



CARDIOMEMS™ HF SYSTEM

PATIENT DISCHARGE

PROCEDURE

ASSEMBLING A NEW PATIENT ELECTRONICS SYSTEM (PES)

- 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.

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.
- Next you will be prompted to enter the sensor serial number (SN). Select the **Enter** button and then type in the SN. The SN should be written on the Patient ID card that is included in the plastic bag in the PES 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 20 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

- When taking the first reading in the recovery room, walk through the **Take a Home Reading** section of the Patient System Guide with the patient.
- 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.

TECHNICAL SUPPORT

If you have questions on the CardioMEMS™ HF System, please contact Technical Support:

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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.

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

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

POTENTIAL ADVERSE EVENTS: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: Infection, Arrhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death, and Device embolization.

LIMITATIONS: Patients must use their own Apple® or Android® mobile device to receive and transmit information to the myCardioMEMS™ mobile app. To do so the device must be powered on, app must be installed and data coverage (cellular or Wi-Fi) available. The myCardioMEMS™ app can provide notification of medication adjustments and reminders, requests for lab work and acknowledgement that the PA pressure readings have been received. However there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of the notifications and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, clinic environment, schedule/configuration changes, or data processing.

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† Indicates a third-party trademark, which is property of its respective owner.

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- Once turned on, the PES takes a few minutes to warm 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.
- Have the patient hold the handheld unit with the opposite hand from where their implant is located (i.e., right hand if sensor is implanted on the left side). This helps to ensure the patient's back, where the sensor is located, is flat against the pillow.
- 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.

