OPTIMIZER™ Smart Mini System

* * *

For the Treatment of Symptomatic Heart Failure
(With LV Ejection Fraction ≥ 40% and ≤ 60%)

Patient Manual for the AIM HIGH*er* Clinical Trial

Limited by United States (Federal) law to investigational use

Part No.: 12-250-004-US Rev. 00

Impulse Dynamics (USA) Inc.
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401 Route 73 N Bldg. 50
Marlton, NJ 08053-3425

The OPTIMIZER Smart Mini 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

Revision 00, Date of Issue: 2021-08-08

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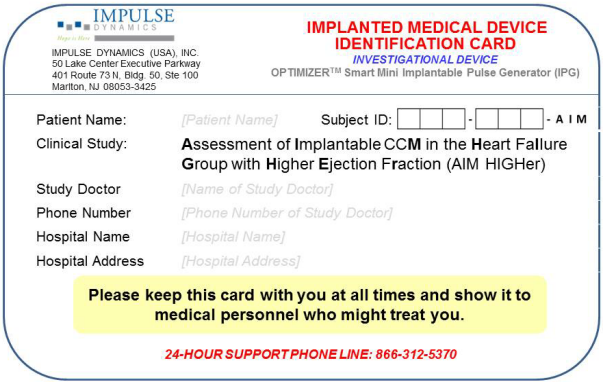
IMPORTANT MEDICAL NOTICE

24-hour Support Hotline: 866-312-5370

You are participating in a blinded clinical research study. If you go to the emergency room, please contact the study doctor or 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 Smart Mini 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.


IMPULSE DYNAMICS

IMPULSE DYNAMICS (USA), INC.
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Marlton, NJ 08053-3425

IMPLANTED MEDICAL DEVICE IDENTIFICATION CARD
INVESTIGATIONAL DEVICE
OPTIMIZER™ Smart Mini Implantable Pulse Generator (IPG)

Patient Name: [Patient Name] Subject ID: ☐☐☐-☐☐☐-AIM

Clinical Study: **A**ssessment of **I**mplantable CC**M** in the **H**eart Fa**i**lure **G**roup with **H**igher **E**jection **F**raction (AIM HIGHer)

Study Doctor [Name of Study Doctor]

Phone Number [Phone Number of Study Doctor]

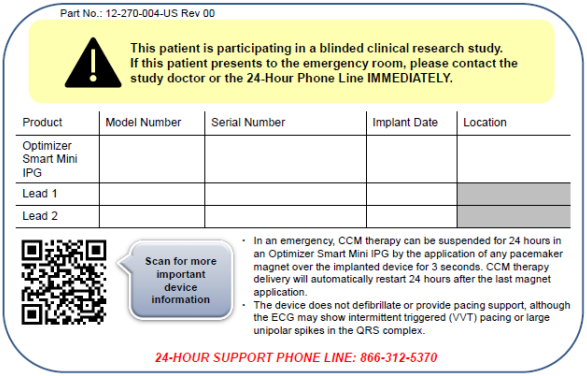
Hospital Name [Hospital Name]

Hospital Address [Hospital Address]

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

Implanted Medical Device Identification Card (front)


Part No.: 12-270-004-US Rev 00

This patient is participating in a blinded clinical research study.
If this patient presents to the emergency room, please contact the study doctor or the 24-Hour Phone Line IMMEDIATELY.

Product	Model Number	Serial Number	Implant Date	Location
Optimizer Smart Mini IPG				
Lead 1				
Lead 2				

Scan for more important device information

- In an emergency, CCM therapy can be suspended for 24 hours in an Optimizer Smart Mini IPG 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.
- The device does not defibrillate or provide pacing support, although the ECG may show intermittent triggered (VVT) pacing or large unipolar spikes in the QRS complex.

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

Implanted Medical Device Identification Card (back)

1.0 INTRODUCTION

You are participating in an investigation called the AIM HIGH*er* Clinical Trial and have received the implantable OPTIMIZER Smart Mini System. The AIM HIGH*er* Clinical Trial is a randomized study to evaluate the effectiveness of the Cardiac Contractility Modulation (CCM) therapy in symptomatic heart failure patients with a Left Ventricular Ejection Fraction (LVEF) of ≥ 40% and ≤ 60%. This is a blinded study and you have been randomly placed into one of two patient groups for the first 18 months of the study. You have 67% chance of being placed in the CCM Therapy ON group and a 33% chance of being placed in the CCM Therapy OFF group. Neither you nor your doctor will know in which group you have been placed.

The purpose of this manual is to provide you with information about the OPTIMIZER Smart Mini 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 Vesta Charger.

2.0 THE OPTIMIZER SMART MINI SYSTEM

The OPTIMIZER Smart Mini system is comprised of the following components:

- OPTIMIZER Smart Mini Implantable Pulse Generator (IPG)
- Vesta Charger

2.1 OPTIMIZER Smart Mini Implantable Pulse Generator

The OPTIMIZER Smart Mini Implantable Pulse Generator (IPG) is a medical device used for the treatment of NYHA Class III heart failure. It is typically implanted under the skin in the upper left or right chest.

Connected to the OPTIMIZER Smart Mini IPG are two (or optionally three) 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 Smart Mini 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.

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

The expected life of the OPTIMIZER Smart Mini IPG is limited by the expected service life of its rechargeable battery.

With weekly charging of your OPTIMIZER Smart Mini IPG, the rechargeable battery inside the OPTIMIZER Smart Mini IPG should provide you with at least 20 years of service.

Your OPTIMIZER Smart Mini IPG will need to be replaced when its 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 Smart Mini IPG 7 days before your scheduled routine checkup. During your checkup, your doctor may evaluate the charge capacity of the battery in your OPTIMIZER Smart Mini IPG.

