

CardioMEMS™ HF System
Patient System Guide



- Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

- **Indications**

The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

- **Contraindications**

The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

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Introduction

You have been diagnosed with heart failure. Heart failure results from damage to the heart that makes it difficult for the heart to pump enough blood to your body. Heart failure is a progressive disease that often gets worse over time. The most common causes of heart failure are high blood pressure and coronary artery disease, in which blood vessels that supply blood to the heart are narrowed or blocked. Approximately 5 million people in the United States suffer from heart failure. It is one of the most common reasons for hospitalizations in people over 70 years of age.

When is the CardioMEMS HF System used?

Your doctor has determined that you might benefit from the information obtained by the CardioMEMS HF System because you have heart failure and are at an increased risk of hospitalization.

What is the purpose of the CardioMEMS HF System?

A sensor monitors the pressure in your pulmonary artery. You take a reading daily from home using the Patient Electronics System, which sends the information to your doctor. After analyzing the information, your doctor may make medication changes to help treat your heart failure.

This guide will tell you how the system operates. It will discuss what to expect during and after the implant of the device. It, along with the CardioMEMS HF System Patient Instructions, will explain how to set-up the Patient Electronics System in your home and how to take a daily measurement. It will talk about some of the changes that may occur in your life and answer many of the more common patient questions. If you have questions about what you read in this guide, discuss them with your doctor or nurse. They are your best resources for information.

The CardioMEMS HF System includes the following components:

Figure 1. Pulmonary Artery (PA) Sensor (Sensor)



Figure 2. Patient Electronics System (consisting of the electronics unit, antenna and pillow)



Patient Electronics System

The Patient Electronics System consists of the electronics unit, antenna and pillow. Together, the components of the Electronics System read your pulmonary artery (PA) pressure measurements from your sensor wirelessly and then transmit the information to your physician. The antenna is paddle-shaped (as shown below) and is pre-assembled inside a pillow to make it easier and more comfortable for you to take readings.

Figure 3. The Electronics Unit



Figure 4. Antenna for the Patient Electronics System (preassembled inside the pillow)



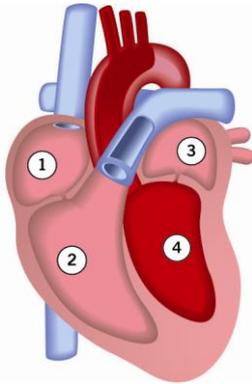
Figure 5. Antenna in the pillow



How your Heart Works

Your heart is a muscle that pumps blood throughout your body. It has four chambers. The upper chambers are called atria (left and right) and the lower chambers are called ventricles (left and right). The right side of the heart receives "used" blood coming back from the body and pumps the blood to the lungs, where it picks up oxygen. Blood then returns to the left side of the heart, which in turn pumps the blood to the rest of the body.

Figure 6. Normal Heart



1. Right atrium
 2. Right ventricle
 3. Left atrium
 4. Left ventricle
-

Heart Failure

Heart failure is a serious illness. It means that your heart cannot squeeze hard enough to move enough blood out to your body, or that your heart muscle is too thick and does not relax enough between beats to allow it to fill with blood. Heart failure can make you feel tired or weak and can also cause swelling and fluid buildup in your legs, feet, stomach, and even your lungs. Fluid buildup in your lungs is often referred to as "congestion", which is why heart failure is sometimes called "congestive heart failure".

Causes of Heart Failure

Anything that weakens the heart muscle so it does not pump blood normally can cause heart failure. Some of the common causes of heart failure include:

Coronary Artery Disease

Blocked arteries can trigger heart attacks that cause heart muscle cells to die. The muscle is weakened and pumps less efficiently.

Untreated High Blood Pressure

High blood pressure forces the heart to pump harder to move blood through the body. That can cause the heart to weaken over time.

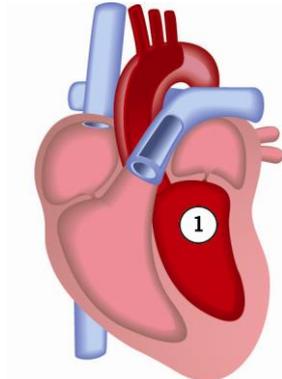
Faulty Heart Valves

Heart valves that do not work properly (either because they are leaky or because they do not open wide enough) can cause the heart muscle to weaken.

Cardiomyopathy (Heart Muscle Disease)

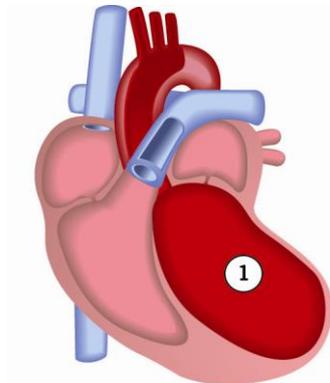
The heart muscle becomes enlarged or weakened for unknown reasons. Over time, the heart muscle weakens and the heart becomes enlarged, as shown below. The ventricles are unable to contract with the same strength as before. As a result, the flow of blood and oxygen to the body is poor.

Figure 7. Normal Heart



1. Left ventricle
-

Figure 8. Enlarged Heart



1. Left ventricle
-

Symptoms of Heart Failure

It is important to tend to your symptoms as soon as they begin. Like many people, you may fail to notice symptoms in their early stages, or you may shrug them off. Ignoring symptoms is risky. Symptoms such as trouble breathing or swollen ankles can mean that your heart failure is getting worse. Worsening symptoms can quickly lead to urgent problems that require a hospital stay. Some of the most common symptoms that patients with heart failure experience include:

Fatigue, loss of energy

You may find that you get very tired from very little effort, like walking up the stairs or doing your daily chores.

Shortness of breath

Shortness of breath is often described as "not getting enough air." You may become more short of breath with exertion. You may awaken abruptly at night with a sensation of shortness of breath or feel the need to sit up to sleep. You may also experience a frequent, dry cough that is often made worse when you lie down in bed.

Weight gain

Weight gain over several days in a row is a common sign that there is fluid buildup in the body. You may experience a weight gain of 3 pounds or more before you notice any swelling or shortness of breath.

Swelling

You may notice swelling of your feet, legs or abdomen. This is usually worse later in the day and in the lowest part of your body. Swelling occurs because the extra fluid seeps into the tissues from the small blood vessels. You may notice that your shoes, socks or pants are fitting more tightly at the end of the day.

Loss of Appetite or Bloating Sensation

Many people with heart failure notice retention of fluid in the abdomen. When this happens, you may experience a distended or bloated sensation. You may also experience loss of appetite or even an upset stomach. Medicines may not be absorbed as well and therefore will not work as effectively.

Decreased Urination during the Day, Increased Urination at Night

The heart works harder during the day than at night, when you are at rest. This leads to less urine production during the day. When you are sleeping, the work of the heart is lessened, which allows the kidneys to make more urine.

The pressure in the vessels around your heart changes before you feel any of these symptoms. Such changes can be detected by the CardioMEMS HF System sensor. Your doctor may change some of your medications based on the information obtained from the sensor. It is important to follow all directions your physician gives you, even if you are not feeling bad.

Managing Your Heart Failure

Good management of your heart failure will lessen the impact of the symptoms on your daily life. Your doctor will determine and discuss the best treatment options with you. Making changes in your food selections and daily activities, taking pressure readings, and taking the medications that your doctor prescribes can make a major difference in how you feel.

