IMPULSE DYNAMICS

Hope is Here

Guardio/Vesta Charger System

INSTRUCTIONS FOR USE

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

Part No.: 13-290-021-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: 2024-08-30

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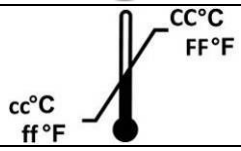
EXPLANATION OF SYMBOLS ON LABELS

Symbol	Description
CE 0344	CE Conformity marking, 0344 - Notified Body Number
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Consult instructions for use
	Do not use if package is damaged
	Storage and transport temperature limits
	Date of manufacture
	Manufacturer
EC REP	Authorized representative in the European Community
REF	Catalogue number
SN	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/VESTA CHARGER SYSTEM

1.1 Description

The Guardio/Vesta Charger is designed to charge the rechargeable battery of the OPTIMIZER® Smart Mini/OPTIMIZER Integra™ CCM-D® IPG (henceforth collectively referred to as "OPTIMIZER 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/Vesta 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 the implanted device, etc.).

The Guardio/Vesta Charger has a permanently attached charging wand and is powered by a rechargeable battery. To recharge this battery, the Guardio/Vesta 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/Vesta 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/Vesta 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/Vesta Charger is not operating as expected, such interference has to be taken into account.

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

The Guardio/Vesta Charger charges the OPTIMIZER IPG at a frequency range of 13.56 MHz.

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

When the distance between the Charging Wand and the OPTIMIZER IPG is > 2.0 cm, the Guardio/Vesta Charger should be able to recharge the OPTIMIZER 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/Vesta Charger's battery may become depleted before the rechargeable battery in the OPTIMIZER IPG is fully charged

Table 1: IPG Charge Levels Attained with Fully Charged Guardio/Vesta 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/Vesta Charger should be able to perform two IPG charging cycles, charging the IPG rechargeable battery from 10% to 90% each time, when the distance between the Charging Wand and the OPTIMIZER IPG is between 0.5 cm and 2.0 cm.

1.2 User Profile and Training

The operators of the Guardio/Vesta Charger system include patients, physicians (and the trained medical personnel who assist them), and Impulse Dynamics representatives. Physicians, any assisting medical personnel, and Company representatives who operate the Guardio/Vesta 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/Vesta Charger.

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

1.3 Charging Method

The charging method utilized by the Guardio/Vesta Charger to charge the rechargeable battery of the OPTIMIZER 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 rechargeable battery of the IPG is as follows:

1. Electrical energy from the battery of the Guardio/Vesta 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 rechargeable battery of the IPG.

1.4 System Components

The Guardio/Vesta Charger System consists of the following components:

Figure 1: Guardio/Vesta Charger System Components

- **Guardio/Vesta Charger** (with attached charging wand and charging wand cable clip) – used to charge the OPTIMIZER IPG.
- **AC Adapter** – used to charge the internal battery of the Guardio/Vesta 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/Vesta Charger System.

1.5 Features

The Guardio/Vesta Charger has the following features:

- **Graphical Display:** Display screen used by the Guardio/Vesta Charger to communicate information to the patient
- **Power Button:** Press-button switch used to initiate and terminate charging of the OPTIMIZER IPG and to silence alerts displayed by the Guardio/Vesta 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/Vesta Charger for charging as well as short-range communications with the OPTIMIZER IPG
- **Radio Transceiver:** Device used by the Guardio/Vesta Charger for long-range communications [between zero and at least 1.5 m (5 ft)] with the OPTIMIZER IPG
- **Cellular Modem (Guardio Only):** Modem is used to send data downloaded from the OPTIMIZER IPG to the Remote Patient Monitoring Service (RPMS)

1.6 Overview of the Screens Displayed by the Guardio/Vesta Charger

The Guardio/Vesta Charger displays a different screen for each operational state. This section presents an overview of each screen displayed by the Guardio/Vesta 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/Vesta Charger. The number of bars shown on the battery icon will vary depending on the current level of charge in the Guardio/Vesta Charger battery (see **Table 2**).

Table 2: Guardio/Vesta 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/Vesta Charger, when the AC Adapter is connected to the Guardio/Vesta Charger and the battery charge level of the Guardio/Vesta Charger is above 75%, or when the AC Adapter is charging the Guardio/Vesta Charger and the AC Adapter current is less than 50 mA.

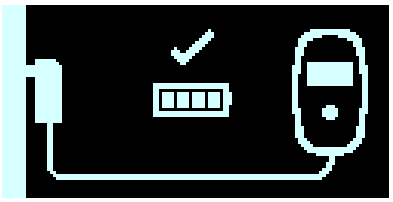


Figure 3: Charger Self-Charge Success Screen

1.6.1.3 IPG Data Download Screen

This screen is displayed whenever the Guardio/Vesta Charger is actively attempting to download data from the OPTIMIZER IPG. The encrypted data downloaded from the device includes information regarding the current status of the 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/Vesta Charger and then plugged into the wall outlet.

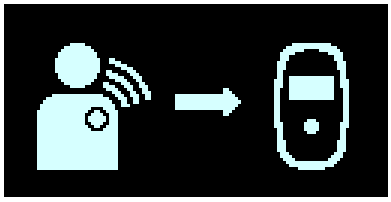


Figure 4: IPG Data Download Screen

1.6.1.4 IPG Data Download Success Screen

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

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

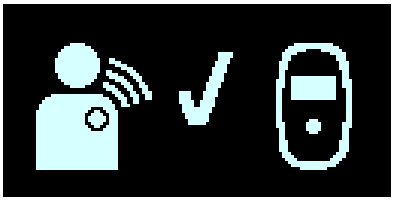


Figure 5: IPG Data Download Success Screen

1.6.1.5 IPG Data Download Error Screen

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

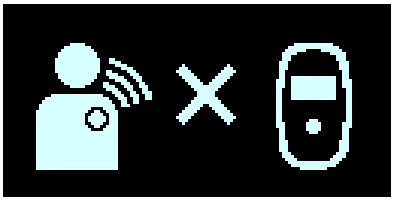


Figure 6: IPG Data Download Error Screen

1.6.1.6 Data Upload Status Screen (Guardio Only, If Enabled)

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

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

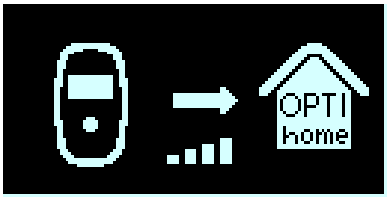


Figure 7: Data Upload Status Screen

1.6.1.7 Data Upload Success Screen (Guardio Only, If Enabled)

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

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

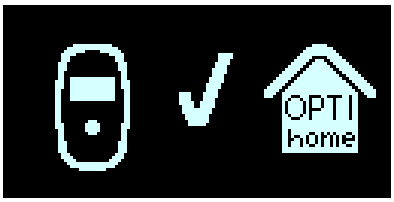


Figure 8: Data Upload Success Screen

1.6.1.8 Data Upload Error Screen (Guardio Only, If Enabled)

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

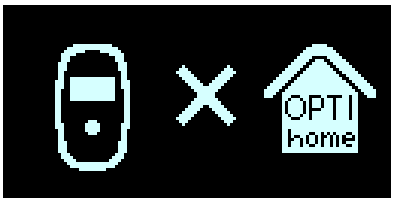


Figure 9: Data Upload Error Screen

1.6.2 Screens Displayed When Pairing with the OPTIMIZER IPG

1.6.2.1 Charger/IPG Pairing Screen

This screen is displayed whenever the Guardio/Vesta Charger is actively pairing with the OPTIMIZER IPG.