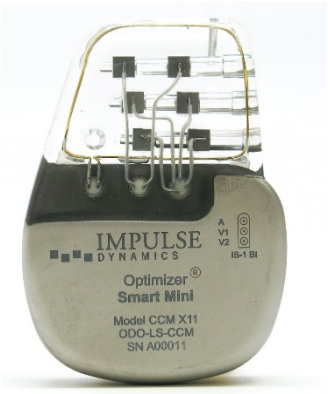


Figure 1: OPTIMIZER Smart Mini IPG

2.2 Vesta Charger

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

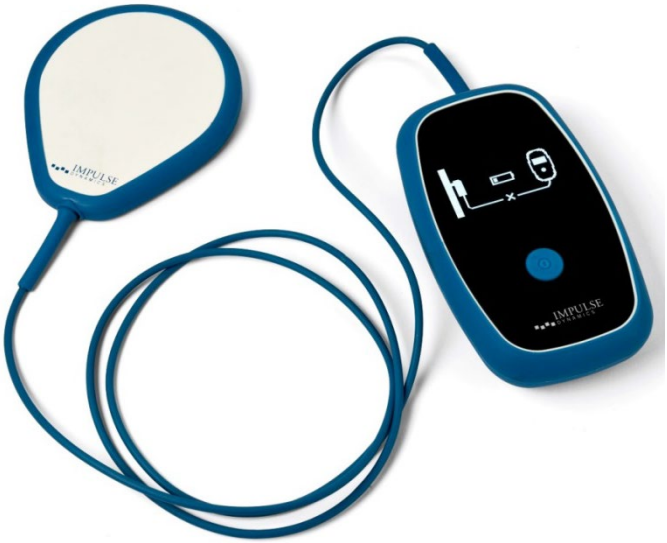


Figure 2: Vesta Charger

3.0 POTENTIAL COMPLICATIONS

3.1 Complications Associated with Implantation

As with any surgical procedure, the implantation of the OPTIMIZER Smart Mini 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 Smart Mini 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 (greater than or equal to 5%)
• Post-procedural pain, bruising, and discomfort at insertion site • Bleeding • Infection at site of insertion • Pocket hematoma • Migration of leads • Migration of implanted IPG
Uncommon (between 1-5%)
• Chest trauma (such as a collapsed lung or bleeding into the chest) • Generator complication • Cardiac perforation (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 • Vessel trauma (perforation, dissection, or rupture) • Thrombosis (formation of blood clots in the veins) • Damage to the specific type of heart tissue responsible for triggering heartbeats (i.e., the cardiac conduction system) • Allergic reaction
Rare (less than 1%)
• 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

The OPTIMIZER Smart Mini IPG uses its leads to detect the electrical activity of your heart. 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.

3.2 Complications Associated with Device / Charger Operation

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

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

4.0 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.

5.0 LIVING WITH YOUR OPTIMIZER SMART MINI IPG

5.1 General Expectations

You will be able to feel your OPTIMIZER Smart Mini 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 Vesta Charger.

5.2 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 Smart Mini IPG is unaffected by walking, bending over, or other normal daily activities.

5.3 Medications

Prescription medications, taken as directed, have no effect upon the proper operation of your OPTIMIZER Smart Mini IPG.

In general, the implantation of your OPTIMIZER Smart Mini IPG should not require you to alter the use of any medication.

5.4 How Other Devices May Affect Your OPTIMIZER Smart Mini IPG

In general, household appliances in good repair and personal communication devices held 25 cm (10 in) or more from your implanted OPTIMIZER Smart Mini 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 Smart Mini IPG may cause false detection of your heartbeat and improper timing of CCM therapy 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 Smart Mini IPG contains a magnetic switch that, when exposed to a strong magnet for 3-5 seconds, will disable CCM therapy delivery. If this occurs by accident, your doctor may require you to come to their office to restore CCM therapy delivery. Since your OPTIMIZER Smart Mini IPG is not a life-sustaining device, you are unlikely to be placed at risk by such an event.

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 Smart Mini 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 Smart Mini IPG.

Caution: Your OPTIMIZER Smart Mini 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 Smart Mini IPG should not be directly exposed to therapeutic ultrasound or therapeutic radiation. This type of exposure may damage the device that may not be immediately detectable.

Caution: Store anti-theft systems and airport security screening systems normally will not harm your OPTIMIZER Smart Mini 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.

5.5 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 Smart Mini 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 Smart Mini 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.

6.0 VESTA CHARGER

6.1 System Components

Your Vesta Charger System consists of the following components:

Figure 3: Vesta Charger System Components

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

6.2 Features

Your Vesta Charger has the following features:

- **Graphical Display:** Display screen used by your Vesta Charger to communicate information to you
- **Power Button:** Press-button switch used to initiate charging of your OPTIMIZER Smart Mini 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 Vesta Charger for charging as well as short-range communications with your OPTIMIZER Smart Mini IPG
- **Radio Transceiver:** Device used by your Vesta Charger for long-range communications [between zero and at least 1.5 m (5 ft)] with your OPTIMIZER Smart Mini IPG

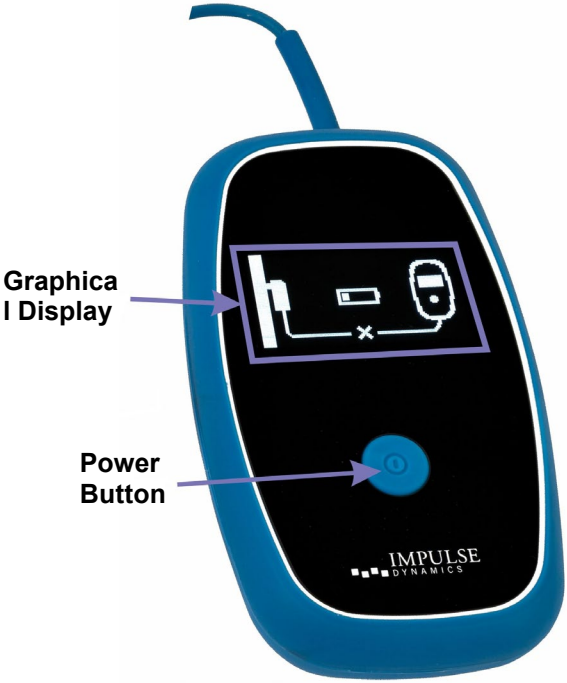


Figure 4: Vesta Charger Features

6.3 Description

Your Vesta Charger is designed to charge the battery of your OPTIMIZER Smart Mini IPG with minimal intervention while ensuring your safety during the charging process.

