Maestro® Rechargeable System

Patient Manual

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

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The Maestro System is protected under U.S., European, Japanese and Australian Patents, and patent applications.

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EP1922111

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1. Glossary

Abbreviations and Acronyms

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<th>Term</th>
<th>Description</th>
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<tr>
<td>AC Recharger</td>
<td>Charges the battery of the mobile charger</td>
</tr>
<tr>
<td>AE</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>EMI</td>
<td>Electromagnetic Interference</td>
</tr>
<tr>
<td>%EWL</td>
<td>Percent Excess Weight Loss</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>MR</td>
<td>Magnetic Resonance</td>
</tr>
<tr>
<td>MC</td>
<td>Mobile Charger</td>
</tr>
<tr>
<td>PET</td>
<td>Positron Emission Tomography</td>
</tr>
<tr>
<td>RF</td>
<td>Radiofrequency</td>
</tr>
<tr>
<td>RFID</td>
<td>Radio Frequency Identification</td>
</tr>
<tr>
<td>%TBL</td>
<td>Percent Total Body Weight Loss</td>
</tr>
<tr>
<td>VBLOC</td>
<td>Vagal Block for Obesity Control</td>
</tr>
</tbody>
</table>

Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>Adverse Event</td>
<td>Any troublesome medical episode in a patient</td>
</tr>
<tr>
<td>Atelectasis</td>
<td>When your lung or a part of your lung becomes partially impaired (it may partially collapse)</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>A disease in which normal liver cells are damaged and are then replaced by scar tissue</td>
</tr>
<tr>
<td>Diathermy</td>
<td>A procedure that heats and destroys tissue with short wave, high-frequency electromagnetic radiation, electric currents, or ultrasonic waves</td>
</tr>
<tr>
<td>Defibrillator</td>
<td>A device used to shock a patient’s heart when it goes into a life threatening rhythm</td>
</tr>
<tr>
<td>Electrocardiogram</td>
<td>A record of the electrical activity of the heart showing certain waves that are linked with contraction of the heart</td>
</tr>
<tr>
<td>Electromagnetic Interference</td>
<td>Refers to a disruption from an electromagnetic energy source that can affect the function of an electrical circuit</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Electrosurgical</td>
<td>An electrosurgical tool that uses electricity</td>
</tr>
<tr>
<td>Esophagus</td>
<td>The muscular food tube from the mouth to the stomach.</td>
</tr>
<tr>
<td>Esophageal Varices</td>
<td>Veins at the lower end of the esophagus that are enlarged and swollen can turn into ulcers and bleed</td>
</tr>
<tr>
<td>%EWL</td>
<td>Refers to weight loss as the percent of your extra weight lost. For example if you are 100 pounds overweight and you lose 30 pounds, your %EWL is 30%.</td>
</tr>
<tr>
<td>Gallbladder Disease</td>
<td>Inflammation of your gallbladder (a small organ next to your liver) often caused by stones inside your gallbladder that causes pain and discomfort and sometimes requires medical or surgical treatment</td>
</tr>
<tr>
<td>Hiatal Hernia</td>
<td>Happens when part of your stomach pushes up on or through the small opening in your diaphragm where your food tube passes through on its way to connect to the stomach</td>
</tr>
<tr>
<td>Hyperbaric Chamber</td>
<td>Chamber designed to supply oxygen at a higher pressure than normal air pressure</td>
</tr>
<tr>
<td>Ileus</td>
<td>When the part of the small intestine does not move normally</td>
</tr>
<tr>
<td>Implant</td>
<td>To place a device or object in a person’s body</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>A minimally-invasive surgical or diagnostic procedure that uses a flexible endoscope (laparoscope) to view and operate on structures in the abdomen</td>
</tr>
<tr>
<td>Lithotripsy</td>
<td>The use of high-energy shock waves to break up kidney or ureter stones</td>
</tr>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>A medical imaging technology that can get a highly refined image of the body’s interior without surgery by using strong magnets and pulses of radio waves</td>
</tr>
<tr>
<td>Monopolar Electrosurgical</td>
<td>A type of surgical instrument that uses a single electrode to deliver energy</td>
</tr>
<tr>
<td>Instruments</td>
<td></td>
</tr>
<tr>
<td>Neuroregulator</td>
<td>Refers to the Maestro System implantable disc that sends very small electrical signals to the vagus nerve</td>
</tr>
<tr>
<td>Neurostimulator</td>
<td>Is a device that is implanted in the body and designed to provide an electrical stimulation to the nerves</td>
</tr>
<tr>
<td>Obesity</td>
<td>Generally speaking, those individuals with a body mass index (BMI) &gt; 30 Kg/m² are considered obese</td>
</tr>
<tr>
<td>Oncologic Radiation</td>
<td>Radiation therapy using high energy to kill cancer cells using Cobalt 60 or gamma radiation</td>
</tr>
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</table>
### Portal Hypertension
High blood pressure in the liver veins. This condition can happen with cirrhosis of the liver or other illnesses that can cause a blockage in the liver veins.

### Radiofrequency Ablation
The destruction of tissue during a surgery using an energy source such as radiofrequency energy.

### RF Emitter
A device that radiates radiofrequency signals.

### RFID
Radio Frequency Identification refers to a system with which objects can be tracked and identified. It is used most often in stores to prevent theft.

### Sleep Apnea
It is a potentially dangerous sleep disorder during which breathing repeatedly starts and stops.

### %TBL
Refers to weight loss as the percent of your total body weight lost. For example, if you weigh 300 pounds overweight and you lose 30 pounds, your %TBL is 10.

### Telemetry Link
Transmission of data or energy between two devices without having direct contact.

### Vagus Nerve
The longest nerve in the body. The vagus nerve is one of the nerves between the brain and the stomach that controls hunger and feelings of fullness.

### VBLOC Therapy
Delivered by the Maestro System, VBLOC Therapy uses high frequency to block messages in the vagus nerve between the brain and the gut (stomach, liver, pancreas, intestine).
2. Getting Started

2.1 About this manual
This manual is intended to reinforce the training you received from your doctor and nurse and support your learning as you become accustomed to living with your Maestro System. If you have any questions or concerns, contact your doctor or nurse right away or call 1800 MY-VBLOC (1-800-698-2562) for technical support.

2.2 About Obesity
Two of every three adults in the U.S. are either overweight or obese. As a disease, obesity is one of the leading causes of preventable death. Obesity can increase your risk of death from all causes.

There are a number of weight loss options available, like diet and exercise, drugs and other types of surgical procedures. After discussions between you and your treating doctors, you have decided to take an important step in the management and control of your weight, using VBLOC Therapy.

2.3 About The Maestro System and VBLOC® Therapy
The Maestro System is intended to help you lose weight by blocking signals in the nerves that control how hungry you feel. This therapy is called VBLOC therapy.

