



# Abbott P100045/S056 HF SYSTEM CardioMEMS Device for Monitoring Advanced Heart Instructions

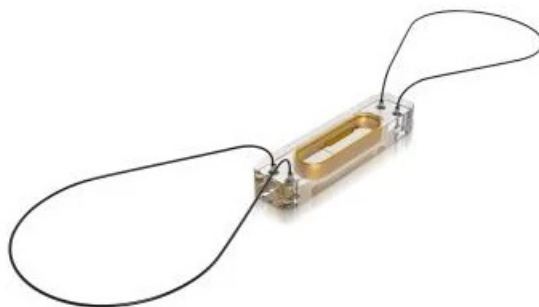
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**Abbott P100045/S056 HF SYSTEM CardioMEMS Device for Monitoring Advanced Heart**



**Product Information**

**Specifications**

- **Product Name:** CARDIOMEMSTM HF SYSTEM
- **Manufacturer:** Abbott
- **Model:** HF System
- **Power Adapter:** Included
- **Language Options:** Multiple, English default
- **Network Connectivity:** Merlin.net Patient Care Network (PCN)
- **Location for Sensor Implant:** Routinely left side
- **Reading Time:** Approximately 18 seconds

## Product Usage Instructions

### Assembling a New Patient Electronics System (PES)

1. Insert the power cable into the power adapter.
2. Attach the included power cord clip onto the power adapter.
3. Plug the cable into the power connector plug on the back of the PES so they are connected all the way. Press the connected plugs securely into the molded groove.
4. Plug the other end of the power cable into the wall electrical outlet.

### Pairing the New PES

1. Power on the PES by pressing the clear button on the back of the unit. The button will light up blue.
2. Remove the handheld unit from the storage area on the right side of the pillow, and completely unwind the cable from its groove on the PES.
3. Follow on-screen prompts to select language, country, and enter sensor serial number (SN).
4. Once setup is complete, screen will display patient's name above the Start button.

### Taking the First PES Reading with the Patient

1. Place the pillow under the patient with the elevated portion at their head and align the sensor implant in the middle of the pillow.
2. Instruct the patient to press the green Start button on the handheld unit when relaxed.
3. Ensure patient remains still during reading process. Reading will take about 18 seconds.
4. After reading completion, patient can get up. Reading successful message will be displayed.

### Frequently Asked Questions (FAQ)

- **Q: What should I do if I encounter connectivity issues?**

A: If you are unable to attain connectivity, refer to the Setup – No Wireless Connection Available section of the Hospital Electronics System Guide. You may also try repositioning for a stronger cellular connection.

- **Q: How can I get technical support?**

A: For technical support, contact Abbott Technical Support at 1-844-692-6367.

- Abbott 6101 Stoneridge Dr., Pleasanton, CA 94588 USA,
- **Tel:** 1 925 847 8600

- Cardiovascular.Abbott/CardioMEMS

## CARDIOMEMS™ HF SYSTEM

### PATIENT DISCHARGE PROCEDURE

ASSEMBLING A NEW PATIENT ELECTRONICS SYSTEM (PES) (see PES Quick Start Guide (QSG) for images)

- Insert the power cable into the power adapter.
- Attach the included power cord clip onto the power adapter.
- Plug the cable into the power connector plug on the back of the PES so they are connected all the way. Press the connected plugs securely into the molded groove.
- Plug the other end of the power cable into the wall electrical outlet.

### PAIRING THE NEW PES

- Power on the PES by pressing the clear button on the back of the unit. The button will light up blue.
- Remove the handheld unit from the storage area on the right side of the pillow, and completely unwind the cable from its groove on the PES.
- After the system starts, it will prompt for the language and country. To select the language and country, press the Next button until the desired language or country appears and then press the Select button. English is the first option.
- Next you will be prompted to enter the sensor serial number (SN). Select the Enter button and then type in the SN. The SN is on the temporary Patient ID card that is included in the plastic bag in the sensor box. Remember to give the patient this ID card for their records once you have paired the unit.
- The PES will then download the necessary information for the patient from the Merlin.net™ Patient Care Network (PCN) and, once complete, will prompt you to confirm the information.
- When the system is successfully set up, the screen will display “Welcome, [patient’s name]” above the Start button.

### TAKING THE FIRST PES READING WITH THE PATIENT

- Place the pillow under the patient with the elevated portion of the pillow at the patient’s head. The location of the sensor implant (routinely left side) should be in the middle of the pillow, which is where the center of the antenna is located.
- Once the patient is relaxed, have them press the green Start button located on the handheld unit.
- If the patient’s position is correct on the pillow, you will hear, Good position on pillow. Stay still.
  - If you hear, Shift slightly on pillow, change body position by making slight movements toward the shoulder opposite where the sensor is located (i.e., if the sensor is implanted in the left pulmonary artery (PA), the patient should shift to the right so the left PA is more centered over the pillow).
  - The signal strength bar on the right side of the screen should be green and at 90% signal strength. This indicates you have a strong connection to your sensor.
  - A yellow signal strength indicates you do not have a strong connection to the sensor and it is related to the patient’s position. Have the patient shift slightly on the pillow.