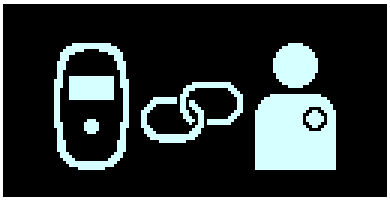


Figure 10: Charger/IPG Pairing Screen

1.6.2.2 Charger/IPG Pairing Success Screen

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

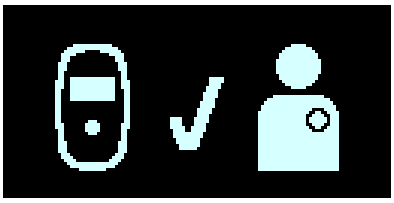


Figure 11: Charger/IPG Pairing Success Screen

1.6.2.3 Charger/IPG Pairing Error Screen

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

Figure 12: Charger/IPG Pairing Error Screen

1.6.3 Screens Displayed When Charging the OPTIMIZER IPG

1.6.3.1 IPG Data Download Screen

This screen is displayed whenever the Guardio/Vesta Charger is actively downloading data from the OPTIMIZER IPG.

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

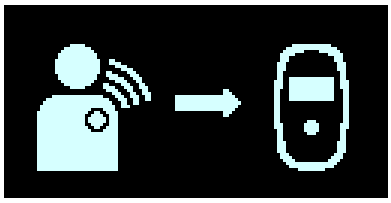


Figure 13: IPG Data Download Screen

1.6.3.2 IPG Data Download Success Screen

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

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

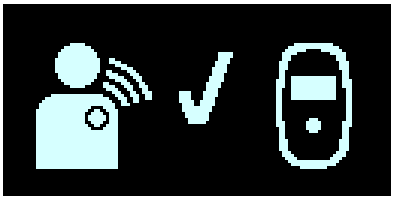


Figure 14: IPG Data Download Success Screen

1.6.3.3 IPG Data Download Error Screen

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

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

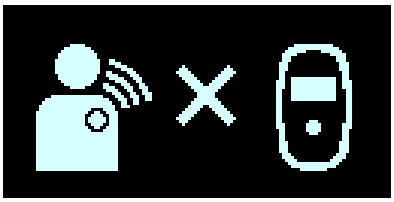


Figure 15: IPG Data Download Error Screen

1.6.3.4 Charging IPG Status Screen

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

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

The number of bars shown on the Guardio/Vesta 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/Vesta Charger Battery Charge Levels

Guardio/Vesta 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 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%

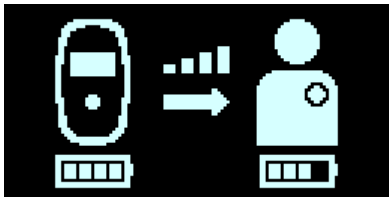


Figure 16: Charging IPG Status Screen (actively charging)

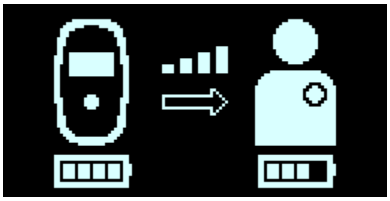


Figure 17: Charging IPG Status Screen (not actively charging)

1.6.3.5 Charging IPG Coupling Error Screen

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

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

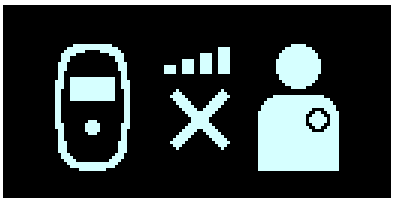


Figure 18: Charging IPG Coupling Error Screen

1.6.3.6 IPG Charging Successfully Completed Screen

This screen is displayed whenever the Guardio/Vesta Charger has successfully completed charging the rechargeable battery of the OPTIMIZER IPG.

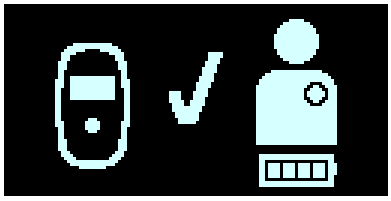


Figure 19: IPG Charging Successfully Completed Screen

1.6.3.7 Charging IPG Timeout Error Screen

This screen is displayed by the Guardio/Vesta Charger whenever the charging duration of the OPTIMIZER IPG exceeds 5 hours ± 5 minutes.

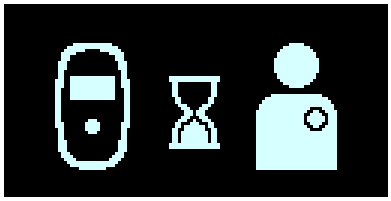


Figure 20: Charging IPG Timeout Error Screen

1.6.3.8 Charging IPG Temperature Error Screen

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

- The reported temperature of the OPTIMIZER 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 IPG remaining consistently high for more than 10 minutes.

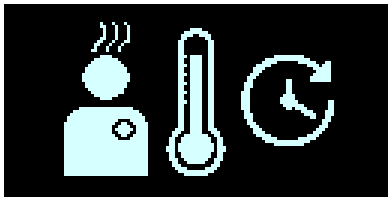


Figure 21: Charging IPG Temperature Error Screen

1.6.3.9 Power Supply Error Screen

This screen is displayed whenever the AC Adapter is connected to the Guardio/Vesta Charger while it is charging the OPTIMIZER IPG.