Medications

Medicines are important in the treatment of heart failure. Many research studies have shown that heart failure medicines can help stabilize your heart function and can help you:

- Live longer
- Have fewer symptoms
- Increase activity level
- Have more energy
- Have less swelling
- Breathe more easily
- Stay out of the hospital

The major classes of medications used in the treatment of heart failure are:

Angiotensin-Converting Enzyme Inhibitors (ACE Inhibitors)

ACE inhibitors are very beneficial for people with heart failure. Research studies have shown that ACE Inhibitors help people live longer and decrease hospitalizations. They block the effects of harmful stress hormones (substances produced by your body that make heart failure worse). They help to relax blood vessels and lower blood pressure, which make it easier for the heart to pump blood out to the body.

Angiotensin-Receptor Blockers (ARB)

ARBs are similar to the ACE Inhibitors and are most commonly used when patients cannot take ACE inhibitors because of the side effects. Research studies have shown that ARB's also help people live longer

Beta Blockers

Beta-blockers reduce the damaging effects of the hormone adrenalin on the heart and help you live longer. They also lower blood pressure and heart rate.

Diuretics ("water pill")

Diuretics help your body get rid of extra fluid. Less fluid in your lungs makes breathing easier. Less fluid also means less swelling in other parts of your body. Having less fluid in your body will help you feel more comfortable.

Aldosterone Antagonist

Aldosterone antagonists block the effects of a stress hormone called aldosterone, which can make heart failure worse. Research has shown that aldosterone antagonists help people live longer.

Vasodilator and Nitrate Combination

Vasodilators relax the arteries, which reduces the heart's workload. Nitrates reduce the amount of oxygen the heart needs and improves blood flow to the heart. Research has shown that these medicines also help people live longer.

Daily Pulmonary Artery Pressure Reading

The pressures in the vessels around your heart change before you notice any weight gain or swelling. Taking daily pressure readings with the Patient Electronics System

allows your doctor to treat you before these symptoms occur and to manage your heart failure more effectively.

Daily Weights

Your doctor may have instructed you to weigh yourself every morning using the same scale. Weighing yourself every day will help you notice any extra fluid buildup. If you ignore the weight gain, the fluid will find its way to your lungs, abdomen, legs and feet. By the time you see swelling in your ankles, you may have already retained an extra five to seven pounds of fluid.

Low Sodium Diet

Table salt is composed of sodium and chlorine. It is important to decrease the amount of sodium you eat because heart failure causes your body to hold on to extra sodium. The sodium causes extra fluid to build up. That leads to symptoms such as swelling of the ankles, feet or abdomen, shortness of breath, or weight gain.

By reducing the amount of sodium in your diet, you will retain less fluid and reduce many of the symptoms of heart failure. You cannot eliminate sodium entirely because it is present in most foods, but any reduction in the amount of sodium you eat will have big benefits for you. It may take some time to adjust to a low-sodium diet, but it is worth the effort. A low-sodium diet can help you feel better and allow your heart failure medicines to work more efficiently.

Fluid Control

Many people with heart failure take diuretics to remove excess fluid. However, the action of these medications can be overwhelmed if you drink too much fluid. Patients with more advanced cases of heart failure are often advised to limit their total daily fluid intake to two quarts a day. The guidelines for sodium and fluid intake may vary depending on the severity of your heart failure and should be discussed with your physician.

Alcohol

Alcohol has a direct effect on the heart by decreasing the strength of the contraction. With a muscle that is already weak, as in heart failure, this is not a good idea. You should limit alcohol to one drink or less per day or avoid alcohol completely.

Tobacco Cessation

Tobacco products (not just cigarettes) contain nicotine. Nicotine causes blood vessels to become narrower. This raises the blood pressure and pulse rate, making more work for your weakened heart.

Activity and Exercise

Your heart is a muscle. It needs exercise, just like all the other muscles in your body. Activity can help you feel better, may decrease your symptoms, and may improve your heart's function. Ask your doctor or nurse about an exercise or walking program to help build your tolerance for activity.

Precautions

Failure to follow these precautions may result in system malfunction, damage to the system, or delay in information getting to your doctor.

- Do not place the electronics unit near an open window. Exposing the unit to rain, water, moisture or direct sunlight may severely damage it.
- Do not apply excessive pressure to the display screen. Excessive pressure may damage the display.
- Do not apply excessive or damaging force to any part of the electronics unit.
- Do not expose the electronics to excessive vibration, impact, or rough handling.
- To avoid potential damage caused by lightning, unplug the electronics unit during electrical storms.
- Allow the electronics unit to shut-down automatically. Failure to do so may corrupt the files.
- The model numbers for the Patient Electronics System are CM1000 (cellular or GSM) and CM1010 (Land line). All warning and precautions noted for the CM1000 also apply to the CM1010 model unless otherwise noted.
- The electronics unit should not be used adjacent to or stacked with other equipment. If it is necessary to operate it adjacent to or stacked with other equipment, verify that the electronics unit is operating normally in the configuration in which it will be used.
- Exposure to excess lint, dust, or corrosive materials may result in a malfunction.
- If your electronics unit uses a telephone line communication, be aware that other equipment may interrupt the communication. Contact Technical Support, if you have questions about such equipment.
- Your Patient Electronics System communicates securely through the internet to transmit your reading. Portions of this internet pathway may become unavailable for periods of time for a variety of reasons including but not limited to: internet connectivity outage, hardware failure, power outage, or general infrastructure failures. Readings that are unable to transmit are stored and will transmit when internet connectivity is available.

Warnings

Failure to follow these warnings may result in damage to the system, system malfunction, delay in information getting to your doctor, inaccurate readings, or injury.

- Only authorized personnel should use the Patient Electronics System.
- Do not remove the cover or attempt to service the electronics unit. Service should be performed by an authorized technician.
- If any of the following occurs, immediately unplug the electronics unit and call Technical Support:
 - Any cords are noticeably frayed or damaged.
 - Liquid has been spilled onto the electronics unit, or it has been exposed to rain.
 - The electronics unit has been dropped or damaged.
 - If you lose the power cord, you must replace it with an identical power cord. Contact Technical Support.
- Medical Electrical Equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service

according to the EMC information provided. If interference is noted, remove or stop using the interfering equipment.

- Portable and mobile RF communications equipment can affect medical electrical equipment and may cause a malfunction of the system.
- Use only cables and accessories provided. The use of other attachable parts other than the parts provided may result in inaccurate readings, damage to the electronics, or injury to the user.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Patient Electronics System as replacement parts for internal components, may result in increased emissions or decreased immunity.
- Other equipment may interfere with the electronics unit operation, even if the other equipment complies with CISPR emission requirements. See the Electromagnetic Interference and Electromagnetic Compatibility section for guidance.
- Two Patient Electronics Systems may interfere with each other. Only operate one electronics unit at a time in the same general vicinity.
- While in use, ensure that the power supply is easily accessible since unplugging the electronics unit from the outlets is the only means of completely isolating from mains.
- Do not attempt to connect the electronics unit to any network or data coupling equipment in your home other than specified in the instructions for use.
- If redness of the skin develops or a change in skin sensitivity occurs, discontinue use of this product immediately and contact your physician.
- Keep the Patient Electronics System away from pets and children. Ingestion of any part may cause injury.
- Care should be taken to keep all cables away from the neck and face to prevent airway blockage.
- Do not attempt to connect the electronics unit or antenna to any other electronic equipment.
- Your Patient Electronics System has been calibrated to work with your sensor. Use of different electronics unit may result in inaccurate information.
- Do not change the computer configuration without authorization. Changes to the configuration may result in inaccurate information.