- A blue signal strength bar indicates that the PES is picking up interference from something other than the sensor. Ensure that the area around the unit is free of metal objects. See the Troubleshooting section on back for a list of potential interferences.
- Once the Measuring... message appears on the screen, music will begin to play. The patient should remain still and not speak until the reading is complete. The reading will take about 18 seconds.
- When the reading is finished, you will hear, Reading completed, you may get up. Patient can get up at this point. The screen will display Reading Successful.
- The PES will connect to the Merlin.net PCN to send the reading. The screen will display Connecting to send reading. Once the reading is sent, the PES will also automatically check for software updates and will automatically shut down.
- DO NOT POWER OFF THE PES.

## TIPS

- It is recommended that you show the patient the training video BEFORE the procedure so they are familiar with the process of taking a reading. The video can be viewed on the Patient Education Video Player and also online at [Cardiovascular.Abbott/usingCardioMEMS](http://Cardiovascular.Abbott/usingCardioMEMS).
- When taking the first reading in the recovery room, walk through the Taking a Reading section of the QSG with the patient. This QSG is packaged with their PES and they can reference it when they are at home.
- To experience the most benefit from the CardioMEMS™ HF System, it is important that the patient take readings daily or as instructed by their physician. Taking readings should become part of their daily routine. It should only take about 2–3 minutes.
- Many patients place the PES on their bed to take their readings.
- Once turned on, the PES may take a few minutes to power up for use.
- **There are three options for connectivity for the PES:** cellular, Wi-Fi† or landline. The PES will default to a cellular connection. There is no cost to the patient for cellular service.
- If the patient does not have cellular coverage in their area, they can use Wi-Fi or landline connectivity. Refer the patient to the QSG for instructions on how to connect to Wi-Fi or landline in their home.

## TROUBLESHOOTING

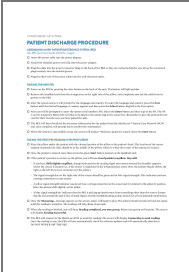
- If the PES will not connect to the Merlin.net™ PCN when you are trying to pair the unit, take the PES to an outside window to obtain a stronger cellular connection. If you are still unable to attain connectivity, reference the Setup – No Wireless Connection Available section of the Hospital Electronics System Guide.
- **To avoid interference during a home reading, instruct the patient to:**
  - Avoid placing the handheld unit directly on their chest during a reading.
  - Ensure that there are no metal objects near the PES. This could include jewelry, keys, belts, electric heating blankets, metal bed frame or rails, or other medical equipment such as a continuous positive airway pressure (CPAP) machine, hearing aid charger or oxygen supply.
- Have the patient take slow deep breaths if they are having trouble getting a strong signal strength. Breathing quickly or taking really big breaths causes respiratory variability, making it hard for the system to get a strong signal.
- If the volume needs to be adjusted on the PES, select Options on the start screen of the handheld unit. Select Volume and then toggle up or down to increase or decrease.

For questions, contact Abbott Technical Support at 1-844-692-6367.

- **Abbott**
  - 6101 Stoneridge Dr., Pleasanton, CA 94588 USA,
  - **Tel:** 1 925 847 8600 Cardiovascular.Abbott/CardioMEMS
- **Rx Only**
- **Brief Summary:** Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.
- **CardioMEMS™ HF System Indications and Usage:** 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.
- **CardioMEMS™ HF System Contraindications:** The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.
- **CardioMEMS™ HF System Potential Adverse Events:** Potential adverse events associated with the implantation procedure include, but are not limited to, the following: air embolism, allergic reaction, infection, delayed wound healing, arrhythmias, bleeding, hemoptysis, hematoma, nausea, cerebrovascular accident, thrombus, cardiovascular injury, myocardial infarction, death, embolization, thermal burn, cardiac perforation, pneumothorax, thoracic duct injury and hemothorax. ™ Indicates a trademark of the Abbott group of companies.
- Indicates a third-party trademark, which is property of its respective owner.

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Documents / Resources

	<p><a href="#">Abbott P100045/S056 HF SYSTEM CardioMEMS Device for Monitoring Advanced Heart [pdf] Instructions</a></p> <p>P100045 S056 HF SYSTEM CardioMEMS Device for Monitoring Advanced Heart, P100045 S056, HF SYSTEM CardioMEMS Device for Monitoring Advanced Heart, SYSTEM CardioMEMS Device for Monitoring Advanced Heart, CardioMEMS Device for Monitoring Advanced Heart, Device for Monitoring Advanced Heart, for Monitoring Advanced Heart, Monitoring Advanced Heart, Advanced Heart, Heart</p>
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References

- [User Manual](#)