The main component of the Maestro System is the neuroregulator disc. It is designed to operate for up to 8 years. This disc is implanted just under the skin and is attached to nerves on your stomach by two small leads (wires). These are implanted using minimally invasive surgery.

The Maestro System may help you feel less hungry. It may help you reduce the amount of food you eat during a meal. You may feel full longer so that you don’t have to eat in between meals.

After you receive your Maestro System, it is important that you pay attention to the change in your body’s hunger signals. You should stop eating when you feel full. You may be full after eating smaller portions than you are used to eating.

The Maestro System will work best when used correctly, in combination with a healthy diet of suitable portion sizes, and where possible, increasing the amount of physical activity you do each day.

Your doctor or nurse will provide you with information on how to use the system. This manual is intended to be used in addition to the information and instructions your doctor or nurse has given to you.

2.4 Who is a candidate for the Maestro System?
The Maestro System is intended for use by individuals aged 18 years through age 65 who are obese, with a BMI of 40 to 45 kg/m² or a BMI of 35 to 39.9 kg/m² with a related health condition such as high blood pressure or high cholesterol levels. Individuals should have first tried to lose weight by diet and exercise in a supervised program within the last 5 years before receiving the Maestro System.
2.5 **Who is not a candidate for the Maestro System?**

You are not a candidate for the Maestro System if you have any of these medical conditions:

- **Cirrhosis** of the liver
- **Portal hypertension**
- **Esophageal varices**
- A **hiatal hernia** that is clinically significant and cannot be corrected by surgery

You are not a candidate for the Maestro System if you have another permanently implanted, electrically powered medical device (such as a heart pacemaker, implanted defibrillator or neurostimulator) or if your doctor does not feel it is safe for you to have surgery.

If you are not sure whether you have any of these conditions, consult with your doctor.

You should not have the following medical procedures if you have been implanted with the Maestro System:

- **Magnetic Resonance Imaging (MRI)** – The Maestro System is not safe for use with MRI scans. Use of Magnetic Resonance (MR) could deliver energy to your implanted device. This may cause tissue damage resulting in injury.
- **Diathermy** – You **CANNOT** have surgical procedures where a shortwave, microwave, or therapeutic ultrasound diathermy device may be used. The use of diathermy with the Maestro System **HAS NOT** been studied but could deliver energy to your implanted device. This may cause tissue damage resulting in injury.

Make sure that all of your health care providers know that you have the Maestro System implanted, and show them your Patient Identification Card.
3. Warnings and Precautions

3.1 Warnings

3.1.1 Medical or Surgical Procedures

**DO** seek guidance from your doctor before you undergo a medical or surgical procedure. Some of these procedures may harm you, cause damage to your neuroregulator disc or may turn therapy off. These may include:

- Shock wave **lithotripsy**
- **Oncologic radiation** or any **cobalt 60** or **gamma radiation**
- **Mono-polar** electrosurgical instruments
- **Positron Emission Tomography** (PET) scans, or
- **Radiofrequency ablation**

You **CANNOT** have surgical procedures where a diathermy device may be used. The use of diathermy with the Maestro System **HAS NOT** been studied. Please consult with your doctor before undergoing any procedure where diathermy may be used.

Infections at the implant site have been observed, and severe infections could require another surgery and removal of your device. You may need to be put on antibiotic medications.

3.1.2 Radio Frequency Identification Devices (RFID)

RFID systems could produce electromagnetic interference with the Maestro System. Please refer to section 3.2.4 “EMI, RFID, Security and Theft Management Systems” for specific risks associated with RFID and other common RF emitters.

3.1.3 Magnetic Resonance (MR) Safety

The Maestro System is MR unsafe and is contraindicated for anyone thinking of undergoing a MRI procedure.

**DO** tell the radiologist, MRI nurse or technician if you were informed by your surgeon that not all parts were removed after your Maestro System was explanted. Tell them that you **DO** have remnants of a medical device that has been categorized as MR unsafe.

3.1.4 Charging Your Neuroregulator Disc

**DO** fully charge your neuroregulator disc at least once every two months. If you don’t regularly charge your neuroregulator disc, the battery may no longer be chargeable. The neuroregulator disc may no longer be able to deliver therapy.

If you make the decision to stop therapy, fully charge the neuroregulator disc prior to stopping therapy (deactivation). Your doctor **MUST** verify that the
neuroregulator disc is fully charged before it is turned off. A deactivated neuroregulator disc may be turned on by your doctor.

### 3.1.5 Migration of Your Neuroregulator Disc

**DO NOT** turn, twist or manipulate the neuroregulator disc in any way. This may result in damage to the nerves or the implanted device. The leads of your Maestro System can become entangled, fractured, or the insulation can erode. Therapy delivery may be limited until a surgical repair or replacement can be performed.

Your neuroregulator disc will continuously monitor the leads and inform your doctor during your follow-up about their condition.

### 3.2 Precautions

#### 3.2.1 Pregnancy

**Caution:** The safety and effectiveness of the Maestro System has not been established during pregnancy. As soon as you know you are pregnant, **DO** tell your doctor so the neuroregulator disc can be fully charged and therapy can be stopped.

During your pregnancy, the leads of the Maestro System should be checked on a regular basis by your doctor. The Maestro System has not been tested with fetal monitoring systems and may interfere with their operation.

Inform your obstetrician about your implanted device before ultrasound or fetal monitoring devices are used.

#### 3.2.2 General

**Caution:** The safety and effectiveness of this device has not been determined for patients under the age of 18 years.

**Caution:** The Maestro Rechargeable System may interact with implantable devices such as cardiac pacemakers and defibrillators, implanted spinal cord and peripheral nerve stimulators, other neurostimulators, and body worn medical devices, such as insulin pumps.

**Caution:** The safety and effectiveness of defibrillation devices has not been established with the Maestro Rechargeable System. If use of an external defibrillator is necessary, it is possible that defibrillation energy may go through the Maestro System leads (wires), possibly causing the defibrillation to not work and damage the nerves.

**Caution:** Allergic reaction to the leads or the transmit coil of the Maestro System is possible. Symptoms may include redness, swelling, itching, pain, etc. Discuss with your doctor any symptoms related to a possible allergic reaction.

**DO NOT** operate the Maestro Rechargeable System in flammable environments. Maestro Rechargeable System components produce small electrical currents that may ignite flammable liquids and gasses.
DO NOT use the mobile charger, AC recharger or transmit coil if they appear damaged to avoid the potential for electric shock.

DO NOT attempt to modify or fix the equipment yourself. Contact your Doctor or Technical Support at 1-800-MY-VBLOC (1-800-698-2562).

DO NOT pull, tie in knots, wrap around the mobile charger, or have stick pins placed through the transmit coil cable. This could damage the device. The transmit coil and cable should be regularly inspected for damage, to avoid a potential electric shock.