Clinical Study Information

Introduction

Heart failure is a major public health problem in the United States affecting over 5 million people with over 1 million heart failure hospitalizations per year. Elevated pulmonary artery pressures may occur prior to signs and symptoms of heart failure decompensation and can provide a physiologic basis for heart failure patient management.

The CardioMEMS HF System provides a novel method for measuring pulmonary artery pressure using a wireless pressure sensor implanted into the pulmonary artery, an external communication device, and a patient database. The CardioMEMS HF System provides physicians with knowledge of pulmonary artery pressure while the patient is at home. This new and additional information allows the physician to manage the patient's heart failure proactively with the goal of reducing heart failure hospitalizations.

Purpose

The goal of the CHAMPION trial (CardioMEMS Heart Sensor Allows Monitoring of Pressures to Improve Outcomes in NYHA Functional Class III Heart Failure Patients) was to determine if physicians could reduce heart failure hospitalizations by managing patient pulmonary artery pressures using the CardioMEMS HF System.

Study Design

The CHAMPION trial was conducted at 64 study sites in the U.S. and enrolled 550 patients with New York Heart Association (NYHA) Class III heart failure who had been hospitalized for heart failure in the previous year. All patients were implanted with a sensor and then randomized (assigned by chance) to either the Treatment group (heart failure management on the basis of pulmonary artery pressure and standard of care) or the Control group (heart failure management on the basis of standard of care).

Results

CHAMPION met its two primary safety endpoints with 1.4% of patients experiencing a device-related complication and no patients experiencing a sensor failure.

The CHAMPION trial was not designed to assess the benefit of this treatment strategy by gender. Since most of the patients who participated in the trial were men, it was not possible to determine the effect of the device in women.

The CHAMPION trial met its primary efficacy endpoint of reduction in the rate of heart failure hospitalizations with Treatment group patients having 28% fewer heart failure hospitalizations compared to Control group patients at 6 months. Men and women in the Treatment group had similar heart failure hospitalization rates. The CHAMPION trial also met its secondary efficacy endpoints with Treatment group patients having lower pulmonary artery pressures, fewer days in the hospital, and better quality of life compared to Control group patients.

Over the entire randomized follow-up in the trial of 1½ years, Treatment group patients had 33% fewer heart failure hospitalizations compared to Control group patients. For every 100 patients treated, 23 heart failure hospitalizations were prevented per year.

After the completion of the randomized portion of the trial, physicians managed all patients (former Treatment and Control groups) on the basis of pulmonary artery pressure and standard of care. When both groups were managed in the same fashion, their heart failure hospitalization rates were similar.

Potential Risks within 30 days of the Implant Procedure

The following table is a summary of the minor and major clinical risks observed within 30 days of the implant procedure.

Risk	Treatment Group	Control Group (Standard Therapy)
Death	0 out of 100 patients	1 out of 100 patients
Stroke	0 out of 100 patients	0 out of 100 patients
Myocardial Infarction (heart attack) or Chest Pain	2 out of 100 patients	3 out of 100 patients
Bleeding	3 out of 100 patients	3 out of 100 patients
Hematoma (bruising at catheterization site)	1 out of 100 patients	1 out of 100 patients
Thrombus (blood clot)	0 out of 100 patients	0 out of 100 patients
Arrhythmias (abnormal heart rhythm)	5 out of 100 patients	3 out of 100 patients
Kidney Dysfunction/Failure	2 out of 100 patients	2 out of 100 patients
Infection	5 out of 100 patients	4 out of 100 patients
Hypotension (low blood pressure)	3 out of 100 patients	2 out of 100 patients
Dehydration	0 out of 100 patients	0 out of 100 patients
Device Embolization (device movement)	0 out of 100 patients	0 out of 100 patients

Potential Risks within 6 months of the Implant Procedure

The following table is a summary of the major clinical risks observed within 6 months of the implant procedure.

Risk	Treatment Group	Control Group (Standard Therapy)
Death	5 out of 100 patients	7 out of 100 patients
Stroke	0 out of 100 patients	1 out of 100 patients
Myocardial Infarction (heart attack) or Chest Pain	5 out of 100 patients	6 out of 100 patients
Bleeding	1 out of 100 patients	1 out of 100 patients
Thrombosis (blood clot)	1 out of 100 patients	0 out of 100 patients
Ventricular Arrhythmia (abnormal rhythm of the lower chambers of the heart)	2 out of 100 patients	3 out of 100 patients
Kidney Dysfunction/Failure	5 out of 100 patients	3 out of 100 patients
Pulmonary Infections	3 out of 100 patients	4 out of 100 patients
Hypotension (low blood pressure)	3 out of 100 patients	3 out of 100 patients
Dehydration	1 out of 100 patients	0 out of 100 patients
Device Embolization (device movement)	0 out of 100 patients	0 out of 100 patients

Potential Risks within 1½ years of the Implant Procedure

The following table is a summary of the major clinical risks observed within 1½ years of the implant procedure.

Risk	Treatment Group	Control Group (Standard Therapy)
Death	18 out of 100 patients	22 out of 100 patients
Stroke	2 out of 100 patients	2 out of 100 patients
Myocardial Infarction (heart attack) or Chest Pain	14 out of 100 patients	11 out of 100 patients
Bleeding	2 out of 100 patients	3 out of 100 patients
Thrombosis (blood clot)	2 out of 100 patients	0 out of 100 patients
Ventricular Arrhythmia (abnormal rhythm of the lower chambers of the heart)	7 out of 100 patients	8 out of 100 patients
Kidney Dysfunction/Failure	10 out of 100 patients	6 out of 100 patients
Pulmonary Infections	5 out of 100 patients	9 out of 100 patients
Hypotension (low blood pressure)	5 out of 100 patients	5 out of 100 patients
Dehydration	2 out of 100 patients	1 out of 100 patients
Device Embolization (device movement)	0 out of 100 patients	0 out of 100 patients

Sensor Implantation

Before the Implant Procedure

The CardioMEMS HF System technology provides physicians with reliable, accurate trends of pulmonary artery pressure measurements. This technology proved to be extremely valuable in the management of care for heart failure patients.

The CardioMEMS HF System provides a method to measure pulmonary artery pressure by using a wireless sensor implanted into the pulmonary artery (a vessel close to your heart). Once inserted, the System can provide this valuable information to your doctor as often as desired. This can be performed in the physician's office, clinic, or hospital. You will also be able to take pulmonary artery pressure measurements yourself at home. These home pressure measurements are then sent to a secure website. Your doctor can access the secure website to view your measurements allowing him/her to make earlier interventions (usually changes in medications) to manage your heart failure remotely.

Prior to the implant procedure, your doctor will discuss with you the benefits and risk associated with receiving the CardioMEMS HF System. You will be given detailed instructions about the implant procedure and any questions you may have will be answered.

