CardioMEMS™ HERO Device
(HEart Remote Observation)
Model CM1200

Instructions for Use

Abbott

Indications

The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and 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.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Contents

Introduction

You have been diagnosed with heart failure (HF). 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.

Heart failure (HF) affects over 64 million people worldwide, accounts for more than 1 million hospital admissions annually in the United States (US) and Europe, and is associated with high societal and economic costs. It is one of the most common reasons for hospitalization in people over 70 years of age.[1]

When is the CardioMEMS™ HF System used?

Your clinician has determined that you might benefit from the information obtained by the CardioMEMS ™ HF System because you have heart failure and would benefit from monitoring the pressures in your heart, since you are at an increased risk of hospitalization.

What is the purpose of the CardioMEMS™ HF System?

The CardioMEMS HF System uses an implanted sensor to monitor the pressure in your pulmonary artery (PA). Your clinician can use pulmonary artery pressures to make informed decisions about your heart failure treatment, including whether to change critical medications. You will take a sensor reading each day from home using the HERO Device, which sends the information to your clinician. After analyzing the information, your clinician may contact you to 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 your device. This guide will explain how to set up the HERO Device in your home and how to take a daily reading. It will talk about some of the changes that may occur in your life and answer many of the questions you may have about using your device. If you have questions about what you read in this guide, discuss them with your clinical care team. They are your best resources for information.

The CardioMEMS™ HF System includes the following components:

Figure 1. Pulmonary Artery (PA) Sensor (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 a small paper clip and has a thin, curved wire at each end. This sensor does not require any batteries. The sensor is able to measure changes in pressure in your pulmonary artery and send the information to your care team when used with the CardioMEMS HERO Device.

The HERO Device wirelessly captures PA pressure measurements and heart rate from your PA Sensor and transmits the information to your clinician.

The pressure in the vessels around your heart changes before you feel any Heart Failure symptoms. These early pressure changes can be detected by the CardioMEMS PA Sensor, helping your clinician to make changes to your medications before your heart failure gets worse. It is important to follow all directions your clinician gives you, even if you are not feeling well.

The system includes the following components:

- Antenna Pad with Fabric Cover
- Controller
- Power Adapter
- Power Cord
- Power Cord Clip
- Controller Strap

[1] Savarese, et.al. ESC Cardiovascular Research. 2022; 118, 3272-3287

- Orientation Ball
- Zipper Pull

Precautions

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

- Do not place the HERO Device 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 HERO Device.
- Do not expose the HERO Device to excessive vibration, impact, or rough handling.
- Allow the cover to air dry after washing it (hand wash or machine gentle cycle). Do not place the cover in a clothes dryer.
- To avoid potential damage caused by lightning, unplug the HERO Device during electrical storms.
- Allow the HERO Device to shut-down automatically. Failure to do so may corrupt the files.
- Exposure to excess lint, dust, or corrosive materials may result in a malfunction.
- The HERO Device 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 the next time the device is powered on and internet connectivity is available.
- Avoid a system reset. A reset erases all data from your HERO Device and makes your device unusable until it is re-configured.
- The accuracy of the system may be affected by various factors. If your clinician suspects that the PA Sensor pressure readings may not be accurate, the use of the pressure information may be temporarily suspended. Recalibration of the PA Sensor may be necessary to continue use of the system. Recalibration of the PA Sensor may require the performance of a right heart catheterization procedure.
- The touchscreen display on the controller can be sensitive to electrostatic discharge (ESD) at high levels. To reduce the potential for ESD discharge to the touchscreen, store the controller inside the fabric cover between each use.
- If the touchscreen becomes damaged due to ESD, the screen will be discolored or may be unresponsive. Contact Technical Support for replacement options.
- Please note that high levels of ESD are more likely in situations where the relative humidity is very low, such as inside a heated building during the winter in areas where it is cold outside. In order to reduce the potential for high levels of ESD, there are common situations which create static electricity that can be avoided prior to use, for example, putting on and removing clothes, dragging your feet across a carpet or rug, vacuuming, or removing clothes from a dryer.
- The HERO Device is not intended to be used in a severe electromagnetic radiation environment or an industrial environment.
- The HERO Device should not be used in conjunction with devices emitting large magnetic fields, such as Magnetic Resonance Imaging (MRI), Radio Frequency Identification (RFID), and electromagnetic security systems such as metal detectors. The HERO Device should also not be used in conjunction with computerized axial tomography (CT) or diathermy.

Warnings

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

- Using someone else's HERO Device could result in inappropriate medication treatment and could result in serious injury or death.

- Do not attempt to service or modify while in use unless directed by Abbott. The HERO Device should be off during service.
- If any of the following occurs, immediately unplug the HERO Device and call Technical Support at 1 844 692 6367 (1 844 MY CMEMS):
  - Any cords are noticeably frayed or damaged.
  - Liquid has been spilled onto the HERO Device, or it has been exposed to rain.
  - The HERO Device has been dropped or damaged.
  - If you lose or damage the power cord, you must replace it with an identical power cord from Abbott. Contact Technical Support.
- Do not kink, sharply bend, or crush cables, including wrapping the power cable around the power adapter, which may lead to cable fraying or damage.
- Medical Electrical Equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be used according to the EMC information provided. If interference is noted, remove or stop using the interfering equipment.
- Portable and mobile wireless communications equipment can affect medical electrical equipment and may cause a malfunction of the system.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The use of attachable parts other than the parts provided may result in inaccurate readings, damage to the system, or injury to the user.
- The HERO Device should not be used adjacent to or stacked with other electronic equipment. If it is necessary to operate it adjacent to or stacked with other equipment, verify that the HERO Device is operating normally in the configuration in which it will be used.
- 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.
- If two devices are close to each other and are used at the same time, pressure measurements may be affected due to interference between the two systems. In such isolated cases, it is recommended that operation of each device occur at separate times.
- While in use, ensure that the power supply is easily accessible since unplugging the HERO Device from the outlet is the only means of completely isolating it from the power source.
- Do not attempt to connect the HERO Device 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 clinician.
- Keep the HERO Device 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 HERO Device or Controller to any other electronic equipment.
- Do not change the computer configuration without authorization. Changes to the configuration may result in inaccurate information.
- Do not use USB ports for anything other than updating with an Abbott-provided drive.
- Do not use the HERO Device in oxygen-rich environments; do not use with flammable anesthetics.
- The patient is the intended operator, except in case of patients that require special assistance.

About the CardioMEMS™ HERO Device

The HERO Device reads the pressure measurement from your PA Sensor wirelessly. The Controller has a touchscreen which can be used to set up the unit and change settings. The system uses either cellular or Wi-Fi‡ to transmit information to your clinician.

The HERO Device consists of:

- Antenna Pad
- Controller
- Power Adapter
- Power Cord
- Power Cord Clip
- Controller Strap
- Orientation Ball
- Zipper Pull

NOTE: The Antenna Pad comes with a fabric cover that can be removed for cleaning. The Antenna Pad should not be used without the fabric cover in place.

Figure 2. Antenna Pad (Includes Non-Detachable Controller)

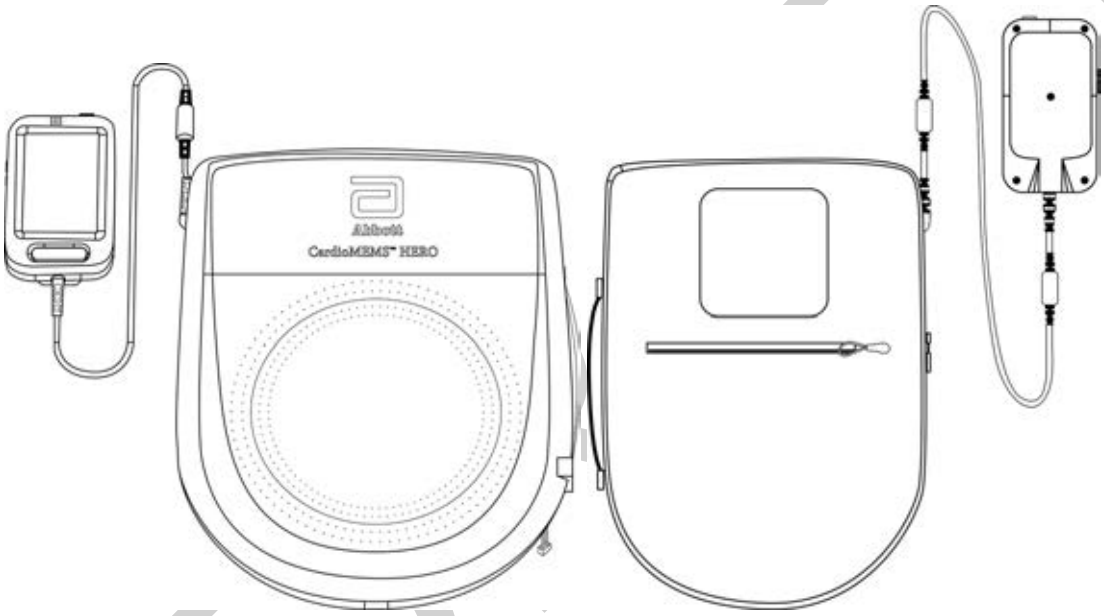


Figure 3. Controller

Figure 4. Power Adapter

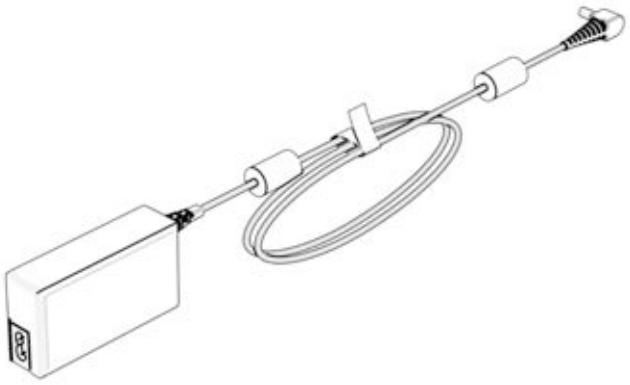


Figure 5. Power Cord

Figure 6. Power Cord Clip

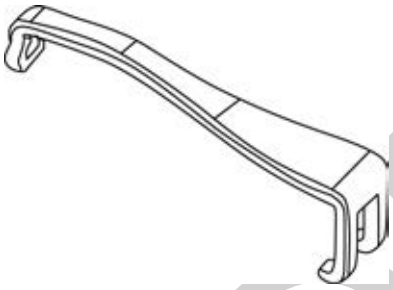


Figure 7. Controller Strap

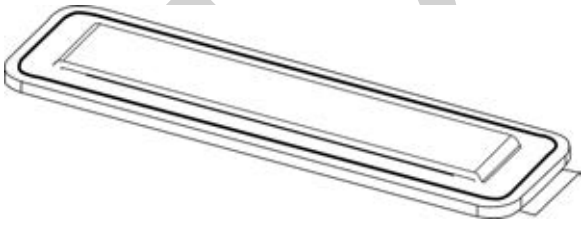
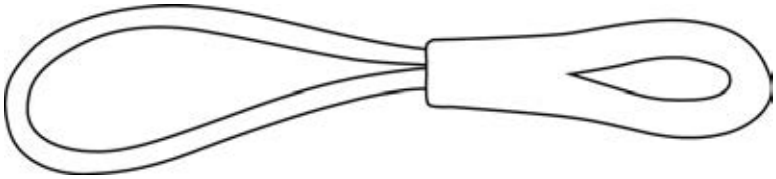


