IMPULSE DYNAMICS

Hope is Here

Guardio Charger for OPTIMIZER® INTEGRA™ CCM-D™ System

INSTRUCTIONS FOR USE

Limited by United States (Federal) law to investigational use

Part No.: 12-290-011-US Rev. 01

Impulse Dynamics (USA) Inc.
Suite 100
50 Lake Center Executive Parkway
401 Route 73 N Bldg. 50
Marlton, NJ 08053-3425

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

Revision 01, Date of Issue: 2023-06-09

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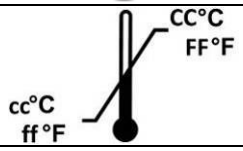
EXPLANATION OF SYMBOLS ON LABELS

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
	Type BF applied part
	Non-ionizing electromagnetic radiation
IP22	Protected against the ingress of solid foreign objects greater than 12.5 mm (0.5 in) in width Protected against the ingress of vertically falling water drops when the enclosure is tilted at an angle of 15° from its normal position

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LIST OF ACRONYMS

Acronym	Description
AC	Alternating Current
ATP	Antitachycardia Pacing
BF	Body Floating
CCM®	Cardiac Contractility Modulation
EOS	End of Service
ERI	Elective Replacement Indicator
FCE	Field Clinical Engineer
FVT	Fast Ventricular Tachycardia
HV	High Voltage
ICD	Implantable Cardioverter Defibrillator
IPG	Implantable Pulse Generator
RF	Radio Frequency
RRT	Recommended Replacement Time (synonymous with ERI)
VT	Ventricular Tachycardia
VF	Ventricular Fibrillation

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1.0 THE GUARDIO CHARGER SYSTEM

1.1 Description

The Guardio Charger is designed to charge the battery of the OPTIMIZER® INTEGRA™CCM-D™ IPG with only minimal patient intervention while ensuring patient safety and maintaining proper operation of the IPG during the charging process.

In addition, the Guardio Charger is programmed to display alerts and other messages that may require action by the patient (e.g., Call Doctor Alert Codes that require the patient to call the 24-hour Support Hotline, reminders to charge your implanted device, etc.).

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

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

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

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

The Guardio Charger charges the OPTIMIZER INTEGRA CCM-D IPG at a frequency range of 13.56 MHz.

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

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

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

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

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

1.2 User Profile and Training

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

Physicians and any assisting 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 Guardio Charger.

Patient training on the use of the Guardio Charger will be provided post-implant.

1.3 Charging Method

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

The manner in which inductive energy transfer is used to charge the battery of the OPTIMIZER INTEGRA CCM-D IPG is as follows:

1. Electrical energy from the battery of the Guardio Charger passes through a primary coil connected to the electronic circuitry of the charger that converts it into an oscillating electromagnetic field.
2. When a primary coil is placed in close proximity to a secondary coil, the oscillating electromagnetic field generated by a primary coil is picked up by a secondary coil.
3. The secondary coil that picks up the oscillating electromagnetic field is connected to the electronic circuitry of the implant that converts it back into electrical energy. That electrical energy is used to charge the battery of the OPTIMIZER INTEGRA CCM-D IPG.

1.4 System Components

The Guardio Charger System consists of the following components:

Figure 1: Guardio Charger System Components

- **Guardio Charger** (with attached charging wand and charging wand cable clip) – used to charge the OPTIMIZER INTEGRA CCM-D IPG.
- **AC Adapter** – used to charge the internal battery of the Guardio Charger.
- **EU/US Plug Adapters** – plug adapters for the AC Adapter, allowing the AC Adapter to be connected to wall outlets in the EU and US.
- **Carrying Case** – used to store and transport the Guardio Charger System.

1.5 Features

The Guardio Charger has the following features:

- **Graphical Display:** Display screen used by the Guardio Charger to communicate information to the patient
- **Power Button:** Press-button switch used to initiate and terminate charging of the OPTIMIZER INTEGRA CCM-D IPG and to silence alerts displayed by the Guardio Charger
- **Buzzer:** An internal buzzer that produces beeping tones to inform the patient of a condition that requires action
- **Charging Wand:** Wand containing a coil and circuitry used by the Guardio Charger for charging as well as short-range communications with the OPTIMIZER INTEGRA CCM-D IPG
- **Radio Transceiver:** Device used by the Guardio Charger for long-range communications [between zero and at least 1.5 m (5 ft)] with the OPTIMIZER INTEGRA CCM-D IPG
- **Cellular Modem:** Modem is used to send data downloaded from the OPTIMIZER INTEGRA CCM-D IPG to the Remote Patient Monitoring Service (RPMS) (future capability)

1.6 Overview of the Screens Displayed by the Guardio Charger

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

1.6.1 Screens Displayed When Connected to the AC Adapter

1.6.1.1 Charger Self-Charge Status Screen

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

Table 2: Guardio Charger Battery Charge Levels

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

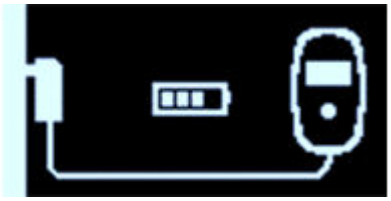

Figure 2: Charger Self-Charge Status Screen

1.6.1.2 Charger Self-Charge Success Screen

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

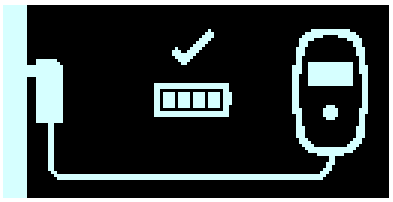

Figure 3: Charger Self-Charge Success Screen

1.6.1.3 IPG Data Download Screen

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

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

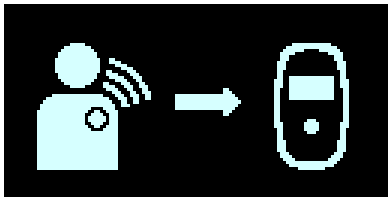

Figure 4: IPG Data Download Screen

1.6.1.4 IPG Data Download Success Screen

This screen is displayed whenever the Guardio Charger has successfully completed downloading data from the OPTIMIZER INTEGRA CCM-D IPG.

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

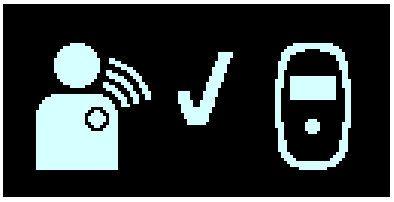

Figure 5: IPG Data Download Success Screen

1.6.1.5 IPG Data Download Error Screen

This screen is displayed whenever the Guardio Charger has not successfully completed downloading data from the OPTIMIZER INTEGRA CCM-D IPG.

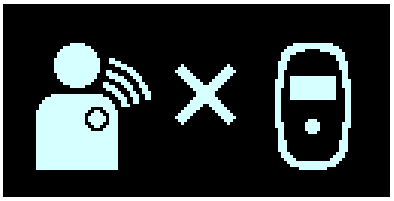

Figure 6: IPG Data Download Error Screen

1.6.2 Screens Displayed When Paring with the OPTIMIZER INTEGRA CCM-D IPG

1.6.2.1 Charger/IPG Pairing Screen

This screen is displayed whenever the Guardio Charger is actively pairing with the OPTIMIZER INTEGRA CCM-D IPG.

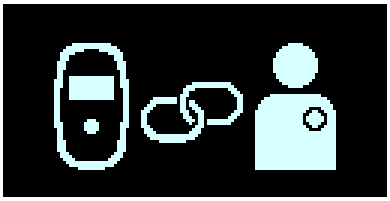

Figure 7: Charger/IPG Pairing Screen

1.6.2.2 Charger/IPG Pairing Success Screen

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

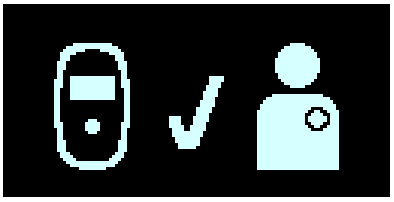

Figure 8: Charger/IPG Pairing Success Screen

1.6.2.3 Charger/IPG Pairing Error Screen

This screen is displayed whenever an error has occurred during the pairing of the Guardio Charger and the OPTIMIZER INTEGRA CCM-D IPG.