As with any medical procedure, there are risks associated with the implantation of a sensor, although complications do not happen very often. You should talk with your doctor about these risks before undergoing the medical procedure. Some of these risks include but are not limited to:

- Infection
 - Upper respiratory infection
 - Bronchitis
 - Pneumonia
 - Acute Bronchitis
 - Groin abscess
 - Methicilin-resistant staphylococcal aureus infection
 - Pulmonary Infiltration
 - Sepsis
- Arrhythmias
 - Ventricular tachycardia
 - Atrial fibrillation
 - Ventricular arrhythmia
 - Ventricular fibrillation
 - Atrial fibrillation with rapid ventricular response
 - Atrial flutter
 - Cardiac dysrhythmias
 - Tachycardia
 - Wide complex tachycardia
- Bleeding
 - Epistaxis
 - Hemoptysis
 - GI bleed
 - Bleeding

- Blood in stool
- Catheter site bleeding
- Catheter site ecchymosis
- Hematuria
- Nose bleeds
- Hematoma
 - Hematoma
 - Catheter site hematoma
 - Vessel puncture site hematoma
- Thrombus
 - Arterial thrombosis (limbs)
 - Blood clot
- Myocardial infarction
- Transient ischemic attack
- Stroke
- Death
- Device embolization

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this system.

Implant Procedure

PA Sensor

The PA Sensor is permanently placed in the pulmonary artery (the blood vessel that moves blood from your heart to your lungs) during a right heart catheterization procedure.

The PA Sensor is about the size of small paper clip and has a thin, curved wire at each end. This sensor does not require any batteries or wires. It sends its pressure measurements to the Patient Electronics System.

Figure 9. PA Sensor



Implant Procedure

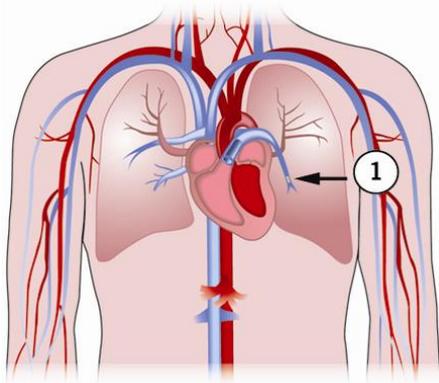
The steps of the implant procedure are:

1. You may receive a mild sedative before and/or during the procedure, but you will be awake so you can follow instructions.
2. A nurse will clean an area on your groin and a local anesthetic (numbing) medicine will be injected at that site.
3. An electrocardiogram (EKG) will constantly monitor your heart rate and rhythm.
4. The doctor will make a small incision in your groin.

5. He or she will thread a device called a pulmonary artery catheter into your femoral vein. Using a fluoroscope (a type of x-ray), he or she will thread the PA catheter through your body to your heart and into your pulmonary artery.
6. Once the catheter is in the pulmonary artery, a small amount of contrast material (dye) is injected and pictures are taken to make sure the catheter is in the right position and to make sure the branch of the pulmonary artery is the appropriate size. This procedure is called angiography.
7. Next, the pulmonary artery catheter is removed and a delivery catheter with the PA Sensor attached is carefully threaded to your pulmonary artery over a guide wire (a very small wire used to guide catheters). The PA Sensor is then positioned in the pulmonary artery and released from the delivery catheter.
8. The delivery catheter will be removed and the pulmonary artery catheter positioned next to the Sensor. Once the PA Sensor is confirmed by x-ray to be in the correct position, it will stay inside the pulmonary artery permanently.
9. The doctor will hold a monitor (called an antenna) to your back, chest or side to obtain the Sensor's signal. Pulmonary artery pressure readings will be recorded from both the Sensor and the pulmonary artery catheter.
10. The heart catheter is removed and the Sensor will remain in your pulmonary artery (Figure 10).

Typically, the procedure may last up to one hour. If the doctor cannot safely pass the catheter into the pulmonary artery or if the pulmonary artery is not the appropriate size, you will not be able to receive the sensor.

Figure 10. Location of the Sensor Implant



1. Implant location in Pulmonary Artery
-

After the Implant Procedure

After the procedure is completed, you may be asked to lie flat on your back for a few hours to prevent any bleeding from the catheter insertion site. You may feel some discomfort at the site as you recover. You should be able to return to normal activities soon after the procedure.

Your PA Sensor is permanently implanted. You will not feel it, and it will not interfere with your daily activities. The sensor will not interfere with other devices you may have such as a pacemaker, defibrillator, etc.

As you recover from your implant procedure, it is important that you follow your doctor's instructions, including:

- Report any redness, swelling, or drainage from the insertion site in your groin
- Walk, exercise, and bathe according to your doctor's instructions
- Contact your doctor if you develop a fever that does not go away in two or three days
- Ask your doctor any questions you may have about your device, heart failure, or medication

Before you go home, you will receive training about how to set-up and take readings with your Patient Electronics System. For your convenience, the steps for taking a reading are also provided in an easy to use patient instruction guide.

Your doctor or nurse will complete a temporary Patient Implant Identification Card before you go home from the hospital. A permanent card will be mailed to you within a few weeks. This card provides information about the sensor to health care professionals so that the sensor can be identified correctly if you need a chest x-ray, CT scan, MRI or other testing. It contains your name, your doctor's name, and the serial numbers of your device. Always carry your Patient Implant Identification Card with you. It will alert medical and security personnel that you have an implanted device.

Taking a Home Reading

You will take readings using the Patient Electronics System (electronics) as instructed by your physician. To experience the most benefit from the CardioMEMS HF System, it is important that you take readings daily or as instructed by your physician. Taking readings should become part of your daily routine. It should only take about 2-3 minutes. If you are having trouble taking a reading, contact Technical Support at 877-696-3754.

Important Safety Information

The electronics are not affected by interference produced by most common household electrical equipment. Electromagnetic interference from theft detection systems, airport security systems, etc., could make it difficult to take sensor measurements. However, it is highly unlikely that you would be taking measurements when you are close to these devices.

Electric Blankets, waterbeds, or metal in the vicinity of the antenna could cause interference. If so, move the electric blanket or metal out of the room. If you have a waterbed, take the measurement in another room.

Patient Electronics System

The Patient Electronics System reads the pressure measurement from your sensor wirelessly. The electronics unit has a touchscreen which can be used to set up the unit and change settings. You can connect the electronics to either a regular telephone line (Model #CM1010) or a wireless cellular (GSM, Model # CM1000) telephone system.

The Patient Electronics System consists of the Electronics Unit, the Antenna encased within the pillow.

Figure 11. The Electronics Unit



Antenna

The antenna is paddle-shaped (as shown below) and comes preassembled inside the pillow to make it easier and more comfortable for you to take readings.

Figure 12. Antenna for the Patient Electronics System



Figure 13. Antenna in the pillow



Setting Up the Patient Electronics

1. Place the pillow where you will lie down to take your reading. The thickest part of the pillow is under your head during the reading.

Figure 14. Pillow Placement



2. Place the electronics unit on a table 4-5 feet from the pillow.
3. Locate the connector at the end of the pillow cable. Line up the alignment mark on the connector with the alignment mark on the side of the electronics unit. Press the connector firmly into the electronics unit. Rotate the connector clockwise until it stops.

Figure 15. Pillow Cable



4. Plug the end of the power supply cable into the electronics unit. Line up the alignment mark on the plug with the alignment mark on the back of the electronics unit.

Figure 16. Power Cable



5. Plug the other end of the power supply cable into the wall electrical outlet. Make sure the power supply cable is inserted into the power supply box.
6. Locate the connector at the end of the remote button cable. Line up the alignment mark on the connector with the alignment mark on the side of the electronics unit. Press the connector firmly into the electronics unit.

Figure 17. Remote Button Cable



The following instructions are specific to the type of Patient Electronics System you have received.