Figure 8. Orientation Ball

Figure 9. Zipper Pull

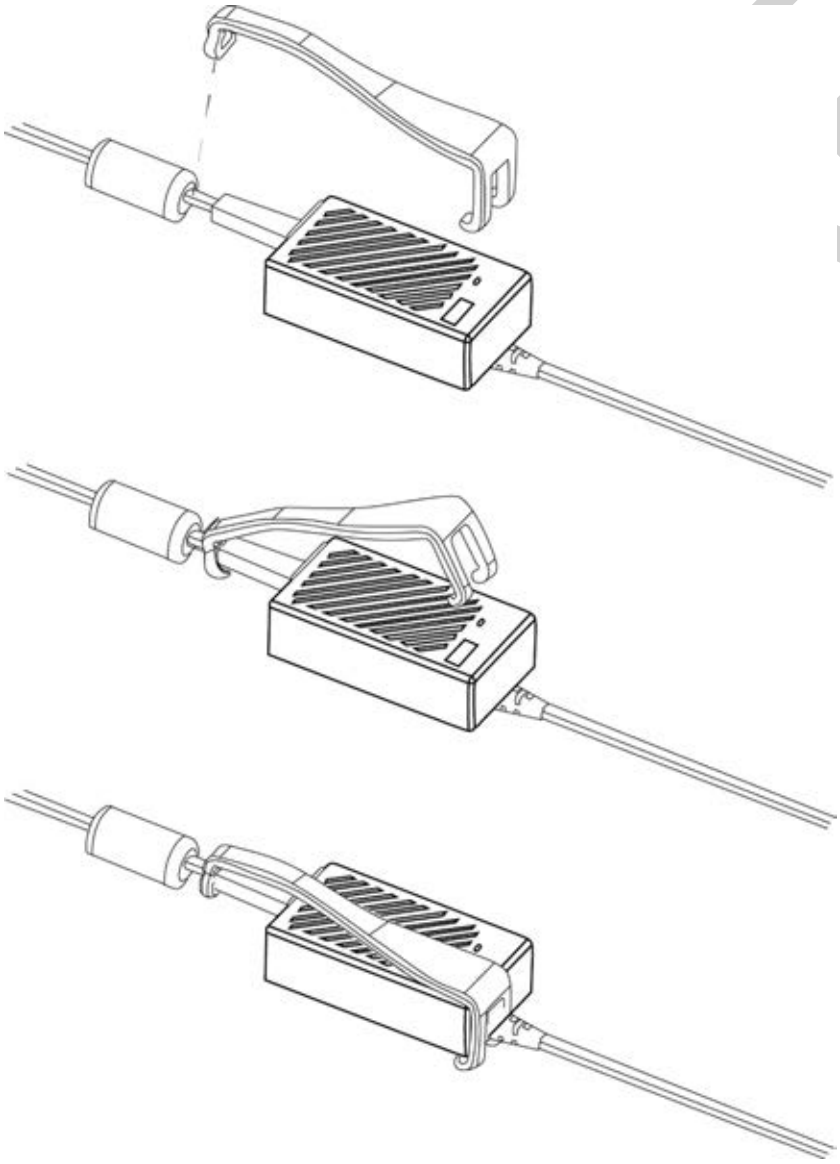


Setting Up the CardioMEMS™ HERO Device

1. Locate the power adapter, power cord and power cord clip.
2. Inspect the cables prior to each use to make sure they are not frayed or damaged.

   WARNING: If any cords are noticeably frayed or damaged, immediately unplug the HERO Device and call Technical Support.
3. Insert the power cord into the power adapter.
4. Attach the included power cord clip onto the power adapter. Position the small hook of the clip on the thinnest section between power adapter and the power cord. Place the double hook on the other side of the adapter so the cable is placed between the two hooks. The clip goes over the black-stripped side of the power adapter.

   NOTE: Make sure the power cord clip does not cover the label on the power adapter.

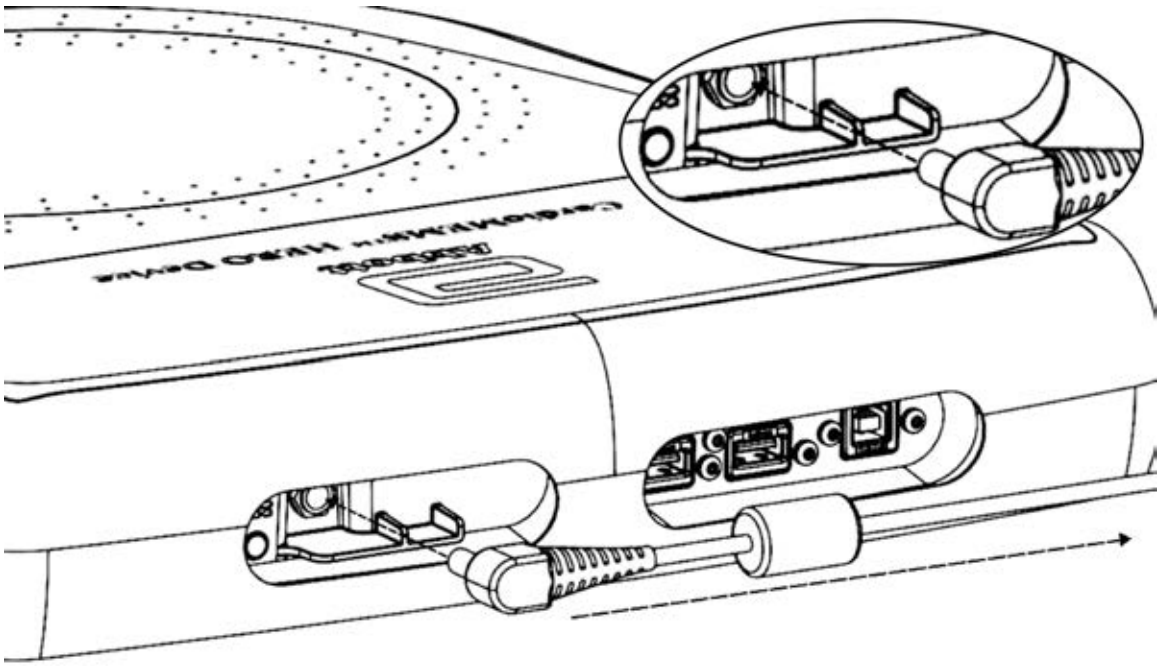


5. Plug the power adapter cord into the power cable port on the top edge of the antenna pad. Make sure to push the connector all the way in.

6. Plug the power cord into an outlet.
7. If desired, attach the controller strap to your preferred location by removing the liner and pressing the adhesive part of the strap to the back of the controller.

   NOTE: Once the controller strap is in position, press firmly to ensure the adhesive is secure and the strap does not detach from the controller.

Figure 10. Power Cable Port



User Interface With Your HERO Device

Review the user interface icons and elements of your HERO Device controller before configuration.

Figure 11. Status Icons

Icon	Meaning
	Mute
	Cellular
	Wi-Fi®

Once your device is turned on, review the icons of your HERO Device before you continue setting up your device.

Figure 12. Action Icons

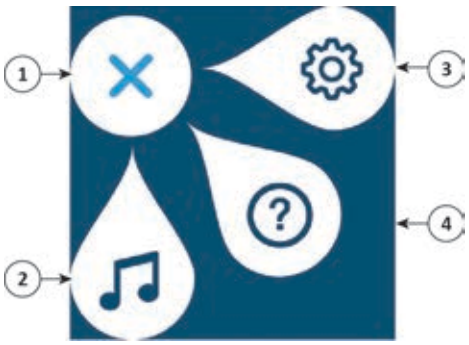
Control element	Meaning
	System menu
	Exit system menu
	Previous screen
	Next screen

Certain action icons are used on various screens. Not all action icons are used on every screen, and some screens have no control elements at all.

The system menu icon expands to display four icons:

NOTE: Options selected from within a list on the Controller are shown in bold type.

Figure 13. System Icons



1. Exit: Close the system menu.
2. Sounds: Control sounds that play when taking a reading.
3. Settings: Actions include set up of language, internet connection, system information, advanced settings, send saved readings and system reset.

   NOTE: Settings are not intended for daily use. Adjust connection settings only if your home Wi-Fi network or cellular connectivity has changed. System information, advanced settings and system reset are intended for use only when you are speaking with a Technical Support representative.
4. Help: Opens a list of help resources.

Customize and Connect Your HERO Device

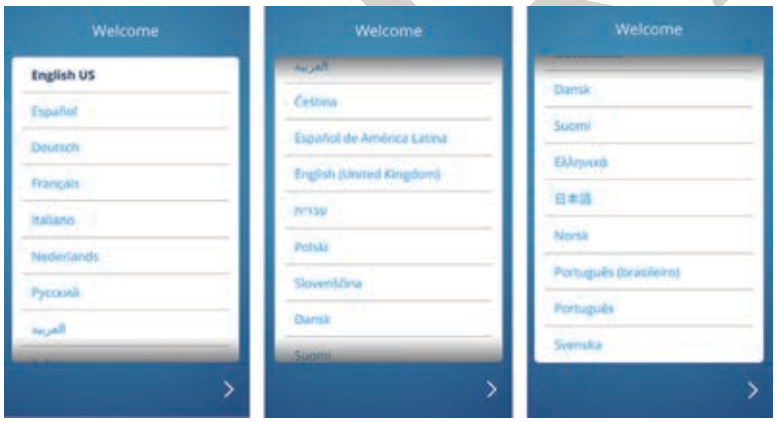
1. Connect the HERO Device to the power outlet.
2. Press the power button on the Controller.

   The HERO Device will automatically guide you to set up your device if it has not been connected to a PA Sensor. This set up process begins with a request to choose your preferred language.
3. Choose your language on the select language screen.

   NOTE: If you change the language, the system restarts.

   To change screens, use the next (right arrow) and back (left arrow) located in the bottom corners of the screens.

Figure 14. Select Language screen



4. Enter your PA Sensor serial number (provided on your patient ID card) and the year of your birth on the Confirmation screen. The birth year must be four digits. Press the next button (right arrow) at the bottom right of the screen.

   After entering the PA sensor serial number and birth year, the HERO Device checks for internet connectivity.

