IMPULSE DYNAMICS

Hope is Here

OPTIMIZER® Integra CCM-D System

* * *

Patient's Manual

Limited by United States (Federal) law to investigational use

Part No.: 12-250-005-US Rev. 00

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The OPTIMIZER Integra CCM-D system and the CCM technology are protected by several U.S. Patents. For an up-to-date list of relevant patents and patent applications, visit our patents page: http://www.impulse-dynamics.com/us/patents

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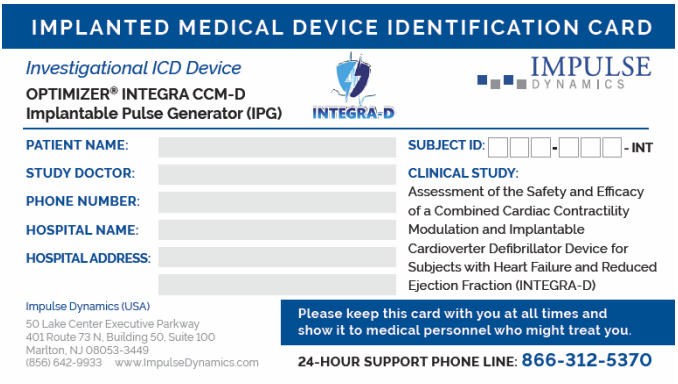
IMPORTANT MEDICAL NOTICE

24-hour Support Hotline: 866-312-5370

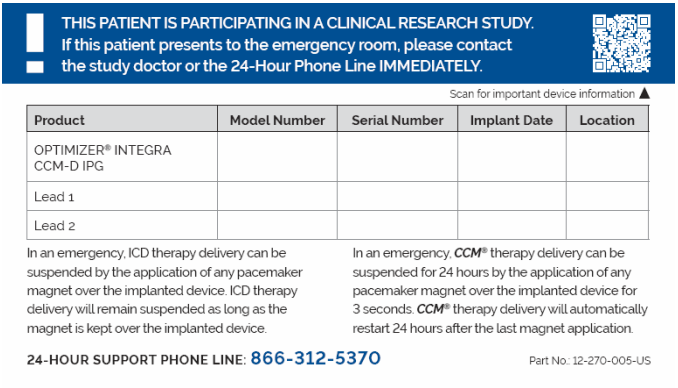
You are participating in a clinical research study. If you go to the emergency room, please contact the study doctor or call the 24-hour Support Hotline IMMEDIATELY.

It is important that you carry your Implanted Medical Device Identification Card and a current list of your medications with you at all times. In the event of a medical emergency, the Implanted Medical Device Identification Card contains information of great importance to an attending physician and will assist in expediting any emergency medical care you may require.

In addition, it is important to notify all your health care providers that you have an OPTIMIZER Integra CCM-D device implanted. As such, the next time you visit your doctor or dentist, show them your Implanted Medical Device Identification Card (see example below) so that a copy of it may be made for their records. If you have a smart phone with a camera, it may be helpful to take a picture of both the front and back of your Implanted Medical Device Identification Card in case you ever misplace it or forget to bring it with you.



Implanted Medical Device Identification Card (front)



THIS PATIENT IS PARTICIPATING IN A CLINICAL RESEARCH STUDY.
If this patient presents to the emergency room, please contact the study doctor or the 24-Hour Phone Line IMMEDIATELY.

Scan for important device information ▲

Product	Model Number	Serial Number	Implant Date	Location
OPTIMIZER® INTEGRA CCM-D IPG				
Lead 1				
Lead 2				

In an emergency, ICD therapy delivery can be suspended by the application of any pacemaker magnet over the implanted device. ICD therapy delivery will remain suspended as long as the magnet is kept over the implanted device.

In an emergency, ***CCM***® therapy delivery can be suspended for 24 hours by the application of any pacemaker magnet over the implanted device for 3 seconds. ***CCM***® therapy delivery will automatically restart 24 hours after the last magnet application.

24-HOUR SUPPORT PHONE LINE: 866-312-5370

Part No.: 12-270-005-US

Implanted Medical Device Identification Card (back)

1.0 INTRODUCTION

Congratulations on receiving your OPTIMIZER Integra CCM-D System. The purpose of this manual is to provide you with information about the OPTIMIZER Integra CCM-D system, what to expect after your implant procedure, introduce you to the components of the system, and provide you with instructions on how to use the Guardio Charger.

2.0 THE OPTIMIZER INTEGRA CCM-D SYSTEM

The OPTIMIZER Integra CCM-D system is comprised of the following components:

- OPTIMIZER Integra CCM-D Implantable Pulse Generator (IPG)
- Guardio Charger

Note: In certain circumstances, the Vesta Charger may be substituted for the Guardio Charger

2.1 OPTIMIZER Integra CCM-D Implantable Pulse Generator

The OPTIMIZER Integra CCM-D Implantable Pulse Generator (IPG) is a medical device used for the treatment of heart failure. In addition, it functions as an implantable cardioverter defibrillator (ICD) for the prevention of sudden cardiac death (SCD). It is typically implanted under the skin in the upper left chest.

Connected to the OPTIMIZER Integra CCM-D IPG are two cardiac leads that your doctor will insert through a large vein and into the heart during the implantation process. These leads have electrodes that allow the OPTIMIZER Integra CCM-D IPG to monitor the electrical activity of your heart and deliver special Cardiac Contractility Modulation (CCM) therapy pulses to the heart at a specific time during each heartbeat. One of the two leads has an external coil that may deliver a shock when the IPG detects an abnormal heart rhythm. In addition, the OPTIMIZER Integra CCM-D IPG can provide emergency short-term pacing support by delivering a low-voltage electrical pulse to your heart if it beats too slowly.

The primary effect of this CCM therapy is an increase in the efficiency and strength of each cardiac contraction, with the intended result being that more blood is pumped out by the heart with every heartbeat.

The OPTIMIZER Integra CCM-D IPG is powered by a rechargeable battery to extend its service life. A charger specifically designed to recharge the battery of the OPTIMIZER Integra CCM-D IPG will be provided to you after your implant surgery.

The OPTIMIZER Integra CCM-D IPG also contains a non-rechargeable battery that provides the extra power needed to deliver defibrillation shocks to your heart if it detects a life-threatening heart rhythm.

The expected life of the OPTIMIZER Integra CCM-D IPG is limited by the expected service life of its batteries.

With weekly charging of your OPTIMIZER Integra CCM-D IPG, the rechargeable battery inside the OPTIMIZER Integra CCM-D IPG should provide you with at least 20 years of service.

The non-rechargeable battery inside the OPTIMIZER Integra CCM-D IPG should provide you with at least 20 years of service if the following conditions are met:

- your device delivers a limited number of shocks per year
- your device is not required to deliver pacing therapy for an extended period of time
- the rechargeable battery in your OPTIMIZER Integra CCM-D IPG is fully recharged on a weekly basis

Your OPTIMIZER Integra CCM-D IPG will need to be replaced when the battery voltage of its non-rechargeable battery drops below a certain level. Your OPTIMIZER Integra CCM-D IPG monitors this voltage and will provide advance warning to your healthcare provider regarding the state of its non-rechargeable battery whenever your device is interrogated during a follow up visit.

Your OPTIMIZER Integra CCM-D IPG will need to be replaced when its rechargeable battery, after being fully recharged, can no longer maintain enough charge to deliver CCM therapy for an entire week without becoming severely depleted.

When being evaluated for elective replacement, you will be instructed to fully charge your OPTIMIZER Integra CCM-D IPG 7 days before your scheduled routine checkup. During your checkup, your doctor may evaluate the charge capacities of both batteries in your OPTIMIZER Integra CCM-D IPG.

Figure 1: OPTIMIZER Integra CCM-D IPG

2.2 Guardio Charger

The Guardio Charger is powered by a rechargeable battery and is specifically designed for use with the OPTIMIZER Integra CCM-D IPG. After your implant procedure, you will be provided with a Guardio Charger and receive instructions on its usage. Please proceed to Section 7.0 for more details about your Guardio Charger.

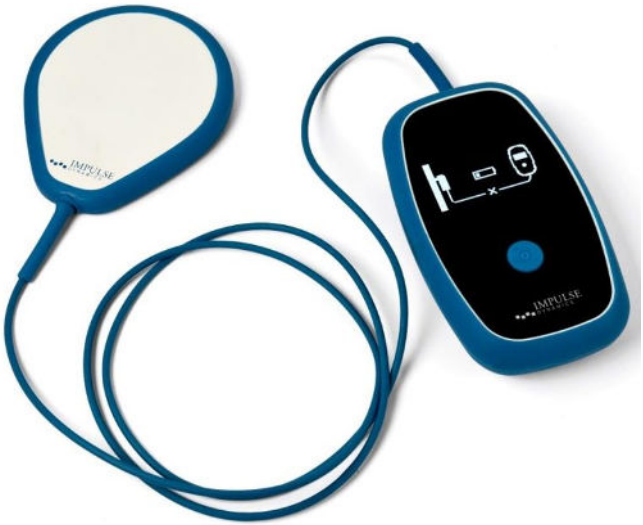


Figure 2: Guardio Charger

3.0 INDICATIONS OF USE

The OPTIMIZER INTEGRA CCM-D System is indicated for the prevention of sudden cardiac death, improvement of quality of life, and 6-minute walk in Stage C or D heart failure patients who remain symptomatic despite being on guideline-directed medical therapy (GDMT), are not indicated for Cardiac Resynchronization Therapy (CRT), and have heart failure with reduced left ventricular ejection fraction (LVEF ≤ 40%).

