Abbott

CARDIOMEMS™ HF SYSTEM

PROGRAM PRACTICE GUIDE

VOLUME 2

CARDIOMEMS™ HF SYSTEM

PROGRAM PRACTICE GUIDE

This CardioMEMS™ HF System *Program Practice Guide* is a comprehensive resource to help clinicians more efficiently manage clinical programs for heart failure patients who have received a CardioMEMS HF System.

Much of the information in this *Program Practice Guide* is based on:

- In-depth research and feedback[1] on the common practices and attitudes of more than 160 heart failure clinicians managing heart failure patients on 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.

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.

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 WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. *The Lancet*. 2011;377(9766):658-666.

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PATIENT SELECTION

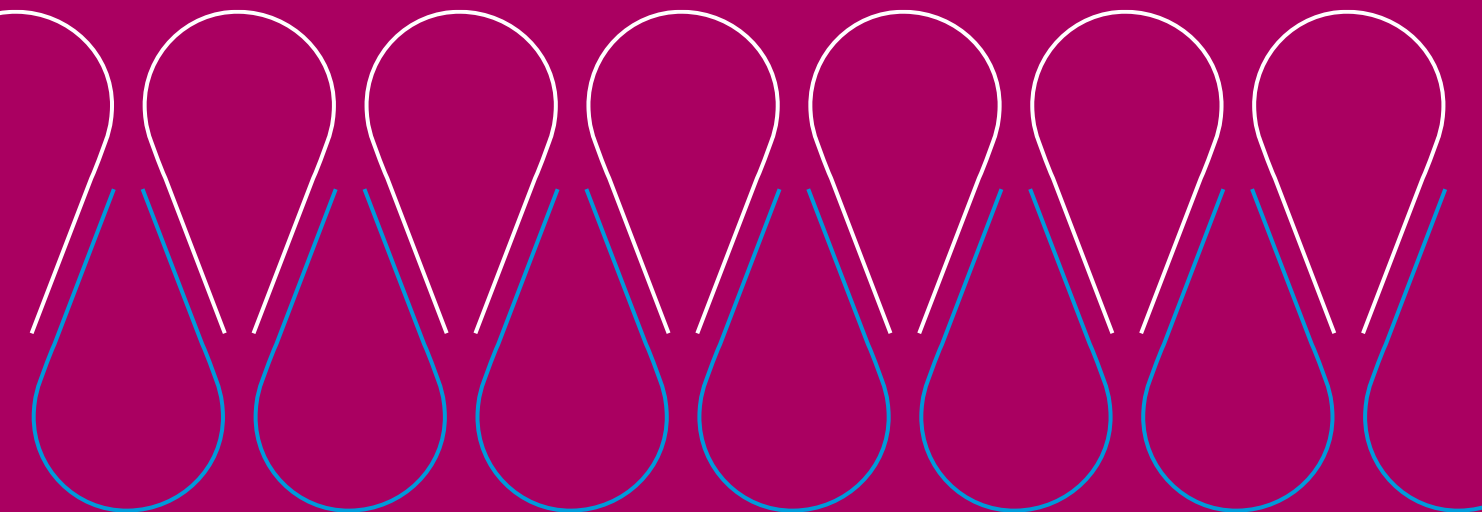PATIENT EDUCATION

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IDENTIFYING APPROPRIATE PATIENTS

FOR THE CARDIOMEMS™ HF SYSTEM

As you begin to identify your heart failure patients who would be appropriate candidates for the CardioMEMS™ HF System, please use this section as a resource to help ensure that your patients have the best possible outcomes with this valuable monitoring technology.

The CardioMEMS HF System is indicated for these patients[1]:

☑ NYHA Class III heart failure

☑ One heart failure hospitalization in the past 12 months

> **HELPFUL TIP:**
>
> A typical NYHA Class III patient has marked limitation of physical activity. Less than ordinary activity leads to symptoms (moderate CHF). Doctors commonly look at what the patient's heart failure symptoms have predominantly been in the last 30 days.

The CardioMEMS HF System is contraindicated for these patients:

• Patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

Patients who most commonly receive the CardioMEMS HF System are those on GDMT and those who exhibit any of the following[1]:

• Fluid volumes are hard to know or manage

• Physical assessment is challenging

• Is a patient with HFpEF or HFrEF

• Compliant with heart failure medical care

• Would benefit from remote monitoring if they live far from clinic

> **HELPFUL TIP:**
>
> The CHAMPION trial specifically excluded patients with ACC/AHA stage D heart failure who needed advanced therapies (i.e., LVAD, transplant, or inotropic support). Even if inotropic support improved heart failure symptoms, a patient would still be defined as stage D, with refractory heart failure.[1]

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The following patients may not be appropriate for implantation of the CardioMEMS™ HF System[2]:

- Patients with an active infection.

- Patients with a history of recurrent (> 1) pulmonary embolism or deep vein thrombosis.

- Patients unable to tolerate right heart catheterization.

- Patients with a Glomerular Filtration Rate (GFR) < 25 ml/min who are non-responsive to diuretic therapy or who are on chronic renal dialysis.

- Patients with congenital heart disease or mechanical right heart valve(s).

- Patients with known coagulation disorders.

- Patients with a hypersensitivity or allergy to aspirin, and/or clopidogrel.

- Patients who have undergone implantation of a Cardiac Resynchronization Device (CRT) within the past three months.

- If the patient's BMI is greater than 35, measure the patient's chest circumference at the axillary level. If the chest circumference is > 165 cm, sensor implantation should not occur.

NEW YORK HEART ASSOCIATION (NYHA)

FUNCTIONAL CLASSIFICATION[3]

As the most commonly used classification system, the NYHA Functional Classification places patients into one of four categories on how much they are limited during physical activity.

STAGES OF HEART FAILURE

CLASS I	CLASS II	CLASS III	CLASS IV
No limitation of physical activity.	Slight limitation of physical activity.	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.	Unable to carry on any physical activity without discomfort.
Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).	Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).	NYHA Class III is the approved heart failure patient classification for the CardioMEMS HF System.	Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

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EDUCATIONAL RESOURCES

FOR PATIENT SELECTION

Available at **Cardiovascular.Abbott/CardioMEMSWorkflow**

CARDIOMEMS™ HF SYSTEM PATIENT APPROACH EXAMPLE VIDEO #1

with Jamie Pelzel, M.D.

CARDIOMEMS HF SYSTEM PATIENT APPROACH EXAMPLE VIDEO #2

with Stephanie Preister, CNP

CARDIOMEMS HF SYSTEM PATIENT APPROACH EXAMPLE VIDEO #3

with Philip Adamson, M.D., MSc, FACC

PHYSICIAN PEER-TO-PEER PRESENTATION FOR THE CARDIOMEMS HF SYSTEM

PATIENT ID TOOL

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REFERENCES

1. Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. *The Lancet.* 2011;377(9766):658-666.

2. CardioMEMS™ HF System Instructions for Use.

3. http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article. jsp#.WYIcvK3Mw0o. Accessed Aug. 2, 2017. Adapted from Dolgin M, Association NYH, Fox AC, Gorlin R, Levin RI, New York Heart Association. Criteria Committee. Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. 9th ed. Boston, MA: Lippincott Williams and Wilkins; March 1, 1994. Original source: Criteria Committee, New York Heart Association, Inc. Diseases of the Heart and Blood Vessels.Nomenclature and Criteria for diagnosis, 6th edition Boston, Little, Brown and Co. 1964, p 114.

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EDUCATING YOUR HEART FAILURE PATIENTS

ABOUT THE CARDIOMEMS™ HF SYSTEM

Once you've identified the heart failure patients you think could benefit from the CardioMEMS™ HF System, you will need resources to help educate them.

We've asked clinicians across the U.S. to share with us their best practices[1] when educating patients about the CardioMEMS HF System. Drawing from these findings, this section provides you with an overview of the tools Abbott makes available to you and your team to educate and prepare your heart failure patients to receive the CardioMEMS HF System.

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PATIENT EDUCATION TIMELINE

FOR THE CARDIOMEMS™ HF SYSTEM

1   **INTRODUCING THE CARDIOMEMS™ HF SYSTEM**
Provide a brief introduction of the CardioMEMS HF System to the patient and caregiver.

2   **POST DISCHARGE CLINIC FOLLOW-UP**
Provide a detailed description of the CardioMEMS HF System and its benefits.

3   **PRIOR TO IMPLANT — UP TO ONE WEEK**
Train the patient and their caregiver on the equipment they will receive and how to take daily pressure readings at home BEFORE the procedure.

4   **RECOVERY ROOM AFTER IMPLANT**
Set the patient up for success at home by walking through the Patient Quick Start Guide and each piece of equipment they will take home with them.

5   **POST IMPLANT — DAY ONE**
Check to see if the patient is doing OK and if they have any questions.

6   **POST IMPLANT — WITHIN ONE WEEK**
See the patient and their caregiver in clinic to assess recovery and how they are doing with readings.

HELPFUL TIP:

Many private payers and Medicare Advantage plans require Prior Authorization before the implant. Abbott's Patient Therapy Access (PTA) team can help with this process (some payers' Prior Authorizations can take up to a few months). See contact information below.

FOR MORE INFORMATION, PLEASE REFER TO

the Billing and Reimbursement chapter of this document.
Or, you can contact the Abbott PTA Team:

Call toll-free at 1-855-569-6430

Email hce@sjm.com

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① INTRODUCING THE CARDIOMEMS™ HF SYSTEM

Introduce the CardioMEMS™ HF System to a patient while they are still in the hospital. This may be done by a hospitalist or the patient's managing heart failure clinician when they are doing rounds.

Explain that you want to share another option — the CardioMEMS HF System — to better manage their heart failure, with a goal of reducing future hospitalizations.

HELPFUL TIP:
Having a caregiver present can help patients better understand the information and support them as they make their decision.

Each Event Accelerates Downward Spiral of Myocardial Function

With each subsequent heart failure related admission, the patient leaves the hospital with a further decrease in cardiac function.

Acute Event

Myocardial Function

Time
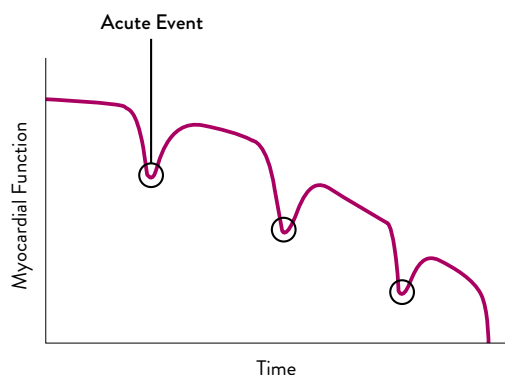
THE GOAL:
Maintain fluid volume to avoid acute decompensation and hospitalization, using proven drug and device therapies.

Graph adapted from Gheorghiade MD, et al. *Am J. Cardiol,* 2005.

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② POST DISCHARGE CLINIC FOLLOW-UP

At the first clinic visit, after a heart failure hospitalization (usually within one week), explain the following:

• The gravity of a heart failure prognosis and the importance of carefully managing their health to stay ahead of heart failure. Remind them of how they felt before they were hospitalized.

• With the CardioMEMS™ HF System, patients may have fewer clinic visits.

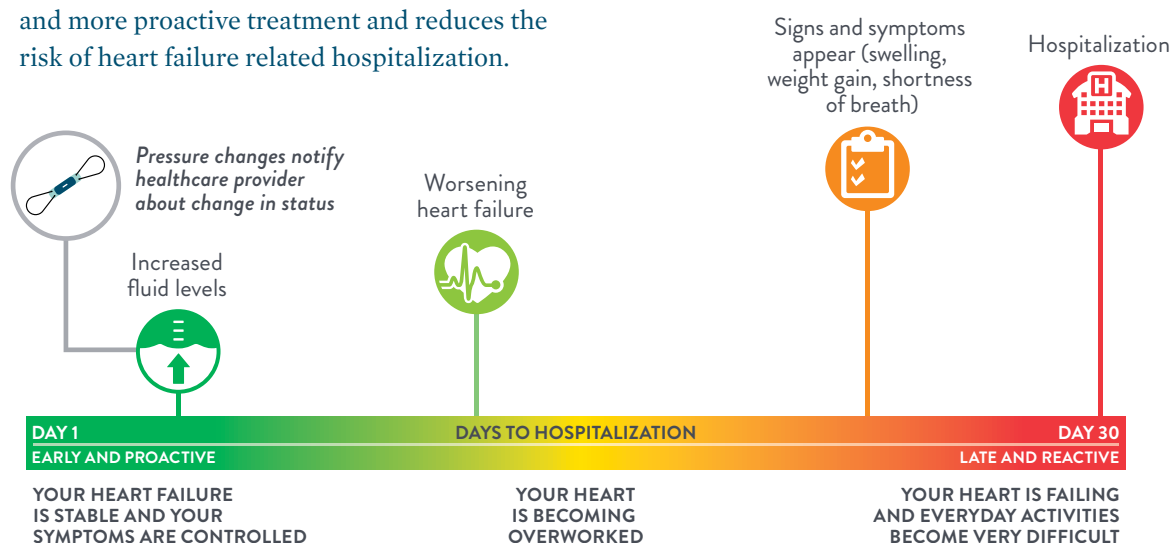• With the CardioMEMS HF System and Merlin.net™ Patient Care Network, clinicians can see when a patient's PA pressures change so that they can adjust medications before their heart failure worsens, sometimes even before a patient notices symptoms.

• That the CardioMEMS HF System monitors the pressures inside their heart and lungs.

• How increased pressure in the heart's pulmonary artery (PA) typically indicates that:

– Fluids are rising

– Heart failure will soon get worse

– Another hospitalization is likely soon

– Further damage may occur to their heart

• The graphic below can be found on the Patient Quick Education Tool and may be a helpful guide when explaining how monitoring and managing PA pressure with the CardioMEMS HF System may help your patients stay ahead of heart failure.

EARLY TREATMENT IS ESSENTIAL

The CardioMEMS HF System enables earlier and more proactive treatment and reduces the risk of heart failure related hospitalization.