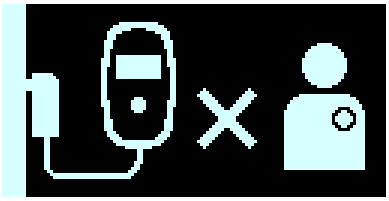


Figure 22: Power Supply Error Screen

1.6.3.10 Charge Session Cancellation Screen

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

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

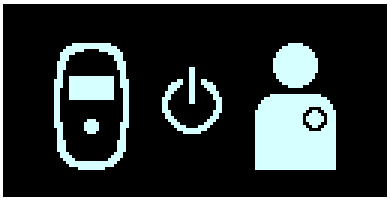


Figure 23: Charge Session Cancellation Screen

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/Vesta Charger's battery charge level drops below 10%. The display of this screen is accompanied by short beeping tones.

Figure 24: 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 Smart Mini or Optimizer Integra Programmer application (henceforth collectively referred to as "Optimizer Programmer application") and the number of days since the OPTIMIZER 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 25: 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 Programmer application and the number of days since the last successful communication between the Guardio/Vesta Charger and the OPTIMIZER IPG has exceeded the number of days set for this Patient Alert. The display of this screen is accompanied by short beeping tones.

Figure 26: Long Time Without Downloading Data From IPG Alert Screen

1.6.4.4 Long Time Without Uploading Data To RPMS Alert Screen (Guardio Only, If Enabled)

This screen is displayed whenever the Patient Alert “Long time without transmitting data to the remote monitor” is enabled using the Optimizer Programmer application and the number of days since the last successful data upload from the Guardio Charger to the OPTIHome Remote Patient Monitoring Service has exceeded the number of days set for this Patient Alert.

Figure 27: Long Time Without Uploading Data To RPMS Alert Screen

1.6.4.5 Abnormal Condition Error Screen

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

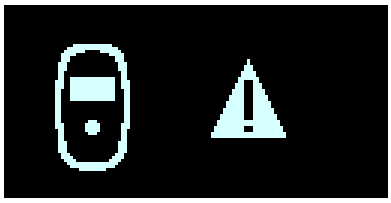


Figure 28: Abnormal Condition Error Screen

1.6.4.6 Call Doctor Alert Screen

This screen is displayed whenever a Call Doctor Patient Alert that is enabled by the Optimizer 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 29: Call Doctor Alert Screen

1.6.4.7 Snooze Buzzer Alert Screen

This screen instructs the patient to press the button on the Guardio/Vesta 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.

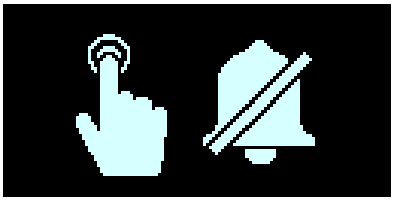


Figure 30: Snooze Buzzer Alert Screen

1.6.4.8 Snooze Alert Screen

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

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

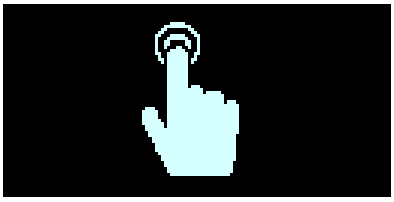


Figure 31: Snooze Alert Screen

1.6.5 Info Screens

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

- The AC Adapter is connected to the Guardio/Vesta 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.

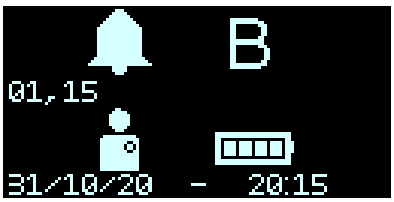


Figure 32: First Info Screen

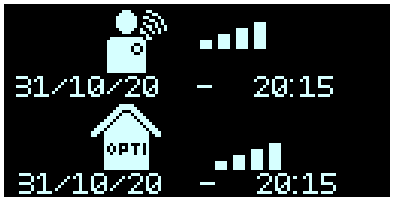
1.6.5.2 Second Info Screen

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 (if enabled)
- The date and time of the last successful IPG data upload session (if enabled)

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



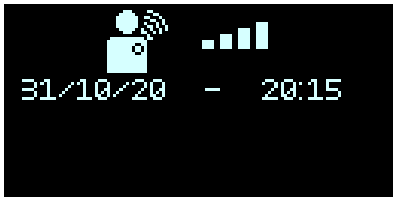
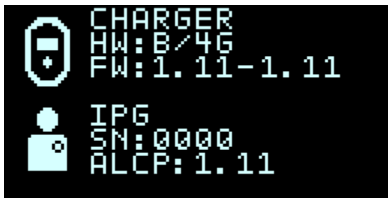


Figure 33: Second Info Screen (Guardio) **Second Info Screen (Vesta)**

1.6.5.3 Third Info Screen

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

- **CHARGER**
  - **HW:**
    - Guardio Charger: hardware version/modem type
    - Vesta Charger: “VESTA”
  - **FW:** Firmware versions of the Guardio/Vesta Charger’s Charger and GUI modules (CHG-GUI)
- **IPG**
  - **SN:** Serial number of IPG currently paired with the Guardio/Vesta Charger.
  - **ALCP:** Application Level Communication Protocol (ALCP) version of firmware in the IPG currently paired with the Guardio/Vesta Charger.



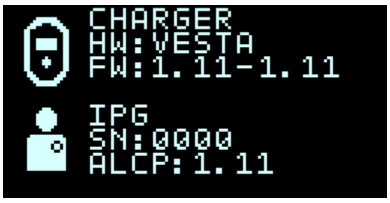


Figure 34: Third Info Screen (Guardio) **Third Info Screen (Vesta)**

1.7 Pairing the Guardio/Vesta Charger with the OPTIMIZER IPG

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

During the pairing process, the Guardio/Vesta 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/Vesta Charger for all its subsequent communications sessions with the paired device.

To pair the Guardio/Vesta Charger with the OPTIMIZER IPG, perform the following steps:

1. Determine the location of the OPTIMIZER Smart Mini IPG (typically right upper chest area) or OPTIMIZER Integra CCM-D IPG (typically left upper chest area) and then place the charging wand directly over the 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/Vesta Charger. **See Figure 35**.

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

Figure 35: Pairing Magnet on Guardio/Vesta 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/Vesta Charger is actively attempting to pair with the OPTIMIZER IPG. **See Figure 36**.

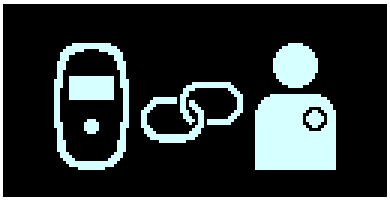


Figure 36: Charger/IPG Pairing Screen

5. When the pairing process has been completed, the Guardio/Vesta Charger will emit 3 short beeping tones and display the Charger/IPG Pairing Success screen. **See Figure 37**.

