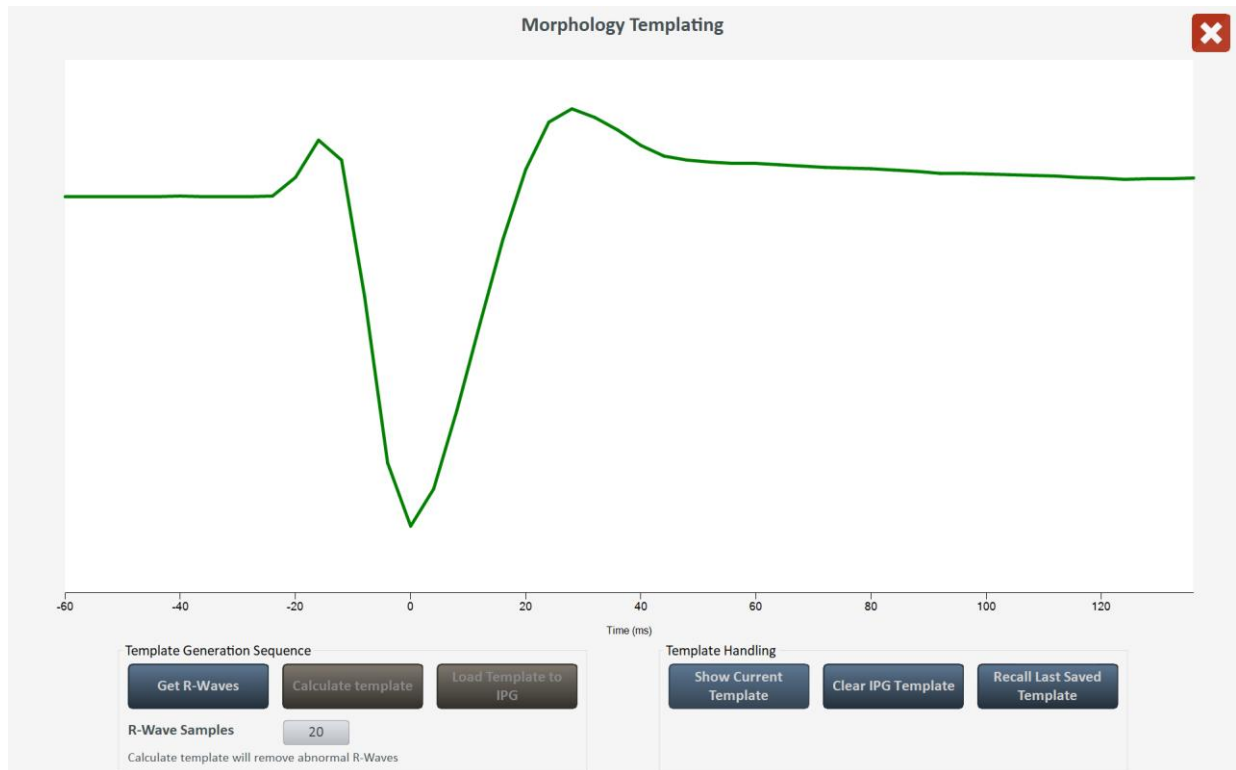


Figure 57: Example of Waveform Template Stored in the OPTIMIZER Integra CCM-D IPG

To delete a template file stored in the OPTIMIZER Integra CCM-D IPG:

1. Tap the **Clear IPG Template** button

A pop-up window will appear asking to confirm the deletion of the saved template. If **Yes** is tapped, the template will be deleted from the OPTIMIZER Integra CCM-D IPG. A pop-up message will then appear indicating that the template was deleted.

To exit the Morphology Templating tool:

1. Tap the red "X" at the top right of the Morphology Templating window

3.12.2 Morphology Matching

To view morphology matching with respect to the morphology template stored in the OPTIMIZER Integra CCM-D IPG:

1. Tap the **Show Morphology Matching** toggle switch (located above the Undo button on the Programming Buttons Pane) to enable (**ON**)

The IEGM Sub-pane will display a Morphology Matching percentage next to each R-wave.

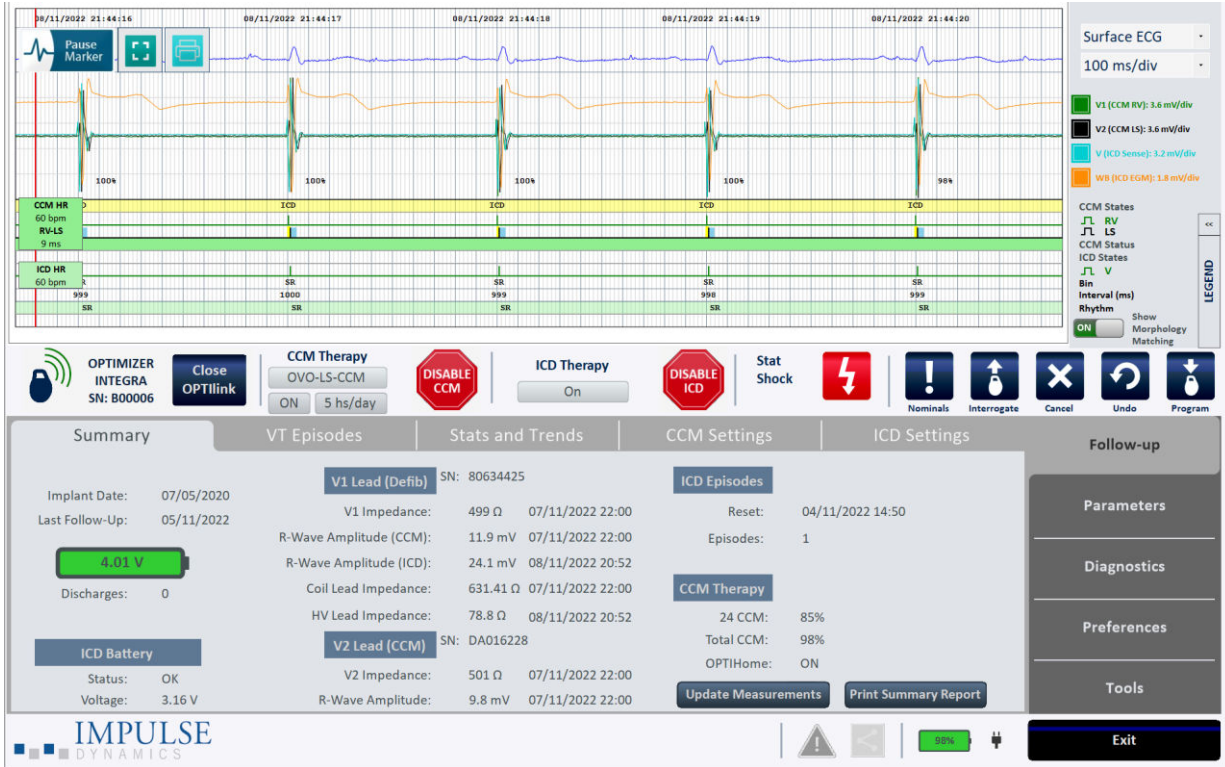


Figure 58: Example of IEGM Sub-Pane Showing Morphology Matching

To discontinue the IEGM Sub-pane from displaying the Morphology Matching percentage next to each R-wave:

1. Tap the **Show Morphology Matching** toggle switch (located above the Undo button on the Programming Buttons Pane) to disable (**OFF**)

3.13 ICD Detection

ICD detection is initiated whenever the R-R intervals in a series of sensed R-waves are less than the interval threshold set for an enabled ICD detection zone interval. Whenever ICD detection is active, the OPTIMIZER Integra CCM-D IPG undertakes the following actions:

- switches to the 3 - 40Hz bandpass filter
- disables CCM therapy

If the number of sensed R-wave within an enabled ICD detection zone exceeds the Binning parameter value set for the zone (e.g., 18 of 24), OPTIMIZER Integra CCM-D IPG declares the ICD detection zone as the prevailing rhythm and begins recording the EGM of the episode at a sampling rate of 250 samples per second.

3.13.1 Episode EGM Storage

The Integra CCM-D IPG has a maximum of eight buffers available to store recorded episode EGMs. Each buffer is divided into two sections that collectively store a 2 minute recording of each episode EGM. The first section stores the EGM that occurs about 15 seconds before the start of the episode and about 45 seconds after the start of the episode (if the “Pre-trigger EGM Recording” is enabled) or about 60 seconds after the start of the episode (if the “Pre-trigger EGM Recording” is disabled). The second section stores the EGM that occurs about 45 seconds before the end of the episode end and about 15 seconds after the end of the episode.

Note: If the length of the entire episode is less than 90 seconds (with “Pre-trigger EGM Recording” enabled) or 105 seconds (with “Pre-trigger EGM Recording” disabled), the EGM will continue to be recorded at the conclusion of the episode until the episode recording is 2 minutes in length.

If all the buffers are full and an EGM needs to be stored for a new episode that has priority over any of the already stored EGMs, a stored EGM that has a lower priority will be deleted from one of the buffers to allow for the storage of the new episode EGM. The order of priority used for the storage of episode EGMs is the following:

1. Stored EGMs corresponding to episodes where ICD therapy was delivered, in chronological order (the more recent the episode, higher the priority)
2. Other stored EGMs in chronological order (the more recent the episode, higher the priority)

3.13.2 ICD Detection Episode Termination

An ICD detection episode is terminated when any of the following criteria are met:

- Eight consecutive R-R intervals of sensed R-waves are greater than the interval threshold set for all the enabled ICD detection zone intervals
- Prevailing rhythm is classified as “Not Determined” when one of the following events occur:
 - Eight consecutive R-R intervals are a mix of SR, Monitor, or unsensed intervals
 - Sensing noise detection triggered during VT or FVT detections zones episodes
- The Optimizer Integra Programmer application is used to send the Program command to the OPTIMIZER Integra CCM-D IPG during an ICD Detection episode

3.13.3 ICD Detection Zone

The Optimizer Integra Programmer application has following four ICD detection zones:

- **Monitor:** When this zone is set to ON, the parameter settings for the Monitor zone become visible.
- **VT:** When this zone is set to ON, the parameter settings for the VT zone become visible.
- **FVT:** When this zone is set to ON, the parameter settings for the FVT zone become visible.
- **VF:** When this zone is set to ON, the parameter settings for the VF zone become visible.

3.13.4 Rate [Interval]

The Rate [Interval] parameter sets the interval threshold used by the ICD to classify each R-wave. The ICD measures the R-R interval of each sensed R-wave and then classifies it as belonging to a particular zone (e.g., VT) if its R-R interval is less than the interval threshold set for that zone.

The Optimizer Integra Programmer application features the ability to set a unique rate (interval) for each enabled detection zone.

Note: The Rate [Interval] setting for each enabled zone cannot overlap and must be set to a higher rate for each subsequent enabled zone. As such, this parameter has the following restriction: Monitor rate < VT rate < FVT rate < VF rate.

3.13.5 Binning

Successive heartbeat intervals are often not uniform in length, especially during an episode, so the OPTIMIZER Integra CCM-D IPG uses an X-of-Y heuristic to identify the prevailing arrhythmia at any given time. Each interval is classified by length into a set of “bins”, of which there is one for each of the four zones. If X of the most recent series of Y intervals is of a single type, then the OPTIMIZER Integra CCM-D IPG identifies that as the prevailing arrhythmia type. If no single type meets the X-of-Y threshold, then the prevailing type is Unknown. This X-of-Y binning is referred to as “majority”. If the programmed Binning count for an ICD detection zone has been met, then the arrhythmia for that zone is declared as the prevailing arrhythmia.

The Binning parameter sets the majority criteria that the ICD will use to declare a prevailing arrhythmia.

The Optimizer Integra Programmer application features the ability to set a unique Binning count for each detection zone.

3.13.6 Stability (Δ variability)

Rate Stability assesses the consistency of R-R intervals to discriminate atrial fibrillation (AF), which is generally associated with inconsistent interval lengths, from ventricular tachycardia (VT), which produces a high-rate ventricular rhythm with more consistent interval lengths. A rhythm is deemed to be stable when 6/8 of the prior intervals fall within a programmed window defining the maximum allowable difference between the longest and shortest interval in the group of 8. Variation in the R-R interval outside of the window implies that the rhythm is AF rather than VT. The Rate Stability gate opens whenever the stability criteria are met and closes whenever it is not.

The Stability parameter enables rate stability criteria to be used for AF discrimination when it occurs within the VT or FVT detection zones. The Stability Window setting defines the maximum allowable difference between the longest and shortest interval in the group of 8 within these two detection zones.

The Optimizer Integra Programmer application features unique Stability Window settings for the VT and FVT detection zones.

3.13.7 AF Gap (gap)

An AF Gap is identified whenever an R-R interval is greater than the average of the prior four R-R intervals plus a programmed gap duration. The AF Gap gate remains closed for 24 cardiac cycles following the identification of an AF Gap and opens thereafter. The 24-cycle count is reset every time an AF Gap is observed. **See Figure 59.**

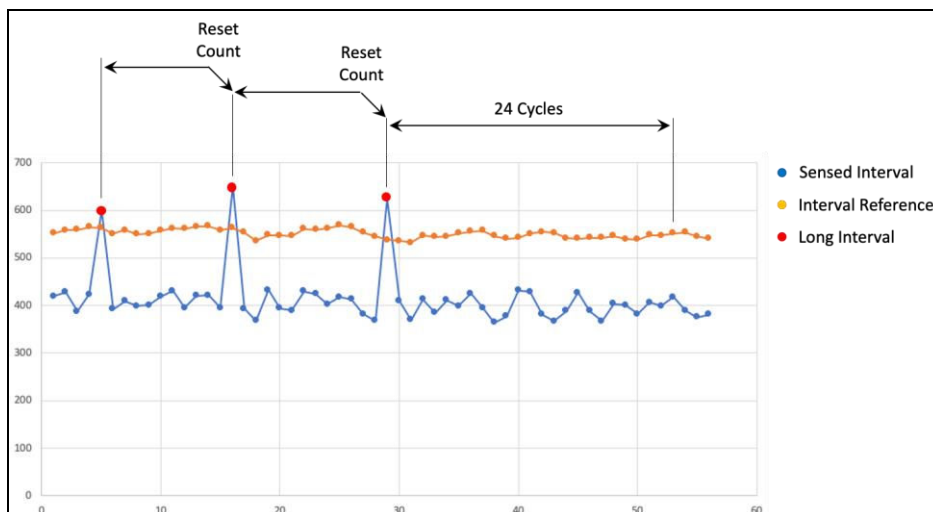


Figure 59: Example of AF Gap

The AF Gap parameter enables the AF gap to be used for AF discrimination when it occurs within the VT or FVT detection zones. The AF Gap threshold setting specifies the gap duration to be used when identifying an AF Gap in these two detection zones.

The Optimizer Integra Programmer application features unique AF gap threshold settings for the VT and FVT detection zones.

3.13.8 AF Gap Persistence Interval

The AF Gap persistence interval specifies the number of cardiac cycles the AF Gap remains closed when an AF Gap is detected within the VT or FVT detection zones.

The Optimizer Integra Programmer application features a unique AF gap persistence interval setting for the VT and FVT detection zones.

Note: If a new gap is detected during the AF Gap persistence interval, then the interval cycle is restarted.

3.13.9 Conduction Velocity

The Conduction Velocity setting uses LS Alert Window timing to prevent ICD therapy intended for VT and FVT. Timing measurements are provided by CCM module and compared against programmed limits by the ICD module in order to determine whether the gate should be opened or closed.

The Optimizer Integra Programmer application features a unique Conduction Velocity setting for the VT and FVT detection zones.

3.13.10 Morphology Binning

The Morphology Binning setting enables morphology binning for the VT or FVT detection zones. Once enabled, the Morphology Binning count parameter sets the majority criteria used by the morphology matching algorithm to discriminate SVTs when they occur within these two detection zones.

The Optimizer Integra Programmer application features unique Morphology Binning settings for the VT and FVT detection zones.

Note: A Morphology Template must be loaded into the OPTIMIZER Integra CCM-D IPG before the Morphology Binning is enabled.

To modify the ICD Detection parameters:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **ICD Detection** tab
4. On the **ICD Detection** panel, modify the ICD Detection parameters as needed
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.14 ICD Therapy

The ICD Therapy panel contains the following parameters:

- **Shock Waveform:** This parameter specifies the waveform (Biphasic – 50/50 tilt) or (Monophasic – 75% tilt) used for all high voltage (HV) therapy pulses. **See Figure 60.**
- **Shock Waveform Polarity:** This parameter sets the polarity of the high voltage (HV) therapy pulse for the first shock of an episode. **See Figure 60.**

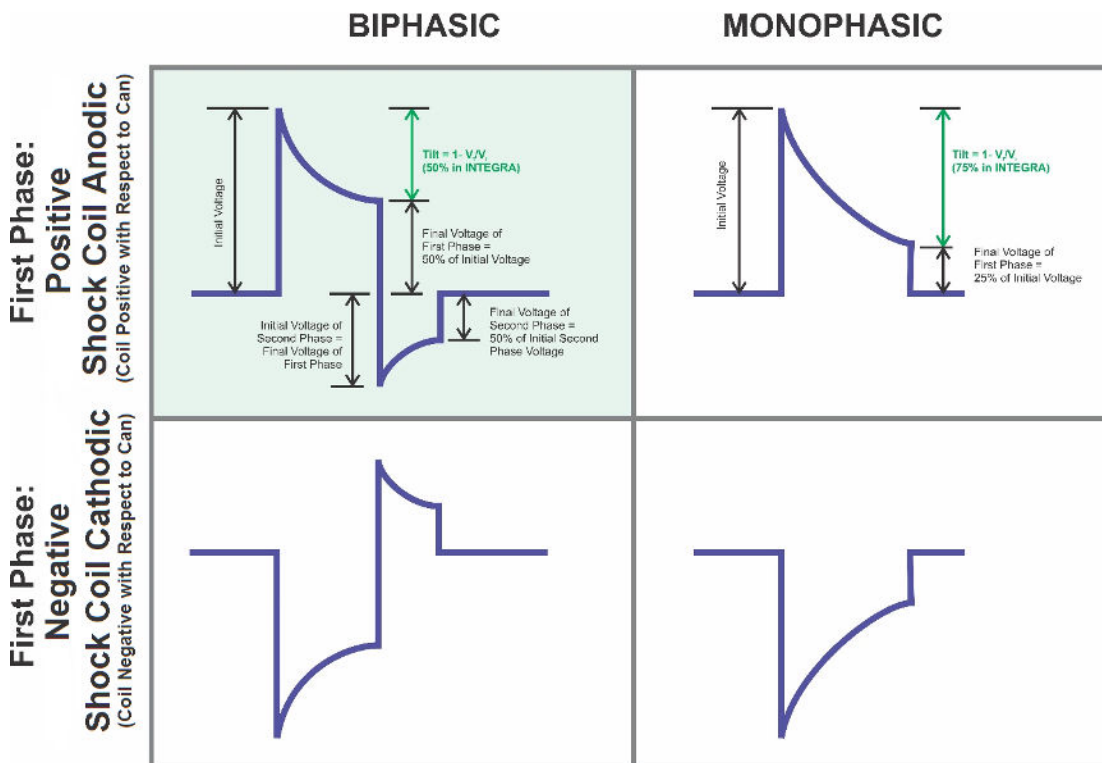


Figure 60: Illustration of the Shock Waveforms Options in the OPTIMIZER Integra CCM-D IPG

- **Inverting Shock Polarity:** When this parameter is set to ON, the ICD alternates the polarity of each subsequent shock after the first failed shock in an episode.
- **Rescue Brady Pacing:** When this parameter is set to ON, the ICD delivers monophasic VVI bradycardia pacing at a fixed rate of 40 bpm when the sensed R-R interval falls below 1500 ms (40 bpm).