Figure 9: Charger/IPG Pairing Error Screen

1.6.3 Screens Displayed When Charging the OPTIMIZER INTEGRA CCM-D IPG

1.6.3.1 IPG Data Download Screen

This screen is displayed whenever the Guardio Charger is actively downloading data from the OPTIMIZER INTEGRA CCM-D IPG.

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

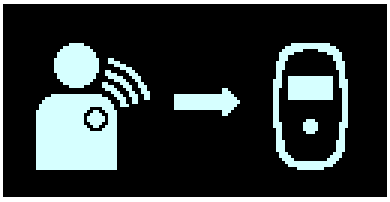

Figure 10: IPG Data Download Screen

1.6.3.2 IPG Data Download Success Screen

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

If the Guardio Charger has successfully completed downloading data from the OPTIMIZER INTEGRA CCM-D IPG, this is the second screen that is displayed after pressing the Power Button on the Guardio Charger to begin a charging session.

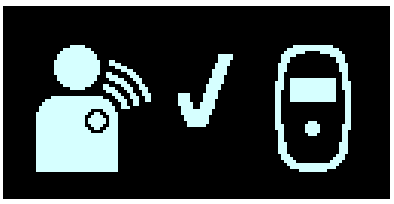

Figure 11: IPG Data Download Success Screen

1.6.3.3 IPG Data Download Error Screen

This screen is displayed whenever the Guardio Charger has not successfully completed downloading data from the OPTIMIZER INTEGRA CCM-D IPG. The display of this screen is accompanied by 3 long beeping tones.

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

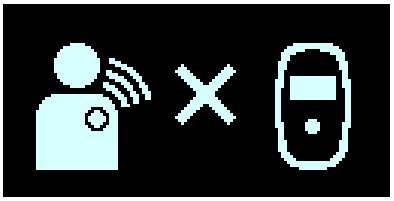

Figure 12: IPG Data Download Error Screen

1.6.3.4 Charging IPG Status Screen

This screen is displayed whenever the Guardio Charger has successfully coupled with the OPTIMIZER INTEGRA CCM-D IPG and is charging the implanted device.

If the Guardio Charger has successfully coupled with the OPTIMIZER INTEGRA CCM-D IPG, this is the third screen displayed after pressing the Power Button on the Guardio Charger.

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

Table 3: Guardio Charger Battery Charge Levels

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

Table 4: OPTIMIZER INTEGRA CCM-D IPG Battery Charge Levels

IPG Battery Icon	IPG Battery Charge Level
1 flashing bar	Below 25%
2 bars, last one flashing	Between 25% and 50%
3 bars, last one flashing	Between 50% and 75%
4 bars, last one flashing	Above 75%

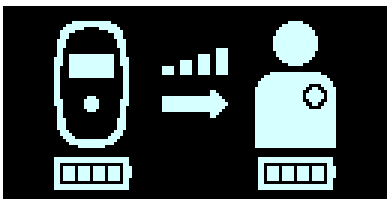

Figure 13: Charging IPG Status Screen

1.6.3.5 Charging IPG Coupling Error Screen

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

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

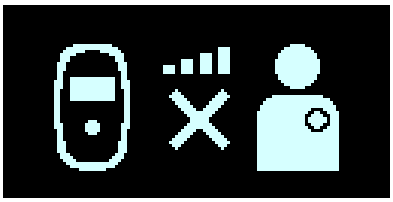

Figure 14: Charging IPG Coupling Error Screen

1.6.3.6 IPG Charging Successfully Completed Screen

This screen is displayed whenever the Guardio Charger has successfully completed charging the battery of the OPTIMIZER INTEGRA CCM-D IPG.

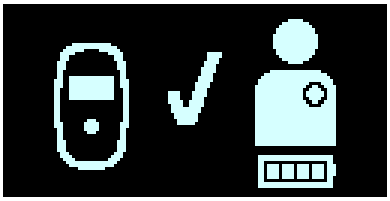

Figure 15: IPG Charging Successfully Completed Screen

1.6.3.7 Charging IPG Timeout Error Screen

This screen is displayed by the Guardio Charger whenever the charging duration of the OPTIMIZER INTEGRA CCM-D IPG exceeds 5 hours ± 5 minutes.

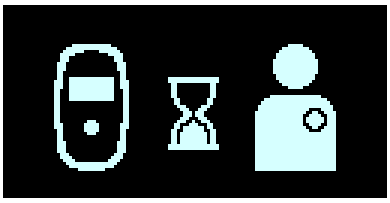

Figure 16: Charging IPG Timeout Error Screen

1.6.3.8 Charging IPG Temperature Error Screen

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

- The reported temperature of the OPTIMIZER INTEGRA CCM-D IPG at the beginning of the charging session is outside the accepted range.
- The charging session is suspended due to the temperature of the OPTIMIZER INTEGRA CCM-D IPG remaining consistently high for more than 10 minutes.

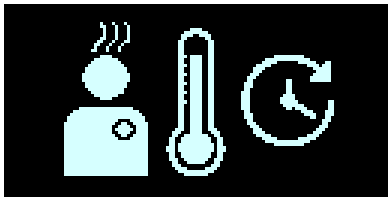

Figure 17: Charging IPG Temperature Error Screen

1.6.3.9 Power Supply Error Screen

This screen is displayed whenever the AC Adapter is connected to the Guardio Charger while it is charging the OPTIMIZER INTEGRA CCM-D IPG.

Figure 18: Power Supply Error Screen

1.6.3.10 Charge Session Cancelation Screen

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

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

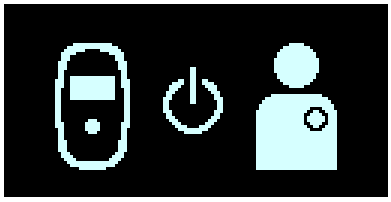

Figure 19: Charge Session Cancelation Screen

1.6.4 Screens Displayed After the Detection of an Alert Condition

1.6.4.1 Low Charger Battery Alert Screen

This screen is displayed whenever the Guardio Charger's battery charge level drops below 10%. The display of this screen is accompanied by short beeping tones.

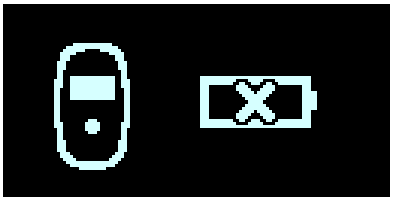

Figure 20: Low Charger Battery Alert Screen

1.6.4.2 Long Time Without Charging IPG Alert Screen

This screen is displayed whenever the Patient Alert “Battery Recharge Reminder” is enabled using the Optimizer INTEGRA Programmer application and the number of days since the OPTIMIZER INTEGRA CCM-D IPG was last charged has exceeded the number of days set for this Patient Alert. The display of this screen is accompanied by short beeping tones.

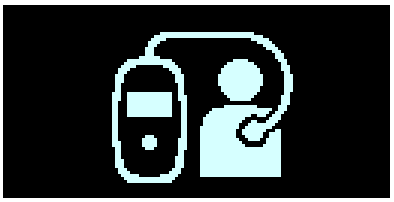

Figure 21: Long Time Without Charging IPG Alert Screen

1.6.4.3 Long Time Without Downloading Data From IPG Alert Screen

This screen is displayed whenever the Patient Alert “Long Time Without Communicating with the IPG” is enabled using the Optimizer INTEGRA Programmer application and the number of days since the last successful communication between the Guardio Charger and the OPTIMIZER INTEGRA CCM-D IPG has exceeded the number of days set for this Patient Alert. The display of this screen is accompanied by short beeping tones.