The OPTIMIZER Integra CCM-D system delivers non-excitatory CCM signals to the heart and performs ICD and short-term pacemaker functions.

4.0 POTENTIAL COMPLICATIONS

4.1 Complications Associated with Implantation

As with any surgical procedure, the implantation of the OPTIMIZER Integra CCM-D IPG involves some degree of risk. This section is intended to provide you with an explanation of the various potential complications associated with having a device implanted. These potential complications are not unique to the OPTIMIZER Integra CCM-D IPG, as they may also occur during the implantation of other implantable cardiac devices (e.g., cardiac pacemakers or defibrillators).

The risks associated with the implantation are listed in **Table 1** and are grouped based on their prevalence.

Table 1: Risks Associated with Implantation

Common (more frequently than 5%)
• Post-procedural pain, bruising, and discomfort at insertion site • Bleeding • Infection at site of insertion • Pocket hematoma • Movement of leads • Movement of IPG in the pocket
Uncommon (less frequently than 5%) but serious
• Chest trauma (such as a collapsed lung or bleeding into the chest) • Inappropriate detection of arrhythmia resulting in an unnecessary ICD shock delivered

- Failure to detect an arrhythmia and failure to deliver a life-saving shock when needed
- Puncture of the heart caused by the leads
- Endocarditis (infection of the heart valves)
- Arrhythmia (irregular heartbeat, including heartbeats that are too slow or too fast)
- Tricuspid valve damage (the valve between the right upper and lower chambers of the heart that prevents blood from flowing back into the upper chamber), possibly leading to tricuspid valve regurgitation or leakage
- Thrombosis (formation of blood clots in the veins)
- Vessel trauma (puncture or tear of a blood vessel)
- Damage to the specific type of heart tissue responsible for triggering heartbeats (i.e., the cardiac conduction system)
- Bradycardia (slow heart rate)
- Cardiac tamponade (build up of fluid around the heart that can be life-threatening)
- Myocardial infarction (heart attack)
- Mini stroke (TIA), or stroke
- Death (in rare cases)

Rare (less frequently than 1%)

- Allergic reaction (allergic reaction to the dye used during the implant procedure)
- Death (in rare cases)

The OPTIMIZER Integra CCM-D IPG uses its leads to detect the electrical activity of your heart as well as deliver CCM therapy, shocks, and short-term emergency pacing. Complications that can affect the lead's ability to perform this function may occur. These include:

- A lead may become dislodged from where it was placed during implantation, necessitating re-operation.
- A lead may fracture or break producing a poor electrical connection, necessitating re-operation.

The lead problems described above can occur at any time during the implant life of a lead. Surgical correction is typically required.

4.2 Complications Associated with Device / Charger Operation

Complications associated with device/charger operation include, but are not limited to:

- An OPTIMIZER Integra CCM-D IPG may not properly sense and deliver CCM signals due to a software or hardware problem, necessitating replacement.
- An OPTIMIZER Integra CCM-D IPG may detect environmental interference and inappropriately deliver CCM therapy or antitachycardia therapy. See Section 6.4.
- A Guardio Charger may not function as designed due to a software or hardware problem and not charge your OPTIMIZER Integra CCM-D IPG as intended. A replacement charger will be required.

5.0 FOLLOWING IMPLANTATION

You must become actively involved in your own recovery by following your doctor's instructions carefully, including:

- Report any redness, swelling, or drainage from your incision to your doctor.
- Avoid lifting heavy objects until instructed by your doctor.
- Walk, exercise, and bathe according to your doctor's instructions.
- Be sure to contact your doctor if you develop a fever that persists for more than two or three days.
- Ask your doctor any questions you may have about your device, heart rhythm, or medications. Be sure to take all medications as directed by your doctor.
- Do not wear tight clothing that could irritate the skin over the device.
- Avoid rubbing the device or the surrounding chest area.
- If directed by your doctor, limit any arm movements that may affect the implanted lead system.
- Avoid rough contact that could result in blows to the implant site. If you fall or are in an accident that results in an impact to the implant site, contact your doctor.

Note: If you have a slender build, your implanted device may appear more prominently under the skin. If this is the case, extra care should be taken to avoid any direct blows to your implant site.

- Contact your doctor if you notice anything unexpected or unusual such as new symptoms.
- Inform your doctor if you plan to engage in long-distance travel.
- If you plan to change your place of residence, inform your doctor, and discuss the need for a referral in the new area.
- Your doctor may limit your driving, at least initially, to avoid putting undue strain on your wounds.

6.0 LIVING WITH YOUR OPTIMIZER INTEGRA CCM-D IPG

6.1 General Expectations

You will be able to feel your OPTIMIZER Integra CCM-D IPG beneath the skin. Normal body movement will cause no harm to it or the attached leads. However, it is important that you not try to move or turn your implanted IPG. It has been implanted with a specific orientation to the skin to ensure proper communication with the Intelio Programmer and your Guardio Charger.

6.2 Effect on Your Activities

Once the wounds from your surgery are healed, you can expect to resume your normal activities, including sexual intimacy. Your implanted OPTIMIZER Integra CCM-D IPG is unaffected by walking, bending over, or other normal daily activities.

Caution: While healing from your surgery, refrain from engaging in activity that involves excessive movement of the arm and shoulder that is closest to your implant site.

6.3 Medications

Prescription medications, taken as directed, have no effect upon the proper operation of your OPTIMIZER Integra CCM-D IPG.

In general, the implantation of your OPTIMIZER Integra CCM-D IPG should not require you to alter the use of any medication.

6.4 How Other Devices May Affect Your OPTIMIZER Integra CCM-D IPG

Warning: A minimum of separation distance of 6 inches must be maintained between hand-held transmitters and your implanted OPTIMIZER Integra CCM-D IPG.

In general, household appliances in good repair and personal communication devices held 10 inches or more from your implanted OPTIMIZER Integra CCM-D IPG should not affect its operation. However, you should be cautious when in the vicinity of devices that generate strong electrical or magnetic fields. For example, interference may occur from some electric razors, electric power tools, and electrical ignition systems, including those used on gasoline-powered equipment.

In general, gasoline-powered equipment may be operated provided that protective hoods, shrouds, and other shielding are not removed.

Any such interference detected by your OPTIMIZER Integra CCM-D IPG may cause false detection of your heartbeat and improper timing of CCM therapy delivery or inappropriate shock delivery.

You should avoid getting too close to equipment or devices that contain strong magnets (e.g., stereo speakers) or leaning over an open automobile engine compartment, as the alternator generates a strong electromagnetic field. Your OPTIMIZER Integra CCM-D IPG contains a magnetic switch that disables the IPG's ability to deliver CCM and ICD therapy whenever it is in the presence of a strong magnetic field.

Once your OPTIMIZER Integra CCM-D IPG is no longer in the presence of a strong magnetic field, ICD therapy delivery is once again automatically enabled but CCM therapy delivery will continue to be disabled for 24 hours. If this occurs by accident, your doctor may require you to come to their office to restore CCM therapy delivery.

ICD therapy functionality is only disabled when your OPTIMIZER Integra CCM-D IPG is actively being exposed to a strong magnet. Once your OPTIMIZER Integra CCM-D IPG is no longer exposed to the strong magnet, it automatically resumes its ICD therapy functionality.

Always seek medical advice before entering an area posted with a warning for pacemaker patients (or other medical implantable devices) or where there is industrial machinery or radio transmitters, including ham radios and mobile radios.

Always inform your doctor that you have an implanted OPTIMIZER Integra CCM-D IPG before you undergo the following procedures:

- Surgery where electrocautery is going to be used
- A procedure involving Radiofrequency (RF) Ablation
- Medical Diathermy
- Cardioversion
- Therapeutic Radiation
- Therapeutic Ultrasound
- Lithotripsy
- Nuclear Magnetic Resonance (NMR)
- Magnetic Resonance Imaging (MRI)

Warning: DO NOT undergo an MRI procedure when implanted with an OPTIMIZER Integra CCM-D IPG.

Caution: Your OPTIMIZER Integra CCM-D IPG should either be deactivated or closely monitored prior to and during any medical treatment in which electrical current is passed through the body.

Caution: Your OPTIMIZER Integra CCM-D IPG should not be directly exposed to therapeutic ultrasound or therapeutic radiation. This type of exposure may damage the device in such a way that may not be immediately detectable.