DO NOT cover the mobile charger when in use. The mobile charger becomes warm when charging. Overheating of the mobile charger could damage the device. Keep the mobile charger well ventilated when in use.

DO NOT use the mobile charger when bathing, swimming, in a sauna or wet environments. You should not expose the mobile charger or transmit coil to fluids. This could damage the device.

ALWAYS turn the mobile charger off and disconnect the transmit coil when on any aircraft so as not to potentially interfere with airplane operation.

If you have impaired vision, you may not be able to successfully operate the Maestro System.

The capacity of the battery in the neuroregulator disc will be reduced over time. You may have to charge more often as the neuroregulator disc nears the end of its life.

DO NOT use any multiple outlet extension cords with the AC recharger. For consistent operation of the AC recharger, connect the power cord directly to a power outlet.

DO keep metal or strong magnets at least six inches away from the neuroregulator disc. This includes metal or magnetic objects, such as those in speakers, Cathode Ray Tubes (including television tubes), electric motors and on refrigerator and freezer doors, power tools, as well as magnets used therapeutically or worn on the body. Magnets may deactivate your neuroregulator disc. See section 3.2.4 “EMI, RFID, Security and Theft Management Systems” for further possible effects of exposure to strong magnetic fields or electromagnetic interference.

Do make sure that all of your health care providers are aware that the Maestro System has been implanted. You should register your implant information with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

### 3.2.3 Temperature

DO NOT use heating and cooling devices, such as electric blankets, heating pads, hot and cold packs, near the implantation site. The neuroregulator disc is designed to work between 16°C (60°F) and 45°C (113°F). If you are exposed to temperatures outside of this range, the neuroregulator disc may stop working (deactivate). You will see the red status icon on the mobile charger blinking any
time you position the transmit coil. A deactivated neuroregulator disc may be restarted by your doctor.

### 3.2.4 EMI, RFID, Security and Theft Management Systems

**Caution:** Radio Frequency Identification (RFID) systems may interfere with your Maestro System and may result in longer charging times, or your neuroregulator disc may be unable to fully charge. Your doctor should be aware that RFID systems near the Maestro System in the clinic may result in difficulty with programming the neuroregulator disc. RFID sources may be present in health care facilities, retail stores, libraries, airports and other business environments.

**DO** tell people working with security and theft management systems that you have a Maestro System, and show them your Patient Identification Card.

The effects of Electromagnetic Interference (e.g., electronic article surveillance (EAS) systems, metal detectors, other security systems, strong magnetic fields etc.) on device safety or performance are unknown. These systems may be strong enough to interfere with the function of the Maestro System and may produce the following effects:

- **Serious injury:** it is possible for these sources to generate enough energy in the Maestro leads to damage the vagal nerve trunks and surrounding tissue.

- **Damage to the Maestro System:** resulting in permanent loss of therapy.

- **Operational changes to the neuroregulator disc:** resulting in therapy turning off.

The Maestro System may activate EAS systems, metal detectors or other security systems. **DO NOT** wear your mobile charger or transmit coil near these systems.

Strong magnetic fields and RF emitters, including RFID systems, may not always be visible and could result in accidental exposure without your awareness. You should keep as much distance between your Maestro System and these sources as possible, and never recharge your neuroregulator disc when near these sources. We recommend that you turn the neuroregulator disc off, using your MC, before you enter an area with known strong magnetic fields.

If your device has stopped working because of exposure to a strong magnetic field, then you must schedule a visit with your doctor to restart the neuroregulator disc. Refer to section 10.0 “Electromagnetic Interference” for more information.

### 3.2.5 Hyperbaric Chambers

**DO NOT** use the Maestro System in a hyperbaric chamber. The effects on device safety, operation or performance when within a hyperbaric chamber are unknown and could result in damage to the device.

### 3.2.6 Telemetry Link

**Caution:** The telemetry link between the neuroregulator and mobile charger may stop functioning when two or more Maestro Systems are operating within 10 cm of
each other. The telemetry link will be re-established and normal operation will resume when this distance is increased to greater than 10 cm.

Radio frequency transmitters operating near the neuroregulator and mobile charger may affect battery charging; transmit coil positioning and device programming. Issues may be resolved by moving to a different place.

Interference to the radio telemetry link between the neuroregulator and mobile charger may be experienced in countries outside the USA, where frequency and radio transmission may differ from those in the USA.

Interference to the radio telemetry link between the neuroregulator and the mobile charger may be experienced when using EKG telemetry monitoring equipment (e.g. portable telemetry units worn to record cardiac arrhythmias). These monitoring systems may also be affected by the telemetry link of the Maestro System.

Unintended access to the neuroregulator disc is prevented by the short range of radio telemetry link and the way the neuroregulator disc and mobile charger communicate.
4. The Maestro System Components

The Maestro Neuroregulator and Leads
The Maestro System is made up of multiple components. A neuroregulator disc and leads (wires) are implanted into your body during the surgical procedure. In most cases, the neuroregulator disc is implanted just under the skin on the left side of your body, against your ribs. You and your doctor can discuss the most appropriate place for the neuroregulator to allow for your comfort.

The leads (wires) are implanted in your abdomen and are connected to the neuroregulator disc. The neuroregulator disc creates very small electrical pulses that travel along the leads to the vagus nerve. These pulses block nerve signals that control how hungry you feel. This can help you reduce the amount of food you eat during a meal. You may feel full longer so that you don’t want to eat in between meals. This is called VBLOC Therapy.

Mobile Charger and AC Recharger
The mobile charger (MC) is used to charge the neuroregulator. The MC has a button and a display which shows information that is important to you, such as the battery level. There are also two ports on the mobile charger, the uncovered one is used to connect the mobile charger to both the AC recharger and the transmit coil.

The second port, under the rubber cover, is only used by your doctor or nurse. You should leave this port covered at all times to protect it.

The battery in the mobile charger needs to be charged using the AC recharger.

The Transmit Coil
The Transmit Coil is used to help find the neuroregulator disc and then works to charge the neuroregulator disc when needed.
The mobile charger status indicator tells you if your system is working. The indicator will be green and blink from time to time when the system is working as intended.

The bar graph indicator at the bottom of the mobile charger display is used three ways, each depicted by a unique symbol when that function is being used by the mobile charger:

- The symbol shaped like a circle with a cross inside indicates the best position of the transmit coil.
- The symbol shaped like a battery indicates the battery level of your mobile charger.
- The symbol shaped like a circle with a battery inside indicates the battery level of your neuroregulator disc.

Only one of these symbols will light up at any given time. By looking at the symbol, you can tell which function the bar graph indicator is showing.

The illustration below shows how the implantable and external components work together.
5. **Charging the Mobile Charger and the Neuroregulator**

This section describes the charging process for your device. Please read the instructions carefully before attempting to charge your system components.