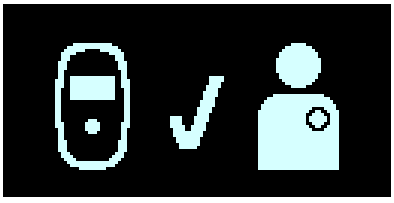


Figure 37: Charger/IPG Pairing Success Screen

6. Remove the pairing magnet from the Guardio/Vesta Charger.

1.8 Charging the Guardio/Vesta Charger

Note: When the Guardio/Vesta 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/Vesta Charger fully charged and ready to be used the next time they need to charge their implanted OPTIMIZER IPG.

Note: Charging the Guardio/Vesta Charger and charging the OPTIMIZER IPG CANNOT be done simultaneously. Always charge the internal battery of the Guardio/Vesta Charger before attempting to charge the rechargeable battery of the OPTIMIZER 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/Vesta Charger to charge the battery in the Guardio/Vesta Charger. Otherwise, damage to the Guardio/Vesta Charger may result.

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

1. Turn the Guardio/Vesta 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.

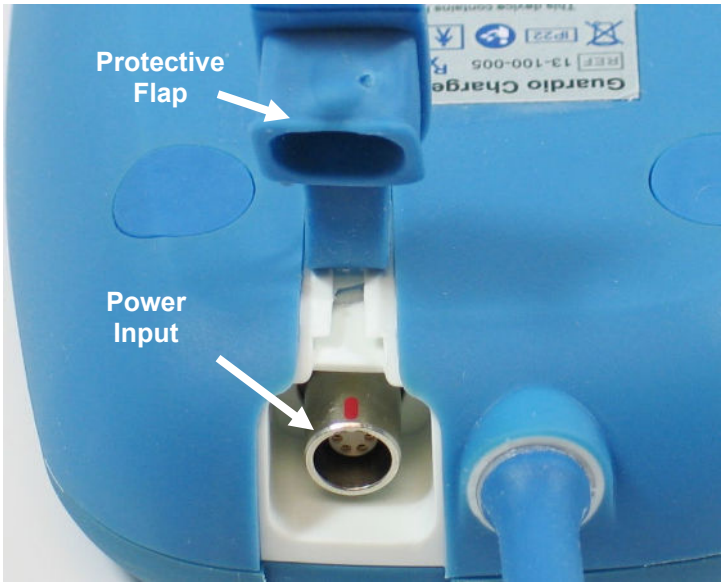


Figure 38: Back of the Guardio/Vesta Charger

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/Vesta Charger and then insert in the DC output connector into the power input connector. **See Figure 39.**

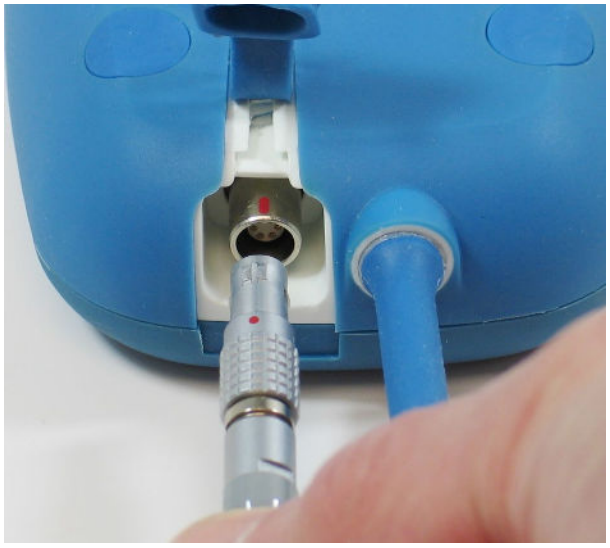


Figure 39: Alignment of the DC Output and Guardio/Vesta Charger Connectors

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/Vesta Charger.

When the Charging Self-Charge Success screen is displayed on the Guardio/Vesta Charger screen, the battery in the Guardio/Vesta Charger is fully charged. **See Figure 40**.

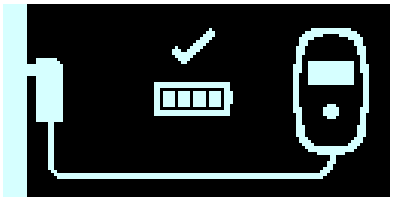


Figure 40: Charger Self-Charge Success Screen

To disconnect the AC Adapter from the Guardio/Vesta 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/Vesta Charger.

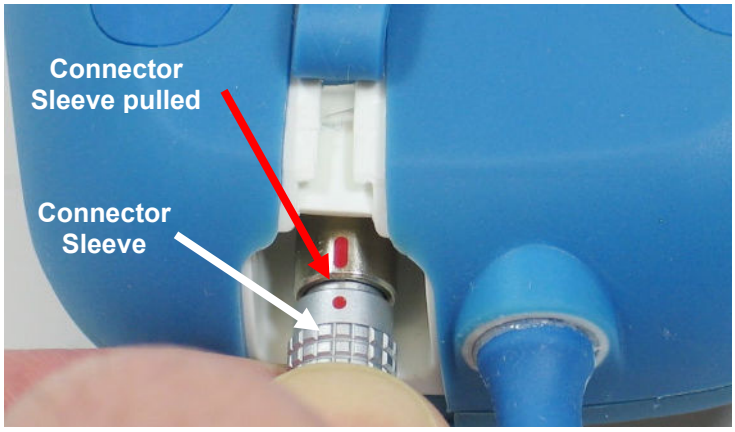


Figure 41: Close-up of the Connector Sleeve

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

1.9 Charging the OPTIMIZER IPG

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

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

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

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

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

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

1. Place the patient in a stationary, comfortable sitting position, ideally reclining at a 45° angle (e.g., on a sofa or armchair).
2. Determine the location of the OPTIMIZER Smart Mini IPG (typically right upper chest area) or OPTIMIZER Integra CCM-D IPG (typically left upper chest area) and then place the flat side of the Guardio/Vesta charging wand (the side with the four blue rubber screw covers) directly over the 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 42 and 43**.

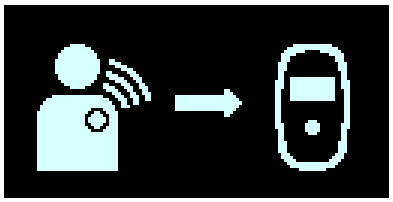


Figure 42: IPG Data Download Screen

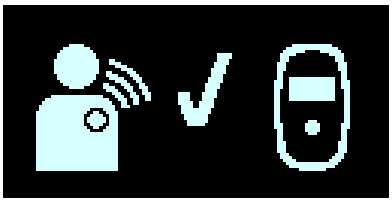


Figure 43: IPG Data Download Success Screen

5. After the data download has been completed, the Guardio/Vesta Charger displays the Charging IPG Status screen. **See Figure 44**.