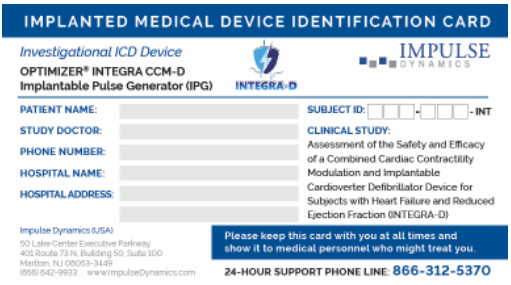
Caution: Store anti-theft systems and airport security screening systems normally will not harm your OPTIMIZER Integra CCM-D IPG. However, do not linger around the equipment. Before going through airport security screening, it is recommended that you show your Implanted Medical Device Identification Card to security personnel for review.

6.5 The Importance of Your Implanted Medical Device Identification Card

Following your implantation surgery, your doctor will provide you with an Implanted Medical Device Identification Card indicating that you are implanted with an OPTIMIZER Integra CCM-D Implantable Pulse Generator.

It is important that you carry your Implanted Medical Device Identification Card and a current list of your medications with you at all times. In a medical emergency, the Implanted Medical Device Identification Card contains information of great importance to an attending physician and will assist in expediting any emergency medical care you may require.

In addition, it is important to notify all your health care providers that you have had an OPTIMIZER Integra CCM-D device implanted. As such, the next time you visit your doctor or dentist, show them your Implanted Medical Device Identification Card so that a copy of it may be made for their records.


IMPLANTED MEDICAL DEVICE IDENTIFICATION CARD

Investigational ICD Device

OPTIMIZER® INTEGRA CCM-D
Implantable Pulse Generator (IPG)

INTEGRA-D

IMPULSE DYNAMICS

PATIENT NAME:

STUDY DOCTOR:

PHONE NUMBER:

HOSPITAL NAME:

HOSPITAL ADDRESS:

SUBJECT ID: - INT

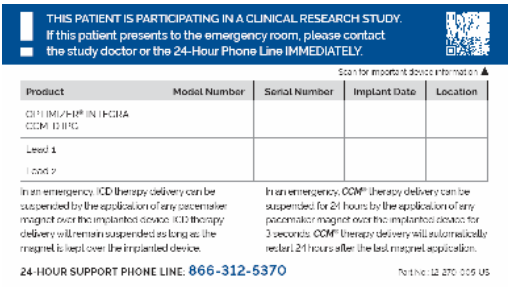
CLINICAL STUDY:
Assessment of the Safety and Efficacy of a Combined Cardiac Contractility Modulation and Implantable Cardioverter Defibrillator Device for Subjects with Heart Failure and Reduced Ejection Fraction (INTEGRA-D)

Impulse Dynamics (USA)
50 Lake Center Executive Parkway
401 Route 73 N, Building 50, Suite 100
Marlton, NJ 08053-3449
(856) 642-9933 www.ImpulseDynamics.com

Please keep this card with you at all times and show it to medical personnel who might treat you.

24-HOUR SUPPORT PHONE LINE: 866-312-5370

Figure 3: Implanted Medical Device Identification Card (front)


THIS PATIENT IS PARTICIPATING IN A CLINICAL RESEARCH STUDY.
If this patient presents to the emergency room, please contact the study doctor or the 24-Hour Phone Line IMMEDIATELY.

Scan for important device information ▲

Product	Model Number	Serial Number	Implant Date	Location
OPTIMIZER® INTEGRA CCM-D IPG				
Lead 1				
Lead 2				

In an emergency, ICD therapy delivery can be suspended by the application of any pacemaker magnet over the implanted device. ICD therapy delivery will remain suspended as long as the magnet is kept over the implanted device.

In an emergency, CCM® therapy delivery can be suspended for 24 hours by the application of any pacemaker magnet over the implanted device for 3 seconds. CCM® therapy delivery will automatically restart 24 hours after the last magnet application.

24-HOUR SUPPORT PHONE LINE: 866-312-5370

Part No.: 12 270 009 US

Figure 4: Implanted Medical Device Identification Card (back)

7.0 GUARDIO CHARGER

7.1 System Components

Your Guardio Charger System consists of the following components:

Figure 5: Guardio Charger System Components

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

7.2 Features

Your Guardio Charger has the following features:

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

Figure 6: Guardio Charger Features

7.3 Description

Your Guardio Charger is designed to charge the battery of your OPTIMIZER Integra CCM-D IPG with minimal intervention while ensuring your safety during the charging process.

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

Caution: The operation of other electrical devices in the vicinity of your Guardio Charger may potentially cause electromagnetic or other interference with the charger. Portable and mobile Radio Frequency (RF) equipment are especially prone to impair the normal function of the charger.

Caution: When in operation, your Guardio Charger System may be a potential source of electromagnetic interference for other electronic equipment in close proximity to the charger system.

7.4 Charging Method

The charging method utilized by your Guardio Charger to charge the battery of your OPTIMIZER Integra CCM-D IPG is called inductive energy transfer. Since magnetic fields can easily pass through the skin with little to no resistance, the charging method used by your Guardio Charger is a proven and effective way to transfer energy to your implanted device. Charging may be performed over clothing.

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

1. The electronic circuitry of your Guardio Charger takes the electrical energy from its battery and converts it into an oscillating electromagnetic field in a primary coil of the charging wand.
2. When the charging wand is placed in close proximity to the implant site, the oscillating electromagnetic field generated by its primary coil is picked up by the secondary coil of the implanted device.
3. The oscillating electromagnetic field picked up by the secondary coil is converted back into electrical energy by the electronic circuitry of the implanted device and used to charge its rechargeable battery.

7.5 Removal and Installation of the Plug Adapter

Your Guardio Charger system includes an AC Adapter installed with a U.S. Plug Adapter. If a different Plug Adapter is required, the AC Adapter allows the option of removing and installing a different Plug Adapter.

7.5.1 Removal of the Plug Adapter

To remove the Plug Adapter from the AC Adapter, perform the following steps:

1. Grasp the AC Adapter in your hand and place your thumb on the ridged area below the plug prongs of the Plug Adapter.
2. Using your thumb, push up on the Plug Adapter to unlock it from the AC Adapter. **See Figure 7**.
3. Slide the Plug Adapter upwards to remove it from the AC Adapter.

Push Upwards to Unlock and Remove Plug Adapter

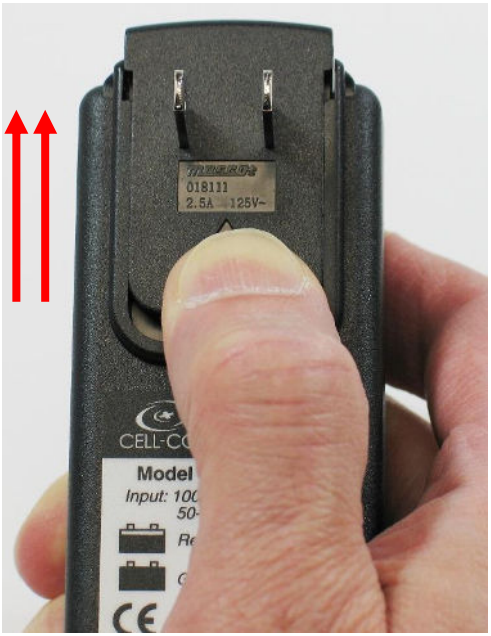


Figure 7: Removing the Plug Adapter

7.5.2 Installation of the Plug Adapter

To install the Plug Adapter onto the AC Adapter, perform the following steps:

1. While holding the AC Adapter in your hand, insert the Plug Adapter into its corresponding slot on the AC Adapter.
2. Using your index finger, push down on the Plug Adapter until it is fully inserted onto the AC Adapter. **See Figure 8**.

Push Down to Install Plug Adapter

Figure 8: Installing the Plug Adapter

7.6 Charging Your Guardio Charger

Note: Charging your Guardio Charger and charging your OPTIMIZER Integra CCM-D IPG CANNOT be done at the same time. Always charge the internal battery of your Guardio Charger before attempting to charge the battery of your OPTIMIZER Integra CCM-D IPG.

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

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

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

1. Turn your Guardio Charger around so that the back of the Charger is facing up.
2. Remove the protective cover flap from the power input connector located next to the base of the charging wand cable. **See Figure 9**.

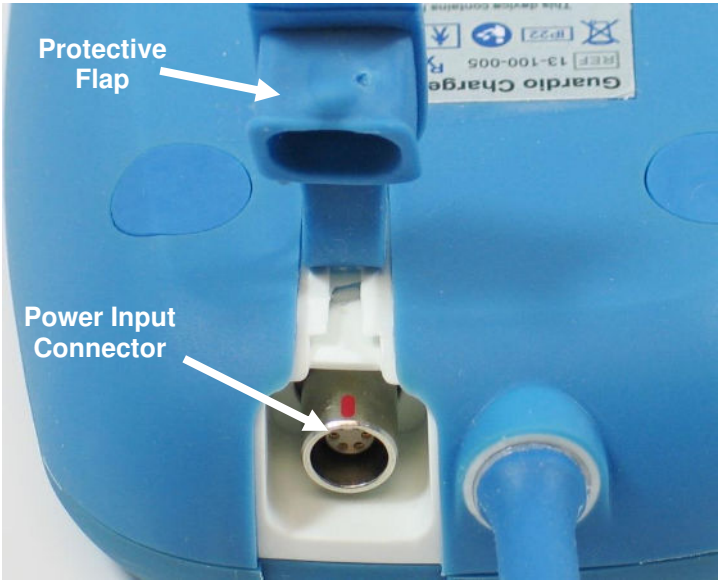


Figure 9: Back of the Charger

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 your Guardio Charger (see **Figure 10**) and then insert the DC output connector into the power input connector.