In addition, your Vesta 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 contact your doctor, reminders to charge your implanted device, etc…).

Caution: The operation of other electrical devices in the vicinity of your Vesta 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 Vesta Charger System may be a potential source of electromagnetic interference for other electronic equipment in close proximity to the charger system.

6.4 Charging Method

The charging method utilized by your Vesta Charger to charge the battery of your OPTIMIZER Smart Mini 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 Vesta 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 Smart Mini IPG is as follows:

1. Electrical energy from the battery of your Vesta Charger passes through a primary coil connected to the electronic circuitry of the charger that converts it into an oscillating electromagnetic field.
2. When a primary coil is placed in close proximity to a secondary coil, the oscillating electromagnetic field generated by a primary coil is picked up by a secondary coil.
3. The secondary coil that picks up the oscillating electromagnetic field is connected to the electronic circuitry of the implant that converts it back into electrical

energy. That electrical energy is used to charge the battery of your OPTIMIZER Smart Mini IPG.

6.5 Removal and Installation of the Plug Adapter

Your Vesta 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.

6.5.1 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 5**.
3. Slide the Plug Adapter upwards to remove it from the AC Adapter.

Push Upwards to Unlock and Remove Plug

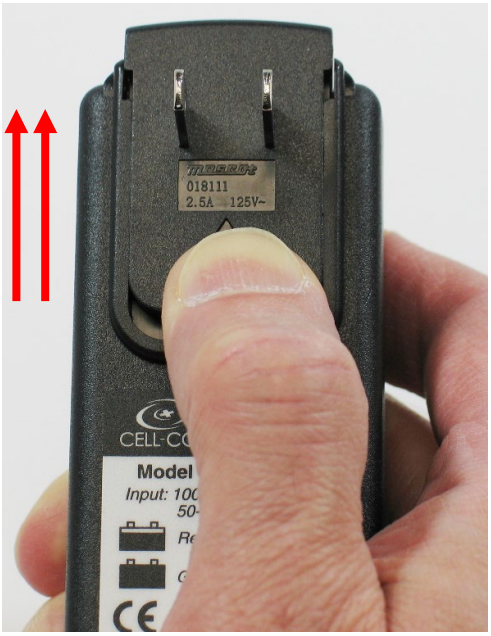


Figure 5: Removing the Plug Adapter

6.5.2 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 6**.

Push Down to Install Plug Adapter

Figure 6: Installing the Plug Adapter

6.6 Charging Your Vesta Charger

Note: Charging your Vesta Charger and charging your OPTIMIZER Smart Mini IPG CANNOT be done at the same time. Always charge the internal battery of your Vesta Charger before attempting to charge the battery of your OPTIMIZER Smart Mini IPG.

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

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

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

1. Turn your Vesta Charger around so that the back of the Charger is facing up.
2. Remove the protective cover flap from the power input connector located next to the base of the charging wand cable. **See Figure 7**.

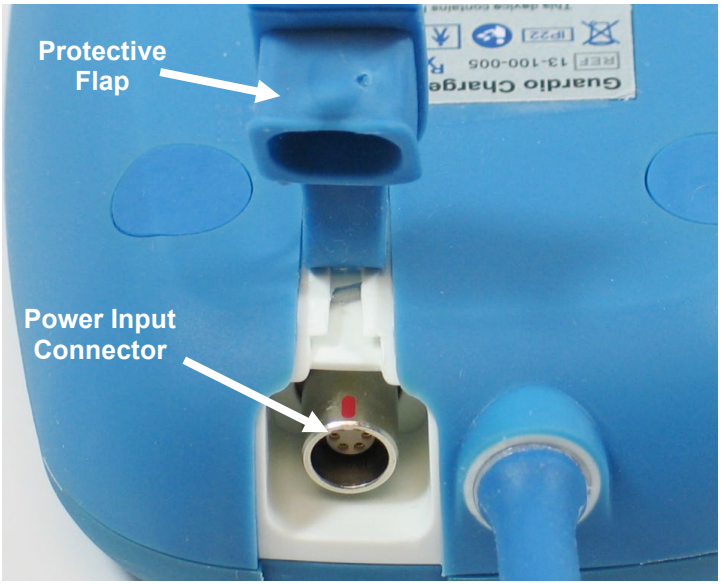


Figure 7: Back of the Charger

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 Vesta Charger (see **Figure 8**) and then insert the DC output connector into the power input connector.

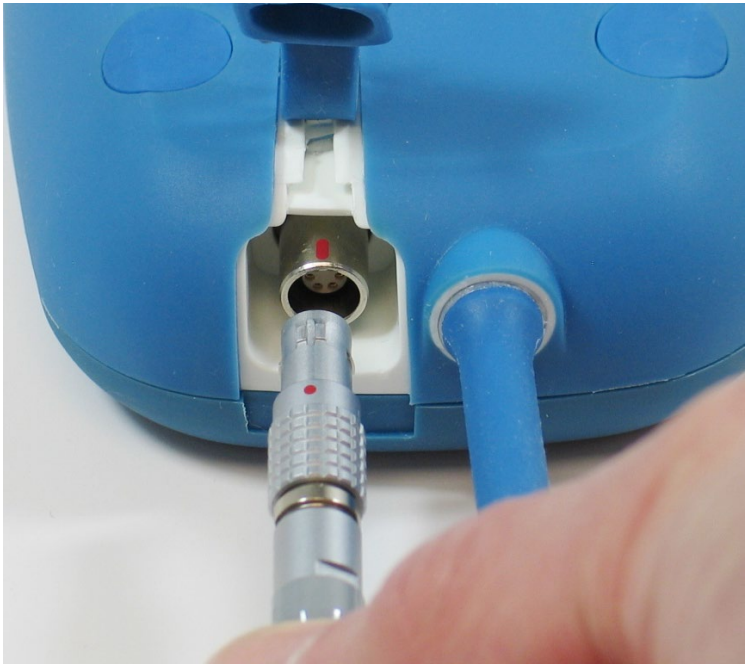


Figure 8: Alignment of the DC Connectors

Once the AC Adapter is connected to your Vesta Charger, it will display the Charger Self-Charge Status screen. **See Figure 9**.