Note: Rescue Brady Pacing is not available while in an episode or during a post-shock bradycardia pacing period.

WARNING: The OPTIMIZER Integra CCM-D IPG is not indicated for the treatment of sustained bradyarrhythmias. The delivery of pacing stimulation by the OPTIMIZER Integra CCM-D IPG quickly drains the non-rechargeable battery. Hence, the Rescue Brady Pacing feature is to be used only as an emergency measure when a patient develops profound bradycardia until a device indicated for the treatment of bradyarrhythmia is implanted.

- **Post-Shock Brady:** When this parameter is set to ON, the ICD delivers monophasic VVI bradycardia pacing at 60 bpm for a programmable duration of time after any shock delivery if the detected R-R interval after a shock is below 1000 ms (60 bpm).

Note: Post-Shock Brady Pacing will be terminated if patient's heart rate exceeds 60 bpm at any time during the post-shock period and will no longer be available until after the delivery of another shock.

- **Pacing Duration:** When the Post-Shock Brady parameter is set to ON, this parameter sets the post-shock bradycardia pacing duration.

3.14.1 ICD Therapy Zone

The Optimizer Integra Programmer application has three ICD therapy zones:

- **VT:** When this parameter is set to ON, the parameter settings for the VT zone become visible.
- **FVT:** When this parameter is set to ON, the parameter settings for the FVT zone become visible.
- **VF:** When this parameter is set to ON, the parameter settings for the VF zone become visible.

Note: An ICD therapy zone cannot be enabled unless its corresponding ICD Detection zone is enabled.

Note: The VT or FVT therapy zone cannot be enabled unless the VF therapy zone is also enabled.

3.14.2 HV Shock

The HV Shock setting specifies the number of high-voltage (HV) shocks to be delivered and the energy used for each HV shock.

The Optimizer Integra Programmer application features the ability to set unique shock counts and energies for each ICD therapy zone.

Note: If the VT or FVT therapy zone is set to ON, at least one shock or ATP Burst Sequence must be enabled for that zone.

Note: If the number of shocks selected for the VF therapy zone is 1 or 2, the last shock value must be set to 36 J. If the number of shocks for the VF therapy zone is set to 3, 4, 5, or 6, then all subsequent shocks after the second shock will be delivered at 36 J.

3.14.3 Therapy Delay

The Therapy Delay setting specifies the amount of time ICD therapy is delayed for the VT and FVT therapy zones before the delivery sequence for the therapy zone is initiated.

The Optimizer Integra Programmer application features a unique Therapy Delay setting for the VT and FVT therapy zones.

3.14.4 ATP Bursts

The ATP Bursts setting specifies the number of biphasic antitachycardia pacing (ATP) bursts to be delivered for the VT and FVT therapy zones.

The Optimizer Integra Programmer application features a unique ATP Burst Sequence setting for the VT and FVT therapy zones.

3.14.4.1 ATP Initial Train

Setting the ATP Bursts to a non-zero value for either the VT or FVT therapy zone enables the Initial Trains parameter, which sets the number of antitachycardia pacing (ATP) pulses to be delivered during the initial ATP Burst.

3.14.4.2 Start from Last Successful

Setting the ATP Bursts to a non-zero value for either the VT or FVT therapy zone allows this parameter to become visible and to be set. When this parameter is set to ON, the OPTIMIZER Integra CCM-D IPG uses the number of ATP train pulses delivered in the last successful ATP Burst as the number of ATP train pulses it delivers in subsequent initial ATP Bursts.

3.14.4.3 ATP R-S1 (%RR)

Setting the ATP Bursts to a non-zero value for either the VT or FVT therapy zone enables the R-S1 (%RR) parameter, which specifies the interval of the ATP therapy pulses as a percentage of the detected R-R interval.

To modify the ICD Therapy parameters:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **ICD Therapy** tab
4. On the **ICD Therapy** panel, modify the ICD Therapy parameters as needed
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.15 ICD Magnet Mode

Note: To find out how the placement of a magnet over the implant site of the OPTIMIZER Integra CCM-D IPG affects CCM Therapy delivery, see section 3.7.

Placing a pacemaker magnet over the implant site of the OPTIMIZER Integra CCM-D IPG sets the OPTIMIZER Integra CCM-D IPG into ICD Magnet Mode (indicated by a yellow bar in **ICD Status** row of the Marker Sub-pane), which suspends ICD therapy delivery. The delivery of ICD therapy will remain suspended as long as the magnet is maintained over the implant site. When the magnet is removed from the implant site, the OPTIMIZER Integra CCM-D IPG will resume ICD therapy delivery using the previously programmed parameters.

To set the parameter associated with this Magnet Mode suspension:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Parameters** button on the Menu Bar
3. Select the **ICD Therapy** tab
4. On the **ICD Therapy** panel, tap the **Magnet Mode** button

The **Magnet Mode** parameter window will display the following options for this parameter:

- **Therapy OFF when applied:** ICD therapy delivery is suspended whenever a pacemaker magnet is applied and maintained over the implant site of the OPTIMIZER Integra CCM-D IPG.
 - **Disabled:** ICD therapy delivery is not suspended whenever a pacemaker magnet is applied over the implant site of the OPTIMIZER Integra CCM-D IPG.
5. Select one of the parameter choices and then tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.16 Lead Measurements

3.16.1 CCM Lead Impedance

The OPTIMIZER Integra CCM-D IPG measures the CCM lead impedance of the ventricular leads by sending a biphasic pulse through each ventricular lead with the following characteristics:

- **Amplitude:** 4.5 V \pm 10%
- **Phase Duration:** 0.5 ms \pm 0.031 ms
- **Interval:** 60 μ s \pm 10 μ s
- **Balancing:** 40 ms \pm 5%

The CCM lead impedance can be measured by the OPTIMIZER Integra CCM-D IPG, with a tolerance of 20%, if it is within the range of 75 Ω to 2000 Ω .

Warning: CCM 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 CCM lead impedances:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **Leads** tab
4. On the **Leads** panel, tap the **Measure CCM Leads Impedance** button

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

3.16.2 Coil Lead Impedance

The OPTIMIZER Integra CCM-D IPG measures the impedance of the coil lead by sending a 15 V, 10 ms pulse between the coil and tip of the defibrillation (V1) lead.

The OPTIMIZER Integra CCM-D IPG can measure the coil lead impedance (CLI), with a tolerance of 20%, if it is within the range of 125 Ω to 1600 Ω .

To measure the coil lead impedance:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **Leads** tab
4. On the **Leads** panel, tap the **Measure Coil Lead Impedance** button

When completed, the **Coil Lead Impedance:** field will become populated with the impedance of coil lead.

3.16.3 HV Lead Impedance

The OPTIMIZER Integra CCM-D IPG measures the impedance of the High Voltage (HV) lead by sending a 15 V, 10 ms pulse between the coil of the defibrillation (V1) lead and the can of the IPG.

The OPTIMIZER Integra CCM-D IPG can measure the high-voltage lead impedance (HVLI), with a tolerance of 15% or 5 Ω (whichever is greater), if it is within the range of 25 Ω to 150 Ω .

Warning: Do not conduct a high-voltage lead impedance (HVLI) measurement when the patient is awake. The pulse used to measure HVLI will cause significant discomfort to the patient.

To measure the HV lead impedance:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **Leads** tab
4. On the **Leads** panel, tap the **Measure HV Lead Impedance** button

When completed, the **HV Lead Impedance:** field will become populated with the impedance of the HV lead.

3.16.4 Measure V1 R-Wave Amplitude (ICD)

The CCM module of the OPTIMIZER Integra CCM-D IPG automatically measures the R-wave amplitude of both leads and also allows for the manual measurement of the V1 R-wave amplitude by the ICD module.

To measure the R-wave amplitude of the V1 lead by the ICD module:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **Leads** tab
4. On the **Leads** panel, tap the **Measure V1 R-Wave Amplitude (ICD)** button

When completed, the **V1 R-Wave Amplitude (ICD):** field will become populated with the R-wave amplitude of the V1 lead measured by the ICD module.

3.16.5 Retrieve Last Measured HV Lead Impedance

The last measured HV lead impedance is stored by the OPTIMIZER Integra CCM-D IPG and can be retrieved by using the **Retrieve Last Measured HV Lead Impedance** command.

To retrieve the last measured HV lead impedance:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **Leads** tab
4. On the **Leads** panel, tap the **Retrieve Last Measured HV Lead Impedance** button

When completed, the **Retrieve Last Measured HV Lead Impedance:** field will become populated with the last measured HV lead impedance.

3.17 VT Episodes

In addition to detecting and treating tachycardia episodes, the OPTIMIZER Integra CCM-D IPG also keeps a record of such episodes. These episodes can be downloaded to the programmer using the Optimizer Integra Programmer application, allowing the user to review each recorded episode.

3.17.1 Downloading Tachy Episodes

To download the Tachy Episodes:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **VT Episodes** tab
4. On the **VT Episodes** panel, tap the **Get Episodes** button

When the download is completed, the panel will display a listing of recent tachy episodes.

Note: To view episodes that were previously downloaded from the OPTIMIZER Integra CCM-D IPG, tap the **Show Episodes from Past Sessions** checkbox.

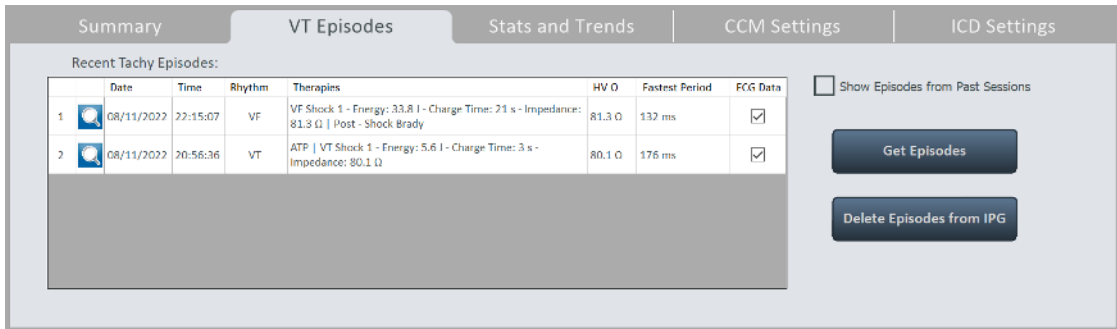


Figure 61: VT Episodes Panel Showing Recent Tachy Episode Downloaded from the OPTIMIZER Integra CCM-D

3.17.2 Viewing a Tachy Episode

To view a Tachy Episode:

1. On the **VT Episodes** panel, tap the magnifying glass icon next to the number of the episode

The **Recorded Episode Review** window will be displayed, allowing the user to view either the **Event** panel, which contains a brief description of the specific event, or the **Programmed Settings** panel, which lists the programmed ICD settings at the time of the event.

Below the panel, the recorded EGM associated with the episode is displayed for review. This includes 16 seconds of EGM waveform prior to the onset of the event (if the Pre-trigger EGM Recording parameter has been enabled), the event itself, any therapy delivered by the ICD during the event, and 30 seconds of post-event EGM waveform.

Note: If the source of the recorded EGM is Bipolar, the color of the EGM will be light blue. If the source of the recorded EGM is Unipolar, the color of the EGM will be orange.

To view the entire recorded EGM, double tap on the gray bar below the ECG, and keep the stylus in contact with the gray bar with the second tap. When the bar's color turns dark gray, move the stylus left or right on the screen to scroll the length of the recorded EGM.

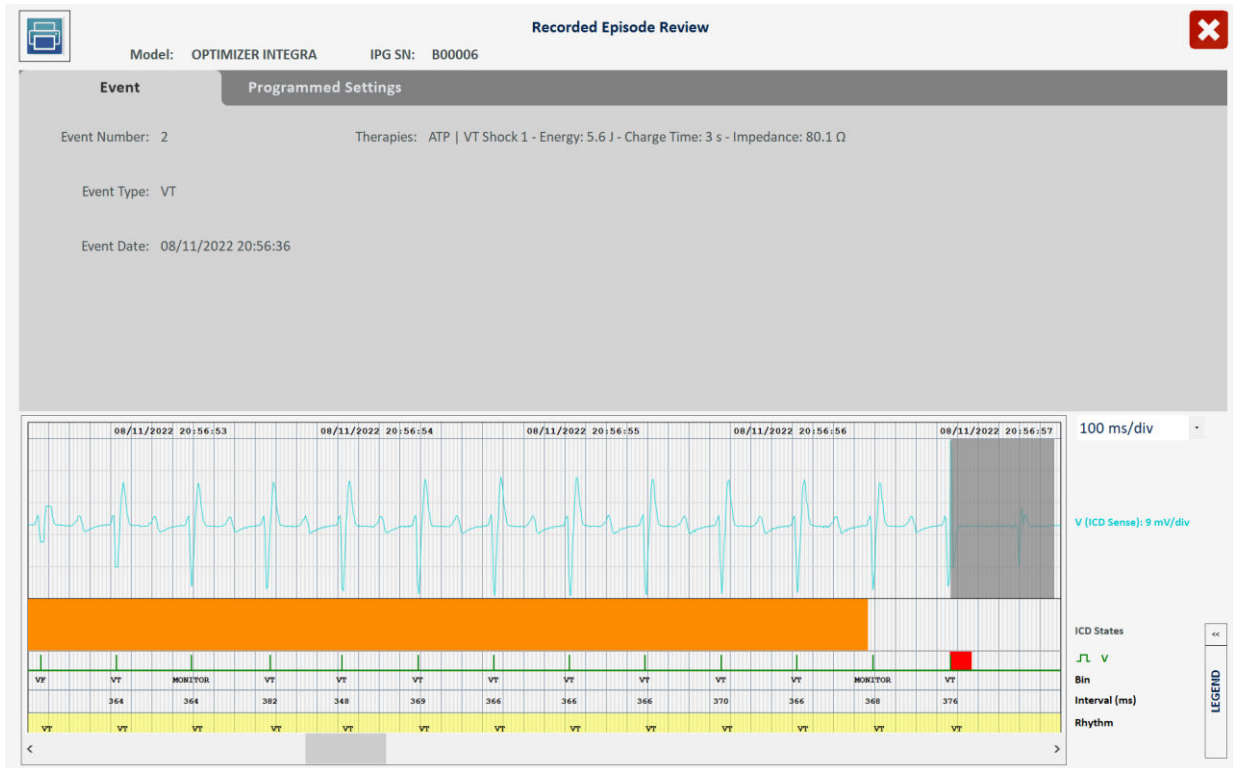


Figure 62: Example of Recorded Episode Review of VT Episode (Bipolar EGM)

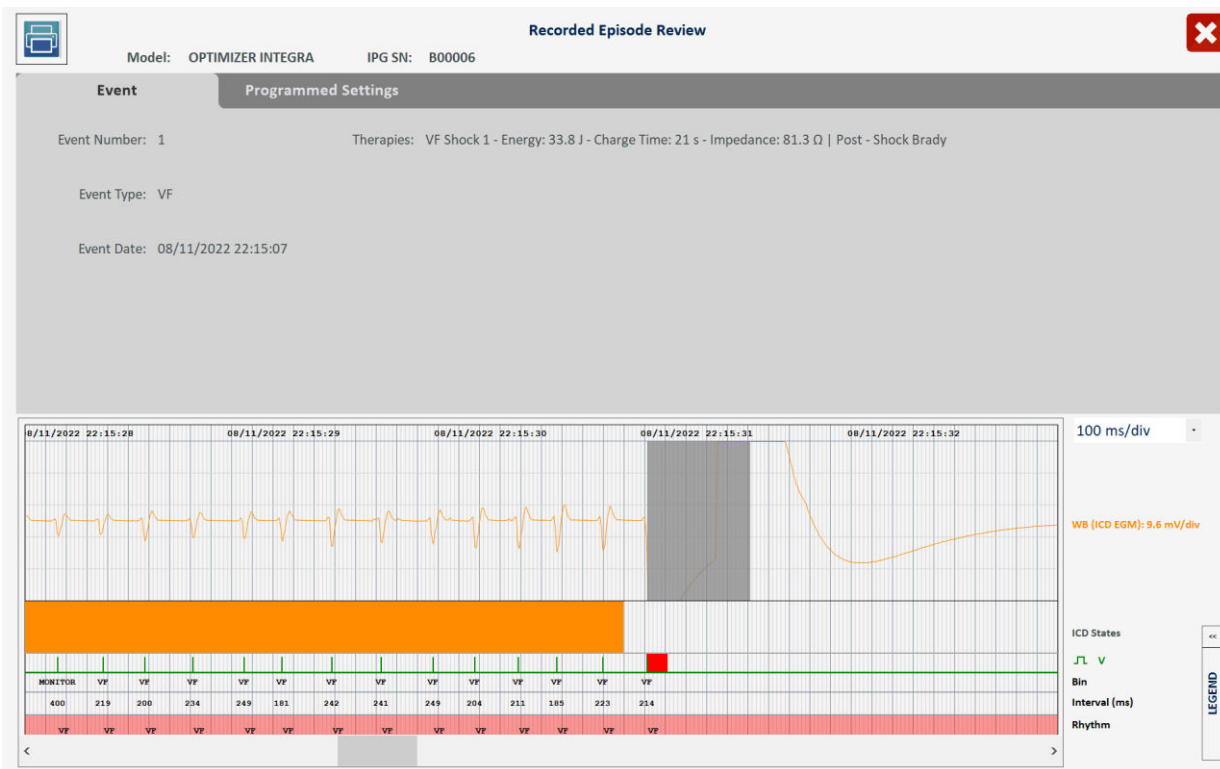


Figure 63: Example of Recorded Episode Review of VF Episode (Unipolar EGM)

To view the programmed ICD settings when the episode occurred, select the **Programmed Settings** tab on the **Recorded Episode Review** window.