   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.

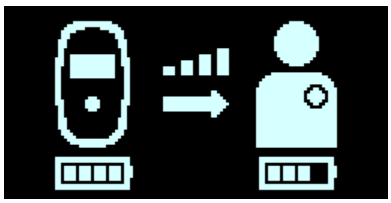


Figure 44: Charging IPG Status Screen

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/Vesta 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 IPG.

7. The Charging IPG Status screen (see **Figure 44**) will continue to be displayed as the OPTIMIZER 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 the patient 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/Vesta 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 IPG during the charging session. Also, inform the patient that charging their implanted device may take longer than one hour if its rechargeable battery is significantly depleted. If the recharging of the OPTIMIZER 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 rechargeable battery of the OPTIMIZER IPG is fully charged, the Guardio/Vesta Charger will emit three short beeping tones and display the IPG Charging Successfully Completed screen (see **Figure 45**). The Guardio/Vesta Charger will then shut off automatically.

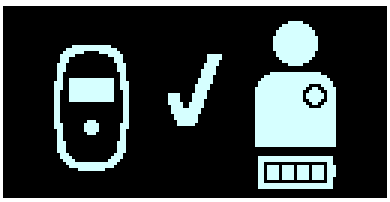


Figure 45: IPG Charging Successfully Completed Screen

9. Detach the charging wand cable clip from the patient's clothing (if necessary), then remove the Guardio/Vesta 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/Vesta 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/Vesta Charger will emit 3 short beeping tones and display the Charge Session Cancellation screen. **See Figure 46**.

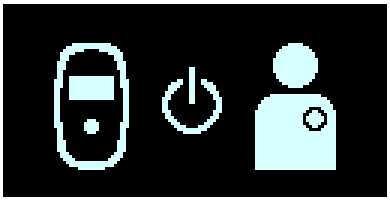


Figure 46: Charge Session Cancellation Screen

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

Note: During the charging process, the Guardio/Vesta Charger monitors the temperature of the OPTIMIZER IPG. To resume charging the OPTIMIZER IPG after terminating a charging session, please wait for approximately 20 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 IPG in Special Charge Mode

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

Note: The OPTIMIZER IPG must be paired with the Guardio/Vesta 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/Vesta Charger with the OPTIMIZER IPG before proceeding.

To charge an OPTIMIZER 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 Smart Mini IPG (typically right upper chest area) or OPTIMIZER Integra CCM-D IPG (typically left upper chest area) and then place the flat side of the Guardio/Vesta charging wand (the side with the four blue rubber screw covers) directly over the 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/Vesta Charger. **See Figure 47**.

   Note: Placing a pairing magnet (or a standard pacemaker magnet) to the left of the **Power Button** on the Guardio/Vesta Charger is not required when charging an OPTIMIZER Integra CCM-D IPG in Special Charge Mode.

Figure 47: Pairing Magnet on Guardio/Vesta Charger

4. Start the charging process by pressing and holding down the **Power Button** (> 5 seconds) until the Guardio/Vesta Charger emits a single beeping tone, and then releasing it.
5. When the Guardio/Vesta 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 48** will be displayed during the charging session.

Figure 48: Charging IPG Status Screen When Charging IPG in Special Charge Mode

1.11 Guardio/Vesta Charger Placement When Not Being Used for Device Charging

Whenever the Guardio/Vesta Charger is not being used to charge the OPTIMIZER 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/Vesta Charger fully charged as well as ensure regular communications between the OPTIMIZER IPG and the Guardio/Vesta Charger.

1.12 Frequency of Charging Sessions

The optimal performance of the rechargeable battery in the OPTIMIZER IPG is only ensured if the battery is fully recharged every week. The day or time chosen to charge the OPTIMIZER 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/Vesta Charger is not used to perform a charging session on the OPTIMIZER IPG within the time period set by the Optimizer Programmer application, the patient may see the Long Time Without Charging IPG alert screen (see **Figure 49**) displayed by the Guardio/Vesta Charger.

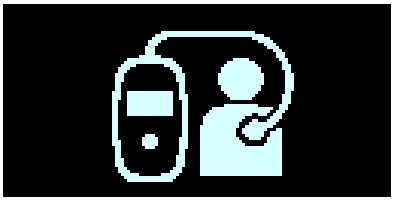


Figure 49: Long Time Without Charging IPG Alert Screen

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

If the battery voltage of the OPTIMIZER IPG rechargeable battery drops below 3.5 V, CCM therapy delivery is automatically suspended. If this occurs, the OPTIMIZER IPG will need to be recharged before it resumes delivering CCM therapy. Once the OPTIMIZER 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 IPG

When the Guardio/Vesta Charger is connected to the AC Adapter, it attempts to communicate with its paired IPG every 10 minutes. **See Figure 50**.

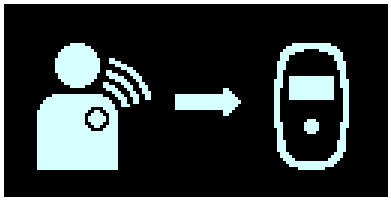


Figure 50: IPG Data Download Screen

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/Vesta Charger. **See Figure 51**.

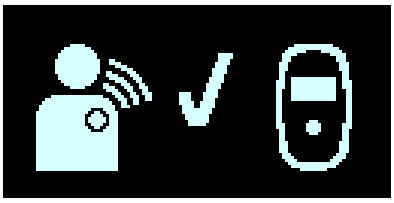


Figure 51: IPG Data Download Success Screen

If the communication session is unsuccessful, an X will be displayed at the end of the communication attempt. **See Figure 52**.

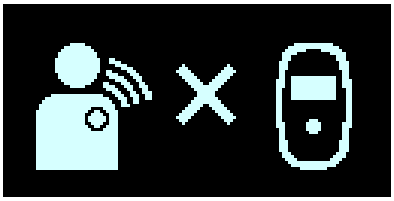


Figure 52: IPG Data Download Error Screen

If the Guardio/Vesta Charger and the OPTIMIZER IPG do not communicate within the time period set by the Optimizer Programmer application, the patient may see the Long Time Without Downloading Data From IPG alert screen (see **Figure 53**) displayed by the Guardio/Vesta Charger.

