



## CARDIOMEMS™ HF SYSTEM

# CATH LAB IMPLANT CHECKLIST\* FOR THE CARDIOMEMS™ PA SENSOR

\*Refer to the CardioMEMS™ HF System Instructions for Use (IFU) for complete implant instructions.<sup>1</sup>

### PRE-PROCEDURE SETUP

- 1 Once Hospital Electronics System (HES) is on, select New Implant and then Cancel to bypass Wi-Fi<sup>†</sup>/cellular connection attempt.
- 2 Enter patient's first and last name and date of birth.
- 3 Remove the USB from the system package and insert into one of the ports on the right side of the HES. 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. On the HES, move the search bar on left of screen to -20 mmHg. Place the sensor package next to the HES antenna, look for the signal strength indicator bar on the right of the screen to raise to 99% and then fall as you move the package away from the antenna field. Return the search bar back to 30 mmHg.

### IMPLANT PROCEDURE

- 5 Gain access via femoral vein using 12 F sheath.
- 6 Perform right heart catheterization using either a Swan-Ganz<sup>†</sup> or Pulmonary Wedge Catheter – generically referred to hereafter as Pulmonary Artery Catheter (PAC).
- 7 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.
- 8 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.
- 9 Save reference angiogram image to use as a roadmap for target implant site.
- 10 Introduce the 0.018 guidewire (GW) through the PAC and advance 5–6 cm beyond target location.
- 11 Remove the PAC, being careful to maintain GW position.
- 12 Flush sheath and maintain GW position.
- 13 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.
- 14 Load the delivery catheter over the GW, introduce through the sheath and advance to target implant site.
- 15 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.
- 16 Under fluoroscopy, slowly and gently remove the delivery catheter leaving the GW.
- 17 Using fluoro 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.

## BASELINE CALIBRATION

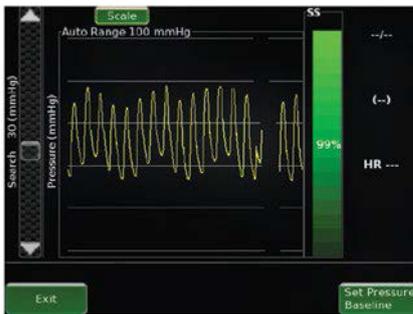
18

Place HES 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.

19

Verify a physiologic PA waveform (see example image) and that the signal indicator on the HES is a green bar, indicating a pulsatile waveform and above 70%. If not, ensure 3M<sup>+</sup> Bair Hugger<sup>+</sup> 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.



20

Once a full screen of good quality data is displayed, select the **Set Pressure Baseline** button and enter mean PA pressure from the PAC.

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Confirm that the sensor mean pressure matches the PAC mean pressure within +/- 1 mmHg.

22

Once a full screen of good quality data is displayed, set Cardiac Output baseline (optional).

23

Once a full screen of good quality data is displayed, select the **Take Reading** button and enter corresponding PAC pressure values. At the same time, have the control room operator record the pressure from the PAC.

**NOTE:** Have the control room operator say "NOW" when the **Take Reading** button is pressed to help coordinate the readings.

24

If reading is acceptable, select the **Yes** button to save the reading. Obtain two more readings to verify measurements. If mean PA is not within +/- 1 mmHg of PAC mean pressure, then re-set the PA mean pressure baseline (steps 21–22).

25

Select **Exit** button. Data transfer to the Merlin.net<sup>™</sup> PCN website will occur automatically.

26

Follow the on-screen prompts to save implant information to the USB drive for backup. This USB can be used to transfer implant data to the Merlin.net PCN if connectivity is an issue. Refer to the CardioMEMS<sup>™</sup> HF System Hospital Electronics System Quick Reference Guide for more details on how to do this.

27

Follow the on-screen prompt to print PA pressure waveforms if desired.

## TECHNICAL SUPPORT

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

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1. Abbott. Data on File. CardioMEMS<sup>™</sup> HF System IFU.

### ABBOTT

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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<sup>™</sup> 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<sup>+</sup> or Android<sup>+</sup> mobile device to receive and transmit information to the myCardioMEMS<sup>™</sup> 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<sup>™</sup> 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.

<sup>+</sup> Indicates a trademark of the Abbott group of companies.

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

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