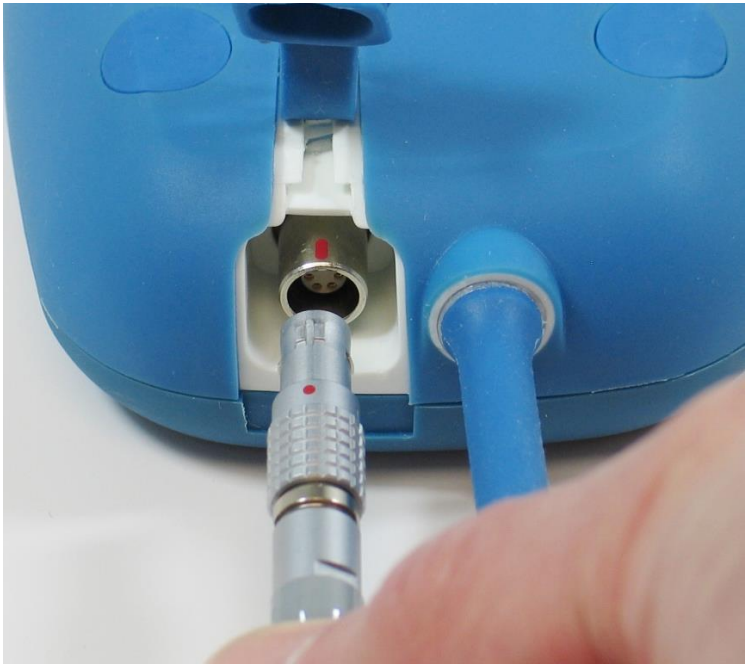


Figure 10: Alignment of the DC Connectors

Once the AC Adapter is connected to your Guardio Charger, it will display the Charger Self-Charge Status screen. **See Figure 11**.

Figure 11: Charger Self-Charge Status Screen

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 your Guardio Charger.

   When the Charging Self-Charge Success screen is displayed on your Guardio Charger (see **Figure 12**), the battery in your Guardio Charger is fully charged, as indicated by the checkmark above the charge level indicator in the center of the screen.

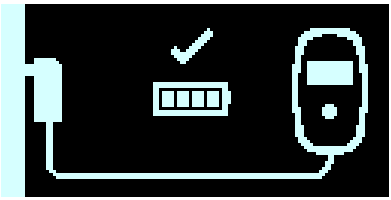


Figure 12: Charger Self-Charge Success Screen

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

1. Hold and pull back on the metal sleeve of the DC output connector to disconnect the connector from your Guardio Charger. **See Figure 13**.

   WARNING: DO NOT TWIST CONNECTOR!

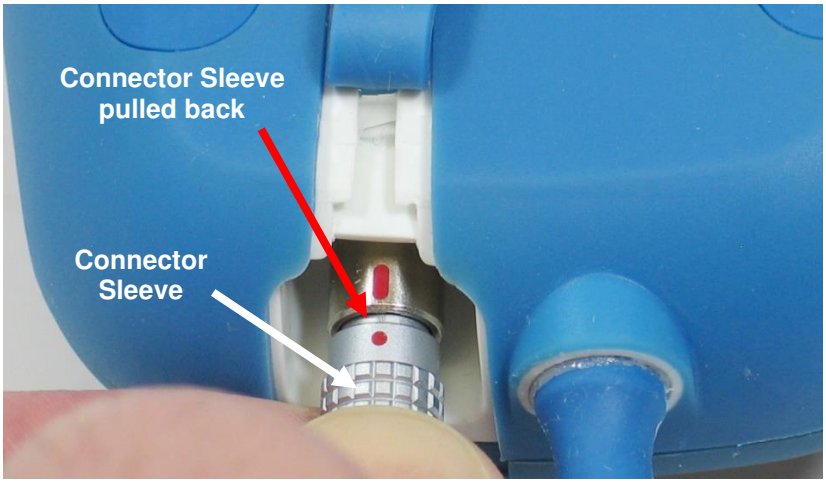


Figure 13: Close-up of the Connector Sleeve

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

7.7 Charging Your OPTIMIZER Integra CCM-D IPG

Note: Charging your device will take approximately 90 minutes (if charge weekly)

Warning: If your OPTIMIZER Integra CCM-D IPG is not charged regularly, it will shut down when the battery becomes depleted, suspending CCM therapy delivery!

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

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

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

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

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

1. Assume a stationary, comfortable sitting position, ideally reclining at a 45° angle (such as on a sofa or armchair).
2. Determine the location of your OPTIMIZER Integra CCM-D IPG (typically left upper chest area). Drape the wand cable loosely around your neck and then place the flat side of the Guardio charging wand (the side with the four blue rubber screw covers) directly over your OPTIMIZER Integra CCM-D IPG implant site (over your clothes). To prevent the charging wand from becoming displaced while charging your implanted OPTIMIZER Integra CCM-D IPG, you may attach the charging wand cable clip to your clothing.

3. Start the charging process by pressing the **Power Button**, holding the button down for 1-2 seconds, and then releasing it. **See Figure 14**.

Figure 14: Pressing the Power Button on the Charger

Note: If any alerts have been triggered, the Call Doctor Alert screen may be displayed. If a Call Doctor Alert Code appears on the screen of your Guardio Charger, follow the instructions described in Section 7.12.

4. The charging process begins by displaying the IPG Data Download screen as your Guardio Charger downloads information from your OPTIMIZER Integra CCM-D IPG. The animated arrow pointing to the charger icon indicates that your Charger is actively downloading information from your implanted device. **See Figure 15**.

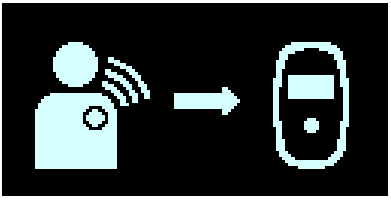


Figure 15: IPG Data Download Screen

5. When your Guardio Charger has successfully completed downloading the data, it will display the IPG Data Download Success screen accompanied by 3 short beeping tones. The flashing checkmark indicates that your Guardio Charger was able to successfully able to download information from your implanted device. **See Figure 16**.

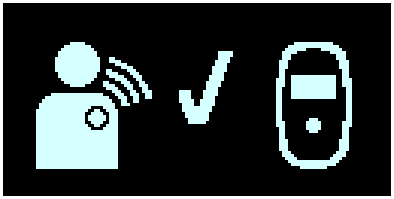


Figure 16: IPG Data Download Success Screen

6. After the data download has been completed, the Charging IPG Status screen will be displayed, indicating that your Guardio Charger has begun actively charging your OPTIMIZER Integra CCM-D IPG. **See Figure 17**.

   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 two bars of the Coupling Level icon are illuminated.

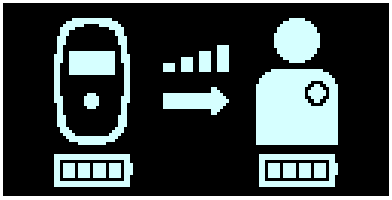


Figure 17: Charging IPG Status Screen

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 your implant site within 20 seconds, your Guardio Charger will emit 3 long beeping tones, display the Charging IPG Coupling Error screen (see **Figure 18**), and then shut off. If this occurs, press the **Power Button** again to initiate a new charging session.

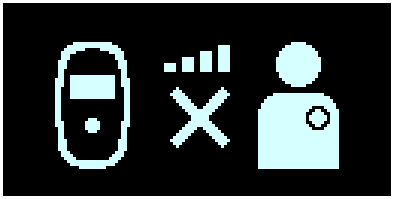


Figure 18: Charging IPG Coupling Error Screen

7. The number of bars on the Charging IPG Battery icon (see icon image on the right) depicts the current charge level of the rechargeable battery in your OPTIMIZER Integra CCM-D IPG. **See Table 2**.

Table 2: OPTIMIZER Integra CCM-D IPG Battery Charge Levels

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

8. The Charging IPG Status screen (see **Figure 17**) will continue to be displayed as your OPTIMIZER Integra CCM-D IPG is being charged.

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

Note: It is recommended that you remain stationary during the charging process. If the charging wand becomes significantly

displaced during charging, the Coupling Level icon will show zero illuminated bars and your Guardio Charger will begin to emit an audible beeping tone. If this occurs, please reposition the charging wand until at least two bars of the Coupling Level icon are illuminated.

Note: If weekly charging of your OPTIMIZER Integra CCM-D IPG is not performed as instructed, charging the battery of your OPTIMIZER Integra CCM-D IPG may take longer. If the recharging of your OPTIMIZER Integra CCM-D IPG cannot be completely recharged in one session, repeat the charging sessions (at least daily) until it is fully charged.