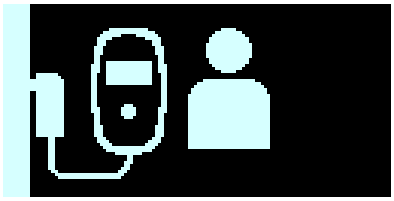


Figure 53: Long Time Without Downloading Data From IPG Alert Screen

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

1.13.2 Communications with the OPTIhome Remote Patient Monitoring Service (Guardio Only, If Enabled)

If enabled, when the Guardio Charger is connected to the AC Adapter, it will attempt to communicate with OPTIhome Remote Patient Monitoring Service (RPMS) once a day using its cellular modem to access the local cellular network and connect to the OPTIhome server. When this occurs, the patient will first see the Guardio Charger display the Data Upload screen. **See Figure 54**.

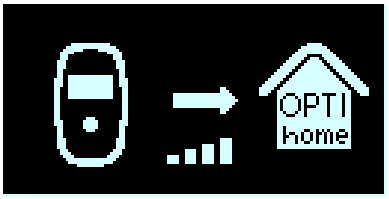


Figure 54: Data Upload Screen

If the data upload is successful, flashing checkmark at the center of the screen will be displayed at the end of the communication session. **See Figure 55**.

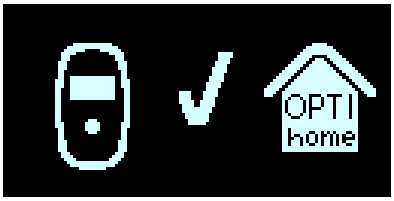


Figure 55: Data Upload Success Screen

If the data upload is unsuccessful, a flashing “X” at the center of the screen will be displayed at the end of the communication attempt (see **Figure 56**). If this occurs, the Guardio Charger will attempt to upload data to the server again in an hour.

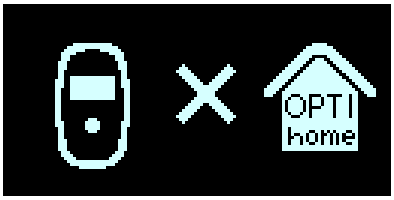


Figure 56: Data Upload Error Screen

If the Guardio Charger does not upload data to the OPTIhome Remote Patient Monitoring Service (RPMS) server within the time period set by the Optimizer Programmer application, the patient may see the Long Time Without Uploading Data To Server alert screen (see **Figure 57**) displayed by the Guardio Charger.

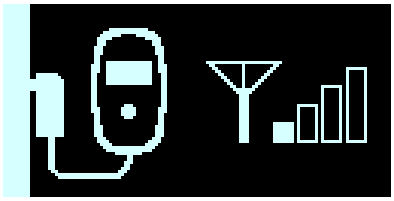


Figure 57: Long Time Without Uploading Data To Server Alert Screen

If a patient reports seeing this screen displayed by the Guardio Charger, instruct the patient to relocate their Guardio Charger and its AC Adapter to an area more conducive to cellular network communication and then plug the AC Adapter into the nearest wall outlet. If the Guardio Charger is subsequently able to successfully upload data to the OPTIhome Remote Patient Monitoring Service (RPMS) server, then the alert screen should no longer be displayed by the Guardio Charger. If the patient continues to report seeing this screen on their Guardio Charger two or more days after they have placed it in a new location, please call the 24-hour Support Hotline (866-312-5370).

1.14 Call Doctor Alert Codes

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

If a detected alert condition is associated with a Direct Action Alert, its alert screen will be displayed by the Guardio/Vesta Charger. Please refer to **Figures 24, 49, 53, and 57** to identify the Direct Action Alert displayed by the Guardio/Vesta Charger.

If the detected condition is associated with a Call Doctor Alert, the Guardio/Vesta 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 Programmer application.

Table 5: Call Doctor Alert Codes for the OPTIMIZER 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 no longer paired with Charger (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/Vesta 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

1.14.2.1 Alert Code 1 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 OPTIMIZER IPG has been deactivated and placed in Safe Mode. If the Guardio/Vesta Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370). For AIM HIGHer subjects, please call the AIM HIGHer 24-hour Support Hotline (1-855-246-4437).

1.14.2.6 Alert Code 11 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 (OPTIMIZER Integra CCM-D IPG Only)

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 IPG has detected a significant change in the impedance in one or both ventricular leads. If the Guardio/Vesta Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370). For AIM HIGHer subjects, please call the AIM HIGHer 24-hour Support Hotline (1-855-246-4437).

1.14.2.15 Alert Code 21

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

Note: This alert is disabled for the AIM HIGHer clinical trial.

1.14.2.16 Alert Code 23

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

Note: This alert is disabled for the AIM HIGHer clinical trial.

1.14.2.17 Alert Code 25

When Alert Code 25 is displayed, it means that the OPTIMIZER IPG has detected that an implanted lead is not sensing or sensing an excessive amount of noise. If the Guardio/Vesta Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370). For AIM HIGHer subjects, please call the AIM HIGHer 24-hour Support Hotline (1-855-246-4437).

1.14.2.18 Alert Code 27

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

Note: This alert is disabled for the AIM HIGHer clinical trial.

1.14.2.19 Alert Code 29 (OPTIMIZER Integra CCM-D IPG Only)

When Alert Code 29 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/Vesta Charger has detected repeated internal errors during its operation. If the Guardio/Vesta Charger displays this Alert Code, please call the 24-hour Support Hotline (866-312-5370). For AIM HIGHer subjects, please call the AIM HIGHer 24-hour Support Hotline (1-855-246-4437).

1.14.2.21 Alert Code 32

When Alert Code 32 is displayed, it means that the Guardio/Vesta Charger has determined that it is attempting to be used on an unrecognized device. If the Guardio/Vesta Charger displays this Alert Code, please pair the Guardio/Vesta Charger with the implanted OPTIMIZER IPG and then restart the charging process. If the Guardio/Vesta Charger still displays this code after it has been successfully paired with the implanted OPTIMIZER IPG, please call the 24-hour Support Hotline (866-312-5370). For AIM HIGHer subjects, please call the AIM HIGHer 24-hour Support Hotline (1-855-246-4437).

1.15 FCE Charger

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

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

The FCE Charger is intended to be used in a clinical setting to charge a patient's implanted OPTIMIZER IPG whose rechargeable 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 rechargeable battery charge level is too low to allow for an IPG reset.