   The CardioMEMS™ HERO Device has two modes of internet connectivity: cellular and Wi-Fi. The HERO Device automatically tries to connect to a cellular network when it is powered on. If a cellular connection is unavailable, the HERO Device guides you through configuring a Wi-Fi‡ connection.

5. The Confirmation screen displays your sensor, serial number, the first three letters of your first name followed by the first three letters of your last name, and your birth year.

   To confirm your information is correct, press Yes on the confirmation screen. If the information is incorrect, press No on the confirmation screen. Update your information as needed.

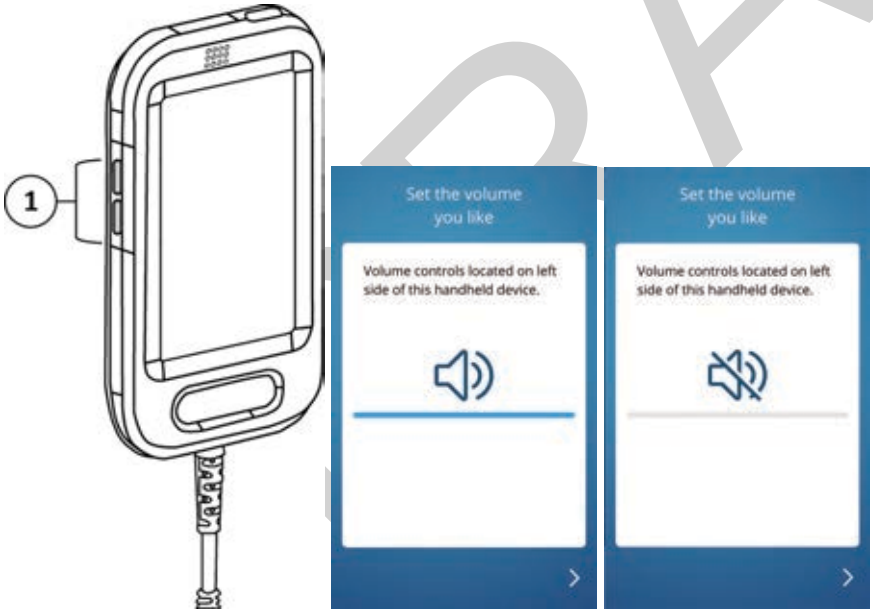
   NOTE: Once the configuration is complete, the system restarts.

   NOTE: If connectivity to a cellular or Wi-Fi is unavailable for your device, follow the Manual Setup section.

Figure 15. Confirmation screen

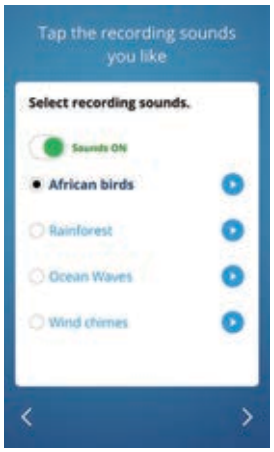
6. To set the system volume, press the buttons on the left side of the controller. The upper button raises the volume, and the lower button lowers the volume. To mute the system, continuously press the lower button. The volume setting also displays on the screen.

Figure 16. Volume Control



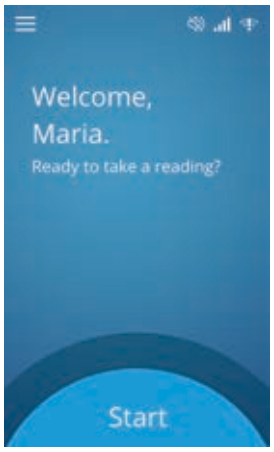
7. Select the preferred recording sound your device plays during your sensor readings. To turn the recording sounds off, toggle the sound off and navigate to the next screen.

Figure 17. Recording Sounds



When the set up is complete, the Welcome screen displays.

Figure 18. Welcome screen



Setting up a Wi-Fi Connection

The system automatically connects to a cellular network when it is powered on. If a cellular connection is unavailable when setting up the HERO Device or sending readings, the system guides you through configuring a Wi-Fi‡ connection. To access connection settings, press the menu icon and then the settings icon. Select Connection from the settings menu. Select Wi-Fi on the connection screen.

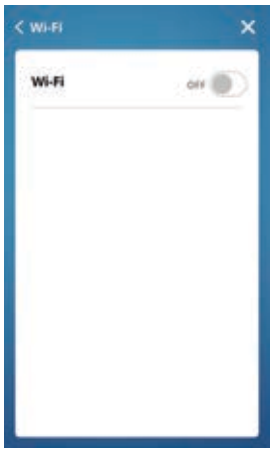
NOTE: Prior to setting up the Wi-Fi connection on your system, locate and write down your Wi-Fi network name and password. If you cannot find it, call your Internet service provider for assistance.

1. Allow your HERO Device to find your Wi-Fi network by switching the Wi-Fi toggle to On. The toggle will turn green.

   NOTE: If a Wi-Fi network is available, Wi-Fi connection is preferred for daily use.

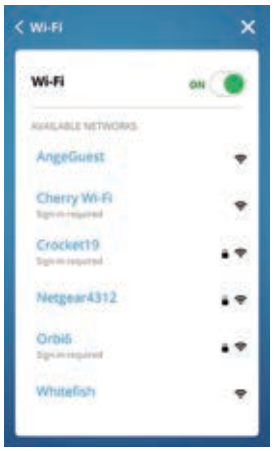
   NOTE: The CardioMEMS™ HERO Device only shows and connects to password protected Wi-Fi networks.

Figure 19. Wi-Fi On



2. Choose your Wi-Fi network.

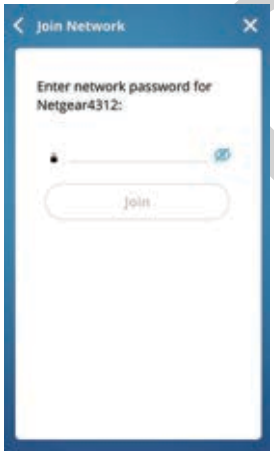
Figure 20. Choose Wi-Fi



3. Enter the network password.

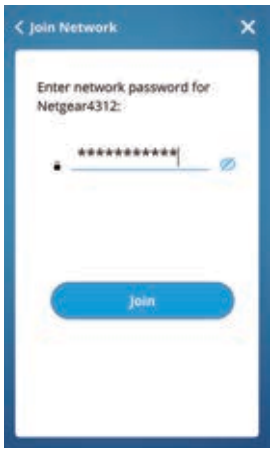
   NOTE: To see the password as you type, press the eye icon on the enter password screen. To hide the password, press the eye icon twice.

Figure 21. Enter Password



4. Press the join or OK button on the screen. If you press the OK button first, click the button on the lower right corner to display and click the Join button.

Figure 22. Join Network

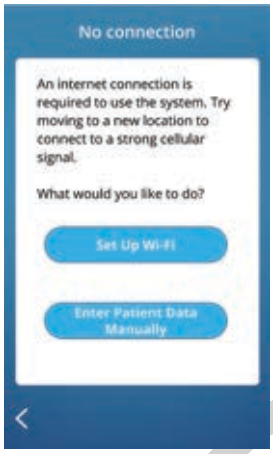


Manual Setup

This section explains how to manually set up your HERO Device without internet connectivity. If network connectivity is unavailable and you are not able to connect your device to your sensor, follow these methods.

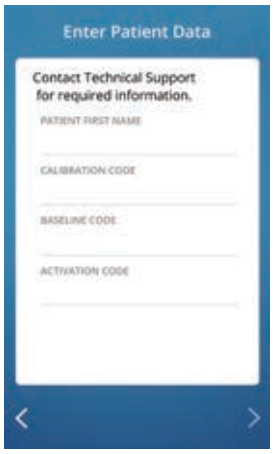
NOTE: Before trying to manually set up, try to setup using the Customize and Connect Your HERO Device section.

Figure 23. No internet connectivity



1. To continue with manual setup, choose the Enter Patient Data Manually option.
2. If you do not know calibration, baseline and activation codes, call Abbott Technical Support. The Technical Support team will verify your identity before sharing this information.
3. Enter patient information into the fields and continue setup as described in the Customize and Connect Your HERO Device section.

Figure 24. Manual set up



Daily Use

1. Ensure the antenna pad cover is in place. Press and hold the power button and turn on the HERO Device.

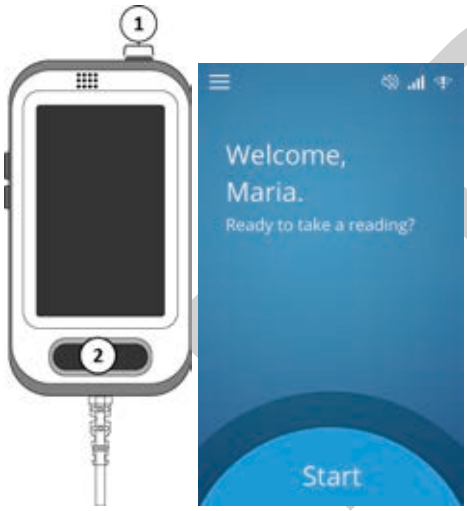
   When your HERO Device is powered on and ready, you will see the Welcome screen. A green light appears next to the power connector on top of the antenna pad. If your system has not been set up, follow the instructions in the Customize and Connect Your HERO Device section.

2. Lie down on the antenna pad as directed by your clinician or Abbott support representative.

   NOTE: Most people will have the strongest fastest sensor connection when they position their implanted sensor over the circle on the antenna pad.

   NOTE: The HERO Device powers down automatically after several minutes.

Figure 25. Power button (1), start button (2) and reading ready screen



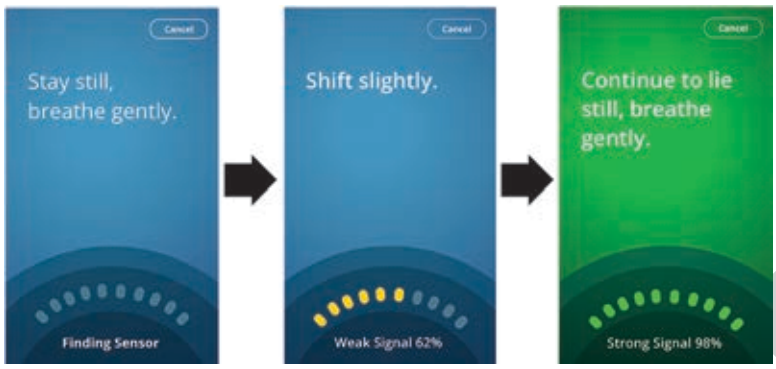
After a moment, you will be asked to take a reading. To verify you are using your own device before taking a reading, check your name on the Welcome screen.

WARNING: Failure to use your own device could result in inappropriate medication treatment and could result in serious injury or death.

NOTE: To help mark your unique HERO Device, zipper pulls in different colors are provided.