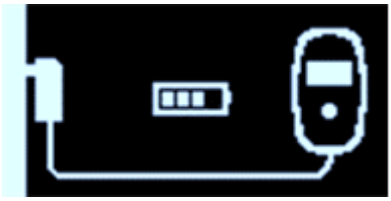


Figure 9: Charger Self-Charge Status Screen

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 Vesta Charger.

   When the Charging Self-Charge Success screen is displayed on your Vesta Charger (see **Figure 10**), the battery in your Vesta Charger is fully charged, as indicated by the checkmark above the charge level indicator in the center of the screen.

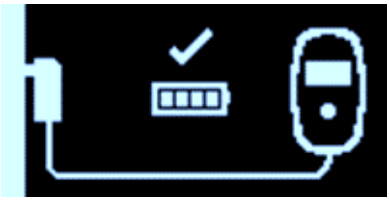


Figure 10: Charger Self-Charge Success Screen

To disconnect the AC Adapter from your Vesta 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 Vesta Charger. **See Figure 11**.

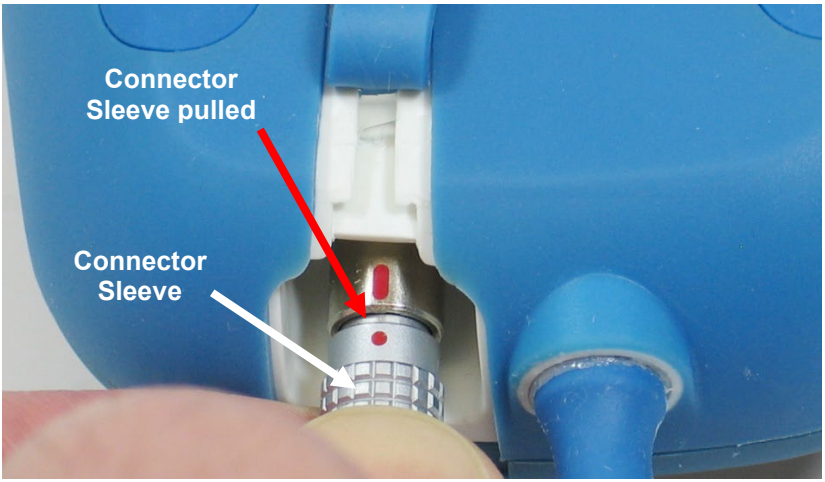


Figure 11: Close-up of the Connector Sleeve

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

6.7 Charging Your OPTIMIZER Smart Mini IPG

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

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

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

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

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

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

To charge the battery of your OPTIMIZER Smart Mini 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 Smart Mini IPG (typically right upper chest area). Drape the wand cable loosely around your neck and then place the flat side of the Vesta charging wand (the side with the four blue rubber screw covers) directly over your OPTIMIZER Smart Mini IPG implant site (over your clothes). To prevent the charging wand from becoming displaced while charging your implanted OPTIMIZER Smart Mini 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 12**.

Figure 12: 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 Vesta Charger, follow the instructions described in Section 6.12.

4. The charging process begins by displaying the IPG Data Download screen as your Vesta Charger downloads information from your OPTIMIZER Smart Mini IPG. The animated arrow pointing to the charger icon indicates that your Charger is actively downloading information from your implanted device. **See Figure 13**.

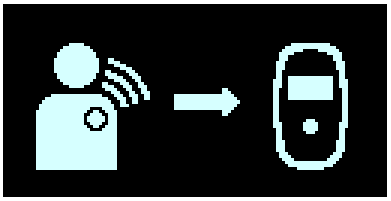


Figure 13: IPG Data Download Screen

5. When your Vesta 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 Vesta Charger was able to successfully able to download information from your implanted device. **See Figure 14**.

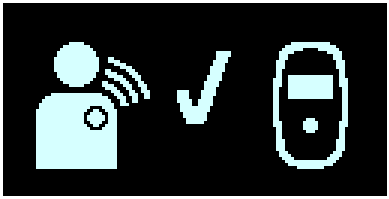


Figure 14: IPG Data Download Success Screen

6. After the data download has been completed, the Charging IPG Status screen will be displayed, indicating that your Vesta Charger has begun actively charging your OPTIMIZER Smart Mini IPG. **See Figure 15**.

   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.

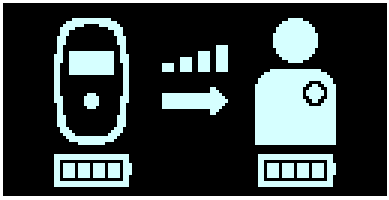


Figure 15: Charging IPG Status Screen

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 Vesta Charger will emit 3 long beeping tones, display the Charging IPG Coupling Error screen (see **Figure 16**), and then shut off. If this occurs, press the **Power Button** again to initiate a new charging session.

Figure 16: Charging IPG Coupling Error Screen

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

Table 2: OPTIMIZER Smart Mini IPG Battery Charge Levels

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

8. The Charging IPG Status screen (see **Figure 15**) will continue to be displayed as your OPTIMIZER Smart Mini IPG is being charged.