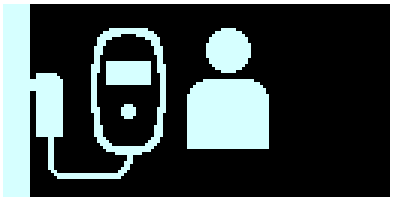

Figure 22: Long Time Without Downloading Data From IPG Alert Screen

1.6.4.4 Abnormal Condition Error Screen

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

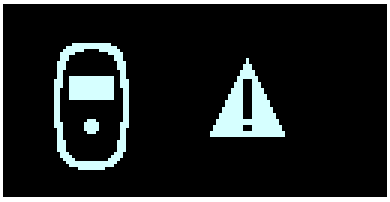

Figure 23: Abnormal Condition Error Screen

1.6.4.5 Call Doctor Alert Screen

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

Figure 24: Call Doctor Alert Screen

1.6.4.6 Snooze Buzzer Alert Screen

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

It is the screen that is displayed after the alert screen of a newly activated alert.

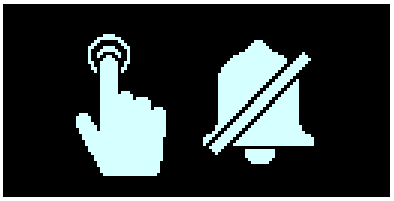

Figure 25: Snooze Buzzer Alert Screen

1.6.4.7 Snooze Alert Screen

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

This screen is displayed after the alert screen if the Guardio Charger is used outside the scheduled Patient Alert Delivery period set by the Optimizer INTEGRA Programmer application (usually between 09:00 and 21:00) or when an alert that was previously activated is retriggered.

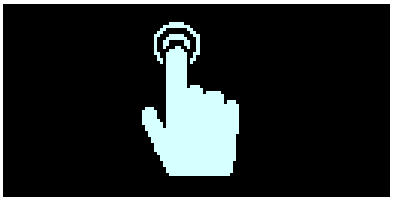

Figure 26: Snooze Alert Screen

1.6.5 Info Screens

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

- The AC Adapter is connected to the Guardio Charger.
- The **Power Button** is continuously pressed until a beeping tone is heard and then released (usually more than 5 seconds and less than 10 seconds).

1.6.5.1 First Info Screen

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

- The list of active and snoozed Call Doctor Alert Codes
- The IPG model code
- The battery charge level of the IPG after the completion of its last charge session
- The date and time of the last successful charge of the IPG

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

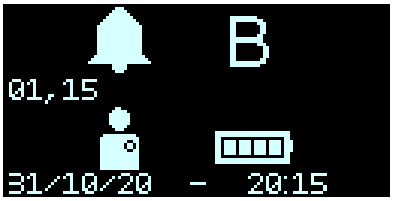

Figure 27: First Info Screen

1.6.5.2 Second Info Screen

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

- The signal strength level during the last successful IPG data download session
- The date and time of the last successful IPG data download session

  Note: The date format is (DD/MM/YY) and the time format is 24 hours.
- The signal strength level during the last successful data upload session (future capability)
- The date and time of the last successful IPG data upload session (future capability)

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

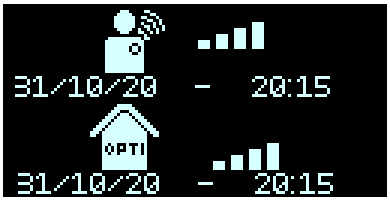

Figure 28: Second Info Screen

1.7 Pairing the Guardio Charger with the OPTIMIZER INTEGRA CCM-D IPG

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

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

To pair the Guardio Charger with the OPTIMIZER INTEGRA CCM-D IPG, perform the following steps:

1. Determine the location of the OPTIMIZER INTEGRA CCM-D IPG (typically left upper chest area) and then place the charging wand directly over the OPTIMIZER INTEGRA CCM-D implant site (over the patient's clothes).
2. Place a pairing magnet (or a standard pacemaker magnet) to the left of the **Power Button** on the Guardio Charger. **See Figure 29**.

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

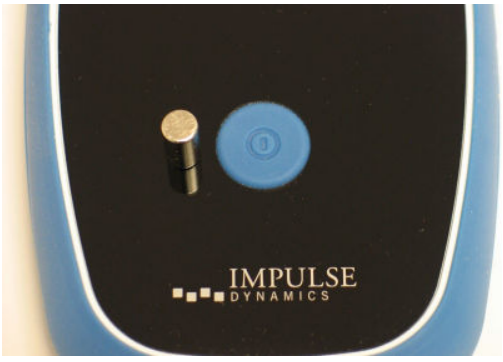

Figure 29: Pairing Magnet on Guardio Charger

3. Begin the pairing process by pressing the **Power Button**, holding the button down for 1-2 seconds, and then releasing it.
4. The Charger/IPG Pairing screen is displayed while the Guardio Charger is actively attempting to pair with the OPTIMIZER INTEGRA CCM-D IPG. **See Figure 30**.

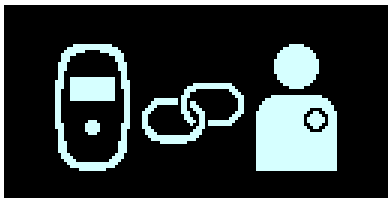

Figure 30: Charger/IPG Pairing Screen

5. When the pairing process has been completed, the Guardio Charger will emit 3 short beeping tones and display the Charger/IPG Pairing Success screen. **See Figure 31**.

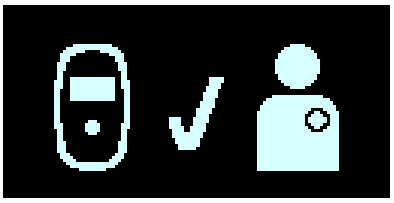

Figure 31: Charger/IPG Pairing Success Screen

6. Remove the pairing magnet from the Guardio Charger.

1.8 Charging the Guardio Charger

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

Note: Charging the Guardio Charger and charging the OPTIMIZER INTEGRA CCM-D IPG CANNOT be done simultaneously. Always charge the internal battery of the Guardio Charger before attempting to charge the battery of the OPTIMIZER INTEGRA CCM-D IPG.

Note: Inspect the AC Adapter for any damage before each use. Please call the 24-hour Support Hotline (866-312-5370) if a replacement AC Adapter is needed.

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

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

1. Turn the Guardio Charger around so that the back of the charger is facing up.
2. Remove the protective cover flap from the power input connector located next to the base of the charging wand cable.

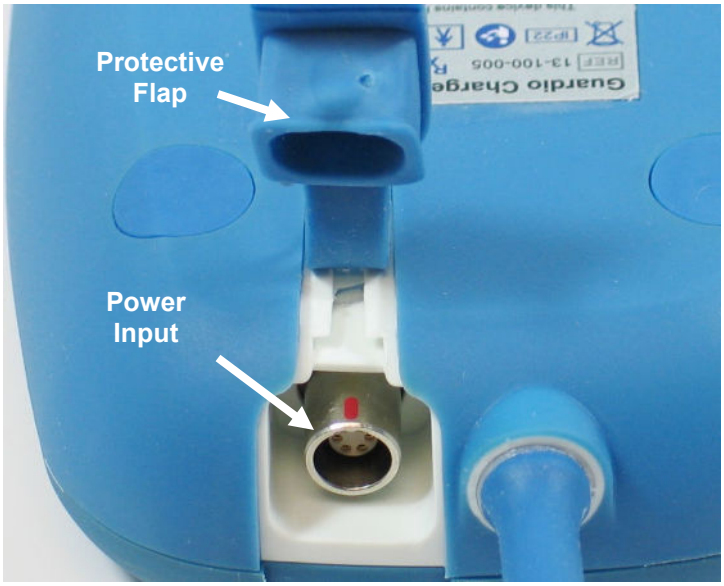

Figure 32: Back of the Guardio Charger

3. Obtain the AC Adapter from the Carrying Case and rotate its DC output connector until the red dot on its connector is visible.
4. Line up the red dot on the DC output connector of the AC Adapter with the red line on the power input connector of the Guardio Charger and then insert in the DC output connector into the power input connector. **See Figure 33.**

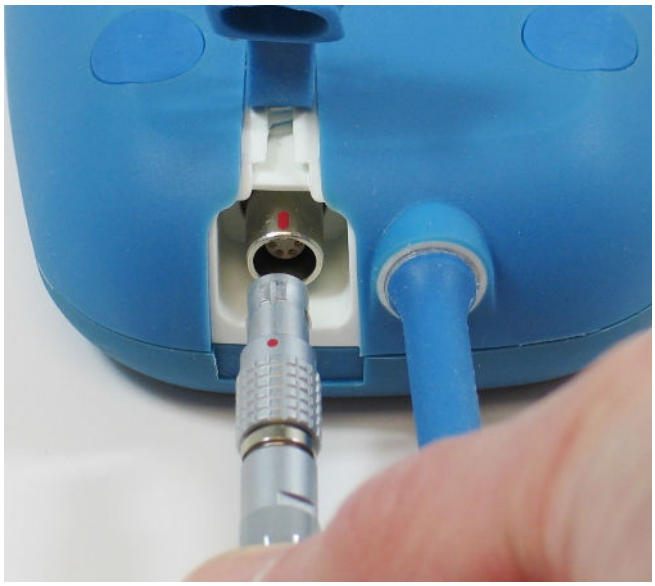

Figure 33: Alignment of the DC Output and Guardio Charger Connectors

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

When the Charging Self-Charge Success screen is displayed on the Guardio Charger screen, the battery in the Guardio Charger is fully charged. **See Figure 34**.