7. If you have a wireless/cellular (GSM) version, screw the wireless antenna into the gold connector.

Figure 18. GSM Wireless Antenna



8. If you have a landline version, insert one end of the telephone cord into the back of the electronics unit. Insert the other end into a telephone jack in the wall.

Figure 19. Telephone Cord Connection



Steps for Taking a Reading

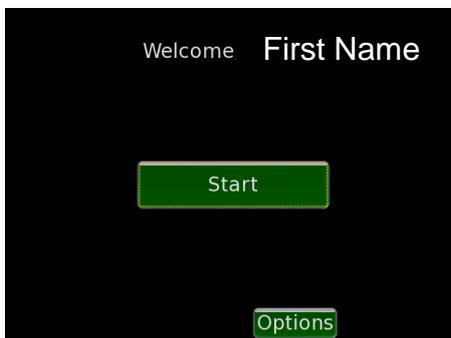
Step 1. Press the power switch on the back of the electronics unit to turn it on.

Figure 20. Back of electronics unit



Step 2. After turning on the electronics unit, the first screen you will see will have both a Start Button and an Options Button (Figure 21). Once you see this screen, you know that the system is ready to use.

Figure 21. Initial Startup Screen



- All screenshots are simulations and do not represent actual patients or actual patient data.

Step 3. The Start button may be used to take a reading, however the preferred method is to use the remote button described in step 3. The Options Button is used when you want to make changes in settings (for example when you want to make it louder) and is described in the Additional Features section of the manual.

Step 4. Lie down in a comfortable position on the pillow (Figure 22) and press the remote button (Figure 23).

Figure 22. Position on pillow



Figure 23. Remote button



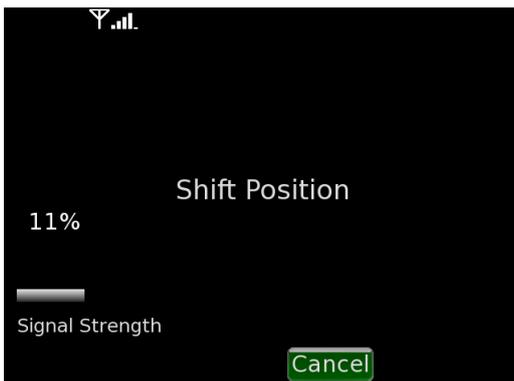
Step 5. Lie still on the pillow. The system will guide you with voice prompts. The screen in Figure 24 below appears while the system searches for a signal.

The Signal Strength bar indicates the robustness with which the electronics unit is measuring the sensor. The Signal Strength bar should be greater than 70% and a green color to take a reading.

If your body position is good you will hear, “Good position on pillow. Stay still”. If you hear, “Shift slightly on pillow”, change your body position.

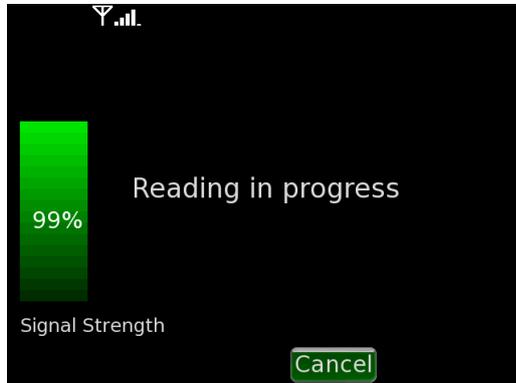
If you have difficulty obtaining a good position on the pillow, an orientation ball may help and is discussed further in the Orientation Ball section below. You may also refer to the troubleshooting section or contact technical support.

Figure 24. Acquiring Signal



Step 6. After the “Reading in progress” message appears, remain still for about 18 seconds (Figure 25). When the reading is finished, you will hear “Reading completed, you may get up”.

Figure 25. Reading in Progress

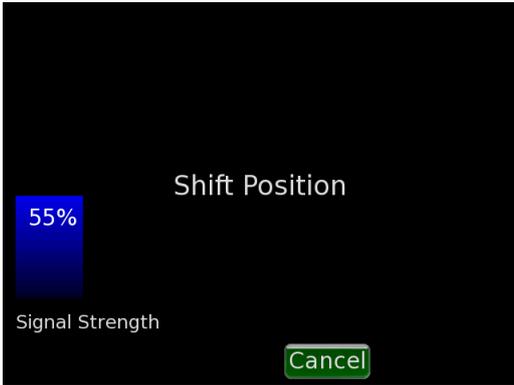
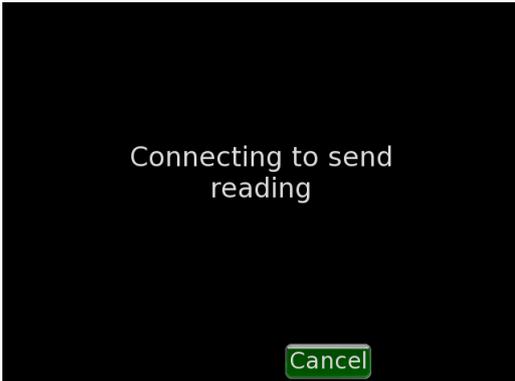


Step 7. Your information is then automatically sent to your doctor.

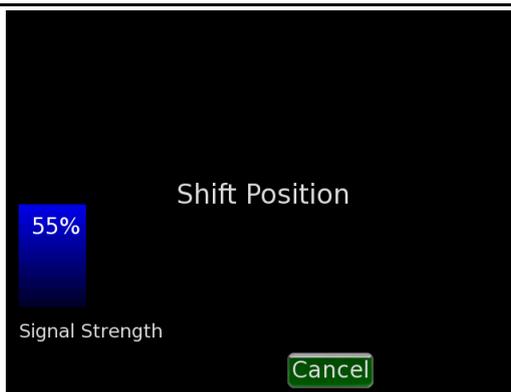
Step 8. Once transmission is complete, the electronics unit turns off automatically.

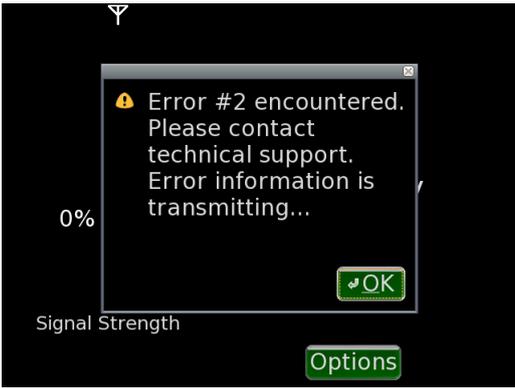
If you cannot complete a reading after following the above steps, refer to the Troubleshooting section or call technical support.