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 Vesta 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 Smart Mini IPG is not performed as instructed, charging the battery of your OPTIMIZER Smart Mini IPG may take longer. If the recharging of your OPTIMIZER Smart Mini 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 Smart Mini IPG is fully charged, your Vesta 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 17**). Your Vesta Charger will then shut off automatically.

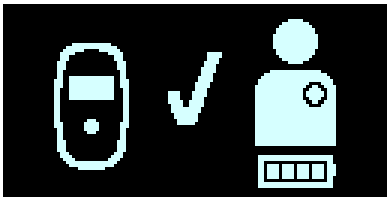


Figure 17: IPG Charging Successfully Completed Screen

10. Detach the charging wand cable clip from your clothing (if necessary), then remove the Vesta charging wand from your implant site and undrape the wand cable from around your neck.
11. Reconnect the AC Adapter to your Vesta Charger as described in Section 6.9.

6.8 Termination of the Charging Session

6.8.1 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 Vesta 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 18**.

Figure 18: Charge Session Cancelation Screen

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

Note: If you wish to resume charging your OPTIMIZER Smart Mini 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 Smart Mini IPG to return to its baseline temperature.

6.8.2 Termination of Charging Session Due to IPG Temperature

To ensure your safety while charging your OPTIMIZER Smart Mini IPG, the temperature of your IPG is monitored during the charging process. If the reported temperature of your OPTIMIZER Smart Mini IPG at the beginning of the charging session is outside the acceptable temperature range or if the temperature of your implanted OPTIMIZER Smart Mini IPG remaining consistently high for more than 10 minutes while it is being charged, then your Vesta 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 19**). Your Charger will then shut off. If this should occur, please wait for approximately 10 minutes before initiating a new charging session.

Figure 19: Charging IPG Temperature Error Screen

6.8.3 Termination of Charging Session Due to Charging IPG Timeout

If the duration of the charging session exceeds 5 hours ± 5 minutes, your Vesta 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 20**). Your Charger will then shut off. If this should occur, please wait for approximately 10 minutes before initiating a new charging session.

Figure 20: Charging IPG Timeout Error Screen

6.8.4 Termination of Charging Session Due to Low Charger Battery Level

If the battery charge level of your Vesta Charger drops below 10% during a charging session, your Vesta 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 21**). Your Charger will then shut off. If this occurs, recharge the battery of your Vesta Charger as described in Section 6.6.

Figure 21: Low Charger Battery Alert Screen

6.9 Vesta Charger Placement When Not Being Used for Device Charging

Whenever your Vesta Charger is not being used to charge your OPTIMIZER Smart Mini 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 Vesta Charger fully charged as well as ensure regular communications between your OPTIMIZER Smart Mini IPG and your Vesta Charger.

Note: Keeping your Vesta 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.

6.10 Frequency of Charging Sessions

The optimal performance of the rechargeable battery in your OPTIMIZER Smart Mini 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 Smart Mini IPG, but it is recommended that you do not let more than seven days pass between charge sessions.

If your Vesta Charger is not used to perform a charging session on your OPTIMIZER Smart Mini IPG within the time period set by your doctor, you may see the Long Time Without Charging IPG alert screen displayed by your Vesta Charger, indicated by an animated image of the Vesta's Charging Wand being placed over a patient's implanted device. **See Figure 22**.

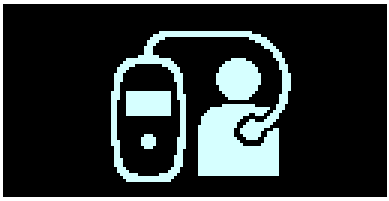


Figure 22: Long Time Without Charging IPG Alert Screen

If you see this message displayed by your Vesta Charger, proceed to use your Vesta Charger to charge your OPTIMIZER Smart Mini IPG. If your attempt to charge your OPTIMIZER Smart Mini IPG with your Vesta Charger is unsuccessful, contact your doctor as soon as possible.

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

6.11 Communications with Your OPTIMIZER Smart Mini IPG

Your Vesta Charger is configured to communicate with your implanted OPTIMIZER Smart Mini IPG at least once a day. This communication occurs whenever you are within 1.5 m (5 ft) of your Vesta Charger for a few minutes.

When this occurs, you will first see your Vesta Charger display the IPG Data Download screen, indicated by the animated arrow pointing to the charger icon (see **Figure 23**). This indicates that your Vesta Charger is actively attempting to download data from your OPTIMIZER Smart Mini 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.

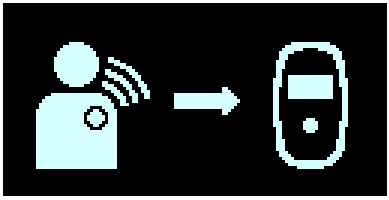


Figure 23: IPG Data Download Screen

When your Vesta Charger has successfully completed downloading data from your OPTIMIZER Smart Mini IPG, it will display the IPG Data Download Success screen, indicated by the flashing checkmark at the center of the screen. **See Figure 24**.

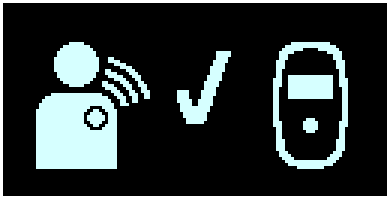


Figure 24: IPG Data Download Success Screen

If your Vesta Charger is not able to successfully complete downloading data from your OPTIMIZER Smart Mini IPG, it will display the IPG Data Download Error screen, indicated by a flashing “X” at the center of the screen (see **Figure 25**). Should this happen, your Vesta Charger will retry downloading data from your OPTIMIZER Smart Mini IPG in a few minutes.