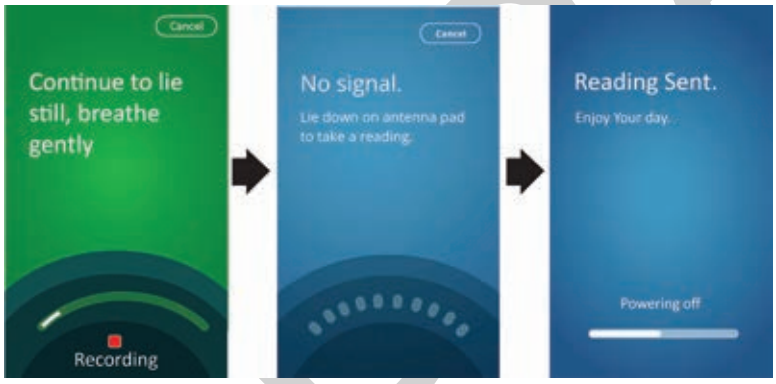
1. To begin, press Start or the blue button on the front of the Controller button on the screen.
   The screen displays instructions on both blue and green backgrounds. The blue background indicates the system is searching for a strong signal from your PA Sensor, and a search tone plays. More ovals will turn yellow as the signal strength increases. The green background is shown and green ovals show strong signal after a strong PA Sensor signal has been detected. Recording sounds play when the signal is strong. If a strong signal is not detected, change your body position by making slight movements toward the opposite shoulder of your sensor location. The HERO Device may take a moment to find your sensor after you shift position. Pause a few breaths before moving again. Breathe gently and remain still until the recording completes. Call Technical Support if you are unable to maintain a strong signal strength.
2. Follow the Instruction screens.

Figure 26. Instruction screens



3. When the reading is complete, the screen will tell you that you may get up. Do not turn off the system.
   The system will begin sending your data to your clinician. Once the system has successfully sent your data, the Reading Sent screen displays and the system powers off.

Figure 27. Recording and reading sent screens



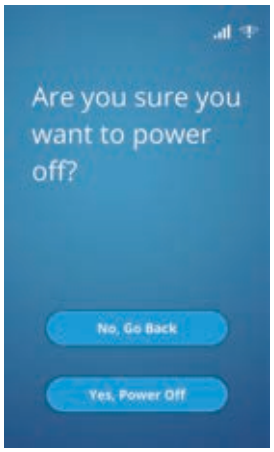
If you have difficulty hearing the voice prompts, follow the instructions on the screen or have someone assist you in taking your reading. If you have difficulty seeing the instructions on the screen, follow the voice prompts or have someone assist you in taking your reading.

Turning Off Your HERO Device

The HERO Device powers off automatically after you have completed a reading.

In case you need to power off your device manually, briefly press the power button on top of the controller for three seconds, then choose the Yes, Power Off option on the screen. The device turns off.

Figure 28. Turning off your HERO Device



NOTE: Follow the above process to turn off your device. It is not recommended to use a continuous press and hold to turn off your device.

Sensor Implantation

Before the Implant Procedure

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

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

Prior to the implant procedure, your clinician 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 clinician about these risks before undergoing the medical procedure. Some of these risks include but are not limited to:

- Air Embolism
- Allergic Reaction
- Arrhythmias
- Bleeding
- Cardiovascular Injury
- Cardiac Perforation
- Cerebrovascular Accident
- Death
- Delayed Wound Healing
- Device Embolism
- Hematoma
- Hemoptysis
- Hemothorax
- Infection

- Myocardial Infarction
- Nausea
- Pneumothorax
- Pulmonary Infarct
- Pulmonary Embolism
- Thermal Burn
- Thoracic Duct Injury
- Thrombus
- Valve Damage

Be sure to talk with your clinician so you thoroughly understand all of the risks and benefits associated with the implantation of the sensor.

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 HERO Device.

Figure 29. PA Sensor (approximate size)

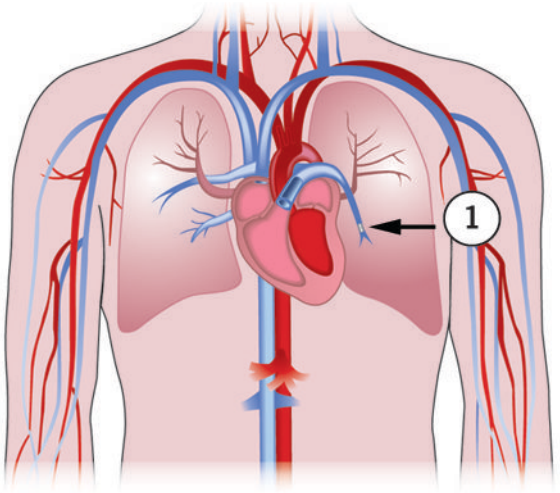
Implant Procedure

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 clinician will clean an area on either your neck or 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 clinician will make a small incision at the site.
5. The clinician will thread a device called a pulmonary artery catheter into your femoral or internal jugular vein. Using a fluoroscope (a type of x-ray), they will thread the PA catheter through your body to your heart and then 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 will be 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 clinician 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 pulmonary artery catheter is removed and the Sensor will remain in your pulmonary artery (see figure below).

Typically, the procedure may last up to one hour. If the clinician 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 PA Sensor.

Figure 30. 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 PA Sensor will not interfere with other implanted devices you may have such as a pacemaker, defibrillator, etc.

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

- Report any redness, swelling, or drainage at the insertion site.
- Walk, exercise, and bathe according to your clinician's instructions.
- Contact your clinician if you develop a fever that does not go away in two or three days.
- Ask your clinician 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 HERO Device. For your convenience, the steps for taking a reading are also provided in an easy to use Quick Start Guide.

Your clinician 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 PA 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. The card also contains your name, your clinician's name, and the serial number 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.

Troubleshooting

This section provides information on how to solve issues you may encounter when using the device. Refer to the instructions below to solve the issue.

Table 1. Initial Setup

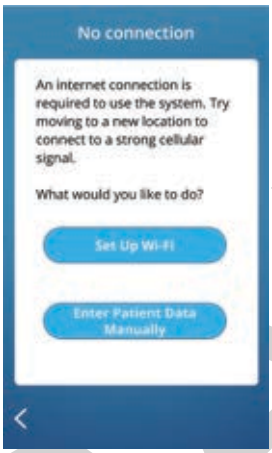
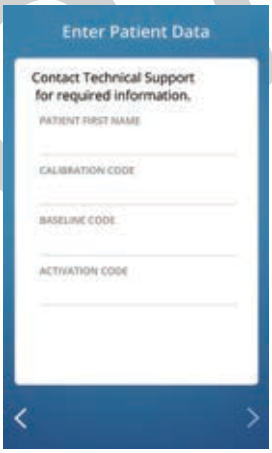
Problem	Symptom	Solution
Record of implanted sensor not found		Verify the correct serial number and birth year on the screen. Correct any errors and try again. If the information you have entered is correct and the problem persists, call Technical Support.
No internet connectivity		If unable to connect to Wi-Fi‡, see the Network Connection section. If cellular or Wi-Fi connection is unavailable, select Enter Patient Data Manually on the No Connection screen (see Manual Set-Up section).
Manual set-up		Select Enter Patient Data. For required information, contact Technical Support. The screen advances when the correct information and format is entered. If there are errors in any field, check the entries with help from Technical Support.

Table 2. Daily Use

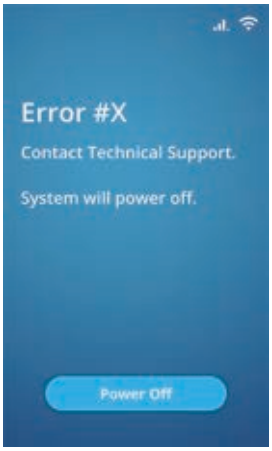
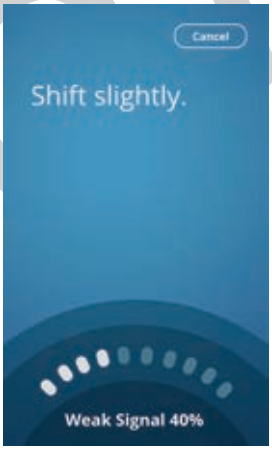
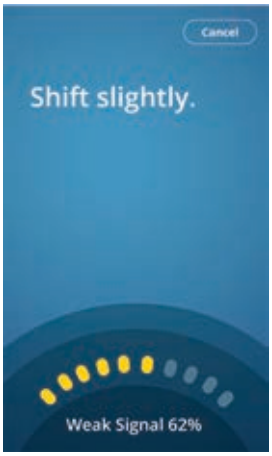
Problem	Symptom	Solution
Startup error		Click Power Off on the Error #X screen. To restart the system, press the power button on the top of the controller. If the problem persists, call Technical Support.
No signal		Lie directly on the device so the connection between the sensor and the device can be established. If the screen is still showing no signal, make sure the correct side of your body (with implanted sensor) is on the device.
Low signal		If a strong signal is not detected, change your body position by making slight movements towards the shoulder opposite of where your sensor is located. The HERO Device may take a moment to find your sensor after you shift position. Pause a few breaths before moving again. Carefully reposition yourself on the device until the screen becomes green.
Weak signal		Carefully reposition yourself on the device until the screen becomes green.

Table 2. Daily Use

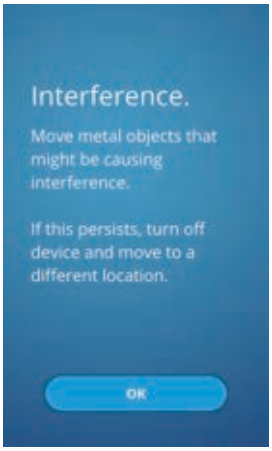
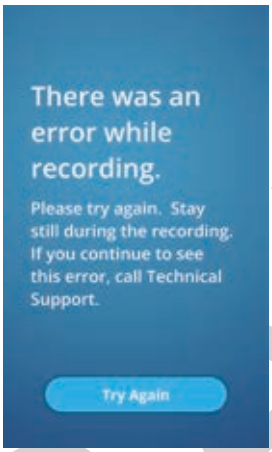
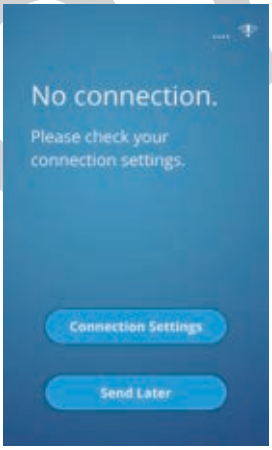
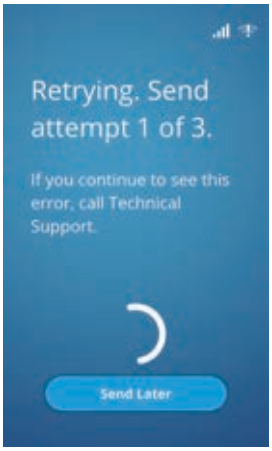
Problem	Symptom	Solution
Interference		Move metal and conductive objects and other electronic devices (such as power supplies, tablets, phones, electric blankets, cables, spring mattresses or box springs, and heating pads) away from your device. Press the OK button to retry. If the problem persists, move to another room (location) and try again.
Recording error		Try to take another reading by pressing the Try Again button. If the problem persists, call Technical Support.
No connection to transmit recordings		Try to connect to the internet. Press Connection Settings and follow the screens. You can also press Send Later to save the recording and the system will try to send the data the next time it is connected to the internet. The system shows Reading saved and powers off automatically.
Difficulty sending recordings		In some cases, although there is an established internet connection, the system is unable to send your readings. After three attempts the system automatically saves your readings and powers off the device. The unsent readings are saved on the HERO Device and sent the next time the system connects. If the problem persists, call Technical Support.