9. When the battery of your OPTIMIZER Integra CCM-D IPG is fully charged, your Guardio Charger will emit 3 short beeping tones and display the IPG Charging Successfully Completed screen, indicated by the flashing checkmark in the center of the screen (see **Figure 19**). Your Guardio Charger will then shut off automatically.

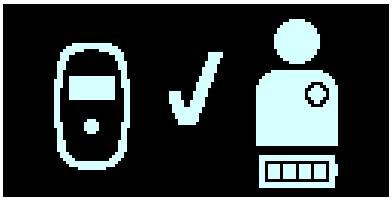


Figure 19: IPG Charging Successfully Completed Screen

10. Detach the charging wand cable clip from your clothing (if attached), then remove the Guardio charging wand from your implant site and undrape the wand cable from around your neck.
11. Reconnect the AC Adapter to your Guardio Charger as described in Section 7.9.

7.8 Termination of the Charging Session

7.8.1 Early Termination of Charging Session

To terminate a charging session before it has been completed, press and hold the **Power Button** down for one second and then release it. Your Guardio Charger will emit 3 short beeping tones and display the Charge Session Cancelation screen, indicated by a flashing universal power icon in the center of the screen. **See Figure 20**.

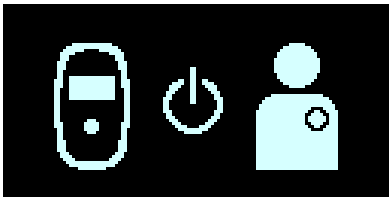


Figure 20: Charge Session Cancelation Screen

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

Note: If you wish to resume charging your OPTIMIZER Integra CCM-D IPG after you terminate a charging session, please wait for approximately 10 minutes before initiating a new charging session to allow the temperature of your OPTIMIZER Integra CCM-D IPG to return to its baseline temperature.

7.8.2 Termination of Charging Session Due to IPG Temperature

To ensure your safety while charging your OPTIMIZER Integra CCM-D IPG, the temperature of your IPG is monitored during the charging process. If the reported temperature of your OPTIMIZER Integra CCM-D IPG at the beginning of the charging session is outside the acceptable temperature range or if the temperature of your implanted OPTIMIZER Integra CCM-D IPG remaining consistently high for more than 10 minutes while it is being charged, then your Guardio Charger will emit 3 long beeping tones and display the Charging IPG Temperature Error screen, indicated by a thermometer icon in the center of the screen (see **Figure 21**). Your Charger will then shut off. If this should occur, please wait for approximately 10 minutes before initiating a new charging session.

Figure 21: Charging IPG Temperature Error Screen

7.8.3 Termination of Charging Session Due to Charging IPG Timeout

If the duration of the charging session exceeds 5 hours, your Guardio Charger will emit 3 long beeping tones and display the Charging IPG Timeout Error screen, indicated by a flashing hourglass icon in the center of the screen (see **Figure 22**). Your Charger will then shut off. If this should occur, please wait for approximately 20 minutes before initiating a new charging session.

Figure 22: Charging IPG Timeout Error Screen

7.8.4 Termination of Charging Session Due to Low Charger Battery Level

If the battery charge level of your Guardio Charger drops below 10% during a charging session, your Guardio Charger will emit 3 long beeping tones and display the Low Charger Battery Alert screen, indicated by an empty battery icon with a flashing “X” over it (see **Figure 23**). Your Guardio Charger will then shut off.

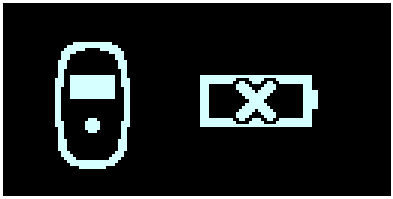


Figure 23: Low Charger Battery Alert Screen

If this occurs, recharge the battery of your Guardio Charger as described in Section 7.6.

7.9 Guardio Charger Placement When Not Being Used for Device Charging

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

Note: Keeping your Guardio Charger continuously connected to its AC Adapter while it is plugged into the wall outlet will not in any way harm or weaken the battery in your Charger.

7.10 Frequency of Charging Sessions

The optimal performance of the rechargeable battery in your OPTIMIZER Integra CCM-D IPG can only be ensured if the battery is fully recharged every week. It is not important which day or what time you choose to charge your OPTIMIZER Integra CCM-D IPG, but it is recommended that you do not let more than seven days pass between charge sessions.

Note: Your OPTIMIZER Integra CCM-D IPG consumes energy from the rechargeable battery when recording information during arrhythmic episodes. Please charge your OPTIMIZER Integra CCM-D IPG soon after experiencing an arrhythmia episode, even if you recently recharged your device, to avoid interrupting the delivery of CCM therapy or consuming energy from the non-rechargeable battery.

If your Guardio Charger is not used to perform a charging session on your OPTIMIZER Integra CCM-D IPG within the time period set by your doctor, you may see the Long Time Without Charging IPG alert screen displayed by your Guardio Charger, indicated by an animated image of the Guardio's Charging Wand being placed over a patient's implanted device. **See Figure 24**.

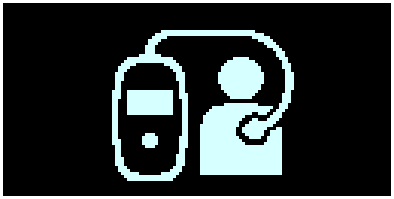


Figure 24: Long Time Without Charging IPG Alert Screen

If you see this message displayed by your Guardio Charger, proceed to use your Guardio Charger to charge your OPTIMIZER Integra CCM-D IPG. If your attempt to charge your OPTIMIZER Integra CCM-D IPG with your Guardio Charger is unsuccessful, please call the 24-hour Support Hotline (866-312-5370).

If the rechargeable battery voltage in your OPTIMIZER Integra CCM-D IPG drops below a certain level, CCM therapy delivery is automatically suspended. If this occurs, your OPTIMIZER Integra CCM-D IPG will need to be recharged before it resumes delivering CCM therapy. Once your OPTIMIZER Integra CCM-D IPG has been recharged, it will automatically resume CCM therapy delivery with its previously programmed settings.

Note: If the voltage of the rechargeable battery in your OPTIMIZER Integra CCM-D IPG drops below a certain level, ICD functionality of your implanted OPTIMIZER Integra CCM-D IPG will continue to be maintained until the non-rechargeable battery in the OPTIMIZER Integra CCM-D IPG is also depleted.

7.11 Communications with Your OPTIMIZER Integra CCM-D IPG

When your Guardio Charger is connected to the AC Adapter, it will attempt to communicate with its paired IPG every 10 minutes.

When this occurs, you will see your Guardio Charger display the IPG Data Download screen, indicated by the animated arrow pointing to the charger icon (see **Figure 25**). This indicates that your Guardio Charger is actively attempting to download data from your OPTIMIZER Integra CCM-D IPG. The encrypted data downloaded from your device includes information regarding the current status of your IPG, statistical information regarding its operation, and any active alerts that require action.

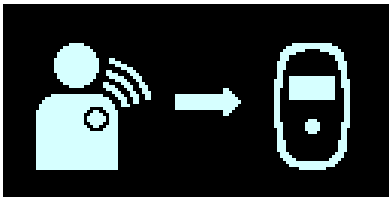


Figure 25: IPG Data Download Screen

When your Guardio Charger has successfully completed downloading data from your OPTIMIZER Integra CCM-D IPG, it will display the IPG Data Download Success screen, indicated by the flashing checkmark at the center of the screen. Your Guardio Charger should be able to successfully download data from your implanted device whenever you are within 5 ft of your Guardio Charger. **See Figure 26**.

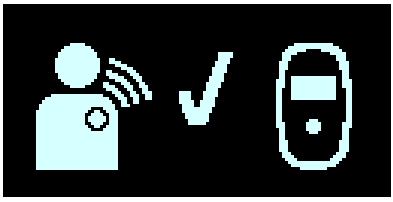


Figure 26: IPG Data Download Success Screen

If your Guardio Charger is not able to successfully complete downloading data from your OPTIMIZER Integra CCM-D IPG, it will display the IPG Data Download Error screen, indicated by a flashing “X” at the center of the screen (see **Figure 27**). Should this happen, your Guardio Charger will retry downloading data from your OPTIMIZER Integra CCM-D IPG in a few minutes.

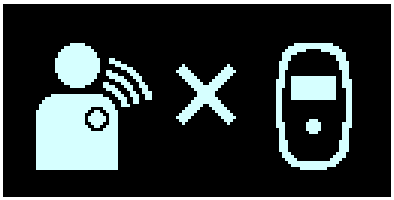


Figure 27: IPG Data Download Error Screen

If your Guardio Charger and your implanted OPTIMIZER Integra CCM-D IPG do not communicate within the time period set by your doctor, your Guardio Charger will emit a beeping tone and display the Long Time Without Downloading Data From IPG alert screen, indicated by an animated image of a patient moving closer to their Guardio Charger. **See Figure 28**.

