Abbott

CARDIOMEMS™ HF SYSTEM

PATIENT MANAGEMENT CLINICAL QUICK GUIDE

Information in this Clinical Quick Guide is based on:

- In-depth clinician feedback[1] on the common practices and attitudes from more than 160 heart failure clinicians managing heart failure patients with the CardioMEMS™ HF System at over 125 facilities in the U.S.
- The clinical practices[2] of Philip B. Adamson, M.D., MSc, FACC, a CHAMPION trial[3] principal investigator

Refer to the CardioMEMS HF System Program Practice Guide and the CardioMEMS HF System Instructions for Use (IFU)[4] for more details.

Medical care of the patient is the sole responsibility of the acting practitioner. This document is not intended to replace the judgment of the acting practitioner nor the establishment of final protocols within the hospital setting.

This document does not represent any opinion or endorsement by Abbott of any particular approach to patient management or treatment.

IMPLANT PROCEDURE PREPARATION

CONTRAINDICATIONS

The CardioMEMS™ HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

PRE-IMPLANT MEDICATION MANAGEMENT

Review the patient's current medications and adjust as needed per your clinic's standard pre-procedural protocol.

Patients on anticoagulant therapy[4]:	• Discontinue use of anticoagulant therapy one to two days prior to sensor placement. • INR of < 1.5 recommended prior to sensor implant. • Restart treatment after sensor implantation.
Patients not currently being treated with chronic anticoagulant therapy[4]:	• For one month following the procedure, anticoagulant therapy should be aspirin (81 mg or 325 mg) and clopidogrel (75 mg) daily. • After one month, patients should continue with aspirin therapy only.[4]

PHASE I: POST IMPLANT PATIENT EVALUATION

Goal: Understand patient pulmonary artery (PA) pressure baseline

DURING THE RIGHT HEART CATHETERIZATION

- Compare pulmonary capillary wedge pressure (PCWP) and right atrial pressure (RAP) numbers to determine whether volume versus vascular resistance is driving the elevated PA pressures.
- Note differences of ≥ 5 mmHg between PCWP and sensor pulmonary artery diastolic (PAD) and consider the discordance when establishing PA pressure threshold range.
- Enter right heart catheterization numbers in the Merlin.net™ Patient Care Network (PCN).

PHASE II: PA PRESSURE OPTIMIZATION

Goal: Manage patients to achieve optimal PA pressures

WITHIN THREE TO SEVEN DAYS OF IMPLANT

1. Review patient's initial at-home readings to determine PAD pressure goal and threshold range. Set wide initial threshold range (10 mmHg).
2. On the Merlin.net™ PCN, select the Optimization phase for the patient and program the initial PAD pressure goal and threshold range.
3. Decide how and when you want to receive patient notifications.
4. Subscribe to your patient on the Merlin.net PCN so they will show up on your Notifications List.

PATIENT MANAGEMENT

- Monitor the Notifications List on the Merlin.net PCN and address any notifications for the patient.
- Assess PAD pressure goal and threshold range every two weeks; adjust and reprogram accordingly on the Merlin.net PCN.

ASSESSMENT CONSIDERATIONS

- Electrolytes
- Adverse patient symptoms
- Hypotension
- Renal function (increase in creatinine by 20%)[2]

NOTE

It may take 30–90 days to reach optivolemic status.

PHASE III: PA PRESSURE MAINTENANCE

Goal: Maintain optivolemia

WHEN VOLUME STATUS IS OPTIMIZED

1. Determine optimal PAD pressure goal to maintain optivolemic state.
2. On the Merlin.net™ PCN, select the Maintenance phase for the patient and enter the PAD pressure threshold range 2–3 mmHg above/below target PAD pressure goal.

PATIENT MANAGEMENT

- Monitor the Notifications List on the Merlin.net PCN and address any notifications for the patient.
- Evaluate pressures at least one time per month, reassess PAD pressure goals and/or reprogram PAD pressure threshold ranges as needed.[1]

PATIENT MANAGEMENT WORKFLOW EFFICIENCY TIPS

- There is no need to check PA pressures every day. Remember, PA pressures will rise long before the patient is in crisis.[2]
- Set customized PAD pressure goal and threshold range on the Merlin.net PCN, and rely on the Notifications List to inform you of patients needing attention.
- Communicate with your patients efficiently by using the Patient Messaging feature on the Merlin.net PCN.

NOTIFICATIONS LIST

- Subscribe to each of your patients on the Merlin.net™ PCN so they show up on your Notifications List.
- Choose one to two days per week to review the Notifications List.
- Utilize the Notifications List and Notifications List report to triage patients that need attention.

NOTE

As heart failure progresses, a patient's PA pressures may no longer respond to medication changes and the patient may benefit from a left ventricular assist device (LVAD). Consider LVAD evaluation for HFrEF if the patient:

- Has persistently high PA pressures
- Shows no response to diuretics or neurohormonal agents
- Completes six-minute walk distance less than 300 m
- Has had a heart failure hospitalization
- Echo exam did not change

GUIDELINES FOR REMOTE MONITORING OF PA PRESSURE TRENDS

PAD < 10 mmHg	PAD > 25 mmHg

Low PA Pressures (Hypovolemic)

PAD *trending* below the normal hemodynamic range

Poor perfusion in the absence of signs and symptoms of congestion

Lower or discontinue diuretic

- if on thiazide and loop diuretic, lower or discontinue the thiazide diuretic
- if only on loop diuretic, lower the dose or discontinue
- consider liberalization of oral fluid or salt restriction

Lower or hold vasodilators
if postural hypotension presents

Re-evaluate PA pressures
2–3 days per week until PA pressures stabilize

Lower or hold ACE/ARB dose
if worsening renal function presents with hypotension

Elevated PA Pressures (Hypervolemic)

PAD *trending* above the normal hemodynamic range

Add or increase diuretic

- increase/add loop diuretic
- change loop diuretic
- add thiazide diuretic
- IV loop diuretic

Add or increase vasodilators
add or increase nitrate

Re-evaluate PA pressures
2–3 days per week until PA pressures stabilize

Evaluate other etiologies
if PA pressures remain elevated (e.g., dietary indiscretion, sleep apnea)

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker

NOTE

The guidelines presented graphically above should be individualized to the patient based on their specific pressure ranges.

OTHER POTENTIAL ACTIONS[1]

- Add thiazide diuretic or change loop diuretic.
- See patient, add vasodilator (nitrate or hydralazine) and check labs.
- Consider in-office IV furosemide.
- Remember to adjust potassium.

1. Abbott. Data on File. 90305907 Rev. A. The CardioMEMS™ HF System Workflow Research. May 2017.
2. Abbott. Data on File. Adapted from: "CardioMEMS HF System Clinical Protocol Example, Philip B. Adamson, MD, MSc, FACC, Medical Director at Abbott, and former Director Heart Failure Institute at Oklahoma Heart Hospital, shares his experience with patient management of heart failure using PA Pressure."
3. Abraham W, Adamson P, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. *The Lancet*. Feb. 19, 2011;377:658-666.
4. CardioMEMS HF System Instructions for Use.

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
Abbott.com

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.

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.

35439 MAT-1900910 v1.0 | Item approved for U.S. use only.

Abbott