Just like a mobile phone, your neuroregulator disc has a battery which must be charged daily. If the battery is not charged, your neuroregulator disc will not be able to provide the therapy to help you manage your weight. It is important that you keep the battery charged and check the battery levels *daily*. When you travel, take your AC recharger, mobile charger and transmit coil with you.

You cannot over-charge the battery in the neuroregulator disc. Charging the batteries cannot harm you or damage the neuroregulator disc. Checking your battery levels *every day* and charging them regularly will keep your neuroregulator disc functioning properly.

Please read the following instructions for detailed steps.

- **Section 5.1** Charging the battery in the mobile charger
- **Section 5.2** Checking the battery level of your mobile charger
- **Section 5.3** Positioning the transmit coil
- **Section 5.4** Checking the battery level of your neuroregulator disc
- **Section 5.5** Charging the battery in your neuroregulator disc
5.1 Charging the Battery in the Mobile Charger

1. Connect the AC recharger to a powered wall outlet. Use only the power cord provided to you by your doctor.

2. Attach the connector on the short wire of the AC recharger to the port on the mobile charger.
3. Check that the indicator light on the AC recharger turns orange. This indicates that the MC is charging.

![Indicator Light on AC Recharger will be orange](image)

4. The MC will show a single lighted segment on the bottom of the bar graph moving from left to right. If the bar graph remains blank, the MC is not charging and you should refer to the trouble shooting guide at the end of this section.

![Mobile Charger Charging Display](image)

**Note:** Allow the mobile charger to charge for an extended period of time. An MC with a low battery charge may take several hours to reach a full charge. Also, keep the MC and AC recharger in a cool and well ventilated location while charging.
5. Once the MC is fully charged, the light on the AC recharger will turn green. The display on the MC’s bar graph will continue to show a single lighted segment moving from left to right as shown in the MC charging sequence in point 4.

You can leave the AC recharger connected to the Mobile Charger until you are ready to charge your neuroregulator disc. This will ensure the MC will always be fully charged and ready for use. Remember – you cannot overcharge the MC.

Always take care when connecting or disconnecting the AC recharger to the MC and do not pull on the cable.

5.1.1 Troubleshooting: Charging the Battery in the Mobile Charger

If the bar graph on the MC display remains blank, it is not charging. To resolve this:

- With the MC connected to the AC recharger, press and release the MC button once. This sends a wake-up signal to the MC.
- If the MC charging display does not begin within 30 seconds, wait half an hour and press the button again.

If the light on the AC Recharger remains green when the MC is connected to the AC Recharger, the MC is not charging. To resolve this:

- Leave the power cord of the AC Recharger connected to the wall outlet and leave the MC still connected to the AC recharger.
- Then disconnect and quickly reconnect the power cord from the AC recharger.
- Check the indicator light in the AC recharger. Orange indicates the MC is charging. Repeat this process if the indicator light is still green.

Note: If the AC Recharger indicator remains green after several tries, the MC may be full and not require recharging.
5.2 Checking the Battery Level of your Mobile Charger

1. With the MC disconnected from the AC Recharger and the transmit coil, press the MC button once.

2. The mobile charger battery indicator will light up and the bar graph will indicate the charge level of the mobile charger’s battery.

**Note:** If the bar graph indicator shows all five bars, the battery in the mobile charger is full. The mobile charger is ready to charge the battery in your neuroregulator disc.

If the bar graph indicator shows four bars or less, the battery in the mobile charger needs to be charged. Proceed with the instructions in Section 5.1 “Charging the Battery in the Mobile Charger.”

5.2.1 Troubleshooting Tips: Checking the Battery Level of your Mobile Charger

If the MC battery indicator is on and the first bar on the bar graph is flashing, the mobile charger battery is low and must be charged before use. To resolve this:

- Follow the instructions in Section 5.1 “Charging the Battery in the Mobile Charger.”
5.3 Positioning the Transmit Coil

1. Disconnect the AC recharger from the mobile charger.
2. Attach the transmit coil (TC) to the uncovered port on the fully charged mobile charger.

3. Holding the transmit coil away from your body, press and hold the MC button until the transmit coil indicator starts to flash.

4. Bring the coil up to your body and slowly sweep it COMPLETELY across the location of your neuroregulator disc. Look at the bar graph on the bottom of the MC display. The display should change as you move the coil.
5. Move the transmit coil back to the position that shows the most bars on the bar graph.

**Note:** Typically, 4 or 5 bars result in the quickest charging of your neuroregulator disc.
You may secure the transmit coil in the best position with an elastic belt or any other method that is comfortable for you and does not contain metal or magnetic objects within at least six inches of the transmit coil.

### 5.3.1 Troubleshooting: Positioning the Transmit Coil

If during charging of your neuroregulator disc the transmit coil becomes displaced, the transmit coil indicator will light up. To resolve this:

- Try moving the coil back into position to see if charging resumes.
- If the coil indicator does not go off, reposition the transmit coil as described in section above (Section 5.2).

If the red status indicator starts blinking, your neuroregulator disc cannot be charged.

- Contact your doctor or nurse during normal business hours. This does not indicate an emergency. It means you need some support from your doctor or nurse to trouble-shoot the system.

### 5.4 Checking the Battery Level of your Neuroregulator Disc

1. Position the transmit coil over your neuroregulator disc as described in Section 5.3 “Positioning the Transmit Coil.”

2. As soon as the display of the mobile charger goes blank, press the MC button on the mobile charger once.

3. The neuroregulator disc battery indicator will light up and the bar graph will indicate the charge level of the battery in your neuroregulator disc.
Note: The bar graph indicator should show 5 bars meaning the neuroregulator disc is fully charged. If the bar graph indicator shows four bars or less, the battery in the neuroregulator disc needs to be charged. Proceed with the instructions in Section 5.5 “Charging the Battery in your Neuroregulator Disc.”

5.4.1 Troubleshooting Tips: Checking the Battery Level of your Neuroregulator Disc

If the first bar on the bar graph is flashing, the battery level of the neuroregulator disc is very low and must be charged as soon as possible. To resolve this:

- Follow the instructions in Section 5.5 “Charging the Battery in your Neuroregulator Disc.”

If you press the MC button two or three times you will pass the menu item that helps you check the battery level of the neuroregulator disc. To resolve this:

- Press the MC button a fourth time and wait for the display to return the mobile charger menu to its original blank position, and repeat Section 5.4 “Checking the Battery Level of your Neuroregulator Disc.”

5.5 Charging the Battery in your Neuroregulator Disc

1. Check to make sure your mobile charger is fully charged as described in Section 5.2 “Checking the Battery Level of your Mobile Charger.”
2. Check the battery level of your neuroregulator disc as described in 5.4 “Checking the Battery Level of your Neuroregulator Disc.”

3. With the battery level of the neuroregulator disc still displayed by the bar graph, press and hold the MC button. As soon as you see the lighted segment of the bar graph on the display moving from left to right, release the MC button.