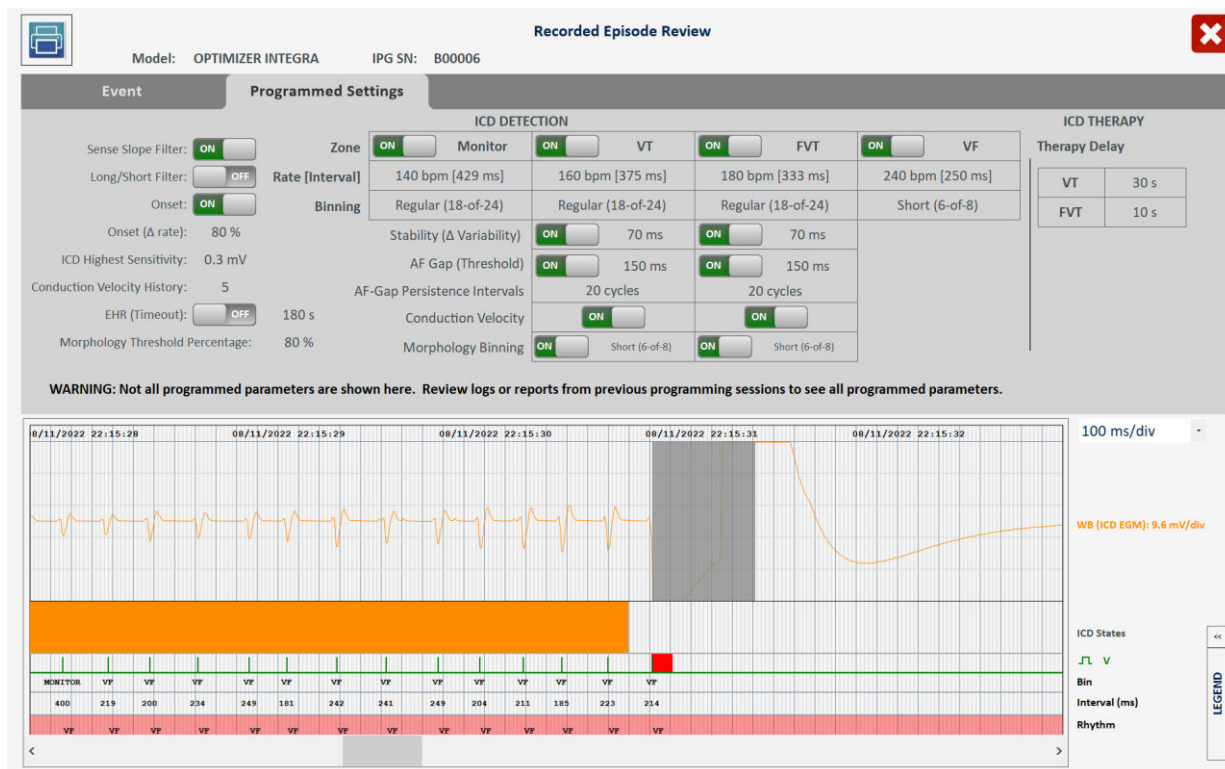


Figure 64: Example of Programmed Settings Tab of Recorded Episode Review

3.17.3 Creating and Saving an Episode Report

To create and save an Episode Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. On the **Recorded Episode Review** panel, tap the printer icon on the top left-hand corner of the window to create an Episode Report.
3. When the **Report Viewer** window appears, tap the PDF icon at the top right-hand corner of the window to save a PDF file of the Episode Report.

The Episode Report is saved in the Reports folder of the USB flash drive. The file name of the Episode Report has the following format:

EpisodeReport_NNNNNN_YYYYMMDDhhmmss_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- The first group of numbers after the serial number is the date and time when the episode occurred and the second group of numbers is the date and time when the file was created and saved. The format for the dates and times in the file name is the following:
 - YYYY = year
 - MM = month
 - DD = day
 - hh = hour
 - mm = minute
 - ss = second

3.18 Stats and Trends

The OPTIMIZER Integra CCM-D IPG continuously monitors the patient's heart rhythm, collecting a statistical record of events and conditions that occur throughout the day. In addition, the OPTIMIZER Integra CCM-D IPG monitors the status of its batteries, the sensing amplitude and impedance of each implanted lead, the status of its high voltage capacitors, and its functional status for any alert conditions that may occur during its operation.

If enabled, the OPTIMIZER Integra CCM-D IPG can also continuously monitor the patient's activity, collecting a record of the patient's activity throughout the day.

These records can be all loaded into the Optimizer Integra Programmer application and viewed using the CCM Statistics, ICD Statistics, and various Trends buttons located on the **Stats and Trends** panel of the Optimizer Integra Programmer application.

3.18.1 CCM Statistics

3.18.1.1 Viewing CCM Statistics

To view the CCM Statistics from the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **CCM Statistics** button

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

3.18.1.2 CCM Statistics Tabs

The following are the list of tabs for the CCM Statistics and the statistics that are shown under each tab:

- **On - General:** Events occurring when the OPTIMIZER Integra CCM-D IPG is scheduled to deliver CCM therapy (On Time).
 - **Events**
 - **Ventricular:** The number of ventricular (RV) events sensed during scheduled CCM delivery.
 - **LS in Alert:** The number of local sense (LS) events sensed during scheduled CCM delivery.
 - **Periods**
 - **Normal:** The number of normal event cycles (i.e., detected ventricular and LS in Alert events) during scheduled CCM delivery.
 - **Inhibited:** The number of inhibited event cycles during scheduled CCM delivery.
 - **Post-Inhibited:** The number of post-inhibited event cycles during scheduled CCM delivery.
 - **Trains Delivered**
 - **Total:** The total number of CCM trains delivered during scheduled CCM delivery.
- **On - Inhibition:** Inhibitions occurring when the OPTIMIZER Integra CCM-D IPG is scheduled to deliver CCM therapy (On Time).
 - **Causes**
 - **LS out of Window:** The number of Local Sense events outside the LS Alert Window during scheduled CCM delivery.
 - **LS Absence:** The number of ventricular events detected without corresponding Local Sense events during scheduled CCM delivery.
 - **VT:** The number of ventricular events exceeding the tracking rate during scheduled CCM delivery.
 - **Charger:** The number of normal event cycles where CCM delivery was inhibited during scheduled CCM delivery due to the IPG being subjected to a charging session.
 - **Inhibit Due to ICD:** The number of ventricular events cycles where CCM delivery was inhibited during scheduled CCM delivery due to ICD initiated inhibition.
 - **Noise Episodes**
 - **V Noise:** The number of ventricular noise episodes detected during scheduled CCM delivery.
- **Off - General:** Events occurring when the OPTIMIZER Integra CCM-D 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 Integra CCM-D IPG is not scheduled to deliver CCM therapy (Off Time).

Displays the same list of CCM statistical counters as detailed under **On - Inhibition**.

- **Other**
 - **Last Session:** The period between the previous day's CCM Therapy Start Time and End Time.
 - **Sensed V:** The number of ventricular events sensed during the previous day's CCM scheduled delivery sessions.
 - **Delivered Trains:** The number of CCM trains delivered during the previous day's CCM scheduled delivery sessions.
 - **CCM%:** CCM delivery percentage during the previous day's CCM scheduled delivery sessions.
 - **Lead Displacement Alert:** Indicates whether the Maximum lead impedance change alert was triggered as a result of the previous day's impedance measurement.
 - **CCM % Low Alert:** Indicates whether the Minimum CCM% alert was triggered as a result of the previous day's CCM scheduled delivery sessions.
 - **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 rechargeable battery voltage dropping to 3.5 V.

3.18.1.3 CCM Statistics Buttons

The CCM Statistics panel has the following buttons:

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

3.18.1.4 Resetting CCM Statistics Counters

To reset the OPTIMIZER Integra CCM-D CCM Statistics counters to zero:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **CCM Statistics** button
5. Tap the **Reset** button at the bottom of the **CCM Statistics** panel

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

3.18.1.5 Displaying the Difference Between Two Rows of CCM Statistical Data

The Optimizer Integra Programmer application features the option of displaying the difference between any two rows of CCM statistical data collected from the OPTIMIZER Integra CCM-D IPG.

To display the difference between any two rows of CCM statistical data:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **CCM Statistics** button
5. Tap once on the box to the left of a particular row of statistical data. One asterisk will appear in the selected box.
6. Double tap on the box to the left of another row of statistical data. Two asterisks will appear in the selected box.

The absolute difference between the two selected rows of statistics will be shown in the dark gray row named **Difference** for each statistics counter.

On - General		On - Inhibition		Off - General		Off - Inhibition		Other	
Events		Periods		Trains Delivered					
Date	Ventricle	IS in Alert	Normal	Inhibited	Post-Inhibited	Total			
Difference	29262	29168	28924	382	0	28914			
** 08/11/2022 19:48:29	933095	930770	918334	14910	0	917905			
08/11/2022 21:47:47	936335	933977	921364	15129	0	920934			
08/11/2022 23:53:12	938218	935858	923235	15157	0	922804			
* 10/11/2022 16:31:01	962357	959938	947258	15292	0	946819			

Figure 65: CCM Statistics Showing Difference Between Two Selected Rows of Statistics

3.18.2 Daily Activity Trends

3.18.2.1 Viewing Daily Activity Trends

To view the Daily Activity trends stored by the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **Daily Activity** button

If successful, the Programmer will display the Daily Activity screen.

Note: The date range for the Daily Activity trends displayed on the screen may be changed by selecting the arrow to the right of the “1 Month” date range. One may then select the desired date range from the pull-down menu.

3.18.2.2 Daily Activity Screen

The Daily Activity screen includes the following information:

- **Model:** Displays device model.
- **IPG SN:** Displays the serial number of the device
- **Average HR (bpm):** Displays average daily heart rate (HR)
- **Activity:** Displays the average daily activity level of the patient (line graph) and the amount of time the patient was engaged in each of the 5 different activity levels during the day (bar graph).

- **Position:** Displays what percentage of time the patient was in each position throughout the day.
 - **Average HRV (ms):** Displays average daily heart rate variability (HRV).
- Note:** Tap on a specific data point on one of the graphs to view the numerical data for that day.

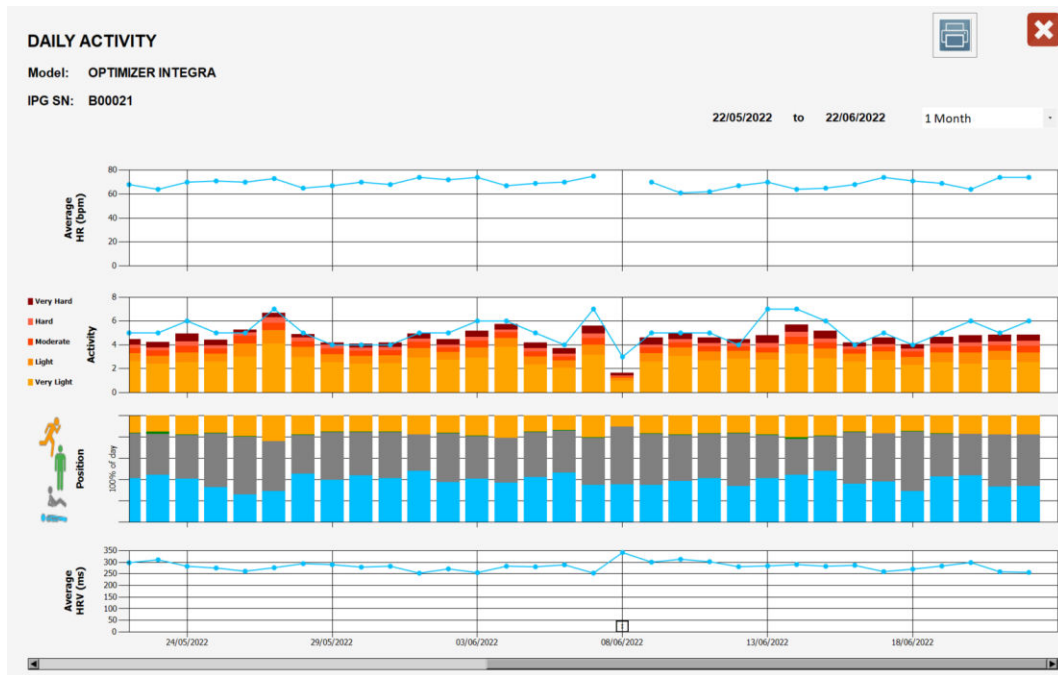


Figure 66: Example of Daily Activity Screen

3.18.2.3 Creating and Saving a Daily Activity Trends Report

To create and save a Daily Activity Trends Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the Printer icon at the top right of the Daily Activity screen.
3. When the Report Viewer window appears, tap the PDF icon at the top right of the window.
4. If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

To close the Daily Activity screen, tap the "X" at the top right corner of the Daily Activity screen.

The Daily Activity Trends Report is saved in the Reports folder of the USB flash drive. The file name of the Daily Activity Trends Report has the following format:

ActivityTrendDay_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.18.3 Activity Per Hour Trends

3.18.3.1 Viewing Activity Per Hour Trends

To view the Activity Per Hour trends stored by the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **Activity Per Hour** button

If successful, the Programmer will display the Activity Per Hour screen.

Note: The date range for the Activity Per Hour trends displayed on the screen may be changed by selecting the arrow to the right of the “Last 48 hs” date range. One may then select the desired date range from the pull-down menu.

3.18.3.2 Activity Per Hour Screen

The Activity Per Hour screen includes the following information:

- **Model:** Displays device model.
- **IPG SN:** Displays the serial number of the device
- **Average HR (bpm):** Displays average hourly heart rate (HR)
- **Activity:** Displays the average hourly activity level of the patient (line graph) and the amount of time the patient was engaged in each of the 5 different activity levels each hour (bar graph).
- **Position:** Displays what percentage of time the patient was in each position each hour.
- **Average HRV (ms):** Displays average hourly heart rate variability (HRV).

Note: Tap on a specific data point on one of the graphs to view the numerical data for that hour.

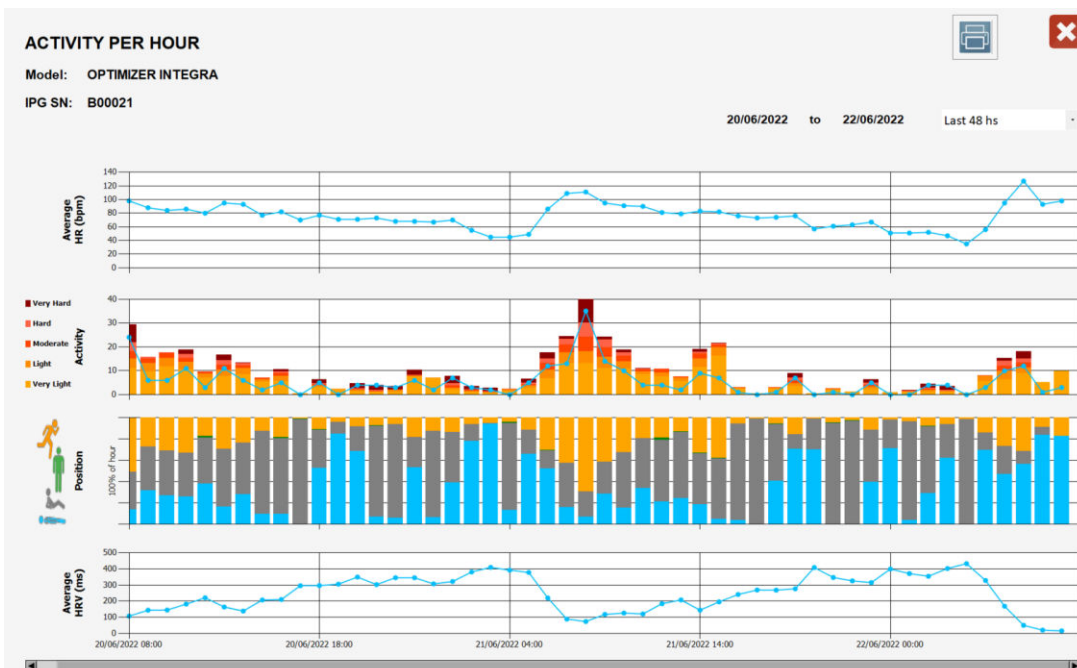


Figure 67: Example of Activity Per Hour Screen

3.18.3.3 Creating and Saving an Activity Per Hour Trends Report

To create and save an Activity Per Hour Trends Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the Printer icon at the top right of the Activity Per Hour screen.
3. When the Report Viewer window appears, tap the PDF icon at the top right of the window.
4. If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

To close the Activity Per Hour screen, tap the “X” at the top right corner of the Activity Per Hour screen.

The Activity Per Hour Trends Report is saved in the Reports folder of the USB flash drive. The file name of the Activity Per Hour Trends Report has the following format:

ActivityTrendHour_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.18.4 Alerts Trend

3.18.4.1 Viewing Alerts Trend

To view the Alerts trend stored by the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **Alerts** button

If successful, the Programmer will display the Alerts Trend screen.

3.18.4.2 Alerts Trend Screen

The Alerts Trend screen includes the following information:

- **Model:** Displays device model.
- **IPG SN:** Displays the serial number of the device.
- A list of CCM alerts that have been detected by the device.

3.18.4.3 Creating and Saving an Alerts Trend Report

To create and save an Alerts Trend Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC

2. Tap the Printer icon at the top right of the Alerts Trend screen.
3. When the Report Viewer window appears, tap the PDF icon at the top right of the window.
4. If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

To close the Alerts Trend screen, tap the “X” at the top right corner of the Alerts Trend screen.

The Alerts Trend Report is saved in the Reports folder of the USB flash drive. The file name of the Alerts Trend Report has the following format:

AlertTrend_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.18.5 Rechargeable Battery Trend

3.18.5.1 Viewing Rechargeable Battery Trend

To view the Rechargeable Battery trend stored by the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **Rechargeable Battery** button

If successful, the Programmer will display the Rechargeable Battery screen.

Note: The date range for the Rechargeable Battery trend displayed on the screen may be changed by selecting the arrow to the right of the “1 Month” date range. One may then select the desired date range from the pull-down menu.

3.18.5.2 Rechargeable Battery Screen

The Rechargeable Battery screen includes the following information:

- **Model:** Displays device model.
- **IPG SN:** Displays the serial number of the device.
- **Time Since Implant:** Displays the time since the device was implanted.
Note: This time is dependent on the implant date information entered on the Implant Data screen (see section 3.23).
- **Current Status:** Current rechargeable battery voltage.
- **Remaining Charge:** Current remaining charge for the rechargeable battery.
- **Last Charge Session:** Displays information regarding the last time the device was charged.

- **Cell Voltage:** Displays a line graph of the rechargeable battery's daily voltage level and when a charge session occurred.

Note: Tap on a specific data point on the Cell Voltage graph to view the numerical data for that day.