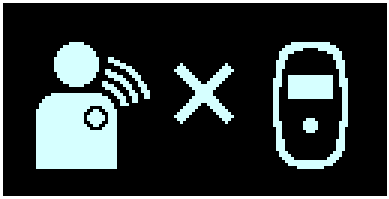


Figure 25: IPG Data Download Error Screen

If your Vesta Charger and your implanted OPTIMIZER Smart Mini IPG do not communicate within the time period set by your doctor, your Vesta 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 Vesta Charger. **See Figure 26**.

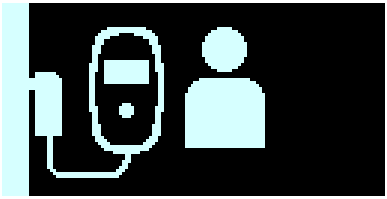


Figure 26: Long Time Without Downloading Data From IPG Alert Screen

If you see this message displayed by your Vesta Charger, attempt to use your Vesta Charger to charge your OPTIMIZER Smart Mini IPG. If you can successfully charge your implanted OPTIMIZER Smart Mini IPG, then the alert screen should no longer be displayed by your Vesta Charger. If your attempt to charge your OPTIMIZER Smart Mini IPG with your Vesta Charger is unsuccessful, contact your doctor as soon as possible.

6.12 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 Smart Mini IPG, your Vesta 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 Smart Mini IPG or Vesta Charger.

When an alert condition occurs, your OPTIMIZER Smart Mini IPG is programmed to send this information to your Vesta Charger.

If a detected alert condition is associated with a Direct Action Alert, an alert screen such as the one shown in **Figure 26** will be displayed by your Vesta Charger accompanied by a beeping tone.

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 27**), accompanied by 3 long beeping tones.

Figure 27: Abnormal Condition Error Screen

If a detected alert condition is associated with a Call Doctor Alert, your Vesta 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 28**.

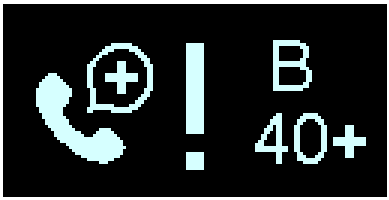


Figure 28: Example of Call Doctor Alert Screen

The Call Doctor Alert screen will be followed by the Snooze Buzzer Alert screen (see **Figure 29**), or if at night, the Snooze Alert screen (see **Figure 30**).

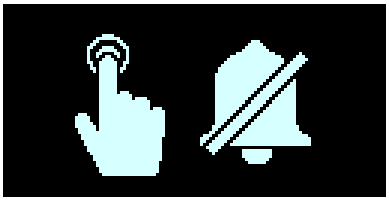


Figure 29: Snooze Buzzer Alert Screen

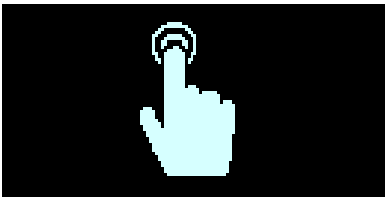


Figure 30: Snooze Alert Screen

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

- If the Call Doctor Alert Code “A19” is displayed, please call the 24-hour Support Hotline (866-312-5370) and inform them of the alert code displayed by your Vesta Charger.
- If the Call Doctor Alert Code “A31” is displayed, it means that your Vesta Charger has detected repeated internal errors during its operation. Please contact your doctor to obtain a replacement Vesta Charger.

- If the Call Doctor Alert Code “A32” is displayed, it means that you are attempting to use your Vesta Charger on an unpaired device. If this code is displayed by your Vesta Charger, perform the following steps:

    1. Verify that the Vesta 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 Smart Mini IPG and the charging process has been restarted, please contact your doctor.

6.13 Cleaning

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

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

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

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

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

6.14 Maintenance

Your Vesta Charger does not contain any user-serviceable parts. If your Vesta Charger is not operational, please contact your doctor to obtain a replacement charger.

Warning: No modification of this equipment is allowed.

The battery inside your Vesta Charger is expected to have a service life of 5 years. If your Vesta Charger is unable to fully charge your OPTIMIZER Smart Mini IPG after the Charger’s internal battery has been fully charged, please contact the 24-hour Support Hotline (866-312-5370) to obtain a replacement charger.

6.15 Storage and Handling

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

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

- **Ambient Temperature:** 10°C to 27°C (50°F to 81°F)
- **Relative Humidity:** 20% to 75%
- **Atmospheric Pressure:** 700 hPa to 1060 hPa (20.73 inHg to 31.39 inHg)

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

6.16 Disposal

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

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

7.0 REPLACEMENT OF YOUR OPTIMIZER SMART MINI IPG

Your implanted OPTIMIZER Smart Mini IPG contains a rechargeable battery and the need to replace it because the battery is unable to hold a charge is **not** expected within the warranty period. However, there maybe instances where the OPTIMIZER Smart Mini IPG or one of its implanted leads may not function as intended. 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.

8.0 FREQUENTLY ASKED QUESTIONS

1. What does my OPTIMIZER Smart Mini IPG do?

Your OPTIMIZER Smart Mini 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. Your OPTIMIZER Smart Mini 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 Smart Mini 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 Smart Mini IPG ever need to be replaced?

Your OPTIMIZER Smart Mini IPG is powered by a rechargeable battery that should provide you with at least 20 years of service. Using the instructions in this manual, your doctor will show you how to recharge your device.

With regular charging, should your OPTIMIZER Smart Mini IPG reach its 20th year of service, your doctor will need to assess the condition of the battery during your routine check-up visits. To help facilitate this battery assessment, please fully charge your OPTIMIZER Smart Mini IPG 7 days before your scheduled routine check-up 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). Since your OPTIMIZER Smart Mini IPG is not a life-sustaining device, you are unlikely to be placed at risk if your device should not operate as expected.

APPENDIX I

Statement of FCC Compliance

FCC Compliance of the Vesta Charger

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

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

This device complies with part 18 of the FCC Rules.