Note: If the bar graph indicator shows all five bars, the battery in your neuroregulator disc is fully charged, you will not be able to charge your device.
4. Allow the neuroregulator disc to charge until it becomes fully charged (all 5 bars flashing at the same time) or until the MC battery becomes fully depleted (MC display has gone blank).

**Note:** During charging of your neuroregulator disc, the battery in the mobile charger will deplete.

**Note:** Continue to charge the neuroregulator disc without stopping even if the mobile charger shows its battery is low (MC battery icon flashes).

5. Once you have completed charging your neuroregulator disc, disconnect the transmit coil and proceed with the instructions in Section 5.1 “Charging the Battery in the Mobile Charger.”

**Note:** The charging time will typically take 30 to 60 minutes when you charge your neuroregulator disc with the battery level at four bars on the bar graph indicator. Uninterrupted charging with a transmit coil in the best position will result in the shortest charging time.

**Note:** While charging the neuroregulator disc, keep the mobile charger in a cool and well ventilated location. The mobile charger may heat up during use; this is a part of normal use.

### 5.5.1 Troubleshooting Tips: Charging the Battery in your Neuroregulator Disc

If the Transmit Coil moves out of position during charging, the green transmit coil icon will light up and charging will stop. To resolve this:

- Move the coil back to the position you selected in Section 5.3 “Positioning the Transmit Coil.” When the coil is positioned correctly, the green transmit icon will go away on the MC display.

If the charging sequence on the MC display is blank, the mobile charger may not be fully charged. To resolve this:

- Check the charge on the MC. You should fully charge the MC battery before returning to charge the neuroregulator disc.

If you have not charged your neuroregulator disc in a few days, your MC battery may deplete before your neuroregulator disc battery is fully charged. To resolve this:

- Recharge the MC as above and charge your neuroregulator disc again.
6. Living with VBLOC Therapy

In addition to the information included in this guide, your doctor and nurses will give you detailed instructions about living with VBLOC Therapy.

To get started, here are a few important steps you’ll need to take when living with VBLOC Therapy:

- You can keep the mobile charger attached to a power source when not in use. This will ensure that the mobile charger will always be charged and ready for use.
- Keep the mobile charger and the transmit coil clean and dry.
- Visit your doctor regularly.
- Although you aren’t required to restrict the types of foods in your diet, it’s important to take an active role in your health. Follow your doctor and nurses’ diet and eating guidance and take your prescribed medications.
- In the main clinical study of the Maestro System (called the ReCharge Study) patients who received VBLOC therapy also received counseling on healthy eating, being active and how to lose weight. Studies have shown that treatment for weight loss (such as diet drugs or weight loss surgeries) is more effective when combined with diet and exercise.

6.1 Maintaining the Charge in your Neuroregulator Disc

You should get into the habit of charging your neuroregulator disc using the mobile charger daily. You should also leave the AC recharger connected to the mobile charger and power outlet during the time you do not need your mobile charger.

If you don’t charge your neuroregulator disc for two months or longer, the neuroregulator disc may no longer be able to deliver therapy.

If you and your doctor decide to stop the therapy, the battery in the neuroregulator disc must be fully charged before the neuroregulator disc is turned off. If you do this, you should make a yearly visit to your doctor to check the battery charge level of your neuroregulator disc.

6.2 Maintaining the Mobile Charger and Transmit Coil

Your mobile charger and transmit coil are electrical devices, they are not intended to be used when showering, bathing, swimming, or in a sauna.

You may clean the transmit coil and mobile charger from time to time with a damp soapy cloth. Do not place or splash the mobile charger or transmit coil in any liquid. Use a clean damp cloth to remove any soap residue. Allow components to dry before you use them.

If you use an elastic belt to hold the transmit coil in place, you may wash the belt by hand or with a machine using a cold, gentle cycle and air dry.

Check the mobile charger, transmit coil, and AC recharger regularly for wear or damage. Discuss the condition of these components with your doctor or nurse during follow up visits so they make certain your Maestro System is working properly at all times.
6.3 Home and Work Environments
Your neuroregulator disc can be turned off in an emergency situation by placing a strong magnet over it. If you have magnets, you must be careful to keep a six inch distance between the magnets and your neuroregulator disc. Many refrigerators and freezers have a magnetic strip in the door. Be careful not to lean against this magnetic strip.

Keep metal and magnetic objects at least six inches away from the transmit coil during recharging of the neuroregulator disc.

Equipment that generates large magnetic fields may turn off your neuroregulator disc if you are in close proximity. They can include:

- Electric arc or resistance welding equipment
- Electric induction heaters
- Electric “blast” furnaces found in steel mills

Your neuroregulator disc is turned off when the red status indicator on the MC starts blinking after you position the transmit coil. This does not indicate an emergency. It indicates you must contact your doctor during normal business hours to schedule an appointment.

6.4 If You Become Pregnant
The safety and effectiveness of the Maestro System has not been established for use during pregnancy. As soon as you know you are pregnant, you must contact your doctor or nurse. They will instruct you to fully recharge your neuroregulator disc and visit the office to turn off your neuroregulator disc.

Because leads (wires) are implanted in your abdomen, your doctor will monitor the position of these leads relative to the fetus on a regular basis.

The Maestro System has not been tested with fetal monitoring systems and may interfere with their operation.

6.5 Theft Detectors and Security Gates
Recharging the neuroregulator disc close to a theft detector or security gate should be avoided. The neuroregulator disc may set off theft detectors.

Walk through security arches or gates found in department stores, libraries, government buildings, airports, etc. at your normal pace. Do not stand near them for long periods of time.

When at the airport and security personnel are available, avoid walking through security gates. Instead show the Patient Identification Card and ask for a pat down. Some airports use security wands. Ask security personnel to avoid passing the wand directly over your neuroregulator disc since this may stop therapy. For more information, contact your local airport security office or TSA (Transport Safety Administration).
6.6 Electromagnetic Interference

Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments. Strong electromagnetic forces and permanent magnets can stop your device from working (see section 3.2.4 “EMI, RFID, Security and Theft Management Systems”).

6.6.1 Hospital or Medical Environments

You should always inform medical staff that you have an implanted Maestro System (and show your Patient Identification Card) before any procedure is performed. Most diagnostic procedures, such as x-rays and ultrasounds, may be performed safely. Other stronger diagnostic and therapeutic equipment may interfere with the Maestro System. Refer to Section 3 “Warnings and Precautions.”

6.6.2 Home, Work or Public Environments

You should **AVOID** or use caution when in the presence of the following:

- Radiofrequency identification (RFID) sources
- Power lines and transmission towers
- Electric Substations, power generators and large transformers
- Portable and mobile RF communications equipment
- Electric arc welding equipment
- Electric steel furnaces
- Electric induction heaters
- Electric fences
- Jackhammers
- Stun guns

For more information about devices that generate EMI contact your doctor or EnteroMedics at 1-800-MY-VBLOC (1-800-698-2562). If you suspect EMI is impacting the performance of your Maestro System, move away from the source of the EMI.

