CardioMEMS™ HF System

Hospital 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 New York Heart Association (NYHA)
 Class II and III patients.¹² When used by clinicians to manage HF, the
 CardioMEMS HF System is:
 - Safe and reliable demonstrated 99.6% freedom from device or system complications³
 - Clinically proven reduced HF hospitalizations by 57%³
 - Proactive and personalized patient management through direct monitoring of pulmonary artery (PA) pressure and titration of medications
- The CardioMEMS HF System provides direct PA pressure monitoring using the sensor, the 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 hospital system is used by the implanting physician to zero the sensor, based upon simultaneous readings from the PA catheter.
- The hospital system is designed for use by healthcare professionals to record PA pressure from the sensor, eliminating the need for patients to carry their electronics to the hospital or doctor's office.
- The hospital system powers the sensor using radiofrequency energy; receives and processes the frequency information from the sensor; and converts the data into pressure waveforms, PA pressure values and heart rate measurements.



Ordering Information

Contents: Hospital System and Cart

| MODEL NUMBER | DESCRIPTION |
|--------------|---|
| CM3100 | CardioMEMS™ Hospital System |
| CM3150 | CardioMEMS™ Hospital System Cart |
| CM3120 | CardioMEMS™ Hospital System U.S. Power Cord |

CardioMEMS[™] HF System

Hospital System

Product Specifications

| | 18 |
|---|---|
| Model Electronics Unit | CM3100 |
| $\begin{array}{l} \text{Dimensions (H} \times \text{W} \times \text{L, inches)} \\ \text{Weight (lbs)} \end{array}$ | 14.0 × 10.5 × 2.5 13.5 |
| Power | |
| Power Supply Provided Power Supply | Internal power supply is a 12VDC, 8.34A output Medical Grade Class II, provides between 100–240 volts AC incoming at a 50–60 Hz input frequency range |
| Power Cord | Use only power cord supplied by manufacturer |
| Radiofrequency (RF) Character | ristics |
| Transmitted Electrical Power Operating Pressure Range | < 0.2 mW e.r.p 600-860 mmHg |
| Processing Capabilities | |
| I/O Network Connection Storage | USB, Ethernet [‡] and HDMI Ethernet [‡] , Wi-Fi [‡] and cellular 4 GB |
| Display | |
| Touchscreen Brightness Resolution | Minimum 12" diagonal display 375 cd/m² 1024 × 768 pixels, color |
| Antenna | |
| Diameter (inches) Weight (lbs) Cable | Between 8" and 15", inclusive 4.5 9-10 feet long, inclusive |
| Connectivity | |
| Cellular Wi-Fi | 4G networks, with fallback to 3G and 2G 2.4 and 5 GHz WPA and WPA2 networks with EAP-TLS security WPA Enterprise and WPA2 Enterprise with PEAP- |
| | MSCHAPv2 security IEEE 802.11 a/b/g/n |
| Environmental | 1 (.)(|
| Operation | Normal use when operated at 10°C-35°C with 30% to |
| Transportation | 75% relative humidity Shall be functional after storage or transport at the following environmental conditions: -25°C-60°C with |
| Storage | 10% to 90% noncondensing relative humidity, inclusive Shall be functional after storage or transport at the following environmental conditions: -25°C-60°C with 10% to 90% noncondensing relative humidity, inclusive |
| System Cart | CM3150 |
| Dimensions | Height: 60 inches ± 10.0 inches |
| Weight (lbs) | Diameter: less than 36 inches (0.91 m) 42 |

- 1. Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. Lancet. 2021;398(10304):991-1001. doi:10.1016/S0140-6736(21)01754-2
- 2.Brugts JJ, Radhoe SP, Clephas PRD, et al; MONITOR-HF Investigators. Remote haemodynamic monitoring of pulmonary artery pressures in patients with chronic heart failure (MONITOR-HF): a randomised clinical trial. *Lancet.* 2023;401(10394):2113-2123. doi:10.1016/S0140-6736(23)00923-6
- 3. Shavelle DM, Desai AS, Abraham WT, et al. Lower rates of heart failure and all-cause hospitalizations during pulmonary artery pressure-guided therapy for ambulatory heart failure: one-year outcomes from the CardioMEMS post-approval study. Circ Heart Fail. 2020;13(8):e006863. doi:10.1161/CIRCHEARTFAILURE.119.006863

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.

- $^{\scriptscriptstyle\mathsf{TM}}$ Indicates a trademark of the Abbott group of companies.
- ‡ Indicates a third-party trademark, which is property of its respective owner.
- @ 2025 Abbott. All Rights Reserved.

MAT-2117012 v3.0 \mid Item approved for U.S. use only.