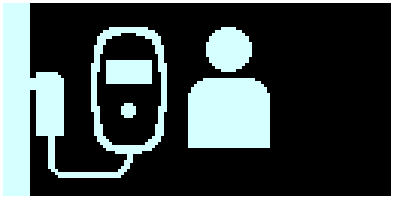


Figure 28: Long Time Without Downloading Data From IPG Alert Screen

If you see this message displayed by your Guardio Charger, attempt to use your Guardio Charger to charge your OPTIMIZER Integra CCM-D IPG. If you can successfully charge your implanted OPTIMIZER Integra CCM-D IPG, then the alert screen should no longer be displayed by your Guardio Charger. If your attempt to charge your OPTIMIZER Integra CCM-D IPG with your Guardio Charger is unsuccessful, please call the 24-hour Support Hotline (866-312-5370).

7.12 Call Doctor Alert Codes

Note: "Doctor" in the context of this manual is referring to the doctor mentioned in the clinical trial informed consent.

In addition to charging your OPTIMIZER Integra CCM-D IPG, your Guardio Charger is also able to notify you of an alert condition that requires action.

Alert conditions are triggered by the detection of certain events by your OPTIMIZER Integra CCM-D IPG or Guardio Charger.

When an alert condition occurs, your OPTIMIZER Integra CCM-D IPG is programmed to send this information to your Guardio Charger.

If a detected alert condition is associated with a Direct Action Alert, an alert screen will be displayed by your Guardio Charger accompanied by a beeping tone. Please refer to **Figures 23, 24, and 28** to identify the Direct Action Alert displayed by your Guardio Charger. Once the displayed alert has been identified, read the paragraph following the figure to learn what action is required.

For certain alert conditions, the Call Doctor Alert will be preceded by the Abnormal Condition Error screen, indicated by a warning icon with a flashing exclamation point (see **Figure 29**), accompanied by 3 long beeping tones.

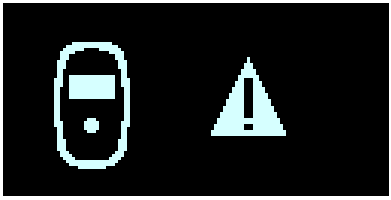


Figure 29: Abnormal Condition Error Screen

If a detected alert condition is associated with a Call Doctor Alert, your Guardio Charger will emit a beeping tone and display a Call Doctor Alert screen, with a flashing exclamation point at the center of the screen and a Call Doctor Code (preceded by a letter denoting the IPG model code). **See Figure 30**.

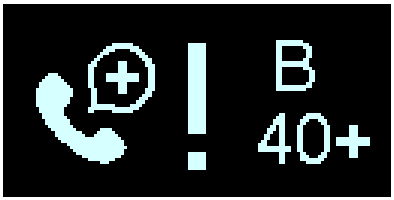


Figure 30: Example of Call Doctor Alert Screen

The Call Doctor Alert screen will be followed by the Snooze Buzzer Alert screen (see **Figure 31**), or if at night, the Snooze Alert screen (see **Figure 32**).

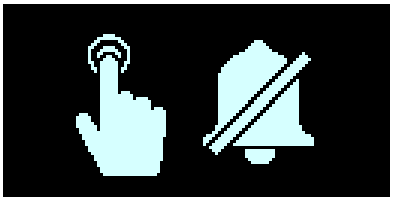


Figure 31: Snooze Buzzer Alert Screen

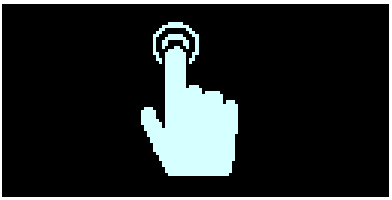


Figure 32: Snooze Alert Screen

If a Call Doctor Alert Code appears on the screen of your Guardio Charger, take note of the code that is displayed and then press the **Power Button** on your Guardio Charger to snooze the activated alert. Afterwards, use the information below to determine your next course of action.

- If the Call Doctor Alert Code “B1”, “B3”, “B5”, “B7”, “B9”, “B11”, “B12”, “B13”, “B14”, “B15”, “B16”, “B17”, “B18”, “B19”, “B21”, “B23”, “B25”, “B27” or “B29” is displayed, please call the 24-hour Support Hotline (866-312-5370) and inform them of the alert code displayed by your Guardio Charger. Then, unless the alert code displayed is “B1” or “B9”, proceed to charge your implanted OPTIMIZER Integra CCM-D IPG.
- If the Call Doctor Alert Code “B31” is displayed, it means that your Guardio Charger has detected repeated internal

errors during its operation. Please call the 24-hour Support Hotline (866-312-5370) to obtain a replacement Guardio Charger.

- If the Call Doctor Alert Code “B32” is displayed, it means that you are attempting to use your Guardio Charger on an unpaired device. If this code is displayed by your Guardio Charger, perform the following steps:

    1. Verify that the Guardio Charger you are using is the one that was assigned to you and then restart the charging process.
    2. If this code is still displayed after the Charging Wand has been placed over your implanted OPTIMIZER Integra CCM-D IPG and the charging process has been restarted, please call the 24-hour Support Hotline (866-312-5370).

7.13 Cleaning

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

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

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

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

Warning: DO NOT submerge any part of your Guardio Charger in water. Damage to the unit may result.

7.14 Maintenance

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

Warning: No modification of this equipment is allowed.

The battery inside your Guardio Charger is expected to have a service life of at least 5 years. If your Guardio Charger is unable to fully charge your OPTIMIZER Integra CCM-D IPG after the Charger's internal battery has been fully charged, please call the 24-hour Support Hotline (866-312-5370) to obtain a replacement Guardio Charger.

7.15 Storage and Handling

Your Guardio Charger System should not be exposed to excessively hot or cold conditions. Store your Guardio Charger System in a cool, dry place, with your Guardio Charger connected to its AC Adapter and the AC Adapter plugged into the wall outlet. Do not leave your Guardio Charger System in your car or outdoors for extended periods of time. The sensitive electronics of your Guardio Charger System can be damaged by temperature extremes, particularly high heat.

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

- **Ambient Temperature:** 50°F to 81°F
- **Relative Humidity:** 20% to 75%
- **Atmospheric Pressure:** 20.73 inHg to 31.39 inHg

Note: Your Guardio Charger is designed for indoor use.

If necessary, move to a location that meets these conditions prior to using your Guardio Charger.

7.16 Disposal

If your Guardio Charger is no longer needed, you may return it to your doctor's office.

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

8.0 REPLACEMENT OF YOUR OPTIMIZER INTEGRA CCM-D IPG

Your implanted OPTIMIZER Integra CCM-D IPG contains a rechargeable battery, which provides power for the operation of your implanted device, and a non-rechargeable battery, which provides the extra energy needed for the delivery of potentially life-saving defibrillation shocks to your heart. The need to replace your OPTIMIZER Integra CCM-D IPG because the rechargeable battery is unable to hold a charge is **not** expected within the warranty period. However, noncompliance with regular charging of your OPTIMIZER Integra CCM-D IPG rechargeable battery or repeated instances of antitachycardia or pacing therapy delivery may deplete the non-rechargeable battery power to a level that requires the replacement of your implanted OPTIMIZER Integra CCM-D IPG. If such an instance occurs, your doctor will explain the reason(s) to you and schedule you for replacement surgery.

This procedure is typically more limited in scope and may not require you to stay overnight in the hospital. In general, the post-surgical care associated with replacement surgery is no different than what you experienced during your initial surgery.

9.0 FREQUENTLY ASKED QUESTIONS

1. What does my OPTIMIZER Integra CCM-D IPG do?

Your OPTIMIZER Integra CCM-D IPG monitors your heart rhythm and delivers Cardiac Contractility Modulation (CCM) therapy pulses at a particular time when the heart contracts. These signals are intended to increase the strength of each contraction, thus improving your heart failure symptoms. If your OPTIMIZER Integra CCM-D IPG detects an abnormal heart rhythm, it can also deliver emergency shock therapy or pacing support to your heart. Your OPTIMIZER Integra CCM-D IPG is programmed to your specific requirements by your doctor using an external programmer connected to a wand that is placed over your implanted OPTIMIZER Integra CCM-D IPG.

2. Will I still be able to participate in the same activities that I do now?

Yes, unless you are involved in contact sports or other activities or have an accident that can damage your implanted system or interfere with its operation. Your doctor will discuss this matter with you in detail.

3. Will my OPTIMIZER Integra CCM-D IPG ever need to be replaced?

Your OPTIMIZER Integra CCM-D IPG is powered by a rechargeable battery that should provide you with at least 20 years of service. Using the instructions in this manual, you will be shown you how to recharge your device.

Your implanted OPTIMIZER Integra CCM-D IPG also contains a non-rechargeable battery, which provides the extra power needed for the delivery of defibrillation shocks to your heart if it detects an abnormal heart rhythm. Noncompliance with regular charging of the rechargeable battery in your OPTIMIZER Integra CCM-D IPG or repeated instances of defibrillation shocks to the heart will significantly deplete the non-rechargeable battery power to a level that will necessitate the replacement of your implanted OPTIMIZER Integra CCM-D IPG sooner than 20 years.

Your OPTIMIZER Integra CCM-D IPG will need to be replaced when the battery voltage of its non-rechargeable battery drops below a certain level. Your OPTIMIZER Integra CCM-D IPG monitors this voltage and will display a message to your healthcare provider whenever your device is interrogated using a programmer during a follow up visit.