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

1.15.1 Screens Displayed When FCE Charger is Connected to AC Adapter

1.15.1.1 FCE Charger Self-Charge Status Screen

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

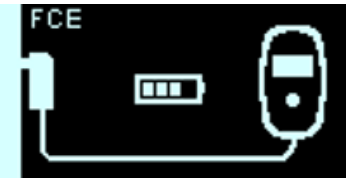


Figure 58: FCE Charger Self-Charge Status Screen

1.15.1.2 FCE Charger Self-Charge Success Screen

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

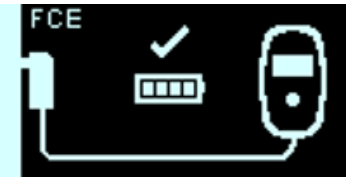


Figure 59: FCE Charger Self-Charge Success Screen

1.15.2 Charging the OPTIMIZER IPG Using the FCE Charger

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

1. Place the patient in a stationary, comfortable sitting position.
2. Determine the location of the OPTIMIZER Smart Mini IPG (typically right upper chest area) or OPTIMIZER Integra CCM-D IPG (typically left upper chest area) and then place the flat side of the FCE Charger charging wand (the side with the four blue rubber screw covers) directly over the 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 Charger, the charging process begins by displaying the FCE Charger/IPG Pairing screen as the FCE Charger attempts to pair with the OPTIMIZER IPG. **See Figure 60**.

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

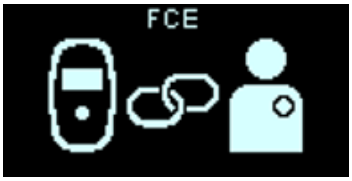


Figure 60: FCE Charger/IPG Pairing Screen

5. When the pairing process has been successfully completed, the FCE Charger will emit 3 short beeping tones and display the Charger/IPG Pairing Success screen. **See Figure 61**.

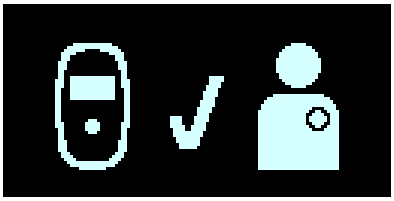


Figure 61: Charger/IPG Pairing Success Screen

6. After the pairing has been successfully completed, the FCE Charger will display the FCE Charging IPG Status screen. **See Figure 62**.

   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 62: 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 FCE 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 62**) will continue to be displayed as the OPTIMIZER 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 Charger is only to charge the rechargeable battery of the OPTIMIZER 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 62**) 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 rechargeable battery of the OPTIMIZER IPG is fully charged, the FCE Charger will emit three short beeping tones and display the IPG Charging Successfully Completed screen (see **Figure 63**). The FCE Charger will then shut off automatically.

Figure 63: IPG Charging Successfully Completed Screen

9. Remove the FCE Charger 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 IPG in Safe Mode

When charging an OPTIMIZER IPG that is in Safe Mode, the FCE Charging IPG Status screen shown in **Figure 64** will be displayed during the charging session.

Figure 64: FCE Charging IPG Status Screen When Charging IPG in Safe Mode

1.15.3 Charging the OPTIMIZER IPG in Unpaired Charge Mode

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

1. Place the patient in a stationary, comfortable sitting position.
2. Determine the location of the OPTIMIZER Smart Mini IPG (typically right upper chest area) or OPTIMIZER Integra CCM-D IPG (typically left upper chest area) and then place the flat side of the FCE Charger charging wand (the side with the four blue rubber screw covers) directly over the 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 FCE Charger. **See Figure 65**.

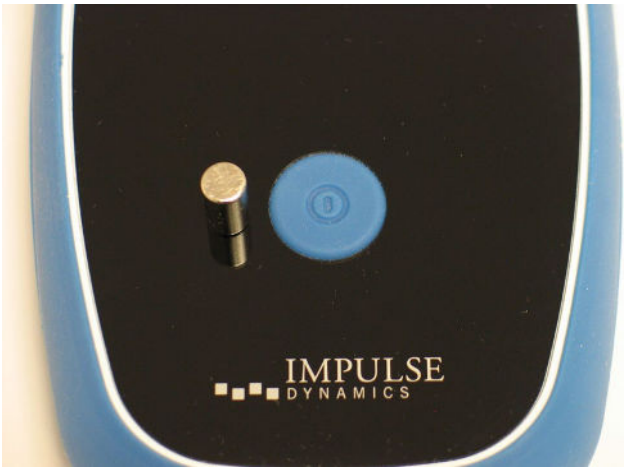


Figure 65: Pairing Magnet on FCE Charger

4. Start the unpaired charging process by pressing and holding down the **Power Button** (> 10 seconds) until the FCE Charger automatically starts the charging process, and then releasing it.
5. When using the FCE Charger in Unpaired Charge Mode, the charging process begins by displaying the FCE Charging IPG Status screen. **See Figure 66**.

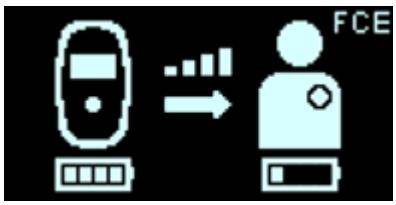


Figure 66: FCE Charging IPG Status Screen in Unpaired Charge Mode

6. If the FCE Charger is able to reestablish communications with the OPTIMIZER IPG within 5 minutes of charging in Unpaired Charge Mode, the FCE Charger will emit three short beeping tones, display the Charge Session Cancellation screen (see **Figure 67**), and then automatically terminate the Unpaired Charge Mode charging session. When this occurs, remove the Pairing Magnet from atop the FCE Charger and then proceed Step 3 in section 1.15.2.

   Note: If the FCE Charger is not able to reestablish communications with the OPTIMIZER IPG after 5 minutes of charging in Unpaired Charge Mode, it will emit three short beeping tones, display the Charge Session Cancellation screen (see **Figure 67**), and then terminate the Unpaired Charge Mode charging session. If this occurs, repeat Step 4 to initiate another charge session in Unpaired Charge Mode.

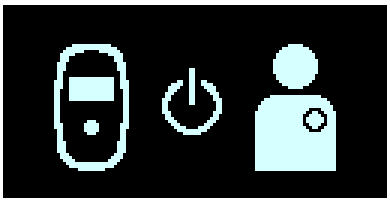


Figure 67: Charge Session Cancellation Screen

1.16 Cleaning

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

The exterior surface of the Guardio/Vesta 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 the Guardio/Vesta Charger.

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

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

1.17 Maintenance

The Guardio/Vesta Charger does not contain any user-serviceable parts. If the Guardio/Vesta 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/Vesta Charger is expected to have a service life of at least 5 years. If the Guardio/Vesta Charger cannot fully charge an OPTIMIZER 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/Vesta 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/Vesta Charger System should not be exposed to excessively hot or cold storage conditions. Patients should be instructed not to leave the Guardio/Vesta 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/Vesta Charger System.

For proper operation, the Guardio/Vesta 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/Vesta Charger is designed for indoor use.

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

1.19 Disposal

If the Guardio/Vesta 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/Vesta Charger in the trash bin. The Guardio/Vesta Charger contains Lithium batteries as well as non-RoHS components. If disposal of the Guardio/Vesta Charger is necessary, properly dispose of the Guardio/Vesta Charger in accordance with local regulations governing the disposal of such material.

