

# CardioMEMS™ HF System

Patient Electronics System



## Product Highlights

- The CardioMEMS™ HF System is a CE Marked heart failure (HF) monitor proven to significantly reduce HF hospital admissions and improve quality of life in NYHA Class III patients. When used by clinicians to manage HF, the CardioMEMS HF System is:
  - **Safe and reliable** – demonstrates 98,6% freedom from device or system complications<sup>1</sup>
  - **Clinically proven** – reduced HF admissions by 62%<sup>2</sup>
  - **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
- 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 – (GSM, Wi-Fi <sup>1</sup> , Landline)
CM1130	Handheld Display
CM1140	GSM Modem
CM1170	Fabric Cover
CM1050	Accessory – Positioning Ball
CM3040	Accessory – WiFi Adaptor
CM1120	Electronics Travel Case
CM3025	AUS Power Cord 250V, 2,5A, A,0 250V 2,5A
CM3021	EU Power Cord CEE 7/16, C7, 8 ft min, Class II, A,0 250V 2,5A
CM3023	UK Power Cord 2,5 Amp, C7, A,0, 250V 2,5A
CM1110	Power Supply
CM3020	US Power Cord 125V 7A
CM3024	Power Cord Clip

1. Abraham, W. T., Adamson, P. B., Bourge, R. C., Aaron, M. F., Costanzo, M. R., Stevenson, L. W., Yaday, J. S., (2011). Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. *The Lancet*, 377(9766), 658-666. doi:10.1016/S0140-6736(11)60101-3.

2. Angermann C., Abmus B., et al. Pulmonary Artery Pressure Guided Therapy in Ambulatory Patients with Symptomatic Heart Failure The CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF). *European J of Heart Failure*. 2020.10.1002/ejhf.1943

#### Physical Specifications

<b>Model</b>	<b>CM1100</b>
<b>Electronics Unit</b>	
Dimensions (H x W x L, cm)	12,7 x 41,28 x 54,36
Weight (kg)	4,54
<b>Power</b>	
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 manufacturer.
<b>Radiofrequency (RF) Characteristics</b>	
Transmitted Electrical Power	< 1mW e.r.p.
Operating Frequency	30-37,5 MHz (under normal operating conditions the measurement bandwidth is approximately 1 MHz within the operating frequency range)
<b>Processing Capabilities</b>	
I/O	USB, VGA
Handheld Display	Reference manufacturer's part number CS-001261
<b>Display</b>	
Touch Screen	Resistive
Brightness	250 cd/m <sup>2</sup>
Resolution	320 x 240, color
<b>Environmental</b>	
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° C to 70° C (-13° to 158° F), 15% to 93% humidity
Storage	-25° C 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)

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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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