Troubleshooting the Patient Electronics System

Problem	Symptom	Solution
Cannot get a signal		<p>Check the antenna cable. Make sure there is no metal near the pillow. Make sure there is no electric blanket near the pillow. Reposition yourself on the pillow. Call Technical Support.</p>
	<p>Signal Strength bar never goes above 70% and never turns green. Voice continues to indicate low signal Not able to complete a reading successfully</p>	
Reading completes but cannot send data to your doctor		
	<p>Error message repeats "Connecting to send reading" Error message says "Unable to complete transmission" Error message says "NO DIALTONE"</p>	<p>Check the phone line or wireless antenna. Make sure the phone line is working or you are getting adequate signal strength on your wireless connection. Make sure the phone line is not busy. Make sure the electronic unit is dialing with the correct pre-fix, if necessary. Call Technical Support.</p>

Problem	Symptom	Solution
<p>Takes a long time to get a reading</p>	<p>Takes a long time (>30 seconds) to get a good signal. System loses signal during reading and must re-start.</p>	<p>Reposition yourself on the pillow until the Signal Strength bar shows a higher signal strength and turns green. Make sure there are no electronics or metal in the vicinity of the measurement that may cause interference. Use the orientation ball to find the correct position. Call Technical Support.</p>
<p>Reading completes but is rejected by System</p>	<p>Error message says to repeat reading and reposition pillow away from any cords or metal objects</p>	<p>Remove any cords or metallic objects near the pillow or the pillow cable. Make sure there is no metal near the pillow. Make sure there is no electric blanket near the pillow.</p>

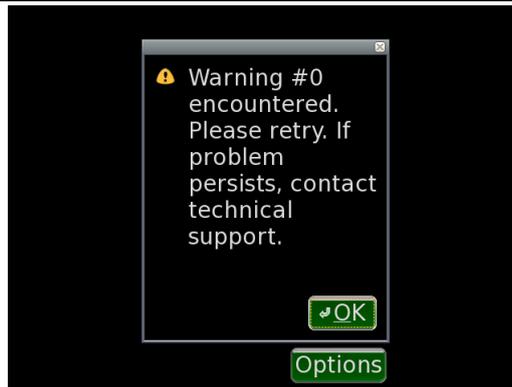


Problem	Symptom	Solution
Numeric error message		<p>Note the error. Select the OK button to acknowledge the error, wait for the error to transmit, and let the electronics unit shut down. Call Technical Support</p>
	Error #0	<p>There is a problem with the connections in the system such that important information cannot be sent.</p>
	Error #1	<p>The electronics system recorded an obviously incorrect value for the atmospheric pressure.</p>
	Error #2	<p>The two atmospheric pressure sensors in the electronics system do not agree.</p>
	Error #3	<p>Important data needed to make a measurement was not available.</p>
	Error #4	<p>The internal settings values needed to make a measurement were missing or damaged.</p>
	Error #5	<p>The atmospheric pressure sensor indicated an error in recording pressure or temperature.</p>
	Error #6	<p>An important part of the software was not able to run.</p>

Problem

Symptom

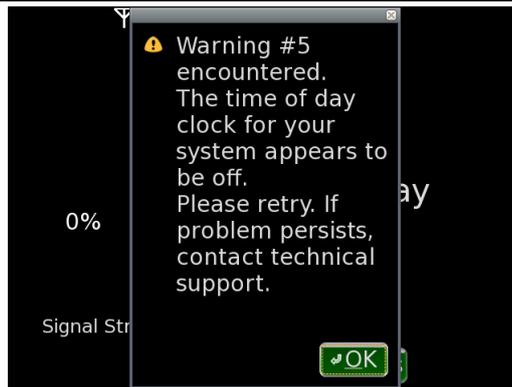
Solution



Numeric warning message

Warning message with a number appears on the screen

Note the warning.
Retry the steps that caused the warning.
If the warning appears a second time, call Technical Support.
Continue to take your readings if possible.



Time of Day Clock is incorrect

Warning message regarding the time of day clock

Note the warning.
Turn off the electronics unit from the Options menu.
Restart the electronics unit.
If the warning appears a second time, call Technical Support.
Continue to take your readings.

Orientation Ball

You may have used an Orientation Ball (shown below) during your initial training to help you find the best position for reading your sensor. After training, if you have difficulties remembering that position, use the ball to mark the right spot.

Figure 26. Orientation Ball



To find the best position and place the ball on the pillow:

Step 1. Take several readings in various positions. Watch the signal strength bar and follow the voice instructions.

Step 2. Find the position in which the signal strength is highest.

Step 3. Peel the paper on the flat side of the ball from the adhesive.

Step 4. Place the ball in a location on the pillow that will help you return to this body position.

Step 5. For all future readings, position yourself so you can feel the ball at the same location on your body.

Figure 27. Orientation Ball on the Pillow



Additional Features

The first screen on your electronics unit has an Options button. This button opens a menu with additional buttons that allow you to customize your System.

Figure 28. Options Button

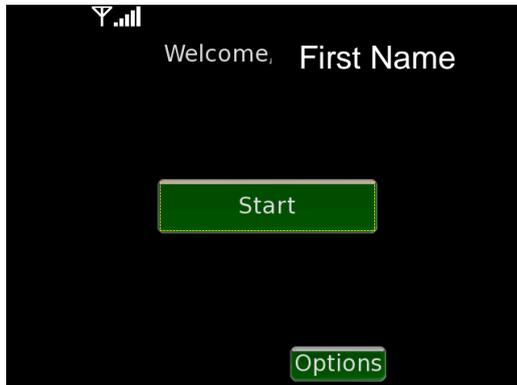


Figure 29. Additional Features



Volume Control

Select the Volume Up button to increase and the Volume Down button to decrease. Adjust the volume so that you can clearly hear the signals and the voice commands.

Troubleshooting/Allow Access

Selecting the Troubleshooting button on the Options screen and then the Allow Access button on the next screen gives the technical support representative the ability to diagnose a problem. When instructed by technical support, turn this feature on by selecting the Allow Access button.

Living with your CardioMEMS HF System

It is important to follow your doctor's instructions as well as the following recommendations:

- To experience the most benefit from the CardioMEMS HF System, it is important that you take readings daily or as instructed by your physician.
- Attend your scheduled doctor's office visits. Your doctor will arrange a follow-up plan with you to check your device and overall health on a regular basis.
- You should take your CardioMEMS HF System with you when you travel.
- Your doctor may also use the CardioMEMS HF system when you are seen in the office, the hospital or the emergency room and use that information with the PA pressure information you have transmitted from home to determine the best way to manage your heart failure, so it is very important that you take readings as instructed.
- Carry your identification card with you at all times
- Tell your family doctor, dentist, and emergency personnel that you have an implanted device.

Your sensor will not alert airport security when you pass through the security checkpoint.

You can travel with your Patient Electronics System. Pack the electronics in its carrying case and check it as luggage.

When packing the electronics, disconnect the GSM antenna and place in foam insert to prevent damage.

The radiofrequency that powers your sensor only works with the Patient Electronics System; it will not "pick up" anything else.

When to Call Your Doctor

Your doctor will provide instructions for when you should contact him or her. In general, phone your doctor if you:

- Have worsening shortness of breath or chest pain
- Develop a fever that does not go away in two or three days
- Have questions about your device, heart failure, or medications
- Notice anything unusual or unexpected, such as new symptoms that you have not had before

Care of the Patient Electronics System

Pillow

If the pillowcase becomes soiled, you may machine or hand wash it with any soap or detergent. This may be done as frequently as needed.

If the plastic pillow becomes soiled, you may wipe the plastic pillow with a damp cloth and mild detergent. This may be done as frequently as needed. Do not machine wash or immerse the plastic pillow in water or any cleaning solution.

Cables and Electronics Unit

Turn off and unplug the unit before cleaning it.

Wipe the electronics unit and cables with a slightly damp cloth using soap, a mild detergent, or water. You should not use cleaning agents that contain acid or harsh chemicals such as bleach or ammonia. Dry all parts before plugging the unit back in.

Touchscreen on the Electronic Unit

To clean the touchscreen use either water or a commercially available cleaning solution designed for display or touchscreens.

Stand away from the electronics unit and spray the cleaning solution onto a clean, lint-free cloth until it is slightly damp. Without applying excessive pressure, clean the screen.