Pressure changes notify healthcare provider about change in status

Increased fluid levels

Worsening heart failure

Signs and symptoms appear (swelling, weight gain, shortness of breath)

Hospitalization

DAY 1 — DAYS TO HOSPITALIZATION — DAY 30
EARLY AND PROACTIVE — LATE AND REACTIVE

YOUR HEART FAILURE IS STABLE AND YOUR SYMPTOMS ARE CONTROLLED

YOUR HEART IS BECOMING OVERWORKED

YOUR HEART IS FAILING AND EVERYDAY ACTIVITIES BECOME VERY DIFFICULT

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2 POST DISCHARGE CLINIC FOLLOW-UP (CONTINUED)

When talking to patients about the CardioMEMS™ HF System, clinicians may want to start the discussion by showing their patient and caregiver a short video overview of how the CardioMEMS HF System works, which can be found online at **Cardiovascular.Abbott/CardioMEMSWorkflow.**

HOW THE CARDIOMEMS™ HF SYSTEM WORKS
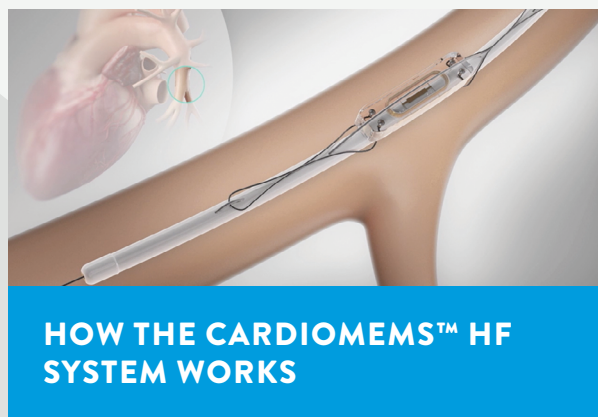
Consider using the following descriptions of the system when talking to your patients[1]:

- Implanting the CardioMEMS™ PA Sensor is a short, low-risk procedure. The sensor is secured in the patient's PA with a catheter accessed through a vein in their groin area. This approach is very similar to other heart procedures.

- The sensor is small and self-contained — about the size of a paper clip. There are no batteries or wires. The patient should not feel the sensor inside their body. This is a good time to show the sensor demo to the patient.

- The patient will take a wireless reading from their PA sensor once a day from the comfort of their home. Daily data transmissions are also easily done while traveling in the United States.

- Pressure data from this daily wireless reading is transmitted to a secure website for the physician and clinical team to review.

- Pacemakers, Implantable Cardioverter Defibrillators (ICDs) and Ventricular Assist Devices (VADs) can work in conjunction with the PA sensor and will not affect the performance of the system.

- If a patient decides they do not want to continue, or cannot continue, transmitting data, they can stop. However, the sensor will remain in their PA with no risk to the patient.

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3 PRIOR TO IMPLANT — UP TO ONE WEEK

Clinic staff should train patients and their caregivers on the equipment they will receive, and how to take daily pressure readings at home BEFORE the procedure. Training can take place up to a week before the procedure. A clinic may want to consider training two or three clinicians who will educate patients so that there is always someone available during vacations or in case of staff turnover, etc.

PATIENT TRAINING VIDEO
that is included with the equipment the patient takes home after implant.

View video at Cardiovascular.Abbott/CardioMEMSWorkflow

For the patient/caregiver education prior to implant, Abbott recommends the following process:

- Show patients/caregivers the in-home training video included with the equipment they will take home with them.

- **Review patient responsibilities**
  Remind the patient that they play a very important role in ensuring that the CardioMEMS™ HF System helps to better manage their heart failure.
  Reinforce the following:

  – They will be required to take readings (usually daily) as directed by their clinic.

  – They need to have a working phone (cell, landline) or Wi-Fi[‡] network.

  – They will need to respond to calls or text messages from their clinic in case a medication change is needed or there is a question from the clinic about a daily PA pressure reading.
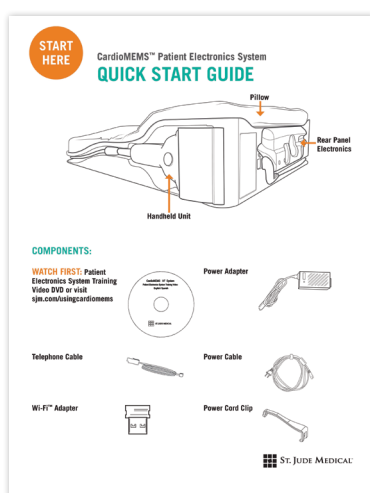
HELPFUL TIP:
It's important to verify the patient's contact information so that you are able to contact them if you need to change medications or to find out more about a PA pressure reading.
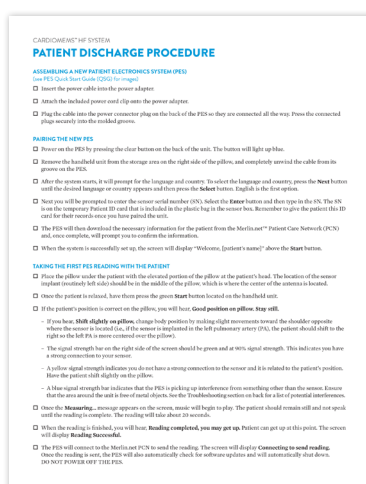
4 **RECOVERY ROOM AFTER IMPLANT**

Set patients up for success at home by reviewing these important steps. Use the Patient Discharge Procedure Checklist to guide your education.

- Walk through the Patient Quick Start Guide and each piece of equipment the patient will take home with them. Explain that this Quick Start Guide (which is in their equipment case) is meant to help them easily set up their equipment at home and take their first in-home reading.

- After the unit has been paired to the patient's sensor, have the patient take their first PA pressure reading with the Patient Electronics System they will take home. This will allow the patient to experience what it is like to take a PA pressure reading at home.

- Does the patient have a cell phone, a landline phone or a Wi-Fi‡ network in their home? The CardioMEMS™ HF System will work with all three communication options. Ask the patient during their pre-implant education which phone/Wi-Fi‡ system they have so that you can educate them on their equipment according to the way it should be set up at home.

Patient Electronics System Quick Start Guide

Patient Discharge Procedure Checklist

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5   POST IMPLANT — DAY ONE

Contact your CardioMEMS™ HF System patient at home.

- Check to see if they are doing OK and if they have any questions about their home electronics equipment or taking daily readings.

- Troubleshoot any issues, and/or refer them to Abbott Remote Care for support.

6   POST IMPLANT — WITHIN ONE WEEK

See the patient and their caregiver in clinic. At this meeting, you can:

- Check the patient's recovery after the implant procedure.

- Assess if they understand how to properly take daily readings. If they are not taking daily readings, find out why, and reinforce the clinical value of daily pressure readings.

- If they are having any technical problems taking readings remind them to reference the training video on the DVD and/or Quick Start Guide packaged with their Patient Electronics System.

- Tell your patient that you will be monitoring their PA pressures and finding the right balance of pressures for their heart; explain that you will tell them you will contact them only if their pressures are out of range.

> **HELPFUL TIP:**
>
> Introduce the myCardioMEMS™ Patient Application as a helpful tool for communicating treatment instructions to your patient.

ABBOTT REMOTE CARE TEAM

Phone: 1-844-MYCMEMS

Monday–Friday, 8 a.m. to 8 p.m. Eastern Time

COMMON TROUBLESHOOTING ISSUES

Abbott recommends that patients and their caregivers read the Quick Start Guide and Patient Electronics System Guide for complete details. These are both packaged with their Patient Electronics System.

Here is a list of the most frequently encountered troubleshooting items:

- Metal in the vicinity (within about three feet) of the Patient Electronics System could cause interference. This could include jewelry, keys, belts, eyeglasses, electric heating blankets, metal bed frames or rails, or other medical equipment, such as a CPAP machine, hearing aid charger or oxygen supply. Instruct the patient to move these objects away from the system.

- Readings should not be taken on a waterbed.

- Before taking their reading, make sure the patient unwraps the handheld unit and handheld cable completely from the storage area.

- When they are taking a reading, the patient should avoid placing the handheld unit directly on their chest.

- When positioning on the pillow for a reading, educate the patient to shift slightly left or right so that their sensor is centered over the lower section of the pillow. This is where the antenna is located. Remind the patient that their sensor is located just in front of their right or left shoulder blade.

  – Each Patient Electronics System includes a positioning ball that can be placed on the pillow to help the patient remember the best position for reading their CardioMEMS™ PA Sensor. You can position this ball on the patient's pillow when they do their first reading before they leave. Often, people position the ball where the neck meets the shoulder on the side where their sensor is located.

- If the Patient's Electronic System is having trouble connecting, educate the patient that their reading is stored on the machine and will automatically upload the next time they connect.

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FAQ

PATIENT FREQUENTLY ASKED QUESTIONS

Below is a list of the most common FAQ from patients. Remind the patient that the Quick Start Guide has a FAQ section that they can easily reference.

Will the CardioMEMS™ HF System interfere with my pacemaker?

No. Pacemakers, ICDs and VADs can work in conjunction with the CardioMEMS™ PA Sensor and will not affect the performance of the system.

How do I change the volume on my electronics system?

Once your system is set up and powered on, click **Options** on the start screen. Select **Volume** and toggle up or down to increase or decrease.

What happens with my readings?

Every time you take a reading, it is transmitted to a secure website that your medical team can access. Your doctor or nurse regularly reviews the information and contacts you if changes to your medications or treatment plan are necessary. If everything is going well, you most likely will not hear from your medical team.

I am getting a warning on the screen, what do I do?

If you experience any issues with your Patient Electronics System, please review the "Troubleshooting the Patient Electronics System" section in the Patient Electronics System Guide.

What do I need to setup my Wi-Fi‡ network?

Prior to setting up the Wi-Fi connection on the Patient Electronics System, locate and write down your Wi-Fi network name and password. If you cannot find it, call your Internet Service Provider for assistance.

I have received a replacement Patient Electronics System. How do I set it up?

Refer to the "Setting Up a Replacement System" section of the Patient Electronics System Guide. You will need your six-digit sensor serial number that can be found on your patient identification card.

Can I travel with my Patient Electronics System?

Yes, you can travel with your system. If you are flying, the travel case meets the size requirements of carry-on baggage. If you choose to check the travel case, tell the airline that you are carrying medical equipment and they will check it for free. To repack the system, refer to the "Repacking" section in the Patient Electronics System Guide. A travel letter is available for patients to expedite TSA security screening when traveling with the Patient Electronics System. The letter can be downloaded from **Cardiovascular.Abbott/CardioMEMSWorkflow.**

ABBOTT REMOTE CARE TEAM

Abbott's Remote Care Team is available as a resource for you and your heart failure patients to help them with their CardioMEMS HF System.

To contact the Remote Care Team, please see contact information below:

Phone: 1-844-MYCMEMS

Monday–Friday, 8 a.m. to 8 p.m. Eastern Time

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EDUCATIONAL RESOURCES

TO HELP CLINICIANS DISCUSS THE CARDIOMEMS™ HF SYSTEM WITH THEIR HEART FAILURE PATIENTS

Visit **Cardiovascular.Abbott/CardioMEMSWorkflow** to access these resources.

CARDIOMEMS™ HF SYSTEM PATIENT APPROACH EXAMPLE VIDEO #1
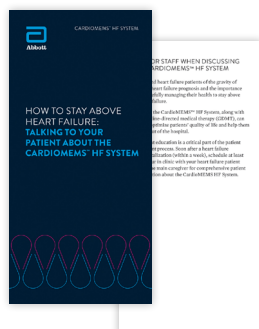with Jamie Pelzel, M.D.

CARDIOMEMS HF SYSTEM PATIENT APPROACH EXAMPLE VIDEO #2
with Stephanie Preister, CNP

CARDIOMEMS HF SYSTEM PATIENT APPROACH EXAMPLE VIDEO #3
with Philip Adamson, M.D., MSc, FACC

HOW TO STAY ABOVE HEART FAILURE: TALKING TO YOUR PATIENT ABOUT THE CARDIOMEMS HF SYSTEM

MYCARDIOMEMS™ APP INSTRUCTIONAL VISUAL GUIDE

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EDUCATIONAL RESOURCES

FOR YOUR HEART FAILURE PATIENTS

Abbott has many resources to help you educate your heart failure patients about the CardioMEMS™ HF System. No matter where they are in their journey, these materials will help your patients and their caregivers become more informed on the value of monitoring with the CardioMEMS HF System.

Please ask your Abbott Sales Representative if you would like any of these printed resources for your patient education programs or visit **Cardiovascular.Abbott/CardioMEMSWorkflow.**

PATIENT BROCHURE
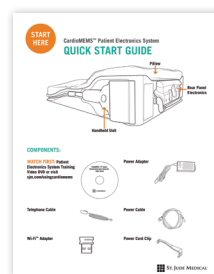
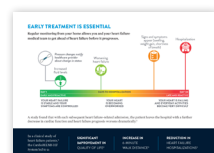**PATIENT ELECTRONICS SYSTEM QUICK START GUIDE**

SEVERAL PATIENT TESTIMONIALS

PATIENT QUICK EDUCATION TOOL

CLINIC WAITING ROOM/EXAM ROOM POSTER WITH TEAR-OFF PAD FOR MORE INFORMATION

PATIENT CONNECT FLYER

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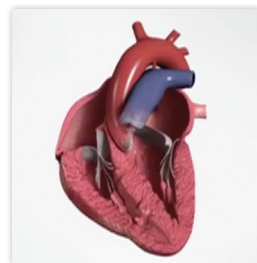MERLIN.NET™ PCN

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FOR YOUR HEART FAILURE PATIENTS (CONTINUED)

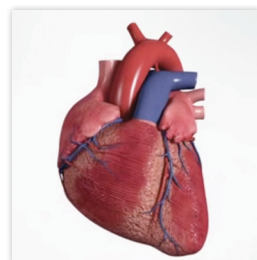
OVERVIEW VIDEO

for the CardioMEMS™ HF System.

ANIMATION VIDEO

for patients on the different types of heart failure (right- and left-sided heart failure).
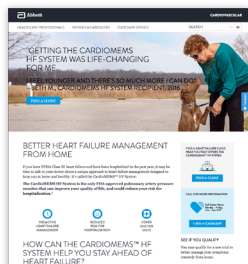

PATIENT TRAINING VIDEO

that is included with the equipment the patient takes home after implant.

ANIMATION VIDEO

for patients on how the heart works.

PATIENT INFORMATION AND PATIENT TESTIMONIAL VIDEOS

on the web at StayAheadofHF.com

REFERENCES

1. Abbott. Data on File. 90305907 Rev. A. The CardioMEMS™ HF System Workflow Research. May 2017.

This document is not intended to replace the judgment of the acting practitioner nor the establishment of final protocols within the hospital setting. It does not represent any opinion or endorsement by Abbott of any particular approach to patient management or treatment.

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

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.

Limitations: Patients must use their own Apple‡ or Android‡ mobile device to receive and transmit information to the myCardioMEMS™ 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™ 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.

™ 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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IMPLANTATION

OF THE CARDIOMEMS™ PA SENSOR

After you have identified your heart failure patient as an appropriate candidate for the CardioMEMS™ HF System you will schedule them for an implant or refer them to an implanting Cardiologist for the procedure.

The purpose of this section is to provide you with an overview of the technical aspects of the sensor implant so you are aware of the main procedural steps, and can answer questions from your patients.