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

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

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

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

FCC Compliance of the OPTIMIZER Smart Mini IPG

The OPTIMIZER Smart Mini IPG has been tested to the following FCC rule:

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

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

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

Electromagnetic Immunity

Electromagnetic Immunity of the Vesta Charger

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE VESTA CHARGER			
Essential Performance of the Vesta Charger: • The Vesta Charger shall not charge the OPTIMIZER Smart Mini IPG inappropriately. • The patient shall be made aware of inappropriate charging either by an explicit message, or by the absence of an expected message from the Vesta Charger			
The Vesta Charger, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Vesta Charger must ensure that it is used within the specified environment. The test levels follow FDA recommendations for the home environment per "Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff", November 24, 2014			
Immunity test	**IEC 60601-1-2:2014 test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Electrostatic discharge as defined in IEC 61000-4-2	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV	Contact Discharge: ± 8 kV Air Discharge: ± 2 kV, ± 4 kV, ± 8 kV, and ± 15 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be 30% or greater.
Electrical fast transient / burst as defined in IEC 61000-4-4	± 2 kV for mains power supply ± 1 kV for in-/output lines	± 2 kV for mains power supply ± 1 kV for in-/output lines	Mains power quality should be that of a typical home healthcare, business, or hospital environment. Do not operate motors or other noisy electrical equipment on the same mains circuit as the Vesta Charger.
AC line voltage surges as defined in IEC 61000-4-5	Line-to-Earth ± 2 kV; Line-to-Line ± 1 kV	Line-to-Earth ± 2 kV; Line-to-Line ± 1 kV	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	Dips: 100% reduction for 0.5/1 cycles 30% reduction for 25/30 cycles Interruptions: 100% reduction for	Dips: 100% reduction for 0.5/1 cycles 30% reduction for 25/30 cycles Interruptions: 100% reduction for	Mains power quality should be that of a typical home healthcare, business, or hospital environment. **Note:** If the user of the Vesta Charger requires uninterrupted operation during power mains

IEC 61000-4-11	250/300 cycles	250/300 cycles	interruptions, it is recommended to power the Vesta Charger from an uninterruptible power supply.
Power line frequency magnetic fields (50/60 Hz) as defined in IEC 61000-4-8	3 A/m	3 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:** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, “a” should be less than the compliance level in each frequency range “b”. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF as defined in IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010	10 V/m: 80 MHz to 2.7 GHz and wireless frequencies	10 V/m: 80 MHz to 2.7 GHz and wireless frequencies	

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

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

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

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

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

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

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

Electromagnetic Immunity of the OPTIMIZER Smart Mini IPG

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY OF THE OPTIMIZER SMART MINI IMPLANTABLE PULSE GENERATOR

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

Essential Performance of the OPTIMIZER Smart Mini IPG:

The IPG shall be able to operate 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 Smart Mini IPG and maintaining it in close proximity to the device for at least two cardiac cycles (2–3 seconds), sets the OPTIMIZER Smart Mini IPG into Magnet Mode, suspending CCM therapy.

Immunity test[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** • 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 4.3 - 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	
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, 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)** • Exercise caution in the vicinity of equipment that generates strong 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 4.8 - 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. Electromagnetic fields > 3 GHz 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	N/A	Avoid direct exposure to the main lobe of high-power radar and microwave communication beams.

	frequencies, the expected performance of EMI control features implemented to meet lower-frequency requirements, and the reduced sensitivity of circuits at microwave frequencies.		
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 Smart Mini 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 Smart Mini 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 Smart Mini 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 Smart Mini IPG is not a pacemaker, CRT, or ICD device. As such, the criteria of ISO 14117:2019 were adapted to be applicable to CCM.
[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 Smart Mini IPG.

Electromagnetic Emissions

Electromagnetic Emissions from the Vesta Charger

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

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

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

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

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

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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE VESTA CHARGER PURSUANT TO: **FCC - 47 CFR 95 Subpart I - Medical Device Radio Communications Service**		
The Vesta Charger, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Vesta Charger must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidelines**
Duration of Transmissions	Complies with clause 95.2557	The Vesta Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected
Frequency Monitoring	Complies with clause 95.2559	
Frequency 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 VESTA CHARGER PURSUANT TO: **ETSI EN 301 839 V2.1.1 - Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU**		
The Vesta Charger, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Vesta Charger must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidelines**
Frequency Error	Complies with clause 5.3.1	The Vesta Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected
Occupied Bandwidth	Complies with clause 5.3.2	
Power Output	Complies with clause 5.3.3	
Transmitter Spurious Emissions (30 MHz to 6 GHz)	Complies with clause 5.3.4	
Frequency Stability Under Low Voltage Conditions	Complies with clause 5.3.5	
Spurious Radiation of Receivers	Complies with clause 5.3.6	

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

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

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

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

The Vesta Charger, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Vesta Charger must ensure that it is used within the specified environment.

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

Emissions Test	Compliance	Electromagnetic environment - guidelines
Radiated Emissions EN 55032:2012/AC:2013	Class B	The INTELIO Programmer with INTELIO Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected
Conducted Emissions EN 55032:2012/AC:2013	Class B	The INTELIO Programmer with INTELIO Programming Wand must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. Class A equipment is equipment suitable for use in all establishments other than domestic buildings, and Class B equipment is equipment suitable for use in domestic establishments and in establishments directly connected to a low
AC Harmonic Emissions IEC 61000-3-2:2014	Class A	
Voltage Flicker IEC 61000-3-3:2013	Pass for all parameters	

		voltage power supply network which supplies buildings used for domestic purposes.