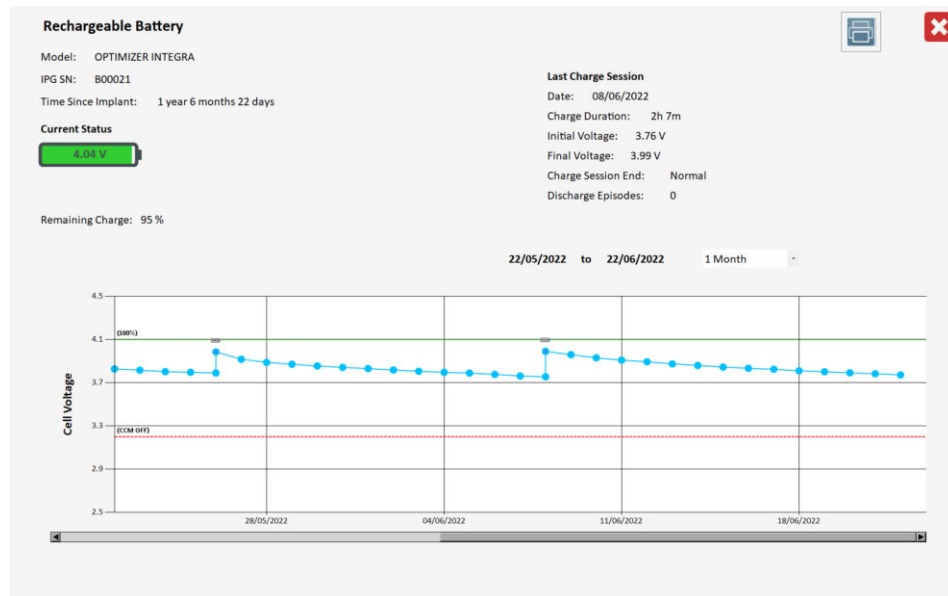


Figure 68: Example of Rechargeable Battery Screen

3.18.5.3 Creating and Saving a Rechargeable Battery Trend Report

To create and save a Rechargeable Battery Trend Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the Printer icon at the top right of the Rechargeable Battery screen.
3. When the Report Viewer window appears, tap the PDF icon at the top right of the window.
4. If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

To close the Rechargeable Battery screen, tap the "X" at the top right corner of the Rechargeable Battery screen.

The Rechargeable Battery Trend Report is saved in the Reports folder of the USB flash drive. The file name of the Rechargeable Battery Trend Report has the following format:

RechargeableBatteryTrend_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.18.6 Leads Trend

3.18.6.1 Viewing Leads Trend

To view the Leads trend stored by the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **Leads** button

If successful, the Programmer will display the Leads Trend screen.

Note: The date range for the Leads Trend displayed on the screen may be changed by selecting the arrow to the right of the “3 Month” date range. One may then select the desired date range from the pull-down menu.

3.18.6.2 Leads Trend Screen

The Leads Trend screen includes the following information:

- **Model:** Displays device model.
- **IPG SN:** Displays the serial number of the device
- **V1 Lead (Defib) SN:** Displays the serial number of the V1 lead.
Note: The serial number shown is dependent on the V1 lead information entered on the Implant Data screen (see section 3.23).
- **V2 Lead (CCM) SN:** Displays the serial number of the V2 lead.
Note: The serial number shown is dependent on the V2 lead information entered on the Implant Data screen (see section 3.23).
- **V1 Ω :** Displays the weekly measured impedance value for the V1 lead.
- **V1 mv:** Displays the weekly measured R-wave amplitude value for the V1 lead.
- **Coil Lead Ω :** Displays the weekly measured impedance value for the coil lead.
- **V2 Ω :** Displays the weekly measured impedance value for the V2 lead.
- **V2 mv:** Displays the weekly measured R-wave amplitude value for the V2 lead.

Note: Tap on a specific data point on one of the graphs to view the numerical data for that week.

- **HV Ω :** Displays the measured impedance value for the high voltage lead.
Note: The impedance for the high voltage lead is only measured during an HV shock or when using the Measure HV Lead command (see section 3.16.3).

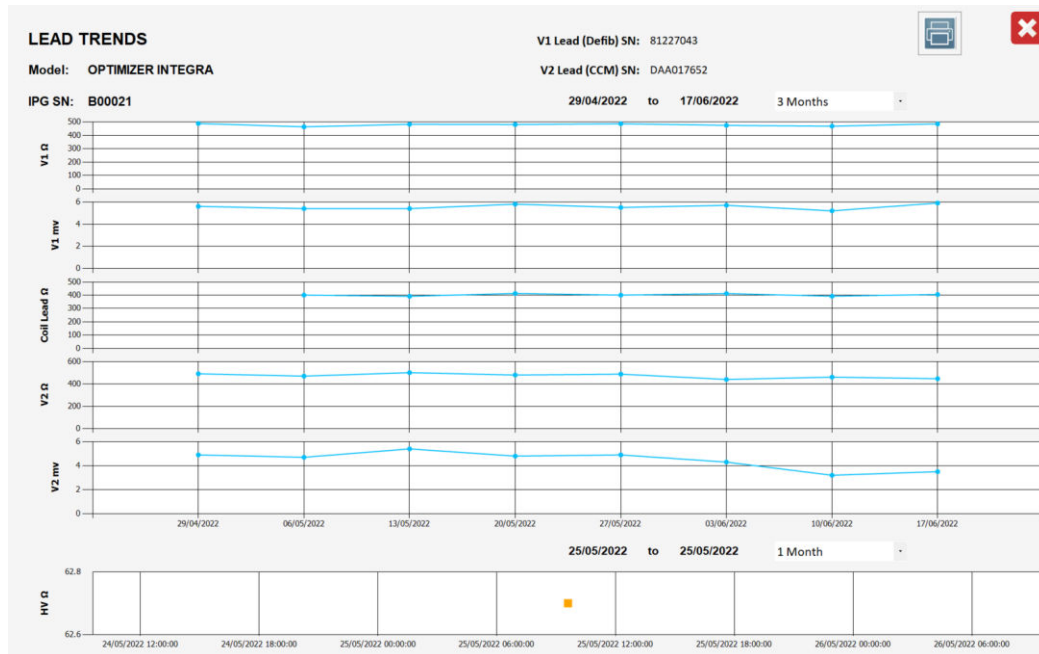


Figure 69: Example of Leads Trend Screen

3.18.6.3 Creating and Saving a Leads Trend Report

To create and save a Leads Trend Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the Printer icon at the top right of the Leads Trend screen.
3. When the Report Viewer window appears, tap the PDF icon at the top right of the window.
4. If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

To close the Leads Trend screen, tap the “X” at the top right corner of the Leads Trend screen.

The Leads Trend Report is saved in the Reports folder of the USB flash drive. The file name of the Leads Trend Report has the following format:

LeadsTrend_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.18.7 ICD Statistics

3.18.7.1 Viewing ICD Statistics

To view the ICD Statistics from the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG

- a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
- b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **ICD Statistics** button

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

Note: Unlike the CCM statistics, the latest ICD statistics are not automatically downloaded from the OPTIMIZER Integra CCM-D IPG whenever a link is established with the Optimizer Integra Programmer application. To display the latest ICD statistics, tap the **Read** button on the **ICD Statistics** panel.

3.18.7.2 ICD Statistics Tabs

The following are the list of tabs for the ICD Statistics and the statistics that are shown under each tab:

- **Zone Interval**
 - **SR:** The number of slow rate (SR) R-wave intervals detected by the ICD. The slow rate interval classification is dependent on the lowest interval set for the enabled ICD detection zones.
 - **MONITOR:** The number of monitor rate zone R-wave intervals detected by the ICD.
 - **VT:** The number of ventricular tachycardia (VT) rate zone R-wave intervals detected by the ICD.
 - **FVT:** The number of fast ventricular tachycardia (FVT) rate zone R-wave intervals detected by the ICD.
 - **VF:** The number of ventricular fibrillation (VF) rate zone R-wave intervals detected by the ICD.
 - **UNSENSED:** The number of unsensed intervals detected by the ICD. An interval is classified as unsensed when 2048 ms has passed without a detected R-wave interval.
- **Zone Episode**
 - **MONITOR:** The number of monitor rate zone episodes detected by the ICD.
 - **VT:** The number of VT rate zone episodes detected by the ICD.
 - **FVT:** The number of FVT rate zone episodes detected by the ICD.
 - **VF:** The number of VF rate zone episodes detected by the ICD.
- **HV Charge**
 - **6 Joule:** The number of times the ICD charged to 6 Joules.
 - **11 Joule:** The number of times the ICD charged to 11 Joules.
 - **16 Joule:** The number of times the ICD charged to 16 Joules.
 - **21 Joule:** The number of times the ICD charged to 21 Joules.
 - **26 Joule:** The number of times the ICD charged to 26 Joules.
 - **31 Joule:** The number of times the ICD charged to 31 Joules.
 - **36 Joule:** The number of times the ICD charged to 36 Joules.
- **Delivered Shock**

- **6 Joule:** The number of 6 Joule shocks delivered by the ICD.
- **11 Joule:** The number of 11 Joule shocks delivered by the ICD.
- **16 Joule:** The number of 16 Joule shocks delivered by the ICD.
- **21 Joule:** The number of 21 Joule shocks delivered by the ICD.
- **26 Joule:** The number of 26 Joule shocks delivered by the ICD.
- **31 Joule:** The number of 31 Joule shocks delivered by the ICD.
- **36 Joule:** The number of 36 Joule shocks delivered by the ICD.
- **Other**
 - **Capacitor Maintenance HV Charge:** The number of 36 Joule charge events that have occurred for capacitor maintenance.
 - **Commanded Shocks Delivered:** The number of commanded shocks delivered by the ICD.
 - **Successful ATP Bursts:** The number of successful anti-tachycardia pacing (ATP) bursts delivered by the ICD.
 - **Unsuccessful ATP Bursts:** The number of unsuccessful anti-tachycardia pacing (ATP) bursts delivered by the ICD.
 - **40 Hz Bandpass Filter Entry:** The number of times the sensing of the ICD switched to the 40 Hz bandpass filter.
 - **Sensing Noise:** The number of sensing noise events detected by the ICD.
 - **Rescue Brady Pace:** The number of rescue bradycardia pacing pulses delivered by the ICD.

3.18.7.3 ICD Statistics Buttons

The ICD Statistics panel has the following buttons:

- **Read:** Reads the latest ICD statistics from the OPTIMIZER Integra CCM-D IPG.
- **Reset:** Resets the ICD statistics stored in the OPTIMIZER Integra CCM-D IPG.

3.18.7.4 Resetting ICD Statistic Counters

To reset the OPTIMIZER Integra CCM-D IPG ICD Statistics counters to zero:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **ICD Statistics** button
5. Tap the **Reset** button at the bottom of the **ICD Statistics** panel

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

3.18.7.5 Displaying the Difference Between Two Rows of ICD Statistical Data

The Optimizer Integra Programmer application features the option of displaying the difference between any two rows of ICD statistical data collected from the OPTIMIZER Integra CCM-D IPG.

To display the difference between any two rows of ICD statistical data:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTlink** button on the OPTlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **ICD Statistics** button
5. Tap once on the box to the left of a particular row of statistical data. One asterisk will appear in the selected box.
6. Double tap on the box to the left of another row of statistical data. Two asterisks will appear in the selected box.

The absolute difference between the two selected rows of statistics will be shown in the dark gray row named **Difference** for each statistics counter.

Zone Interval		Zone Episode	HV Charge		Delivered Shock		Other
Date	SR	MONITOR	VT	FVT	VF	UNSENSED	
Difference		89124	1	7	0	0	24
** 08/11/2022 23:53:31	445530	21	97	31	103	131	
09/11/2022 00:15:11	447000	21	97	31	103	131	
* 10/11/2022 16:31:31	534654	22	104	31	103	155	

Figure 70: ICD Statistics Showing Difference Between Two Selected Rows of Statistics

3.18.8 High Voltage Capacitors Trend

3.18.8.1 Viewing High Voltage Capacitors Trend

To view the High Voltage Capacitors trend stored by the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTlink** button on the OPTlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **Leads** button

If successful, the Programmer will display the High Voltage Capacitors screen.

Note: The date range for the High Voltage Capacitors displayed on the screen may be changed by selecting the arrow to the right of the “1 Month” date range. One may then select the desired date range from the pull-down menu.

3.18.8.2 High Voltage Capacitors Screen

The High Voltage Capacitors screen includes the following information:

- **Model:** Displays device model.
- **IPG SN:** Displays the serial number of the device

- **Charges:** Displays the number of charges stored by the high voltage capacitors at each energy level.
- **Time to 36J Charge:** Displays the amount of time it took each time the high voltage capacitors charged up to 36 J.

Note: Tap on a specific data point on the graph to view the numerical data for that charge.

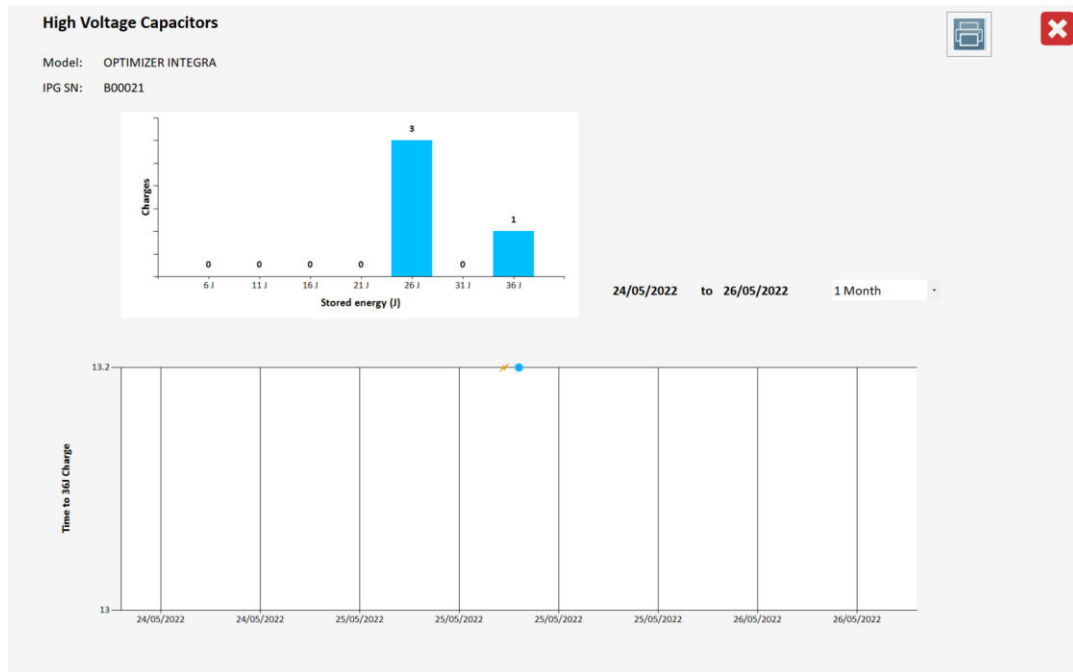


Figure 71: Example of High Voltage Capacitors Screen

3.18.8.3 Creating and Saving a High Voltage Capacitors Trend Report

To create and save a High Voltage Capacitors Trend Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the Printer icon at the top right of the High Voltage Capacitors screen.
3. When the Report Viewer window appears, tap the PDF icon at the top right of the window.
4. If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

To close the High Voltage Capacitors screen, tap the “X” at the top right corner of the High Voltage Capacitors screen.

The High Voltage Capacitors Trend Report is saved in the Reports folder of the USB flash drive. The file name of the High Voltage Capacitors Trend Report has the following format:

HVCapacitors_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created

- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.18.9 QHR Battery Trend

3.18.9.1 Viewing QHR Battery Trend

To view the QHR Battery trend stored by the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTlink** button on the OPTlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Stats and Trends** tab
4. On the **Stats and Trends** panel, tap the **QHR Battery** button

If successful, the Programmer will display the Rechargeable Battery screen.

Note: The date range for the QHR Battery trend displayed on the screen may be changed by selecting the arrow to the right of the “1 Month” date range. One may then select the desired date range from the pull-down menu.

3.18.9.2 QHR Battery Screen

The QHR Battery screen includes the following information:

- **Model:** Displays device model.
- **IPG SN:** Displays the serial number of the device
- **Time Since Implant:** Displays the time since the device was implanted
Note: This time is dependent on the implant date information entered on the Implant Data screen (see section 3.23).
- **Battery Voltage:** Displays the current voltage level of the QHR battery
- **Cell Voltage:** Displays a line graph of daily voltage level of the QHR battery
Note: Tap on a specific data point on the Cell Voltage graph to view the numerical data for that day.

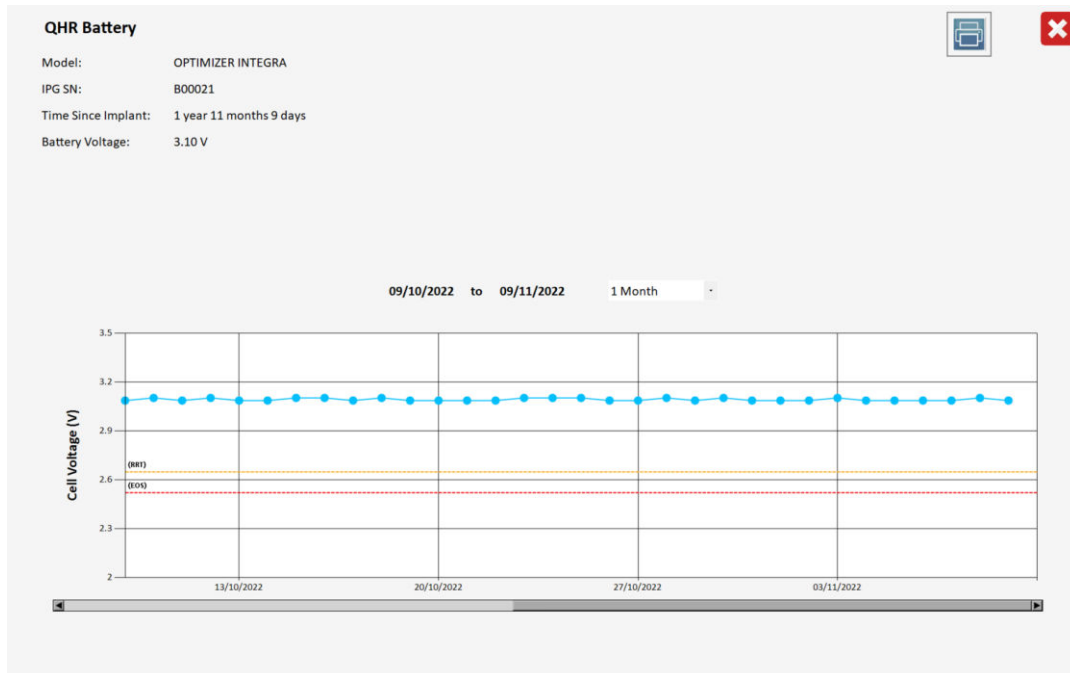


Figure 72: Example of QHR Battery Screen

3.18.9.3 Creating and Saving a QHR Battery Trend Report

To create and save a QHR Battery Trend Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the Printer icon at the top right of the QHR Battery screen.
3. When the Report Viewer window appears, tap the PDF icon at the top right of the window.
4. If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

To close the QHR Battery screen, tap the “X” at the top right corner of the QHR Battery screen.

The QHR Battery Trend Report is saved in the Reports folder of the USB flash drive. The file name of the QHR Battery Trend Report has the following format:

QHRBattery_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.19 Special Modes

3.19.1 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 Integra CCM-D IPG is in **OVO** mode and **CCM Therapy Mode** is set to **ON**.

To start continuous CCM therapy delivery:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **Special Mode** tab
4. On the **Special Mode** panel, tap the **Start Continuous Mode** button

The OPTIMIZER Integra CCM-D IPG will begin delivering continuous CCM therapy delivery for up to one hour.