Table 2. Daily Use

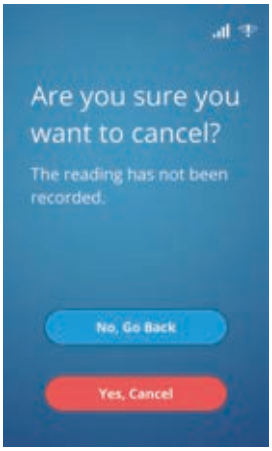
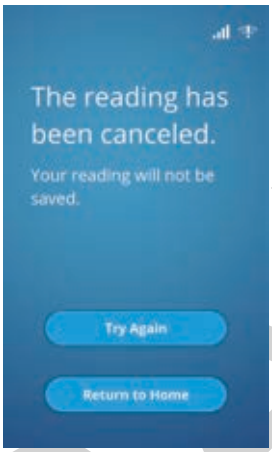
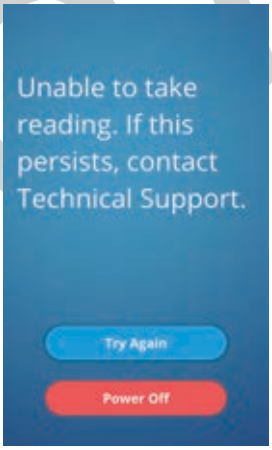
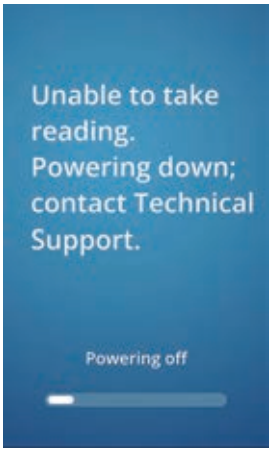
Problem	Symptom	Solution
Cancelling a recording		The recording process may be cancelled at any time during the recording session. To cancel, press the cancel button on the top-right side of the screen. The Cancelling a Recording screen displays.
		If you confirm cancellation by pressing the Yes, Cancel button the Reading has been Cancelled screen displays. You can choose to Return to Home or Try Again.
Unable to take a reading		The device attempts to acquire a strong signal from the sensor for 5 minutes. If the device has tried to acquire a sensor signal for 15 minutes without success, it automatically turns off. If this is the first time seeing this problem, retry and press the Try Again button. The device retrys for another 5 minutes before you see the Unable to take a Reading screen.
		If the device has tried unsuccessfully for 15 minutes, the system automatically powers off. If the problem persists, call Technical Support.

Table 2. Daily Use

Problem	Symptom	Solution
Touchscreen does not respond	Buttons are not activated by repeated presses.	Restart the device and try to use the touchscreen again. If the problem is not resolved, call Technical Support.

Table 3. Errors

If your device is unable to perform one or more critical functions, you will see an error screen. When an error happens, you will be unable to use your device regularly. Refer to the instructions below to solve the issue.

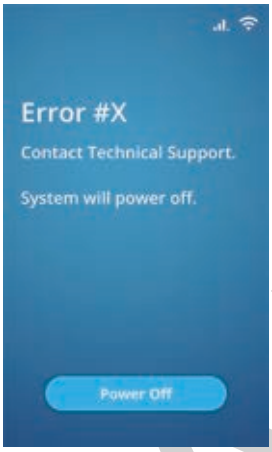
Problem	Symptom	Solution
		Write down the error number and power off. Refer to the error number in the sections below for a solution.
Numeric error message	Error message with a number appears on the screen	Note the error. Press the OK button to acknowledge the error, wait for the error to transmit, and let the electronics unit shut down. Call Technical Support.
	Error #0	There is a problem with the connections in the system and important information cannot be sent.
	Error #1	The electronics system recorded an incorrect value for the atmospheric pressure.
	Error #2	The two atmospheric pressure sensors in the electronics system do not agree.
	Error #3	Important data needed to make a measurement was unavailable.
	Error #4	The internal settings values needed to make a measurement were missing or damaged.
	Error #5	The atmospheric pressure sensor indicated an error in recording pressure or temperature.
	Error #6	An important part of the software was unable to run.

Table 3. Errors

If your device is unable to perform one or more critical functions, you will see an error screen. When an error happens, you will be unable to use your device regularly. Refer to the instructions below to solve the issue.

	Error #9	The system temperature is above or below operational limits. Let your device rest in a room within operational temperature for thirty minutes. Try powering it on afterwards. If the problem persists, call Technical Support.

Table 4. Cautions

If your device is unable to perform a non-critical function, it displays a caution screen. When a caution occurs, you will still be able to use your device. Please follow instructions below to prevent any further issues with your device.

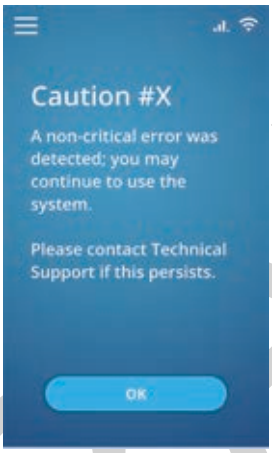
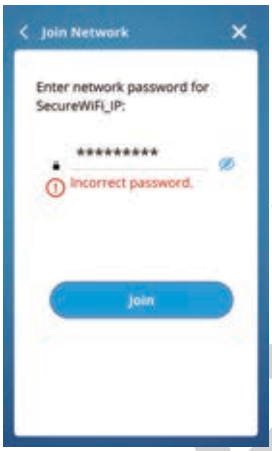
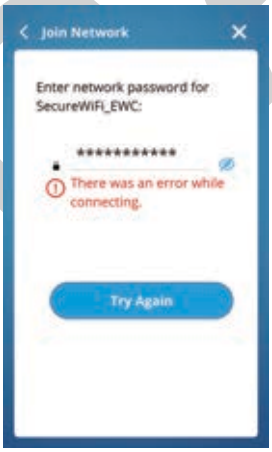
Problem	**Symptom**	**Solution**
Caution #X		Write down the caution number, Press the OK button and continue to use the device normally. If the problem persists, refer to the sections below to find a solution for each caution.
Numeric caution message	Caution message with a number appears on the screen	Note the caution. Press the OK button to acknowledge the caution. If the caution message recurs, note the caution number and call Technical Support.
	Caution #0	Volume control is not initialized.
	Caution #1	Selected language is not configured properly.
	Caution #5	Time of day clock off.
	Caution #8	Unable to read patient and sensor information downloaded.
	Caution #19	Unable to communicate with cellular modem. Call Technical Support to get instructions to check the cellular modem connection.
	Caution #20	Issue with certificates for Over-the-Air Software Update.

Table 5. Network Connection

Problem	Symptom	Solution
Cellular signal strength is low		If the cellular signal strength is three or lower, and the device has problems transmitting data, move the device to another location and try again. You can also try to connect to Wi-Fi‡.
Wi-Fi signal strength is low		If the Wi-Fi signal strength is weak, and the device has problems transmitting data, turn on cellular connectivity (if it is off) or try a different Wi-Fi network.
Wi-Fi password is incorrect		To view the entered password, press the eye icon on the right hand side of the password. Correct the password (if necessary) and press Join again.
Wi-Fi connectivity error		This usually occurs when your router is offline and has no network connectivity. Check your internet connectivity.

Living with your CardioMEMS™ HF System

It is important to follow your clinician'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 clinician.
- Attend your scheduled clinician's office visits. Your clinician will arrange a follow-up plan with you to check your device and overall health on a regular basis.
- You should take your HERO Device with you when you travel.
- Your clinician may also take readings from your PA Sensor 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 clinician, dentist, and emergency personnel that you have an implanted device. Your PA Sensor will not alert airport security when you pass through the security checkpoint.

You can travel with your HERO Device. Pack it as a carry-on or put it in your checked-in baggage. The device should be taken out of any carry-on baggage and put through the security screening separately, like a laptop. A letter stating that your HERO Device is a medical device and should be allowed as cabin baggage is available at cardiovascular.abbott.com.

The radio frequency that powers your sensor only works with the HERO Device, it will not pick up signals from other equipment.

When to Call Your Clinician

Your clinician will provide instructions for when you should contact them. In general, contact your clinician 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 HERO Device

Antenna Pad Cover

The antenna pad cover is a cotton and polyester blend. Machine wash the cover in cold water on the delicate cycle or hand wash when necessary. Make sure that you use mild cleaning agents only. Lay flat to dry and do not use a clothes dryer.

If the gray foam surface of the Antenna Pad becomes dirty, you may wipe it with a damp cloth and mild detergent. This may be done as frequently as needed. Do not machine wash or immerse the antenna pad in water or any cleaning solution.

HERO Device and Controller

Turn off and unplug the unit before cleaning it.

If the Controller screen surface becomes contaminated, breathe on the surface and gently wipe it with a soft dry cloth. If it is heavily contaminated, moisten a cloth with one of the following solvents:

- Isopropyl alcohol
- Ethyl alcohol

  Do not scrub hard to avoid damaging the display surface.

Solvents, other than those above-mentioned may damage the polarizer. Do not use the following solvents:

- Water
- Ketone
- Aromatic solvents

Wipe off saliva or water drops immediately. Contact with water over a long period of time may cause deformation or color fading. Avoid contacting oils or fats.

For protection, store the handheld controller inside the built-in pocket when not in use.

Do not submerge the antenna pad or controller in any liquid. Do not spray them or allow fluid to enter them. Should this occur, do not use the moisture damaged unit and call Technical Support for assistance.