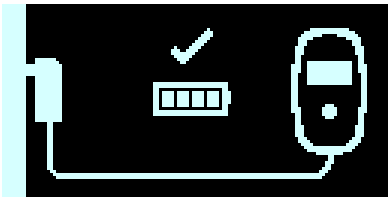

Figure 34: Charger Self-Charge Success Screen

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

1. Unplug the AC Adapter from the wall outlet.
2. Hold and pull back on the metal sleeve of the DC output connector to disconnect it from the Guardio Charger.

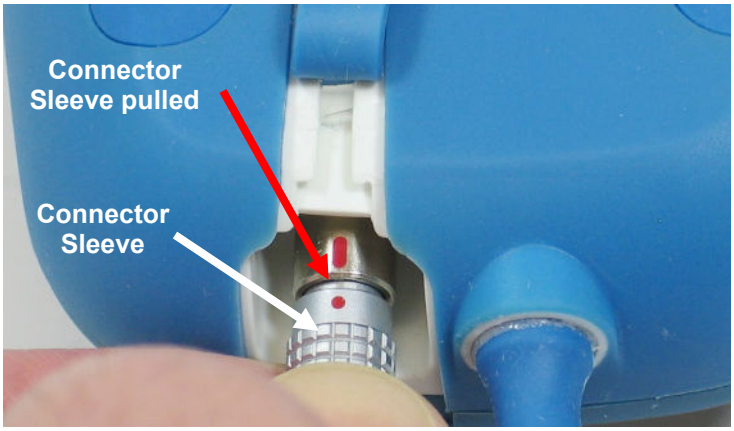

Figure 35: Close-up of the Connector Sleeve

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

1.9 Charging the OPTIMIZER INTEGRA CCM-D IPG

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

Note: The Guardio Charger cannot be used to charge the OPTIMIZER INTEGRA CCM-D IPG until the AC Adapter is disconnected from the Guardio Charger.

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

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

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

To charge the battery of the OPTIMIZER INTEGRA CCM-D IPG, perform the following steps:

1. Place the patient in a stationary, comfortable sitting position, ideally reclining at a 45° angle (e.g., on a sofa or armchair).
2. Determine the location of the OPTIMIZER INTEGRA CCM-D IPG (typically left upper chest area) and then place the flat side of the Guardio charging wand (the side with the four blue rubber screw covers) directly over the OPTIMIZER INTEGRA CCM-D implant site (over the patient's clothes). To prevent the charging wand from becoming displaced while charging, the charging wand cable may be draped around the patient's neck or the clip on the charging wand cable may be attached to the patient's clothing.
3. Start the charging process by pressing the **Power Button**, holding the button down for 1-2 seconds, and then releasing it.
4. The charging process begins with a display of the IPG Data Download and IPG Data Download Success screens. **See Figures 36 and 37**.

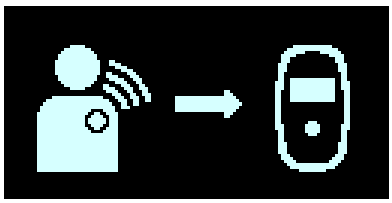

Figure 36: IPG Data Download Screen

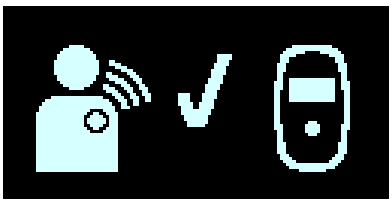

Figure 37: IPG Data Download Success Screen

5. After the data download has been completed, the Charging IPG Status screen is displayed by the Guardio Charger. **See Figure 38**.

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

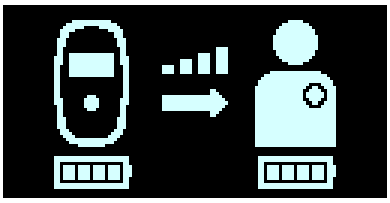

Figure 38: Charging IPG Status Screen

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

6. The number of bars on the Charging IPG Battery icon (see icon image on the right) depicts the current charge level of the OPTIMIZER INTEGRA CCM-D IPG.
7. The Charging IPG Status screen (see **Figure 38**) will continue to be displayed as the OPTIMIZER INTEGRA CCM-D IPG is being charged.

   Caution: Fault conditions in the charger could cause it to overheat. If any part of the charger becomes uncomfortably warm at any time during the charging session, remove it from your body and place it on a non-flammable surface. Then, if possible, terminate the charging session by pressing the Power Button for 1-2 seconds and then releasing it.

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

   Note: Instruct the patient to try to fully charge their OPTIMIZER INTEGRA CCM-D IPG during the charging session. Also, inform the patient that charging their implanted device may take longer if its battery is significantly depleted. If the recharging of the OPTIMIZER INTEGRA CCM-D IPG cannot be completed in one session, instruct the patient to repeat charging sessions (at least daily) until their implanted device is fully charged.
8. When the battery of the OPTIMIZER INTEGRA CCM-D IPG is fully charged, the Guardio Charger will emit three short beeping tones and display the IPG Charging Successfully Completed screen (see **Figure 39**). The Guardio Charger will then shut off automatically.

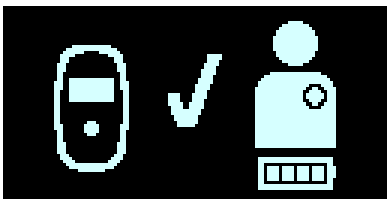

Figure 39: IPG Charging Successfully Completed Screen

9. Detach the charging wand cable clip from the patient's clothing (if necessary), then remove the Guardio charging wand from the patient's implant site and undrape the wand cable from around the patient's neck.
10. Reconnect the AC Adapter to the Guardio Charger as described in Section 1.11.

1.9.1 Early Termination of Charging Session

To terminate a charging session before it has been completed, instruct the patient to press and hold the **Power Button** down for one second and then release it. The Guardio Charger will emit 3 short beeping tones and display the Charge Session Cancelation screen. **See Figure 40**.

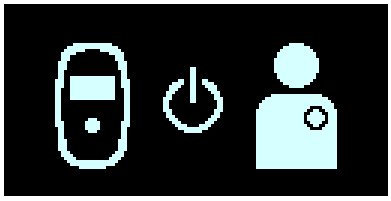

Figure 40: Charge Session Cancelation Screen

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

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

1.10 Charging the OPTIMIZER INTEGRA CCM-D IPG in Special Charge Mode

If an OPTIMIZER INTEGRA CCM-D IPG is unable to be charged conventionally because of an alert condition (i.e., Safe Mode), the OPTIMIZER INTEGRA CCM-D IPG may be charged using the Special Charge Mode.

Note: The OPTIMIZER INTEGRA CCM-D IPG must be paired with the Guardio Charger before using it to charge the IPG in Special Charge Mode. If necessary, use the instructions in section 1.7 to pair the Guardio Charger with the OPTIMIZER INTEGRA CCM-D IPG before proceeding.