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

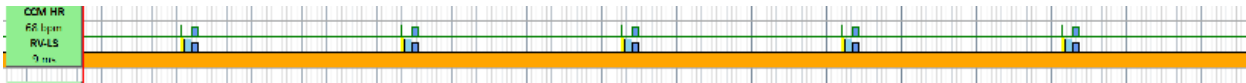


Figure 73: CCM Marker Sub-Pane with CCM Therapy in Continuous Mode

To stop continuous CCM therapy delivery:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **Special Mode** tab
4. On the **Special Modes** panel, tap the **Stop Continuous Mode** button

3.19.2 Medical Procedure

The Medical Procedure mode allows the user to turn OFF the OPTIMIZER Integra CCM-D IPG's CCM and ICD therapy functions for patients scheduled to undergo a medical procedure that will subject them to an environment that may adversely affect the functionality of their implanted device.

To place the OPTIMIZER Integra CCM-D IPG into Medical Procedure mode:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostic** button on the Menu Bar
3. Select the **Special Modes** tab
4. On the **Special Modes** panel, tap the **Start Medical Procedure Mode** button
5. When the confirmatory pop-up window appears, tap **Yes**

If the OPTIMIZER Integra CCM-D IPG has successfully been placed into Medical Mode, the ECG/IEGM/Marker Pane on the Integra Programmer application screen should not display any IEGM signals or markers.

To exit Medical Procedure mode:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. If the pop-up window appears indicating that the device is in Medical Procedure Mode, tap **Close**
3. Tap the **Diagnostic** button on the Menu Bar
4. Select the **Special Modes** tab
5. On the **Special Modes** panel, tap the **Stop Medical Procedure Mode** button
6. When the confirmatory pop-up window appears, tap **Yes**

If the OPTIMIZER Integra CCM-D IPG has successfully exited from Medical Mode, the Integra Programmer application screen should begin displaying the IEGM signals and markers again.

3.20 Defibrillation Testing

WARNING: Make sure cardiac resuscitation equipment is available and functioning before performing Defibrillation Testing!

The Optimizer Integra Programmer application provides the following tools for use in performing Defibrillation Testing.

3.20.1 Induce Arrhythmia

The Induce Arrhythmia function can be used to induce VF, allowing for the testing of ICD functionality. To induce an arrhythmia, the Optimizer Integra Programmer application sends a series of 8 V biphasic pulses at 50 Hz to the heart. The duration of these pulses can be set using the **Duration** setting.

To induce arrhythmia, perform the following steps:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **DFT Testing** tab
4. If needed, change the Induce Arrhythmia Duration parameter
 - a. Tap the numerical value
 - b. Select a value from the **Induce Arrhythmia Duration (s)** parameter window
5. On the **DFT Testing** panel, tap the **Induce Arrhythmia** button
6. When the confirmatory pop-up window appears, tap **Yes Induce Arrhythmia**

The ICD Marker Sub-pane will display the arrhythmia induction in yellow with red markers.

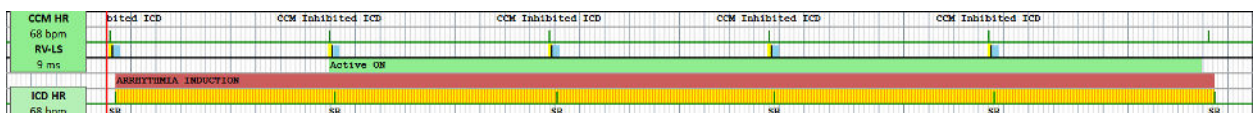


Figure 74: ICD Marker Sub-Pane Showing Arrhythmia Induction

3.20.2 Deliver Pacing

The Deliver Pacing function can be used to deliver VOO pacing pulses to the heart, allowing for the testing of emergency bradycardia pacing functionality of the ICD. The

rate and number of these pacing pulses can be set using the **Rate** and **Number of pulses** settings, respectively.

To deliver VOO pacing, perform the following steps:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **DFT Testing** tab
4. If needed, change the Deliver Pacing parameters
 - a. Tap the numerical value for **Rate**
 - b. Select a value from the **Rate** parameter window
 - c. Tap the numerical value for **Number of Pulses**
 - d. Select a value from the **Number of Pulses (pulses)** parameter window
5. On the **DFT Testing** panel, tap the **Deliver Pacing** button
6. When the confirmatory pop-up window appears, tap **Yes Deliver Pacing**

The ICD Marker Sub-pane will display each pacing pulse in light blue with an upward arrow marker.



Figure 75: ICD Marker Sub-Pane Showing Pacing Pulses

3.20.3 Stat Shock

The Stat Shock function can be used to deliver an emergency 36 J shock, allowing for the testing of the shock delivery functionality of the ICD.

To deliver a Stat Shock, perform the following steps:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostics** button on the Menu Bar
3. Select the **DFT Testing** tab
4. On the **DFT Testing** panel, tap the **Stat Shock** button
5. When the confirmatory pop-up window appears, tap **Yes Deliver 36J Shock**

The Marker Pane will display the shock in gray in the IEGM sub-pane and red in the ICD marker sub-pane.

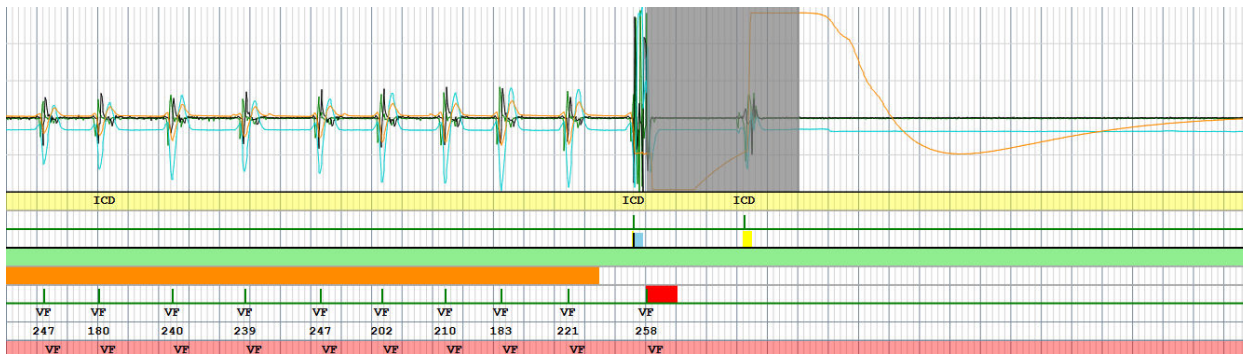


Figure 76: Marker Pane Showing Shock Being Delivered

3.21 Expert Features

The features listed on the Expert Features panel can only be used after entering the correct passcode. To obtain the passcode for the Expert Feature tab, contact your Impulse Dynamics representative.

3.21.1 Blinded Mode Charge

Note: Blinded Mode is to be used only for blinded clinical investigation protocols.

When the OPTIMIZER Integra CCM-D IPG is used for a blinded clinical investigation, the study protocol may stipulate that the OPTIMIZER Integra CCM-D IPG implanted in one group of patients be programmed not to deliver CCM therapy. Since the battery discharge rate of an OPTIMIZER Integra CCM-D IPG programmed to not deliver CCM therapy is significantly less than an OPTIMIZER Integra CCM-D 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 charge feature allows the charging behavior of an OPTIMIZER Integra CCM-D IPG that is not programmed to deliver CCM therapy to mimic the behavior of an OPTIMIZER Integra CCM-D IPG that is programmed to deliver CCM therapy.

3.21.2 IPG Reset

If an OPTIMIZER Integra CCM-D IPG is in Safe Mode, it can be reset using the IPG Reset feature of the Optimizer Integra Programmer application under physician supervision.

To reset the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostic** button on the Menu Bar
3. Select the **Expert Features** tab
4. On the **Expert Features** panel, tap the passcode box, enter the passcode obtained from Impulse Dynamics and then tap **OK**
5. When the **Expert Features** buttons become enabled, tap the **Reset** button below **IPG Reset**

If the OPTIMIZER Integra CCM-D IPG is successfully reset, the CCM Status Pane will show that the CCM Therapy setting for the OPTIMIZER Integra CCM-D IPG is “OOO” and the ICD Status Pane will show that ICD Therapy setting for the OPTIMIZER Integra CCM-D IPG is “Off”, indicating that the device has been set to Standby mode with all therapies off.

3.22 Engineering

The features listed on the Engineering panel can only be used after entering the correct passcode. To obtain the passcode for the Engineering tab, contact your Impulse Dynamics representative.

3.22.1 CCM Log Download

The CCM module of the OPTIMIZER Integra CCM-D IPG keeps a log of any internal events that may occur as well as programming and charging events that occur when interacting with the programmer application or Guardio/Vesta Charger, respectively. This CCM log can be downloaded from the OPTIMIZER Integra CCM-D IPG using the Optimizer Integra Programmer application.

To download the CCM Log:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostic** button on the Menu Bar
3. Select the **Engineering** tab
4. On the **Engineering** panel, tap the passcode box, enter the passcode obtained from Impulse Dynamics and then tap **OK**
5. When the **Engineering** buttons become enabled, tap the **Get CCM Log** button
6. When an **Information** pop-up window appears, tap **Close**

To retrieve the CCM Log from the Intelio Programmer, use the File Exportation application.

3.22.2 ICD Anomaly Log Download

The ICD module of the OPTIMIZER Integra CCM-D IPG keeps a log of any anomalies that may occur during its operation. This ICD Anomaly log can be downloaded from the OPTIMIZER Integra CCM-D IPG using the Optimizer Integra Programmer application.

To download the ICD Anomaly Log:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostic** button on the Menu Bar
3. Select the **Engineering** tab
4. On the **Engineering** panel, tap the passcode box, enter the passcode obtained from Impulse Dynamics and then tap **OK**
5. When the **Engineering** buttons become enabled, tap the **Get ICD Anomaly Log** button
6. When an **Get ICD Anomaly Information** pop-up window appears, tap **Close**

To retrieve the ICD Anomaly Log from the Intelio Programmer, use the File Exportation application.

3.22.3 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 Integra CCM-D IPG, the temperature of the IPG is monitored during the charging process. The temperature limits used by the OPTIMIZER Integra CCM-D IPG when monitoring its temperature are referred to as the Temperature Charge Constants.

To read and set the Temperature Charge Constants:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostic** button on the Menu Bar
3. Select the **Engineering** tab
4. On the **Engineering** panel, tap the passcode box, enter the passcode obtained from Impulse Dynamics and then tap **OK**
5. When the **Engineering** buttons become enabled, tap the **Temperature Charge Constants** button
6. When the **Temperature Charge Constants** window appears, tap the **Read** button
7. Tap the up/down arrows next to any listed charge constant parameter to change its value
8. Tap the **Set** button to program the changes into the OPTIMIZER Integra CCM-D IPG
9. Tap the X at the top right corner of the **Temperature Charge Constants** window to close it

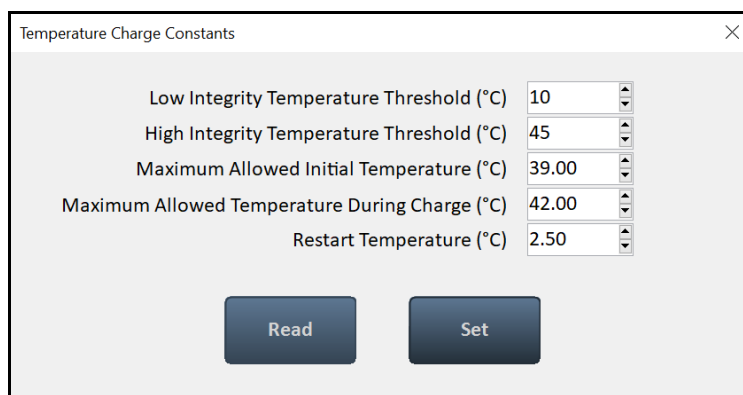


Figure 77: Temperature Charge Constants Window

3.23 Implant Data

Information pertaining to the implant of the system can be entered and stored in the OPTIMIZER Integra CCM-D. This information is displayed by the Optimizer Integra Programmer application whenever the Intelio Programmer is used to interrogate the OPTIMIZER Integra CCM-D IPG.

To edit the implant data:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Diagnostic** button on the Menu Bar
3. Select the **Implant Data** tab

4. On the **Implant Data** panel, tap the **Edit implant data** button
5. When the **Implant Data** window appears, tap a field to display the virtual keyboard and then proceed with setting the implant date and entering the implant data in the fields provided.

Note: The Implant Date is in the following format:

DD/MM/YYYY

Where:

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

Figure 78: Implant Data Window

6. When the data entry has been completed, tap the **Set Implant Data in IPG** button
- The fields on the **Implant Data** panel should now be populated with the implant information.

3.24 Patient Alerts Settings

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

Note: For a detailed description of each Call Doctor Alert Code displayed by the Guardio/Vesta Charger, see the Guardio/Vesta Charger IFU.

3.24.1 Alert Delivery Mode

The Alert Delivery Mode allows the user to set if and when audible tones are emitted by the Guardio/Vesta Charger whenever it displays a Patient Alert received from the OPTIMIZER Integra CCM-D IPG.

To set the Alert Delivery Mode:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **Alert Delivery Mode** button

The **Alert Delivery Mode** parameter window will display the following options for this parameter:

- **Never:** Audible tones are never emitted by the Guardio/Vesta Charger when it displays a Patient Alert received from the OPTIMIZER Integra CCM-D IPG

- **Always:** Audible tones are always emitted by the Guardio/Vesta Charger when it displays a Patient Alert received from the OPTIMIZER Integra CCM-D IPG
- **Scheduled:** Audible tones are emitted by the Guardio/Vesta Charger only when it displays a Patient Alert received from the OPTIMIZER Integra CCM-D 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 active, allowing the user to set these parameters.

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

1. On the **Patient Alerts** panel, select the **Patient Alert Start Time Hour** parameter
2. Select one of the parameter choices shown in the **Patient Alert Start Time Hour (h)** parameter window
3. On the **Patient Alerts** panel, select the **Patient Alert Start Time Minute** parameter
4. Select one of the parameter choices shown in the **Patient Alert Start Time Minute (m)** parameter window
5. On the **Patient Alerts** panel, select the **Patient Alert End Time Hour** parameter
6. Select one of the parameter choices shown in the **Patient Alert End Time Hour (h)** parameter window
7. On the **Patient Alerts** panel, select the **Patient Alert End Time Minute** parameter
8. Select one of the parameter choices shown in the **Patient Alert End Time Minute (m)** parameter window
9. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.2 Charger Battery Low Alert

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

To set the Charger Battery Low alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **Charger Battery Low** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.3 Charger Failure Alert

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

To set the Charger Failure alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site

- b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **Charger Failure** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.4 Rechargeable Battery Low Alert

The **Rechargeable Battery Low** alert is triggered whenever the OPTIMIZER Integra CCM-D IPG's rechargeable battery voltage drops to 3.5 V.

To set the Rechargeable Battery Low alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **Rechargeable Battery Low** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.5 Battery Recharge Reminder Alert

The Guardio/Vesta Charger keeps a record of OPTIMIZER Integra CCM-D IPG charging events. This record is used to determine the number of days since it last charged the OPTIMIZER Integra CCM-D IPG.

The Battery Recharge Reminder alert is triggered if the number of days since the Guardio/Vesta Charger last charged the OPTIMIZER Integra CCM-D IPG exceeds the Battery Recharge Reminder days parameter value set by the Optimizer Integra Programmer application.

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

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **Battery Recharge Reminder** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. If enabled, the default (or previously programmed) value for the Battery Recharge Reminder Days parameter will now appear next to the **Battery Recharge Reminder**
6. If required, change the Battery Recharge Reminder Days parameter
 - a. Tap the numerical parameter value
 - b. Select a value from the **Battery Recharge Reminder Days** parameter window

7. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.6 Long Time Without Communicating With The IPG Alert

The Guardio/Vesta Charger keeps a record of the communication events with the OPTIMIZER Integra CCM-D IPG. This record is used to determine the number of days since its last successful communication event with the OPTIMIZER Integra CCM-D IPG.

The Long time without communicating with the IPG alert is triggered if the number of days since the Guardio/Vesta Charger successfully communicated with the OPTIMIZER Integra CCM-D IPG exceeds the Long time without communicating with the IPG days parameter value set by the Optimizer Integra Programmer application.

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

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **Long time without communicating with the IPG** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. If enabled, the default (or previously programmed) value for the Long time without communicating with the IPG days parameter will now appear next to the **Long time without communicating with the IPG**
6. If required, change the Long time without communicating with the IPG days parameter
 - a. Tap the numerical value
 - b. Select a value from the **Long time without communicating with the IPG days** parameter window
7. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.7 Long Time Without Transmitting Data To The Remote Monitor

The Long Time without transmitting data to the remote monitor alert is not currently applicable and should be disabled.

3.24.8 Minimum CCM% Alert

The OPTIMIZER Integra CCM-D IPG maintains a record of sensed events and CCM trains delivered during each scheduled CCM delivery period. This record is used to determine the percentage of CCM therapy pulses delivered during this period.

The Minimum CCM% alert is triggered if the CCM therapy percentage averaged in the last three days is below the Minimum CCM% Percentage setting.

To set the Minimum CCM% alert and set its % value:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab

4. On the **Patient Alerts** panel, tap the **Minimum CCM%** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. If enabled, the default (or previously programmed) value for the Minimum CCM% percentage parameter will now appear next to the **Minimum CCM%**
6. If required, change the Minimum CCM% Percentage parameter
 - a. Tap the numerical parameter value
 - b. Select a value from the **Minimum CCM% (%)** parameter window
7. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.9 Maximum Lead Impedance Change Alert

The OPTIMIZER Integra CCM-D IPG is configured to automatically conduct an impedance measurement of the ventricular leads every day at midnight whenever it is set to OVO-LS-CCM mode. These daily impedance measurements of the ventricular leads are collected and used by the OPTIMIZER Integra CCM-D IPG to monitor the ventricular leads for changes in impedance.

Note: When the OPTIMIZER Integra CCM-D IPG is set to OVO-LS-CCM mode, the daily impedance measurement of the ventricular leads is conducted even if the **CCM Therapy Mode** is set to **OFF**.

The Maximum Lead Impedance Change alert is triggered if either one of the following conditions occurs:

- The last impedance measurement was lower than 50Ω or greater than 2000Ω
- 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 Percentage (%) setting.

Note: When the OPTIMIZER Integra CCM-D IPG is first programmed to OVO-LS-CCM mode, the lead impedance buffer will initially be empty. When the number of lead impedance measurements in the buffer is three or less, no lead impedance measurement comparison is made and thus the triggering of this alert for this cause would not occur.

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

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **Maximum lead impedance change** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. 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**
6. If required, change the Maximum lead impedance change percentage parameter
 - a. Tap the numerical parameter value
 - b. Select a value from the **Maximum lead impedance change Percentage (%)** parameter window
7. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.10 CCM Not Sensing/Noise Alert

The CCM Not Sensing/Noise alert is triggered if either one of the following conditions occurs:

- The CCM module of the OPTIMIZER Integra CCM-D IPG did not sense an RV event for 17 consecutive cycles (minimum of 30 seconds)
- 1000 cycles of RV noise detected by the CCM module of the OPTIMIZER Integra CCM-D IPG in 1 day (minimum of 30 minutes of noisy cycles)

To set the CCM Not Sensing/Noise alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **CCM Not Sensing/Noise** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.11 CCM Therapy Suspended Alert

The CCM therapy suspended alert is triggered whenever CCM therapy is suspended in the OPTIMIZER Integra CCM-D IPG for any reason.

