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.
**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).

**CARDIOMEMS™ PA SENSOR IMPLANT ANTICOAGULATION**

- Currently Receiving Anticoagulation:\(^4\)
  - Discontinue anticoagulant therapy one to two days prior to sensor implant.
  - INR of < 1.5 is recommended prior to sensor implant.
  - Restart treatment after sensor implantation.

- Not Currently Receiving Anticoagulation:\(^4\)
  - For one month following the procedure, anticoagulant therapy should be aspirin (81 mg or 325 mg) and clopidogrel (75 mg) daily.
PHASE II: PA PRESSURE OPTIMIZATION

Goal: Manage patients to achieve optimal PA pressures

SET INITIAL PAD PRESSURE THRESHOLD RANGE

Within three to seven days of implant

1. Review patient’s initial at-home readings to determine PAD pressure threshold range. Set wide initial threshold range (10 mmHg).

2. Program initial PAD pressure threshold range on the Merlin.net™ PCN.

3. Subscribe to your patient on the Merlin.net PCN to receive email notifications.

ASSESSMENT CONSIDERATIONS

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

NOTE

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

OPTIMIZE PRESSURES

- Assess PA pressures and waveforms two to three times per week until pressure is optimized.

- Respond to trends. Intervene with a patient if there is a 3–5 mmHg change in PA pressure over two to three days or 5 mmHg or more in a single day.

- Assess PAD pressure threshold range every two weeks; adjust and reprogram accordingly on the Merlin.net PCN.
**PHASE III: PA PRESSURE MAINTENANCE**

**Goal:** Maintain optivolemia

**ESTABLISH MAINTENANCE PAD PRESSURE GOAL AND THRESHOLD RANGES**

- Determine optimal PAD pressure goal to maintain optivolemic state.
- Program PAD pressure threshold range on the Merlin.net™ PCN 2–3 mmHg above/below target PAD pressure goal.

**MAINTAIN PRESSURES**

- Evaluate pressures at least one time per month, reassess PAD pressure goals and/or reprogram PAD pressure threshold ranges as needed.¹
- Review Patients of Interest report one to two times per week.

**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 threshold range on the Merlin.net PCN, and rely on email notifications and the Patients of Interest report to inform you of patients needing attention.
- Communicate with your patients efficiently by using the DirectCall™ messages feature on the Merlin.net PCN.
PATIENTS OF INTEREST REPORT

PATIENTS OF INTEREST REPORT USERS

- Clinic administrator: Select one to two days/week to generate the report.
- Individual clinic user: Opt in on the Merlin.net™ PCN user profile.

Patients will be added to a Patients of Interest report for the following reasons:

1. Running an average of seven days of PAD pressure outside their programmed threshold range
2. Weekly PAD average change of +/- 5 mmHg or more over last week’s average within programmed threshold range
3. No transmitted pressure reading for more than seven days

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

<table>
<thead>
<tr>
<th>PAD &lt; 10 mmHg</th>
<th>PAD &gt; 25 mmHg</th>
</tr>
</thead>
</table>
| **Low PA Pressure (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  
**Reevaluate 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 Pressure (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  
**Reevaluate 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

- 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.

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.”


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.

™ Indicates a trademark of the Abbott group of companies.
‡ Indicates a third party trademark, which is property of its respective owner.
© 2019 Abbott. All Rights Reserved.
30314-SJM-MEM-0617-0335(2) | Item approved for global use.