6.7 Magnetic Resonance Imaging (MRI)

An MRI is performed using powerful magnets and radio frequency energy. The Maestro System is not compatible with MRI equipment. The procedure may result in nerve damage, burns, heating or pain. Before you undergo an MRI procedure, you **must** contact your nurse or doctor and inform them of the planned procedure. If the procedure is necessary, tell the radiologist, MRI nurse or technician that you have a medical device that is **MR unsafe**.
You should register your Maestro System with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization. This will ensure doctors and nurses get up-to-date medical information on your medical device.

6.8 Technical Service Information

The Maestro System should not be repaired by untrained people. Do not open any system part since it may cause damage to the device.

If parts of the device are damaged, contact your doctor or nurse during regular business hours to schedule an office visit or call 1800 MY-VBLOC (1-800-698-2562) for technical support.
7. **What to Expect with the Maestro System**

7.1 **The Implant Procedure**

You will need to have the Maestro System implanted at a hospital. The implant procedure can be done as a “same day” surgery. Please speak with your doctor and nurse to determine how long you might stay in the hospital.

Prior to the implant you may have some tests that could include:

- Measure your pulse, body temperature, and blood pressure
- Review of your current medicines
- Your weight
- Other tests such as blood work or an electrocardiogram

You will not be awake during the surgery. Your doctor will implant the Maestro System laparoscopically.

Laparoscopic surgery is done by using up to 5 small incisions in the abdomen and then operating through small tubes placed through these incisions. During this surgery, your doctor will place one lead (wire) next to each of the two main parts of the nerve just above your stomach.

Your doctor will then place a neuroregulator disc under your skin. The best location for this disc will be determined by you and your surgeon prior to surgery. Your doctor will test the device and start the therapy during the surgery. Your doctor will make sure the device is working before you leave the operating room.

Your doctor or nurse will teach you how to use the Maestro System.

7.2 **Risks and Benefits**

There are risks and benefits with all medical procedures. Talk to your doctor about the risks and benefits of the Maestro System to see if it is right for you. Your doctor can answer questions about the information in this manual.

7.2.1 **Risks of Abdominal Surgery and Treatment with the Maestro System**

There may be risks when using the Maestro System. They may include complications from the surgery, and also risks due to the use of the Maestro System.

The following risks may occur as a result of your surgery and the implantation of the Maestro System. They may also occur if you need to have the device removed after placement. Discuss these risks with your doctor.
## Possible Risks of Surgery

<table>
<thead>
<tr>
<th>Event</th>
<th>Likelihood of Event Happening to Patient*</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at the disc site</td>
<td>19 of 100 procedures</td>
<td>Pain where the disc is placed</td>
</tr>
<tr>
<td>Wound redness or irritation</td>
<td>5 of 100 procedures</td>
<td>Incision site becomes red or irritated</td>
</tr>
<tr>
<td>Nausea</td>
<td>4 of 100 procedures</td>
<td>Upset stomach with or without vomiting (throwing up)</td>
</tr>
<tr>
<td>Swallowing difficulty</td>
<td>3 of 100 procedures</td>
<td>Food getting stuck, temporarily hard to swallow</td>
</tr>
<tr>
<td>Dehiscence (opening of incision site)</td>
<td>2 of 100 procedures</td>
<td>Incision site opens and needs to be resutured</td>
</tr>
<tr>
<td>Incision pain</td>
<td>75 of 1000 procedures</td>
<td>Discomfort at the site of the incisions</td>
</tr>
<tr>
<td>Left shoulder or throat pain</td>
<td>54 of 1000 procedures</td>
<td>Discomfort in the upper arm or throat</td>
</tr>
<tr>
<td>Constipation</td>
<td>25 of 1000 procedures</td>
<td>Unable to have a normal bowel movement</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>25 of 1000 procedures</td>
<td>Pain or discomfort in the stomach or abdominal organs</td>
</tr>
<tr>
<td>Vomiting</td>
<td>13 of 1000 procedures</td>
<td>Vomiting (throwing up) may sometimes be severe and on rare occasion can cause the stomach to go up into the chest</td>
</tr>
<tr>
<td>Infection next to implanted disc or leads</td>
<td>13 of 1000 procedures</td>
<td>Location where implanted disc is placed becomes infected with pus and drainage</td>
</tr>
<tr>
<td>Infection of trocar site</td>
<td>13 of 1000 procedures</td>
<td>Location where trocar is placed becomes infected with pus and drainage</td>
</tr>
<tr>
<td>Bleeding at surgical site</td>
<td>8 of 1000 procedures</td>
<td>Bleeding from the sites where the surgery was performed</td>
</tr>
<tr>
<td>Breathing complications</td>
<td>8 of 1000 procedures</td>
<td>Hard time breathing</td>
</tr>
<tr>
<td>Abdominal bloating or difficulty passing gas</td>
<td>8 of 1000 procedures</td>
<td>Stomach feels full of gas</td>
</tr>
<tr>
<td>Ileus</td>
<td>4 of 1000 procedures</td>
<td>The small bowel (intestine) temporarily slows down or stops</td>
</tr>
<tr>
<td>Injury to internal organs</td>
<td>12 of 10,000 procedures^</td>
<td>Injury to the stomach, liver, intestine or other internal organs due to surgery</td>
</tr>
</tbody>
</table>

*From the ReCharge Study through the first year after implantation unless noted

^From the ReCharge study through the first year and one half after implantation
Rarely, a small hole could be made in the esophagus or stomach which would need to be repaired. It would be expected that any problems due to a hole occurring would be temporary. There have been no deaths caused by the Maestro System in the ReCharge Study. Death is a rare possibility with laparoscopic surgery. It has been reported in 2 out of 1000 patients after laparoscopic surgery for a gastric band for weight loss (Ren CJ, et al. Surgical Endoscopy 2004; 18: 543-546). Pulmonary embolism (blood clot in the lungs) also did not occur in the ReCharge Study. It has been reported after laparoscopic surgery at a rate of 9 out of 1000 patients (Gargiulo NJ, et al; Annals of Vascular Surgery. 2007 21:556-9).

As described above, risks may happen after surgery, from using the device or from weight loss. Those risks are described below.