With regular charging and infrequent use of your OPTIMIZER Integra CCM-D IPG' non-rechargeable battery power, should reach its 20th year of service, your doctor will need to assess the condition of the rechargeable battery during your routine checkup visits. To help facilitate this battery assessment, please fully charge your OPTIMIZER Integra CCM-D IPG 7 days before your scheduled routine checkup visit.

In addition, there is a risk that a problem will develop with a component or a lead necessitating surgery to replace the IPG or lead(s).

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APPENDIX I

Electromagnetic Immunity

Electromagnetic Immunity of the OPTIMIZER Integra CCM-D IPG

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE OPTIMIZER Integra CCM-D IMPLANTABLE PULSE GENERATOR

The OPTIMIZER Integra CCM-D IPG, part of the OPTIMIZER Integra CCM-D System is intended for use in an electromagnetic environment as specified below. The patient implanted with the OPTIMIZER Integra CCM-D IPG must ensure that it is used within the specified environment.

The Optimizer Integra CCM-D IPG **is** a life-support device. Essential Performance of the OPTIMIZER Integra CCM-D IPG:

- The IPG shall be able to detect and discriminate ventricular tachyarrhythmias.
- The IPG shall be able to deliver anti-tachycardia therapy, including ATP and defibrillation shocks.
- No changes in the settings of tachycardia arrhythmia detection or discrimination shall occur unless programmed.
- No changes in the settings of anti-tachycardia therapies shall occur unless programmed.
- ATP and/or shocks shall not be inappropriately delivered.
- The IPG shall be able to detect profound ventricular bradycardia (< 40 bpm) and post-shock bradycardia (< 60 bpm).
- The IPG shall be able to deliver anti-bradycardia pacing therapy
- No changes in the settings of anti-bradycardia therapies shall occur unless programmed.
- Pacing shall not be inappropriately delivered.

CCM therapy is **not** life-support. CCM shall be delivered with safe settings. It is allowable that these settings disable CCM stimulation.[a]

Note: In case of emergency, placing a pacemaker magnet over the implant site of the OPTIMIZER Integra CCM-D IPG and maintaining it in close proximity to the device, sets the OPTIMIZER Integra CCM-D IPG into Magnet Mode, suspending CCM therapy and inhibiting the delivery of antiarrhythmic therapies.

Immunity test[b]	Test level	Compliance level	Electromagnetic environment – guidelines[c]
ISO 14117:2019 Clause 4.2 – Induced lead current – 16.6 Hz to 20 kHz	Test 1 and Test 2 per standard	Induced lead current does not exceed limits for Test 1 and Test 2 per standard	Seek the advice of your physician or other qualified health provider regarding **Environmental Conditions**

ISO 14117:2019 Clause 4.3 - Protection from persisting malfunction attributable to ambient electromagnetic fields	Per clauses 4.3.2.1, 4.3.2.2, and 4.3.2.3 of standard	Does not exhibit malfunction which persists after the removal of the electromagnetic test signal per clauses 4.3.2.1, 4.3.2.2, and 4.3.2.3 of standard	• Exercise caution in the vicinity of equipment that generates strong electrical or electromagnetic fields. • Do not enter an area with posted warnings advising pacemaker patients (or patients with other types of implantable devices) not to approach. • Interference may occur in the vicinity of equipment marked with the following symbol: 
ISO 14117:2019 Clause 4.4 - Protection from malfunction caused by temporary exposure to CW sources	Per standard	Maintains essential performance[a] per standard	
ISO 14117:2019 Clause 4.5 - Protection from sensing EMI as cardiac signals	Per clauses 4.5.2, 4.5.3, 4.5.4	Maintains essential performance[a] per clauses 4.5.2, 4.5.3, 4.5.4	
ISO 14117:2019 Clause 4.6 - Protection from static magnetic fields of flux density up to 1 mT	Per standard	Device operation is unaffected per standard	Maintain 6 inches (15 cm) distance between household magnets or items containing magnets (e.g., headphones, mobile phones, exercise equipment containing magnets, etc.) and implant
ISO 14117:2019 Clause 4.7 - Protection from static magnetic fields of flux density up to 50 mT	Per standard	Does not exhibit malfunction which persists after the removal from the field per standard	Seek the advice of your physician or other qualified health provider regarding **Magnetic Resonance (NMR), Magnetic Resonance Imaging (MRI)**

ISO 14117:2019 Clause 4.8 - Protection from AC magnetic field exposure in the range of 1 kHz to 140 kHz	Per standard	Does not exhibit malfunction which persists after the removal from the field per standard	Seek the advice of your physician or other qualified health provider regarding **Environmental Conditions**, **Industrial Machinery**, and **Home Appliances**. • Exercise caution in the vicinity of equipment that generates strong AC magnetic fields. • Do not enter an area with posted warnings advising pacemaker patients (or patients with other types of implantable devices) not to approach.
ISO 14117:2019 Clause 4.9 - Test requirements for the frequency range of 385 MHz ≤ f ≤ 3000 MHz	Per standard	Functions as it did before the test without further adjustment after application of the test signal per standard	Seek the advice of your physician or other qualified health provider regarding **Transmitting Devices** and **Cellular and Mobile Phones** • Exercise caution in the vicinity of equipment that generates strong radio-frequency fields. • Do not enter an area with posted warnings advising pacemaker patients (or patients with other types of implantable devices) not to approach. • Interference may occur in the vicinity of equipment marked with the following symbol: 

ISO 14117:2019 Clause 5 - Testing above frequency of 3000 MHz	Standard does not require testing of devices above 3 GHz[e]	N/A	Avoid direct exposure to the main lobe of high-power radar and microwave communication beams.
ISO 14117:2019 Clause 6.1 - Protection of the device from damage caused by high-frequency surgical exposure	Per standard	Does not exhibit malfunction which persists after the removal of the electromagnetic test signal per standard	Inform your physician or other qualified health provider that you are implanted with an OPTIMIZER Integra CCM-D IPG and that they should consult the IPG's Instructions for Use regarding **Electrocautery** and **RF Ablation**
ISO 14117:2019 Clause 6.2 Protection of the device from damage caused by external defibrillators	Per standard	Does not exhibit malfunction which persists after the removal of the electromagnetic test signal per standard	Inform your physician or other qualified health provider that you are implanted with an OPTIMIZER Integra CCM-D IPG and that they should consult the IPG's Instructions for Use regarding **Defibrillation and Cardioversion**

GTRI E3 Representative Security and Logistical Systems (Electronic article surveillance, metal detectors, RFID)	Per E3 protocol	Per E3 protocol	Seek the advice of your physician or other qualified health provider regarding **Store Anti-Theft Systems/Airport Security Screening Systems** Electronic Article Surveillance (EAS) systems, such as those found at department stores: • Do not linger near an EAS system longer than is necessary. • Be aware that EAS systems are often hidden or camouflaged near the exits for businesses such as retailers. • Do not lean against the system's sensors. Metal detector archways: • Do not stop or linger in a walk-through archway; simply walk through the archway at a normal pace. • Radiofrequency identification (RFID) readers: • Maintain separation from wall unit (reader) and the implanted device. • Do not lean against the reader. Radiofrequency identification (RFID) and checkout counter tag deactivators: • Maintain an arm's length separation from the deactivator's surface. • Do not lean against the deactivator.

Notes:

[a] No inappropriate stimulation shall be delivered by the OPTIMIZER Integra CCM-D IPG. Normal CCM delivery or inhibition of CCM delivery due to interference is permissible, but inappropriately triggering of CCM delivery by interference is not allowed.

[b] The OPTIMIZER Integra CCM-D IPG does not fall within the clear definitions of ISO 14117:2019. As such, the criteria of ISO 14117:2019 were adapted to be applicable to CCM-D.

[c] This guidance shall not be considered the exclusive or only source for this information. It is best practice to consult the original manufacturer of the item with potential electromagnetic interference to verify any specific guidance concerning operation and compatibility with implantable devices. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding the OPTIMIZER Integra CCM-D IPG.

[d] Electromagnetic fields > 3GHz are not expected to interfere with device operation because of the increased device protection afforded by the attenuation of the enclosure and body tissue at microwave frequencies, the expected performance of EMI control features implemented to meet lower-frequency requirements, and the reduced sensitivity of circuits at microwave frequencies.

Electromagnetic Immunity of the Guardio Charger

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

Essential Performance of the Guardio Charger:

- The Guardio Charger shall not charge any IPG inappropriately.
- The Guardio Charger shall only charge a paired IPG appropriately.
- The patient shall be made aware of inappropriate charging either by an explicit message, or by the absence of an expected message from the Guardio Charger.
- If essential performance is lost due to electromagnetic disturbances, the Guardio Charger shall not be able to charge any IPG.

The Guardio Charger, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.

The test levels follow FDA recommendations for the home environment per "Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff", November 24, 2014

Immunity test	IEC 60601-1-2:2014 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge as defined in IEC 61000-4-2	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be 30% or greater.