To set the CCM therapy suspended alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **CCM therapy suspended** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.12 CCM Safe Mode Alert

The CCM Safe Mode alert is triggered when the CCM module of the OPTIMIZER Integra CCM-D IPG has been placed into Safe Mode for any reason.

To set the CCM Safe Mode alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **CCM Safe Mode** toggle switch to enable (**ON**) or disable (**OFF**) the alert

5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.13 ICD Battery RRT Alert

The ICD Battery RRT alert is triggered when the voltage of the high-rate battery in the OPTIMIZER Integra CCM-D IPG drops to 2.65 V (± 5 mV).

To set the ICD Battery RRT alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **ICD Battery RRT** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.14 ICD Not Sensing Alert

The ICD Not Sensing alert is triggered if either one of the following conditions occurs:

- No R-wave is detected by the ICD module of the OPTIMIZER Integra CCM-D IPG for 5 or more consecutive seconds
- 30 minutes of escape timeouts are accumulated by the ICD module of the OPTIMIZER Integra CCM-D IPG in a 24-hour calendar day (a 24-hour calendar day starts at 00:00 in ICD time and ends at 00:00 of next calendar day)

To set the ICD Not Sensing alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **ICD Not Sensing** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.15 ICD Battery EOS Alert

The ICD Battery EOS alert is triggered when the voltage of the high-rate battery in the OPTIMIZER Integra CCM-D IPG drops to 2.52 V (± 5 mV).

To set the ICD Battery EOS alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **ICD Battery EOS** toggle switch to enable (**ON**) or disable (**OFF**) the alert

5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.16 HV Lead Impedance Not OK Alert

The OPTIMIZER Integra CCM-D IPG is configured to automatically conduct a coil lead impedance measurement every day at midnight whenever the ICD Mode is set to **ON**. These daily coil lead impedance measurements are collected and used by the OPTIMIZER Integra CCM-D IPG to monitor the coil lead for changes in impedance.

The HV Lead Impedance Not OK alert is triggered whenever the measured daily Coil Lead impedance (CLI) is outside the expected range of 125 Ω to 1600 Ω .

To set the HV Lead Impedance Not OK alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **HV Lead Impedance Not OK** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.17 ICD Safe Mode Alert

The ICD Safe Mode alert is triggered whenever the ICD module of the OPTIMIZER Integra CCM-D IPG has been placed into Safe Mode for any reason.

To set the ICD Safe Mode alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **ICD Safe Mode** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.18 ICD Anomaly Alert

The ICD Anomaly alert is triggered whenever the OPTIMIZER Integra CCM-D IPG detects the occurrence of a reset or an anomalous condition in its ICD module.

To set the ICD Anomaly alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel, tap the **ICD Anomaly** toggle switch to enable (**ON**) or disable (**OFF**) the alert

5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.19 Detected VF Event Alert

The Detected VF Event alert is triggered whenever the ICD module of the OPTIMIZER Integra CCM-D IPG detects the occurrence of a VF zone episode event.

To set the Detected VF Event alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel under the column **High-Priority Alert Delivered by Charger**, tap the **Detected VF Event** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.20 Detected FVT Event Alert

The Detected FVT Event alert is triggered whenever the ICD module of the OPTIMIZER Integra CCM-D IPG detects the occurrence of an FVT zone episode event.

To set the Detected FVT Event alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel under the column **High-Priority Alert Delivered by Charger**, tap the **Detected FVT Event** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.21 Detected VT Event Alert

The Detected VT Event alert is triggered whenever the ICD module of the OPTIMIZER Integra CCM-D IPG detects the occurrence of a VT zone episode event.

To set the Detected VT Event alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel under the column **High-Priority Alert Delivered by Charger**, tap the **Detected VT Event** toggle switch to enable (**ON**) or disable (**OFF**) the alert

5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.22 Detected Monitor Event Alert

The Detected Monitor Event alert is triggered whenever the ICD module of the OPTIMIZER Integra CCM-D IPG detects the occurrence of a monitor zone episode event.

To set the Detected Monitor Event alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel under the column **High-Priority Alert Delivered by Charger**, tap the **Detected Monitor Event** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.23 Delivered HV Shock Alert

The Delivered HV Shock alert is triggered whenever the ICD module of the OPTIMIZER Integra CCM-D IPG delivers a high-voltage (HV) shock.

To set the Delivered HV Shock alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel under the column **High-Priority Alert Delivered by Charger**, tap the **Delivered HV Shock** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.24 Delivered ATP Alert

The Delivered ATP alert is triggered whenever the ICD module of the OPTIMIZER Integra CCM-D IPG delivers antitachycardia pacing (ATP).

To set the Delivered ATP alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel under the column **High-Priority Alert Delivered by Charger**, tap the **Delivered ATP** toggle switch to enable (**ON**) or disable (**OFF**) the alert

5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.24.25 Delivered Rescue Brady Pacing Alert

The Delivered Rescue Brady Pacing alert is triggered whenever the ICD module of the OPTIMIZER Integra CCM-D IPG delivers rescue bradycardia pacing.

To set the Delivered Rescue Brady Pacing alert:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Patient Alerts** tab
4. On the **Patient Alerts** panel under the column **High-Priority Alert Delivered by Charger**, tap the **Delivered Rescue Brady Pacing** toggle switch to enable (**ON**) or disable (**OFF**) the alert
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.25 Activity

3.25.1 Activity Sensor Setup

The OPTIMIZER Integra CCM-D 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:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Activity** tab
4. On the **Activity** panel, tap the **Activity Sensor Setup** button
5. When the Activity Sensor Setup window appears, have the patient stand upright and then tap the **Vertical** button
6. Have the patient assume a supine position and then tap the **Horizontal** button
7. If successful, a pop-up message will be displayed indicating that the calibration was successfully saved. Tap the **Close** button
8. Tap the red “X” at the top right of the Activity Sensor Setup window

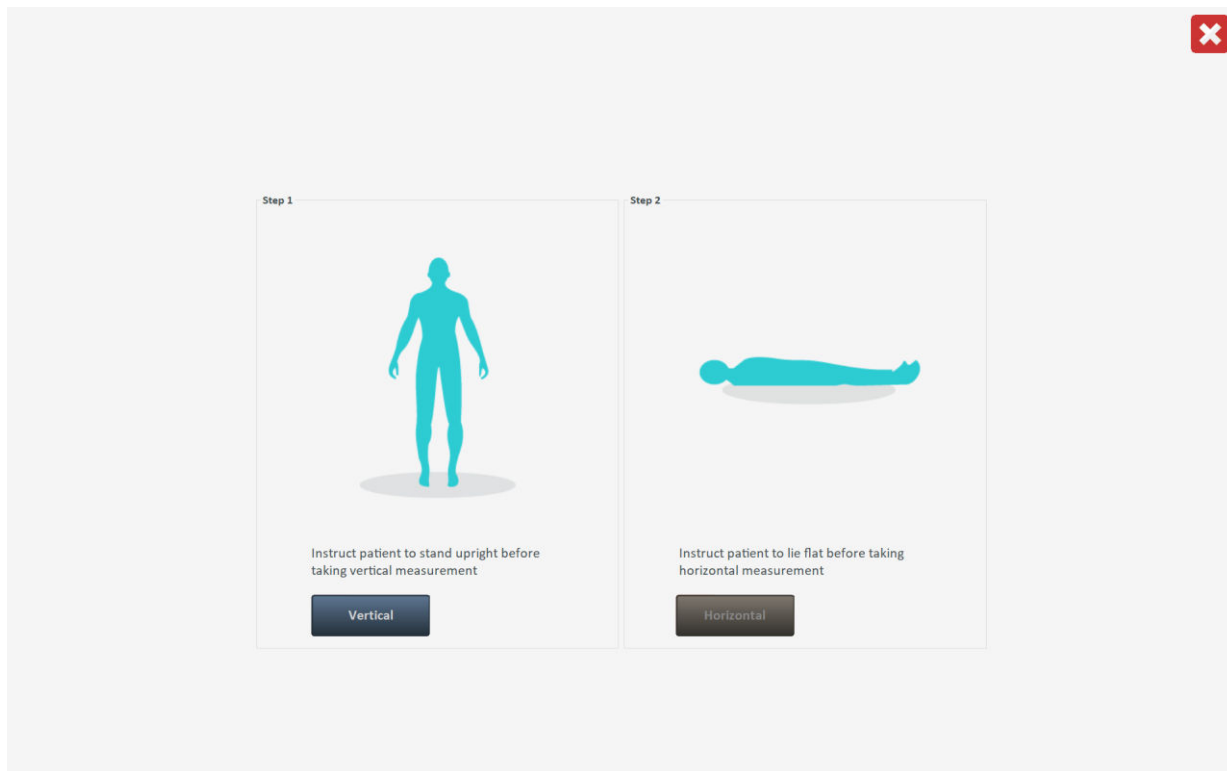


Figure 79: Activity Sensor Screen

3.25.2 Activity Tracking

Information about a patient's activity level can be obtained by using the Activity Tracking data collected and stored by the OPTIMIZER Integra CCM-D 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:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Activity** tab
4. On the **Activity** panel, tap the **Activity Tracking** toggle switch 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.

3.25.2.1 Accelerometer

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

To set the Accelerometer:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site

- b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Activity** tab
4. On the **Activity** panel, tap the **Activity Tracking** toggle switch to enable (**ON**) the setting
5. Tap the **Accelerometer** toggle switch to enable (**ON**) or disable (**OFF**) the setting
6. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.25.2.2 Posture

The **Posture** setting controls the use of the built-in accelerometer in the OPTIMIZER Integra CCM-D IPG to collect information about the patient's posture (e.g., lying vs. standing).

To set the Posture:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Activity** tab
4. On the **Activity** panel, tap the **Activity Tracking** toggle switch to enable (**ON**) the setting
5. Tap the **Posture** toggle switch to enable (**ON**) or disable (**OFF**) the setting
6. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.25.2.3 HRV

The **HRV** setting controls the use of the OPTIMIZER Integra CCM-D IPG to collect information about the patient's heart rate variability (HRV). HRV is calculated using Root Mean Square of Successive Differences (RMSSD).

To set the HRV:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Activity** tab
4. On the **Activity** panel, tap the **Activity Tracking** toggle switch to enable (**ON**) the setting
5. Tap the **HRV** toggle switch to enable (**ON**) or disable (**OFF**) the setting
6. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with the new parameter setting

3.26 Clock Settings for the OPTIMIZER Integra CCM-D IPG

The date and time of the OPTIMIZER Integra CCM-D IPG is maintained by an internal clock and is used by the following IPG operations:

- The delivery of CCM therapy in accordance with the programmed CCM therapy scheduling parameters
- The completion of daily and weekly lead measurements (lead impedance, IEGM amplitudes, etc...)
- The monitoring and collection of Activity, Rechargeable Battery, Leads, QHR Battery, and Alerts trends data
- The assignment of a date and time to logged events
- Updating the date and time in the Guardio/Vesta Charger

3.26.1 Reading the OPTIMIZER Integra CCM-D IPG Time

The real-time clock in the OPTIMIZER Integra CCM-D 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 Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Clock** tab
4. On the **Clock** panel, tap the **Read IPG Clock** button

3.26.2 Setting the OPTIMIZER Integra CCM-D IPG Real Time Clock

The real-time clock of the OPTIMIZER Integra CCM-D IPG can be set by synchronizing it to the programmer's clock or by manually changing the clock values.

3.26.2.1 Synchronize IPG Clock to Programmer Clock

To synchronize the clock of the OPTIMIZER Integra CCM-D IPG to the programmer's clock:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Clock** tab
4. On the **Clock** panel, tap the **Read IPG Clock** button
5. Tap the **Synchronize IPG Clock To Programmer Clock** button

3.26.2.2 Set the IPG Clock Manually

To manually set the date and time of the OPTIMIZER Integra CCM-D IPG:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Clock** tab
4. On the **Clock** panel, tap the **Read IPG Clock** button

5. When the IPG's Local time window appears, tap the date or time value of the IPG's Date and Time to be changed
6. When the selected value is highlighted in blue, use the arrow to the right of the IPG's Date and Time to change the value as needed
7. Tap the **Set IPG Clock** button

3.27 Clock Settings for the Intelio Programmer

The Optimizer Integra Programmer application features the ability to change the clock and the time zone of the Intelio Programmer.

Note: The clock and the time zone of the Intelio Programmer may also be set while the Optimizer Integra Programmer application is linked with an OPTIMIZER Integra CCM-D IPG. If either one is changed while the programmer application is linked with a device, the clock of the OPTIMIZER Integra CCM-D IPG will need to be re-synchronized to the programmer's clock after the clock of the Intelio Programmer.

3.27.1 Setting the Programmer Clock

To manually set the date and time of the Intelio Programmer:

1. If necessary, boot up the Optimizer Integra Programmer application
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Clock** tab
4. On the **Clock** panel, tap the date or time value of the Programmer's Date and Time to be changed
5. When the selected value is highlighted in blue, use the arrow to the right of the Programmer's Date and Time to change the value as needed
6. Tap the **Set programmer clock** button
7. Verify that a Programmer Clock pop-up window appears stating that the Programmer Clock updated correctly
8. Tap **Close** to close the pop-up window

The Programmer's Date and Time should now display the new date and time.

3.27.2 Setting the Programmer Time Zone

To set the time zone of the Intelio Programmer:

1. If necessary, boot up the Optimizer Integra Programmer application
2. Tap the **Preferences** button on the Menu Bar
3. Select the **Clock** tab
4. On the **Clock** panel, tap the current time zone and then select the desired time zone from the drop-down menu (if the desired time zone is not shown, place the stylus on the scroll bar to the right of the drop-down menu and move it vertically across the screen until the desired time zone is found)

Once the new time zone is selected, the Programmer's Date and Time will automatically be updated to the date and time of the selected time zone. In addition, the field below the Time Zone will indicate if the chosen time zone is currently in Standard Time or Daylight Saving Time.

3.28 Print/File

The Optimizer Integra Programmer application features the ability to print reports, export data, and perform database activities.

3.28.1 Printing Report

The Optimizer Integra Programmer application features the ability to print the following types of reports:

- **Summary Report**
- **Complete Report**
- **Parameters Report**

3.28.1.1 Summary Report

The Summary Report for the OPTIMIZER Integra CCM-D IPG includes the following information:

- Contents of Summary tab
- Marker Signals
- Parameters
- Statistics

To create a Summary Report:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Follow-up** button on the Menu Bar
3. Select the **Summary** tab
4. On the **Summary** panel, tap the **Print Summary Report** button

To save a PDF copy of the Summary Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the PDF icon at the top right-hand corner of the Report Viewer window to save a PDF file of the Summary Report.

If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

The Summary Report is saved in the Reports folder of the USB flash drive. The file name of the Summary Report has the following format:

SummaryReport_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.28.1.2 Complete Report

The Complete Report for the OPTIMIZER Integra CCM-D IPG includes the following information:

- Contents of Summary tab
- Marker Signals

- Parameters
- Statistics
- Alerts Trend Report
- Rechargeable Battery Trend Report
- Daily Activity Trends Report
- Activity Per Hour Trends Report
- Leads Trend Report
- High Voltage Capacitors Trend Report
- QHR Battery Trend Report
- Episodes

To create a Complete Report:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Tools** button on the Menu Bar
3. Select the **Print/File** tab
4. On the **Print/File** panel, tap the **Complete Report** button
5. When the Complete Report Generation pop-up window appears, tap **Yes**

To save a PDF copy of the Complete Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the PDF icon at the top right-hand corner of the Report Viewer window to save a PDF file of the Complete Report.

If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

The Complete Report is saved in the Reports folder of the USB flash drive. The file name of the Complete Report has the following format:

CompleteReport_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.28.1.3 Parameters Report

The Parameters Report is a printout of the current parameter settings programmed into the OPTIMIZER Integra CCM-D IPG.

To create a Parameters Report:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Tools** button on the Menu Bar
3. Select the **Print/File** tab
4. On the **Print/File** panel, tap the **Parameters Report** button

To save a PDF copy of the Parameters Report:

1. Insert a USB flash drive into the USB port on the left side of the Intelio programmer tablet PC
2. Tap the PDF icon at the top right-hand corner of the Report Viewer window to save a PDF file of the Parameters Report.

If successful, a pop-up window will appear indicating that the report was saved in the USB drive. Tap **Close** to close the pop-up window.

The Parameters Report is saved in the Reports folder of the USB flash drive. The file name of the Parameters Report has the following format:

ParametersReport_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.28.2 Export Data

The Optimizer Integra Programmer application features the ability to Export Statistics in the form of a CSV file.

To Export Statistics:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Tools** button on the Menu Bar
3. Select the **Print/File** tab
4. On the **Print/File** panel, tap the **Export Statistics** button

If successful, a pop-up window will appear indicating that the Export statistics was completed. Tap **Close** to close the pop-up window.

The Statistics file is saved in the Statistics folder of the USB flash drive. The file name of the Statistics file has the following format:

Statistics_NNNNNN_YYYYMMDDhhmmss

Where:

- NNNNNN = serial number of device
- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

3.28.3 Database

The Optimizer Integra Programmer application features the ability to backup and restore its database.

To backup the database:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Tools** button on the Menu Bar
3. Select the **Print/File** tab
4. On the **Print/File** panel, tap the **DB Log Backup** button

If successful, a pop-up window will appear indicating that the backup was completed. Tap **Close** to close the pop-up window.

To restore the database:

1. If necessary, initiate a link with OPTIMIZER Integra CCM-D IPG
 - a. Place (or replace, if necessary) the Intelio Programming Wand over the OPTIMIZER Integra CCM-D IPG implant site
 - b. Tap the **Start OPTIlink** button on the OPTIlink Session Pane
2. Tap the **Tools** button on the Menu Bar
3. Select the **Print/File** tab
4. On the **Print/File** panel, tap the **DB Log Restore** button

If successful, a pop-up window will appear indicating that the backup was completed. Tap **Close** to close the pop-up window.

3.29 Standards

Baseline parameter combinations are useful in certain clinical situations. With the Optimizer Integra Programmer application, the user is able to create and save these baseline parameter combinations as a *standard* (also known as *user presets*) file on the Intelio Programmer. Then when needed, this saved standard file can be loaded onto the Optimizer Integra Programmer application and then programmed into an OPTIMIZER Integra CCM-D IPG.

3.29.1 Saving a Standard File

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

1. Tap the **Tools** button on the Menu Bar
2. Select the **Standards** tab
3. On the **Standards** panel, tap the **Save Program** button
4. When the **Save Standard** window appears, enter a file name for the standard to be saved and then tap **Save**

3.29.2 Loading a Standard File

Warning: Loading a User Presets standard file may set certain parameters to undesired values.