**Risks that may occur following your surgery, as a result of weight loss or from using the device**

<table>
<thead>
<tr>
<th>Event</th>
<th>Likelihood of Event Happening to Patient*</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>21 of 100 procedures</td>
<td>Pain or discomfort in the stomach or abdominal organs</td>
</tr>
<tr>
<td>Belching</td>
<td>5 in 100 procedures</td>
<td>Burping</td>
</tr>
<tr>
<td>Device stops working</td>
<td>2 of 100 patients who had the Maestro System implanted</td>
<td>Disc stops working and need another surgery to place a new disc.</td>
</tr>
<tr>
<td>Pain at the disc site</td>
<td>238 of 1000 procedures</td>
<td>Pain and discomfort when lying on top of disc or when the disc is bumped. In some cases pain at the disc site or movement of disc from the original position may require that the disc be moved to another location under the skin or be re-sutured in the original position which requires another surgery.</td>
</tr>
<tr>
<td>Heartburn</td>
<td>163 of 1000 procedures</td>
<td>Pain or discomfort in the throat</td>
</tr>
<tr>
<td>Chest pain</td>
<td>42 of 1000 procedures</td>
<td>Pain or discomfort in the chest</td>
</tr>
<tr>
<td>Swallowing difficulty</td>
<td>33 of 1000 procedures</td>
<td>Difficulty in passing food through the esophagus and into the stomach.</td>
</tr>
<tr>
<td>Constipation</td>
<td>29 in 1000 procedures</td>
<td>Cannot have a normal bowel movement</td>
</tr>
<tr>
<td>Appetite increases</td>
<td>29 in 1000 procedures</td>
<td>Feel more hungry</td>
</tr>
<tr>
<td>Condition</td>
<td>Incidence</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>--------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Headache</td>
<td>21 in 1000 procedures</td>
<td>Head hurts</td>
</tr>
<tr>
<td>Bloating</td>
<td>17 in 1000 procedures</td>
<td>Stomach feels full of gas</td>
</tr>
<tr>
<td>Vomiting</td>
<td>17 in 1000 procedures</td>
<td>Threw up food or drink</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>13 in 1000 procedures</td>
<td>Runny stools</td>
</tr>
<tr>
<td>Nausea</td>
<td>13 in 1000 procedures</td>
<td>Feel like throwing up</td>
</tr>
<tr>
<td>Dizzy/lightheadedness</td>
<td>13 in 1000 procedures</td>
<td>Loss of balance, or feeling faint</td>
</tr>
<tr>
<td>Vitamin or mineral deficiency</td>
<td>8 in 1000 procedures</td>
<td>Blood tests show that vitamin or mineral levels are low</td>
</tr>
<tr>
<td>Erosion or wire breakage</td>
<td>4 of 1000 procedures through 18 months</td>
<td>The wire breaks requiring another surgery to place a new wire.</td>
</tr>
<tr>
<td>Potential allergic reaction with implanted or skin contact materials</td>
<td>4 of 1000 procedures</td>
<td>Redness formed on the skin where the coil was placed, and/or swelling</td>
</tr>
<tr>
<td>Therapy delivery stopped when passing through theft detector gates</td>
<td>4 of 1000 patients who had the Maestro System implanted</td>
<td>Therapy is not delivered for a short period of time but starts up right away</td>
</tr>
<tr>
<td>Seroma</td>
<td>4 in 1000 procedures</td>
<td>Swelling under skin due to tissue fluid pooling where surgery was performed</td>
</tr>
<tr>
<td>Flatulence</td>
<td>4 in 1000 procedures</td>
<td>Passing gas</td>
</tr>
<tr>
<td>Depression</td>
<td>4 in 1000 procedures</td>
<td>Feel sadder than usual</td>
</tr>
<tr>
<td>If diabetic, may experience hypoglycemia</td>
<td>4 in 1000 procedures</td>
<td>Low blood sugar</td>
</tr>
<tr>
<td>Formation of gallstones requiring removal of gallbladder</td>
<td>4 in 1000 procedures</td>
<td>Stones are made in your gallbladder that cause pain and need to be removed</td>
</tr>
</tbody>
</table>

*Data from the ReCharge Study through the first year after implantation*

Serious adverse events that were related to abdominal surgery or treatment with the Maestro System from the ReCharge Study were neuroregulator disc not working properly, gallbladder disease, nausea, vomiting, bleeding duration operation, ileus, atelectasis and pain at the disc site.

### 7.2.2 Benefits of the Maestro System

The Maestro System was shown to help patients lose weight. Most patients (52.5%) who received VBLOC therapy in the ReCharge Study lost at least 20% of their excess weight in comparison to approximately one third of the sham control patients (32.5%). For example, if a patient was 100 pounds overweight, they lost 20 pounds over one year. Patients also had smaller waists one year after implantation compared to the start of the study.
8. **Clinical Studies of the Maestro System.**

A clinical study of the Maestro System was done with 239 patients who are being followed for 5 years after getting the device. Two out of three patients were in the treatment group. This group got the Maestro System device and VBLOC Therapy. One out of three was in the control group which got a sham device that did not deliver VBLOC therapy (placebo). All patients participated in a weight management program that discussed a healthy diet, exercise, and behavior changes. Patients did not know if they got the Maestro device or the control device until after the 12-month follow-up visit.

**Adverse Events**

The ReCharge Study examined the safety risks of the Maestro System from implant through the first year. The study looked at the number of patients in the treatment group who had a serious complication due to using the device or implanting the device. At 12 months, 6 of 162 treatment patients (3.7%) had a serious complication. This rate was better than expected in the study. The complications were two cases of device not working correctly, one case of pain at the site of neuroregulator disc, one case of gallbladder disease, one case of severe vomiting and one case of lung collapse due to surgery.

There were other serious complications associated with or identified during the surgery itself. These included 6 cases of nausea after surgery, cirrhosis (liver disease, identified during the surgery, in a patient who was not implanted with the device), the small intestine temporarily not working (ileus) and bleeding from a body part that was operated on. One other serious complication occurred later in the study when a small hole was made in the stomach while removing the device.

More common complications that were not serious were pain at the neuroregulator disc site, other kinds of pain, heartburn, abdominal (stomach) pain, nausea, difficulty swallowing, pain where the doctor made the cuts in the skin to place the device and burping (see table in **Risks and Benefits** section). Most complications got better over time and did not require any more surgery. Some patients had their VBLOC therapy parameters adjusted to help with discomfort like heartburn and abdominal pain. These changes often helped these symptoms.

**Reoperation and Device Removal**

There were 9 reoperations due to a complication or the device not working correctly among 8 patients through the first year after implant. An additional 3 of these surgeries occurred between one and one and 1/2 years after implant.

There were 5 VBLOC-treated patients who had their device explanted in the first year. Two explants were for subject decision, one for pain at the neuroregulator disc site, one for pain with therapy, and one for heartburn. An additional 16 patients had their device removed between one and one and 1/2 years after implant. Twelve explants were for subject decision, one for pain in arm not related to the device, one for pain at the neuroregulator disc site, and two for abdominal pain.

**Weight Loss through 12 Months**
Patients who received VBLOC therapy with the Maestro device lost more weight than patients in the control group. Patients who received VBLOC therapy lost an average of 24 pounds in the first year after implant compared to 16 pounds in the control group. At 12 months, patients in the Maestro device group had an average of 9.7% total body weight loss (%TBL), compared to 6.4% TBL for the control group.