Do not submerge the electronics unit in any liquid. Do not spray it or allow fluid to enter it. Should this occur, do not use the electronics unit and contact technical support for assistance.

Replacing your Patient Electronics System

There may be a time when your Patient Electronics System will need to be exchanged. Should this occur, technical Support will assist with the return and exchange of your system with minimal interruption. During the exchange period, notify your doctor and follow his/her instructions.

Repacking

Step 1. Unplug the electronics unit power supply

Step 2. Unplug the power supply cable from the electronics unit.

Figure 30. Power Cable



Step 3. Unplug the remote button cable from the electronics unit.

Figure 31. Remote button



The following instructions are specific to the type of Patient Electronics System you have received.

Step 4. If you have a wireless GSM version, unscrew the wireless antenna at the top of the unit.

Figure 32. GSM Wireless Antenna



Step 5. If you have a landline version, unplug the telephone cord from the back of the electronics unit and from the wall.

Figure 33. Telephone Cord Connection



Step 6. Rotate the connector at the end of the pillow cable.

Figure 34. Pillow Cable



Step 7. Gently lift the electronics unit and place it securely into the carrying case.

Figure 35. Carrying Case



Step 8. Place the cables, remote button, power supply, and wireless antenna into the carrying case.

Step 9. Coil the pillow cable and place it under the pillow. Lift the pillow and cable together and place them into the carrying case on top of the other cables.

Figure 36. Pillow Being Placed into Carrying Case



Step 10. Place your instructions in the carrying case. Close and zip the carrying case.

Electromagnetic Interference and Electromagnetic Compatibility

This section provides a brief overview of Electromagnetic Interference and Electromagnetic Compatibility guidance associated with the use of the CM1000 (also applies to the CM1010 model).

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The CM1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CM1000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The CM1000 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The CM1000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The CM1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CM1000 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment --guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines	<5 % U_T (>95% dip in U_T) For 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	<5 % U_T (>95% dip in U_T) For 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	Mains power should be that of a typical commercial or hospital environment. If the user of the CM1000 requires continued operation during power mains interruptions, it is recommended that the CM1000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The CM3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the CM3000 should assure that it is used in such an environment.

Immunity Test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communication equipment should be no closer to any part of the CM3000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <p align="center">(((⦿))) ▲</p>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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 predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CM3000 is used exceeds the applicable RF compliance level above, the CM3000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CM3000.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the CM1000			
The CM1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CM1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CM1000 as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter W	Separation distance according to frequency of transmitter, m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$1.2 \sqrt{P}$	$1.2 \sqrt{P}$	$2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.79	3.79	7.27
100	12.00	12.00	23.00
For transmitters rated at a maximum output not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.			
Note			
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
Note			
These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

FCC Statement

This device complies with Part 18 of the FCC rules.

The PA Sensor is approved for wireless transmission under FCC ID number R3PCS-A-000051. The sensor complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference and 2) this device must accept any interference received, including interference that may cause undesired operation.

RTTE Statement

The CardioMEMS HF System has an operating frequency of 30-37.5 MHz. This band is recognized for wireless applications in healthcare in certain member states of the European Union. The following is a list of countries in which the 30-37.5MHz operating frequency has not been implemented.

The following countries have not implemented the Wireless Applications in Healthcare (30-37.5 MHz) band:

- Georgia
- Russian Federation
- Serbia
- Slovak Republic
- Ukraine

This list of countries is current as of October 2012. For operation within countries that have not implemented the frequency band, please contact the local authorities concerning specific licensing requirements or more current information.

Reference: ERC Recommendation 70-03.

System Specifications

Electrical Characteristics

Power

- Power Supply: Medical Grade Class II. Input: 100-240V, 50-60Hz, output: 12VDC, 6A.
- Manufacturer part number: CS-001301.
- Only use power cord (CM3020) supplied by the manufacturer.

Radiofrequency (RF) Characteristics

- Transmitted Electrical Power – < 1mW e.r.p.
- Operating Frequency – 30-37.5 MHz. Under normal operating conditions the measurement bandwidth is approximately 1 MHz within the operating frequency range.

Mechanical Characteristics

Electronics Unit

- Weight – approximately 8 pounds
- Dimensions – Height: 11.5 inches Width: 10.5 inches Length: 5.5 inches
- Product Life: 5 years
- I/O – 2 USB, VGA, RS-232
- User Button: Reference manufacturer's part number FP-900068

Display

- Touch Screen – Resistive
- Brightness – 250 cd/m²
- Resolution – 800 x 480, color

Antenna

- Weight – approximately 4 pounds
- Diameter – 9 inches
- Cable: Reference manufacturer's part number CS-001005

Environmental Information

- Operation: 5° to 40° C (41° to 104° F), 15% to 93% humidity (non-condensing), 700-1060 hPa (System), 800-1150 hPa (implanted sensor)
- Transportation: -25° to 70° C (-13° to 158° F), 15% to 93% humidity (non-condensing)
- Storage: -25 ° C to 70 (-13° to 158° F), 15% to 93% humidity (non-condensing)

Classification

- Class II equipment
- Type BF insulation
- Ordinary Equipment IP21
- Continuous Use

Testing

System Testing

- System Accuracy (under typical environmental conditions): +/- 2 mmHg at baseline and +/-3% of difference between measured pressure and baseline
- System Accuracy: +/-4 mmHg over the range of environmental conditions
- The CM1000 was issued an ETL/cETL Listing Mark

Safety Testing

- IEC 60601-1
- ANSI ES 60601-1
- CENELEC EN 60601-1
- CAN/CSA-C22.2 No. 60601-1

EMI/EMC Testing

- CENELEC EN 60601-1-2
- ETSI EN 301 489-1

Wireless Testing

- FCC part 18 (Patient Electronics System)
- FCC part 15 (Sensor)
- ETSI EN 301 489-3
- ETSI EN 302 510
- CISPR 22

Symbols

The following symbols are used on the Patient Electronics System labels.

Symbol	Description
	Calibration Code
	Reorder number
	Authorized EC Representative in the European Community
	Non-ionizing radiation
	Operating Instructions
	Alternating Current (AC) Power
	Direct Current (DC) Power
	Type BF Patient Applied Part.
	Manufacturer
	Serial number
	This device complies with Part 18 of the FCC rules
	MR Conditional
	Class II equipment
	Momentary push button
IP21	IEC 60529 Ingress Protection Level
	<p>The device contains a battery and the label is affixed to this device in accordance with European Council Directives 2002/96/EC and 2006/66/EC.</p> <p>These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem.</p> <p>Return the device to manufacturer at the end of its operating life.</p>
	<p>Affixed in accordance with European Council Directive 90/385/EEC ("0086") and 1999/5/EC ("0982"). Hereby, the manufacturer declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.</p>

Symbols

The following symbols are used on the Patient Electronics System labels.

Symbol	Description
	Use By Prescription Only
	Temperature limitations
	Humidity limitation
	Keep dry

WEEE Compliance Statement

The 2002/96/EC Directive on Waste Electrical and Electronic Equipment (the WEEE Directive) states that new equipment placed on the market within the European Union must comply with the WEEE directive which aims to ensure that products can be easily broken down or recycled at the end of the life cycle. We are committed to complying with the EC WEEE directive. Products put on the market are required to be marked with the crossed through recycling bin symbol and something that identifies that it was put on the market on or after this date.

Replacement and Warranty

This Limited Warranty is available for a period of five (5) years following delivery to the original purchaser if the CardioMEMS™ Patient Electronics System (“System”) fails to function within expected operating specifications due to defects in materials or workmanship.

This warranty does not cover damage due to external causes, including but not limited to accident, electrical power problems, servicing not authorized by CardioMEMS, Inc., usage not in accordance with product instructions, or due to abuse or misuse.

During the five-year warranty period, CardioMEMS, Inc. will repair or replace a malfunctioning System if it is returned to CardioMEMS, Inc. To qualify for such repair or replacement, CardioMEMS, Inc. must be notified within 30 days of the malfunction and, if so directed by CardioMEMS, Inc., the purchaser or user must return the System for repair or replacement to:

CardioMEMS, Inc.
Attention: Returned Goods
387 Technology Circle, NW, STE 500
Atlanta, GA 30313

If warranty service is required, contact CardioMEMS, Inc. If CardioMEMS, Inc. repairs or replaces the System, the warranty term will be for the remainder of the original term or 60 days, whichever is longer.

See the Limited Warranty card supplied in the packaging for more details.

Setting Up a Replacement System

Most Patient Electronics Systems will have cellular connections. Follow these steps if a cellular connection is available:

1. When the system starts, it will prompt for the 6 digit sensor serial number that can be found on the patient identification card.
2. Touch the screen in the gray rectangle next to SN to enter the serial number and then click OK.
3. The Patient Electronics System will then download the necessary information from the CardioMEMS HF website and then prompt you to confirm the information.
4. When the system is successfully setup the system will display your name above the ‘Start’ button.

The following screens illustrate the sequence:

Figure 37. The Patient Electronics System will prompt to enter sensor serial number.

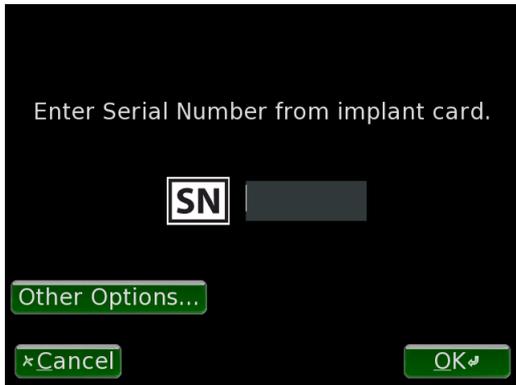


Figure 38. Confirm name and sensor information.

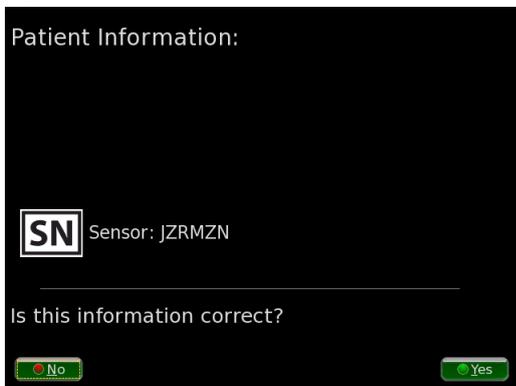
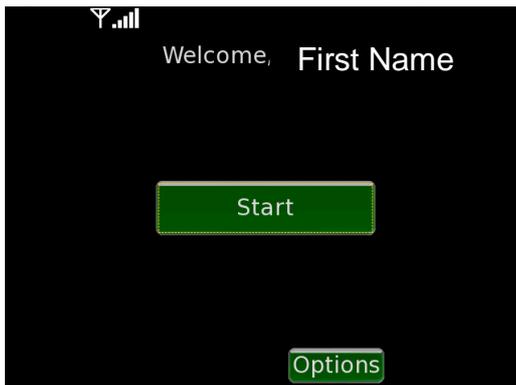


Figure 39. Your name will be displayed on starting screen every time the system is started.



For Patient electronics systems using a landline connection, follow these step:

1. When the system starts, it will prompt to plug in the telephone line and click OK.
2. The next screen will prompt for the 6 digit sensor serial number that can be found on the patient identification card.
3. Touch the screen in the gray rectangle next to SN to enter the serial number and then click OK.
4. The Patient Electronics System will then download the necessary information from the CardioMEMS HF website and then prompt you to confirm the information.
5. When the system is successfully setup the system will display your name above the 'Start' button.

The following screens illustrate the sequence:

Figure 40. Patient name will be displayed on starting screen every time the system is started.

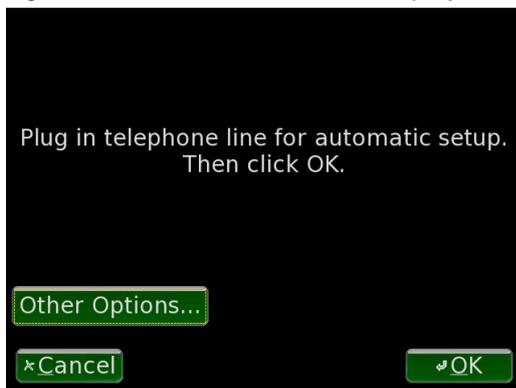


Figure 41. The Patient Electronics System will prompt to enter sensor serial number.

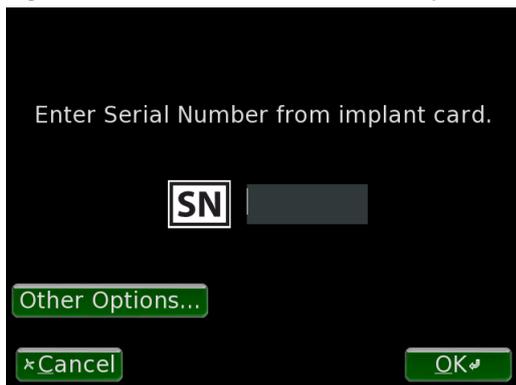


Figure 42. Confirm name and sensor information.

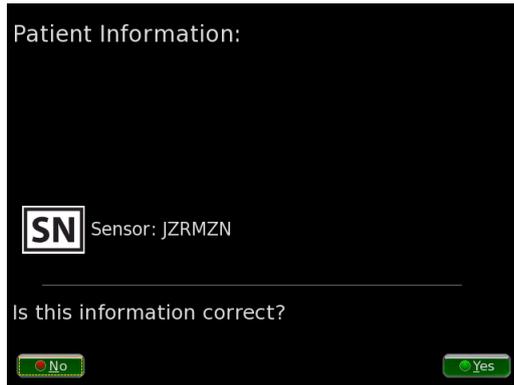
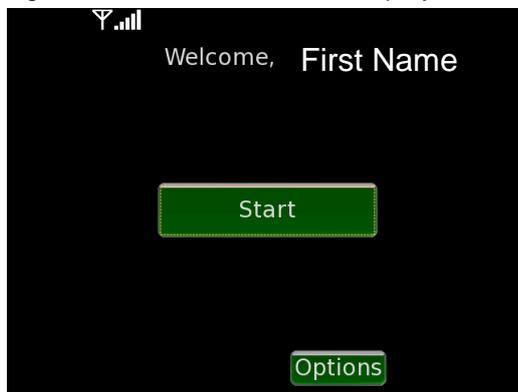


Figure 43. Your name will be displayed on starting screen every time the system is started.



Technical Support

- 877-696-3754.



Manufacturer:
CardioMEMS, Inc.
387 Technology Circle NW
Atlanta, Georgia 30313 USA
866-240-3335

LA-400236-04



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