To load a standard (.mips) file:

1. Tap the **Tools** button on the Menu Bar
2. Select the **Standards** tab
3. On the **Standards** panel, tap the **Load Program** button
4. When the **Load Standard** window appears, select the file to be loaded, and then tap **Open**
5. Tap the blinking **Program** button on the Programming Buttons Pane to load the OPTIMIZER Integra CCM-D IPG with a new set of parameters from the standard file

When parameter values are loaded from a standard file but not yet programmed into the OPTIMIZER Integra CCM-D 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.

3.30 Programmer Log

The Optimizer Integra Programmer application keeps a log of all the interactions that occur between the programmer application and an OPTIMIZER Integra CCM-D IPG. This record can be used as an index to provide quick access to specific data retrieved from the OPTIMIZER Integra CCM-D IPG during its interactions with the programmer application.

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

- The log file for a particular OPTIMIZER Integra CCM-D IPG is created when the device is interrogated for the first time.
- Each communications event that occurs between the Optimizer Integra Programmer application and the OPTIMIZER Integra CCM-D IPG appears in the **Programmer Log**, together with the date and time of each interaction.
- More information regarding a communication event may be obtained by double-tapping 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 Integra Programmer application represent the parameter values programmed into the OPTIMIZER Integra CCM-D IPG when the selected communication event occurred.
 - If an event such as Get Battery Capacity is chosen, the data shown is the value associated with the event 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 entirety of the log, double tap on the gray bar to the right of the Programmer Log, keeping the stylus in contact with the gray bar with the second tap. 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 DEVICE SETTINGS FOR INTEGRA-D STUDY

The following device parameter settings are to be used for the Integra-D study:

Note: The parameter values listed below assume the presence of normal operating conditions.

CCM THERAPY

Parameter Name	Value
Mode	OVO-LS-CCM
CCM Therapy Mode	ON
Timed	5 hs/day
CCM Magnet Mode	Off 1 day
Extend on low CCM%	ON

CCM SCHEDULE

Parameter Name	Value
Start Time	00:00
End Time	23:59

CCM SENSING

Parameter Name	Value
Ventricle 1 Sensitivity	(set using OPTIset or adjust setting as needed)
Ventricle 1 Polarity (CCM only)	Bipolar
Ventricle 2 Sensitivity	(set using OPTIset or adjust setting as needed)
Ventricle 2 Polarity (CCM only)	Bipolar

V REFRACTORY

Parameter Name	Value
Post-V RV Refractory Period	(adjust setting as needed)

CCM INHIBIT

Parameter Name	Value
CCM Inhibit Cycles	1 beat
Tracking	110 bpm
After ATP	24 hours
After HV Shock	24 hours

TIMING ALGORITHM

Parameter Name	Value
LS Assignment	(set using OPTIset or adjust setting as needed)
LS Alert Start	(set using OPTIset or adjust setting as needed)
LS Alert Width	(set using OPTIset or adjust setting as needed)

LS BLANKING REFRACTORIES

Parameter Name	Value
Pre RV LS Refractory Period	(adjust setting as needed)
Post RV LS Refractory Period	(adjust setting as needed)
Post LS Refractory Period	(adjust setting as needed)

CCM TRAIN

Parameters Name	Value
CCM Train Delay	(set using OPTIset or adjust setting as needed)
CCM Amplitude	7.5 V (adjust as needed to prevent sensation)
Number of Biphasic Pulses	2
Balancing	40 ms
First Phase Polarity	(adjust setting as needed)
Phase Duration	5.13 ms
Interval	(adjust setting as needed)
CCM Channels	(adjust setting as needed)

ICD GENERAL

Parameters Name	Value
ICD Mode	ON
Sense Slope Filter	ON or physician discretion
Long/Short Filter	OFF or physician discretion
Onset	ON or physician discretion
Onset (Δ rate)	80% or physician discretion
Morphology Threshold Percentage	N/A
ICD Highest Sensitivity	0.3 mV or physician discretion
Conduction Velocity History	N/A
EHR (Timeout)	OFF or physician discretion
Pre-trigger EGM Recording	ON
Stored EGM Waveform Source	Bipolar or physician discretion

ICD DETECTION

Note: ICD Detection parameter values must be programmed in accordance with the INTEGRA-D Clinical Trial Protocol.

Parameters Name	Category	Value
Zone	Monitor	ON
	VT	OFF unless secondary indication present
	FVT	ON
	VF	ON
Rate [Interval]	Monitor	175 bpm [343 ms] – unless VT zone enabled, then physician discretion
	VT	OFF – unless VT zone enabled, then physician discretion
	FVT	190 bpm [316 ms]
	VF	250 bpm [240 ms]
Binning	Monitor	Extended (30 of 40)
	VT	OFF – unless VT zone enabled, then Extended (30 of 40)
	FVT	Extended (30 of 40)
	VF	Regular (18 of 24)
Stability (Δ variability)	VT	OFF – unless VT zone enabled, then ON
	FVT	ON
Stability Window	VT	OFF – unless VT zone enabled, then 70 ms or physician discretion
	FVT	70 ms or physician discretion
AF gap	VT	OFF – unless VT zone enabled, then ON or physician discretion
	FVT	ON or physician discretion
AF Gap threshold	VT	OFF – unless VT zone enabled, then 150 ms or physician discretion
	FVT	150 ms or physician discretion
AF-Gap persistence intervals	VT	OFF – unless VT zone enabled, then 20 cycles or physician discretion
	FVT	20 cycles or physician discretion
Conduction Velocity	VT	OFF
	FVT	OFF
Morphology Binning	VT	OFF
	FVT	OFF
Morphology Binning Count	VT	OFF
	FVT	OFF

ICD THERAPY (General)

Note: ICD Therapy parameter values must be programmed in accordance with the INTEGRA-D Clinical Trial Protocol.

Parameters Name	Value
Magnet Mode	Therapy OFF when applied
Shock Waveform	Biphasic
Shock Waveform Polarity	Positive or physician discretion
Inverting Shock Polarity	ON or physician discretion
Rescue Brady Pacing	OFF or physician discretion
Post-Shock Brady	ON
Pacing Duration	60 s or physician discretion
ATP Initial Train	8 pulses or physician discretion
ATP Start from last successful	ON or physician discretion
ATP R-S1 (%RR)	90% or physician discretion

ICD THERAPY (Zone-Specific)

Note: ICD Therapy parameter values must be programmed in accordance with the INTEGRA-D Clinical Trial Protocol.

Parameters Name	Category	Value
Zone	VT	OFF unless secondary indication present
	FVT	ON
	VF	ON
HV Shocks	VT	OFF – unless VT zone enabled, then 1 shock at 26 J and 3 shocks at 36 J (total of 4 shocks)
	FVT	4 shocks at 36 J
	VF	6 shocks at 36 J
Therapy Delay	VT	OFF – unless VT zone enabled, then 30 s or physician discretion
	FVT	10 s or physician discretion
ATP Bursts	VT	OFF – unless VT zone enabled, then 2 ATP bursts
	FVT	1 ATP burst

LOW-PRIORITY ALERTS

Parameters Name	Value
Alert Delivery Mode	Scheduled
Alert Delivery Mode Start Time, End Time	09:00, 21:00
Charger Battery Low	ON
Charger Failure	ON
Rechargeable Battery Low	ON
Battery Recharge Reminder	ON
Battery Recharge Reminder days	10 days
Long time without communicating with the IPG	ON
Long time without communicating with the IPG days	3 days
Long time without transmitting data to the remote monitor	OFF
Long time without transmitting data to the remote monitor days	N/A
Minimum CCM%	ON
Minimum CCM% Percentage	70%
Maximum lead impedance change	ON
Maximum lead impedance change Percentage	50%
CCM Not Sensing/Noise	ON
CCM Therapy Suspended	ON
CCM Safe Mode	ON
ICD battery RRT	ON
ICD Not sensing	ON
ICD battery EOS	ON
HV lead impedance not OK	ON
ICD Safe Mode	ON
ICD Anomaly	ON

HIGH-PRIORITY ALERTS

Parameters Name	Value
Detected VF Event	ON
Detected FVT Event	ON
Detected VT Event	ON
Detected Monitor Event	ON
Delivered HV Shock	ON
Delivered ATP	ON
Delivered Rescue Brady Pacing	ON

5.0 FILE EXPORTATION

The Intelio Programmer includes an application that allows a user to export OPTIMIZER Integra CCM-D and files generated by their respective programmer applications onto a USB flash drive. The application creates a zip file on the USB flash drive containing the folders and files selected for export. The name of the zip file has the following format:

Exported_Data_YYYYMMDD_hhmmss

Where:

- YYYY = year the file was created
- MM = month the file was created
- DD = day the file was created
- hh = hour the file was created
- mm = minute the file was created
- ss = second the file was created

To export files:

1. On the left-hand side of the Intelio Programmer tablet PC, push the flap covering the USB ports towards the back of the tablet PC to unlock it and then fold the flap outwards.
2. Insert a USB flash drive into one of the two USB ports on the Intelio Programmer tablet PC.
3. When the Password pop-up window appears, enter the password *rfgt433wqa* and then tap **OK**.
4. Tap the “+” next to each folder checkbox to view the contents of each folder.
5. Select the check box to the left of each folder or file to add it to the list of files to be exported to the USB flash drive. **See Figure 80.**

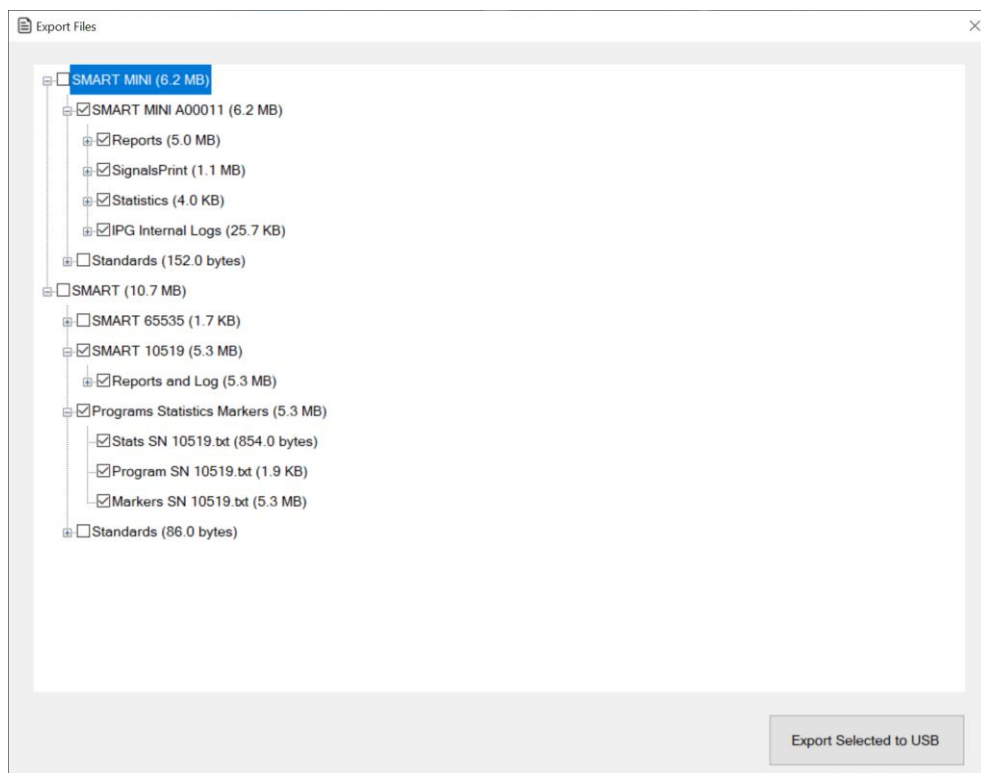


Figure 80: Example of Export File Screen

6. Tap the **Export Selected to USB** button
7. The message “Data exported successfully” will appear when data exportation has been completed. **See Figure 81.**

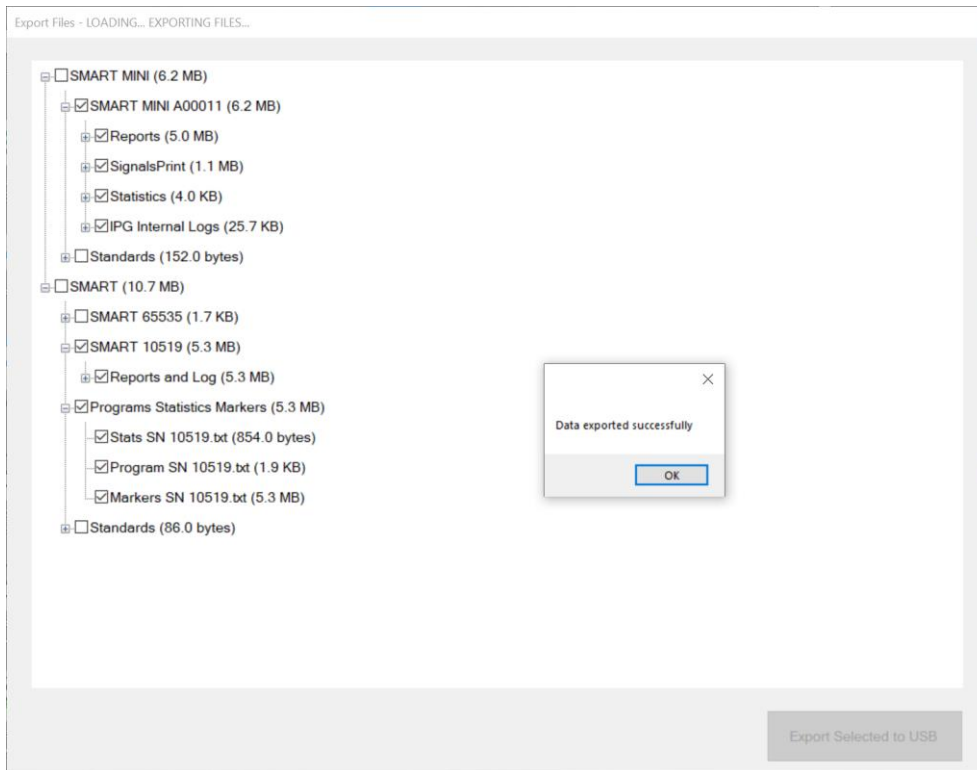


Figure 81: Completion of Successful File Exportation

8. Tap **OK** and then tap the X in the top right corner of the **Export Files** window to close it.

6.0 GUARDIO/VESTA CHARGER FIRMWARE UPDATE

The Intelio Programmer includes an application that allows a user to update the firmware installed on a Guardio/Vesta Charger.

To update the Guardio/Vesta Charger firmware:

1. On the left-hand side of the Intelio Programmer tablet PC, push the flap covering the USB ports towards the back of the tablet PC to unlock it and then fold the flap outwards.
2. Insert the USB flash drive containing the Guardio or Vesta Charger firmware into one of the two USB ports on the Intelio Programmer tablet PC.
3. Obtain the Guardio/Vesta Charger to be updated and then it around so that the back of the charger is facing upwards.
4. Remove the protective cover flap from the input connector of the charger located next to the base of the charging wand cable. **See Figure 82.**

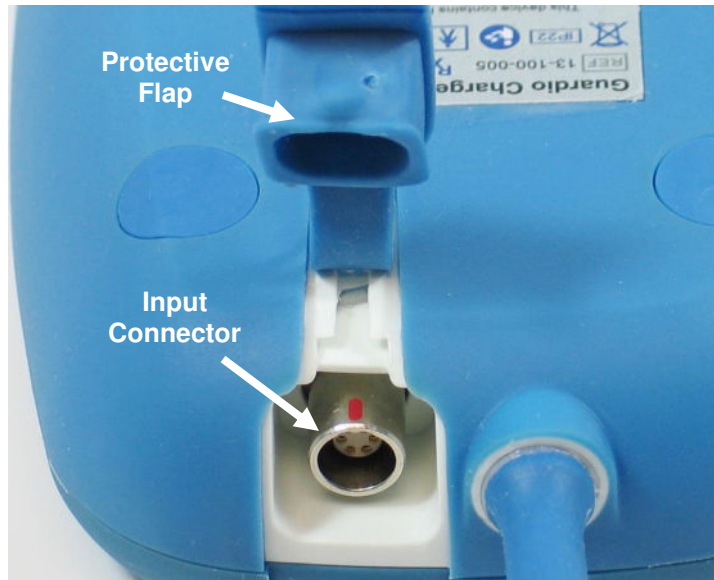


Figure 82: Back of the Guardio/Vesta Charger

5. Obtain the Bootstrap Loader Cable from the Intelio Programmer Carrying Case and rotate its metal connector until the red dot on its connector is visible.
6. Line up the red dot on the connector of the Bootstrap Loader Cable with the red line on the input connector of the Guardio/Vesta Charger and then insert the Bootstrap Loader cable connector into the charger's input connector. **See Figure 83.**



Figure 83: Alignment of the Bootstrap Loader Cable and Guardio/Vesta Charger Connectors

7. Plug the LEMO connector of the Bootstrap Loader cable into the gray-ringed port on the right side of the Intelio Programming Interface.
8. Tap the **Charger Firmware Update** button found on the Selector screen of the Intelio Programmer.
9. When the first Password pop-up window appears, enter the appropriate password obtained from Impulse Dynamics and then tap **OK**.
10. When the second Password pop-up window appears, enter the appropriate password obtained from Impulse Dynamics and then tap **OK**.