To charge an OPTIMIZER INTEGRA CCM-D IPG in Special Charge Mode, perform the following steps:

1. Place the patient in a stationary, comfortable sitting position.
2. Determine the location of the OPTIMIZER INTEGRA CCM-D IPG (typically left upper chest area) and then place the flat side of the Guardio charging wand (the side with the four blue rubber screw covers) directly over the OPTIMIZER INTEGRA CCM-D implant site (over the patient's clothes).
3. Place a pairing magnet (or a standard pacemaker magnet) to the left of the **Power Button** on the Guardio Charger. **See Figure 41**.

Figure 41: Pairing Magnet on Guardio Charger

4. Start the charging process by pressing and holding down the **Power Button** (> 5 seconds) until the Guardio Charger emits a single beeping tone, and then releasing it.
5. When the Guardio Charger is used in Special Charge Mode, the charger skips the IPG data download and begins charging the IPG. The Charging IPG Status screen shown in **Figure 42** will be displayed during the charging session.

Figure 42: Charging IPG Status Screen When Charging IPG in Special Charge Mode

1.11 Guardio Charger Placement When Not Being Used for Device Charging

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

1.12 Frequency of Charging Sessions

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

If the Guardio Charger is not used to perform a charging session on the OPTIMIZER INTEGRA CCM-D IPG within the time period set by the Optimizer INTEGRA Programmer application, the patient may see the Long Time Without Charging IPG alert screen (see **Figure 43**) displayed by the Guardio Charger.

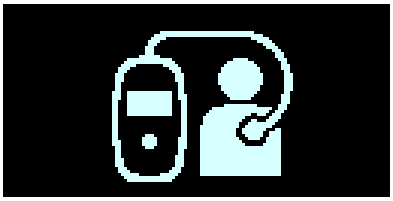

Figure 43: Long Time Without Charging IPG Alert Screen

If a patient reports seeing this screen displayed by the Guardio Charger, instruct the patient to use their Guardio Charger to charge their OPTIMIZER INTEGRA CCM-D IPG. If the patient reports that their attempt to charge their OPTIMIZER INTEGRA CCM-D IPG with their Guardio Charger was unsuccessful, please call the 24-hour Support Hotline (866-312-5370).

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

1.13 Communications

1.13.1 Communications with the OPTIMIZER INTEGRA CCM-D IPG

When the Guardio Charger is connected to the AC Adapter, it attempts to communicate with its paired IPG every 10 minutes. **See Figure 44**.

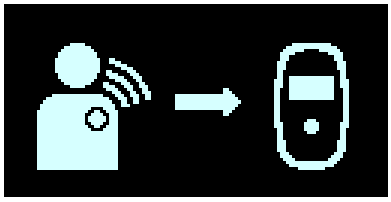

Figure 44: IPG Data Download Screen

If the communication session is successful, a checkmark will be displayed at the end of the communication session. A successful communication session will occur if the IPG is within 1.5 m (5 ft) of the Guardio Charger. **See Figure 45**.

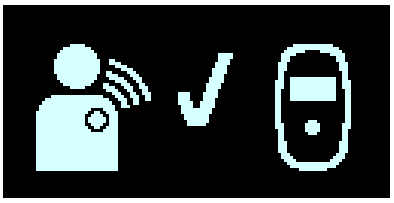

Figure 45: IPG Data Download Success Screen

If the communication session is unsuccessful, an X will be displayed at the end of the communication attempt. **See Figure 46**.

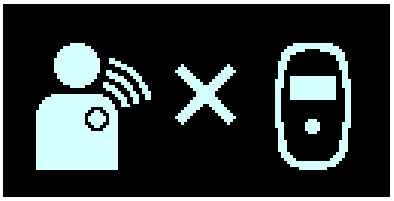

Figure 46: IPG Data Download Error Screen

If the Guardio Charger and the OPTIMIZER INTEGRA CCM-D IPG do not communicate within the time period set by the Optimizer INTEGRA Programmer application, the patient may see the Long Time Without Downloading Data From IPG alert screen (see **Figure 47**) displayed by the Guardio Charger.

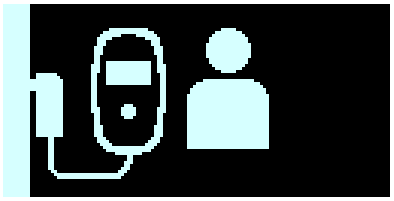

Figure 47: Long Time Without Downloading Data From IPG Alert Screen

If a patient reports seeing this screen displayed by the Guardio Charger, instruct the patient to attempt to charge their OPTIMIZER INTEGRA CCM-D IPG with their Guardio Charger. If the patient is able to charge their implanted device successfully, then the alert screen should no longer be displayed by the Guardio Charger. If the patient reports that their attempt to charge their OPTIMIZER INTEGRA CCM-D IPG with their Guardio Charger was unsuccessful, please call the 24-hour Support Hotline (866-312-5370).

1.14 Call Doctor Alert Codes

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

If a detected alert condition is associated with a Direct Action Alert, an alert screen such as Long Time Without Downloading Data from IPG (see **Figure 47**) will be displayed by the Guardio Charger.

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

Table 5: Call Doctor Alert Codes for the OPTIMIZER INTEGRA CCM-D IPG

Alert Code	Alert Description	Prevents Charge	Persistent	Auto Refresh
1	ICD Safe Mode (see section 1.14.2.1)	Yes	No	Yes
3	HV Lead Impedance Not OK (see section 1.14.2.2)	No	Yes	Yes
5	ICD Not Sensing, ICD Noise, Capacitors charge ended by timeout, or Shock phase ended by timeout (see section 1.14.2.3)	No	Yes	Yes
7	ICD Recoverable Failure (see section 1.14.2.4)	No	No	Yes
9	CCM Safe Mode (see section 1.14.2.5)	Yes	No	Yes
11	ICD Battery Reached End of Service (EOS) (see section 1.14.2.6)	No	Yes	Yes
12	Delivered HV Shock (see section 1.14.2.7)	No	Yes	No
13	Delivered Antitachycardia Pacing (ATP) (see section 1.14.2.8)	No	Yes	No
14	Delivered Rescue Brady Pacing (see section 1.14.2.9)	No	Yes	No
15	Detected Ventricular Fibrillation (VF) Event (see section 1.14.2.10)	No	Yes	No
16	Detected Fast Ventricular Tachycardia (FVT) Event (see section 1.14.2.11)	No	Yes	No
17	Detected Ventricular Tachycardia (VT) Event (see section 1.14.2.12)	No	Yes	No
18	Detected Monitor Event (see section 1.14.2.13)	No	Yes	No
19	CCM Lead Impedance Change (see section 1.14.2.14)	No	Yes	Yes
21	CCM Therapy Suspended (see section 1.14.2.15)	No	No	No
23	Rechargeable Battery Low (see section 1.14.2.16)	No	No	Yes
25	CCM Not Sensing/Noise (see section 1.14.2.17)	No	Yes	Yes
27	Low CCM Therapy Rate (see section 1.14.2.18)	No	Yes	Yes
29	ICD Battery Reached Recommended Replacement Time (RRT) (see section 1.14.2.19)	No	No	Yes
31	Charger Failure (see section 1.14.2.20)	Yes	N/A	N/A
32	IPG Mismatch (see section 1.14.2.21)	Yes	N/A	N/A

1.14.1 Call Doctor Alert Code Attributes

Each Call Doctor Alert has the following attributes:

- **Prevents Charge:** An alert that forces the Guardio Charger to terminate the charging process.
- **Persistent:** An alert that will be displayed even if the alert condition that triggered the event is no longer present.
- **Auto Refresh:** An alert that will be displayed again after 24 hours if the alert condition is still present.

1.14.2 Call Doctor Alert Code Definitions

The OPTIMIZER INTEGRA CCM-D IPG supports the following Call Doctor Alert Codes.