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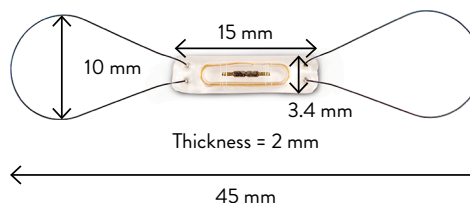
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TECHNICAL INFORMATION

ABOUT THE CARDIOMEMS™ PA SENSOR

The CardioMEMS™ PA Sensor is about the size of a paper clip when deployed in the target pulmonary artery (PA). See actual size image and product schematic image below.

PA sensor shown at actual size

15 mm
10 mm
3.4 mm
Thickness = 2 mm
45 mm

PA sensor not shown at actual size

MR   MR Conditional

The CardioMEMS PA Sensor is MRI conditionally approved for 1.5 or 3.0 Tesla imaging. A patient with this device can be scanned safely under the following conditions:

• Status magnetic field of 1.5 or 3.0 Tesla

• Maximum spatial gradient magnetic field of 720-Gauss/cm (7200-mT/m) or less

HELPFUL TIP:

The patient will receive a device ID card following implant. It will contain relevant information about MRI compatibility.

TARGETING THE PULMONARY ARTERY FOR PLACEMENT

OF THE CARDIOMEMS PA SENSOR

The CardioMEMS PA Sensor is optimally inserted into the left descending PA. At the discretion of the implanting physician, the sensor may be inserted into the right PA, depending on the patient's anatomy.

Target implant site

≥7mm ID
5-8mm ID
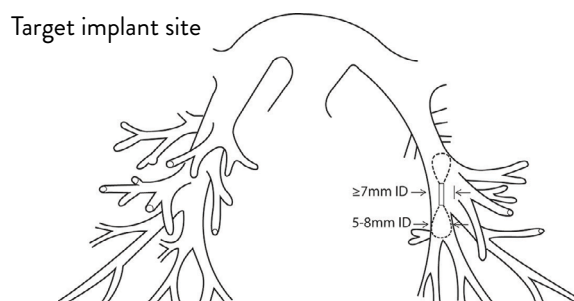
For complete implant procedure and device information, please refer to the Instructions for Use/User's Manual for the CardioMEMS™ HF System, PA Sensor and Delivery System (Model CM2000).

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CATH LAB PROCEDURE FOR IMPLANT
OF THE CARDIOMEMS™ PA SENSOR

While each implanting physician will have their own unique procedural techniques,[1] this is the typical process observed.[2]

1   Right heart catheterization and placement of the CardioMEMS™ PA Sensor

- A PA catheter or Swan-Ganz‡ catheter is placed into the patient's PA via access from the femoral vein.

- The catheter is used to evaluate the patient's baseline hemodynamics, and along with an angiogram, helps to determine the patient's target implant vessel.

- The sensor is advanced over a guidewire to the identified implant site in the PA.

- Once in position, the sensor is released from the delivery tool and its nitinol loops expand to stabilize the sensor in the artery.

- On average, the sensor occupies 10% of the artery's lumen.

- The sensor typically endothelializes within three months of the implant.

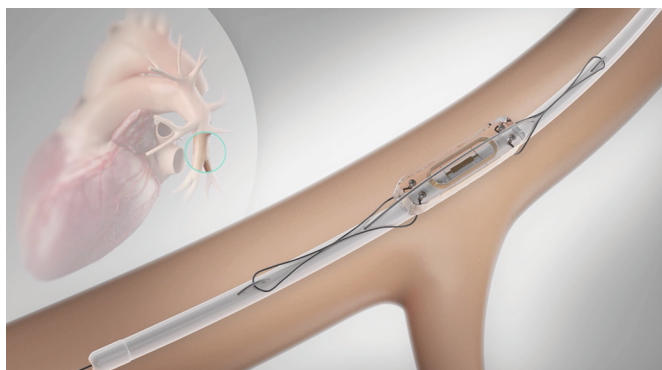**2   Calibrating the sensor with PA catheter mean pressure**

- During the implant procedure the CardioMEMS PA Sensor is calibrated to the PA catheter mean pressure.

- 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 variance when establishing PA pressure thresholds. For more information, see example in the Patient Management chapter.

  – Enter right heart catheterization numbers in the Merlin.net™ Patient Care Network (PCN).

3   Pairing the implanted PA sensor with the Patient Electronics System

- Before the patient leaves the hospital after the implant procedure, a trained hospital staff member will:

  – Pair the patient's implanted sensor serial number with the electronics system they will take home. More information about pairing the sensor is available on the Patient Discharge Procedure Checklist.

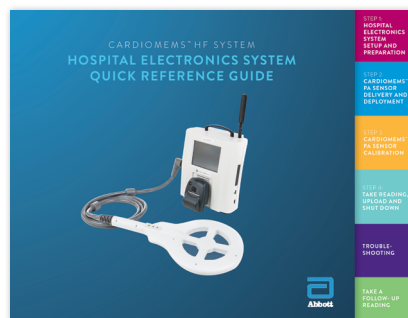 – Assist the patient with taking their first PA pressure reading with their electronics system.

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RESOURCES

IMPLANT ANIMATION FOR THE CARDIOMEMS™ PA SENSOR

A short animation is available at **Cardiovascular.Abbott/CardioMEMSWorkflow** to help you visualize and better understand the implant procedure for the CardioMEMS™ PA Sensor.

CLINICAL REVIEW ARTICLE

Shavelle D, Jermyn R. The CardioMEMS Heart Failure Sensor: A Procedural Guide for Implanting Physicians. *The Journal of Invasive Cardiology*. 2016;28(7):273-279.

HOSPITAL ELECTRONICS QUICK GUIDE

IMPLANT CHECKLIST

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REFERENCES

1. Shavelle D, Jermyn R. The CardioMEMS Heart Failure Sensor: A Procedural Guide for Implanting Physicians. *The Journal of Invasive Cardiology.* 2016;28(7):273-279.

2. Abbott. Data on File. 90305907 Rev. A. The CardioMEMS™ HF System Workflow Research. May 2017.

This document is not intended to replace the judgment of the acting practitioner nor the establishment of final protocols within the hospital setting. It does not represent any opinion or endorsement by Abbott of any particular approach to patient management or treatment.

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MANAGING YOUR HEART FAILURE PATIENTS

WITH THE CARDIOMEMS™ HF SYSTEM

With the CardioMEMS™ HF System, you have a new way to know your patients, by tracking their pulmonary artery (PA) pressures over time to help you better manage their heart failure. This section provides you an overview of patient management best practice methods Abbott has observed[1] in clinics that are effectively using the CardioMEMS HF System with their heart failure patients.

The following methods are the best practices reported by clinicians across the U.S. who are managing many heart failure patients with the CardioMEMS HF System. These clinicians report using a three-phased approach to obtaining and maintaining an optivolemic state with their heart failure patients by monitoring PA pressures with the CardioMEMS HF System[1]:

PHASE I: Post Implant Patient Evaluation, page 3

PHASE II: PA Pressure Optimization, page 5

PHASE III: PA Pressure Maintenance, page 7

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[1]:	• 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[1]:	• 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.

For patients at risk for gastrointestinal bleeding during the period in which dual antiplatelet therapy is given, the physician should consider a proton pump inhibitor. Patients at risk include the elderly or those with a history of gastroduodenal ulcers, gastroesophageal reflux disease, esophagitis, intestinal polyps or cancer. Patients who smoke or who are using steroids or nonsteroidal anti-inflammatory drugs may also be at risk.[1]

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IMPLANT PROCEDURE
PREPARATION (CONTINUED)

PRE-IMPLANT CHECKLIST
[CUSTOMIZE PER YOUR CLINIC PROTOCOL]:

☐ The patient understands that they need to stop eating and drinking _____ hours before the procedure.

☐ I have confirmed that the patient has a ride to the hospital for the procedure.

☐ The patient understands that they should arrive at the hospital _____ hours before the scheduled procedure time.

☐ The patient has confirmed that someone is available to drive them home and stay with them for _____ hours following the procedure.

If applicable:

☐ I have confirmed that the patient has stopped taking their anticoagulation medication as instructed.

☐ The patient has adjusted other medications (i.e., diabetes medications) as directed for their procedure.

ADDITIONAL CLINICAL CONSIDERATIONS

The following patients may not be appropriate for implantation of the CardioMEMS™ HF System:

• Patients with an active infection.

• Patients with a history of recurrent (> 1) pulmonary embolism or deep vein thrombosis.

• Patients unable to tolerate a right heart catheterization.

• Patients with a glomerular filtration rate < 25 mL/min who are nonresponsive to diuretic therapy or who are on chronic renal dialysis.

• Patients with congenital heart disease or mechanical right heart valve(s).

• Patients with known coagulation disorders.

• Patients with a hypersensitivity or allergy to aspirin and/or clopidogrel.

• Patients who have undergone implantation of a cardiac resynchronization device within the past three months.

• If the patient's body mass index is greater than 35, measure the patient's chest circumference at the axillary level. If the chest circumference is > 165 cm, sensor implantation should not occur.

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PHASE I:
POST IMPLANT PATIENT EVALUATION

GOAL: UNDERSTAND PATIENT 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.

- The PCWP is equivalent to left atrial pressure in most patients and the PAD pressure is usually very close to the PCWP. Therefore, ambulatory hemodynamic guided heart failure management many times uses the PAD pressure as a marker of the PCWP (i.e., left atrial pressure). Pressure goals are based on achieving and maintaining normal PCWP by following the PAD pressure. However, in some patients, the PCWP and the PAD pressure are not similar. The difference between PCWP and PAD is called discordance and should be accounted for when setting pressure goals. This information is important to consider when using PA pressure to guide clinical management.

  – **Example of Discordance:**

  During the CardioMEMS™ PA Sensor implant procedure:

  - PAD 28 mmHg
  - PCWP 22 mmHg

PAD	28 mmHg
PCWP	22 mmHg
Discordance	6 mmHg

First Week of PAD Pressures

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
30 mmHg	31 mmHg	32 mmHg	30 mmHg	29 mmHg	29 mmHg	30 mmHg

When setting the patient's PAD pressure threshold range in the Merlin.net™ Patient Care Network (PCN), take the discordance noted during the right heart catheterization (6 mmHg) into account to prevent over-diuresis.

- In this example, the Optimization phase PAD pressure threshold range should be set to 20–30 mmHg.

- This would translate to a PCWP of 14–24 mmHg and aligns with what the actual value of the PCWP is and decreases the risk of over-diuresis.

- When setting the Maintenance phase threshold range, be sure to consider the discordance in the same manner.

HELPFUL TIPS:
- Pressures in the Cath Lab are typically lower than pressure readings at home.
- Use the sensor **PAD pressure** as a surrogate for patient's wedge pressure.

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PHASE I:
POST IMPLANT PATIENT EVALUATION (CONTINUED)

SETTING YOUR PATIENT UP FOR SUCCESS AT HOME

First day after implant

- Contact your CardioMEMS™ HF System patient at home.

- Check to see if they are doing OK after the procedure.

- Ask if they have questions about their Patient Electronics System or taking daily readings.

- Troubleshoot any issues, and/or refer them to Abbott Technical Support at 1-844-MYCMEMS for assistance.

Within the first week after implant

- See your patient and their caregiver (if they have one) in clinic.

- Check your patient's recovery after the implant procedure.

- Assess if they understand how to properly take daily readings. If they are not taking daily readings, find out why, and reinforce the clinical value of daily pressure readings.

- Tell your patient that you will be monitoring their PA pressures and finding the right balance of pressures and heart failure medications for their heart.

- Tell them you will contact them only if their pressures are out of range.

- Evaluate patients for the myCardioMEMS™ app. Use the myCardioMEMS app patient flyer to introduce the app to appropriate patients.

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PHASE II:
PA PRESSURE OPTIMIZATION

Ensure your patient is set up for effective remote monitoring by customizing their settings — including their PAD pressure goal, thresholds and notification settings — within the Merlin.net™ PCN.

For more information on using the Merlin.net PCN, please visit the Merlin.net PCN chapter.

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.

- **During the Optimization phase**, set a wide threshold range — typically a range of 10 mmHg. The highest recorded reading will sit at the upper end of the threshold range (*example below*).

Week 1 Readings

25 mmHg	26 mmHg	25 mmHg	24 mmHg	26 mmHg	25 mmHg	Initial PAD pressure threshold range = 16–26 mmHg

2 On the Merlin.net PCN, select the Optimization phase for the patient and program the PAD pressure goal (if desired) and the initial PAD pressure threshold range. If you enter a PAD pressure goal, a threshold will automatically populate.

3 Decide how and when you want to receive patient notifications by checking the boxes for clinical and administrative notifications on the Merlin.net PCN.

4 Subscribe to your patient on the Merlin.net PCN so they will show up on your Notifications List if their PAD pressure deviates from their threshold range.

- The Notifications List serves as your "inbox" for managing CardioMEMS™ HF System patients.

HELPFUL TIP:

PAD pressure goal = Target clinical PAD pressure for patient management.

PAD pressure threshold range = Programmable range on the Merlin.net PCN to trigger notifications to take action when pressures trend out of range.

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PHASE II:
PA PRESSURE OPTIMIZATION (CONTINUED)

MANAGING THE PATIENT TO ACHIEVE OPTIMAL PA PRESSURES

Patient Management

- Focus on getting to know your patient's PA pressure numbers and how they respond to changes in medication.

- 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.

Adjust patient's medications as necessary

- Those with elevated intravascular volume will initially benefit from increased diuretics.

- Those with vascular resistance will benefit from careful titration of long-acting nitrates.

WHEN INTENSIFYING DIURETICS

CAREFULLY ASSESS

- Electrolytes

- Adverse patient symptoms

- Renal function (increase in creatinine by 20%)[2]

- Hypotension

HELPFUL TIP:

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

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PHASE III:
PA PRESSURE MAINTENANCE

GOAL: MAINTAIN OPTIVOLEMIA

When volume status is optimized, set new target PAD pressure goal to maintain optivolemic state.

1 During the Maintenance phase, set a tight threshold range 2–3 mmHg above/below target PAD pressure goal *(example below)*.

> **EXAMPLE:**
>
> PAD pressure goal = 19 mmHg
>
> PAD pressure threshold range = 16–22 mmHg

2 On the Merlin.net™ PCN, select the Maintenance phase for the patient and enter the PAD pressure goal. When the goal is entered, the PAD pressure threshold range will automatically populate.

Patient Management

- Monitor the Notifications List on the Merlin.net PCN and address any notifications for the patient.

- Be mindful of checking the waveform when notified of any suspect readings.