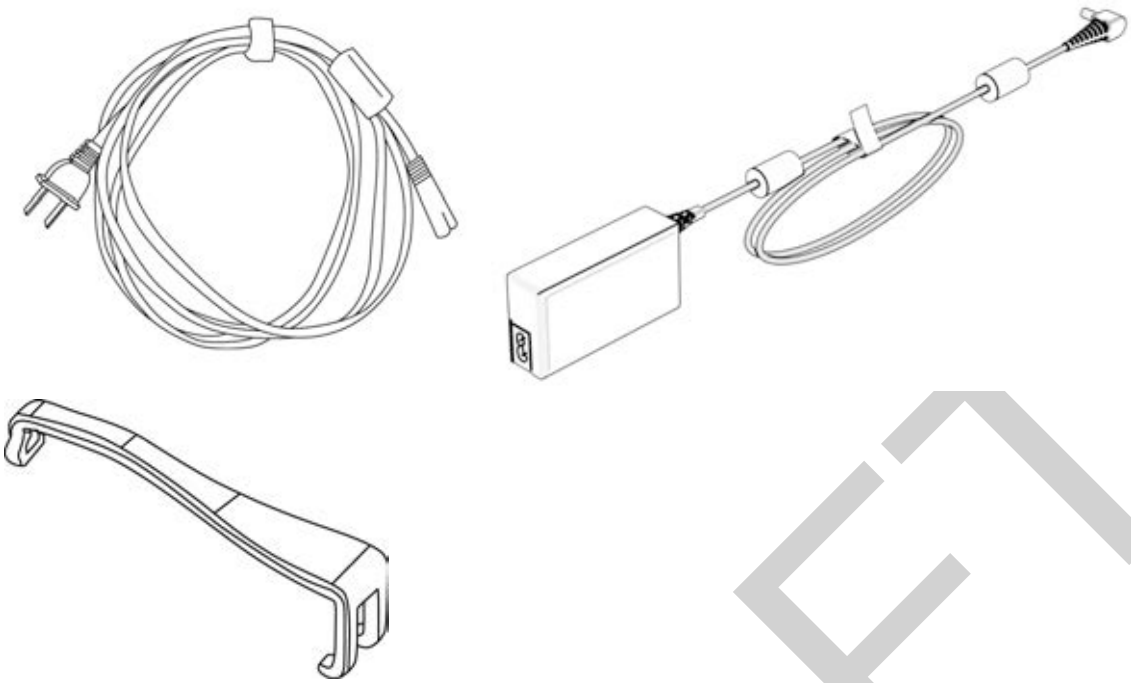
Repacking the HERO Device

1. Unplug the power cord from the wall and remove from the top of the unit.
2. Remove the power cord clip then remove the power cord from the power adapter.

3. Loosely coil the power cord cables and fasten with attached velcro.

   WARNING: Do not kink, sharply bend, or crush cables, including wrapping the power cord around the power adapter, which may lead to cable fraying or damage.

Figure 31. Repack the HERO Device



4. Loosely coil the controller cord.
5. Place the controller with the controller cord, power adapter and power cord clip in the pouch located at the back of the unit; make sure to zip up the pouch.
6. To hold and transport the unit, use the black fabric handle on the side of the unit.

Maintaining the HERO Device

Software Update

Software on your HERO Device can be updated using one of the following methods: Over-the-Air (OTA) or via USB.

OTA Software Update

This method is used for critical updates such as cybersecurity.

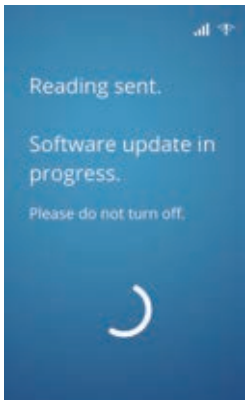
- Your HERO Device automatically checks for an over-the-air software update after a reading is sent.
- If an over-the-air software update is available, the device starts the software update automatically.

  NOTE: The HERO Device must be turned on during the software update to prevent interruption.

  NOTE: During an OTA software update, the HERO Device automatically powers off after 60 minutes to prevent overheating, or once the update is compete.

  NOTE: If the OTA software update is unable to complete, the HERO Device resumes the update process the next time a reading is sent, taken, or a saved reading is sent.

Figure 32. Over-the-air software update screen



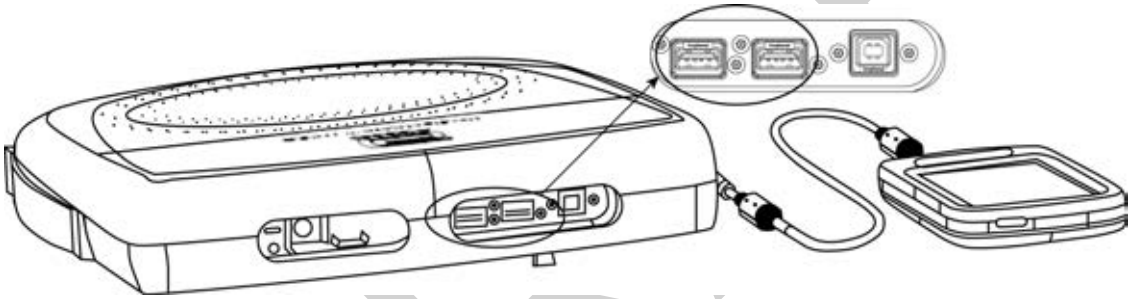
Software Update via USB

This method is commonly used for most updates.

- You may receive an envelope with instructions from Abbott in the mail to update the software on your HERO Device.
- The envelope will also include a USB device with the update stored on it.

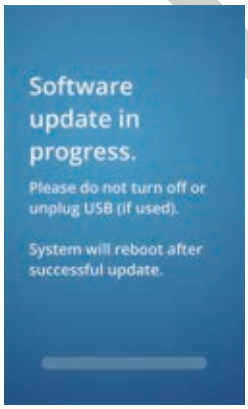
1. Make sure the device is powered off.
2. Insert the software update USB into one of the two USB ports on the flat top edge of your antenna pad.

Figure 33. USB software update



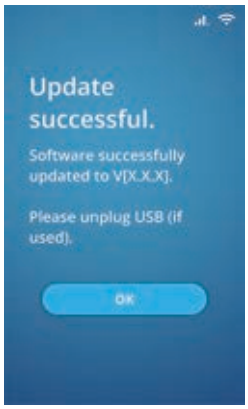
3. To turn on your device, use the power button at the top of the controller. The software update starts automatically and the Software update in progress screen appears. The system boots up and the software update starts.

Figure 34. Software update in progress screen



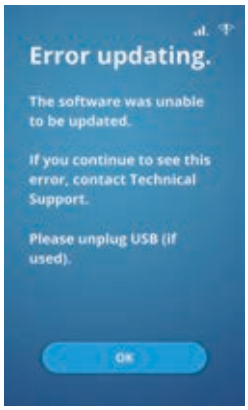
4. When you see the Update successful screen, it means the software has updated successfully. Unplug the USB, press the OK button and press to continue with your daily reading. Please discard the software update USB.

Figure 35. Update successful screen



5. When you see the Error updating screen, it means the software was unable to update successfully. Unplug the USB, press the OK button and press to continue with your daily reading. If the problem persists, call Technical Support.

Figure 36. Error updating screen



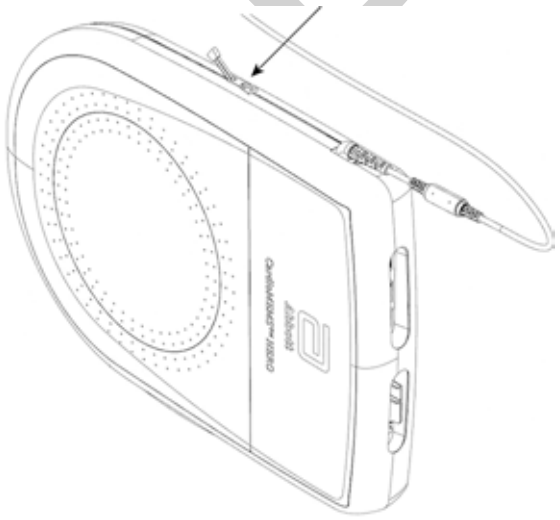
Hardware Update

IMPORTANT: Make sure the device is powered off and unplugged.

As cellular communications technology advances, it may become necessary for you to replace the modem in the remote monitor. Follow the instructions below to replace the system modem.

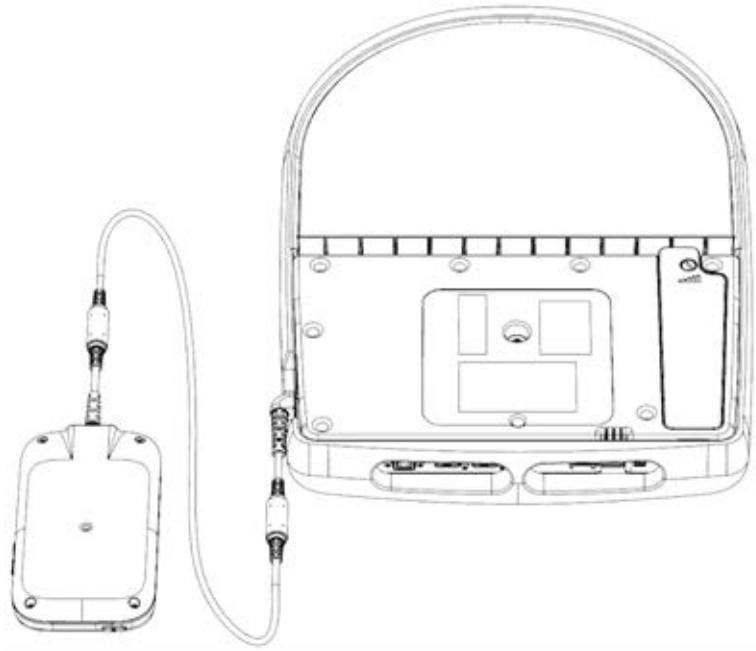
1. Power off and unplug the device.
2. Unzip and remove the antenna pad fabric cover. Please do not attempt to remove the grey foam from the antenna pad.

Figure 37. Remove antenna pad fabric cover



3. Turn the antenna pad over so you can see the modem compartment door.

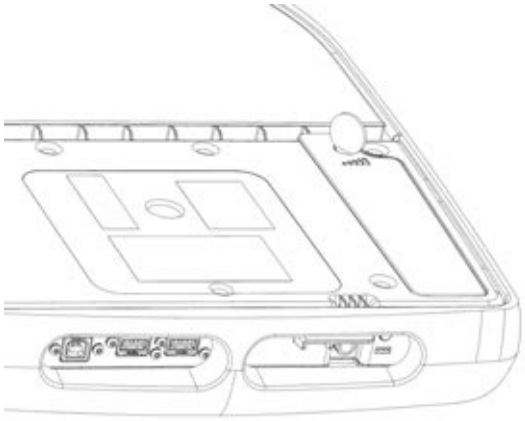
Figure 38. Turn antenna pad



4. Unscrew the screw on the door (turn counter-clockwise to the left) with a coin or a screwdriver and pull the door up slowly. Do not pull too hard.