Electrical fast transient / burst as defined in IEC 61000-4-4	± 2 kV for mains power supply ± 1 kV for in-/output lines	± 2 kV for mains power supply ± 1 kV for in-/output lines	Mains power quality should be that of a typical home healthcare, business, or hospital environment. Do not operate motors or other noisy electrical equipment on the same mains circuit as the Guardio Charger.
AC line voltage surges as defined in IEC 61000-4-5	± 2 kV Common Mode ± 1 kV Differential Mode 1.2/50 µs	± 2 kV Common Mode ± 1 kV Differential Mode 1.2/50 µs	Mains power quality should be that of a typical home healthcare, business, or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines as defined in IEC 61000-4-11	0%, 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles	0%, 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles	Mains power quality should be that of a typical home healthcare, business, or hospital environment. **Note:** If the user of the Guardio Charger requires uninterrupted operation during power mains interruptions, it is recommended to power the Guardio Charger from an uninterruptible power supply.
Power line frequency magnetic fields (50/60 Hz) as defined in IEC 61000-4-8	30 A/m	30 A/m	Power line frequency magnetic fields (50/60 Hz) should be at levels expected in a typical home healthcare, business, or hospital environment.
Conducted RF as defined in IEC 61000-4-6:2013	3 V r.m.s outside industrial, scientific, and medical (ISM) and amateur radio bands between 0.15 MHz and 80 MHz, 6 V r.m.s. in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V r.m.s outside industrial, scientific, and medical (ISM) and amateur radio bands between 0.15 MHz and 80 MHz, 6 V r.m.s. in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.17\sqrt{P}$

Radiated RF as defined in IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010	10 V/m: 80 MHz to 2.7 GHz, 80% 1kHz AM	10 V/m: 80 MHz to 2.7 GHz, 80% 1kHz AM	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: 

Notes:

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

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

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

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

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

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

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

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

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

Electromagnetic Emissions

Electromagnetic Emissions from the OPTIMIZER Integra CCM-D IPG

The OPTIMIZER Integra CCM-D IPG must emit electromagnetic energy in order to perform its intended function when communicating with the Intelio Programmer or the Guardio Charger. Nearby electronic equipment may be affected.

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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE OPTIMIZER INTEGRA CCM-D IPG PURSUANT TO:

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

The OPTIMIZER Integra CCM-D Implantable Pulse Generator, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The patient implanted with the OPTIMIZER Integra CCM-D Implantable Pulse Generator 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 OPTIMIZER Integra CCM-D IPG must emit electromagnetic energy in order to perform its intended function when communicating with the Intelio Programmer or the Guardio Charger. Nearby electronic equipment may be affected.
Frequency Monitoring	Complies with clause 95.2559	
Frequency Accuracy	Complies with clause 95.2565	
EIRP	Complies with clause 95.2567(a)	
Field Strength	Complies with clause 95.2569	
Bandwidth	Complies with clause 95.2573	
Unwanted Emissions	Complies with clause 95.2579	
Permissible Exposure Evaluation	Complies with clause 95.2585	

ETSI EN 301 839

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE OPTIMIZER INTEGRA CCM-D IPG 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 OPTIMIZER Integra CCM-D Implantable Pulse Generator, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The patient implanted with the OPTIMIZER Integra CCM-D Implantable Pulse Generator 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 OPTIMIZER Integra CCM-D IPG must emit electromagnetic energy in order to perform its intended function when communicating with the Intelio Programmer or the Guardio Charger. Nearby electronic equipment may be affected.
Occupied Bandwidth	Complies with clause 4.2.1.2	
Power Output	Complies with clause 4.2.1.3	
Transmitter Spurious Emissions (30 MHz to 6 GHz)	Complies with clause 4.2.1.4	
Frequency Stability Under Low Voltage Conditions	Complies with clause 4.2.1.5	
Spurious Radiation of Receivers	Complies with clause 4.2.2.1	

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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE OPTIMIZER INTEGRA CCM-D IPG 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 OPTIMIZER Integra CCM-D Implantable Pulse Generator, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The patient implanted with the OPTIMIZER Integra CCM-D Implantable Pulse Generator must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidelines**
Radiated Emissions EN 55032:2012/AC:2013	Class B	The OPTIMIZER Integra CCM-D IPG must emit electromagnetic energy in order to perform its intended function when communicating with the Intelio Programmer or the Guardio Charger. Nearby electronic equipment may be affected.

Electromagnetic Emissions from the Guardio Charger

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

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

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

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

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

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

FCC 47 CFR Part 15 – Radio Frequency Devices

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

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

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

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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO:

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

The Guardio Charger, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.

Emissions Test	Compliance	Electromagnetic environment – guidelines
Duration of Transmissions	Complies with clause 95.2557	The Guardio Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Frequency Monitoring	Complies with clause 95.2559	
Frequency Range	Complies with clause 95.2563(a) and 2.1033(c)(5)	
Frequency Stability	Complies with clause 95.2565 and 2.1055	
EIRP	Complies with clause 95.2567(a)(1), 2.1033(c)(6), 2.1033(c)(7), and 2.1046	
Field Strength	Complies with clause 95.2569, 95.2579(a), 2.1053, and 2.1057	
Authorized Bandwidth	Complies with clause 95.2573(a) and 2.1049	
Unwanted Emissions	Complies with clause 95.2579(c), 2.1033(c)(4), and 2.1047	
Permissible Exposure Evaluation	Complies with clause 95.2585 and 2.1093	

ETSI EN 300 330

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

ETSI EN 301 839

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

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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO:

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

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

The Guardio Charger, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.

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

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

IEC 60601-1-2 2014

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE GUARDIO CHARGER PURSUANT TO:

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

The Guardio Charger, part of the OPTIMIZER Integra CCM-D System, is intended for use in an electromagnetic environment as specified below. The customer or user of the Guardio Charger must ensure that it is used within the specified environment.

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

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

APPENDIX II

Wireless Technology

RF wireless technology is used in the communication between an OPTIMIZER Integra CCM-D Implantable Pulse Generator (IPG) and the Guardio Charger. It occurs through an encrypted channel over an RF link that complies with the requirements of the Medical Implant Communication System (MICS) (range specified to 2 m, 402–405 MHz) of the MedRadio Band.

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

OPTIMIZER Integra CCM-D IPG Wireless Nominal Specifications

Characteristic	Nominal
OPTIlink MICS MedRadio	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	< 145 kHz
Modulation	FSK
Radiated Power	< 25 µW E.I.R.P.
Range	0 to at least 1.5 m

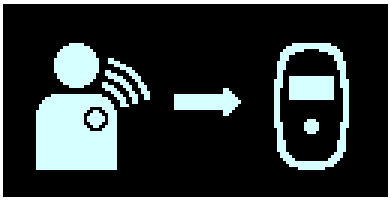
Guardio Charger Wireless Nominal Specifications

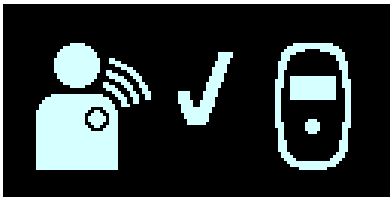
Characteristic	Nominal
MICS MedRadio	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	240 kHz
Modulation	FSK
Radiated Power	-20.6 dBm EIRP
Range	0 to at least 1.5 m
Transcutaneous Energy Transfer	
Frequency Band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

Quality of Service (QoS) for Communications between the Guardio Charger and the OPTIMIZER Integra CCM-D IPG

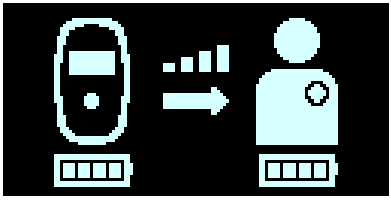
MedRadio in the MICS sub-band (402 to 405 MHz) wireless technology enables communication between the OPTIMIZER Integra CCM-D IPG and the Guardio Charger. The requirements for the Quality of Service (QoS) vary depending on the use environment (operating room, recovery room, clinic, and home environment).

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





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

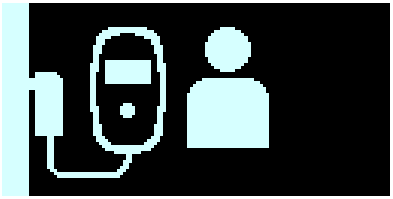


The Coupling Level icon (), whose number of illuminated bars is proportional to the proximity of the charging wand to the implanted OPTIMIZER Integra CCM-D IPG, is indicative of the Quality of Service (QoS) for the transcutaneous energy transmission wireless link. The charging wand should be repositioned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

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

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

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



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

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

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

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

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

IMPORTANT INFORMATION:

Electrophysiologist:	
Address:	
City:	
Country:	Postal Code:
Telephone No.:	
Cardiologist:	
Address:	
City:	
Country:	Postal Code:
Telephone No.:	
Hospital:	
Address:	
City:	
Country:	Postal Code:
Telephone No.:	

Medications:

OPTIMIZER Integra CCM-D Implantable Pulse Generator

Model No.:

Serial No.:

Lead 1 Model No.:	S/N
Lead 2 Model No.:	S/N

NOTES: