



Patient System Guide

***Champion*[™] HF Monitoring System**

IMPLANTABLE WIRELESS HEMODYNAMIC MONITOR

Caution: Federal law restricts this device to sale by or on the order of physicians trained or experienced in device implant and follow-up procedures

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1. INTRODUCTION

Introduction

You have been diagnosed with New York Heart Association (NYHA) Class III Heart Failure. Moderate to severe heart failure is a disorder that 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 (blood vessels that supply blood to the heart are narrowed or blocked). Approximately 6 million people in the United States suffer from heart failure and it is one of the most common reasons for hospitalizations in people over 70 years of age.

This handbook will tell you how the *Champion* HF Monitoring System operates. It will discuss what to expect now that you have a sensor, how to set-up the system in your home and how to take a daily measurement. If you have questions about what you read in this handbook, ask your doctor or nurse. They are your best resource for information.

When is this System used?

Your doctor has decided that you should receive a *Champion* HF Monitoring System because you have NYHA Class III Heart Failure and are at an increased risk of hospitalization due to heart failure symptoms such as shortness of breath, fatigue and retention of fluid.

What does this System do?

The device monitors your pulmonary artery pressure, which is the pressure within your heart. You take a reading daily from home using the Patient Electronics System, which then sends the information to your doctor. After analyzing the information, your doctor can discuss your heart failure condition and determine if any changes to your treatment should occur.

How was the System Clinically Evaluated?

The Champion HF Monitoring System was clinically evaluated in a recent clinical study conducted in the United States. The purpose of the trial was to determine if the System was safe and if it could be used to help physicians reduce heart failure hospitalizations in a group of patients suffering from NYHA Class III heart failure.

The CHAMPION trial was conducted at 64 clinical sites and enrolled 550 NYHA Class III heart failure patients with a heart failure hospitalization in the previous 12 months. Patients were randomized to one of two groups, treatment or control. In the treatment group, the patient's daily pulmonary artery (PA) pressures were monitored and used in conjunction with standard heart failure management (weights, signs & symptoms, etc.). In the control group, the PA pressures were not monitored and the patient's heart failure was managed using standard medical management.

The study demonstrated that the sensor could be safely implanted and successfully measure and transmit PA pressures. No sensors were removed from patients and all sensors remain functional.

The study also showed that patients in the monitored group demonstrated a 28% reduction in heart failure hospitalizations at 6 months and a 37% reduction in heart failure hospitalizations at 15 months compared to patients in the group that were not monitored.

Patients in the monitored group also experienced the following benefits:

- A reduction in PA pressures
- More days out of the hospital
- Fewer were hospitalized
- Improvement in their quality of life

The CardioMEMS Champion HF Monitoring System represents a significant improvement in HF management for NYHA Class III HF patients, leading to fewer HF hospitalizations and better patient quality of life.

Your *Champion* HF Monitoring System includes three components:

1) Sensor/Monitor (Sensor)



2) Patient Electronics System



3) Patient Database





2. YOUR HEART

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.

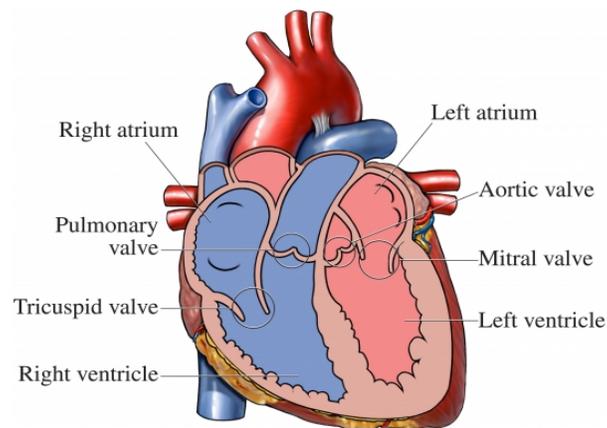


Figure 1. Normal Heart

Your heart is weakened so that it cannot efficiently pump blood out to the body. As a result, you can become weak and tired and may get more short of breath when you start to exercise. Another common symptom is that the body retains salt and water, leading to fluid buildup in the lungs and other areas of the body.

3. HEART FAILURE

Heart Failure

Heart Failure is a serious illness in which the heart muscle cannot pump enough blood to meet the needs of your body. Heart Failure happens when the heart cannot squeeze hard enough to get enough blood out to the body or the heart muscle is too thick and does not relax enough between beats. Heart failure can make you feel tired or weak, short of breath, and can also cause swelling and fluid buildup in your legs, feet, stomach, and even your lungs.

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

Clogged arteries can cause heart attacks where heart muscle cells die. The muscle can weaken and pump less efficiently.

Untreated High Blood Pressure

The heart can weaken over time when pumping harder to be able to move blood through the blood vessels.

Faulty Heart Valves

Heart valves that do not work properly (either because they are leaky or because they do not open sufficiently) can cause the heart muscle to weaken and fluid to back-up.

Cardiomyopathy (Heart Muscle Disease)

The heart muscle becomes either enlarged or weakened due to unknown causes.

Over time, the heart muscle weakens and becomes enlarged as shown in Figure 2 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.

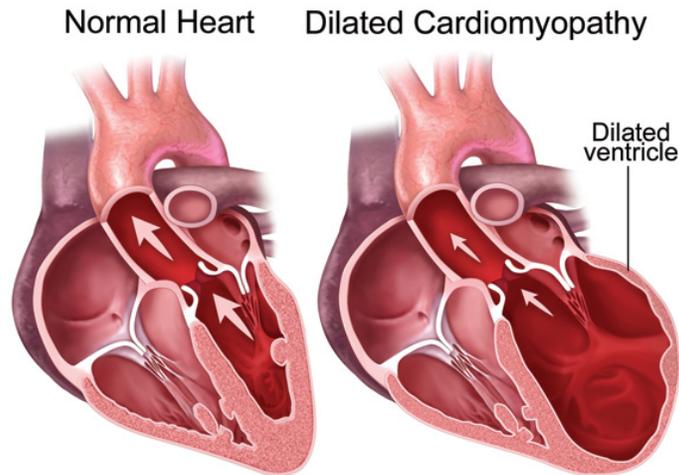


Figure 2. Enlarged Heart

Stages of Heart Failure-NYHA Classification

In order to determine the best course of therapy, physicians often describe the stage of heart failure according to the New York Heart Association (NYHA) functional classification system. This system relates symptoms to everyday activities and the patient's quality of life. Class I patients have virtually no symptoms while Class IV are often confined to a bed.

Class	Patient Symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or shortness of breath.
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or shortness of breath.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or shortness of breath.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

Symptoms of Heart Failure

Pressures in the vessels around your heart change before symptoms occur. Your doctor may change some of your medications based on the information obtained from the *Champion* HF Monitoring System. It is important to follow all directions and take your medications that your physician gives you even if you are not feeling well.

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 ankle swelling can mean that your heart failure is getting worse. Worsening symptoms can quickly lead to urgent problems requiring 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 hardly any 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 or prop up with several pillows in order to sleep. You may also experience a frequent, dry cough often made worse when you lay down in bed.

Weight gain

Weight gain over several days in a row is a common indication that there is fluid buildup in the body. This leads to shortness of breath, swelling of the feet, legs or swelling of the abdomen. 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 greater 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 also notice your shoes, socks or pants are fitting tighter 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 “bloating sensation”. You may also experience loss of appetite or even an upset stomach. In addition, the medicines may not be absorbed as well and therefore will not work as effectively.

Decreased Urination during Day, Increased Urination at Night

During the day, the work of the heart is greater than at rest. This leads to less urine in the day. When you are sleeping, the work of the heart is lessened so it allows the kidneys to make more urine.

Managing Your Heart Failure

Good management of your heart failure will lessen the impact of the symptoms on daily life. Your doctor and other medical professionals will assist you to be successful in your heart failure management by making changes in your daily food selections, daily activities, taking pressure readings and by taking the medications that your doctor prescribes, you 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 help you:

- Live longer
- Have fewer symptoms
- Increase your 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)
- Angiotensin Receptor Blockers (ARBs)
- Beta-Blockers
- Diuretics (water pills)
- Aldosterone Antagonists
- Hydralazine and Nitrates

Angiotensin-Converting Enzyme Inhibitors (ACE Inhibitors)

These medicines are very beneficial for people with heart failure. Research studies have shown that ACE Inhibitors help people live longer and decrease hospitalizations. They work by blocking the effects of harmful stress hormones (substances produced by your body that make heart failure worse). They help to relax blood vessels and for lowering blood pressure which make it easier for the heart to pump blood out to the body. A common ACE Inhibitor is Lisinopril (trade names of Prinivil™ or Zestril®).

Angiotensin-Receptor Blockers (ARB)

These are similar to the ACE Inhibitors and are most commonly used when patients cannot take ACE inhibitors because of side effects. Research studies have shown that ARB's also help people live longer. An example of an ARB is Losartan also called Cozaar®.

Beta-Blockers

These medicines are used to reduce the damaging effects of the hormone, adrenalin, on the heart and help you live longer. They also lower blood pressure and heart rate. An example of a beta blocker is Carvedilol also called Coreg®.

Diuretics (“water pill”)

These medicines work by helping 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. Both of these actions of diuretics will help you feel more comfortable. An example of a diuretic is Furosemide also called Lasix®.

Aldosterone Antagonist

These medicines work by blocking the effects of a stress hormone called Aldosterone which can make heart failure worse. Research has shown that Aldosterone Antagonist also help people live longer. An example of an aldosterone antagonist is Spironolactone also called Aldactone®.

Vasodilator and Nitrate Combination

A vasodilator relaxes the arteries of the body, which reduces the workload of the heart. A nitrate reduces the oxygen demand of the heart and improves blood flow to the heart. Research has shown that these medicines also help people live longer. An example of a nitrate is Isosorbide mononitrate (Imdur®) and a vasodilator is Hydralazine.

Daily Pulmonary Artery Pressure Reading

Before you notice weight gain and/or swelling, the pressures in the vessels around your heart change. Taking daily pressure readings with the Champion HF Monitoring System allows your doctor to treat these changes and 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 to notice any extra fluid buildup. If you ignore the weight gain, the fluid will find its way to your lungs, stomach area, legs and feet. By the time you see swelling in your ankles, you may have already retained an extra 5 to 7 pounds of fluid.

Low Sodium Diet or Low Salt Diet

When you have heart failure, it is important to decrease the amount of sodium or salt you eat, because heart failure causes the body to hold on to extra sodium. The sodium causes extra fluid to build up in your body and causes symptoms such as swelling of the ankles, feet or abdomen, shortness of breath or weight gain.

By reducing the amount of sodium that you eat in your foods, you will retain less fluid and reduce many of the symptoms of heart failure. Sodium is a mineral that is already in most foods so you cannot eliminate it entirely from your diet but, every reduction in the amount of sodium you take in 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 better.

Fluid Control

How much fluid can you drink? Many people with heart failure take diuretics to help in the removal of excess fluid but, 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 2 quarts a day. The guidelines for sodium and fluid intake may vary depending on the severity of heart failure in any given individual and should be discussed with your physician.

Alcohol

Alcohol has a direct effect on the heart by decreasing the strength of the contraction. In a weakened muscle, as in heart failure, this is not a good idea. It is recommended that you limit alcohol intake to one drink or less daily or avoid alcohol completely.

Tobacco Cessation

Tobacco products (not just cigarettes) contain nicotine. Nicotine clamps down blood vessels. This makes the blood pressure and pulse go up and makes more work on your weakened heart. For further information on quitting, you can call the American Heart Association.

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.

5. IMPLANTING YOUR DEVICE

Implanting of Your Sensor

The sensor will be implanted during a standard right heart catheterization (RHC). The RHC has been done routinely since the late 1960's and several hundred thousand procedures are performed per year. As part of the clinical trial for the HF Monitoring System, approximately 600 sensors were implanted.

Actual Sensor Size



Figure 3. CardioMEMS Sensor

You may receive a mild sedative before and/or during the procedure but you will be awake so you can follow instructions. An area on your groin will be cleansed with sterile soap and a local anesthetic (numbing) medicine will be injected at that site.

There are two parts to the procedure, RHC and implant of the sensor. The RHC is performed as follows:

- A Swan Ganz catheter is introduced into your groin
- Once the catheter is in the pulmonary artery, a small amount of contrast material (dye) is injected
- Pictures are taken to make sure the catheter is in the right position and to make sure the branch of pulmonary artery meets the implant criteria
- If the doctor determines that the pulmonary artery is unsuitable for receiving the sensor, the second part of the procedure will not be performed

The sensor implant consists of the following:

- Delivery catheter with the sensor attached is threaded into your pulmonary artery over a guidewire
- The sensor is positioned into the pulmonary artery and confirmed by x-ray to be in the correct position
- Once the position is confirmed, the sensor is released

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- The delivery catheter is removed and the RHC is reinserted
 - The doctor will take a pressure measurement using the RHC and the HF monitoring system
 - Once the pressure measurements are confirmed, the RHC is removed

The procedure may last up to one hour. After the procedure is completed, you may be asked to lay flat on your back for a few hours, to prevent any bleeding from the catheter insertion site. You may experience some discomfort from the catheter insertion site as you recover from the procedure. You should be able to return to normal activities soon after the procedure.

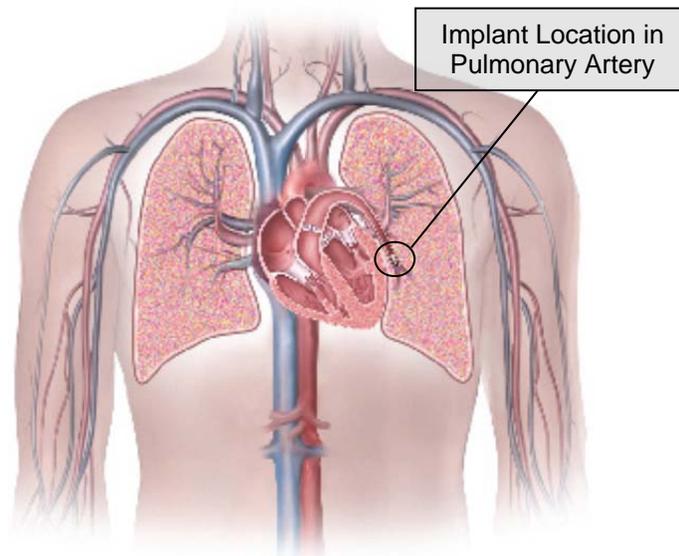


Figure 4. Location of the sensor implant

Implant Risks

As with any medical procedure, it is important to understand that, while complications do not happen very often, there are risks associated with the implantation of a device. You should talk with your doctor about these risks, including those listed below. Some of the possible risks are also complications associated with a heart catheterization and/or drugs associated with the procedure and blood thinning medications. Some of these risks include but are not limited to:

- Air embolism (air bubble in the bloodstream)
- Allergic reaction
- Abnormal heart rate or rhythm
- Bleeding
- Bruising
- Chest pain
- Nausea
- Stroke
- Infection
- Sepsis
- Delayed wound healing
- Atrial Dysrhythmia
- Thrombus formation (blood clots)
- Hematoma
- Venous trauma
- Valve damage
- Pulmonary infarct
- Pulmonary embolism
- Death
- Hemoptysis
- Sensor does not detach from delivery system

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.

After Your Implant

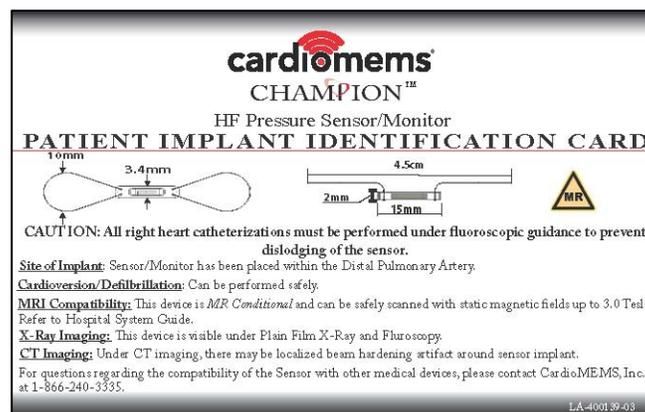
As you recover from your implant procedure, it is important that that you become actively involved in your recovery by following you doctor's instructions including:

- Report any redness, swelling, or drainage from you insertion site in your groin area
- 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

You will receive training about how to set-up and take daily readings with your home electronics before going home. A customer service representative will be available should you have any questions after you go home.

Your Sensor/Monitor information

Your doctor or nurse will complete the CardioMEMS Patient Implant Identification Card before you go home from the hospital. This card will provide 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.



Patient Name:	_____
Implant Date:	_____
Sensor Location: () Right or () Left PA	_____
Heart Failure Physician:	_____
Heart Failure Physician Phone:	_____
Sensor/Monitor Serial Number:	_____
Calibration Code:	_____
Offset Code: O/ /	_____ / _____
Please carry this card with you at all times and show it to any medical personnel who may care for you.	
For more information, your physician may contact CardioMEMS, Inc. at: 1-866-240-3335 CardioMEMS, Inc. Atlanta, Georgia 30313 USA www.cardiomems.com	
<small>CardioMEMS and the CardioMEMS logo are registered trademarks of CardioMEMS, Inc. Champion is a trademark of CardioMEMS, Inc. Copyright © 2010 CardioMEMS, Inc. All rights reserved. LA-400139-03</small>	

Figure 5. Patient Implant Identification Card

You should always carry your CardioMEMS Patient Implant Identification Card with you. The card will alert medical and security personnel that you have an implanted device. Your card contains your name, your doctor’s name and hospital, and the model numbers and serial numbers of your device.

Living with your Champion™ HF Monitoring System

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

- Your doctor will arrange a follow-up plan with you to check your device and overall health on a regular basis. It is important that you attend your scheduled in-office visits.
- Daily readings with your *Champion* HF Monitoring System should be done first thing in the morning or at the same time each day unless otherwise instructed by your doctor.
- Obtaining a reading should only take about 2-3 minutes. If you are having trouble obtaining a signal or reading is taking longer than expected, contact CardioMEMS Technical Support at **1-866-376-5183** (8am-8pm Eastern Standard Time).
- If you have a pacemaker or ICD, your sensor and electronics unit will not interfere with those devices when you are taking a reading
- Airport security: your sensor will not alert airport security when you pass through
- Traveling: you may travel with your electronics system but will need to pack the unit in the carrying case and check it as luggage
- The wireless signal that powers your device only works with the patient electronics system, it will not “pick up” anything else
- Carry your identification card with you at all times
- Tell your family doctor, dentist, and emergency personnel that you have an implanted device.

When to Call Your Doctor

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

- Have symptoms of 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.

Remember that your device is designed to monitor your pulmonary artery pressure to help your doctor better manage your heart failure. It can be a great source of reassurance for you and your family.

Replacing your Patient Electronics System

There might be a time when your patient electronics system will need to be exchanged for a newer unit. If that happens, CardioMEMS will facilitate the return of your old system and shipping of your new electronics system by calling **1-866-376-5183** (8am-8pm Eastern Standard Time).

Additional Information

Your device has built-in features that protect it from interference produced by most electrical equipment. Most of the things you handle or work around on a daily basis are not going to affect your device. Electronic systems could interfere with taking your measurement, for example, theft detection systems, an electric blanket, waterbed, etc. However, it is highly unlikely that you would be taking measurements when these devices are in use. If you are having difficulty taking a reading, contact CardioMEMS Technical Support at 1-866-376-5183.

Warnings/Precautions

- i2-6000 is the model number of the electronics system which includes the i2-6010, i2-6020, and i2-6025. Any specifications or precautions required by the I2-6000 are also required by the i2-6010, i2-6020, and i2-6025.
- Only authorized personnel should use the I2-6000.
- Users should never change computer configuration of the device.
- 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 discontinue use of the interfering equipment.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use only cables and accessories provided by CardioMEMS, Inc.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the I2-6000 as replacement parts for internal components, may result in increased emissions or decreased immunity of the I2-6000.
- The I2-6000 should not be used adjacent to or stacked with other equipment. If necessary to operate adjacent or stacked with other equipment, the I2-6000 should be observed to verify normal operation in the configuration in which it will be used.
- Other equipment may interfere with the I2-6000 operation, even if the other equipment complies with CISPR emission requirements. See EMI/EMC and Troubleshooting sections for guidance.
- Do not place the system near an open window. Exposing the LCD screen to rain, water, moisture or sunlight may severely damage it.
- Do not apply excessive pressure to the LCD screen. Excessive pressure may cause damage to the display.
- If upon use the hospital the system is mounted on a pole, only mount the I2-6000 on a sturdy medical grade pole.

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- If mounted on a customer supplied pole, make sure that the pole can withstand a 10 degree tip without falling over.
 - Do not remove the cover or attempt to service this system by yourself, as you may void the warranty. Servicing of any nature should be performed by an authorized technician.
 - All new or refurbished equipment should be obtained from CardioMEMS, Inc.
 - If any of the following occurs, immediately unplug the system and call CardioMEMS, Inc.
 - Any cords are noticeably frayed or damaged.
 - Liquid has been spilled onto the monitor, or it has been exposed to rain.
 - The system has been dropped or the enclosure has been damaged.
 - If you lose the power cord, you must replace it with an identical power cord.
 - CardioMEMS part number: CS-000015 (Hospital), CS-001145 (Home)
 - Contact CardioMEMS, Inc. for a replacement.
 - To avoid potential damage caused by lightning, unplug unit during electrical storms.
 - Avoid any excessive or damaging force to any part of the Electronics System.
 - Always allow the system to shut-down automatically.

6. TAKING A HOME READING WITH YOUR DEVICE

Overview of the *Champion* HF Monitoring System

The System consists of three components:

- 1) Implantable Sensor/Monitor (Sensor)
- 2) Patient Electronics System
- 3) Patient Database

The *Champion* HF Monitoring System is used to assess the pressure within your lungs by communicating with the implanted Sensor. The measured pressure is sent to the *Champion* HF Patient Database where a physician can review the data. The Patient Electronics System has been designed to effectively obtain information from the Implantable Sensor.

Taking a Home Reading with the Patient Electronics System

Your sensor is a permanent implant. It is implanted in a blood vessel in either the right or left pulmonary artery. You will not feel it and it will not interfere with your activities of daily life. Also, the sensor will not interfere with other devices you may have such as a pacemaker, ICD, etc.

You will take readings by lying on a special pillow that is provided by CardioMEMS. This pillow contains an antenna which will send your information to your doctor automatically after you push a button. Taking readings should be part of your daily routine.

Your patient electronics system is portable. Most patients set up the system in their bedroom.



Figure 6. Patient Electronics System

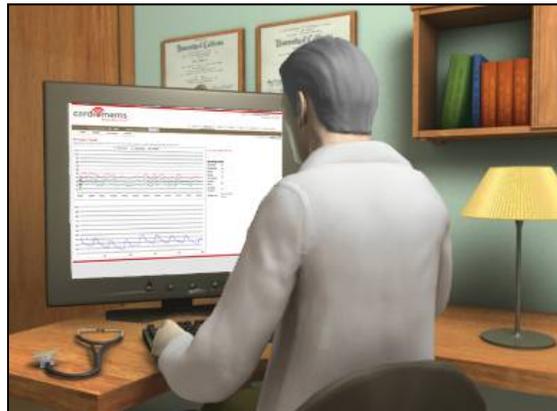


Figure 7. Champion HF Patient Database

The Patient Electronics System consists of a pillow with antenna, the electronics unit, power supply, and a pushbutton.

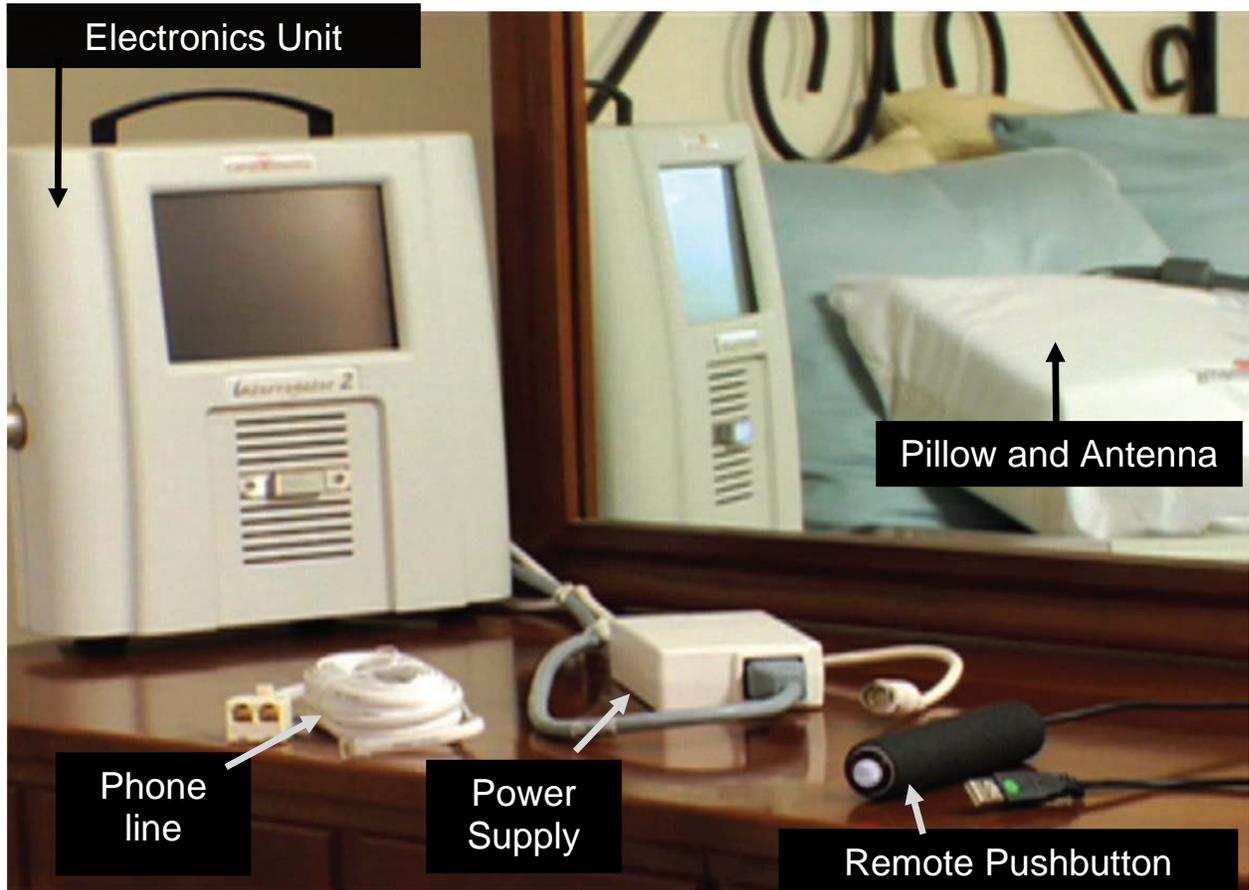


Figure 8. Patient Electronics System

Antenna

The Patient Electronics System was designed for ease of use and simplicity. It comes with a flexible antenna, which can be slid into a pad and pillow assembly. The headrest pad or cushion that is shipped with the system is provided for patient comfort (Figure 9). The antenna assembly rests on a foam pad with shielding material attached to the bottom of the pad. The antenna is supplied to the patient with both a headrest pad and a washable pillowcase.

**Flexible
Antenna**



**Flexible Antenna
inserted into
Headrest Pad**



**Flexible
Antenna in
Headrest Pad**



Figure 9. Antenna for Patient Electronics

Patient Electronics Unit

The Patient Electronics Unit (Figure 10) houses all of the equipment needed to send the pressure measurement from your home to your doctor. It contains special circuitry that generates radiofrequency to get the pressure measurement without any wires or batteries. This circuitry also contains a barometric pressure sensor that provides data to compensate for altitude and atmospheric pressure. The Patient Electronics Unit can be connected to either a Plain Old Telephone System (POTs) or through wireless (GSM) communication

System Set-up

Before you begin to take a reading, ensure that the power cord and telephone wire (Standard Telephone System unit only) are plugged into the back of the Patient Electronics Unit as shown below in Figure 10. (If your system is wireless, see the Additional Instruction for Wireless Electronics System section.)



Figure 10. Back of the Patient Electronics Unit

Next, perform the following three steps to complete the system set-up.

1. Unplug your telephone wire from the phone wall jack and plug it into either side of the Splitter which is supplied with the system.
2. Plug the Unit Phone Wire into the empty side of the splitter.
3. Put the splitter into the phone wall jack.

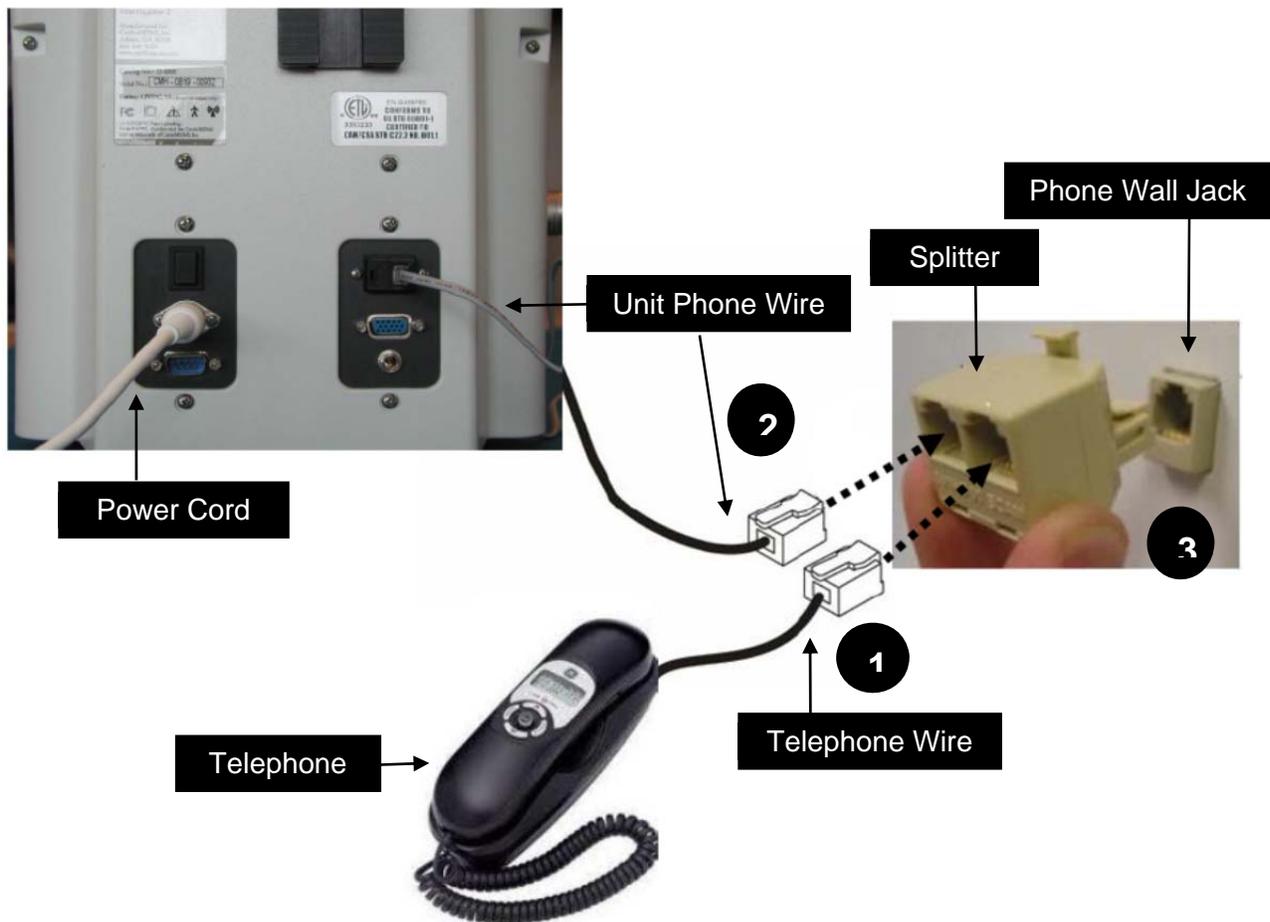


Figure 11. Electronics Unit and Telephone Wires Set-up

Steps for Taking a Reading

Follow these steps for taking a daily reading.

STEP 1

Press the black button on the back of the electronics unit to turn the power on.

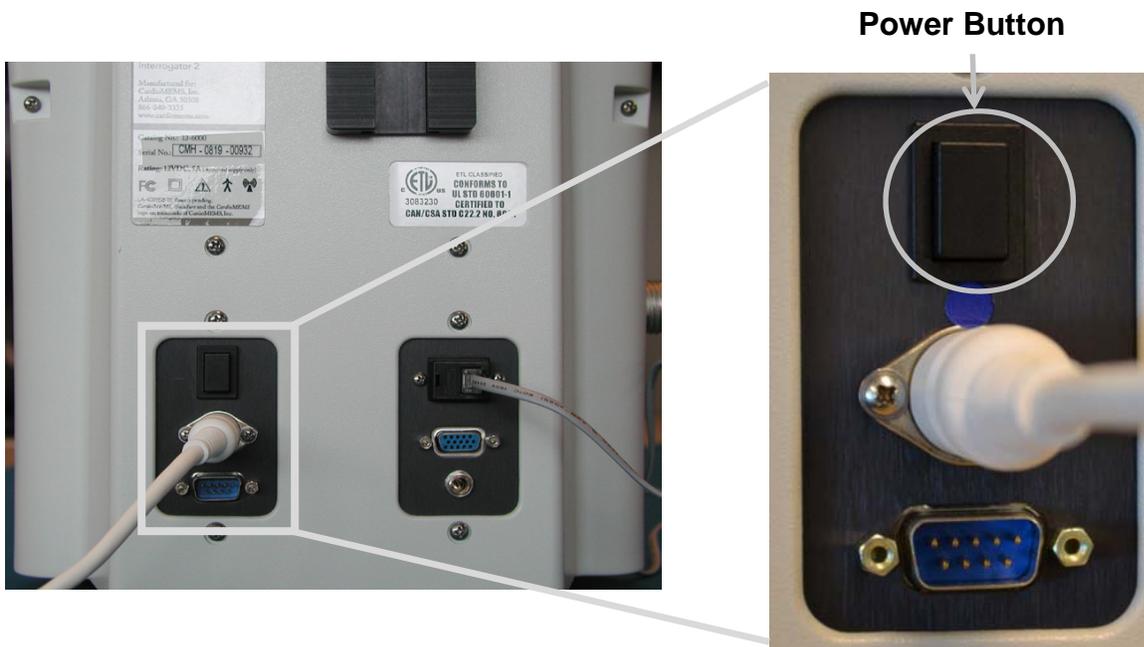


Figure 12. Power Button

STEP 2

After turning on the electronics unit, the first screen you will see will have both a Start Button and a More Button (Figure 13). If you see this screen, you know that the system is ready and can go to the next step. You can start a reading by pushing the Start Button on the screen. This is more difficult so we recommend that you skip this step. The More Button is used when you want to make changes in settings (for example when you want to make it louder). If needed, position the monitor so that you can see the screen when you lie down on the pillow. The system has both audio and visual cues to let you know that the measurement is being taken properly.



Figure 13. Start Button

Position antenna and pillow on your bed, which is the place most patients find to be the best for taking a reading.



Figure 14. Pillow

STEP 3

Lie down comfortably with your back on the CardioMEMS pillow and relax. Get into the optimal position — the position you are normally in when you get a signal.



Figure 15. Lie on pillow

STEP 4

Once you are in position, press the remote button.

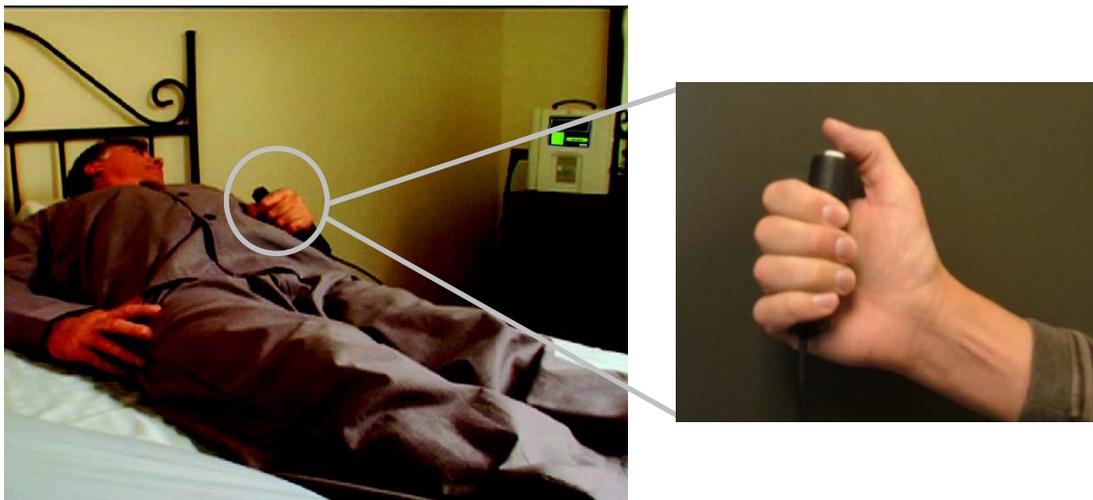


Figure 16. Press Remote Button

The voice and text prompts will guide you through the reading. After a few seconds, the system will say, “Good Signal”. If you are having trouble acquiring a signal, and you hear either a high or low-pitched tones, refer to Troubleshooting section.

STEP 5

You may need to change your position on the pillow slightly until **“Taking Reading”** message appears and you hear a sound indicating that you have a good signal.

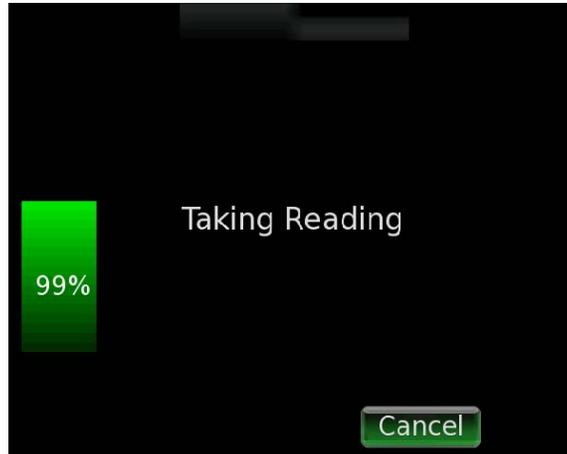


Figure 17. “Taking Reading” Message

STEP 6

Both audio and visual cues will guide you through the reading. After you hear **“Taking Reading”**, lie still for about 18 seconds while the music is playing. When the reading is finished, the music will stop and the screen below appears. When the reading is complete and the data is sent, the unit will turn off automatically. At that point, you are done with your daily upload and you can put the unit away.

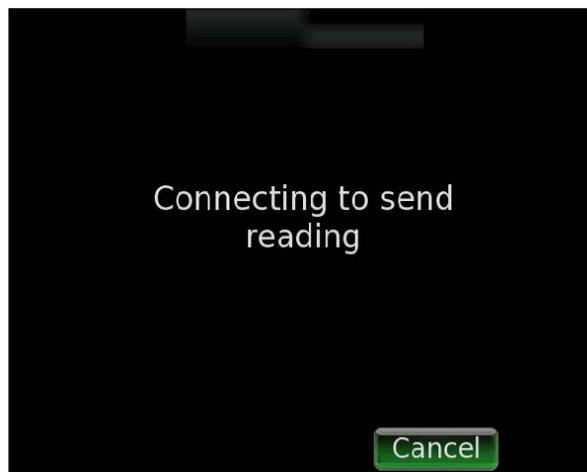


Figure 18. Sending Reading

Additional Features for Changing Settings

On the first screen of your Patient Electronics System you will see a button labeled “More>>”. The More Button allows you to see a menu containing additional screens that will help you customize your device and recording system.

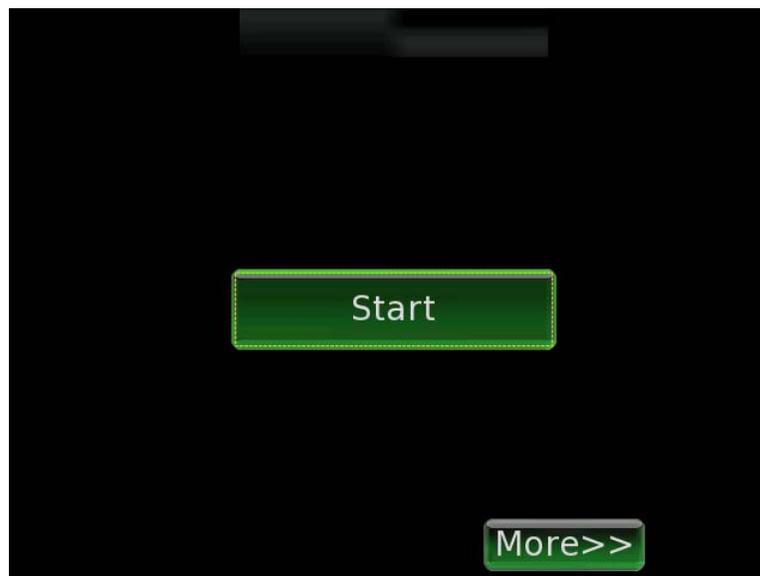


Figure 19. More>> Button

In this screen, there are several things that can be adjusted including volume, telephone numbers, remote session start up and dial-up prefixes.

Volume Adjustment

The volume can be adjusted by pressing the Up to increase and Down to decrease. The volume can be tested by pressing Play button. Adjust the volume so that you can clearly hear the signals and the voice commands.

Telephone Numbers

Your home electronics system transmits data through the telephone line. To do this, it needs to have the dial up number entered into its memory. The correct phone number will be installed for you before you leave the hospital however, if you move or change

telephone numbers, a new dial up number can be entered into the memory of the electronics system. These numbers can be added or edited once the “*Change Local Number*” button is pressed.



Figure 20. Additional Features

Dial-up Prefixes (area codes)

Dial-up prefixes can be changed if a prefix is necessary for the particular phone line, e.g., a hotel room phone. If the dial-up prefix is a number other than a 9 or 8, the pre-fix can be incorporated into the number that is entered.

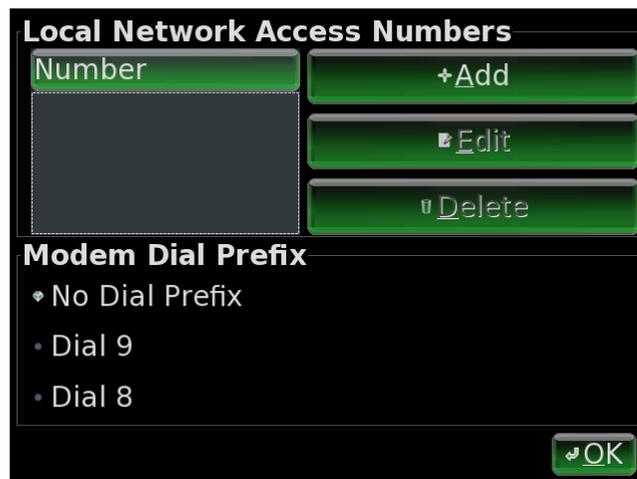


Figure 21. Dial-up Prefixes

Additional Instruction for Wireless Electronics System

You only need to read this section if you require a wireless (no phone line) system.

The Patient Electronics System you have received looks slightly different from those you see in your Patient Instruction Video and in the beginning of this User's Manual. You will note that there is a gold connector on the top right side of your electronics, and that you have an additional black antenna (See Figure 22 below)

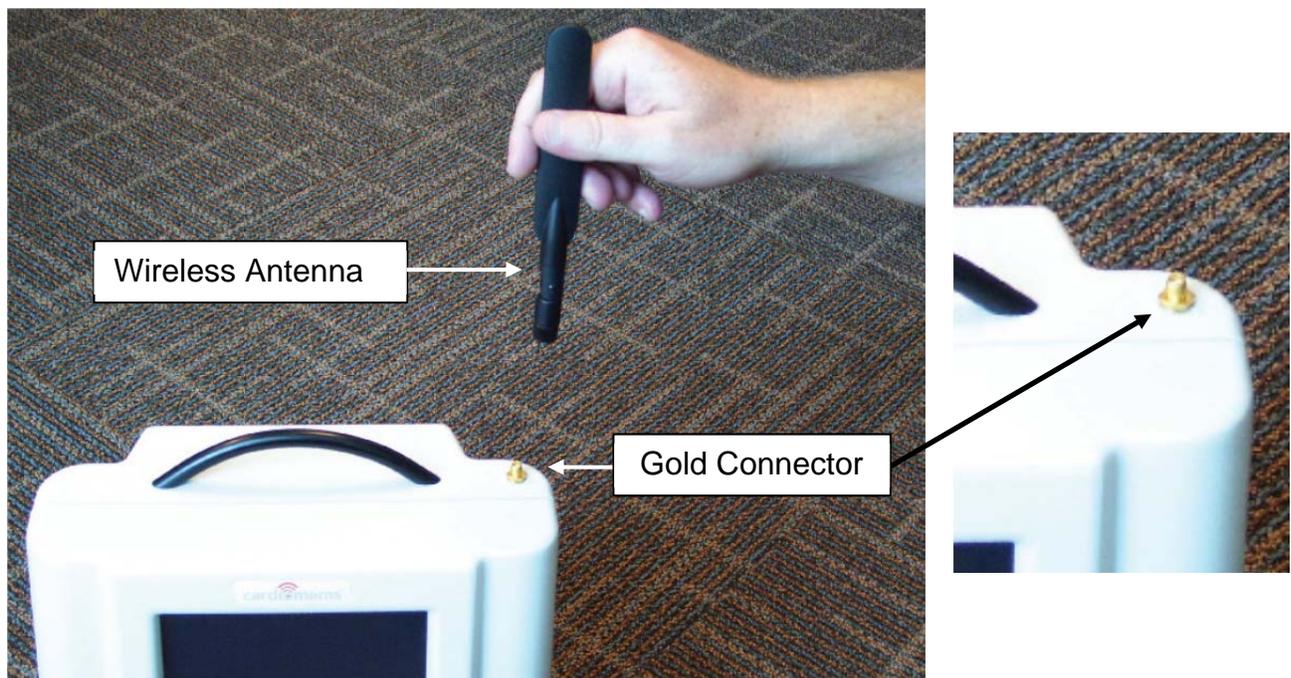


Figure 22. Black Antenna and Gold Connector

Connecting the wireless black antenna



Figure 23. Wireless Black Antenna

Position the black antenna thick side up as in the above photograph. Connect the antenna to the electronics unit by rotating the antenna in a clockwise direction until it stops. Care should be taken to ensure that the threaded connection is not over tightened. You have now completed the assembly of the Wireless Antenna. You do not need to connect a telephone wire to the back of your electronics.

If you need to repackage your electronics, you will need to rotate the Wireless Antenna in a counterclockwise direction to remove it. The electronics and the antenna may be damaged if not removed for shipping.

Cleaning and Repacking

If you are traveling, you will need to place your unit back into the travel case that was supplied with the unit.



Figure 24. Electronics Travel Case

Cleaning the Patient Electronics System

1. Turn off and unplug power and phone lines from the wall. The pillowcase may be machine-washed and the flat plastic pillow may be wiped with a damp cloth using mild detergent. Cables and the electronics unit may be surface cleaned only. Do not spray any fluid onto the unit or allow fluid to seep into it.



Figure 25. Cleaning the Pillow

Note:

- Submerging the HF system in water will cause damage to your unit.
- Unplug the power and phone lines for the system prior to cleaning.
- To clean the LCD screen, make sure the system is in the power off mode.
Unplug the monitor from the power source before cleaning. Stand away from the LCD monitor and spray cleaning solution onto a clean lint free cloth. Without applying excessive pressure, clean the screen with a slightly dampened cloth.
- To clean antenna and main unit enclosure, wipe parts clean with a slightly damp cloth using soap, mild detergent, or water. Make sure parts are dry before powering system.

2. Detach the power cord (a) and the thin, flat telephone wire (b) from the back of the electronics unit as well as the remote button cable (c) from the side of the electronics. Pack these items into the bottom of the carrying case.

Figure 26a. Power Cable Disconnection



Figure 26b. Phone line Disconnection



Figure 26 c. Remote Button Cable Disconnection



-
3. Identify the location on the side of the electronics unit where the gray cable from the pillow attaches. Rotate the black connector counterclockwise to detach the cable.



Figure 27. Grey Pillow/Antenna Disconnection

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



Figure 28. Placing Electronics in Travel Case

5. The pillow and gray cable should be lifted together and placed into the carrying case. Coil the gray cable into the case first, on top of the other cables, and then place the pillow, embroidered CardioMEMS logo down, on top of both the electronics unit and the cables to protect them during transport. Place this manual and *Patient Instructions* in the carrying case and zip the carrying case to close.



Figure 29. Electronics Travel Case

Storage

- Store the system in a temperature controlled, dry place inside the house. See System Specification Section for details.
- Exposing system to excessive vibration, impact, or rough handling may damage the unit.
- Exposing the screen to rain, water, moisture or sunlight may severely damage the unit.
- Unplug the power and phone lines connected to the unit during electrical storms.

Troubleshooting the Patient Electronics System

1. If the green bar does not appear when lying on the antenna, tighten the connection from the antenna to the electronics unit.



Figure 30. Grey Pillow Cable

2. If the system presents a screen indicating a communication error: for standard telephone system (a), ensure that the telephone connection is secured at the back of the electronics unit and at the wall. The electronic unit will continue redialing automatically. For wireless telephone system (b), tighten the wireless antenna connection to the gold connector on the top of the electronics unit.

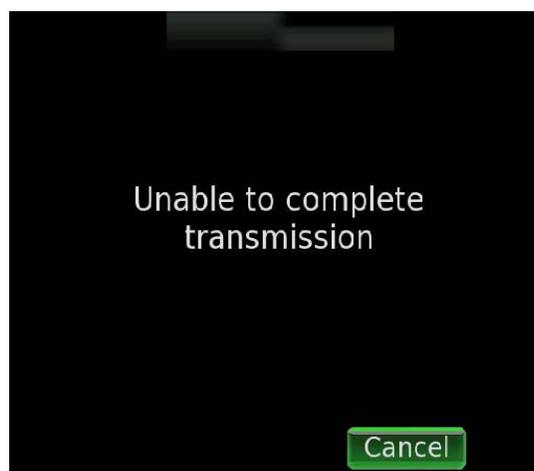


Figure 31. Communication Error

-
3. If the green signal bar is moving, and you are not hearing the good signal voice prompt, or the bar is a color other than green, then continue to reposition yourself on the pillow until the green bar rises.

The tones you are hearing are meant to guide you to the appropriate position. Higher pitched tones indicate you are closer to the optimal position. Move your body until you hear the highest tone and the system will say “Good Signal, Taking Reading.” After 5 minutes, the system will stop trying to take a reading and will prompt to continue back to the ‘Start’ screen.



Figure 32. Signal Lost

Orientation Ball

If you continue to have problems finding the correct position, an Orientation Ball will be provided to you. Additionally, during training, if you have difficulties remembering the best position to take a reading, then you can place an Orientation Ball in a position on your pillow to help you remember the best position.

The orientation ball has adhesive on the flat side, which will allow it to be placed in the best position on the pillow.



Figure 33. Orientation Ball

To place the orientation ball on the pillow:

- Take a reading, looking at the signal strength bar while also listening to the tone.
- Make sure the signal strength is high as possible.
- Peel back the paper protecting the adhesive.
- Place the Orientation Ball in a location on the pillow that will help you return to this body position.
- For all following readings, make sure you position yourself so you can feel the ball at the same location on your body every time.



Figure 34. Orientation Ball on Pillow

-
4. If the unit will not turn on when the power button is pressed, examine the connections to the power block. The green light on the power block will light up when properly connected.

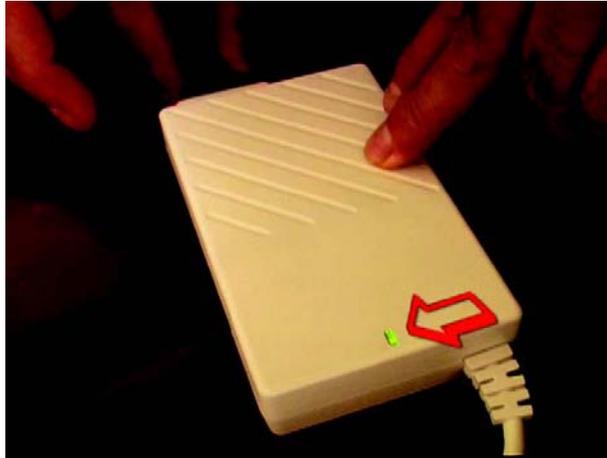


Figure 35. Power Bar Connection

5. If this screen appears, ensure that there are no metal objects such as jewelry or belts near you or the pillow. Press the green Continue rectangle on the screen to begin the process of repeating the reading. If you are still having difficulty, please call CardioMEMS Technical Support.



Figure 36. Repeat Reading

6. For Wireless Unit: As with a cellular phone, signal strength is important in transmitting data to your physician. If you are having problems transmitting a reading and the signal strength indicator is low (less than 50%), move the system to another location within your house. If the problem continues, note the signal strength and call CardioMEMS Technical Support.



Additional Troubleshooting

Problem	Symptom	Solution
Cannot get a signal	<ul style="list-style-type: none"> a. Green bar never goes high. b. Tones stay low c. Never able to complete a reading successfully 	<ul style="list-style-type: none"> a. Check antenna cable as shown in trouble shooting section b. Make sure there is no metal in the vicinity of the pillow c. Make sure there is no electric blanket in the vicinity of the pillow d. Try to re-position yourself on the pillow according to the position you were able to get readings during training e. Call CardioMEMS Technical Support for additional help.
Reading completes but cannot send data to Champion HF Patient Database	<ul style="list-style-type: none"> a. Error message says to check connections b. Error message says reading cannot be sent 	<ul style="list-style-type: none"> a. Check phone line or wireless antenna b. Ensure phone line is working or you are getting adequate signal strength on your wireless connection c. Ensure phone line is not busy d. Ensure the system is calling the correct number e. Call CardioMEMS Technical Support
Takes a long time to get a reading, but eventually you are able.	<ul style="list-style-type: none"> a. Takes the system a long time (>30 seconds) to say good signal b. System loses signal during reading often and reading must re-start 	<ul style="list-style-type: none"> a. re-position on the pillow until the green bar shows higher signal strength b. Use the orientation bar to feel for the correct position c. Call CardioMEMS Technical Support

If are unable to resolve you issues using these troubleshooting tips, please call CardioMEMS Technical Support from 8am to 8pm Eastern Standard Time.

CardioMEMS Technical Support

1-866-376-5183

Summary

It is natural for you to feel anxious or nervous about taking daily measurements and transmitting them to your physician. You have been identified by your physician as having heart failure, as well as having a risk of being hospitalized for decompensated heart failure. Your sensor can help you and your doctor better manage your heart failure and keep you out of the hospital. Having this device can be a great source of reassurance for you and your friends and family.

Visit us on the Internet at www.cardiomems.com

Acronyms, Abbreviations, Symbols, and Terms

Following is a list of acronyms and symbols used in this manual.

Acronym	Meaning
GUI	Graphical User Interface
RF	Radio Frequency
kHz	kilohertz (a measure of frequency equivalent to one thousand Hertz)
MHz	Megahertz (a measure of frequency equivalent to one million Hertz)
mmHg	Millimeters of Mercury (a unit of measure of pressure)
Vac	Volts AC (alternating current)
EMI	Electromagnetic Interference
EMC	Electromagnetic Compatibility
mW e.r.p	milliWatts effective radiated power
LCD	Liquid Crystal Display
RTTE	Radio and Telecommunications Terminal Equipment
	Manufactured By
REF	Catalog /Model Number
SN	Serial Number
	Calibration Code
	Type B Patient Applied Part.
	Non-ionizing radiation.
	Attention: consult accompanying documents.
	Class II equipment
	Alternating current

	This device complies with Part 18 of the FCC rules.
	WEEE directive symbol
	MRI Conditional

Electromagnetic Interference and Electromagnetic Compatibility

This section provides a brief overview of Electromagnetic Interference and Electromagnetic Compatibility guidance associated with the use of the I2-6000. I2-6000 is the model number which includes both the i2-6010 and i2-6020. Any requirements met by the I2-6000 are also met by the i2-6010 and i2-6020.

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The I2-6000 is intended for use in the electromagnetic environment specified below. The customer or the user of the I2-6000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The I2-6000 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The I2-6000 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The I2-6000 is intended for use in the electromagnetic environment specified below. The customer or the user of the I2-6000 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	
Surge IEC 61000-4-5	±1 kV differential Mode ±2 kV common mode	±1 kV differential Mode ±2 kV common mode	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	<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	Mains power should be that of a typical commercial or hospital environment. If the user of the I2-6000 requires continued operation during power mains interruptions, it is recommended that the I2-6000 be powered from an uninterruptible power supply or a battery.

	(30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	(30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	
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 I2-6000 is intended for use in the electromagnetic environment specified below. The customer or the user of the I2-6000 should assure that it is used in such an environment.

Immunity Test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be no closer to any part of the I2-6000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad \text{80 MHz to 800 MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad \text{800 MHz to 2,5 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

^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 I2-6000 is used exceeds the applicable RF compliance level above, the I2-6000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the I2-6000.

^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 I2-6000

The I2-6000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the I2-6000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the I2-6000 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		
	150 kHz to 80 MHz $1,2\sqrt{P}$ $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $1,2\sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2,5 GHz $2,3\sqrt{P}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0,01	0.12 m	0.12 m	0.23 m
0,1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

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 1 At 80 MHz and 800 MHz, the separation distance for 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.

FCC Statement



This device complies with Part 18 of the FCC rules.

RTTE STATEMENT

The Champion HF Monitoring 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 (30–37.5MHz) band		
Czech Republic	Georgia	Italy
Liechtenstein	Norway	Russian Federation
Serbia	Slovak Republic	Spain
Switzerland	Ukraine	

This list of countries is current as of June 2010. 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

Power

- Supply Voltage – 12VDC , 5A
- Provided Power Supply – Medical grade 12 V power supply – Elpac Power Systems, Model: MW6512 or MW6512-D5F-NC-WH
- Power Cord – Detachable 13 amp, approx. 3.5 meters, CardioMEMS part number: CS-000015 (Hospital), CS-001145 (Home)

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.

Processing Capabilities

- Processor Clock Speed – 500 MHz (Hospital), 200 MHz (Home)
- Memory – 512MB (Hospital), 64 MB (Home)
- I/O – USB, Smart Card (Hospital), Extra VGA, RJ11 phone line (Home)

Mechanical Characteristics

Main Unit

- Weight – approximately 8 pounds
- Dimensions – Height: 11.5 inches Width: 10.5 inches Length: 5.5 inches

Display

- Touch Screen – Resistive
- Brightness – 250 cd/m²
- Resolution – 640 x 480, color

Antenna

(Connects to Main Unit as shown in Figure 5)

- Weight – approximately 4 pounds
- Diameter – 9 inches
- Cable Composition – Bundle includes two RG178 cables, two twisted pair, 22 gauge, and ten 24 gauge single wires, 2.90 meters total length, Bay Associates D-CS-B-000183

Environmental

- Operation: 0° to 40° C (32° to 104° F), 10% to 85% humidity, 850-1150 hPa
- Transportation: -20° to 60° C (-4° to 140° F), 10% to 95% humidity, 850-1150 hPa
- Storage: 5 to 60° C (41° to 140° F), 20% to 85% humidity, 850-1150 hPa

System Testing

The I2-6000 was issued an ETL/cETL Listing Mark and is cleared for marketing by the FDA.

Classification

- Class II equipment
- Type B insulation
- Ordinary Equipment IPXX
- Continuous Use

Safety Testing

- IEC 60601-1
- UL 60601-1
- CENELEC EN 60601-1
- CSA C22.2 NO 601.1-M90

EMI/EMC Testing

- CENELEC EN 60601-1-2-2001
- ETSI EN 301 489-1

Wireless Testing

- FCC part 18 (Electronics System)
- FCC part 15 (Sensor)
- ETSI EN 301 489-3
- ETSI EN 302 510
- CISPR 11

Software

IEC 60601-1-4 (Computer Software)

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. CardioMEMS, Inc. is 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.

Instructions for Disposal of WEEE by Users in the European Union.

The symbol shown below is on the product or on its packaging, which indicates that this product must not be disposed of with other waste. Instead, it is the user's responsibility to dispose of the waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where the RTTE equipment can be dropped off for recycling, please contact your local city office or your household waste disposal service.





MedPass International Ltd.
Windsor House, Barnett Way
Barnwood, Gloucester, GL4 3RT, United Kingdom



Manufactured by:
CardioMEMS, Inc.
387 Technology Circle NW
Suite 500
Atlanta, Georgia 30313
USA
www.cardiomems.com



10/2011
LA-400236-02

Atlanta, GA 30313
Tel. 866-240-3335

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The Champion HF Monitoring System is covered by the following U.S. Patents:
7,261,036; 7,245,117; 7,439,723; 7,432,723; 7,492,144; 7,550,978; 7,595,647. Other
US and OUS Patents Pending
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Inc. *Champion* is a trademark of CardioMEMS, Inc. All intellectual property rights and
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Zestril is a trademark of the AstraZenaca group of companies
Prinivil is a registered trademark of Merck & CO., Inc.
Coreg is a registered trademark of GlaxoSmithKline
Lasik is a registered trademark of Sanofi-Aventis U.S. LLC.
Aldactone is a registered trademark of Pzifer
Imdur is a registered trademark of Schering-Plough Corp.
Swan-Ganz is a registered trademark of Edwards Lifesciences Corporation





Patient Instructions



Champion™ HF Monitoring System

COMPONENTS OF THE HF MONITORING SYSTEM

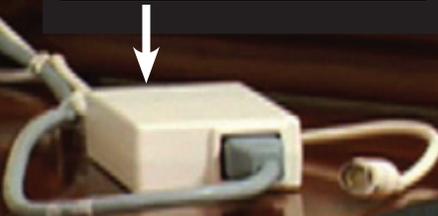
Electronics Unit



Pillow with gray cable



Power Adapter



Telephone Line and Splitter
(Standard Telephone System Only)



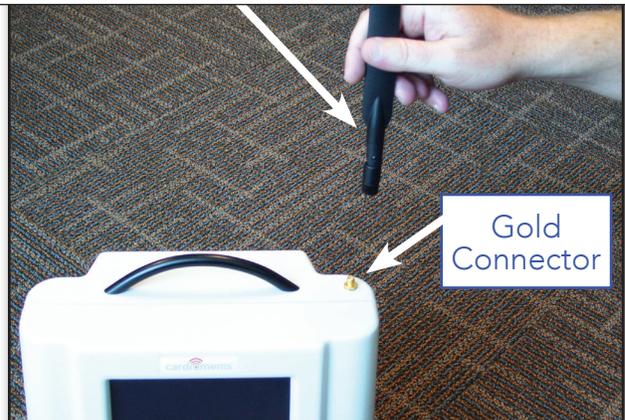
Remote Button



Power Button



Wireless Antenna
(Wireless Telephone System Only)



Gold Connector



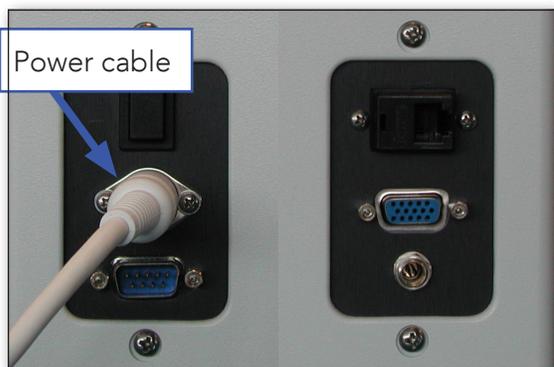
ASSEMBLY



- 1** Remove the white pillow with the gray cable and place it where you will lie down to take your readings. The embroidered CardioMEMS logo should face upwards, and the thickest part of the pillow will be under your head during the readings.



- 2** Place the electronics unit on a flat surface within 4-5 feet of the pillow. At the end of the gray cable is a connector. Press it firmly into the side of the electronics unit by lining up the two alignment marks. Secure the cable by rotating the connector clockwise until it stops.

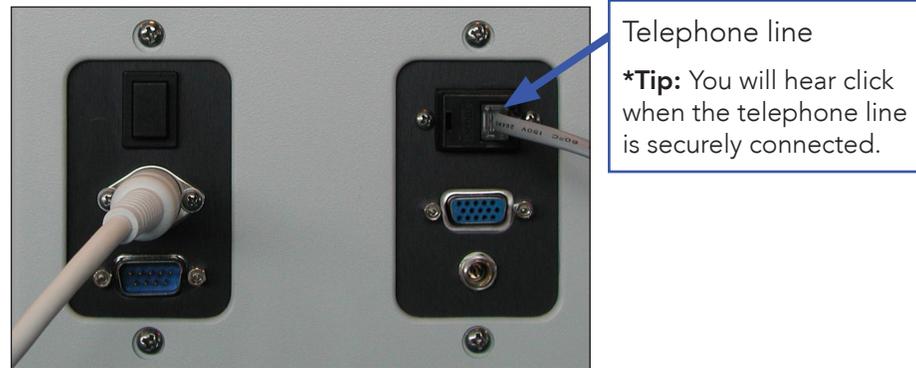


- 3** The white cable connected to the white power adapter can be inserted into the electronics unit (see blue arrow above for location). The three pronged plug attached to the white power adapter can now be connected into the power outlet in your wall.



- 4** At the end of the remote button cable is a connector. Insert this small, metal connector directly into the side of the electronics unit by aligning the two alignment markers.

ASSEMBLY



- 5 Perform this step if you are using Standard Telephone System. One end of the telephone line can be inserted into the back of the electronics unit (see blue arrow above for location). Then insert the other end into a telephone jack in your wall. The phone splitter may be used if the telephone jack already has a phone line connected to it.

TAKING A READING



1 Press the black switch on the back of the Electronics Unit to turn the power on.



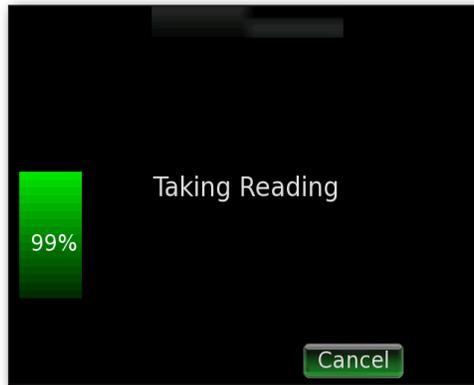
2 Position CardioMEMS pillow where you normally take your reading.



3 Lie down comfortably with your back on the CardioMEMS pillow and relax. Get into the optimal position — the position you are normally in when you get a signal.



4 Once in position, press the remote button. The voice prompt will guide you through the reading. After a few seconds, the system will say “Good Signal”. If you are having trouble acquiring a signal and you hear high or low pitched tones, refer to Troubleshooting Tip #3 on the following page.



5 **Taking Reading** message will appear on the screen and the system will say “Taking Reading”. Lie still for about 18 seconds while the music is playing.



6 When the reading is finished, the music will stop and the screen above appears. When you see this, you may get up and continue with your day.

7 When the reading is complete and has been sent to your doctor, the electronics unit will turn off automatically. Unit can now be put away.

TROUBLESHOOTING TIPS

Tip #1



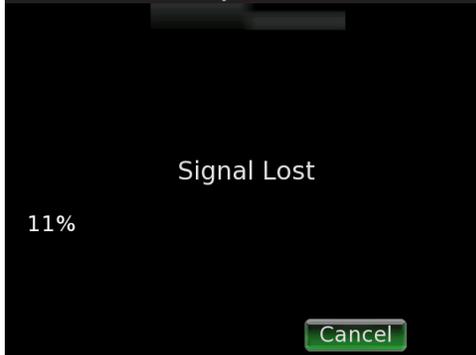
If the green bar does not appear when lying on the antenna, tighten the connection from the antenna to the electronics unit.

Tip #2



If the system presents a screen indicating a communication error: for standard telephone system (a), ensure that the telephone connection is secured at the back of the electronics unit and at the wall. The electronic unit will continue redialing automatically. For wireless telephone system (b), tighten the wireless antenna connection to the gold connector on the top of the electronics unit.

Tip #3



If the green signal bar is moving, and you are not hearing the good signal voice prompt, or the bar is a color other than green, then continue to reposition yourself on the pillow until the green bar rises.

The tones you are hearing are meant to guide you to the appropriate position. Higher pitched tones indicate you are closer to the optimal position. Move your body until you hear the highest tone and the] system will say "Good Signal, Taking Reading." After 5 minutes, the system will stop trying to take a reading and will prompt to continue back to the 'Start' screen.

Tip #4



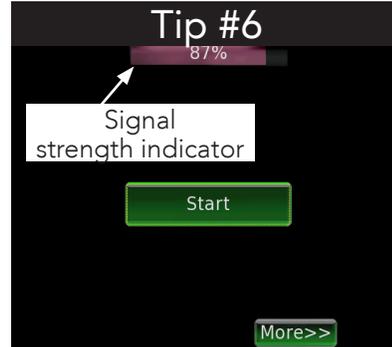
If the unit will not turn on when the power button is pressed, examine the connections to the power adapter. The green light on the power adapter will light up when properly connected.

Tip #5



If this screen appears, ensure that there are no metal objects such as jewelry or belts near you or the pillow. Press the green **Continue** rectangle on the screen to begin the process of repeating the reading. If you are still having difficulty, please call CardioMEMS Technical Support.

Tip #6



For Wireless Unit: As with a cellular phone, signal strength is important in transmitting data to your physician. If you are having problems transmitting a reading and the signal strength indicator is low (less than 50%), move the system to another location within your house. If the problem continues, note the signal strength and call CardioMEMS Technical Support.

CLEANING AND REPACKING

Cleaning



- 1 Turn off and unplug from the wall.**
The pillowcase may be machine washed and the flat plastic pillow may be wiped with a damp cloth using mild detergent. Cables and the electronics unit may be surface cleaned only. Do not spray any fluid onto the unit or allow fluid to seep into it.



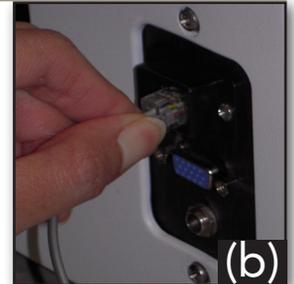
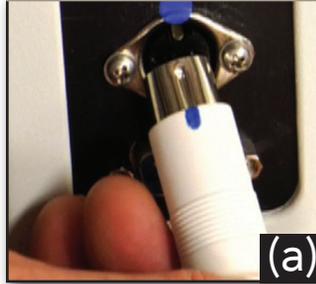
- 3** Identify the location on the side of the electronics unit where the gray cable from the pillow attaches. Rotate the black connector counterclockwise to detach the cable.



- 5** The pillow and gray cable should be lifted together and placed into the carrying case. Coil the gray cable into the case first, on top of the other cables, and then place the pillow, embroidered CardioMEMS logo down, on top of both the electronics unit and the cables to protect them during transport. Place your documentation in the carrying case and zip the carrying case to close.

Repacking

If you are traveling, you will need to place your unit back into the suitcase that was supplied with the unit.



- 2** Detach the white power cord (a) and the remote button from the side of the electronics unit. For Standard Telephone System, detach the thin, flat telephone wire from the back of the electronics unit (b) and from the wall. Pack these items into the bottom of the carrying case.



- 4** Gently lift the electronics unit and place it securely into the carrying case.

DEVICE IMPLANT INFORMATION FOR PATIENTS

cardiomems™

CHAMPION™

HF Monitoring System



Components of the Champion™ HF Monitoring System

The Champion™ HF Monitoring System wirelessly measures and monitors pulmonary artery pressure. The system consists of 3 components: a) sensor/monitor b) patient electronics and c) patient database.

a. Sensor/Monitor



CardioMEMS Sensor/Monitor

The sensor is about the size of small paper clip and has a thin wire loop at each end. It is placed inside your pulmonary artery (one of the vessels close to the heart) with a special delivery catheter.

b. Patient Electronics

Without the use of any batteries or leads, this sensor will wirelessly communicate the pressure measurement to an external Electronics Unit. To communicate with the electronics, the sensor uses a radio-frequency (RF) signal.



c. Patient Database

This pressure measurement is recorded and sent automatically through a telephone line to a secure database where they can be reviewed by your physician.

Sensor Implant

The sensor will be implanted during a standard right heart catheterization (RHC). The RHC has been done routinely since the late 1960's and several hundred thousand procedures are performed per year. As part of the clinical trial for the HF Monitoring System, approximately 600 sensors were implanted.

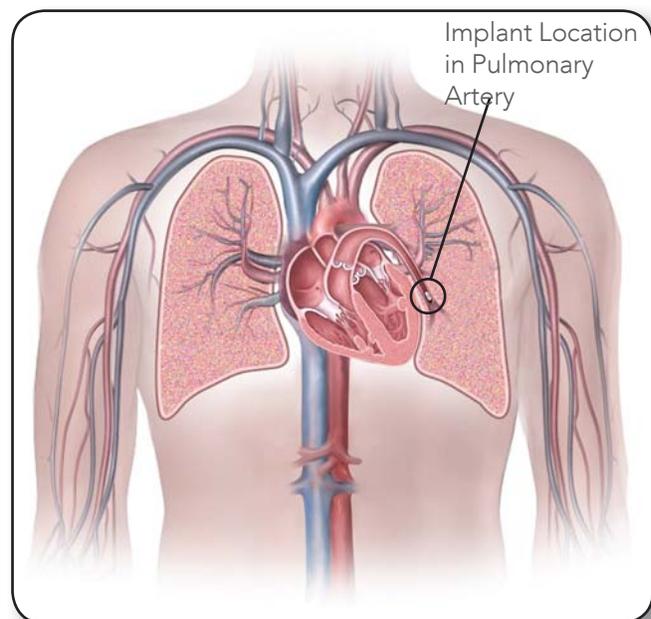
You may receive a mild sedative before and/or during the procedure but you will be awake so you can follow instructions. An area on your groin will be cleansed with sterile cleanser and a local anesthetic (numbing) medicine will be injected at that site.

There are two parts to the procedure, RHC and implant of the sensor. The RHC is performed as follows:

- A Swan Ganz catheter is introduced into your groin
- Once the catheter is in the pulmonary artery, a small amount of contrast material (dye) is injected
- Pictures are taken to make sure the catheter is in the right position and to make sure the branch of pulmonary artery meets the implant criteria
- If the doctor determines that the pulmonary artery is unsuitable for receiving the sensor, the second part of the procedure will not be performed

The sensor implant consists of the following:

- Delivery catheter with the sensor attached is threaded into your pulmonary artery over a guidewire
- The sensor is positioned into the pulmonary artery and confirmed by x-ray to be in the correct position
- Once the position is confirmed, the sensor is released
- The delivery catheter is removed and the RHC is reinserted
- The doctor will take a pressure measurement using the RHC and the HF monitoring system
- Once the pressure measurements are confirmed, the RHC is removed



The procedure may last up to one hour. After the procedure is completed, you may be asked to lay flat on your back for a few hours, to prevent any bleeding from the catheter insertion site. You may experience some discomfort from the catheter insertion site as you recover from the procedure. You should be able to return to normal activities soon after the procedure.

Implant Risks

As with any medical procedure, it is important to understand that, while complications do not happen very often, there are risks associated with the implantation of a device. You should talk with your doctor about these risks, including those listed below. Some of the possible risks are also complications associated with a heart catheterization and/or drugs associated with the procedure and blood thinning medications. Some of these risks include but are not limited to:

- Air embolism (air bubble in the bloodstream)
- Allergic reaction
- Abnormal heart rate or rhythm
- Bleeding
- Bruising
- Chest Pain
- Nausea
- Stroke
- Infection
- Delayed wound healing
- Thrombus formation (blood clots)
- Hematoma (collection of blood internally)
- Venous trauma (injury to your veins)
- Valve damage
- Pulmonary infarct (damage to the lung)
- Pulmonary embolism (blood clot to the lung)
- Death

Some of the side effects that you may experience will go away shortly after the procedure, but in other cases side effects can be serious, long lasting, and/or permanent. 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.

After Your Implant

As you recover from your implant procedure, it is important that you become actively involved in your recovery by following your doctor's instructions including:

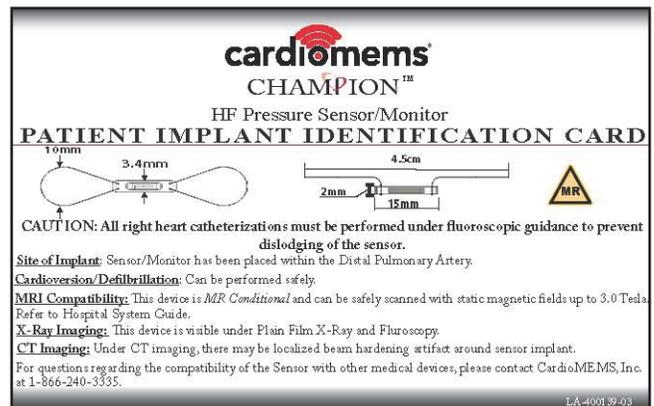
- Report any redness, swelling, or drainage from your insertion site in your groin area
- Walk, exercise, and bathe according to your doctor's instructions
- Contact your doctor if you develop a fever that does not go away in two or three days
- Ask your doctor any questions you may have about your device,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

You will receive training about how to set-up and take daily readings with your home electronics before going home. A customer service representative will be available should you have any questions after you go home.

Your Sensor Information

Have your doctor or nurse complete the CardioMEMS Patient Implant Identification Card before you go home from the hospital. This card was developed to provide 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.

After the sensor implant, always carry your CardioMEMS Patient Implant Identification Card with you. The card will alert medical and security personnel that you have an implanted device. Your card contains your name, your doctor's name and hospital, and the implant date and serial number of your device.



Patient Name:	_____
Implant Date:	_____
Sensor Location: () Right or () Left PA	_____
Heart Failure Physician:	_____
Heart Failure Physician Phone:	_____
Sensor/Monitor Serial Number:	_____
Calibration Code:	_____
Offset Code: O/ /	_____
Please carry this card with you at all times and show it to any medical personnel who may care for you.	
For more information, your physician may contact CardioMEMS, Inc. at: 1-866-240-3335 CardioMEMS, Inc. Atlanta, Georgia 30313 USA www.cardiomems.com	
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