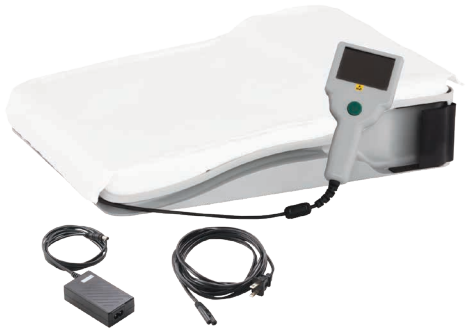
HEART FAILURE MONITORING SYSTEM

CardioMEMS™ HF System

Patient Electronics System



Product Highlights

- The CardioMEMS™ HF System is the fastest growing heart failure (HF) monitor proven to significantly reduce HF hospital admissions and improve quality of life in NYHA Class II and III patients. When used by clinicians to manage HF, the CardioMEMS HF System is:
  - **Safe and reliable** — demonstrates 99.6% freedom from device or system complications[1]
  - **Clinically proven** — reduced HF hospitalizations by 57%[1]
  - **Proactive and personalized** — patient management through direct monitoring of PA pressure and titration of medications
- The CardioMEMS HF System provides direct pulmonary artery (PA) pressure monitoring using the sensor, patient electronics system and the Merlin.net™ Patient Care Network (PCN) to manage patient data
- Patient-initiated sensor readings are wirelessly transmitted to an electronics unit and stored in a secure website for clinicians to access and review
- The patient electronics system is designed for patients to use at home or wherever they may be traveling
- The patient electronics system powers the sensor using RF energy; receives and processes the frequency information from the sensor; and converts the data into pressure waveforms, PA pressure values and heart-rate measurements, and transmits PA data to the Merlin.net PCN website

Ordering Information

Contents: Patient Electronics System

MODEL NUMBER	DESCRIPTION
CM1100	Patient Electronics System – Cellular
CM1170	Fabric Cover
CM1050	Accessory — Orientation Ball
CM3040	Accessory — Wi-Fi Adapter
CM1120	Electronics Travel Case
CM3020	US Power Cord — 125V 7A
CM1110	Power Supply
CM3024	Power Cord Clip

1. Shavelle D, Desai A, Abraham W, et al. Lower rates of heart failure and all-cause hospitalizations during pulmonary artery pressure-guided therapy for ambulatory heart failure. *Circulation: Heart Failure*. Published online 2020. https://doi.org/10.1161/CIRCHEARTFAILURE.119.006863.

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Physical Specifications

Model	CM1100
Electronics Unit	
Dimensions (H x W x L, inches)	5 x 16.25 x 21.4
Weight (lbs)	10
Power	
Supply Voltage	12v DC, 4.2A
Provided Power Supply	Medical Grade Class II. Input: 100-240V, 50-60Hz, output: 12v DC, 4.2A. Manufacturer part number: CC-002403.
Power Cord	Only use power cord supplied by the manufacturer.
Radiofrequency (RF) Characteristics	
Transmitted Electrical Power	< 1 mW e.r.p.
Operating Frequency	30-37.5 MHz (under normal operating conditions the measurement bandwidth is approximately 1 MHz within the operating frequency range)
Processing Capabilities	
I/O	USB, VGA
Handheld Display	Reference manufacturer's part number CS-001261
Display	
Touch Screen	Resistive
Brightness	250 cd/m²
Resolution	320 x 240, color
Environmental	
Operation	5° to 40° C (41° to 104° F), 15% to 93% humidity (non-condensing), 700-1060 hPa (electronics), 800-1150 hPa (implanted sensor)
Transportation	-25° to 70° C (-13° to 158° F), 15% to 93% humidity
Storage	-25° to 70° C (-13° to 158° F), 15% to 93% humidity
Available Languages	
English	
Danish (Dansk)	
Finnish (Suomi)	
Swedish (Svenska)	
Norwegian (Norsk)	
Portuguese	
German (Deutsch)	
French (Français)	
Spanish (Español/España)	
American Spanish (Español/ Latinoamerica)	
Dutch (Nederlands)	
Italian (Italiano)	

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.

myCardioMEMS™ Mobile App 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™ Mobile 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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