- If there are no 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.[3]

Normal PA Pressure Waveform

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PHASE III:
PA PRESSURE MAINTENANCE (CONTINUED)

MONITORING TRENDS IN PA PRESSURE DEVIATIONS USING THE MERLIN.NET™ PCN

Managing by exception is supported by having confidence in the Merlin.net™ PCN Notifications List and reports to help you manage trends in PA pressure changes. Only patients who require your attention are shown to you on the Notifications List. This allows you to efficiently manage the heart failure patients you have today so that you may help more patients tomorrow.

For more information on using the Merlin.net PCN please visit the Merlin.net PCN chapter.

RESPOND TO TRENDS IN PRESSURE CHANGES

- It is recommended to make treatment decisions based on PA diastolic and remove the PA mean and PA systolic threshold notifications. This does not remove the data; it only eliminates notifications for these pressures.

- Intervene if the patient has active notifications for PA pressure changes.

- There is no need to check PA pressures every day. Remember, PA pressures will rise long before the patient is in crisis.[2]

AUTOMATIC NOTIFICATION OF THRESHOLD DEVIATIONS

- Subscribe to each of your patients on the Merlin.net PCN so they show up on your Notifications List.

- Utilize the Notifications List and Notifications List report to triage patients that need attention.

NOTIFICATIONS LIST

- Choose one to two days per week to review the Notifications List.

  – Subscribe to the Notifications List report to be alerted via email about patients on the Notifications List. This report is generated overnight and distributed on the schedule set by your clinic.

    – The Notifications List report is a snapshot in time.

    – It is important to remember that the Notifications List on the website contains the most up-to-date information about your patients.

PATIENT MESSAGING

- Send messages to your patient via phone, text message or the myCardioMEMS™ Patient Application to remind them to take a reading and reinforce healthy lifestyle choices.

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PHASE III:
PA PRESSURE MAINTENANCE (CONTINUED)

NOTIFICATIONS LIST

The Notifications List is the first page shown to you when logging into the heart failure management portal of the Merlin.net™ PCN. If the patient meets the conditions to trigger a notification, they will be shown here.

FILTER. The list automatically shows only the patients you are subscribed to. Change your view by selecting other clinicians.

NOTIFICATIONS. Understand why your patient is on the list by reviewing their notifications.

ACTIONS MENU. Document an intervention or take other actions on your patient.

STATUS NOTE. A status note can be useful for yourself or others in your practice while you are working on a patient. Update a patient's status from the actions menu.

7-DAY TREND. See your patient's readings from the last 7 days, with the latest reading on the right. In-range readings are shown in the green band.

HELPFUL TIP:

Consider the Notifications List your "inbox" for managing CardioMEMS™ HF System patients. On days on which you do not review the Notifications List, consider subscribing to email reports.

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EFFICIENTLY MANAGE YOUR PATIENTS
WITH THE CARDIOMEMS™ HF SYSTEM

KEY TIPS TO REMEMBER

- **There is no need to check PA pressures every day**. Remember, PA pressures will rise long before the patient is in crisis.[2]

- **Let the system work for you**. 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 to remind them to take a reading, or to reinforce good habits with an encouraging message.

- **Phase I: Post Implant Patient Evaluation** review of the right heart catheterization.

  – Compare PCWP and RAP numbers to determine whether volume versus vascular resistance is driving the elevated PA pressures.

  – Note differences of ≥ 5 mmHg between PCWP and sensor PAD and consider the discordance when establishing PA pressure threshold range.

  – Enter right heart catheterization numbers in the Merlin.net PCN.

- **Phase II: PA Pressure Optimization** review patient's pressures to achieve optivolemia.

  – Monitor the Notifications List on the Merlin.net PCN and address any notifications for your patients.

  – **Every two weeks**, assess the PAD pressure threshold range and adjust accordingly on the Merlin.net PCN.

- **Phase III: PA Pressure Maintenance** review patient's pressures **one time per month** and reprogram PAD pressure threshold ranges as necessary.

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EFFICIENTLY MANAGE YOUR PATIENTS
WITH THE CARDIOMEMS™ HF SYSTEM (CONTINUED)

CARDIOMEMS™ HF SYSTEM ACCURACY

Occasionally, clinicians want to confirm the accuracy of a CardioMEMS™ PA Sensor calibration.
If you want to check a sensor's accuracy, remember the following:

- A sensor is only as accurate as its initial calibration.

- Recalibration is rarely necessary, but there are straightforward options if you decide to recalibrate.

- Contact our Technical Heart Failure Specialists — a team of clinician experts — for sensor evaluation and guidance on troubleshooting options.

WHAT CAUSES CLINICIANS TO CHECK SENSOR ACCURACY?	WHAT CAN CAUSE INACCURATE MEASUREMENTS?
• Significant and/or sudden pressure changes	• Miscalibration (Swan wasn't zeroed, suboptimal calibration, etc.)
• Excessive pressure fluctuations	• Sensor placed in undersized vessel
• Sensor PA pressure measurement does not match clinical presentation	• Electrical interference
• Negative pressure readings	• Significant changes in altitude
• Non-physiologic waveforms or pressure data	• Pressure measurement "drift"
• Difference between Patient Electronics System and Hospital Electronics System pressure readings	

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WITH THE CARDIOMEMS™ HF SYSTEM (CONTINUED)

STANDARD TROUBLESHOOTING RESOLVES MOST ISSUES

SUSPECT READING	POSSIBLE CAUSE	RESOLUTION
	Patient visited high elevation area	Pressures will return to normal when patient returns to home altitude
	Electronic interference	Remove possible sources of electrical interference
Low PA pressure, patient is symptomatic	Dehydration, comorbidities, low cardiac output, other issues	Clinically correlate; if questions remain, contact 1-844-MYCMEMS

If you are concerned about sensor accuracy, contact Technical Heart Failure Specialists for sensor evaluation and troubleshooting guidance:

CLINICAL QUESTIONS SUPPORT LINE
Phone: 1-844-MYCMEMS

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MANAGING MEDICATIONS
BASED ON PA PRESSURE CHANGES

Having a patient-specific medication management protocol helps clinicians appropriately respond to changes in PA pressures, and allows them to achieve and maintain the optivolemic state of their heart failure patients who have received the CardioMEMS™ HF System.

The following examples are provided to help clinicians establish a medication titration protocol that can be applied and tailored to their heart failure patient population.

GUIDELINES FOR MANAGING TRENDS OF AMBULATORY PA PRESSURES[2]*

PAD < 10 mmHg	PAD 8–20 mmHg	PAD > 25 mmHg

LOW PA PRESSURES (HYPOVOLEMIC)
PAD trending below the hemodynamic range

NORMAL PA PRESSURES (OPTIVOLEMIC)
PAD trending within the hemodynamic range

ELEVATED PA PRESSURES (HYPERVOLEMIC)
PAD trending above the hemodynamic range

Has poor perfusion in the absence of signs and symptoms of congestion

If on thiazide and loop diuretic, lower or D/C 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 present

Re-evaluate PA pressures

- Two to three days per week until PA pressures stabilize

Lower or hold ACE/ARB dose

- If worsening renal function is present with hypotension

Has minimal symptoms or minimal evidence of poor perfusion

No medication changes based on hemodynamic information

Continue ACC/AHA Guidelines recommended therapies

Evaluate PA pressures:

- If in Optimization phase, review two to three times per week
- If in Maintenance phase, review monthly

Add or increase diuretic

- Add/increase loop diuretic
- Change loop diuretic
- Add thiazide diuretic
- IV loop diuretic

Add or increase vasodilators

- Add/increase nitrate

Re-evaluate PA pressures

- Two to three days per week until PA pressures stabilize

Evaluate other etiologies

- If PA pressures remain elevated consider dietary indiscretion, sleep apnea, etc.

If patient has signs of poor perfusion (cold), consider other interventions such as: admission for monitoring and adjustment of medical management; IV therapeutic agents, IV diuretics, IV fluid repletion; invasive hemodynamic monitoring to evaluate CO.

If patient has signs of poor perfusion (cold), consider other interventions such as: admission for monitoring and adjustment of medical management; IV therapeutic agents, IV diuretics, IV fluid repletion; invasive hemodynamic monitoring to evaluate CO.

*These guidelines were included in the protocol for the CHAMPION clinical trial.

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MANAGING MEDICATIONS
BASED ON PA PRESSURE CHANGES (CONTINUED)

Here is one example of a sliding-scale diuretic Rx illustrated below[2]:

Pressure Range	Low	Optimal	High	Very High
PAD	< 10 mmHg	8–20 mmHg	25–30 mmHg	> 30 mmHg
Diuretic dosing (e.g., torsemide)	Half diuretic dose or hold, call M.D.	50 mg daily	100 mg daily	2x usual dose or add Metolazone, call M.D.

The guidelines presented graphically above should be individualized to 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.

WHEN TO CONSIDER
PATIENTS FOR ADVANCED THERAPIES

Heart failure is a progressive disease, consider left ventricular assist device (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

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PATIENT CO-MANAGEMENT

- Co-management refers to any scenario in which a CardioMEMS™ HF System patient is cared for by two or more professionals who are not part of the same team. While two or more clinicians may have access to the patient and his or her PA pressure data, generally only one is responsible for the day-to-day management of the patient's heart failure care.

- Guidelines and protocols for co-management ensure that care and communications processes are established between providers.

- There are several scenarios where the need for co-management can occur:

  – The implanting team implants the sensor and immediately transitions the patient back to the primary (referring) clinician and the implanting team only provides support until the patient is optimized.

  – The implanting team manages the patient until the PA pressures are optimized, at which time the primary clinician resumes care of the patient.

  – The patient experiences an episode of decompensation and the primary clinician consults the implanting clinician for support.

  – Other clinicians providing care (i.e., general practitioners, general cardiology, pulmonology, nephrology, electrophysiology) want or need to be "kept in the loop" or have view-only access to the patient's PA pressures in the Merlin.net™ PCN.

EFFECTIVE CO-MANAGEMENT BENEFITS EVERYONE

FROM A PATIENT'S PERSPECTIVE, CO-MANAGEMENT ENSURES:

- Multidisciplinary, patient-centered approach to care.
- Increased security that all clinicians are informed of the relevant details and plan of care.
- Ease of transition back to primary (referring) clinician following implant.
- Allowance for care close to home and decreased travel burden.

FROM THE PERSPECTIVE OF THE IMPLANTING CLINICIAN, A CLEAR CO-MANAGEMENT STRUCTURE WILL:

- Build relationships and open communication for patient sharing.
- Decrease follow-up burden by reducing patient volume.

FOR THE REFERRING CLINICIAN, CLEAR CO-MANAGEMENT PROTOCOLS OFFER:

- The ability to continue caring for patients, while offering access to advanced therapies.
- Differentiation from other clinics in the ability to offer state-of-the-art heart failure technologies.

OTHER PRACTITIONERS WILL ALSO BENEFIT FROM CO-MANAGEMENT BECAUSE IT WILL ALLOW THEM TO:

- Stay abreast of the patient's clinical condition.
- Consider PA pressures in their own clinical decision-making.
- Allow for a multidisciplinary, patient-centered approach to care.

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PATIENT CO-MANAGEMENT (CONTINUED)

ESTABLISHING CO-MANAGEMENT PARTNERSHIPS

It's important to remember that there is no one-size-fits-all approach to co-management. Relationships can vary from one referring team to another or even from one patient to another.

When establishing a patient-sharing relationship with a new referrer, consider having an in-person meeting or conference call to establish co-management strategies, goals and expectations.

There are two distinct phases of patient co-management for clinicians to consider: pre-implant and post-implant.

THE PRE-IMPLANT PHASE

This phase is intended to unite the referring and implanting clinicians around the care of the patient and determine roles and responsibilities as they prepare the patient to receive a CardioMEMS™ HF System.

- When the implanting physician has an established relationship and trusts the referring clinician's patient selection, the CardioMEMS HF System may be implanted without the implanting team meeting the patient first.

- If the implanting clinician does not know the referrer, they may request to meet the patient prior to implantation to ensure suitable candidacy for the device.

Pre-implantation written protocols can be helpful to ensure all parties are clear on their responsibilities and expectations in the co-management relationship. Often these protocols are loose but will include agreement around:

ROLES AND RESPONSIBILITIES

- Who will be in charge of patient management? Under what circumstances could this role change?

- Who is responsible for patient education and when it will happen?

- Who will be the Merlin.net™ PCN administrator?

TRANSFER OF CARE

- What will be the timing of the patient's transition back to the referring team?

- Will the implanting team continue to view PA pressures after transfer? If so, for how long?

COMMUNICATION

- Determine if the patient needs to meet the implanting team prior to implant.
  If yes, how will this be scheduled?

- How will clinic notes be shared? Who will be responsible for sending them?

- Who will be responsible for contacting the patient before and after implant?

Other things to consider:

- Prior to gaining access to the data on the Merlin.net PCN, co-managing clinicians should be educated by an Abbott field representative.

- In the case that the implanting team does not know the referring team, it may be helpful to review the patient selection criteria for the CardioMEMS HF System with the referring team to ensure they are appropriately selecting patients.

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PATIENT CO-MANAGEMENT (CONTINUED)

THE POST-IMPLANT PHASE

Post-implant co-management refers to the period after implantation of the CardioMEMS™ PA Sensor but before the patient is fully transitioned back to the care of the referring center.

CONSIDERATIONS

- Review the plan for transitioning the patient back to the referral center. Is this plan still clinically appropriate?

- How are the centers sharing the CardioMEMS™ HF System data, and is the mode of communication working well?

- Who is responsible for setting and changing the patient's goal and thresholds? How will treatment changes be communicated to other care providers?

- How and when will communications occur between caregivers, and who is responsible for ensuring this communication?

- Who is in charge of making changes to the patient's treatment plan, and how is this documented and relayed to the broader team?

- If the patient becomes difficult to manage or is no longer responding to treatment, how will this be communicated and managed?

BILLING

- Define who will bill for remote monitoring.

- Define when the billing for remote monitoring will transition to the referring care team.

COMMUNICATION IS THE KEY TO SUCCESSFUL CO-MANAGEMENT OF CARDIOMEMS™ HF SYSTEM PATIENTS

Referring clinicians want to be kept abreast of their patient's status while they are under the implanting physician's care; implanting centers want to have uncomplicated ways of communicating back to the referrer and the larger care team. It is important to establish communication processes that are both sustainable and scalable.

CARDIOMEMS HF SYSTEM PATIENTS WITH LVADS

As heart failure progresses, PA pressures may no longer respond to medication changes and patients may benefit from an LVAD. In many institutions, after receiving an LVAD, the day-to-day patient management will transition to the LVAD coordinator.

After LVAD Implant:

- It is important that the heart failure team and the LVAD team establish how they will work together to manage the PA pressure data.