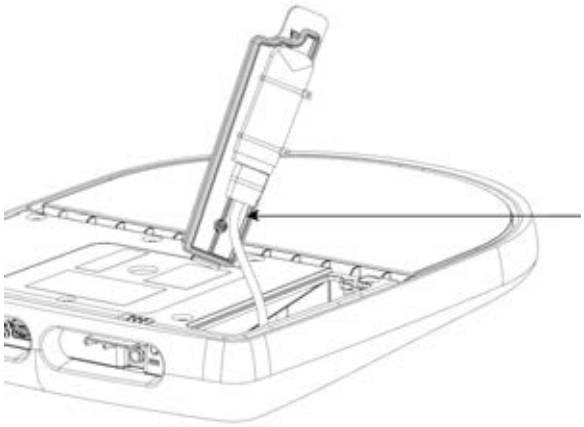
   NOTE: The screw does not come out completely and will stay attached to the door.

Figure 39. Unscrew modem door



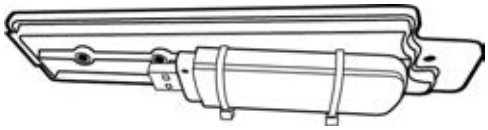
5. Turn the door over so you can see the cellular USB modem underneath the door.
6. Detach the cable from the modem and dispose the modem assembly according to your local regulations. DO NOT detach the cable from your device.

Figure 40. Detach modem cable



7. Attach the new modem assembly to the cable.

Figure 41. Attach new modem



8. Carefully close the modem door and tighten the screw (clockwise to the right).
9. Put the Antenna Pad cover back on and zip it around the antenna pad.
10. Power on the HERO Device. Check for a cellular signal at the top of the screen. If the device is not connecting to a cellular network, change your location and try again. If the problem persists, contact Technical Support.

Resetting Your HERO Device

Sometimes you might need to send your HERO Device back to Abbott. Before you do, Abbott asks that you reset the system to erase all your personal data to protect your identity.

WARNING: Performing a system reset will erase all data and make your HERO Device unusable until it is re-configured.

1. First, click on the Menu Icon in the upper-left-hand corner of the Menu screen, then choose the Settings Icon.

Figure 42. Menu Icon

Figure 43. Settings Icon

2. Click on System Reset on the controller screen. The controller screen prompts you to confirm twice. A password is required to reset the system. Please call Technical Support.
   The system shuts down after the reset is complete.

Send Saved Readings

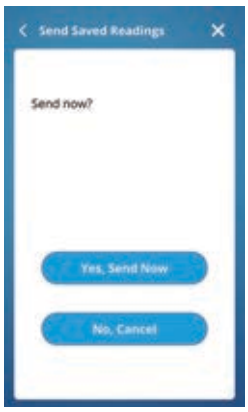
After your HERO Device takes your daily reading, it automatically sends the readings with its built-in cell or Wi-Fi‡ connection. If it is unable to send the reading, it saves the reading on the device (up to 60 readings).

Any saved readings are sent automatically the next time you take a reading and the HERO Device is able to connect with cell or Wi-Fi.

You can also manually send the saved readings.

1. Select the Menu Icon in the upper left hand corner of the screen, then choose the Settings Icon.
2. Choose the Send Saved Readings option on the settings menu.
3. Select the Yes, Send Now option On the Send Saved Readings screen.

Figure 44. Send saved readings screen



If your device is able to connect, it sends all saved readings and then powers off. If it is unable to connect, it continues to save the readings.

Advanced Settings (Clinician Specific)

As a clinicians may need to adjust certain configurations for the CardioMEMS™ HERO Device System to help with acquiring signal from an implanted sensor. These settings are available only by entering a password provided by Abbott Technical Support to prevent inappropriate setting changes. The following configuration settings are available under the Advanced Settings option of the menu:

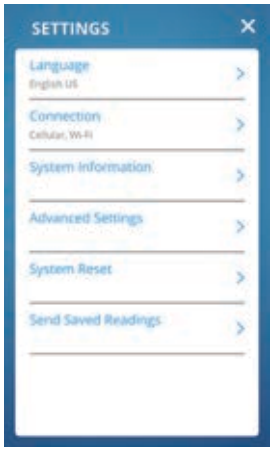
- Changing search pressure
- Changing minimum signal strength
- Displaying pressure and heart rate values

Advanced Settings

1. To start, select the Advanced Settings option from the Settings menu.

   NOTE: This setting is enabled only for the current power cycle and will not be displayed after that.

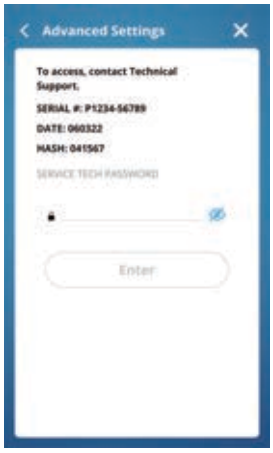
Figure 45. Settings Menu



To access the Advanced Settings option, you will need the Service Tech Password from Technical Support. Technical Support will verify your identity as a clinician before providing the one-time Service Tech Password.

1. Enter the password in the field on the screen and press the Enter option when activated.

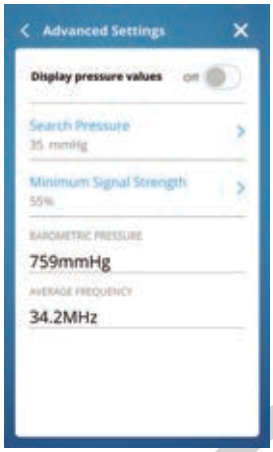
Figure 46. Service Tech Password



The Advanced Settings Menu screen displays.

1. Continue to stay on the phone with Technical Support as they walk you through the necessary steps to change the configuration on the HERO Device.

Figure 47. Advanced Settings Menu



Changing Search Pressure

1. Select Search Pressure from the menu and adjust the search pressure value as instructed by the Technical Support team. Choose the field on the screen and edit values as instructed.

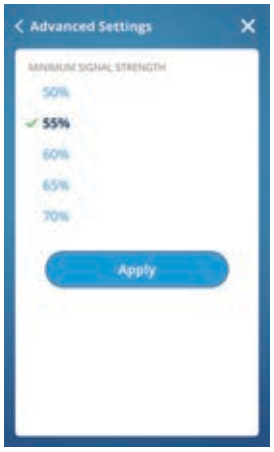
Figure 48. Select Search Pressure

After you enter the new value, press the Apply option to save changes. When you are done, exit the menu and continue as instructed by Technical Support.

Changing the Minimum Signal Strength

1. Select Minimum Signal Strength from the menu and adjust the value as instructed by the Technical Support team. You will need to choose one of the values in the list as instructed by Technical Support.

Figure 49. Minimum Signal Strength

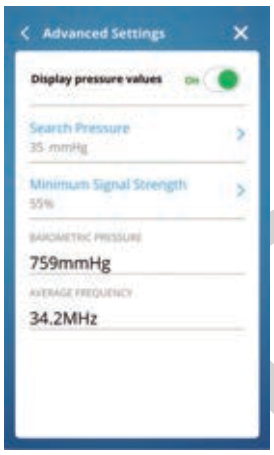


After you choose the new value press the Apply option to save changes. When you are done, you can exit the menu and continue as instructed by Technical Support.

Display Pressure Values

1. Toggle the Display Pressure Values switch to activate the feature. The switch will become green when it is on.

Figure 50. Display Pressure Values



Once complete, you can exit the menu and continue as instructed by Technical Support.

Electromagnetic Interference and Electromagnetic Compatibility

This section provides a brief overview of Electromagnetic Interference and Electromagnetic Compatibility guidance associated with the use of the CM1200.

Table 6. Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions
The electronics unit is intended for use in the residential/home healthcare environment. The customer or the user of the electronics unit should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
Intentional Radiated Emissions, Active TX mode, IEC 60601-1-2, CISPR 11	Class A, Group 2, See below*	The electronics unit must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The electronics unit is suitable for use in professional healthcare environments and home healthcare/residential/domestic environments when precautions are taken for the device to minimize electromagnetic interference while the device is performing its intended function. The emissions characteristics of this equipment might not offer adequate protection to radio-frequency communication services while taking pressure readings. The user might need to take mitigation measures, such as relocating or re-orientating the equipment.
Unintentional Radiated Emissions, Standby mode, IEC 60601-1-2, CISPR 11	Class B, Group 1	
Intentional Conducted Emissions, Active TX mode, IEC 60601-1-2, CISPR 11	Class B, Group 2	
Unintentional Conducted Emissions, Standby mode, IEC 60601-1-2, CISPR 11	Class B, Group 1	
Harmonic Current Emissions, IEC 60601-1-2, IEC 61000-3-2	Not Applicable, Less than 75W	
Voltage Fluctuations/Flicker Emissions, IEC 60601-1-2, IEC 61000-3-3	Complies	

* Per CISPR 11 Section 5.2, the CM1200 patient system is classified as Class B equipment because its intended use is in residential environments. Compliance with CISPR 11 intentional radiated emissions limits for Class B has not been established. Compliance with CISPR 11 intentional radiated emissions limits for Class A limits have been established.

The deviation for intentional radiated emissions limits is the result of the higher levels of RF energy necessary to energize the CM2000 implanted sensor to meet its intended purpose while taking a reading. These intentional radiated emissions results are a component of alternative risk control measures that demonstrate acceptable residual risk of the device emissions per Clause 4.5 of IEC 60601-1. Device interaction testing has been performed to demonstrate the CM1200 RF emissions to not cause disturbances with Abbott pacemakers and implantable defibrillators.

Table 7. Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity

The electronics unit is intended for use in the residential/home healthcare environment. The customer or the user of the electronics unit 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	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±500 V line(s) to line(s)	±1 kV line(s) to line(s) ±500 V line(s) to line(s)	

Table 7. Electromagnetic Immunity

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T [2] (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 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 5 sec	
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz	3 Vrms 6 Vrms	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

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

For two electronics units operating simultaneously and in proximity, test results indicate that the separation distance should be greater than 4 meters (13 feet and 2 inches).

Clinical Study Information

Introduction

Heart failure is a life-threatening condition with debilitating symptoms and is a burden to patients and their caregivers. Over 60 million people are estimated to be living with heart failure worldwide. It has been shown that pulmonary artery (PA) pressures begin to increase earlier than signs and symptoms (for example, weight gain or shortness of breath) of worsening heart failure and can provide a physiologic basis for heart failure patient management.

The CardioMEMS™ HF System provides a proven method for measuring PA pressure using a wireless pressure sensor implanted into the pulmonary artery. The CardioMEMS HF System provides clinicians

[2] U_T is the a.c. mains voltage level prior to application of the test level.

with a patient's PA pressure while the patient is at home, without the need for a procedure or office visit. This information allows the clinician to manage the patient's heart failure proactively with the goal of controlling PA pressures and reducing heart failure hospitalizations.

