

CATH LAB IMPLANT CHECKLIST*

FOR THE CARDIOMEMS™ PA SENSOR

*Refer to the CardioMEMS™ HF System Instructions for Use (IFU) for complete implant instructions.¹

PREPROCEDURE SETUP

1	Once the CardioMEMS™ Hospital System is on, select New Implant .
2	Select Patient from list or Add New. Enter patient's first and last name and date of birth. Select Next . Then select Implanting Physician and Treating Physician. The system automatically populates the corresponding Merlin.net™ Patient Care Network (PCN) clinic in the Treating Clinic Field.
3	If the Hospital System has connected successfully to a network: enter the sensor serial number. If the Hospital System is not connected to a network: remove the USB from the system package. Insert it into the USB port on the front left side of the Hospital System. Once the sensor serial number has been input, the calibration code will automatically populate. Then select Start New Implant . Compare the sensor information on the screen to the information on the brown tag attached to the USB.
4	Check the sensor for signal while sensor is still in package. Move the antenna close to the unopened sensor package, and verify signal strength displayed on the left side of the Hospital System screen is green and 100%. Move antenna away from sensor package and confirm signal strength decreases. Repeat, then press Continue .
5	Wait for the implant message to appear. Press Continue when physician is ready to calibrate the implanted sensor.

IMPLANT PROCEDURE

6	Gain access via femoral or internal jugular vein using 12 F sheath.
7	Perform right heart catheterization using either a Swan-Ganz [†] or Pulmonary Wedge Catheter — generically referred to hereafter as Pulmonary Artery Catheter (PAC).
8	Identify target implant site by angiogram through the PAC distal lumen (5 cc hand injection of radiographic contrast) with the balloon inflated. Perform an AP and 45-degree RAO or LAO angiogram.
9	Identify target vessel using PAC as a reference (PAC is 2.3 mm in diameter): ≥ 7 mm diameter and < 30 degree angulation where sensor body will be placed. 5–8 mm where distal loop will be placed.
10	Save reference angiogram image to use as a roadmap for target implant site.
11	Introduce the 0.018 guidewire (GW) through the PAC, and advance 5–6 cm beyond target location.
12	Remove the PAC, being careful to maintain GW position.
13	Flush sheath, and maintain GW position.
14	Flush delivery catheter lumen at hub with saline, and carefully swirl sensor (distal end of catheter) in bowl of saline for 10 seconds to activate hydrophilic coating prior to advancing on GW.
15	Load the delivery catheter over the GW, introduce through the sheath and advance to target implant site.
16	Deploy sensor: Once in target position, under fluoroscopy, unscrew the blue cap on the hub, then retract cap and remove the wires completely from the delivery catheter.
17	Under fluoroscopy, <i>slowly and gently</i> remove the delivery catheter, leaving the GW.
18	Using fluoroscopy as a guide, reinsert the PAC over the GW into the main pulmonary artery (PA). Slowly remove the GW while maintaining sensor position. Position the PAC tip approximately 5–10 cm proximal to the sensor or within the opposite lung, and measure PA pressure.

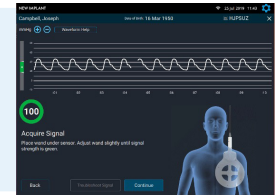
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BASELINE CALIBRATION

19	Place Hospital System antenna under patient's back near the sensor location. Ensure the electrocardiogram leads are out of the antenna path and pressure transducer is leveled and zeroed. On Sensor Position screen, select R or L button to indicate sensor location.
20	Verify a physiologic PA waveform (see example image to the right) and that signal indicator on the left side of the Hospital System screen is green and above 70%, indicating a strong, pulsatile waveform. If not, ensure 3M [†] Bair Hugger [‡] system is turned off and defibrillation patches are disconnected. (Note: If sensor coil is parallel to antenna, position sensor in center of antenna using fluoroscopy as a guide. If sensor coil is perpendicular to antenna, position antenna so that the edge of antenna is under sensor.)
21	If the system detects poor signal quality, the Troubleshoot Signal button turns yellow. Select Troubleshoot Signal to receive guidance on improving sensor signal strength. Select Continue once waveform and signal strength is acceptable.
22	Obtain 10 seconds of valid pressure waveforms. When a strong physiologic signal is acquired, the Freeze to Calibrate button will turn blue. Capture mean PA pressures at the same time Freeze to Calibrate is selected.
23	Enter mean PA pressure measured by the PAC. Sensor pressure values will appear, and the sensor will calibrate to the mean PA pressure entered.
24	If calibration is acceptable, select the Save button. If sensor pressure values do not match PA pressures in real time, select Recalibrate button to capture a new waveform.
25	Obtain 10 seconds of valid pressure waveforms. Record the pressures from the PAC at the same time as you select Take Reading . (Note: Have the control room operator say "NOW" when the Take Reading button is pressed to help coordinate the readings.)
26	Enter systolic, diastolic and mean from the PAC. Next, select patient position. Then, select Save . Obtain two more readings to verify measurements; recorded readings can be discarded by pressing the red Trash button. If mean PA is not within ± 1 mmHg of PAC mean pressure, then reset the PA mean pressure baseline by selecting Recalibrate Sensor .
27	Optional: Input the Cardiac Output (CO) by selecting the Enter CO button. When the signal strength indicator is green and above 70%, press Freeze to Calibrate . Enter the CO, select the forward arrow button on the keyboard, then select Save .
28	Optional: Enter Right Heart Cath (RHC) values. Select the Enter RHC button. Enter the RA, RV, PA and PCWP pressures, then select Save . (Note: RHC information entered on the Hospital System will be displayed in Merlin.net™ PCN.)
29	Select the Review button. Review and confirm the accuracy of all captured data. Select Save , then select End Session . Data transfer to the Merlin.net PCN website will occur automatically.
30	Select from the following options: <ul style="list-style-type: none"> • Send Now to automatically connect to the Merlin.net PCN website and send the implant data (requires a network connection). • Save and Send Later to store in the Unsent Session section of the Main Menu screen. • Export to USB to save implant information to the USB drive for backup. The USB can be used to transfer implant data to Merlin.net PCN if connectivity is an issue. Refer to the CardioMEMS™ Hospital System Quick Reference Guide for more details on how to do this.
31	Select Next. If needed, the summary report can be emailed (network connection required) or exported to the USB. Otherwise, select No . Then select Send and Save . (Note: If login mode is set to Merlin.net PCN or Password Only, a summary report can be emailed or exported to the USB. If login mode is set to No Password, summary report can only be exported.) <ul style="list-style-type: none"> • Session data can no longer be edited. It is critical to send or upload data within 24 hours of implant. The patient will not be able to take their readings until this step is completed.



For Technical Support, please call 1-877-696-3754.

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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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