The table below shows the percent excess weight loss (%EWL), %TBL and actual weight loss for patients in the Maestro device and control group through the first 12 months of the study.

**Percent Excess Weight Loss (%EWL), Total Body Loss (%TBL) and Actual Weight Change in the ReCharge Study through the first 12 months**

<table>
<thead>
<tr>
<th></th>
<th>VBLOC Mean (SE) [95% CI]</th>
<th>Sham Control Mean (SE) [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excess Weight Loss (%)</td>
<td>25.75 (1.32) [23.16, 28.35]</td>
<td>16.85 (1.94) [13.05, 20.65]</td>
</tr>
<tr>
<td>Total Body Loss (%)</td>
<td>9.68 (0.50) [8.71, 10.65]</td>
<td>6.36 (0.73) [4.94, 7.79]</td>
</tr>
</tbody>
</table>

**Other Improvements**

Patients in both treatment and sham control groups in the study showed improvements in risk factors related to their obesity, including cholesterol levels, blood pressure, glucose levels and waist size (see "Changes in Obesity Risk Factors” table). Both groups also improved their ability to have better control of their hunger and showed increased feelings of well-being.

**Changes in Obesity Risk Factors**

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>VBLOC</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screening Mean (SD)</td>
<td>Mean Change from Screening (SD)</td>
</tr>
<tr>
<td>Cholesterols and Blood Sugars</td>
<td>Total Cholesterol (mg/dL)</td>
<td>204.2 (36.0)</td>
</tr>
<tr>
<td></td>
<td>LDL Cholesterol (mg/dL)</td>
<td>121.9 (31.1)</td>
</tr>
<tr>
<td></td>
<td>HDL Cholesterol (mg/dL)</td>
<td>54.3 (14.2)</td>
</tr>
<tr>
<td></td>
<td>Triglycerides (mg/dL)</td>
<td>141 (61)</td>
</tr>
<tr>
<td></td>
<td>Fasting Plasma Glucose (mg/dL)</td>
<td>96.6 (16.8)</td>
</tr>
<tr>
<td></td>
<td>HbA1c (%)</td>
<td>5.66 (0.63)</td>
</tr>
</tbody>
</table>
## Risk Factor

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>VBLOC</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screening Mean (SD)</td>
<td>Mean Change from Screening (SD)</td>
</tr>
<tr>
<td>Heart</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic Blood Pressure (mmHg)</td>
<td>127.4 (12.4)</td>
<td>-5.5 (14.2)</td>
</tr>
<tr>
<td>Diastolic Blood Pressure (mmHg)</td>
<td>80.7 (9.0)</td>
<td>-2.8 (9.6)</td>
</tr>
<tr>
<td>Heart Rate (bpm)</td>
<td>76.2 (9.6)</td>
<td>-3.6 (10.3)</td>
</tr>
<tr>
<td>Waist Size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>121 (12)</td>
<td>-10 (10)</td>
</tr>
</tbody>
</table>
Weight Loss through 18 Months

The graph below shows the difference between the Maestro device and control group in percent excess weight loss (%EWL) and %TBL over the first 18 months of the study. Patients in the control group lost weight at first but began to regain the weight they lost after the first 12 months of the study.

Average Percent of Excess Weight Loss (%EWL) and Total Body Loss (%TBL) in the ReCharge Study through 18 months
9. **Turning off your Neuroregulator disc**

If you are in a situation where you need to turn your neuroregulator disc off and stop therapy (e.g., environments with strong magnetic fields or due to discomfort), you can do so by:

1. Connect the transmit coil to the mobile charger and position it over the neuroregulator disc.
2. With the transmit coil positioned over the neuroregulator disc, press and hold the MC button on the mobile charger for approximately 60 seconds.
3. The MC status indicator will turn red and start to flash.

![MC Status Indicator Flashing Red](image)

If a mobile charger is not available, slowly pass a medical device magnet over the neuroregulator disc. Medical device magnets are commonly found in hospital emergency rooms.

After an emergency shutdown, contact your doctor or nurse during normal business hours to schedule an appointment to restart your therapy and neuroregulator disc.
# 10. Troubleshooting

<table>
<thead>
<tr>
<th>Issue</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>MC Status Indicator is a solid red when checking the neuroregulator disc</td>
<td>Contact your doctor to schedule a visit to check your neuroregulator disc.</td>
</tr>
<tr>
<td>MC Status Indicator is flashing red when checking the neuroregulator disc</td>
<td>Contact your doctor to schedule a visit to check your neuroregulator disc.</td>
</tr>
<tr>
<td>Transmit Coil indicator stays on, or constantly flashes</td>
<td>Try repositioning your coil as described in Section 5. If the problem persists contact your doctor to see if you need to replace your patient coil.</td>
</tr>
<tr>
<td>MC feels hot when charging the neuroregulator disc</td>
<td>Some temperature increase is normal. Make sure the MC is well ventilated. Do not place it in your pocket or other confined space. If it becomes too hot, stop using it and allow it to cool before charging again.</td>
</tr>
<tr>
<td>MC will not start a charging session with the neuroregulator disc</td>
<td>Check to see if the neuroregulator battery indicator shows 5 bars. If 5 bars are shown, the battery is full and does not need a charge. Also check the MC battery, it may need to be recharged before charging the neuroregulator disc</td>
</tr>
<tr>
<td>MC Screen is Blank</td>
<td>Connect MC to AC recharger and press the MC button once. If it remains blank for over 30 seconds quickly disconnect and reconnect the AC recharger power cord. Refer to Section 5 on charging the MC for more details.</td>
</tr>
<tr>
<td>MC low battery indicator flashes while charging the neuroregulator disc</td>
<td>Continue your implant charging session until the MC screen is blank. The MC will continue to provide a charge to the implant when the low MC battery indicator is flashing. Refer to Section 5 for more details.</td>
</tr>
<tr>
<td>Neuroregulator battery indicator does not reach full 5 bars</td>
<td>Charge your implant more frequently. Long continuous charging sessions are best. If the implant battery is too low you may need to charge twice in one day. Also ensure your coil position is optimal for charging. Refer to Section 5 for more details.</td>
</tr>
<tr>
<td>Any other issue</td>
<td>Contact your doctor.</td>
</tr>
</tbody>
</table>
11. Your Patient Identification Card

A patient identification card states you have been implanted with the Maestro System medical device. This card also provides basic information about your system and lists your doctor’s name and telephone number.

This is helpful when you need to bypass a security system, or during a medical emergency. Keep this card with you at all times. You will receive a temporary card at the time of surgery and a laminated card in the mail or at your first follow up visit.
12. Contact Information

Doctor Contact Information:

Doctor name: ______________________
Phone number: _________________

EnteroMedics Contact Information:

Technical Support: Phone: 1800-MY-VBLOC (1-800-698-2562)

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