1.14.2.1 Alert Code 1

When Alert Code 1 is displayed, it means that the ICD module of the OPTIMIZER INTEGRA CCM-D IPG has been deactivated and placed in Safe Mode. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.2 Alert Code 3

When Alert Code 3 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has detected a significant change in the impedance in the high-voltage (HV) lead. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.3 Alert Code 5

When Alert Code 5 is displayed, it means that either the OPTIMIZER INTEGRA CCM-D IPG has detected that its ICD module is not sensing or sensing an excessive amount of noise, an HV capacitors charge ended by a timeout, or an HV shock phase ended by a timeout. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.4 Alert Code 7

When Alert Code 7 is displayed, it means that the ICD module of the OPTIMIZER INTEGRA CCM-D IPG has experienced a recoverable failure. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.5 Alert Code 9

When Alert Code 9 is displayed, it means that the CCM module of the OPTIMIZER INTEGRA CCM-D IPG has been deactivated and placed in Safe Mode. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.6 Alert Code 11

When Alert Code 11 is displayed, it means that the ICD battery of the OPTIMIZER INTEGRA CCM-D IPG has reached its End of Service (EOS) and the IPG needs to be replaced. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.7 Alert Code 12

When Alert Code 12 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has delivered a high-voltage (HV) shock. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.8 Alert Code 13

When Alert Code 13 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has delivered antitachycardia pacing (ATP). If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.9 Alert Code 14

When Alert Code 14 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has delivered rescue bradycardia pacing. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.10 Alert Code 15

When Alert Code 15 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has detected a ventricular fibrillation (VF) event as defined by the rate threshold set for this event type. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.11 Alert Code 16

When Alert Code 16 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has detected a fast ventricular tachycardia (FVT) event as defined by the rate threshold set for this event type. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.12 Alert Code 17

When Alert Code 17 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has detected a ventricular tachycardia (VT) event as defined by the rate threshold set for this event type. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.13 Alert Code 18

When Alert Code 18 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has detected a monitor event as defined by the rate threshold set for this event type. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.14 Alert Code 19

When Alert Code 19 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has detected a significant change in the impedance in one or both ventricular leads. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.15 Alert Code 21

When Alert Code 21 is displayed, it means that CCM therapy in the OPTIMIZER INTEGRA CCM-D IPG has been suspended. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.16 Alert Code 23

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

1.14.2.17 Alert Code 25

When Alert Code 25 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has detected that its CCM module is not sensing or sensing an excessive amount of noise. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.18 Alert Code 27

When Alert Code 27 is displayed, it means that the OPTIMIZER INTEGRA CCM-D IPG has detected that the amount of CCM therapy delivered is below the Minimum CCM% value programmed into the implanted device by the Optimizer INTEGRA Programmer application. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.19 Alert Code 29

When Alert Code 11 is displayed, it means that the ICD battery of the OPTIMIZER INTEGRA CCM-D IPG has reached its Recommended Replacement Time (RRT) and the IPG will need to be replaced soon. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.20 Alert Code 31

When Alert Code 31 is displayed, it means that the Guardio Charger has detected repeated internal errors during its operation. If the Guardio Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370).

1.14.2.21 Alert Code 32

When Alert Code 32 is displayed, it means that the Guardio Charger has determined that it is attempting to be used on an unrecognized device. If this Alert Code is displayed by the Guardio Charger, please pair the Guardio Charger with the implanted OPTIMIZER INTEGRA CCM-D IPG and then restart the charging process. If the Guardio Charger still displays this code after it has been successfully paired with the implanted OPTIMIZER INTEGRA CCM-D IPG, please call the 24-hour Support Hotline (866-312-5370).

1.15 FCE Guardio Charger

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

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

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

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

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

1.15.1.1 FCE Guardio Charger Self-Charge Status Screen

This screen is displayed whenever the AC Adapter is connected to the FCE Guardio Charger. The number of bars shown on the battery icon will vary depending on the current level of charge in the Guardio Charger battery (see **Table 2** in section 1.6.1.1).

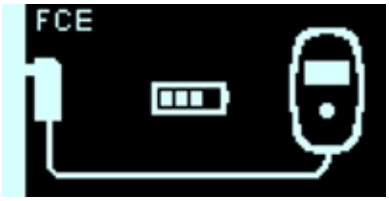

Figure 48: FCE Charger Self-Charge Status Screen

1.15.1.2 FCE Guardio Charger Self-Charge Success Screen

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

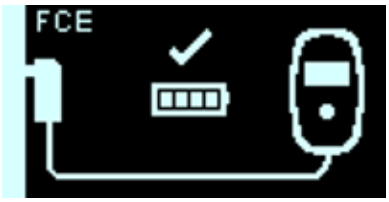

Figure 49: FCE Charger Self-Charge Success Screen

1.15.2 Charging the OPTIMIZER INTEGRA CCM-D IPG using the FCE Guardio Charger

To charge an OPTIMIZER INTEGRA CCM-D IPG using the FCE Guardio Charger, perform the following steps:

1. Place the patient in a stationary, comfortable sitting position.
2. Determine the location of the OPTIMIZER INTEGRA CCM-D IPG (typically left upper chest area) and then place the flat side of the Guardio charging wand (the side with the four blue rubber screw covers) directly over the OPTIMIZER INTEGRA CCM-D implant site (over the patient's clothes).
3. Start the charging process by pressing the **Power Button**, holding the button down for 1-2 seconds, and then releasing it.
4. Using the FCE Guardio Charger, the charging process begins by displaying the FCE Charger/IPG Pairing screen as the FCE Guardio Charger attempts to pair with the OPTIMIZER INTEGRA CCM-D IPG. **See Figure 50**.

   Note: If the FCE Guardio Charger is unable to successfully pair with the patient's implanted OPTIMIZER INTEGRA CCM-D IPG, reposition the charging wand, and repeat Step 3. If pairing is still unsuccessful, proceed to section 1.15.3.

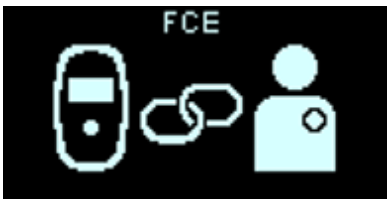

Figure 50: FCE Charger/IPG Pairing Screen

5. When the pairing process has been successfully completed, the FCE Guardio Charger will emit 3 short beeping tones and display the Charger/IPG Pairing Success screen. **See Figure 51**.

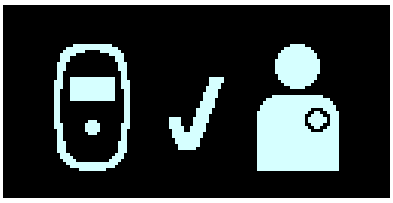

Figure 51: Charger/IPG Pairing Success Screen

6. After the pairing has been successfully completed, the FCE Guardio Charger will display the FCE Charging IPG Status screen. **See Figure 52**.

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

Figure 52: FCE Charging IPG Status Screen

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

7. The FCE Charging IPG Status screen (see **Figure 52**) will continue to be displayed as the OPTIMIZER INTEGRA CCM-D IPG is being charged.

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

   Note: If the intended use of the FCE Guardio Charger is only to charge the battery of the OPTIMIZER INTEGRA CCM-D IPG enough to allow for the interrogation / programming of the device, the charging session may be terminated once the IPG Battery icon (see icon on the right in **Figure 52**) displays 2 bars, with the last one flashing. To terminate the charge session, press the **Power Button**, hold it down for 1-2 seconds, and then release it.

8. When the battery of the OPTIMIZER INTEGRA CCM-D IPG is fully charged, the Guardio Charger will emit three short beeping tones and display the IPG Charging Successfully Completed screen (see **Figure 53**). The Guardio Charger will then shut off automatically.

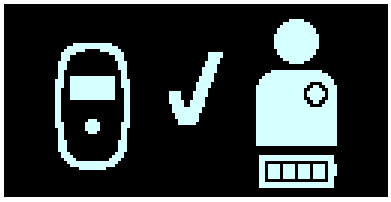

Figure 53: IPG Charging Successfully Completed Screen

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

1.15.2.1 Charging the OPTIMIZER INTEGRA CCM-D IPG in Safe Mode

When charging an OPTIMIZER INTEGRA CCM-D IPG that is in Safe Mode, the FCE Charging IPG Status screen shown in **Figure 54** will be displayed during the charging session.