GUIDE-HF Trial - Randomized Arm

Purpose

The goal of the GUIDE-HF trial (Hemodynamic-GUIDEd Management of Heart Failure) was to determine whether an expanded patient population would benefit from using PA pressure-guided heart failure management: the CardioMEMS™ HF System.

Study Design

The GUIDE-HF trial (Randomized Arm) was conducted at 118 study sites (114 U.S. sites and 4 sites in Canada) and enrolled 1022 patients with NYHA Class II, III, or IV heart failure and either a prior heart failure hospitalization within 12 months or elevated natriuretic peptides (hormones that increase when the heart is not pumping properly). A total of 1000 Patients were randomized (assigned by chance) to one of two groups: the Treatment Group (standard of care plus using the CardioMEMS™ HF System) or the Control Group (standard of care only). All patients were implanted with the CardioMEMS PA Sensor and took daily readings from home, but clinicians only had access to pulmonary artery pressure information for patients in the Treatment Group.

Results

The study was evaluated for success based on the total of heart failure hospitalizations, urgent heart failure visits (emergency department or hospital outpatient visits for intravenous diuretic therapy), and all-cause mortality at 12 months. The study would be considered successful by demonstrating that the hemodynamic-guided heart failure treatment is superior to the control therapy for heart failure outcomes.

Overall, the Treatment group had 12% fewer primary endpoint events than the Control group, but the difference between groups was not significant. The difference between groups was primarily due to the Treatment group having 17% fewer heart failure hospitalizations compared to the Control group. However, the timing of the study overlapped with the COVID-19 pandemic. To account for the impact of the COVID-19 pandemic, the primary endpoint of the GUIDE-HF trial was also evaluated using follow-up data collected prior to the U.S. national emergency declaration date (March 13, 2020). Prior to COVID-19, the Treatment group had 19% fewer primary endpoint events than the Control group, driven by a 27% reduction in risk for heart failure hospitalizations.

The GUIDE-HF trial primary endpoint was also evaluated in subgroups of patients. For NYHA Class, the clinical data demonstrated a treatment effect in NYHA Class II and III heart failure patients, with benefits remaining unclear in NYHA Class IV patients. Prior to COVID-19, NYHA Class II/III patients in the Treatment Group experienced a 24% reduction in primary endpoint events compared with the Control Group. A treatment effect was also observed regardless of whether patients qualified for the study due to a heart failure hospitalization in the prior 12 months or as a result of elevated natriuretic peptides. A greater benefit was observed in women compared to men and in African American subjects compared to Caucasian patients. The subgroup analyses according to other factors (ejection fraction, age, sex, race, ethnicity, ischemic cardiomyopathy, and prior cardiac device implant) showed consistent benefit of the CardioMEMS™ HF System for patients regardless of these factors.

Of the 1022 patients enrolled in the study, 99.2% were free from a device or system-related complication. Potential Risks observed in the GUIDE-HF trial were consistent with those in the CHAMPION clinical trial.

In summary, despite the limitations of the COVID-19 pandemic occurring during the follow-up of the study, the results of the GUIDE-HF Randomized Arm support the continued safety and effectiveness of the CardioMEMS HF System within an expanded population, as shown by reduced heart failure hospitalizations. The treatment benefit observed in NYHA Class II subjects and those with elevated natriuretic peptides but without a recent hospitalization for heart failure suggest that intervention in NYHA Class II heart failure, even before a heart failure hospitalization occurs, can provide benefit.

Pivotal Data from the CHAMPION Trial

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 clinicians 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, clinicians 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.

Table 8. Clinical risks within 30 days

Risks	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

Table 8. Clinical risks within 30 days

Risks	Treatment Group	Control Group (Standard Therapy)
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.

Table 9. Clinical risks within 6 months

Risks	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.

Table 10. Clinical risks within 1½ years

Risks	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

Table 10. Clinical risks within 1½ years

Risks	Treatment Group	Control Group (Standard Therapy)
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

Long-term Data from the CardioMEMS US Post-Approval Study

Purpose

The purpose of the CardioMEMS US Post-Approval Study (PAS) was to show that the CardioMEMS HF System could be used safely and effectively to reduce heart failure hospitalizations in patients with NYHA Class III heart failure who experienced a heart failure hospitalization in the previous year.

Study Design

A total of 1200 subjects were enrolled at 104 study sites in the United States. All patients enrolled in the PAS were implanted with a CardioMEMS sensor and had their heart failure managed using pulmonary pressures in addition to standard of care. Patients were followed for two years after sensor implant.

Results

The PAS met both of its pre-specified safety endpoints with 0.4% of patients (5 out of 1214 patients who had an attempted implant) experiencing a device-related complication and one patient (out of 1200 patients with implanted sensors) experiencing a sensor failure (0.1% of study population).

The PAS also met its pre-specified primary effectiveness endpoint of reducing the rate of heart failure hospitalizations and showed that patients had 57% fewer heart failure hospitalizations at 1 year compared to the year prior to sensor implant.

As noted in the previous section, the CHAMPION trial was not designed to assess the benefit of using the CardioMEMS sensor by gender. Because of this, the PAS had a requirement to enroll at least 35% women and a pre-specified analysis of heart failure hospitalizations for both women and men. The goal to enroll at least 35% women was met and approximately 38% of patients enrolled in the PAS were women. Analysis of heart failure hospitalizations showed that women have a similar response to the use of CardioMEMS as men.

In summary, the CardioMEMS US PAS has demonstrated that the CardioMEMS HF System is safe (99.6% freedom from device-related complications and 99.9% freedom from sensor failure at 2 years) and effective (57% reduction in heart failure hospitalizations at one year), thus demonstrating the long-term safety and efficacy of the CardioMEMS HF system.

FCC Statement

This device complies with Part 18 of the FCC rules.This device also 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.

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.

System Specifications

Electrical Characteristics

Power

- Power Supply: Medical Grade Class II. Input: 100-240 V, 50-60 Hz, output: 12 VDC, 4.2 A.
- Manufacturer part number: 600021007.
- Only use a CardioMEMS™ HERO Device power cord supplied by the manufacturer.

Radiofrequency (RF) Characteristics

- Bandwidth of Receiver: 28-40 MHz
- Frequency Band of Transmission: 30-37.5 MHz
- Type of Modulation: OOK (on/off keying)
- Effective Radiated Power: <1mW e.r.p.
- Cellular Modem Technical Description:
  (a) LTE-FDD: B1/B2/B3/B4/B5/B7/B8/B12/B14/B17/B20/B66
  (b) LTE-EDD: B38/B39/B40/B41
  (c) 3G: B1/B2/B4/B5/B8
  (d) 2G: 850/900/1800/1900 MHz
- Wi-Fi‡ Technical Description: 802.11a/b/g/n/ac

  NOTE: Metal objects and metal tables within a 1.5 meter vicinity of the RF antenna can cause signal strength degradations.

Mechanical Characteristics

Electronics Unit

- Weight: approximately 7 pounds
- Dimensions: Width: 13 inches Height: 2 inches Length: 18 inches
- Expected Device Lifetime: 5 years
- Accessible I/O: 2 USB
- I/O accessible through wireless access panel: USB reserved for cellular modem.

Display

- Touch Screen: Capacitive
- Brightness: Minimum 270 cd/m^2
- Resolution: 800 x 480, RGB

Environmental Information

- Operation: 0°C to 35°C (32°F to 95°F), 15% to 93% humidity (non-condensing), 700-1060 hPa (System), 800-1146 hPa (implanted sensor)
- Transportation: -25°C to 70°C (-13°F to 158°F), and up to 93% humidity (non-condensing)
- Storage: -25°C to 70°C (-13°F to 158°F), and up to 93% humidity (non-condensing)

- Time necessary to cool from 70°C to 35°C (at 20°C ambient) before use: 60 minutes
- Time necessary to warm from -25°C to 0°C (at 20°C ambient) before use: 60 minutes
- Atmospheric pressure: 525 mmHg to 795 mmHg
- Oxygen rich parameters: Do not use in oxygen rich environments such as hyperbaric chambers with Oxygen partial pressure greater than 25% or 27.5kPa.

Classification

- Class II equipment
- Type BF insulation
- Ordinary Equipment IP22

Testing

System Testing

The system has been tested to maintain accuracy as follows under ambient environmental conditions.

- 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 ±2 mmHg should be maintained after immunity testing and ±10 mmHg should be maintained during immunity testing. This is the device's essential performance.
- Loss of essential performance may result in inaccurate readings or injury.
- The CM1200 was issued an ETL/cETL Listing Mark

Safety Testing

- IEC 60601-1
- ANSI ES 60601-1
- CENELEC EN 60601-1

EMI/EMC Testing

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

Wireless Testing

- FCC part 18
- FCC part 15
- ETSI EN 302 510
- CISPR 11

Software

This device contains open source software. Source code is available upon request.

Symbols

Symbol	Description
	Catalog Number

Symbol	Description
	Non-ionizing radiation
	Consult instructions for use
	Temperature limitations
	Humidity limitation
	Keep dry
	Type BF Patient Applied Part
	Manufacturer
	Date of Manufacture
	Direct current
IP22	Protection against ingress of solid objects > 12.5 mm, such as a finger. Protection against dripping water up to 15° from vertical.
	Cellular
	Wi-Fi
	Momentary pushbutton
	Federal Communication Commission Number
	Class II equipment
	The device contains a battery and the label is affixed to this device in accordance with European Council Directives 2012/19/EU and 2006/66/EC. 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 Return the device to Abbott Medical at the end of its operating life.

Symbol	Description
	Prescription use only
	Conforms to AAMI Std ES60601-1 IEC Std 60601-1-11 Certified to CAN/CSA std C22.2 No. 60601-1
	Serial number
	Quantity, package contents
	Manufacturing facility
	Power Plug

WEEE Compliance Statement

The 2012/19/EU 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 Limited Warranty Summary

This Limited Warranty is available for a period of three (3) years following delivery to the original purchaser if the CardioMEMS™ HERO Device 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 Abbott Medical, usage not in accordance with product instructions, due to abuse, or misuse.

During the three-year warranty period, Abbott Medical will repair or replace a malfunctioning System. To qualify for such repair or replacement, Abbott Medical must be notified within 30 days of the malfunction and, if so directed by Abbott Medical, the purchaser or user must return the System for repair or replacement. For instructions on how to return the System, contact Abbott Medical at 844 MY CMEMS (844 692 6367).

If warranty service is required, contact Abbott Medical. If Abbott Medical repairs or replaces the System, the warranty term will be for the remainder of the original term or 60 days, whichever is longer. This summary does not add to, vary or amend any of the terms of the Limited Warranty contained in the Limited Warranty Card supplied in the product packaging.

Refer to the Limited Warranty card.

Technical Support

Monday through Friday (8 a.m. to 8 p.m. Eastern Standard Time)
1 844 692 6367 (1 844 MY CMEMS) (toll-free within North America)

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2025-04
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