11. Enter the serial number of the Guardio/Vesta Charger in the **Serial#** field. **See Figure 84.**

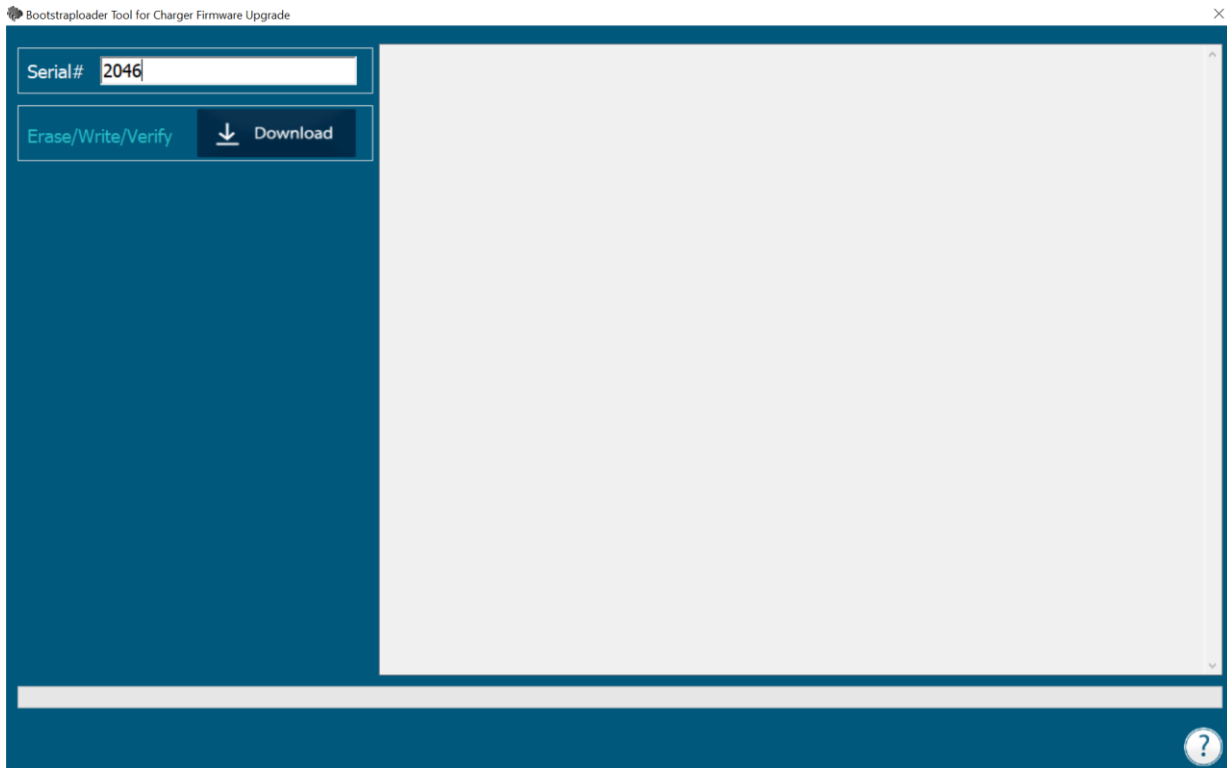


Figure 84: Bootstraploader Tool Screen

12. Tap the **Download** button.

13. Verify that the Bootstraploader tool has begun loading the Charger firmware on the Guardio/Vesta Charger. **See Figure 85.**

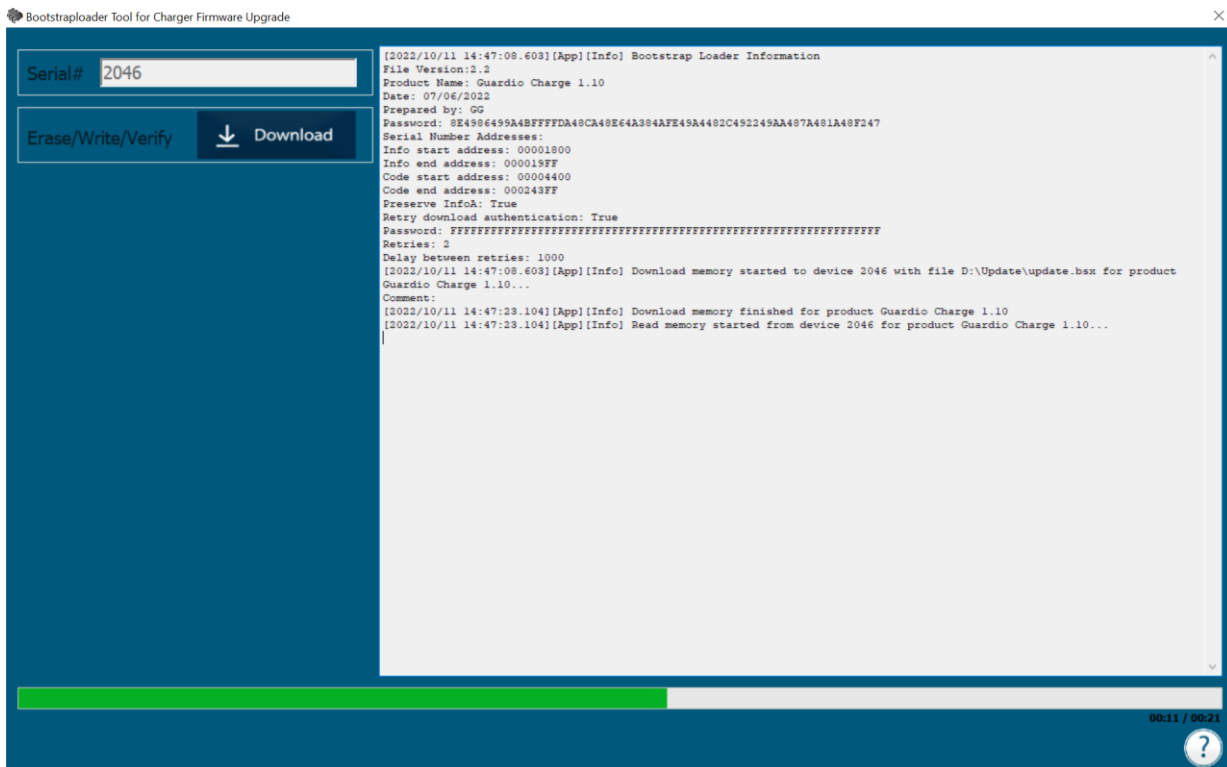


Figure 85: Bootstraploader Screen Indicating Charger Firmware Upload Has Begun

14. Verify that the application has begun loading the GUI firmware on the Guardio/Vesta Charger.
See Figure 86.

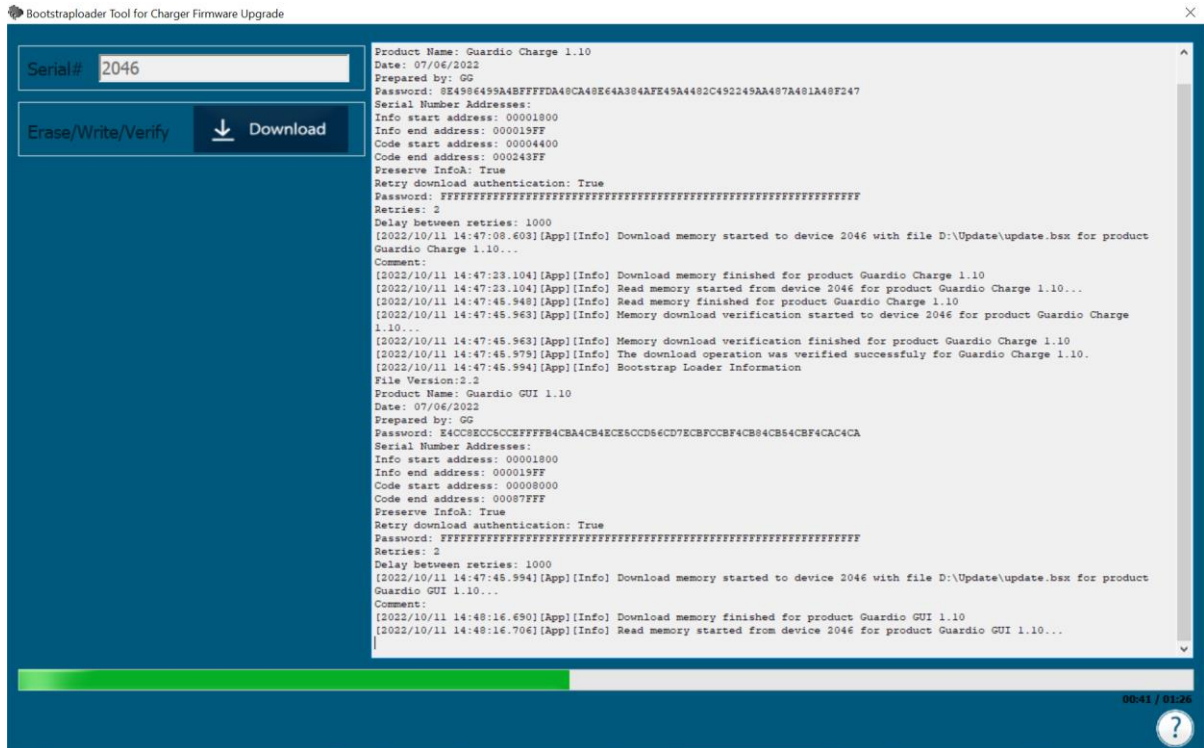


Figure 86: Bootstraploader Screen Indicating GUI Firmware Upload has Begun

15. When the firmware update has been completed, verify that the application displays a message “The firmware has been successfully downloaded to the device”. Tap **OK**. See Figure 87.
16. Tap the X at the top right corner of the **Bootstraploader Tool for Charger Firmware Upgrade** window to close it.

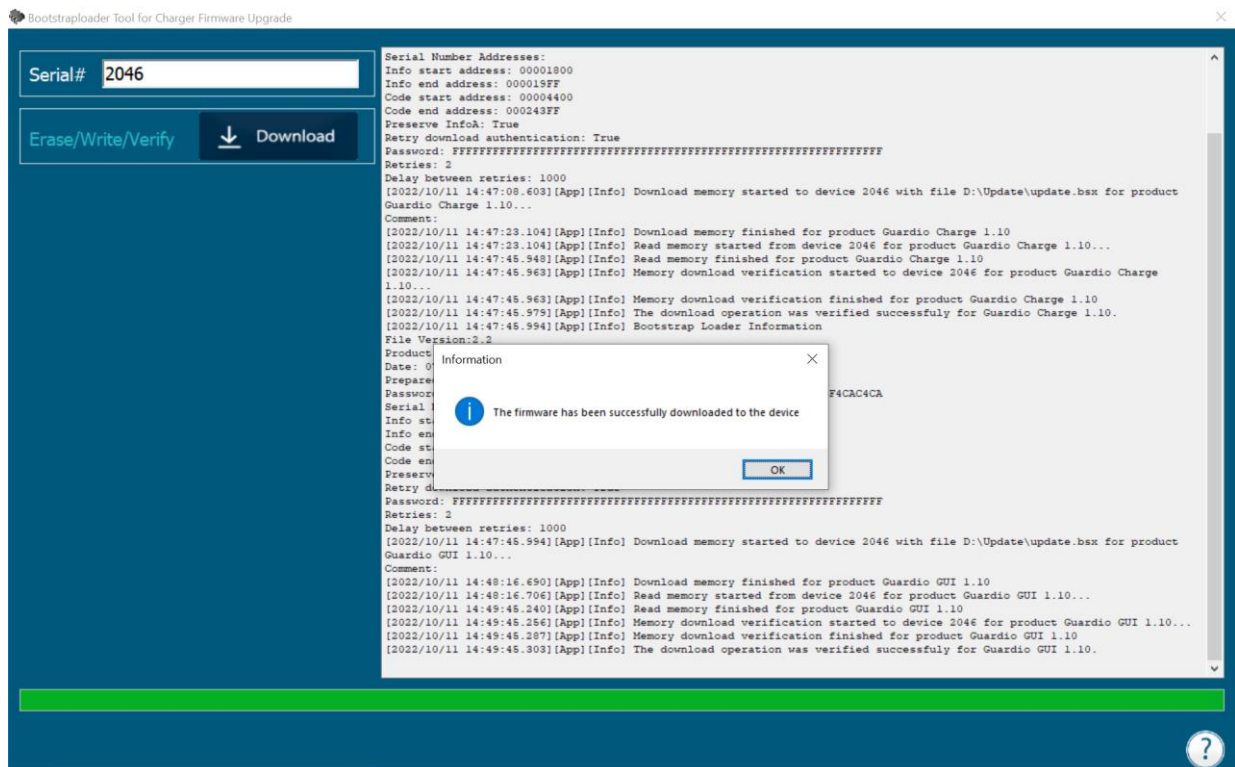


Figure 87: Message Indicating Firmware Successfully Loaded onto Guardio/Vesta Charger

17. Hold and pull back on the metal sleeve of the Bootstrap Loader cable connector to disconnect it from the Guardio/Vesta Charger. **See Figure 88.**

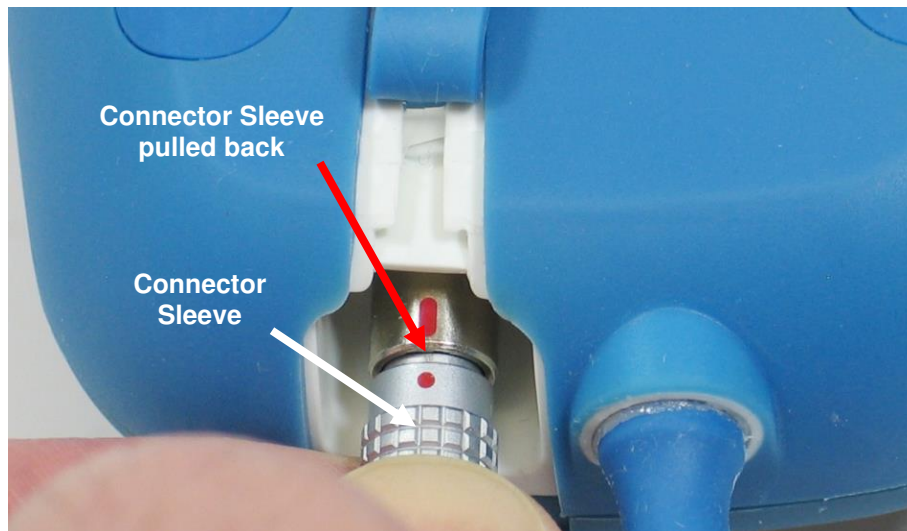


Figure 88: Close-up of the Connector Sleeve

18. Replace the protective cover flap over the input connector of the Guardio/Vesta Charger.
19. Disconnect Bootstrap Loader cable from Intelio Programmer Interface.

7.0 SOFTWARE UPDATE

The Intelio Programmer includes an application that allows a user to update the software on the Intelio Programmer.

To update the software:

1. On the left-hand side of the Intelio Programmer tablet PC, push the flap covering the USB ports towards the back of the tablet PC to unlock it and then fold the flap outwards.
2. Insert a USB flash drive containing the software update files into one of the two USB ports on the Intelio Programmer tablet PC.
3. When the Password pop-up window appears, enter the appropriate password obtained from Impulse Dynamics and then tap **OK**.
4. When the **Install Updates** pop-up window appears, enter the updates password obtained from Impulse Dynamics and then tap **Install Updates**. **See Figure 89.**

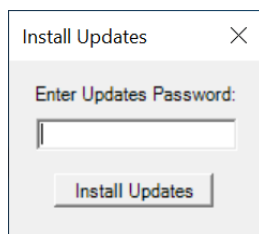



Figure 89: Install Updates Window

APPENDIX I

Electromagnetic Immunity

Electromagnetic Immunity of the Intelio Programmer

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE INTELIO PROGRAMMER			
<p>The Intelio Programmer, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.</p>			
<p>Essential Performance of the Intelio Programmer:</p> <ul style="list-style-type: none"> • 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. <p>Note: In case of emergency, placing a pacemaker magnet over the implant site of the OPTIMIZER Integra CCM-D IPG and maintaining it in close proximity to the device, sets the OPTIMIZER Integra CCM-D IPG into Magnet Mode, suspending CCM therapy and inhibiting the delivery of antiarrhythmic therapies.</p>			
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 Intelio Programmer.
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 Intelio Programmer 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:
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	$d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 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	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: 

Notes:

a - Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be theoretically predicted with accuracy. An electromagnetic site survey should be taken into consideration to assess the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location where the Intelio Programmer is used exceeds the applicable RF compliance level above, the Intelio Programmer should be monitored to ensure normal operation. If an abnormal function is observed, additional measures may be necessary, such as relocating the Intelio Programmer.

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Intelio Programmer or Guardio/Vesta Charger

Recommended separation distances between portable and mobile RF communications equipment and the Intelio Programmer or Guardio/Vesta Charger

The Intelio Programmer or the Guardio/Vesta Charger should be used in an electromagnetic environment with limited radiated RF noise. The customer or user of the Intelio Programmer or the Guardio/Vesta 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/Vesta 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 EMISSIONS 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 Integra CCM-D 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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO: FCC 47 CFR 95 Subpart I – Medical Device Radio Communications Service		
The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.		
Emissions Test	Compliance	Electromagnetic environment – guidelines
Duration of Transmissions	Complies with clause 95.2557	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Frequency Monitoring	Complies with clause 95.2559	
Frequency 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 EMISSIONS 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		
The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Integra CCM-D 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
Permitted range of operating frequencies	Complies with clause 4.3.2.3	The Intelio Programmer with Intelio Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Modulation bandwidth	Complies with clause 4.3.3.3	
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

<p>GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:</p> <p>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</p>		
<p>The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.</p>		
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

<p>GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:</p> <p>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</p> <p>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</p>			
<p>The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.</p> <p>There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.</p>			
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 EMISSIONS OF THE INTELIO PROGRAMMER WITH INTELIO PROGRAMMING WAND PURSUANT TO:

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

The Intelio Programmer with Intelio Programming Wand, part of the OPTIMIZER Integra CCM-D 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 EMISSIONS 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 Integra CCM-D 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

<p>GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH LEGACY PROGRAMMING WAND PURSUANT TO:</p> <p>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</p>		
<p>The Intelio Programmer with Legacy Programming Wand, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.</p>		
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

<p>GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS OF THE INTELIO PROGRAMMER WITH LEGACY PROGRAMMING WAND PURSUANT TO:</p> <p>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</p> <p>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</p>			
<p>The Intelio Programmer with Legacy Programming Wand, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Intelio Programmer must ensure that it is used within the specified environment.</p> <p>There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.</p>			
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 EMISSIONS OF THE INTELIO PROGRAMMER WITH LEGACY PROGRAMMING WAND PURSUANT TO:

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

The Intelio Programmer with Legacy Programming Wand, part of the OPTIMIZER Integra CCM-D 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	

APPENDIX II

Wireless Technology

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

RF wireless technology is also used to transcutaneously transmit energy from the Guardio/Vesta Charger to recharge the OPTIMIZER Integra CCM-D IPG at the 13.56 MHz ISM frequency. The transmission range is specified at a maximum of 4 cm 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.

Intelio Programmer with Intelio Programming Wand Wireless Nominal Specifications

Characteristic	Nominal
OPTIlink 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 μ s
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 μ s, “1” = 270 μ s
Radiated Power	5.14 m W_{peak} per pulse; 1.8 m $W_{average}$
Range	5 mm to 50 mm

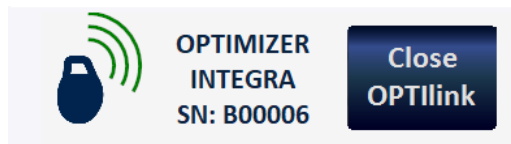
Quality of Service (QoS) for Wireless Technology

QoS for Communications between the Intelio Programmer and the OPTIMIZER Integra CCM-D IPG

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

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

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



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

Wireless Security Measures

Wireless Security Measures in OPTIlink Communications between OPTIMIZER Integra CCM-D IPG and Intelio Programmer

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

- Establishing an OPTIlink communications channel requires the Intelio Programming Wand to be placed within 4 cm of the OPTIMIZER Integra CCM-D 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 Integra CCM-D IPG and the Intelio Programmer encrypt their wireless communications using encryption keys that are randomly generated for each OPTIlink session.
- Only one Intelio Programmer may communicate with the IPG at the same time.

Troubleshooting for Wireless Coexistence Issues

Troubleshooting OPTIlink Connection between the OPTIMIZER Integra CCM-D IPG and the Intelio Programmer

If you experience issues with establishing an OPTIlink session between the OPTIMIZER Integra CCM-D IPG and the Intelio Programmer, try the following:

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

If you experience issues with maintaining an OPTIlink session between the OPTIMIZER Integra CCM-D IPG and the Intelio Programmer, try the following:

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

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

APPENDIX III

Security of the Intelio Programmer Unit

How the Programmer Promotes Security

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

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

Controlling installed software minimizes the potential for vulnerabilities.

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

The disk drive is encrypted.

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

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

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

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