Figure 54: FCE Charging IPG Status Screen When Charging IPG in Safe Mode

1.15.3 Charging the OPTIMIZER INTEGRA CCM-D IPG in Unpaired Charge Mode

To charge an OPTIMIZER INTEGRA CCM-D IPG using the FCE Guardio Charger in Unpaired Charge Mode, perform the following steps:

1. Place the patient in a stationary, comfortable sitting position.
2. Determine the location of the OPTIMIZER INTEGRA CCM-D IPG (typically left upper chest area) and then place the flat side of the Guardio charging wand (the side with the four blue rubber screw covers) directly over the OPTIMIZER INTEGRA CCM-D implant site (over the patient's clothes).
3. Place a pairing magnet (or a standard pacemaker magnet) to the left of the **Power Button** on the Guardio Charger. **See Figure 55**.

Figure 55: Pairing Magnet on Guardio Charger

4. Start the unpaired charging process by pressing and holding down the **Power Button** (> 10 seconds) until the Guardio Charger automatically starts the charging process, and then releasing it.
5. When using the FCE Guardio Charger in Unpaired Charge Mode, the charging process begins by displaying the FCE Charging IPG Status screen. **See Figure 56**.

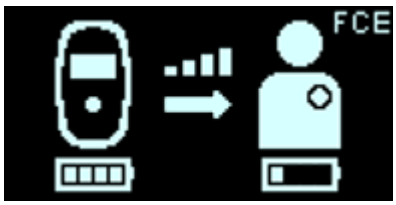

Figure 56: FCE Charging IPG Status Screen in Unpaired Charge Mode

6. If the FCE Guardio Charger is able to reestablish communications with the OPTIMIZER INTEGRA CCM-D IPG within 5 minutes of charging in Unpaired Charge Mode, the FCE Guardio Charger will emit three short beeping tones, display the Charge Session Cancelation screen (see **Figure 57**), and then automatically terminate the Unpaired Charge Mode charging session. When this occurs, remove the Pairing Magnet from atop the FCE Guardio Charger and then proceed Step 3 in section 1.15.2.

   Note: If the FCE Guardio Charger is not able to reestablish communications with the OPTIMIZER INTEGRA CCM-D IPG after 5 minutes of charging in Unpaired Charge Mode, it will emit three short beeping tones, display the Charge Session Cancelation screen (see **Figure 57**), and then terminate the Unpaired Charge Mode charging session. If this occurs, repeat Step 4 to initiate another charge session in Unpaired Charge Mode.

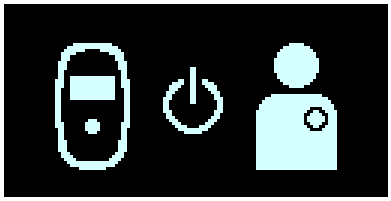

Figure 57: Charge Session Cancelation Screen

1.16 Cleaning

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

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

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

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

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

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

1.17 Maintenance

The Guardio Charger does not contain any user-serviceable parts. If the Guardio Charger is not operational, please call the 24-hour Support Hotline (866-312-5370) to obtain a replacement charger.

Warning: No modification of this equipment is allowed.

The battery inside the Guardio Charger is expected to have a service life of at least 5 years. If the Guardio Charger cannot fully charge an OPTIMIZER INTEGRA CCM-D IPG after the charger battery has been fully charged, please call the 24-hour Support Hotline (866-312-5370) to obtain a replacement charger.

1.18 Storage and Handling

The Guardio Charger System is designed to maintain functionality after it has been exposed to the following environmental extremes:

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

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

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

- **Ambient Temperature:** 10°C to 27°C (50°F and 81°F)
- **Relative Humidity:** 20% to 75%
- **Atmospheric Pressure:** 70 kPa to 106 kPa (20.73 inHg to 31.39 inHg)

Note: The Guardio Charger is designed for indoor use.

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

1.19 Disposal

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

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

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APPENDIX I

Electromagnetic Immunity

Electromagnetic Immunity of the Guardio Charger

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE GUARDIO CHARGER			
Essential Performance of the Guardio Charger: • The Guardio Charger shall not charge any IPG inappropriately. • The Guardio Charger shall only charge a paired IPG appropriately. • The patient shall be made aware of inappropriate charging either by an explicit message, or by the absence of an expected message from the Guardio Charger. • If essential performance is lost due to electromagnetic disturbances, the Guardio Charger shall not be able to charge any IPG.			
The Guardio Charger, part of the OPTIMIZER INTEGRA CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment. The test levels follow FDA recommendations for the home environment per "Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff", November 24, 2014			
Immunity test	**IEC 60601-1-2:2014 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge as defined in IEC 61000-4-2	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be 30% or greater.
Electrical fast transient / burst as defined in IEC 61000-4-4	± 2 kV for mains power supply ± 1 kV for in-/output lines	± 2 kV for mains power supply ± 1 kV for in-/output lines	Mains power quality should be that of a typical home healthcare, business, or hospital environment. Do not operate motors or other noisy electrical equipment on the same mains circuit as the Guardio Charger.
AC line voltage surges as defined in IEC 61000-4-5	± 2 kV Common Mode ± 1 kV Differential Mode 1.2/50 µs	± 2 kV Common Mode ± 1 kV Differential Mode 1.2/50 µs	Mains power quality should be that of a typical home healthcare, business, or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines as defined in IEC 61000-4-11	0%, 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles	0%, 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles	Mains power quality should be that of a typical home healthcare, business, or hospital environment. **Note:** If the user of the Guardio Charger requires uninterrupted operation during power mains interruptions, it is recommended to power the Guardio Charger from an uninterruptible power supply.

<table>
<tr><td>Power line frequency magnetic fields (50/60 Hz) as defined in IEC 61000-4-8</td><td>30 A/m</td><td>30 A/m</td><td>Power line frequency magnetic fields (50/60 Hz) should be at levels expected in a typical home healthcare, business, or hospital environment.</td></tr>
<tr><td>Conducted RF as defined in IEC 61000-4-6:2013</td><td>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</td><td>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</td><td rowspan="3">Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance:
$d = 1.17\sqrt{P}$
$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz
Where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, “a” should be less than the compliance level in each frequency range “b”.
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF as defined in IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010</td><td>10 V/m: 80 MHz to 2.7 GHz, 80% 1kHz AM</td><td>10 V/m: 80 MHz to 2.7 GHz, 80% 1kHz AM</td></tr>
<tr><td>Proximity fields from RF communications equipment as defined in IEC 61000-4-3</td><td>Various per table 9</td><td>Various per table 9</td></tr>
<tr><td colspan="4">Notes:
a - Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be theoretically predicted with accuracy. An electromagnetic site survey should be taken into consideration to assess the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location where the Guardio Charger is used exceeds the applicable RF compliance level above, the Guardio Charger should be monitored to ensure normal operation. If an abnormal function is observed, additional measures may be necessary, such as relocating the Guardio Charger.
b - For frequencies in the range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.</td></tr>
</table>

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Guardio Charger

Recommended separation distances between portable and mobile RF communications equipment and the Guardio Charger

The Guardio Charger should be used in an electromagnetic environment with limited radiated RF noise. The customer or user of the Guardio Charger can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the Guardio Charger recommended below, which is determined by the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance broken down by transmitter frequency(m)**		
	150 kHz to 80 MHz[1] $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz[1]** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.75
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.70	11.70	23.30

For transmitters with a maximum rated output power not listed above, the recommended separation distance “d” in meters (m) can be estimated by using the equation applicable to the frequency of the transmitter, where “P” is the maximum rated output power of the transmitter in watts (W) specified by the transmitter manufacturer.

[1] At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply to all settings. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and people.