- Determine who will educate the LVAD coordinator on the Merlin.net™ PCN to gain access to the PA pressure data.

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PATIENT CO-MANAGEMENT (CONTINUED)

CO-MANAGEMENT WITH THE MERLIN.NET™ PCN

The Merlin.net™ PCN heart failure portal allows patients to be co-managed between two clinics. After completing the following form for a patient who should be co-managed, both clinics will see the patient in their patient list and on their Notifications List. However, only one clinic is considered the primary clinic, which is designated on the form. Review the table below to understand more about a co-managing relationship.

Co-management provides access to a patient's heart failure data to users in different heart failure clinics.

COMMON CAPABILITIES ACROSS CO-MANAGING CLINICS	RESTRICTIONS ACROSS CO-MANAGING CLINICS
Both Clinics Can View and Modify All Patient Data • Heart failure trends • PA readings (accept/reject) • Detailed pressure waveforms • Overlays for hospitalizations, notes and medications • Review/billing reminders **Goal, Thresholds and Notifications** • Goal and thresholds applied to the co-managed patient are those from the primary clinic. • Individual patient overrides can be established by either the primary or co-managing clinic. • Any notifications will show up on the Notifications List for any subscribed primary and co-managing clinic users.	**Patients of Interest Report** • Users in the co-managing clinic will not see co-managed patients on their Patients of Interest report. • Users in the primary clinic will continue to see all their patients, including co-managed patients, in their Patients of Interest report. **Billing** • Only one clinic can bill for monthly physiologic monitoring of a co-managed patient. The primary and co-managing clinic must discuss who will bill. **Combining Patient Heart Failure Data** • Co-managing clinic cannot "merge" the PA pressure and cardiac rhythm management data of a patient with both sensor and device. This can only be done by the primary clinic. **Patient Inactivation** • A co-managing clinic cannot inactivate their co-managed patients. Only the primary clinic can inactivate such patients.

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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."

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Abbott

CARDIOMEMS™ HF SYSTEM

MERLIN.NET™ PATIENT CARE NETWORK (PCN)

CARDIOMEMS™ HF SYSTEM

MERLIN.NET™ PATIENT CARE NETWORK (PCN)

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GETTING STARTED

WHAT IS THE MERLIN.NET™ PCN?

The Merlin.net™ PCN is a remote follow-up system that displays information from a patient's CardioMEMS™ HF System device. Using the Patient Electronics System (PES), patients transmit their CardioMEMS HF System readings to the Merlin.net PCN on a schedule set by the clinic (usually daily). From within the heart failure management portal of the Merlin.net PCN, you can efficiently assess a patient's status and easily make interventions.

SETTING UP YOUR CLINIC

Your Abbott representative will assist your clinic in establishing a Merlin.net PCN account. After your clinic's account has been established, it is important that several basic settings are reviewed and updated by a user with administrative access:

Clinic > Settings > Clinic Profile

- Verify or complete information about the clinic. This includes the clinic phone number that will display on a patient's caller ID, or the phone number or email address that will appear as the "from" address, when used for patient messaging.

- Select the days that users in your clinic will receive the Notifications List report and Patients of Interest report. Individual users can elect to receive these reports in their user profile.

Clinic > Users & Locations > Users

- Add users so that they can access the Merlin.net PCN. Ensure that at least one other user in your clinic is given an Administrator role. Consulting users have read-only access to patient data.

Clinic > Users & Locations > Locations

- Add any additional following clinics (if applicable). At enrollment, patients can be assigned to a specific clinic location.

HELPFUL TIP:

Based on recommended best practices, the Merlin.net PCN comes with default settings that you may customize based on your clinic's preferences. See the section **Enhancing Your Practice** for additional settings you may wish to review and update to increase your clinic's efficiency.

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SETTING UP A PATIENT FOR MONITORING

After a clinic's account has been established and basic settings verified or updated, patients can be enrolled in the system and set up for monitoring.

ENROLLING A PATIENT

While patients can be enrolled in advance of implant directly in the Merlin.net™ PCN, it is strongly recommended that patients be enrolled at the time of implant using the Hospital Electronics System (HES).

After a patient has been implanted and enrolled, **associate the appropriate clinic for follow-up:**

• From All Patients, select the name of the patient from the Scheduled Patients list.

• Under Settings > Patient Profile > PA Sensor, click **Change Clinic Assignment** and select the appropriate clinic. Additionally, assign a treating physician.

> **HELPFUL TIP:**
>
> For centers without the ability to transmit information wirelessly from the HES to the Merlin.net PCN, you may need to manually add the patient to the Merlin.net PCN. From All Patients, click **Enroll a Patient**. Follow the prompts and then import patient data from the USB drive used during the implant process.

SETTING UP A PATIENT PROFILE

As noted above, immediately after enrollment a patient will appear on the clinic's Scheduled list. A patient will be automatically moved from the Scheduled list to the Active list after:

• Data from the implant procedure has been uploaded to the Merlin.net PCN.

• The treating clinic and physician are entered into the Merlin.net PCN.

• One transmission has been sent from the PES.

You can then continue completing the patient's profile.

[Patient Record] > **Settings** > **Patient Profile**

• Confirm the patient's name and date of birth. Enter other demographic information.

• Enter the patient's messaging preferences: phone call, text message or the myCardioMEMS™ Patient Application.

> **HELPFUL TIP:**
>
> If the patient wishes to use the myCardioMEMS™ app to receive messages, they must be registered. Once a patient has registered, the app will become their primary communications vehicle. They will not be able to receive messages via phone call or text message.

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SETTING UP A PATIENT PROFILE (CONTINUED)

- If a patient has an Abbott or St. Jude Medical implantable cardioverter defibrillator or pacemaker and is being followed remotely with the Merlin@home™ transmitter, select the device name and enter the serial number that can be found on their device ID card. Upon save, the Merlin.net™ PCN will prompt you to combine the patient's pulmonary artery (PA) sensor and device profiles.

- Enter right heart cath implant values, which will help you effectively establish a PA pressure goal and threshold range for the patient.

[Patient Record] > **Settings** > **Goals and Thresholds**

Defaults for these settings for newly enrolled patients can be set in the clinic area of the site (page 1).

- Select the Primary Metric that will be used for monitoring the patient — either PA diastolic (PAD) or PA mean.

- Select the phase that the patient is in (Optimization for newly enrolled and implanted patients).

- If desired, enter a PA pressure goal — a single number — in the Goal field. *A goal is optional.*

- Enter the patient's optimal range (threshold) by adjusting the Lower and Upper bound fields. Note that a range will automatically populate based on the goal entered. While a goal is not required, it is important that a range be entered since many notifications are dependent on it.

HELPFUL TIP:

Review any documented differences during implant of ≥ 5 mmHg between pulmonary capillary wedge pressure and sensor PAD in the Merlin.net PCN, and consider the variance when establishing PA pressure goals.

Remember that pressures in the Cath Lab are typically lower than pressure readings at home.

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MANAGING BY EXCEPTION

The Merlin.net™ PCN is designed to support effective and efficient triage and monitoring of CardioMEMS™ HF System patients. The **Notifications List** is key to that efficient workflow, helping you to manage patients by exception. Only patients who require your attention are shown on the Notifications List. (Other patients can be accessed through the **All Patients** list.)

UNDERSTANDING THE NOTIFICATIONS LIST

The Notifications List is the first page displayed when logging into the heart failure management portal of the Merlin.net PCN. If the patient meets the conditions to trigger a notification, they will be shown here.

FILTER. The list automatically shows only the patients you are subscribed to. Change your view by selecting other clinicians.

NOTIFICATIONS. Understand why your patient is on the list by reviewing their notifications.

ACTIONS MENU. Document an intervention or take other actions on your patient.

STATUS NOTE. A status note can be useful for yourself or others in your practice while you are working on a patient. Update a patient's status from the actions menu.

7-DAY TREND. See your patient's readings from the last 7 days, with the latest reading on the right. In-range readings are shown in the green band.

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NOTIFICATION TYPES

Patients are shown on the Notifications List if they meet the criteria for one or more of the following notifications *and* if the notification of that type is enabled (turned "on") for the patient (in a patient's settings). Based on recommended best practices, the Merlin.net™ PCN comes with default notification settings that you may customize based on your clinic's preferences or on a patient-by-patient basis.

CLINICAL NOTIFICATIONS

Clinical notifications include **Primary Notifications** — those related to the patient's Primary Metric, either PA diastolic or PA mean. Clinical notifications also include **Other Clinical Notifications** that are not related to the patient's Primary Metric but are related to other clinical measures, such as heart rate.

PRIMARY NOTIFICATIONS

NOTIFICATION	DEFAULT
High pressure reading greater than <n> from optimal range	OFF, N = 10
Low pressure reading less than <n> from optimal range	OFF, N = 10
Rapid pressure change of <n> over 1 day	ON, N = 10
Pressure reading transition from high to low range (without patient returning to optimal state)	OFF
Pressure reading transitions from low to high range (without patient returning to optimal state)	OFF
1 reading above optimal range	OFF
1 reading below optimal range	OFF
3 readings above optimal range	ON
3 readings above optimal range	ON
7 or more readings above optimal range	ON
7 or more readings below optimal range	ON
Patient returns to optimal state after medication change	OFF

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OTHER CLINICAL NOTIFICATIONS

NOTIFICATION	DEFAULT
Diastolic pressure out of threshold	OFF
Diastolic pressure trend out of threshold	OFF
Mean pressure out of threshold	OFF
Mean pressure trend out of threshold	OFF
Heart rate out of threshold	ON
Pulse pressure out of threshold	OFF
Systolic pressure out of threshold	OFF
Systolic pressure trend out of threshold	OFF

ADMINISTRATIVE NOTIFICATIONS

Administrative Notifications are generally related to a patient's monitoring status.

NOTIFICATION	DEFAULT
No pressure readings for <n> days	ON, N = 3
First pressure reading after <n> days	OFF, N = 3
Pressure reading is suspect	ON
Patient has not been reviewed for 30 days	OFF
Patient does not have a pressure goal established	OFF
Patient is in Optimization phase	OFF
First home reading from a patient after enrollment or transfer	OFF

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GETTING NOTIFIED

- You may wish to receive different types of notifications for different types of patients. Adjust notifications on a per-patient basis in the patient's **Settings**.

- If desired subscribe to the **Notifications List report**, which contains a list of all patients currently on the clinic's Notifications List on the day the report is generated. The Notifications List report is run at 12:00 p.m. local time.

- You may also subscribe to the **Patients of Interest report**, which contains a list of patients who meet specific criteria based on their PAD pressures and reading compliance over seven days.

A clinic must enable the delivery of the Notifications List report and Patients of Interest report on specific days (under Clinic > Settings). Users may then individually subscribe to these reports from their user profile.

> **HELPFUL TIP:**
>
> Consider the Notifications List your "inbox" for managing CardioMEMS™ HF System patients. On days on which you do not review the Notifications List, consider subscribing to email reports.

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REVIEWING PATIENTS AND TAKING ACTION

It is good practice to establish a routine when doing a complete review of a patient's data:

- Patients should be monitored more frequently during the Optimization phase while you are establishing an ideal PA pressure goal and threshold range.

- After a patient has stabilized, and during the Maintenance phase, patients can be reviewed less frequently. You may wish to do a complete review of a patient's data:

    – Each time they appear on the Notifications List

    – Every 30 days, if a patient's readings have not triggered a notification

REVIEWING PATIENT ACTIVITY

The patient's **Activity** tab helps you get the whole picture of the patient quickly.

THE PATIENT AT A GLANCE

Pertinent patient details are found at the top of the patient's detail page.

PATIENT NOTE. Keep track of lifestyle habits or other useful information that helps you better treat the patient.

DIRECTTREND™ VIEWER

Track a patient's readings over time with the interactive DirectTrend™ Viewer.
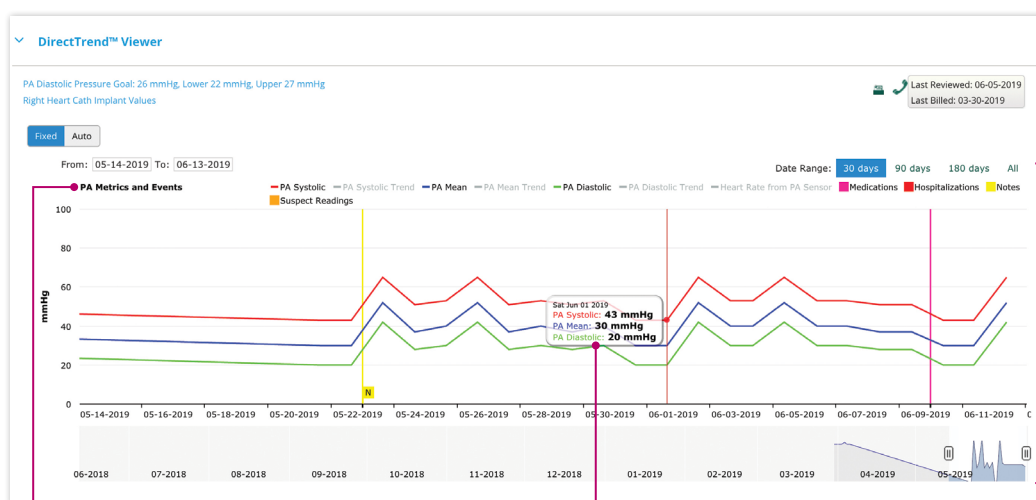
DATE RANGE. Select a 30-, 90- or 180-day date range, or move the slider to view a custom date range.

DATA VISIBILITY. Turn specific features on or off to display only the information that matters to you.

READING DETAILS. Hover over a specific data point to see measurements for that reading.

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READING LIST

Review each reading in more detail.

PA PRESSURE GOAL.
Review individual readings against a patient's goal.

30-DAY SUMMARY.
Quickly assess patient compliance for the last 30 days.

FILTER AND SEARCH.
Narrow the list by filtering, or search on specific readings.

Readings

GOAL	30 DAY READING SUMMARY (does not consider readings received today)		FILTER
23 Set: 04-18-2019 PA Diastolic	**100** Reading Compliance	**0** Missed **0** Suspect	All ⌄ Search 🔍

Taken on	PA Systolic	PA Diastolic	+/- Goal †	PA Mean	Heart Rate	Waveform	Status
06-12-2019, 09:07 AM	51 mmHg	28 mmHg	5	37 mmHg	82 bpm	〰	
06-11-2019, 08:56 AM	53 mmHg	30 mmHg	7	40 mmHg	82 bpm	〰	
06-10-2019, 08:45 AM	51 mmHg	28 mmHg	5	37 mmHg	82 bpm	〰	
06-09-2019, 09:04 AM	53 mmHg	30 mmHg	7	40 mmHg	82 bpm	〰	
06-08-2019, 09:11 AM	51 mmHg	28 mmHg	5	37 mmHg	82 bpm	〰	
06-07-2019, 08:48 AM	65 mmHg	42 mmHg	19	52 mmHg	82 bpm	〰	
06-06-2019, 08:52 AM	43 mmHg	20 mmHg	-3	30 mmHg	82 bpm	〰	
06-05-2019, 09:04 AM	43 mmHg	20 mmHg	-3	30 mmHg	82 bpm	〰	
06-04-2019, 09:02 AM	53 mmHg	30 mmHg	7	40 mmHg	82 bpm	〰	
06-03-2019, 09:09 AM	53 mmHg	30 mmHg	7	40 mmHg	82 bpm	〰	
06-02-2019, 09:10 AM	53 mmHg	30 mmHg	7	40 mmHg	82 bpm	〰	Suspect

WAVEFORM.
Click on the waveform icon to review and update waveform status.

READING STATUS.
Suspect readings are marked in orange. Click to review, then either accept or ignore the reading.

WAVEFORM REVIEW AND MANAGING SUSPECT READINGS

It is important to regularly review and manage suspect readings. Waveforms that the system believes are suspect will be marked with an orange "Suspect" tag. Click on the waveform icon to view the waveform in detail:

- If the waveform appears to be physiologic, click **Change Status** and then **Accept**.

- If the waveform appears non-physiologic or affected by interference, click **Ignore**.

HELPFUL TIP:

Review the patient's PA pressures and these readings regularly (two to three times per week until the patient's volume is optimized) to assist the Merlin.net™ PCN algorithm in scoring the waveforms. Additionally, it is important to assess any changes in the waveform shape over time. Narrowing of the pulse pressure may be indicative of sensor pressure drift, which is defined as a change in pressure over time caused by environment or acute physiologic response.

TAKING ACTION

After you have reviewed a patient, you may wish to take an action — such as changing a medication, sending the patient a message or documenting a clinical note. Actions can be taken by clicking on the **Actions** button next to a patient's notifications.
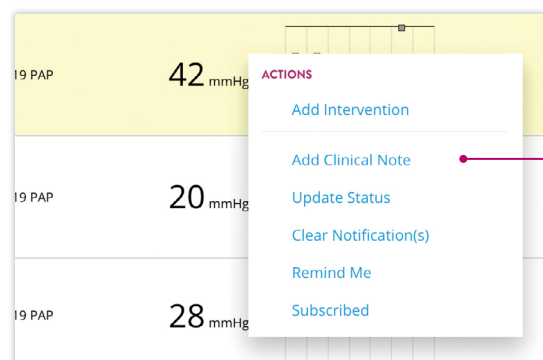
ADD INTERVENTION. Make a change and notify the patient.

ADD CLINICAL NOTE. Document a note about the patient.

UPDATE STATUS. Write a status note to yourself or others while you are working on a patient.

CLEAR NOTIFICATION. Remove the patient from the Notifications List.

REMIND ME. Set a reminder to appear on a specific date.

SUBSCRIBE. Follow a patient so they are shown on your Notifications List.

ADDING AN INTERVENTION

The **Add Intervention** feature is the primary method to document interventions and communicate those interventions to a patient through patient messaging.

Add Intervention

ADD INTERVENTION

Current Notifications :

Pressure is 2 mmHg above optimal range / 06-02-2019
Rapid pressure change of 5 mmHg over 1 day(s) / 06-02-2019
1 reading above optimal range / 06-02-2019
Patient in optimization phase / 05-15-2019
Patient due for review / 05-13-2019

SEND PATIENT MESSAGE(S)

Patient receives their messages via text message in English (US).
(Message preferences can be modified in the patient profile.)

Record messages in the patient's medical record as appropriate.

Select a message to send

○ Call Clinic
○ Reading Reviewed
○ Reading Reminder
○ Labs Request
○ Treatment Plan Reminder due to pressure changes

Custom Message (250 character limit)

The patient's calling window is 09:00 AM to 07:00 PM for messages delivered via text message.

● Deliver at start of calling window
○ Deliver immediately

The last message sent to this patient was the Call clinic message; initiated on 05-13-2019 09:27 AM.
- Text message delivery status: Message Delivered

SEND

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ADDING AN INTERVENTION (CONTINUED)

There are two types of interventions that can be taken from the Add Intervention feature:

1 MESSAGE INTERVENTIONS

Message interventions are messages sent to the patient regarding their treatment. Messages can be sent via phone call, text message or the myCardioMEMS™ app, depending on the patient's messaging preferences:

- **Standard messages** are short pre-written or pre-recorded messages — like "call the clinic." These messages can be delivered to a patient via phone call, text message or the myCardioMEMS app (if the patient is registered to use the app).

- **Custom messages** are free-form messages written at the time of the intervention. They can be used to send a lifestyle reminder or even a medication change to the patient. *Custom messages can only be used for patients who have registered to use the myCardioMEMS app.*

2 MEDICATION INTERVENTIONS

Medication interventions are changes made to a patient's medication list (within the Merlin.net™ PCN interface).

> **HELPFUL TIP:**
>
> Custom messages should *not* be used for medication changes if Medication Management is turned "on" in a patient's myCardioMEMS app settings. A warning message will appear to prevent you from writing a custom message that may conflict with a patient's medication list.

Any interventions made for a patient will be displayed on the patient's **Activity** tab in the **Recent Interventions** section.

Recent Interventions			
Medication Intervention ✓	**Medication Intervention** ✓	**Medication Intervention** ✓	**Medication Intervention**
Stephanie Edwards	Stephanie Edwards	Stephanie Edwards	Stephanie Edwards
Effective: 03-10-2019 Decrease Furosemide Lasix®	Effective: 03-10-2019 Increase Furosemide Lasix®	Effective: 03-10-2019 Change Furosemide Lasix®	Effective: 03-10-2019 Start Fosinopril Monopril®
SENT ON: 03-10-2019, 01:27 PM	SENT ON: 03-10-2019, 01:30 PM	SENT ON: 03-10-2019, 01:32 PM	SENT ON: 03-10-2019, 01:47 PM

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FINISHING YOUR REVIEW

Upon completion of your review, click the **Patient Review** button (directly above the DirectTrend™ Viewer).

Last Reviewed: 06-05-2019
Last Billed: 03-30-2019
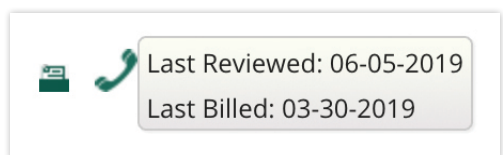
- Select **Mark as Reviewed Today**.

- If desired, write a note about changes or interventions made in response to the review.

- If this is the first time a patient is to be billed for remote monitoring services, select **Mark as Billed on** and enter the billing date. The system will automatically set the Next Billing Reminder 31 days out.

HELPFUL TIP:

The patient review window will appear each time you navigate away from a patient's profile, prompting you to mark the patient as reviewed. To disable this feature, check the **Always show this reminder** box.

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ENHANCING YOUR PRACTICE

Taking advantage of other features in the Merlin.net™ PCN will help drive efficiency in your management of CardioMEMS™ HF System patients.

PATIENT SETTINGS

In addition to the key settings that should be entered at the time a patient is enrolled (page 2), you may wish to enter and/or update other individual patient settings:

- Enter settings for patients enrolled to use the **myCardioMEMS™ app**, such as whether to display a list of their medications in the app.

- Enter **diagnoses** for a patient, which will be shown at the top of the patient's profile page.

- Record the patient's **heart failure medications** in the Merlin.net PCN. While not required, entering medications is of benefit if the patient is enrolled to use the myCardioMEMS app. If Medication Management is turned "on," a list of the patient's medications will be shown in the app.

- Enter the dates of any **hospitalizations** for the patient. Once a hospitalization has been entered, that period will be shaded pink on the DirectTrend™ Viewer. It may help assess any changes in their PA pressures during this time.

- Set other clinical measures you wish to monitor under **goals and thresholds**.

RETURN TO OPTIMAL STATE THRESHOLD

A patient is considered in the "optimal state" when they have had a specific number of consecutive readings in the optimal range (threshold). The optimal state threshold allows a patient to "settle in" to their optimal range for a set number of days before they are actually considered "in range." This default is set to two days but can be adjusted.

CLINIC-WIDE SETTINGS

Based on recommended best practices, the Merlin.net PCN comes with default settings that you may customize based on your clinic's preferences:

- Customize patient messaging settings (on a clinic-wide basis for all patients) for both calling and text messaging your patients.

- Establish default settings that your clinic will use for a majority of your patients, including:

  - Primary Metric (PA diastolic or PA mean)

  - Optimal range for the Primary Metric, based on the goal set

  - Return to optimal state thresholds

  - Thresholds for other clinical metrics

  - Notifications

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USER SETTINGS

Your individual profile can be accessed by clicking on your initials in the navigation bar. Here you can:

- Change your password

- Update your contact information

- Set your All Patients list preferences

- Select default behavior for the DirectTrend™ Viewer (displayed on a patient's profile)

- Subscribe to the Notifications List report or Patients of Interest report

ADMINISTRATIVE TASKS

SETTING BILLING REMINDERS

While you cannot bill a patient directly from the Merlin.net™ PCN, you can set up reminders to do so.

Billing reminders appear on the All Patients list under the Next Billing (Data Collected) column. "Set Reminder" will display for patients without a reminder.

For more information on Billing and Reimbursement, please see the Billing and Reimbursement section in this Program Practice Guide.

TRANSFERRING A PATIENT

Once enrolled and associated with a clinic, a paper form must be used to transfer a patient to another clinic. The form can be requested from your Abbott representative. Once submitted, Abbott's Remote Care team will transfer the patient from one clinic to the other and confirm with both clinics that the transfer is complete.

INACTIVATING A PATIENT

If a patient has passed away or chosen to no longer have their heart failure managed using the CardioMEMS™ HF System, they should be inactivated. From a patient's profile, click on the **More Actions** button at the top of the page and select **Inactivate**.

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MYCARDIOMEMS™ PATIENT APPLICATION

INTRODUCTION

The myCardioMEMS™ Patient Application is a useful tool for heart failure clinics and their patients to streamline communications and reduce time spent on routine phone calls. In the hands of the right patients and caregivers, the myCardioMEMS Patient Application can enhance patient engagement in their own care.

The myCardioMEMS Patient Application has two main features:

1 PA pressure reading compliance tracking, with reading reminder notifications to encourage patient adherence to taking daily readings. Standard and custom messages may be sent by the clinic to the patient.

2 The clinician user can send a notification to the patient and the patient can acknowledge receipt of the medication change notification from the clinician.

In addition to a primary caregiver, other family members can download the myCardioMEMS Patient Application and link to the patient as an Other user with read-only access (page 18).

PATIENT SELECTION

Patient selection is key to ensuring a successful experience with the myCardioMEMS Patient Application. While the app is designed to be easy and intuitive to use, it is recommended for use by patients who meet the following criteria:

• Smartphone users, with a sufficient technical aptitude to install and utilize a mobile app.

• Patients with a cognitive ability to understand and acknowledge notifications and instructions delivered through the app.

• Compliant patients who have demonstrated a willingness to be engaged in their own care and adhere to treatment instructions from the clinic.

• In the absence of the previous criteria, patients with a caregiver who is motivated and capable of utilizing the app on behalf of the patient to assist in managing their treatment regimen may also be considered.

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MYCARDIOMEMS™ PATIENT APPLICATION
MERLIN.NET™ PCN INTERFACE

In the Merlin.net™ PCN, the myCardioMEMS™ Medications column on the All Patients list indicates which patients are registered for use of the app. There are five status notifications that may be displayed on the patient list:

- **Registered:** The patient is registered but a medication change has not been sent.
- **Pending (X days):** A medication change has been sent and is awaiting acknowledgment.
- **Confirmed:** The patient has acknowledged the medication change.

PATIENT SETUP FOR COMPLIANCE MANAGEMENT

In order to use the compliance management features of the myCardioMEMS Patient Application, a user must simply register on the app. Once a user is registered, they will be able to see the history calendar, as well as receive any standard and custom messages via the app.

PATIENT SETUP FOR MEDICATION MANAGEMENT

Note: If you are not managing a patient's medications on the Merlin.net PCN, then skip this section.

In order to use Medication Management with the app, the patient must have the feature enabled.

However, prior to enabling Medication Management, it is important to verify that the patient's medication list is up to date.

[Patient Record] > Settings > Medications

- Add or update heart failure medications.
- Once Medication Management is enabled, medications cannot be deleted from the list without first disabling the feature.

Once the Medication List has been verified, enable Medication Management.

[Patient Record] > Settings > myCardioMEMS™ Mobile Application

- If "Registered" is displayed next to **Patient/Caregiver**, then someone has registered as a Patient/Caregiver user on the app. *For more information on registration modes in the app, please refer to page 18.*
- Enable Medication Management from the drop-down menu.

> **HELPFUL TIP:**
>
> It is possible to view the list of all registered users associated with this patient. This includes both the Patient/Caregiver user and all registered Other users. If a user entered the wrong email address during the registration process, they should call 1-844-MYCMEMS to have it corrected.

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SENDING A MEDICATION CHANGE VIA THE MYCARDIOMEMS™ MOBILE APPLICATION

Once Medication Management has been enabled for a patient, no medications can be deleted from their medication list on the Merlin.net™ PCN. This is a safety mechanism:

• Medications can be added, adjusted and stopped.

• Stopping a medication will remove it from the list on the patient's app, but it will continue to appear on the medications list in their Merlin.net PCN patient profile.

Once a medication adjustment has been entered, you will be asked if the patient should acknowledge the medication. This will require the patient to go through the medication reconciliation process once they see the medication adjustment in the app.

Medication Update   ✕

The following medication update was sent to the patient's app on:
06-25-2019 05:59 AM.

Effective: 06-25-2019

Increase Furosemide (Loop Diuretic)

20.0 mg, 2.0 Tablet   ➡   40.0 mg, 2.0 Tablet
Twice a day   Twice a day

Take before breakfast and wait for 30 minutes before you eat. Sent by Brian,
Dunham

◉ Acknowledgement requested from the patient ⓘ
◯ I acknowledge on behalf of the patient

OK

HELPFUL TIP:

If you have spoken to the patient in the clinic or on the phone regarding the medication adjustment, it is OK to accept on their behalf since they are aware of the change.

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MYCARDIOMEMS™ PATIENT APPLICATION

PATIENT INTERFACE

The myCardioMEMS™ Patient Application can be used on any smartphone or tablet. In order to download the app, the patient should visit the app store on their device. Searching for "myCardioMEMS" is the best way to find the app.

Once the app has been downloaded, the myCardioMEMS app icon will appear on their mobile device home screen. To launch the app, tap the icon.

REGISTRATION

To register as a new user on the app, the patient should select **Register:**

1 **Information required to register includes:**

- A unique email address

- The patient's PA sensor serial number

- The patient's date of birth

If not available, the sensor serial number can be obtained by calling Remote Care Technical Support at 1-844-MYCMEMS or 1-844-692-6367.

2 **Registration is available in two modes.**

There can only be one person registered as the **patient or primary caregiver.** This role is the only one that can acknowledge medication changes, if that feature is enabled by the clinic.

There can be multiple people registered as **other**. This role is able to see messages, but not acknowledge them.

3 **After registering, the app user will be prompted to allow notifications.**

If Medication Management is being utilized, tap OK, as this is how the clinic will send messages and medication change notifications.
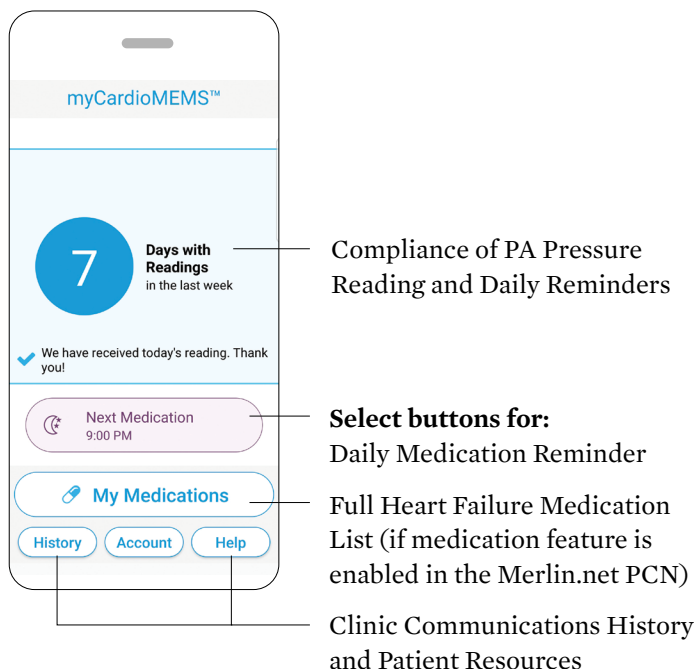
4 **It is suggested that the user choose to stay logged in.**

By making this selection, a password is not required each time the myCardioMEMS™ app is accessed.

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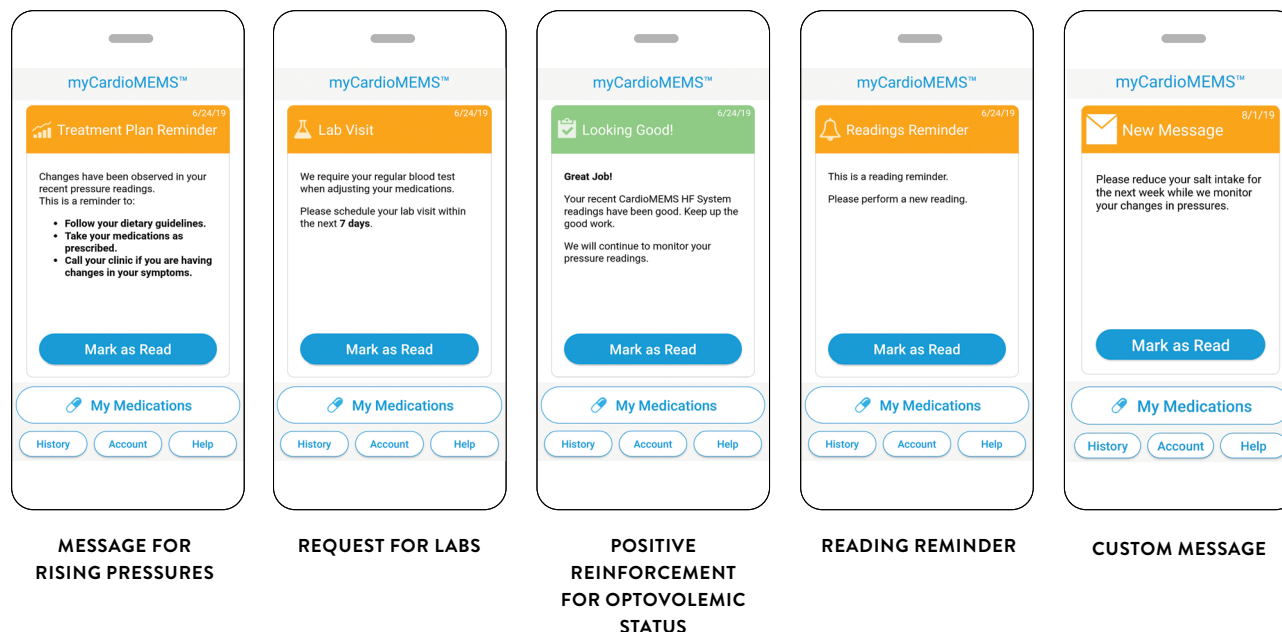MERLIN.NET™ PCN

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HOME SCREEN

The home screen displays a patient's compliance in taking their PA pressure readings, as well as a daily reminder to take their reading. Once a reading has been taken and received on the Merlin.net™ PCN, the reminder will go away and the compliance tracker will change.

Compliance of PA Pressure Reading and Daily Reminders

Select buttons for:
Daily Medication Reminder

Full Heart Failure Medication List (if medication feature is enabled in the Merlin.net PCN)

Clinic Communications History and Patient Resources

STANDARD AND CUSTOM MESSAGES

Messages are shown on the home screen as cards to the patient when they are received. They can also be reviewed in the history calendar.

MESSAGE FOR RISING PRESSURES

REQUEST FOR LABS

POSITIVE REINFORCEMENT FOR OPTOVOLEMIC STATUS

READING REMINDER
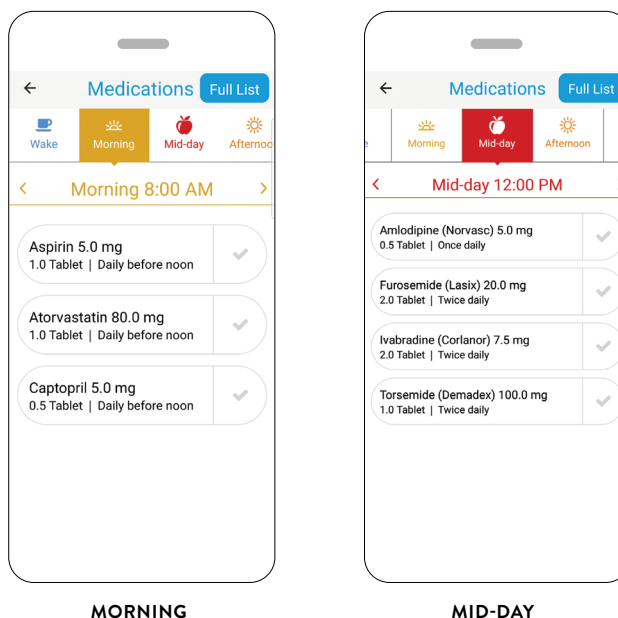
CUSTOM MESSAGE

NAVIGATION BUTTONS

Each button will be discussed in more detail in subsequent sections. **The user can select one of four buttons:**

1 **My Medications:** If Medication Management is turned on for the patient, this button will be active. Tapping it will take the user to the patient's medication list.

2 **History:** This button navigates to a calendar view where the user can see the patient's compliance over the month and review messages that were sent by the clinic.

3 **Account:** The user can view the patient's profile settings, clinic and preferred lab contact.

4 **Help:** This page provides additional resources for the user, including instructional videos and FAQs.

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MY MEDICATIONS

- If a patient has Medication Management enabled in their profile, this button is active. When a user taps **My Medications**, the patient's medication list is displayed.

- Patients can receive reminder notifications when it is time to take their medication and can indicate that they have taken the medication. The reminders have designated times associated with each time slot (i.e., wake, morning, mid-day, afternoon, evening and night). The times can be modified, but cannot be reordered or renamed.

- The exact times for each notification window can be adjusted in Account Preferences.

MORNING
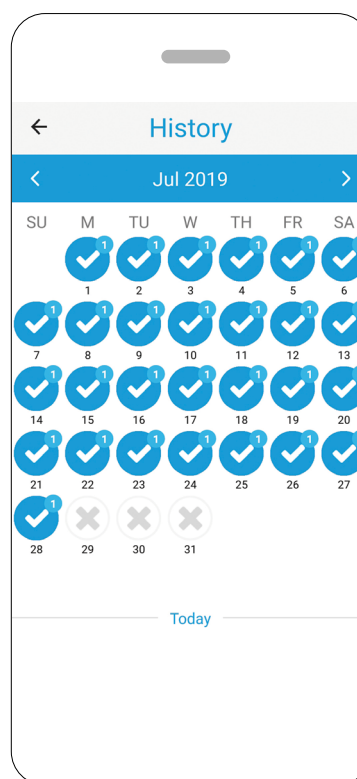

MID-DAY

HISTORY

The history calendar screen shows the days on which PA pressure readings were received.

STANDARD AND CUSTOM MESSAGES

Messages are shown as cards to the patient when they are received. They can be reviewed in the history calendar.

- Gray 'X' means a reading was not received.

- Blue check mark means the reading was received.

- Orange and blue bubbles show days on which messages were sent.

    Note: If the user is registered in the **other** mode, messages will not be visible until the **patient or primary caregiver** user acknowledges the message.

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ACCOUNT

The account button displays the enrolled user's account information. In the **Account** tab, under **Profile**, the user can manage their contact information, password and login preference.
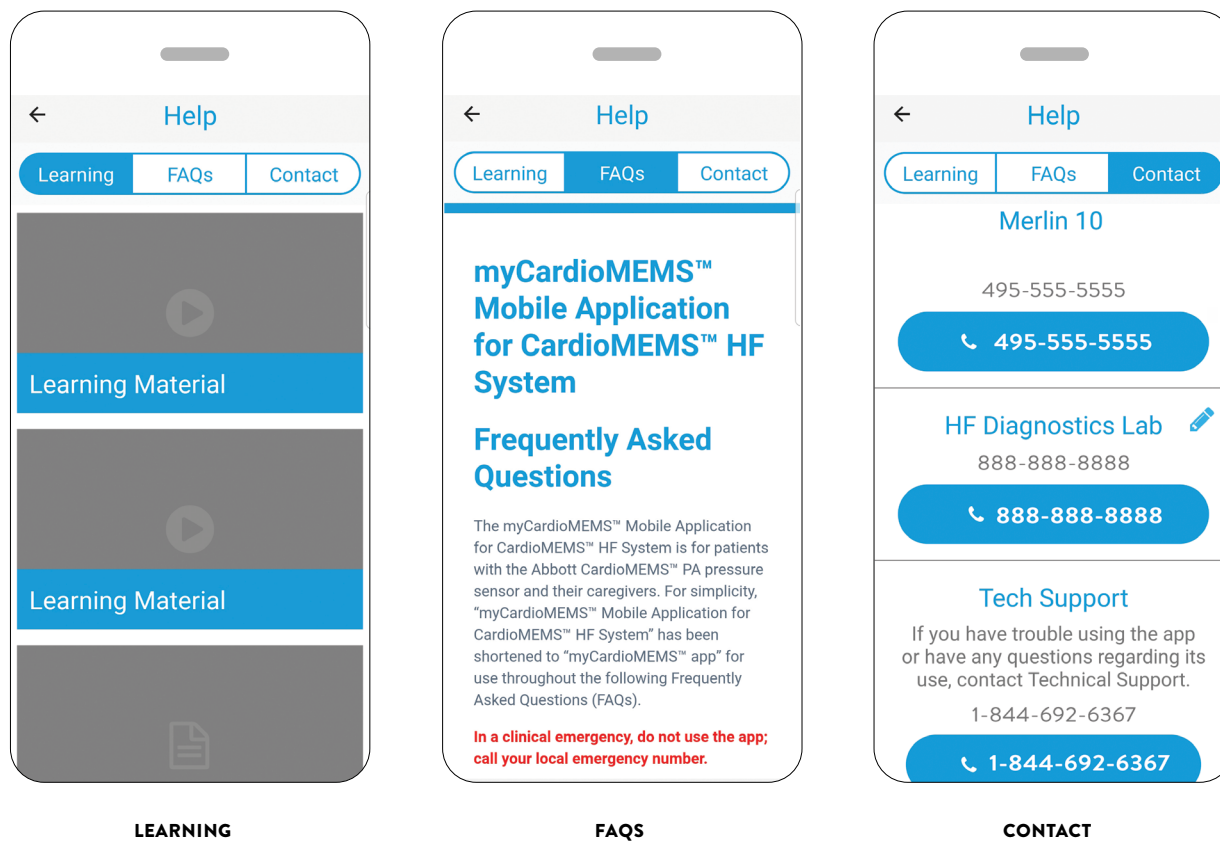
Under **Preferences,** the patient user can only set hospitalization dates and manage medication reminders.

If Medication Management is turned on for the patient and the user wants to receive notifications to be reminded when to take a medication, the user should turn on the reminders. If reminders are turned on, the app should remain open in the background at all times.
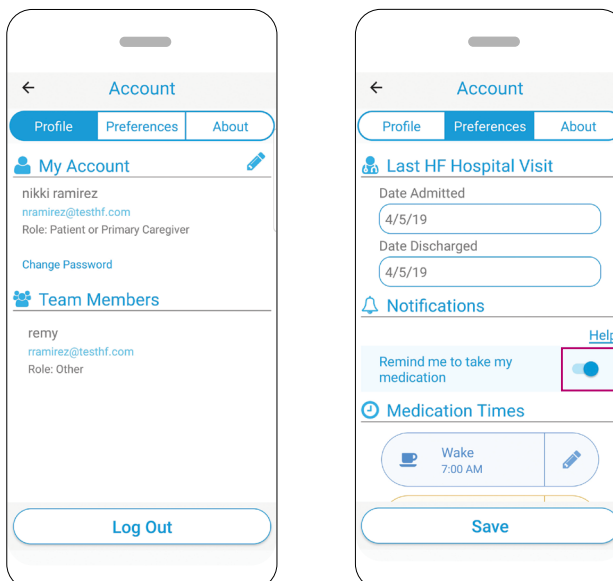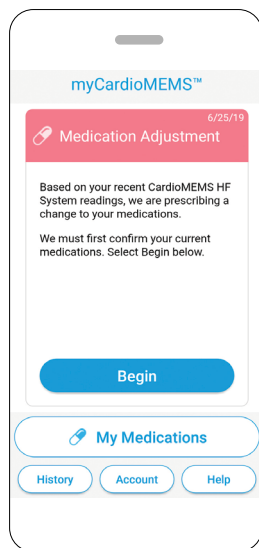

HELP

Selecting the help screen allows the user to view FAQs and help videos related to using the app and contact information for support.

LEARNING

FAQs

CONTACT

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MEDICATION TITRATION

SCREEN SEQUENCE

1

NOTIFICATION:
After a patient is enabled for Medication Management, medication changes made in the Merlin.net™ PCN will be sent to the **patient or primary caregiver** user through the app.
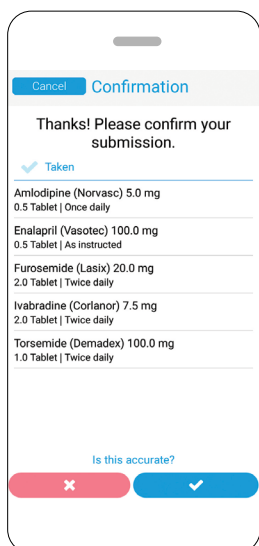
The patient will see a Medication Adjustment card. The patient should select **Begin** to indicate they are taking their medications appropriately.

2

### VIRTUAL MEDICATION RECONCILIATION:
Note: Not all medications will be displayed in the app. Only the heart failure medications that are entered and managed in the Merlin.net PCN will be displayed.

3

RECONCILIATION CONFIRMATION:
If the patient does not indicate that they are taking their current medication appropriately, they will be requested to contact their clinic for further instructions.
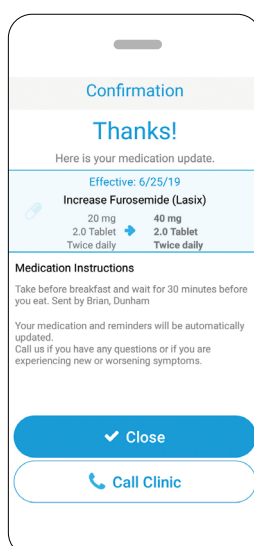
4

TITRATION INSTRUCTION:
If the patient indicates that they are taking their medication appropriately, they will receive details of the new update. At this point reminders may be set up if medication has a daily frequency.

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RESOURCES

**MYCARDIOMEMS™ APP
INSTRUCTIONAL VISUAL GUIDE**

**MERLIN.NET™ PCN
VISUAL GUIDE**

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REFERENCES

1. Abbott. Data on File. 90305907 Rev. A. The CardioMEMS™ HF System Workflow Research. May 2017.

2. Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. *The Lancet*. 2011;377(9766):658-666.

This document is not intended to replace the judgment of the acting practitioner nor the establishment of final protocols within the hospital setting. It does not represent any opinion or endorsement by Abbott of any particular approach to patient management or treatment.

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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.

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.

Limitations: Patients must use their own Apple‡ or Android‡ mobile device to receive and transmit information to the myCardioMEMS™ 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™ 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.

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REIMBURSEMENT LANDSCAPE

FOR THE CARDIOMEMS™ HF SYSTEM

The reimbursement landscape for defining any technology or therapy is highly dependent on three key tenets, which are:

- Coding
- Coverage
- Payment

Abbott is committed to providing customers, patients and providers reimbursement education for the CardioMEMS™ HF System.

It is important to understand that coverage for first in-kind technologies such as the CardioMEMS HF System will take time as Medicare and commercial payers need to better understand utilization of this technology and its impact in improving clinical outcomes for appropriately indicated patients with congestive heart failure. As a breakthrough technology, the Centers for Medicare and Medicaid Services (CMS) granted the CardioMEMS HF System new technology payments for the inpatient and outpatient hospital settings in recognition that this technology is a substantial clinical improvement over current standard of care. Since these new technology payments have expired, CMS has established both inpatient and outpatient reimbursement mechanisms for the CardioMEMS HF System implant procedure, as well as hospital outpatient and office-based reimbursement of ongoing remote monitoring.

At a high level, it is important to note the following:

- Physician and hospital coding is in place for reporting the CardioMEMS™ Pulmonary Artery (PA) Sensor implant procedure.

- Coverage continues to be based on individual consideration based on medical necessity.

- All local Medicare contractors implicitly cover based on reasonable and necessary guidelines. As of July 1, 2020, Novitas Solutions, Inc. (Novitas) and First Coast Service Options, Inc. (FCSO) have retired their local non-coverage policies (LCD L36419 and LCD 33777) to be consistent with the other Medicare contractors. On dates of service on and after July 1, 2020, providers can provide CardioMEMS PA Sensor implant and remote monitoring services to their patients in these jurisdictions.

- Novitas is the Medicare Administrative Contractor (MAC) that administers the Medicare claims for DE, MD, NJ, PA, DC, AR, CO, LA, MS, NM, OK and TX. FCSO is the MAC for FL, Puerto Rico and the Virgin Islands.

- Commercial payers and Medicare Advantage plans may cover depending on the ability to successfully obtain prior authorization.

- Several commercial payers now have positive coverage policies supporting the CardioMEMS HF System. They include Highmark, BCBS of NE and Priority Health. It is always important to check with the payers' coverage policy and prior authorize for services.

- Hospital payment is established for the CardioMEMS PA Sensor implant procedure. The CY2020 Medicare national average payment rate for comprehensive ambulatory payment classification (C-APC) 5200 is $28,518 when performed in the outpatient hospital setting. In the inpatient hospital setting, the CardioMEMS HF System implant procedure maps to MS-DRG 264 with a FY2020 Medicare base payment rate of $20,266.

Please review the following reimbursement resources (available from your Abbott sales representative) that provide physician and hospital coding and payment rates for the CardioMEMS HF System and the remote monitoring services provided after the implant.

- CardioMEMS™ HF System Coding Guide

- CardioMEMS™ HF System Reimbursement FAQs

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CARDIOMEMS™ HF SYSTEM CODING

The American Medical Association (AMA) created CPT[‡] 1 codes to further describe services related to PA pressure implantation and remote monitoring effective on January 1, 2019. These CPT codes make it easier for documenting and reporting the CardioMEMS™ HF System procedures as well as providing defined physician payment. The AMA deleted CPT code 93299, which was used for hospitals to report the technical component of the CardioMEMS HF System remote monitoring for CY2020. CMS finalized a new temporary Healthcare Common Procedure Coding System (HCPCS) code, G0266, effective January 1, 2020, to report this service, which means that hospitals can continue to report this service as appropriate.

Implant Procedure: Physicians will report with 33289 for the CardioMEMS™ PA Sensor implant procedure described by the CPT code descriptor:

Transcatheter implantation of a wireless pulmonary artery pressure sensor for long term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography.

CPT code 33289 replaces reporting with the following code combination prior to January 1, 2019: 93451, +93568 and 93799.

PA Pressure Remote Monitoring: Physicians will report 93264 for CardioMEMS HF System remote monitoring based on the CPT code descriptor:

Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified healthcare professional.

Based on the CPT and CMS requirements, physicians should not report 93297 or G2066 with 93264 except under certain circumstances. The Corrective Coding Initiative (CCI) may allow for modifiers to be utilized when such circumstances exist based on medical necessity and supporting documentation. We advise that you follow up with your coders and payers to determine how they cover and treat the different mechanisms for reporting remote monitoring. This code is billable every 30 days when the requirements of the CPT code are met.

Hospitals will report G2066 for the technical component of the CardioMEMS HF System remote monitoring based on the HCPCS code descriptor:

Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results.

HCPCS code G2066 replaces CPT code 93299, which was deleted by the AMA effective January 1, 2020. This code is billable every 30 days when the requirements of the HCPCS code are met.

Physicians and qualified healthcare professionals may have additional questions about the remote monitoring code for the CardioMEMS HF System as it relates to the CPT requirements. The code defines weekly review of patients' PA pressures. The reasoning for this is to ensure that the clinician work associated with monitoring PA pressures results in maintaining pressures in optimal range to avoid decompensation resulting in heart failure hospitalizations.

Refer to the CardioMEMS HF System 2020 Abbott Reimbursement Guide and FAQ for additional information on the CPT code instructions for these codes and supporting resources for these services.

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REIMBURSEMENT RESOURCES

FOR COVERAGE CHALLENGES

Abbott has many reimbursement resources to assist providers and patients in navigating the coverage challenges with Medicare Advantage and private payer plans. With new technologies like the CardioMEMS™ HF System, it is imperative that providers seek prior authorization from private payers and Medicare Advantage plans to review the medical necessity of the services. In light of non-coverage policies (e.g., investigational and experimental) that may exist for hemodynamic monitoring, it is always a best practice to seek prior authorization before performing the implant. Traditional Medicare fee for service does not offer prior authorization. Most local Medicare contractors implicitly cover hemodynamic monitoring implants based on medical necessity with the exception of FCSO and Novitas. Please check with your local MAC if you are administered by FCSO or Novitas. Abbott also has a regional, field-based Health Economics & Reimbursement (HE&R) team to assist with reimbursement education and coding, coverage and payment questions specific to the CardioMEMS HF System and other Abbott therapies and products. To contact them, please email HeartFailureEconomics@abbott.com.

REIMBURSEMENT WEBSITE AND DIGITAL RESOURCES
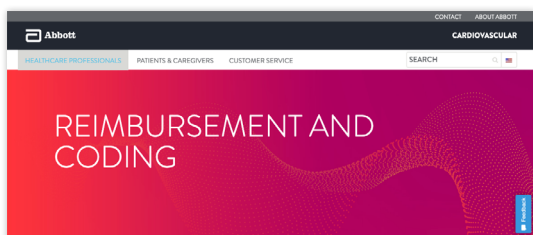
REIMBURSEMENT TOOLS
www.cardiovascular.abbott/reimbursement
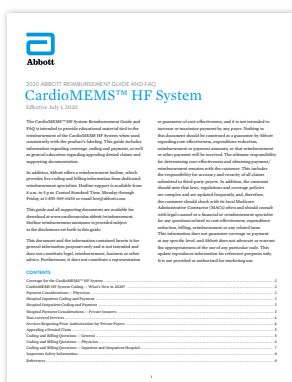
CARDIOMEMS HF SYSTEM 2020 ABBOTT REIMBURSEMENT GUIDE AND FAQ
available for download at Cardiovascular.Abbott/CardioMEMSWorkflow

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FAQ

REMOTE MONITORING FREQUENTLY ASKED QUESTIONS

Is there a new CPT[‡] 1 code for PA pressure remote monitoring?

Yes, the AMA approved new CPT[‡] code 93264 for remote monitoring of PA pressures effective on January 1, 2019. For dates of service on and after January 1, 2019, physicians should use CPT code 93264 and no longer utilize the implantable cardiovascular physiologic monitor system remote monitoring CPT codes 93297 and 93299.

93264: Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified healthcare provider.

What are the requirements for reporting CPT code 93264?

According to the 2020 CPT manual, they provide additional parentheticals and/or criteria around code 93264 that include the following:

- Report 93264, only once per 30 days.

- Do not report 93264 if download(s), interpretation(s), trend analysis, and report(s) do not occur at least weekly during the 30-day time period.

- Do not report 93264 if review does not occur at least weekly during the 30-day time period.

- Do not report 93264 if monitoring period is less than 30 days.

As a provider responsible for remote monitoring of CardioMEMS™ HF System patients, can I bill for remote monitoring if I perform this service?

Yes, this is a billable service when performed based on the CPT requirements established for code 93264. Providers can reasonably bill for services they provide to patients.

What is the 2020 Medicare physician national payment rate for 93264?

The 2020 national physician payment rate for 93264 is $52 when performed in the physician's office and $37 when performed in the hospital.[1]

Will CardioMEMS HF System patients have coinsurance responsibility for remote services performed?

It depends on the patient's insurance. Please verify with your patient's health plan.

Is CPT code 93264 reimbursed when the technical services (e.g., data acquisitions for technical support and distribution of results) are performed in the outpatient hospital?

Based on the CY2020 Medicare Outpatient Hospital Payment Final Rule, CPT code 93264 has a status indicator of "M" in terms of not payable in outpatient hospital. CPT code 93264 is for physician reporting of remote monitoring of PA pressures; therefore, there is no separate breakout of a professional or technical component for the hospital to bill for the technical services.

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REMOTE MONITORING FREQUENTLY ASKED QUESTIONS (CONTINUED)

If the outpatient hospital acquires the PA pressure data for remote technical support and distribution of results, how should they report this service considering the above?

The outpatient hospital cannot bill for 93264 because it is not payable in this site of service (outpatient hospital status indicator "M"). However, if the hospital meets the requirements of the newly created HCPCS code G2066, they should be able to bill with this code based on medical appropriateness and documentation. HCPCS code G2066 has a site of service differential payment when performed in the facility setting (hospital) versus when performed in the physician's office setting. It is important to verify with your institution's coders and your Medicare Administrative Contractor and private payers.

G2066: Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results.

HCPCS code G2066 is reimbursed under C-APC 5741 with a 2020 Medicare National Average Payment rate of $36 when provided in the outpatient hospital.[2]

If a patient has multiple devices such as a CardioMEMS™ PA Sensor for PA pressure monitoring and a device (e.g., CorVue™/OptiVol‡) for monitoring intrathoracic impedance, can the same provider bill for both remote monitoring periods represented by codes 93264 and 93297/G2066, respectively?

According to the CPT‡ code instructions, it states, "Do not report 93297 in conjunction with 93264, 93290, 93298." CPT code 93264 is used specifically for reporting remote monitoring of an implantable wireless pulmonary artery pressure sensor.

We strongly suggest that clinicians verify with their billers and coders to determine if monitoring for intrathoracic impedance with the CorVue™ or OptiVol‡ systems constitutes a distinct service that is different than the work done with remote monitoring via PA pressures. The CCI may allow for modifiers to be utilized when such circumstances exist based on medical necessity and supporting documentation. We advise that you follow up with your coders and payers to determine how they cover and treat the different mechanisms for reporting remote monitoring.

If you have reimbursement questions, please email HeartFailureEconomics@abbott.com.

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REFERENCES

1. Department of Health and Human Services, Centers for Medicare & Medicaid Services. CY2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F. Published November 15, 2019. Accessed December 1, 2019.

2. Department of Health and Human Services, Centers for Medicare & Medicaid Services. Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC. Published November 12, 2019. Accessed December 1, 2019.

This document is not intended to replace the judgment of the acting practitioner nor the establishment of final protocols within the hospital setting. It does not represent any opinion or endorsement by Abbott of any particular approach to patient management or treatment.

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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.

CardioMEMS™ HF System 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.

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: 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.
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myCardioMEMS™ Mobile App Limitations: Patients must use their own Apple‡ or Android‡ mobile device to receive and transmit information to the myCardioMEMS™ 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™ 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.

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