APPENDIX I

Statement of FCC Compliance

FCC Compliance of the Guardio/Vesta Charger

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

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

This device complies with part 18 of the FCC Rules.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

— Reorient or relocate the receiving antenna.

— Increase the separation between the equipment and receiver.

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

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

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

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

Changes or modifications to the Guardio/Vesta Charger not approved by Impulse Dynamics could void the user’s authority to operate the equipment under FCC rules.

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

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

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

Electromagnetic Immunity

Electromagnetic Immunity of the Guardio/Vesta Charger

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE GUARDIO/VESTA CHARGER

Essential Performance of the Guardio/Vesta Charger:

- The Guardio/Vesta Charger shall not charge any IPG inappropriately.
- The Guardio/Vesta 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/Vesta Charger.
- If essential performance is lost due to electromagnetic disturbances, the Guardio/Vesta Charger shall not be able to charge any IPG.

The Guardio/Vesta Charger, part of both the OPTIMIZER Smart Mini System and the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio/Vesta 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/Vesta 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/Vesta Charger requires uninterrupted operation during power mains interruptions, it is recommended to power the Guardio/Vesta 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 rowspan="3">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√P
d = 1.17√P 80 MHz to 800 MHz
d = 2.33√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/Vesta Charger is used exceeds the applicable RF compliance level above, the Guardio/Vesta Charger should be monitored to ensure normal operation. If an abnormal function is observed, additional measures may be necessary, such as relocating the Guardio/Vesta 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/Vesta Charger

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

The Guardio/Vesta Charger should be used in an electromagnetic environment with limited radiated RF noise. The customer or user of the Guardio/Vesta Charger can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and 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 the Guardio/Vesta Charger

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

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

Warning: Permission must be requested from a ship's crew prior to using the Guardio/Vesta 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/Vesta 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/VESTA CHARGER PURSUANT TO: **FCC 47 CFR Part 15 – Radio Frequency Devices**		
The Guardio/Vesta Charger, part of both the OPTIMIZER Smart Mini System and the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio/Vesta 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/Vesta 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/VESTA CHARGER PURSUANT TO: **FCC 47 CFR Part 18 – Industrial, Scientific, and Medical Equipment**		
The Guardio/Vesta Charger, part of both the OPTIMIZER Smart Mini System and the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio/Vesta 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/Vesta 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/VESTA CHARGER PURSUANT TO: **FCC 47 CFR 95 Subpart I – Medical Device Radio Communications Service**		
The Guardio/Vesta Charger, part of both the OPTIMIZER Smart Mini System and the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio/Vesta 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/Vesta 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/VESTA 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/Vesta Charger, part of both the OPTIMIZER Smart Mini System and the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio/Vesta 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/Vesta 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/VESTA 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/Vesta Charger, part of both the OPTIMIZER Smart Mini System and the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio/Vesta 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/Vesta 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/VESTA 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/Vesta Charger, part of both the OPTIMIZER Smart Mini System and the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio/Vesta 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/Vesta 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/VESTA 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/Vesta Charger, part of both the OPTIMIZER Smart Mini System and the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio/Vesta 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/Vesta 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/Vesta Charger to recharge the OPTIMIZER 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/Vesta Charger Wireless Nominal Specifications

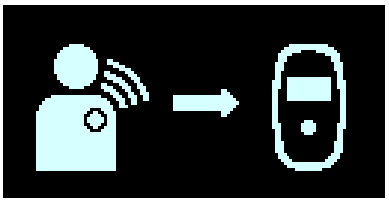
Characteristic	Nominal
MICS MedRadio	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	240 kHz
Modulation	FSK
Radiated Power	-20.6 dBm EIRP
Range	0 to at least 1.5 m
Transcutaneous Energy Transfer	
Frequency Band	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

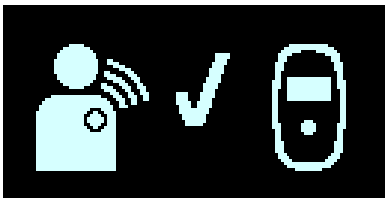
Quality of Service (QoS) for Wireless Technology

QoS for Communications between the Guardio/Vesta Charger and the OPTIMIZER IPG

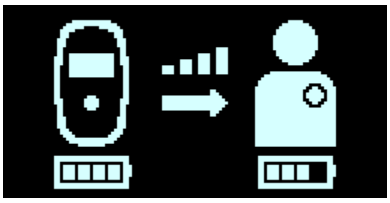
MedRadio in the MICS sub-band (402 to 405 MHz) wireless technology enables communication between the OPTIMIZER IPG and the Guardio/Vesta Charger. The requirements for the Quality of Service (QoS) vary depending on the use environment (operating room, recovery room, clinic, and home environment).

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





After the data download has been completed, the Guardio/Vesta Charger displays the Charging IPG Status screen:

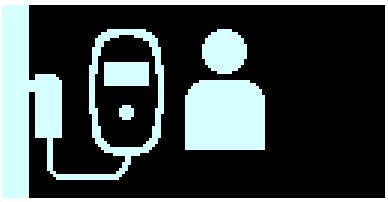


The Coupling Level icon (), whose number of illuminated bars is proportional to the proximity of the charging wand to the implanted OPTIMIZER IPG, is indicative of the Quality of Service (QoS) for the transcutaneous energy transmission wireless link. The charging wand should be repositioned until at least 2 bars of the Coupling Level icon are illuminated, indicating sufficient QoS for charging the OPTIMIZER 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/Vesta Charger will emit 3 long beeping tones, display the Charging IPG Coupling Error screen, and then shut off.

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

If the Guardio/Vesta Charger and the OPTIMIZER 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/Vesta Charger:



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

Wireless Security Measures

Wireless Security Measures in Communications between OPTIMIZER IPG and Guardio/Vesta Charger

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

During the pairing process, the Guardio/Vesta 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/Vesta 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/Vesta Charger and an OPTIMIZER IPG requires the placing of a pairing magnet on the Guardio/Vesta Charger and locating the Charge Wand within 4 cm (1.5 in) of the OPTIMIZER 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 IPG and the Guardio/Vesta Charger encrypt their wireless communications using encryption keys that are generated during the pairing process.
- Only one Guardio/Vesta Charger can be paired with the IPG at any one time.

Troubleshooting for Wireless Coexistence Issues

Troubleshooting Wireless Connection between OPTIMIZER IPG and Guardio/Vesta Charger

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

- Whenever the Guardio/Vesta Charger is not being used to charge the OPTIMIZER 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 IPG and the Guardio/Vesta 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.