Electromagnetic Emissions

Electromagnetic Emissions from the Guardio Charger

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

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

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

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

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

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

FCC 47 CFR Part 15 – Radio Frequency Devices

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

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

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

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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO: **FCC 47 CFR 95 Subpart I – Medical Device Radio Communications Service**		
The Guardio Charger, part of the OPTIMIZER INTEGRA CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidelines**
Duration of Transmissions	Complies with clause 95.2557	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Frequency Monitoring	Complies with clause 95.2559	
Frequency Range	Complies with clause 95.2563(a) and 2.1033(c)(5)	
Frequency Stability	Complies with clause 95.2565 and 2.1055	
EIRP	Complies with clause 95.2567(a)(1), 2.1033(c)(6), 2.1033(c)(7), and 2.1046	
Field Strength	Complies with clause 95.2569, 95.2579(a), 2.1053, and 2.1057	
Authorized Bandwidth	Complies with clause 95.2573(a) and 2.1049	
Unwanted Emissions	Complies with clause 95.2579(c), 2.1033(c)(4), and 2.1047	
Permissible Exposure Evaluation	Complies with clause 95.2585 and 2.1093	

ETSI EN 300 330

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

ETSI EN 301 839

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO: **ETSI EN 301 839 V2.1.1 – Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU**		
The Guardio Charger, part of the OPTIMIZER INTEGRA CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidelines**
Frequency Error	Complies with clause 4.2.1.1	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Emission Bandwidth	Complies with clause 4.2.1.2	
EIRP	Complies with clause 4.2.1.3	
Transmitter Spurious Emissions (30 MHz to 6 GHz)	Complies with clause 5.3.4	
Frequency Stability Under Low Voltage Conditions	Complies with clause 4.2.1.5	
Receiver Spurious Emissions	Complies with clause 4.2.2.1	
Spectrum Access	Complies with clause 4.2.3.1	
Receiver Blocking	Complies with clause 4.2.3.2	

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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO: **ETSI EN 301 489-1 V2.2.3 – ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility** **ETSI EN 301 489-27 – ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P) operating in the 402 MHz to 405 MHz bands; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU**			
The Guardio Charger, part of the OPTIMIZER INTEGRA CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment. There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.			
Emissions Test	**Basic Standard**	**Compliance**	**Electromagnetic environment – guidelines**
Radiated Emissions	EN 55032	N/A – covered by relevant radio standards	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions	EN 55032	Pass	
Harmonic Current Emissions	IEC 61000-3-2	Pass	
Voltage Fluctuations	IEC 6100-3-3	Pass	

IEC 60601-1-2 2014

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO: **IEC 60601-1-2 2014, Edition 4.0 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests**			
The Guardio Charger, part of the OPTIMIZER INTEGRA CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment. There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.			
Emissions Test	**Standard/Section**	**Compliance**	**Electromagnetic environment – guidelines**
Radiated Emissions 30-1000MHz	CISPR11, Section 6, Table 11 (Class B, Group 2)	Group 2, Class B	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions 0.15-30MHz, 230V 50Hz and 120V, 60Hz	CISPR11, Section 6, Table 6 (Class B, Group 2)	Group 2, Class B	
AC Harmonic Emissions	IEC 61000-3-2	Class A	
Voltage Fluctuations	IEC 61000-3-3	Pass	

APPENDIX II

Wireless Technology

RF wireless technology is used to transcutaneously transmit energy from the Guardio 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 (1.5 in) between the Charger's coil and the IPG's receiving coil. Control over the recharge process, as well as the communications of alert messages from the IPG to the Charger take place over an encrypted MICS channel.

Guardio Charger Wireless Nominal Specifications

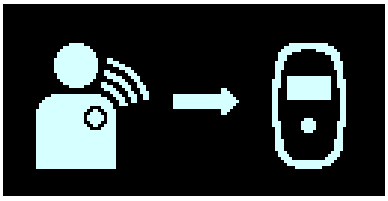
Characteristic	Nominal
MICS MedRadio	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	240 kHz
Modulation	FSK
Radiated Power	-20.6 dBm EIRP
Range	0 to at least 1.5 m
Transcutaneous Energy Transfer	
Frequency Band	13.56 MHz Industrial, Scientific, and Medical radio band (ISM)
Modulation	Amplitude (slow to optimize coupling)
Radiated Power	< 0.6 W reactive near-field
Range	5 mm to 40 mm
Recharge Channel Communication	
Frequency Band	13.56 MHz ± 9.2 ppm Industrial, Scientific, and Medical radio band (ISM)
Bandwidth	< 0.014 MHz
Modulation	PPM
Radiated Power	-6.93 dBm EIRP
Range	5 mm to 40 mm

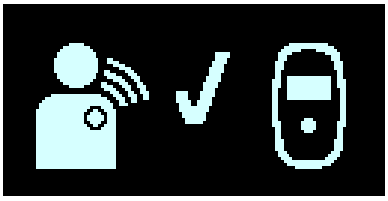
Quality of Service (QoS) for Wireless Technology

QoS for Communications between the Guardio Charger and the OPTIMIZER INTEGRA CCM-D IPG

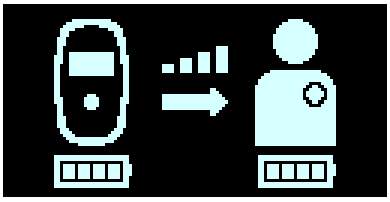
MedRadio in the MICS sub-band (402 to 405 MHz) wireless technology enables communication between the OPTIMIZER INTEGRA CCM-D IPG and the Guardio Charger. The requirements for the Quality of Service (QoS) vary depending on the use environment (operating room, recovery room, clinic, and home environment).

The Guardio Charger will begin by displaying the IPG Data Download and IPG Data Download Success screens:





After the data download has been completed, the Charging IPG Status screen is displayed by the Guardio Charger:

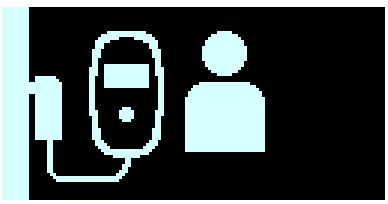


The Coupling Level icon (), whose number of illuminated bars is proportional to the proximity of the charging wand to the implanted OPTIMIZER INTEGRA CCM-D IPG, is indicative of the Quality of Service (QoS) for the transcutaneous energy transmission wireless link. The charging wand should be repositioned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

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

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

If the Guardio Charger and the OPTIMIZER INTEGRA CCM-D IPG do not communicate within a programmable time period, the patient may see the “Long Time Without Downloading Data From IPG” alert screen displayed by the Guardio Charger:



In this case, instruct the patient to attempt to charge their OPTIMIZER INTEGRA CCM-D IPG with their Guardio Charger. If the patient is able to charge their implanted device successfully, then the alert screen should no longer be displayed by the Guardio Charger. If the attempt to charge the OPTIMIZER INTEGRA CCM-D IPG with the Guardio Charger is unsuccessful, please call the 24-hour Support Hotline (866-312-5370).

Wireless Security Measures

Wireless Security Measures in Communications between OPTIMIZER INTEGRA CCM-D IPG and Guardio Charger

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

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

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

- Pairing of a Guardio Charger and an OPTIMIZER INTEGRA CCM-D IPG requires the placing of a pairing magnet on the Guardio Charger and locating the Charge Wand within 4 cm (1.5 in) of the OPTIMIZER INTEGRA CCM-D IPG. The 13.56 MHz short-range channel is used as part of a proprietary process to pair the devices and exchange encryption keys.
- The OPTIMIZER INTEGRA CCM-D IPG and the Guardio Charger encrypt their wireless communications using encryption keys that are generated during the pairing process.
- Only one Guardio Charger can be paired with the IPG at any one time.

Troubleshooting for Wireless Coexistence Issues

Troubleshooting Wireless Connection between OPTIMIZER INTEGRA CCM-D IPG and Guardio Charger

If you experience issues with establishing a wireless connection between the OPTIMIZER INTEGRA CCM-D IPG and the Guardio Charger, try the following:

- Whenever the Guardio Charger is not being used to charge the OPTIMIZER INTEGRA CCM-D IPG, place it in an area that is frequented by the patient (e.g., bedside table in the bedroom), connected to its AC Adapter, and the AC Adapter plugged into the wall outlet. This will ensure regular communications between the OPTIMIZER INTEGRA CCM-D IPG and the Guardio Charger.
- Remain stationary during the charging or data transfer process.
- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Do not operate other wireless devices (i.e., programmers for other devices, laptop, tablet, mobile phone, or cordless phone) at the same time.
- Wait a few minutes and try connecting again.

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

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