IEC 60601-1-2 2014

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE VESTA CHARGER PURSUANT TO: **IEC 60601-1-2 2014, Edition 4.0 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests**		
The Vesta Charger, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The customer or user of the Vesta Charger must ensure that it is used within the specified environment. There may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances		
Emissions Test	**Compliance**	**Electromagnetic environment - guidelines**
Radiated Emissions CISPR 11: 2009 + A1:2010	Group 1, Class B	The Vesta Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions CISPR 11: 2009 + A1:2010; FCC 18	Group 2	The Vesta Charger must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. Class A equipment is equipment suitable for use in all establishments other than domestic buildings, and Class B equipment is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
AC Harmonic Emissions IEC 61000-3-2:2014	Class A	
Voltage Flicker IEC 61000-3-3:2013	Pass for all parameters	

Electromagnetic Emissions from the OPTIMIZER Smart Mini IPG

The OPTIMIZER Smart Mini IPG must emit electromagnetic energy in order to perform its intended function when communicating with the Intelio Programmer or the Vesta 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 SMART MINI IPG PURSUANT TO: **FCC - 47 CFR 95 Subpart I - Medical Device Radio Communications Service**		
The OPTIMIZER Smart Mini Implantable Pulse Generator, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The patient implanted with the OPTIMIZER Smart Mini 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 Smart Mini IPG must emit electromagnetic energy in order to perform its intended function when communicating with the Intelio Programmer or the Vesta 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 SMART MINI 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 Smart Mini Implantable Pulse Generator, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The patient implanted with the OPTIMIZER Smart Mini Implantable Pulse Generator must ensure that it is used within the specified environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidelines**
Frequency Error	Complies with clause 5.3.1	The OPTIMIZER Smart Mini IPG must emit electromagnetic energy in order to perform its intended function when communicating with the Intelio Programmer or the Vesta Charger. Nearby electronic equipment may be affected.
Occupied Bandwidth	Complies with clause 5.3.2	
Power Output	Complies with clause 5.3.3	
Transmitter Spurious Emissions (30 MHz to 6 GHz)	Complies with clause 5.3.4	
Frequency Stability Under Low Voltage Conditions	Complies with clause 5.3.5	
Spurious Radiation of Receivers	Complies with clause 5.3.6	

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

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMMISSIONS OF THE OPTIMIZER SMART MINI 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 Smart Mini Implantable Pulse Generator, part of the OPTIMIZER Smart Mini System is intended for use in an electromagnetic environment as specified below. The patient implanted with the OPTIMIZER Smart Mini 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 Smart Mini IPG must emit electromagnetic energy in order to perform its intended function when communicating with the Intelio Programmer or the Vesta Charger. Nearby electronic equipment may be affected.

Wireless Technology

RF wireless technology is used in the communication between an OPTIMIZER Smart Mini Implantable Pulse Generator (IPG) and the Vesta 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 Vesta Charger to recharge the OPTIMIZER Smart Mini IPG at the 13.56 MHz ISM frequency. The transmission range is specified at a maximum of 4 cm 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.

Vesta Charger Wireless Nominal Specifications

Characteristic	Nominal
MICS MedRadio	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	< 145 kHz
Modulation	FSK
Radiated Power	< 25 µW E.I.R.P.
Range	0 to at least 1.5 m
Transcutaneous Energy Transfer	
Frequency Band	13.56 MHz Industrial, Scientific, and Medical radio band (ISM)
Bandwidth	< 0.014 MHz
Modulation	Amplitude (slow to optimize coupling, no data transmitted)
Radiated Power	< 0.6 W
Range	5 mm to 40 mm

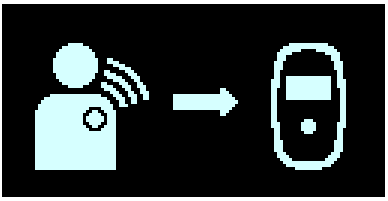
OPTIMIZER Smart Mini IPG Wireless Nominal Specifications

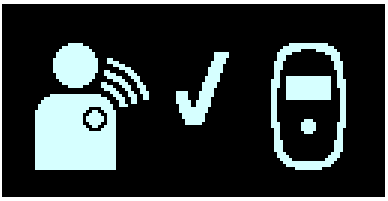
Characteristic	Nominal
OPTI*link* MICS MedRadio	
Frequency Band	402 – 405 MHz Medical Implant Communication Service (MICS) Medical Device Radio Communication Service (MedRadio)
Bandwidth	< 145 kHz
Modulation	FSK
Radiated Power	< 25 µW E.I.R.P.
Range	0 to at least 1.5 m

Quality of Service (QoS) for Communications between the Vesta Charger and the OPTIMIZER Smart Mini IPG

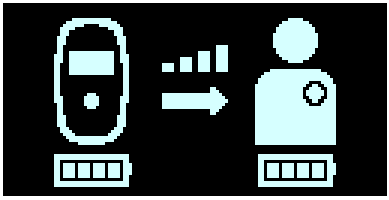
MedRadio in the MICS sub-band (402 to 405 MHz) wireless technology enables communication between the OPTIMIZER Smart Mini IPG and the Vesta Charger. The requirements for the Quality of Service (QoS) vary depending on the use environment (operating room, recovery room, clinic, and home environment).

The Vesta 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 Vesta Charger:

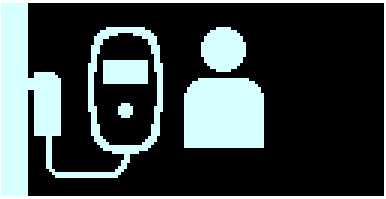


The Coupling Level icon (), whose number of illuminated bars is proportional to the proximity of the charging wand to the implanted OPTIMIZER Smart Mini IPG, is indicative of the Quality of Service (QoS) for the transcutaneous energy transmission wireless link. The charging wand should be repositioned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

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

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

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



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

Troubleshooting Wireless Connection between OPTIMIZER Smart Mini IPG and Vesta Charger

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

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

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

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 Smart Mini Implantable Pulse Generator

Model No.:

Serial No.:

Lead 1 Model No.:	S/N
Lead 2 Model No.:	S/N
Lead 3 Model No.:	S/N

NOTES: