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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM

PATIENT SELECTION

CARDIOMEMS™ HF SYSTEM

PATIENT SELECTION

TABLE OF CONTENTS

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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]

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

CLINICAL CONSIDERATIONS

FOR PATIENT SELECTION

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

No limitation of physical activity.

Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).

CLASS II

Slight limitation of physical activity.

Comfortable at rest.

Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).

CLASS III

Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.

NYHA Class III is the approved heart failure patient classification for the CardioMEMS HF System.

CLASS IV

Unable to carry on any physical activity without discomfort.

Symptoms of heart failure at rest.

If any physical activity is undertaken, discomfort increases.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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

The CardioMEMS™ HF System

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

PATIENT ID TOOL

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

Abbott

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM

PATIENT EDUCATION

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM

PATIENT EDUCATION

TABLE OF CONTENTS

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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.

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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
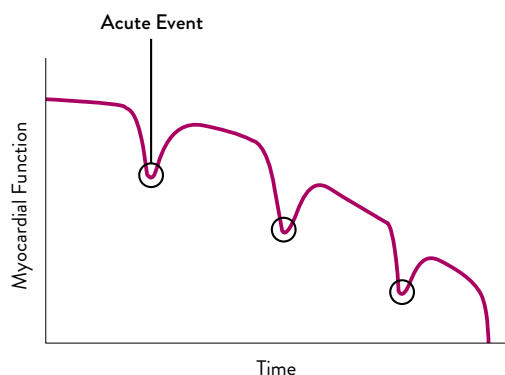
THE GOAL:

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

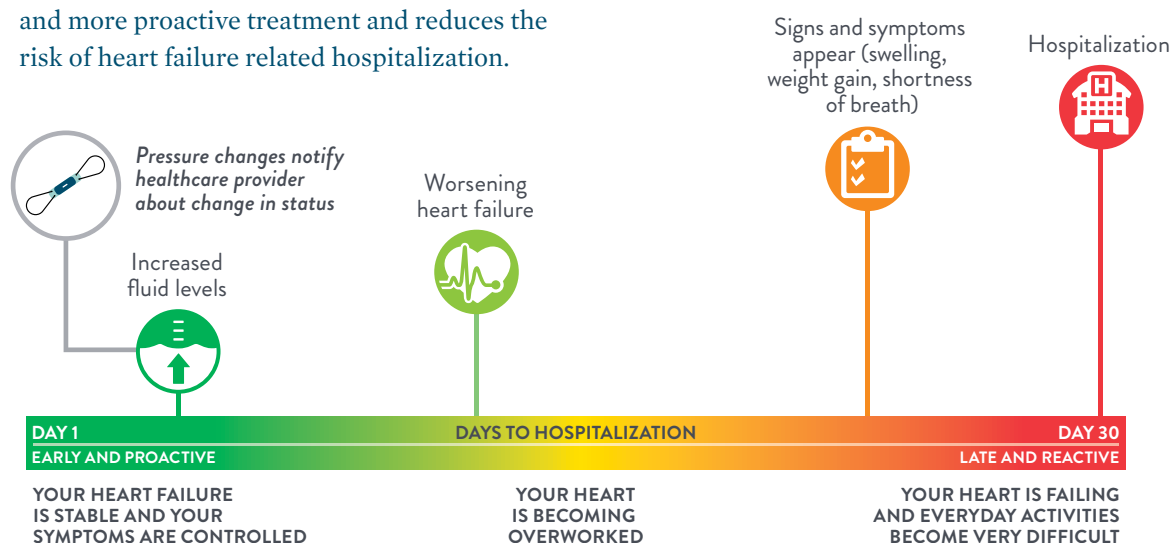Graph adapted from Gheorghiade MD, et al. *Am J. Cardiol,* 2005.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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

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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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.
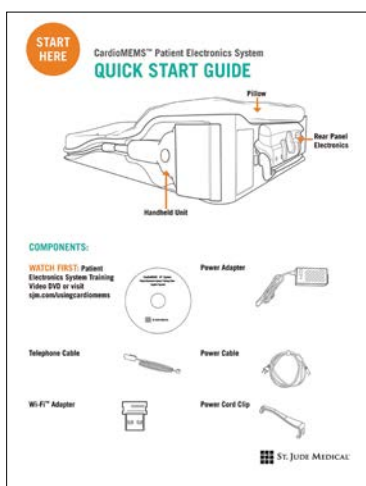
Patient Electronics System Quick Start Guide

Patient Discharge Procedure Checklist

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN
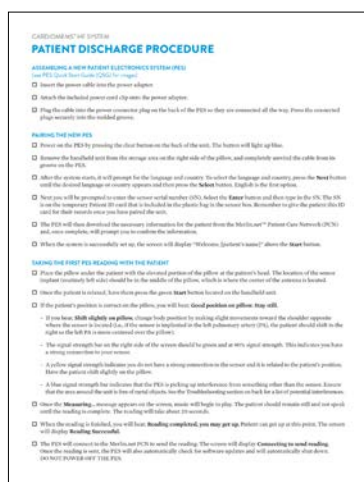
BILLING AND
REIMBURSEMENT

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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

EDUCATIONAL RESOURCES

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

Visit **Cardiovascular.Abbott/CardioMEMSWorkflow** to access these resources.
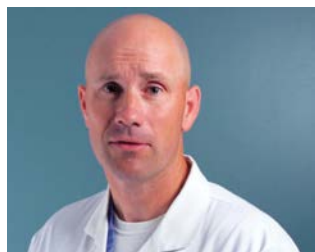
CARDIOMEMS™ HF SYSTEM PATIENT APPROACH EXAMPLE VIDEO #1

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 VISUAL GUIDE

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

EDUCATIONAL RESOURCES

FOR YOUR HEART FAILURE PATIENTS (CONTINUED)

OVERVIEW VIDEO

for the CardioMEMS™ HF System.
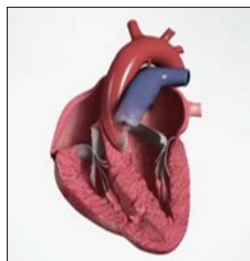
ANIMATION VIDEO

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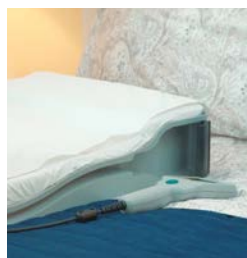
PATIENT TRAINING VIDEO

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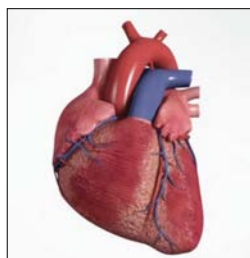
ANIMATION VIDEO

for patients on how the heart works.

PATIENT INFORMATION AND PATIENT TESTIMONIAL VIDEOS

on the web at StayAheadofHF.com

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

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

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

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

Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: Infection, Arrhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death, and Device embolization.

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.

Abbott

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM

IMPLANT CONSIDERATIONS

CARDIOMEMS™ HF SYSTEM

IMPLANT CONSIDERATIONS

TABLE OF CONTENTS

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

ABBOTT TECHNICAL SUPPORT

Phone: 1-844-MYCMEMS

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

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
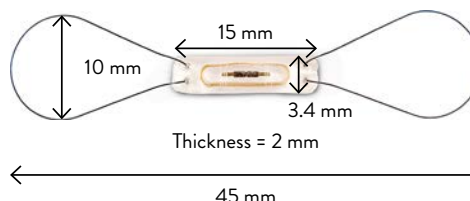
PA sensor not shown at actual size

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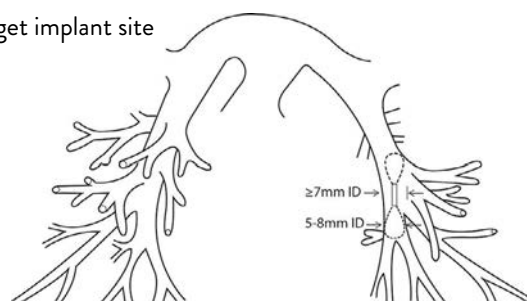
For complete implant procedure and device information, please refer to the Instructions for Use/User's Manual for the CardioMEMS™ HF System, PA Sensor and Delivery System (Model CM2000).

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

Abbott

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM

PATIENT MANAGEMENT

CARDIOMEMS™ HF SYSTEM

PATIENT MANAGEMENT

TABLE OF CONTENTS

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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 1

PHASE II: PA Pressure Optimization, page 3

PHASE III: PA Pressure Maintenance, page 5

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PHASE I:
POST IMPLANT PATIENT EVALUATION (CONTINUED)

CARDIOMEMS™ PA SENSOR IMPLANT ANTICOAGULATION

Currently Receiving Anticoagulant Therapy[2]	• Discontinue anticoagulant therapy one to two days prior to sensor implant. • INR of < 1.5 is recommended prior to sensor implant. • Restart treatment after sensor implantation.
Not Currently Receiving Anticoagulant Therapy[2]	• For one month following the procedure anticoagulant therapy should be aspirin (81 mg or 325 mg) and clopidogrel (75 mg) daily.

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. To better understand selection criteria, refer to the myCardioMEMS App Patient Selection Tool.

ABBOTT TECHNICAL SUPPORT

Phone: 1-844-MYCMEMS

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PHASE II:
PA PRESSURE OPTIMIZATION

GOAL: MANAGE PATIENTS TO ACHIEVE OPTIMAL PA PRESSURES

Within three to seven days of implant:

1 Review patient's initial at-home readings to determine PAD pressure 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 Program initial PAD pressure threshold range on the Merlin.net™ PCN.

3 Subscribe to your patient on the Merlin.net PCN to receive email notifications if their PA pressure deviates from their PAD pressure threshold range.

HELPFUL TIPS:

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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

- Treat to trends generally lasting **three or more days**; program email notifications accordingly.

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

  – Address any suspect readings.

- Assess PAD pressure 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%)[3]

- Hypotension

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PHASE III:
PA PRESSURE MAINTENANCE

GOAL: MAINTAIN OPTIVOLEMIA

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

- Set the maintenance phase target PAD pressure threshold range:

  – Program **PAD pressure threshold range** on the Merlin.net™ PCN 2–3 mmHg above/below target PAD pressure goal.

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

- Evaluate pressures at least one time per month, reassess PAD pressure goals and/or reprogram PAD pressure threshold ranges as needed.[1]

- Be mindful of checking the waveform and addressing any suspect readings.

- Review Patients of Interest report one to two times per week.

Normal PA Pressure Waveform

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT
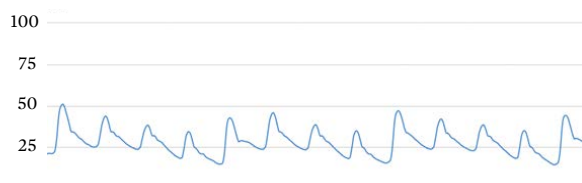
PHASE III:
PA PRESSURE MAINTENANCE (CONTINUED)

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 and reports to help you manage trends in PA pressure changes. 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 PAD and remove the PA mean and PA systolic threshold notifications. This does not remove the data; it only eliminates email notifications for these pressures.

- Intervene if the patient is noted to have a 3–5 mmHg change in PA pressure over two to three days.

- A change of 5 mmHg or more in a single day may warrant evaluation.

AUTOMATIC NOTIFICATION OF THRESHOLD DEVIATIONS

- Subscribe to each patient on the Merlin.net PCN to receive automatic email notifications.

- In the Merlin.net PCN, customize the clinic notifications to three days — this may be done in the clinic and/or patient profile.

PATIENTS OF INTEREST REPORT

- Clinic administrator chooses 1–2 days/week to generate a Patients of Interest report.

- Individual clinic users who wish to view the report opt in via their user profile.

- The Patients of Interest report is generated from all active patients on the clinic's Merlin.net PCN.

DIRECTCALL™ MESSAGES

- Utilize DirectCall™ messages to remind patients to take a reading and reinforce healthy lifestyle choices.

HELPFUL TIP:

There is no need to check PA pressures every day. Remember, PA pressures will rise long before the patient is in crisis.[3]

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PHASE III:
PA PRESSURE MAINTENANCE (CONTINUED)

EXAMPLE OF THE PATIENTS OF INTEREST REPORT:

There are three sections in the Patients of Interest report that work as a "safety net" to catch patients whose PA pressures are rising, but not enough to trigger an email notification.

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

1 They have a running average of seven days of PAD pressure outside their programmed threshold range *(example below)*.

Patient's programmed PAD pressure threshold range in the Merlin.net™ PCN = 18–24 mmHg

DATE 5-6-17	DATE 5-7-17	DATE 5-8-17	DATE 5-9-17	DATE 5-10-17	DATE 5-11-17	DATE 5-12-17	7-day running PAD pressure average = 25.1 mmHg
PAD (mmHg) 25	PAD (mmHg) 24	PAD (mmHg) 27	PAD (mmHg) 28	PAD (mmHg) 26	PAD (mmHg) 24	PAD (mmHg) 22	

2 They have a weekly PAD pressure average change of +/- 5 mmHg or more over last week's average within programmed threshold range *(example below)*.

Patient's programmed PAD pressure threshold range in the Merlin.net PCN = 16–24 mmHg
This week's average PAD pressure = 23.8 mmHg (see chart below)
Last week's average PAD pressure = 18 mmHg
Difference between this week and last week = 5.8 mmHg change

DATE 5-6-17	DATE 5-7-17	DATE 5-8-17	DATE 5-9-17	DATE 5-10-17	DATE 5-11-17	DATE 5-12-17	7-day running PAD pressure average = 23.8 mmHg
PAD (mmHg) 24	PAD (mmHg) 24	PAD (mmHg) 25	PAD (mmHg) 24	PAD (mmHg) 24	PAD (mmHg) 23	PAD (mmHg) 23	

3 They have not transmitted a pressure reading for more than seven days in a row.

- Changing the compliance setting to three days in the clinic profile may allow you to respond sooner to non-compliant patients and reinforce the value of daily readings.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.[3]

- **Let the system work for you**. Rely on email notifications and the Patients of Interest report to inform you of patients needing attention.

- Communicate with your patients efficiently by **using the DirectCall™ messages** feature on the Merlin.net™ PCN 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.

  – **Two to three times a week**, review patient's PA pressures in the Merlin.net PCN and adjust medications as needed to reach PAD pressure goal.

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

  – Treat to trends generally lasting **three or more days**.

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

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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 CardioMEMS 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	

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

EFFICIENTLY MANAGE YOUR PATIENTS
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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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[3]*

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

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.

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 optimizing 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.

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

MANAGING MEDICATIONS
BASED ON PA PRESSURE CHANGES (CONTINUED)

Here is one example of a sliding-scale diuretic Rx illustrated below[3]:

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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 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.

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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 goals? 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.

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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. 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

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

Thresholds

- Global 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.

- Threshold notifications will be delivered to any subscribed primary and co-managing clinic users.

RESTRICTIONS ACROSS CO-MANAGING CLINICS

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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

REFERENCES

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

2. CardioMEMS™ HF System Instructions for Use.

3. 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."

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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM

MERLIN.NET™ PATIENT CARE NETWORK (PCN)

CARDIOMEMS™ HF SYSTEM

MERLIN.NET™ PATIENT CARE NETWORK (PCN)

TABLE OF CONTENTS

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

MERLIN.NET™ PCN

CLINIC ADMINISTRATION

For assistance with establishing a new Merlin.net™ PCN Clinic, consult with your Abbott Representative or call 1-877-MyMerlin (1-877-696-3754).

MERLIN.NET PCN

CLINIC SETUP

First, set up the clinic. Some information will be pre-populated into this page from either the clinic enrollment form, or the existing, affiliated CRM clinic. It is important to verify this information and make necessary changes so that it is accurate for the staff managing patients with the CardioMEMS™ PA Sensor. Note: If the clinic's Merlin.net PCN website is shared with a device clinic, any changes to the clinic profile will affect the device clinic as well.

CLINIC PROFILE

Clinic Details
Confirm that the clinic name is correct. It should be 30 characters or fewer.

Verify clinic location, clinic address and phone number, making sure the appropriate country code is entered in the first box. *Note: This phone number will show on a patient's caller ID when a DirectCall™ Message is sent, so it should be a phone in the clinic, not a personal cell phone.*

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CLINIC PROFILE (CONTINUED)

Clinic Regional Settings
Select the primary clinic administrator from the dropdown menu. If this is a new clinic, there may be only one name. *Note: It is important that at least one other person is assigned administrative privileges when adding clinic users (see page 7).*

Verify the clinic time zone is correct, and change if necessary. All DirectCall™ Message notification windows set in the next section will be based on this time zone.

Select the appropriate setting for password expiration and complexity (i.e., uppercase and lowercase letters, use of special symbols and numbers, etc., in a password) to be in line with the clinic's IT protocol.

Review language; date, time and number format; and weight units. Change if necessary.

DirectCall™ Messaging
Next, set up customized DirectCall Messages. Setting up customized DirectCall Messages will encourage effective use of direct patient communication via the system and will enhance clinic efficiency. These messages will be customized for the entire clinic, not on a user-by-user, or patient-by-patient, basis. The person recording the voice message(s) should be the person who has most commonly been reaching out to patients on the phone.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CLINIC PROFILE (CONTINUED)

Setting Up DirectCall™ Message — Voice
Click **Customize Phone Messages**. The popup box contains all the instructions for setting up voice messages. It is much like setting up a voicemail greeting on a cell phone.

Select the message to be recorded from the dropdown menu. For each of the five messages, there is sample text to assist in recording the message. It is recommended to mention the CardioMEMS™ HF System in the message so it is clear to the patient what the message is regarding. Once recorded, each message may be tested by entering a phone number into the boxes and clicking **Test**. If the message does not come through, verify that the correct country code is entered in the first box. Once all messages have been saved, click **Close**.

DirectCall™ Messaging Customization [×]

Voice Message Customization Instructions — *Follow the phone based customization system prompts and guidance on this page to customize your phone messages.*

Step 1: Access the customization system
Dial 800-597-8360, then enter your Clinic ID **50000020** and PIN Number **4719** when prompted.

Step 2: Select the message to customize
When prompted to provide a **Message ID**,
a) select **Message** and **Language** of the message you want to review or modify.
Message: [Call clinic ▼]   Language: [English (US) ▼]
b) use your phone keypad to enter the **Message ID**.
Message ID: 1607

Step 3: Customize your recorded message
Follow the prompts to record, review, modify, or delete your message. Use the following information as a guide.

The **Call Clinic** message instructs the patient to call the clinic. The default message is:
"Hello. This is your heart failure clinic calling. Please call us during office hours for important information about your treatment."

This is a sample script for a custom message recorded in your own voice:
"Hello. This is **[your clinic name]** calling. Please call us during office hours at **[your phone number]** for important information about your treatment."

You have customized this message in the following languages: ↻   Refresh the list of languages that you have customized for the selected message.
English (US), Spanish

Step 4: Test your message
Test the message selected in Step 2:   Country Code   Area/City Code   Phone Number
1) Enter your phone number
2) Press the **Test** button   [1]   [202]   [7514714]   [Test]

Step 5: Repeat steps 2-4 for each message & language combination you want to update
You may also set a message & language combination on this screen and use the Test feature at any time.   [Close]

DirectCall™ Messages may be recorded in different languages. Contact your Abbott Representative or Technical Service at 1-877-696-3754 for assistance.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

CLINIC PROFILE (CONTINUED)

Setting Up DirectCall™ Message — Text

Click **Customize Text Messages**. Similar to voice messages, there is a suggested text for each. It is important to limit text messages to 160 characters or fewer. Select a message in the dropdown menu, type the desired message and click **Save**. Each message may be tested by entering a mobile/cell number into the boxes and clicking **Test**. If the message does not come through, verify that the correct country code is entered in the first box. Once all messages have been saved, click **Close**.

Messages in Additional Languages for Text Messages

DirectCall™ Message - Text may be saved in any of 27 languages. Contact your Abbott Representative or Technical Service at 1-877-696-3754 for assistance.

Notification Window

Verify that the patient notification window is acceptable. DirectCall Messages will only be sent during this time unless the user chooses to override. This setting should reflect what would be the best time for most patients. If individual patients require different calling windows, they can be customized in their profile.

CLINIC PROFILE (CONTINUED)

EHR Export

It is possible to set up Merlin.net™ PCN to export a PDF report to a clinic's Electronic Health Records (EHR) system. If this is desired, a user may contact Abbott Remote Care via the number provided, and then the Remote Care team can work directly with the clinic IT's team to explore the setup.

PA Reading Compliance

This setting is what determines if a patient is marked non-compliant on the Patient List. This setting also determines which patients meet the criteria for the third section on the Patients of Interest report. The default setting is seven days, but it may be customized to meet the expectations your clinic has set for its patients. Many clinics choose to set it at three days.[1]

Patients of Interest Report

Opting in to the Patients of Interest report is a two-step process.

First, select the days of the week the clinic wishes to receive the report via email. Most commonly two days are selected at opposite ends of the week depending on the clinic schedule.[1]

Second, choose to receive the Patients of Interest report via encrypted or unencrypted email. If encrypted is left selected, users will establish separate log-in information and will see a new password prompt during their first log-in to the encrypted site. Users will receive an email on the days chosen, with a link to the encrypted report. They will then log in to the encrypted server (with their separate encrypted log-in information) to view the report. *For more information on the Patients of Interest report, see page 30.*

Log-in Adherence

If checked, this setting will trigger an email to the administrator if no one has logged in to the heart failure portal for a week.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CLINIC THRESHOLD

Click on the **Clinic Thresholds** tab. To make the most efficient use of email notifications, it is important to customize the thresholds for the clinic. At any time the clinic thresholds can be overridden in the patient profile.

If treating to PA Diastolic pressures, a common practice[1] is to remove the PA Mean and PA Systolic thresholds. This does not remove the data; it only eliminates email notifications for these pressures. In order to remove a threshold, click on it. Select **Remove** and click **OK** when asked to verify the action. Repeat for another threshold if necessary. *Note: Only a clinic administrator is able to change the clinic thresholds, and only a clinic administrator can remove a threshold from a patient's profile.*

Clinic Notification Setting

The clinic notification setting allows the clinic to set the default number of days of PA pressure readings above or below threshold before sending an email notification for out of range readings. Because the CardioMEMS™ HF System is designed to help a clinician respond to trends in changes to a patient's PA pressures, a common practice is to change this from one day to three days so that a user will not receive an email for a single day out of range.[1]

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CLINIC USERS

Appropriate selection of user roles will allow for proper designation of clinic staff to optimize access to the PA pressure data. Click **Add a User** to begin. *Note: Only a user with administrator privileges can add new users and change their profiles.*

User Profile

All fields marked with an * are required. Choose an appropriate user ID and a standard password. It is recommended to use the same password for every user since they will be required to change it the first time they log in.

CLINIC USERS (CONTINUED)

Selecting the Most Appropriate User Roles

Physician User:

1 Select **Physician** in the first dropdown box.

2 User Roles

- In the **User Roles** section, you will need to determine if the user will be **Implant**, **Treating,** or both, and then check the boxes appropriately.

- If the physician should also be able to change the clinic level settings and clinic profile, then also select **Administrator**.

- If this physician will not be implanting or treating, but should have read-only access to their patients, then select **Consulting.** *For more information on adding a consulting user to a patient's profile, see page 14.* Selecting **Consulting User** in the second row will make all other selections unavailable.

3 The third line — **Physician User Roles** — adds the physician to the **Treating** and **Implanting** dropdown boxes in a patient's profile, which are selected at implant. Select appropriately; generally these selections will match the row above.

Other Clinical User:

1 Select **Allied Health Professional.**

2 Is site an **Implant** *and* **Treating** site? If yes, check both boxes. Otherwise, determine if **Implant** or **Treating** is more appropriate. *Note: A clinician must have implant privileges in order to change clinic assignment within a patient's profile.*

3 Does a clinician need to have administrative privileges to change clinic settings and profile? If yes, also select **Administrator.** *Remember, it is important that there are two or more users with administrative privileges in case the primary administrative staff is away.*

Non-clinical User:

*This role can be used if someone in the office needs to have access to Merlin.net™ PCN for any nonclinical reasons, like scheduling or enrolling a patient. This user will only be able to enroll a patient, change a patient's profile and mark the patient as **Billed**.*

1 Select **Assistant**.

2 Select both **Implanting** and **Treating**.

User Contact Information

The user may enter their own address at a later time, but their phone number (can be the clinic number) and email are required. The security stamp is an indicator that appears on all emails generated from Merlin.net PCN so that users are aware it's not a "phishing" email. The security stamp must be entered when adding a user and can be the same for all users in the clinic.

PA Sensor Patients of Interest Report Subscription

Check the box if this user should receive the Patients of Interest report on the days previously selected. Individual users are also able to opt in to the report in their own user profile.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CLINIC LOCATIONS

If the clinic has multiple locations that will be following patients, it is possible to add additional clinic locations under the main Merlin.net™ PCN clinic.

Simply add the name of the secondary location(s) and click **Save**. Then, when enrolling patients, they can be designated to their specific clinic location where they will be followed.

HISTORY

The **History** tab can be used to follow changes made to clinic settings and patient settings for accountability. Any administrator can view the **History** tab.

In the **Select a View** dropdown menu, select a view. Clinic history will show all items related to the clinic level actions. To view patient history, first select it in the dropdown menu, and then enter the patient's Merlin.net PCN number from their profile to view all activity specific to that patient. *For more information on the Patient Profile, see page 16.*

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

VIEWING USER PROFILE

To view your own user profile, click on your name in the upper-right-hand corner of the page.

USER PROFILE

In this section, even if the user has administrative privileges, only the password can be changed. All other items must be changed in the **Clinic Users** section of the **Administration** tab.

USER CONTACT INFORMATION

All contact information can be updated in this section. The email provided should be aligned with your clinic's IT protocols.

HF PATIENT LIST PREFERENCES

Active Patients: If this is selected, upon login the Patient List will display all active PA Sensor and ICD/PM patients in the heart failure portal.

PA Sensor: If this option is selected, the Patient List will display all active PA Sensor patients only.

ICD/PM: If this option is selected, the Patient List will display all active ICD/PM patients only.

Subscribed Patients: If this option is selected, the Patient List will display only the patients that the user is subscribed to upon login.

*Note: If any of the last three options are selected, the Patient List can always be sorted to view all active patients by clicking **ACTIVE** under the Active Patients list at the top.*

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

APPLICATION PREFERENCES

Arrhythmia and Device Management: Select this option if you primarily follow patients with ICDs and pacemakers.

Heart Failure Management: Select this option if you primarily follow patients with a CardioMEMS™ PA Sensor.

> **Application Preferences**
>
> ○ Arrhythmia & Device Management
> ○ Heart Failure Management

PA SENSOR PATIENTS OF INTEREST REPORT SUBSCRIPTION

Check the box to opt in to receiving the Patients of Interest report. This section also shows the days of the week that the report will be sent. If no days are displayed, then an administrator needs to opt in to the report in clinic settings. *See page 30 to learn more about the Patients of Interest report*.

HOSPITAL ELECTRONICS SYSTEM PASSWORD

> **PA Sensor Patients of Interest Report Subscription**
>
> Select the following option to subscribe to Patients of Interest Report email. As per your clinic setting, you will receive an email every week on: Monday, Thursday
> ☑ Receive PA Sensor Patients of Interest Report

This section is used if a user gets locked out of a Hospital Electronics System (HES) associated with the clinic website. In order to receive a temporary password, a user with administrative privileges enters the HES serial number in the box and the system will provide a temporary password that will expire in 24 hours.

> **Hospital Electronics System Password**
>
> Enter the hospital electronics system serial number to view a temporary password. The temporary password expires today.
> **Electronics Serial #:** [_____]

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

ENROLLING A PATIENT

There are multiple methods to enroll a patient in Merlin.net™ PCN prior to a CardioMEMS™ HF System implant. In this guide we will discuss the process that can be applied in any site, whether the HES has connectivity in the Cath Lab or not. This process allows for a streamlined approach to patient enrollment that can be followed consistently from site to site.

PATIENT SETUP ON THE HES

- Prior to implant, do not enroll the patient in Merlin.net PCN.

- At implant, turn on the HES and log in if necessary.

- Select **New Implant**.

- Click **Cancel** to bypass connection attempt.

- On the next screen, enter the patient's first and last names and date of birth (DOB). The phone number and middle name are optional. Click **OK**.

- The next screen prompts to insert the CardioMEMS HF System USB. Remove the USB from the system package and insert into one of the ports on the right side of the HES.

- The HES will automatically pull the sensor information from the USB.

- Compare the sensor information on the screen to the information on the brown tag attached to the USB.

- Confirm the patient's name and DOB are correct; click **Yes** if all is correct and click **No** if not.

- If you clicked **No**, the entry process will start over to ensure that the correct information is entered correctly.

- If you click **Yes**, the system will proceed to the readings screen.

ASSOCIATING THE PATIENT IN MERLIN.NET™ PCN WITH HES CONNECTIVITY

This section is only applicable if the hospital is considered an implant-only site (multiple practices implant at the same hospital and patients are followed by an individual practice). In this case, the patient must be associated with the appropriate clinic for follow-up.

1 Immediately after implant, a hospital staff member must log in to their Merlin.net™ PCN account.

2 When the system loads to the patient list, scroll over **Active Patients** and select **Scheduled Patients** in the dropdown menu.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

3 Select the patient from the list. If the patient isn't showing in the list of scheduled patients, skip to the next section.

4 The system will load the patient's profile. Scroll to the last section: **PA Sensor**.

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

ASSOCIATING THE PATIENT IN MERLIN.NET™ PCN WITH HES CONNECTIVITY (CONTINUED)

5 Click the green link to **Change Clinic Assignment** if the patient will be followed at a clinic other than the hospital.

6 Select the clinic where the patient will be followed from the list. Click **Continue**.

7 Next, select the patient's **Treating Physician** in the dropdown menu.

8 If desired, select the patient's **Implanting Physician** in the dropdown menu.

9 If the clinic has a consulting physician who should have read-only access to this patient, select the appropriate consulting physician.

10 Select the correct sensor location from the dropdown menu.

11 Click **Save**.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

ASSOCIATING THE PATIENT IN MERLIN.NET™ PCN WITHOUT HES CONNECTIVITY (CONTINUED)

If connectivity is a challenge in the Cath Lab, there is a manual upload process that may be easier than attempting to find an area with some connectivity options after the implant. Steps 1–10 must be completed regardless of whether the site is implant only or a mixed site. Implant-only sites should finish the steps for complete patient enrollment.

1. Immediately after implant, a hospital staff member must log in to their Merlin.net™ PCN account.

2. Insert USB flash drive into computer.

3. On the main Patient List, click **Enroll a Patient**.

4. Select **PA Sensor**.

5. Once again, enter the patient's name and DOB. Click **Enroll**.

6. Once loaded to the patient profile, scroll to the PA Sensor section at the bottom of the page and enter the sensor serial number. *Note: The sensor serial number can be found on the brown tag attached to the USB.*

7. Scroll back to the top, and click **Import from Flash Drive** on the right side of the screen.

8. Click **Browse** to open the window to browse files on the USB flash drive.

9. Locate the thumb drive and select the file named with the implant date and sensor serial number.

10. Click **Save** and the system will upload the sensor information to the patient's profile.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PATIENT PROFILE SETUP

After a patient is implanted with the CardioMEMS™ HF System, it is important to appropriately set up the patient for successful remote monitoring. An initial review of Merlin.net™ PCN patient profile should happen three to seven days after implant.[2]

A patient will be moved in Merlin.net PCN from the Scheduled Patients list to the Active Patients list once **all** of the following occur:

• The patient has been implanted with the CardioMEMS HF System and the implant data has been uploaded either automatically or manually into Merlin.net PCN.

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

• One transmission has been sent from the Patient Electronics System (PES).

Note: If the patient does not appear on the Active Patients list after sending a reading from the PES, there was an issue in the enrollment process. A user with an **Implant** user type must go back into the patient's profile in the hospital Merlin.net PCN account from the Scheduled Patients list in Merlin.net PCN and confirm the enrollment process above is followed.

• Locate the newly implanted patient on the Patient List, and click on their name.

• Click on **Patient Profile** to begin the setup of the patient's profile.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PATIENT DETAILS

Patient
- Confirm patient's name and DOB.

- Select their language preference; this will allow the system to send DirectCall™ Messages in this language if the clinic has saved them.

- Confirm phone number, email and address to ensure patient will receive a permanent ID card *(be sure to select appropriate country as well)*.

- Note the location of the patient's Merlin.net™ PCN number; it is used to pull the history of actions from the **Administration** tab.

- Enter gender and disease state information:

  – Cardiomyopathy (if applicable)

  – EF

DirectCall™ Message
- Select patient's preferred DirectCall Message method:

  – **Call/text primary phone number**

  – **Text message to other phone number** (i.e., spouse's mobile) where they will receive text messages

- Verify that the notification window times work for the patient and adjust if needed.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

ICD/PACEMAKER *(Skip if patient does not have another device.)*

- If a patient has an Abbott ICD 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.

- If the patient's ICD or pacemaker is not an Abbott device, the information can still be entered manually by clicking on the **Other Manufacturer** box, but device diagnostics will not be available in their DirectTrend™ Viewer.

- When **Save** is clicked after the next section, Merlin.net™ PCN will prompt the user to combine the patient's PA Sensor and device profiles. Review the third column, **Combined Patient**; make any necessary changes; and click **Continue**. The system will merge the two profiles into one, and all relevant diagnostic trends will be viewable together on the DirectTrend Viewer. *For more information, see the CRM Device Diagnostics section on page 31.*

PA SENSOR

- Verify that the treating physician selected is the clinician managing the patient's heart failure.

- Select sensor location.

- Click **Right Heart Cath Implant Values.**

  – Enter data from the implant, or verify they are accurate. Click **Save** to close the box.

PA SENSOR (CONTINUED)

- Click **Implant Report**.

  - The new tab that opens contains the Calibration Code, Activation Code and Baseline Code specific to the sensor and calibration at the time of implant.

  - This information is necessary when:

    - Manually pairing a PES to a patient's sensor.

    - Conducting a follow-up reading on a HES that was not used at the patient's implant.

  - If a patient's sensor is recalibrated, these codes will change.

- Click **Save** one more time to save all the changes to the patient's profile.

OTHER PATIENT PROFILE ITEMS

How to Inactivate a Patient
If a patient has passed away or chosen to no longer have their heart failure managed using the CardioMEMS™ PA Sensor data, they should be inactivated. In their profile, hover over **More Actions** and then select **Inactivate**. Select the date and enter the reason.

A patient can also be reactivated in the same manner. If a patient is moving to another clinic for follow-up, then they should be transferred, not inactivated. *See page 32 for instructions on how to transfer a patient.*

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PATIENT DATA REVIEW WORKFLOW

It is good practice to establish a routine when doing a complete review of patient's data. In the first weeks after implant, patients should be monitored more frequently such as two to three times per week. Their PA pressure readings should be reviewed and waveforms assessed during these reviews. These heart failure clinicians recommend[1] establishing initial PA pressure thresholds for patients within the first week after the implant to maximize the efficiency of the Patients of Interest report and email notifications.

This workflow will walk through the process of reviewing a patient's data from the DirectTrend™ Viewer. To begin, click on the patient to be reviewed.

DIRECTTREND™ VIEWER

The DirectTrend Viewer contains a lot of useful information. Upon opening the DirectTrend Viewer, the PA Mean, PA Systolic and PA Diastolic Pressures are displayed. These represent discrete data points for each transmission that is received.

Mean, Systolic and Diastolic trends are also available. These trends represent a 30-day rolling average of the data. A heart rate line is also available, which may help correlate PA pressure changes to heart rate changes. The view can be customized by clicking on and off various trends in the **PA Metrics and Events** menu. Use the gray scroll bar below the trend to change the date range.

Actions

- Review the patient's initial readings by hovering over a data point to assess their baseline PA Diastolic measurements.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT
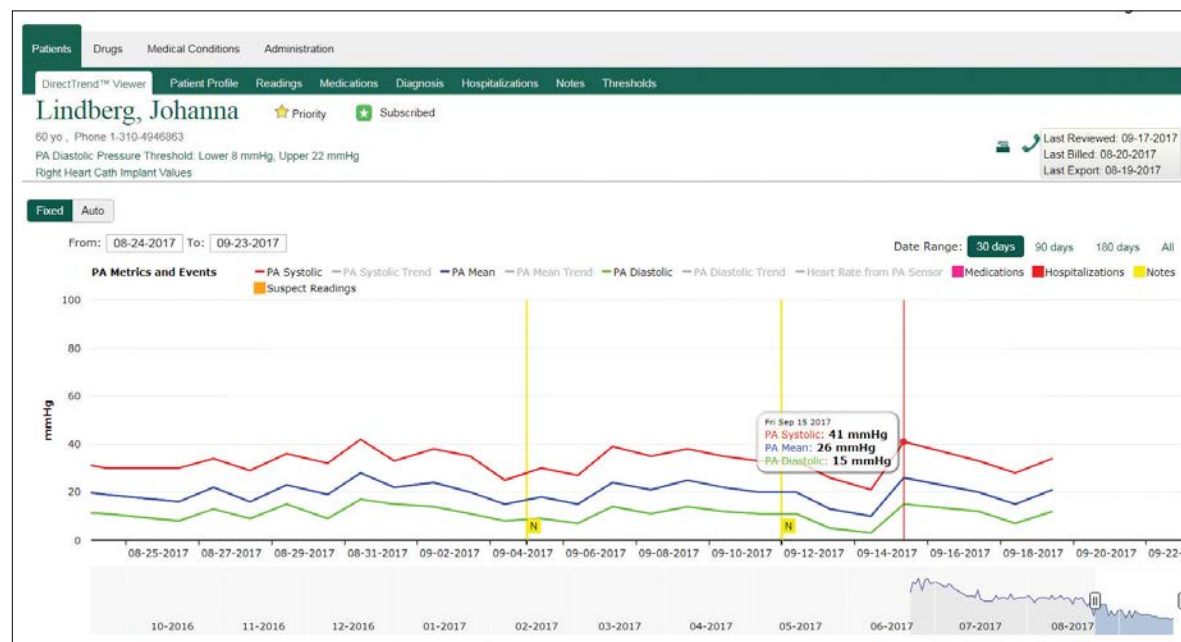
DIRECTTREND™ VIEWER (CONTINUED)

- A single click on a data point should load the waveform for that reading.

Lindberg, Johanna (Fri Jul 28 2017)
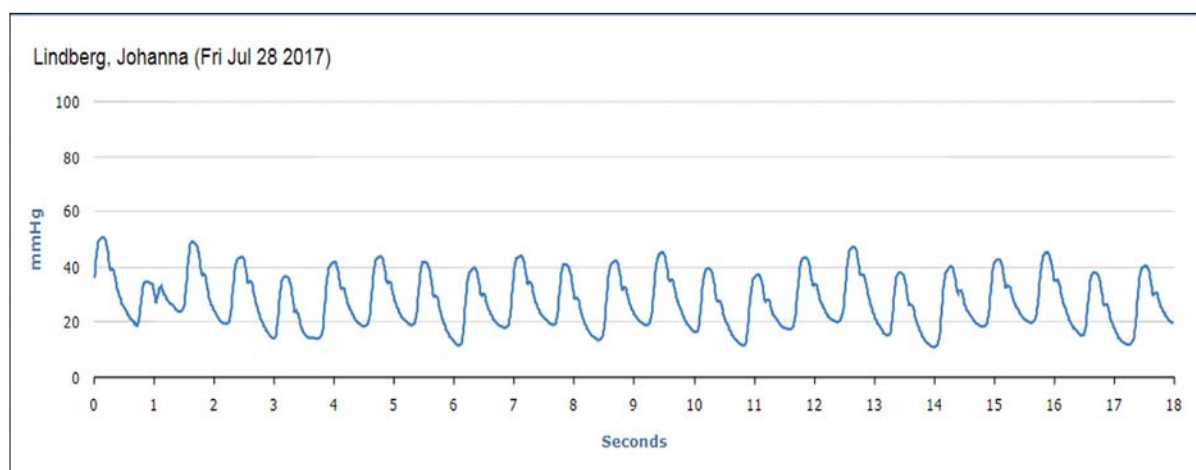
- After reviewing a few readings to establish the patient's baseline pressures, click on **PAD Thresholds** under the patient's name to set initial PA Diastolic Pressure Threshold.

    – Set wide thresholds initially. Typically, the average baseline at-home readings sit at the upper end of the threshold range (example at right).

Week 1 Readings

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

Remember

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

- Pressures in Cath Lab are typically lower than pressure readings at home.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

READINGS TAB

Click on the **Readings** tab to begin reviewing the most recent readings. The calendar view is color coded.

◻ No Reading

🟧 Suspect Reading Received

🟩 Valid PA Pressure Reading Received
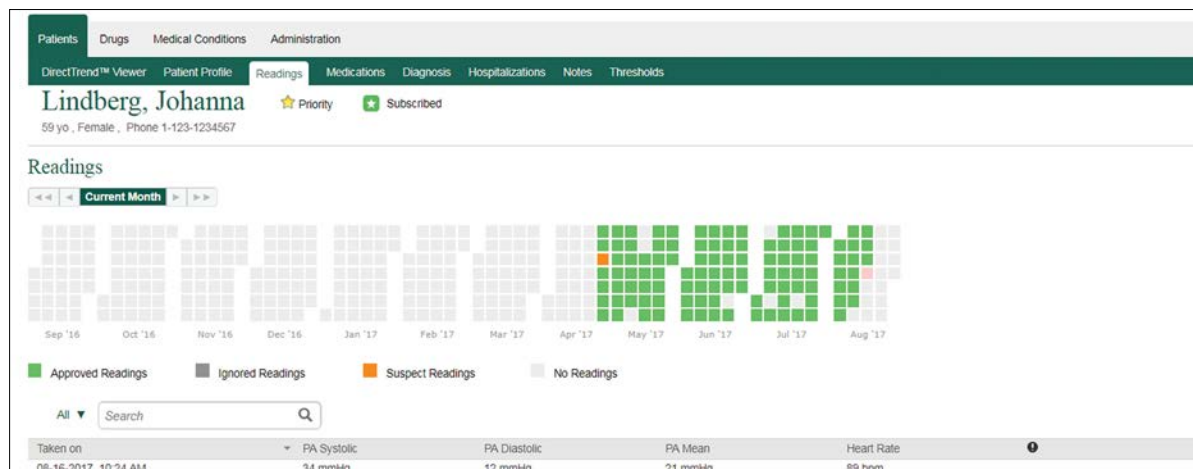
Suspect readings are not counted as valid data until a user reviews the waveform, and if accepted, the data will be counted. If the suspect reading is marked **Ignore**, then the data is thrown out. If there are orange boxes on the calendar view, click the dropdown arrow next to **All** to sort the list to only the suspect readings.
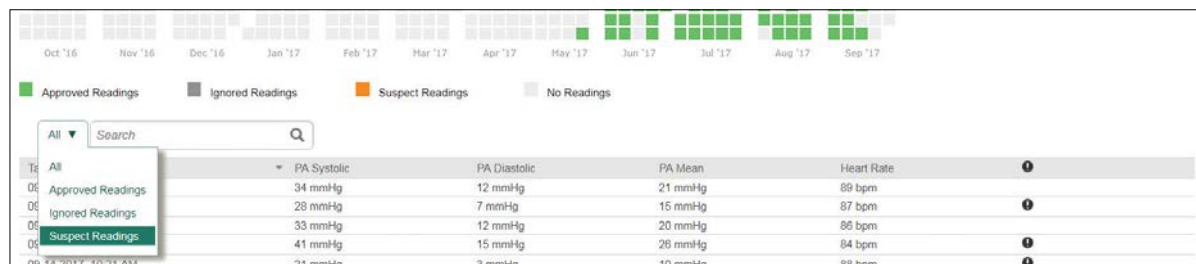
In order to review the waveforms, single-click each date to open the waveform.

If it appears to be a physiologic PA waveform, click **Change Status** and then **Accept**. If the waveform looks like interference or any other nonphysiologic information, click **Ignore. It is important to 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 algorithm in scoring the waveforms.**

Verify the patient has been transmitting daily readings since implant by looking at the dates in the readings column (if not, re-educate patient on the value of daily readings). It is recommended to review waveforms to assess any changes in the shape over time either here on the Readings page or from the DirectTrend™ Viewer. 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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT
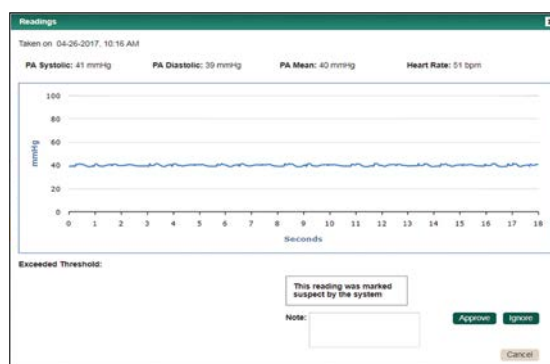
MEDICATIONS TAB (If medications are being recorded on Merlin.net™ PCN)

Add an updated list of the patient's heart failure medications. Click **Add Medication**.

The Drug Selection dropdown menu is dynamic; begin typing to populate the desired medication. If the desired medication does not appear in the dropdown menu, then it needs to be added to the master list.

Complete all fields marked with a red asterisk * and click **Add** to populate the medication to the list.

It is also possible to list any PRN medications that the patient may be taking by clicking **Add Temporary Medication** and completing the necessary fields.

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

OTHER PATIENT ITEMS

After the initial patient data review, there may be other items to be entered into the patient's
Merlin.net™ PCN profile using the additional tabs at the top of the page.

Hospitalizations

If a patient has been hospitalized for any reason,
it may be helpful to enter the dates into the
system. Click **Add Hospitalization** to enter the
information specific to their admission. If it is an
ongoing admission, select **No Discharge Date**.

When the patient has been discharged, return
to the **Hospitalizations** tab, click on the date of
hospitalization and enter the discharge date. 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.

Notes

Clicking on the **Notes** tab will show a historical view of all the notes for the patient made by any user.

A note can also be added here by clicking **Add Note**. *Another opportunity to add a note is reviewed*
on page 26.

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

OTHER PATIENT ITEMS (CONTINUED)

Thresholds

The **Thresholds** tab will show all programmed PA thresholds for the patient. These values determine when a notification is displayed on the Patient List as well as when an email is sent to all users subscribed to the patient. If a user is receiving a lot of emails for a patient who doesn't actually require attention, review the thresholds for appropriateness.

When a patient is enrolled, clinic threshold defaults will be applied initially. The patient's thresholds should be set wide initially, assessed regularly through the Optimization Phase and narrowed as they enter the Maintenance Phase. As long as the clinic default is in place for the patient, the table will display **Clinic Threshold.** This will go away once a threshold has been programmed for the patient. At any time, the clinic defaults can be reset by clicking **Remove Overrides**.

The **Clinic Notification Setting** can also be changed for each patient. Initially, the clinic level default will apply. But if the patient is found to decompensate faster or slower, this setting can be changed to tailor email notifications.

A user can also add a threshold back in if necessary by clicking **Add Threshold**. Select the metric to add and enter the appropriate values. *Note: Any threshold on this page will trigger an email notification for all subscribed users if a patient's readings are outside the optimal range.*

FINAL REVIEW ACTIONS

Upon reviewing all the patient's data for a session, it may be helpful to complete the following actions after navigating back to the patient's DirectTrend™ Viewer.

**To send a DirectCall™ Message:**
Click on the phone icon. 📞

- If patient has been transmitting regularly and the PA pressures look good, send a "Reading Received" DirectCall™ Message.

- If patient has not transmitted in a few days, send a "Reading Reminder" DirectCall Message.

- If the patient's pressures are trending up but do not require intervention, send a "Treatment Plan Reminder" DirectCall Message.

- If it is time for their regular lab work, send a "Labs Request" Reminder.

This popup box will also display how the patient will receive the message and in which language. The last message sent is also recorded along with its delivery status. *Note: If it is outside the notification window, the system will ask to send the message now or to wait until the window starts. Select the appropriate option.*

To print a report:
Click on the printer icon to open up the DirectTrend Viewer in a PDF. When the window opens, right-click on the image to **Save as ...** or **Print**.
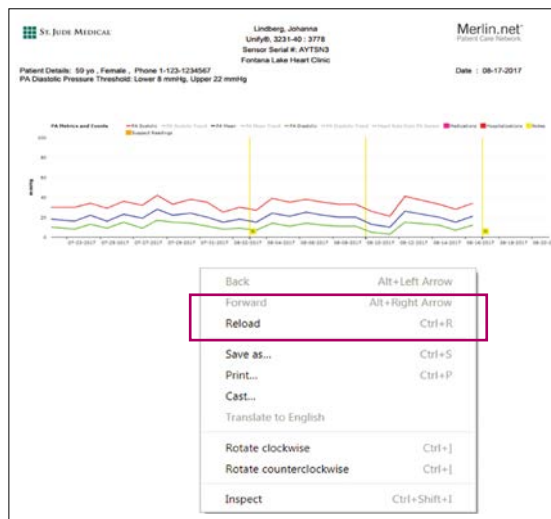
To complete the review:
Click the Patient Review Box.

Last Reviewed: 08-09-2017
Last Billed: ---
Last Export: 08-09-2017

- To receive email notifications for this patient, click **Subscribe**.

- If the patient should be a priority for all clinic users, click **Priority**.

- Select **Mark As Reviewed**.

- If desired, write a **Note** about changes or interventions made in response to today's review.

- If it is the first time a patient is to be billed for remote monitoring services, select **Mark as Billed**. The system will automatically set the **Next Billing Reminder** 31 days out. The date can be changed manually if this is not in line with the practice's billing protocols.

- Click **Save** when finished.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PATIENT LIST

The Patient List is a dynamic view of the clinic's patients. It can be sorted a number of ways to optimize the view for each user. Clicking on any of the column headers will sort the Patient List. Under **Active** the list can be sorted by:
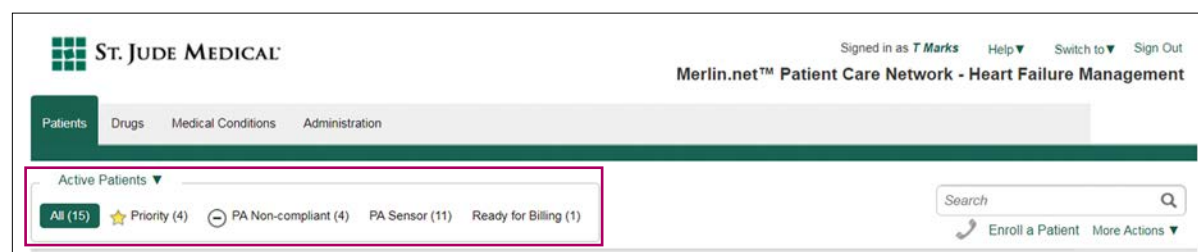
All: Shows all active PA Sensor and ICD/pacemaker patients in the clinic.

Priority: Shows all patients marked **Priority** by any user in the clinic.

PA Non-compliant: Shows patients that have failed to transmit within the compliance setting timeframe.

PA Sensor: Shows only PA Sensor patients.

Ready for Billing: Shows all patients that are ready for billing.

Hovering over **Active Patients** reveals a dropdown menu with the following options:

ICD/PM: Only patients with an ICD or pacemaker.

PA Sensor: Only patients with a PA Sensor.

Subscribed: Shows patients the user is subscribed to.

Inactive Patients: Patients that have been inactivated by a clinic administrator because they have passed away or chosen to no longer follow with the clinic. *Please see page 19 to learn how to inactivate a patient.*

Scheduled Patients: These are patients who have been enrolled in Merlin.net™ PCN prior to implant. Sometimes pre-enrolling causes a patient to show up in the system twice after implant, and the profile without implant data will need to be inactivated from here.

Implanted Patients: This list shows the same subset of patients as the PA Sensor list, but the list view is less detailed. A patient moves here from scheduled once they have transmitted a reading from their patient electronics after implant. If a patient is "stuck" in the **Scheduled List**, review their profile to ensure that the treating clinic and physician are selected appropriately.

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT
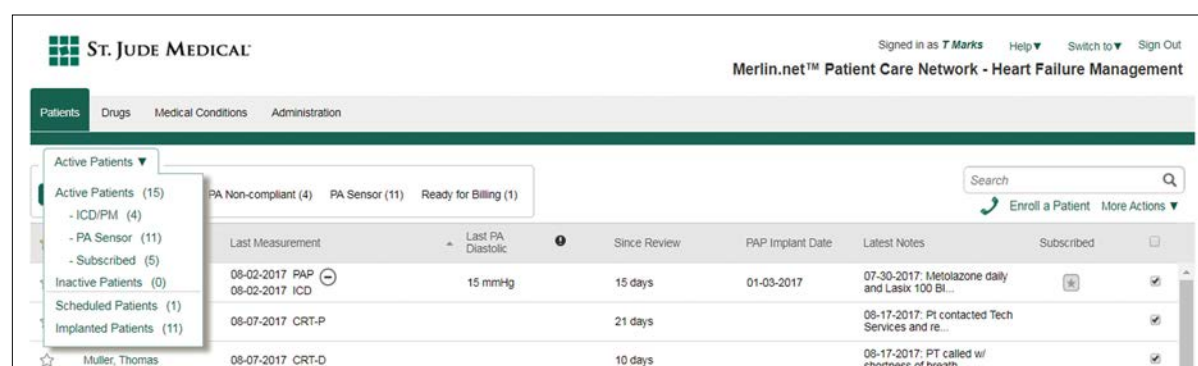
MORE ACTIONS

The **More Actions** dropdown menu contains four options.

1 Combine Two Patients
If a patient is enrolled in the heart failure portal with a PA Sensor and ICD/pacemaker, their profiles can be combined here, as well as within their profile as mentioned above. Select both of the patient's entries on the Patient List and select **Combine Two Patients**. *Follow the same process as outlined in the Patient Profile Setup section on page 16.*

2 Print Patient List
The patient list can be printed by clicking **Print**. Note that it will be printed as is; if there is a need to sort by one of the columns, do so first before printing.

3 Download Spreadsheet
The patient list can be exported to an Excel spreadsheet by selecting **Download Spreadsheet**. Prior to downloading, confirm that the columns you want to export are displayed on the Patient List.

4 Add or Remove Columns
To add or remove columns from the Patient List, click **Add or Remove Columns**. Select the columns that are most appropriate for patient management. The image below shows one example of appropriate column selections.

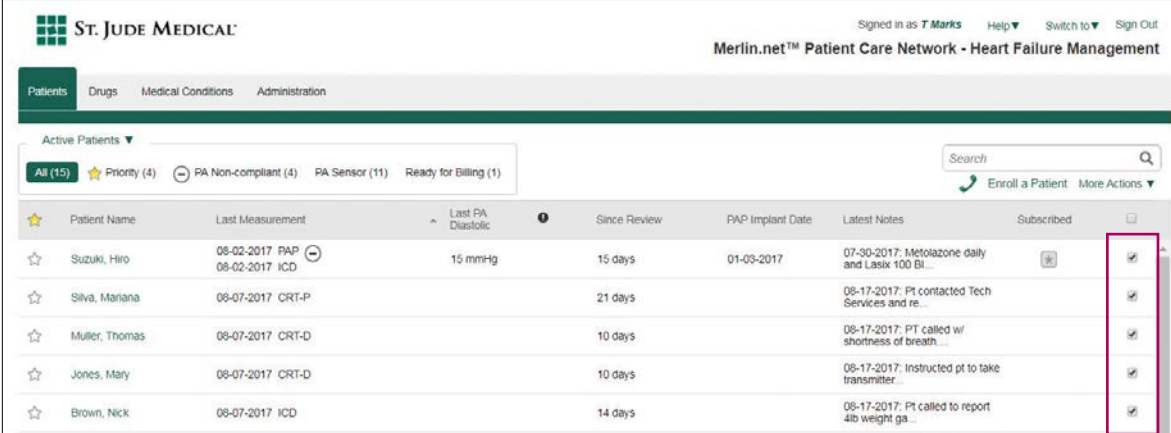**A Few Things to Remember when Reviewing the Patient Columns**

- Regardless of the Clinic Notification Setting for emails, a patient will have a notification icon if they are out of optimal range for one reading. The icon will go away when they are back in range.

- The Since Review column is dependent upon checking the **Mark as Reviewed** box discussed in the patient review section.

- Patients marked Priority are priority for all users in the clinic.

- Patients marked Subscribed are on a user-by-user basis. This also controls who receives email notifications for specific patients.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

SENDING BATCH DIRECTCALL™ MESSAGES

It is possible to send the same message to multiple patients at once. This is especially efficient for patients who need a reminder to transmit a reading. Sort the patient list to make it easier to select subsets of patients. For example, click the **Last Measurement** heading to sort the patients by the date of their last reading. Then select each patient who should receive the message.

Click the phone icon 📞 and select the message to send. The patients will each receive their message via their preferred method and language (if language has been recorded). If any of the patients do not have DirectCall™ Messages turned on, their names will appear in red at the bottom of the box.

MERLIN.NET™ PCN

HEART FAILURE PORTAL FEATURES

Email Notifications
There are three key factors in getting the most out of the email notifications. They are:

• Set patient thresholds appropriately

• Set clinic notification setting appropriately

• Subscribe to the patient

If a user is receiving excessive emails, these three items should be assessed. The thresholds may be too wide or not appropriate for the patient. The clinic notification setting may be too sensitive to truly treat to trends. Perhaps the user is subscribed to patients they are not managing.

PA SENSOR PATIENTS OF INTEREST REPORT

The PA Sensor Patients of Interest report is an email sent on the days specified by the clinic administrator. A PA Sensor Patients of Interest report is available to Treating users only. *A user can opt in for this email in the My Account window as discussed on page 11.*

The report is broken into three sections of interest:

1 **Weekly average PA Diastolic (Weekly PAD) Pressure *outside* of threshold range**
Patients with a weekly PAD average falling outside the optimal range determined by their programmed threshold settings.

2 **Weekly change > 5 mmHg with Weekly PAD Pressure *within* threshold range**
Patients whose weekly PAD threshold has changed 5 mmHg or more over the previous week's average, but are still within their programmed threshold range.

3 **Non-compliant: No readings in last X days**
Patients who are considered non-compliant based on the clinic level setting. This timeframe (i.e., no reading for seven days in a row) can be changed by a clinic administrator.

The report includes the following information for each patient:

- Patient name and ID
- PA reading compliance information
- PA pressure
- Last review

If there are no patients who meet a set of conditions, the applicable table is replaced with **None**. A PA Sensor Patients of Interest report is available to Treating users only. You can sign up for this email in the My Account window by selecting the **Sign in as user name** option.

Weekly PAD Average: The average of all valid readings received in the last seven days, whether the patient transmitted one time or seven times during the week.

St. Jude Medical, Inc. Merlin.net™ Patient Care Network
PA Sensor Patients of Interest Report for ABC Cardiology *(based on data collected as of March, 02, 2017; 11:59:59pm)*

1 Weekly Average PA Diastolic (Weekly PAD) Pressure Outside Threshold Range

Patient	Weekly PAD Avg (Weekly Change)	Days with PAD out of range	Last PAD	Last Reviewed	Last Entered Note
John Smith	30 mmHg (+7)	6 of 7 days	32 mmHg (Mar 01, 2017)	Mar 01, 2017	Change Furosemide 80mg to Torsemide 100mg. Monitor for 48 hrs. If no response arrange clinic visit.
Connie Doe	24 mmHg (-5)	4 of 6 days	22 mmHg (Feb 28, 2017)	Mar 01, 2017	Pt diuresing in response to 20mg Torsemide. Re-assess by end of week.
Jane Doe	21 mmHg (-6)	2 of 4 days	20 mmHg (Feb 26, 2017)	Mar 01, 2017	Pressures lower after addition of nitrates, increased isosorbide to 60 mg daily and encourage daily readings.

2 Weekly Change ≥ 5 mmHg with Weekly PAD in Threshold Range

Patient	Weekly PAD Avg (Weekly Change)	Days with PAD out of range	Last PAD	Last Reviewed	Last Entered Note
Mark Sanchi	20 mmHg (+6)	2 of 7 days	21 mmHg (Mar 01, 2017)	Mar 01, 2017	Double Furosemide dosage to 40mg twice daily for 2 days. Then return to 40mg once daily.
Mary Smith	19 mmHg (+5)	3 of 4 days	18 mmHg (Feb 26, 2017)	Mar 01, 2017	Contact pt if pressures continue to increase. Sent reminder to take daily readings (4 days since last reading).
Tim John	12 mmHg (-5)	0 of 7 days	11 mmHg (Mar 01, 2017)	Mar 01, 2017	Contact pt to see if they are feeling dizzy/lightheaded. Order labs to check renal function and ensure no need to decrease diuretics.

3 Non-Compliant: No Readings in Last 7 days

Patient	Days since last reading	Last Reviewed	Last Entered Note
Leroy John	15 days	Mar 01, 2017	Pt having issues with interrogator. Scheduled visit for pt education.
Dale Miles	8 days	Mar 01, 2017	Sent DirectCall reminder to take readings.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

BILLING REMINDERS

The billing reminder column gives a reviewer a quick look at patients who are ready to bill or those who need their reminder set for the first time. The system counts the days with transmissions to correlate to the instructions related to "10 days of monitoring."
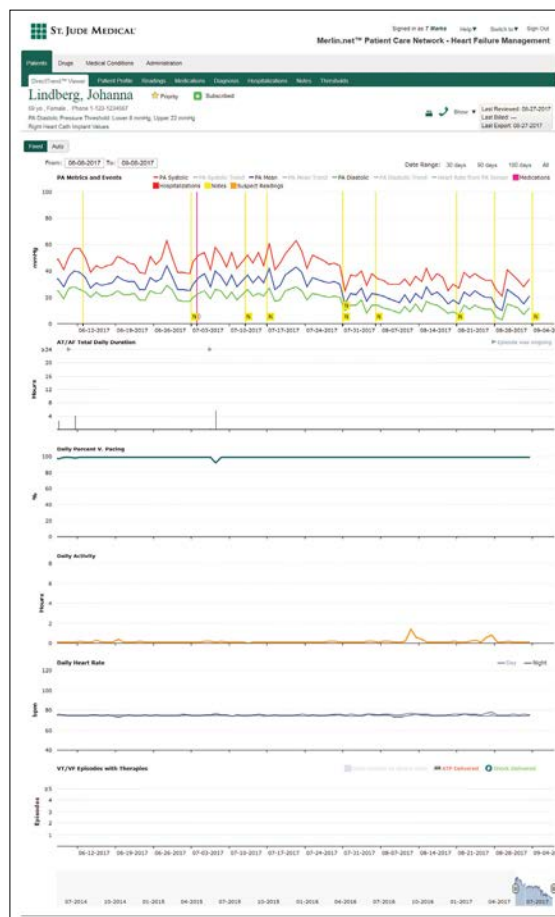
- Once the system counts 10 days with transmissions and the 30-day billing window has finished, their reminder will say **Ready**.

It is important to note that this is a reminder feature only and does not actually trigger a billing instance in any EHR. For more information on Billing and Reimbursement, please see the Billing and Reimbursement section in this *Program Practice Guide*.

CRM DEVICE DIAGNOSTICS

The Integrated Heart Failure Portal on Merlin.net™ PCN is the world's first and only platform that integrates PA pressure data with heart failure diagnostics from Implanted Electronic Devices (IEDs), such as AT/AF Burden, Percent Ventricular Pacing, Patient Activity, Day and Night Heart Rate, and VT/ VF Events with Antitachycardia (ATP) and Shock Therapies. This combined data provides a broader view of heart failure management.

Combining CRM device diagnostics and PA pressure trends on a single portal may allow for more streamlined and comprehensive management of heart failure patients.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

MERLIN.NET™ PCN

HEART FAILURE PORTAL CO-MANAGEMENT

Merlin.net™ PCN heart failure portal allows patients to be co-managed between two clinics. Refer to the Patient Management Chapter to understand more about a co-managing relationship.

TRANSFERRING A PATIENT

FROM ONE CLINIC TO ANOTHER IN MERLIN.NET PCN HEART FAILURE PORTAL

At times, a patient may wish to change practices and have their CardioMEMS™ PA Sensor data followed by another clinic. In this case, the following form is used. 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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM
AND THE MYCARDIOMEMS™ PATIENT APPLICATION

INTRODUCTION

The myCardioMEMS™ Patient Application is intended for use by heart failure clinics and their patients to streamline communications from the clinic to patients and reduce time spent on routine phone calls. The myCardioMEMS Patient Application is set up through the Merlin.net™ PCN heart failure account by the clinic.

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. DirectCall™ Messages may be sent by the clinic to the patient using the myCardioMEMS Patient Application.

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 37).

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:

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

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

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

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

It is recommended that clinicians wait at least 30 days after implant to enroll the patient in use of the myCardioMEMS Patient Application. This will allow time for the patient to become acclimated to the routine of taking daily readings with their CardioMEMS™ HF System PES, and to receiving and responding to treatment instructions from the clinic. Additionally, this time provides an opportunity for clinicians to get to know the patient and determine whether they meet the selection criteria listed above.

MYCARDIOMEMS PATIENT APPLICATION SETUP AND USE

This section walks through setup and use of the myCardioMEMS Patient Application. The app is designed to assist patients in tracking compliance, receiving DirectCall Messages from their clinical team and managing medications (if applicable). If a patient does not have access to a smartphone, their primary caregiver or another family member may use the app with them. This section also reviews the clinician interface on the Merlin.net PCN as it relates to the myCardioMEMS Patient Application.

For technical assistance, please call 1-844-MYCMEMS (1-844-692-6367).

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

MYCARDIOMEMS™ PATIENT APPLICATION — MERLIN.NET™ PCN INTERFACE

The myCardioMEMS™ Patient Application is available for use by all clinics. There are two functions of the myCardioMEMS Patient Application:

1 **Compliance Management and DirectCall™ Messages Receipt:** Patients are able to track the days that they have sent a PA pressure reading as well as receive DirectCall Messages from their clinical team.

2 **Medication Management:** If a clinic is entering medications in the Merlin.net™ PCN, patients can view their medication list, as well as receive medication changes, via the app. This is in addition to the compliance management.

With the launch of the myCardioMEMS Patient Application, a new column will be displayed on the patient list titled **myCardioMEMS Medications**.

The patient list column offers a quick glance of a patient's status on the app for Medication Management as well as showing the status of medication changes. There are five status notifications that may be displayed on the patient list:

1 **Off:** The patient does not have Medication Management enabled.

2 **Not Registered:** Medication Management is enabled for the patient, but a patient/primary caregiver has not yet registered on the app.

3 **Registered:** The patient has Medication Management enabled, a patient/primary caregiver has registered using the app and the medication list is up to date.

4 **Pending (X days):** A medication change has been sent to the patient, but they have not yet accepted the change. The column will display how long it has been since the change was sent from the clinician via the Merlin.net PCN.

5 **Confirmed:** A medication has been sent to, and subsequently accepted by, the patient on the app. The change has been made to their medication list on 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.

A patient is able to use the app for compliance management once the app has been activated by the clinic. However, in order to use medication management, the patient must have the feature enabled. It may be helpful to sort the patient list by the **myCardioMEMS™ Medications** column. Double-click on the column header so that all patients with Medication Management turned off now appear at the top of the list.

In order to enable Medication Management for a patient, click their name in the patient list. This will open the DirectTrend™ Viewer. Prior to enabling medication management, it is important to verify that the patient's medication list is up to date. Click **Medications** and review the list. If heart failure medications need to be added or updated, do so now. Once Medication Management is enabled, medications cannot be deleted from the list without first disabling the feature. *For more information on how to use the Add Medication wizard, please refer to page 23.*

Once the Medication List has been verified, click **Patient Profile**.

Immediately below the patient demographics is the myCardioMEMS Patient Application section. 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 37.*

To enable Medication Management, click the dropdown menu next to **Medications managed on the mobile application** and select **On**. Click **OK** to acknowledge, and then **Save** the patient's profile.

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. To view the list, click **View registered application users.**

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

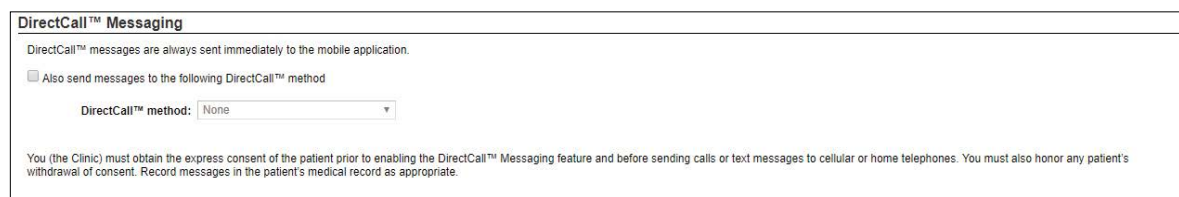MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT
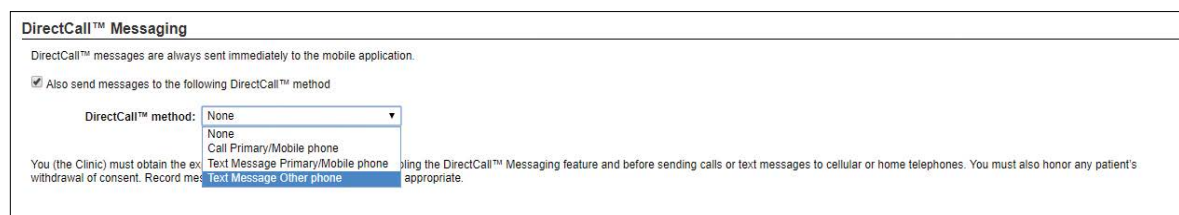
PATIENT SETUP FOR COMPLIANCE MANAGEMENT

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 DirectCall™ Messages via the app.

DirectCall Message
If the clinic administrator has programmed customized DirectCall Messages, it is important to know these will not be sent to the app; only the default messages will be displayed. In order to continue sending the customized messages to the patient, visit the **DirectCall™ Messaging** section of their profile.

Select **Also send messages to the following DirectCall™ method** and select the patient's preferred method of contact in the dropdown menu. If **Text Message Other phone** is selected, be sure to enter a secondary phone number with texting capabilities in the open field.
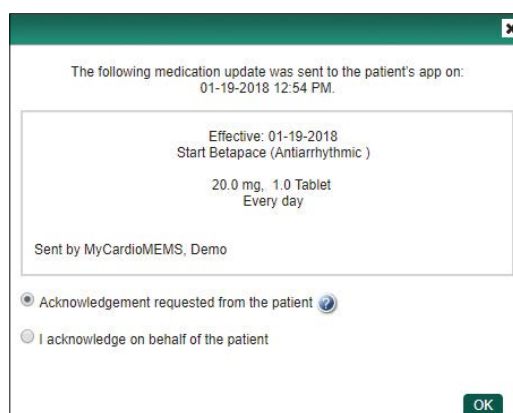

SENDING A MEDICATION CHANGE VIA THE APPLICATION

Once Medication Management has been enabled for a patient and a Patient/Caregiver user is registered on the app, 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.

When adjusting a medication after Medication Management has been enabled, the wizard is the same as before. Any free text entered into **Patient Instructions** will be displayed to the patient on the medication adjustment notification within the app.

Once a medication adjustment has been entered, you will be asked if the patient should acknowledge the medication. If you wish to track the patient's response to the adjustment using the myCardioMEMS medications column on the patient list, select **Acknowledgement requested from the patient.** This will require the patient to go through the medication reconciliation process once they see the medication adjustment in the application.

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. To do so, select **I acknowledge on behalf of the patient.** This will update the medication on their list in the app, but will not require them to complete the medication reconciliation on their smartphone or tablet.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

MYCARDIOMEMS™

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 icon will appear on their mobile device home screen. To launch the app, tap the icon.
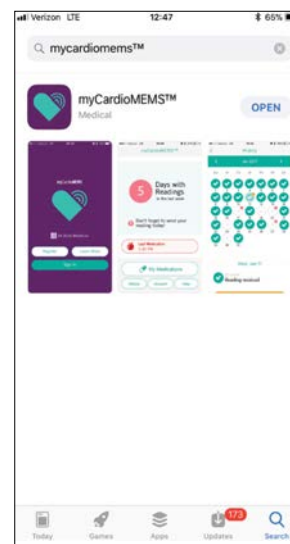
REGISTRATION ON THE APP

To register as a new user on the app, the patient should select **Register.** The first screen will prompt the user to enter the patient's date of birth and PA sensor serial number. The serial number can be found on their ID card, by calling their medical provider's office or by calling Technical Service at 1-844-MYCMEMS.

The next screen will ask the user to identify themselves by entering their:
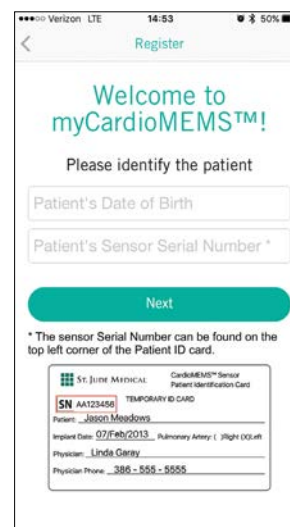
- Name
- Unique email address
- Phone number

Then they should select their account mode. There are two account modes available on the app:

Patient/Primary Caregiver: the patient or primary caregiver can receive all messages from their clinician, as well as complete any medication adjustment reconciliations. They are also able to change the times of the patient's medication schedule if Medication Management is turned on for the patient. There is only one of this user type allowed for each PA sensor patient.

Other: an Other user can be anyone else associated with the patient. This user has read-only access to the app. They can view a patient's compliance and message history, medication list and settings if Medication Management is enabled, but Other users cannot make changes.

On this page it is also suggested that the user choose to remain logged in so that they will receive notifications from the app when appropriate. By making this selection, a password will not be required each time they launch the app.

PROGRAM
PRACTICE GUIDE

—

PATIENT
SELECTION

—

PATIENT
EDUCATION

—

IMPLANT
CONSIDERATIONS

—

PATIENT
MANAGEMENT

—

MERLIN.NET™ PCN

—

BILLING AND
REIMBURSEMENT

—

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.
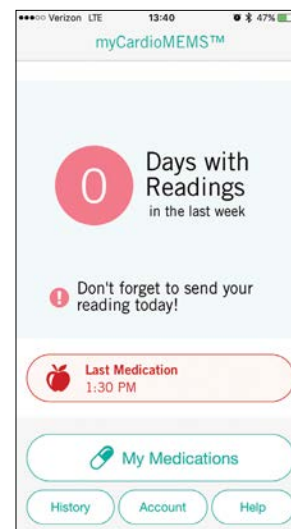
DirectCall™ Messages

If a DirectCall Message is sent by the clinic, it will be displayed over the home screen. Any message received on the app has the default text rather than the clinic's customized messages. Once a patient reads the message, they should select **Mark as Read** to return to the home screen. The five messages are displayed below.
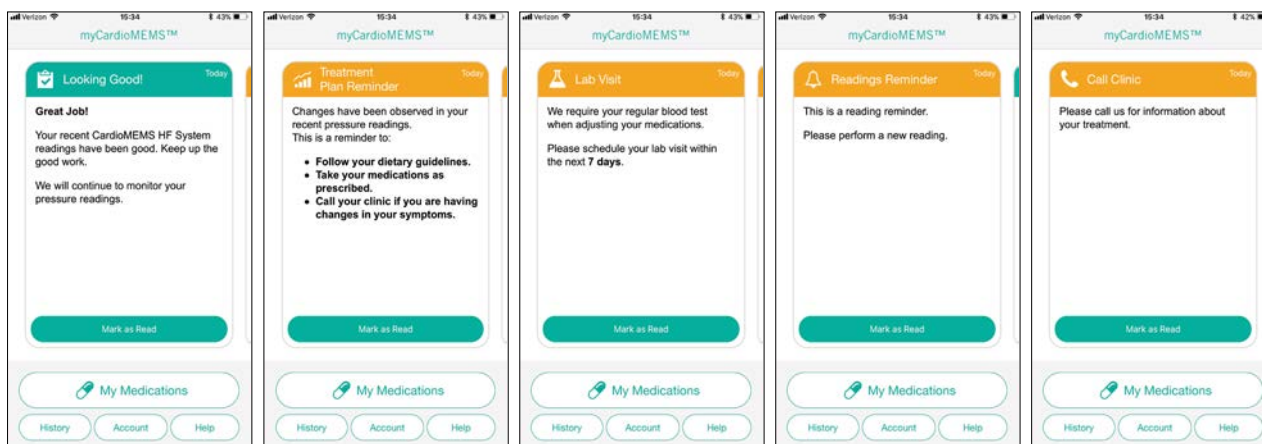
NAVIGATION BUTTONS

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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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. If Medication Management is not activated for the patient, this button will be grayed out.
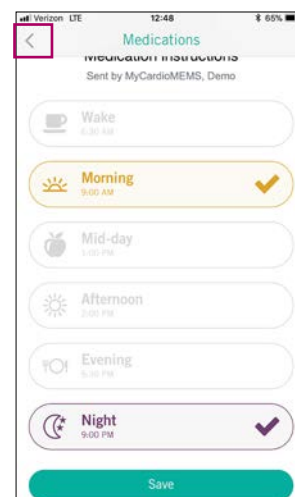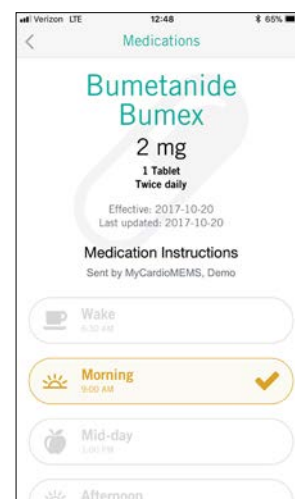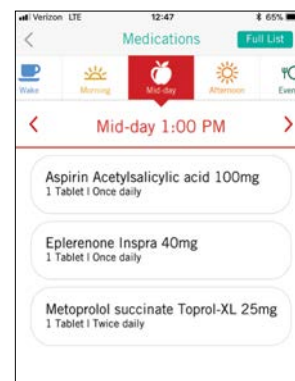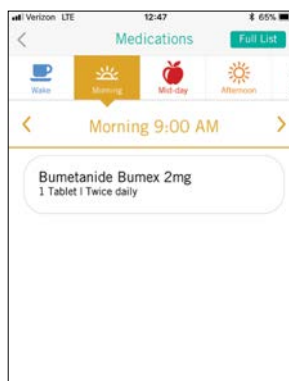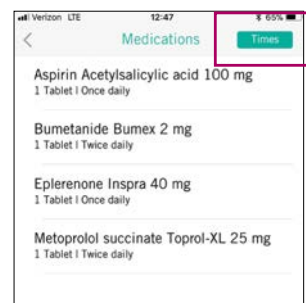
If the user taps **Times** in the upper-right corner, the full list of medications is displayed according to the times of day to be taken. If the user turned notifications on in their profile and the app remains active in the background, they will receive reminders throughout the day.

Notifications can be shown six times during the day:

1. Wake
2. Morning
3. Mid-day
4. Afternoon
5. Evening
6. Nights

The exact times for each notification window can be adjusted in Account Preferences. The times that the medication reminders are displayed depends on the entry in the Merlin.net™ PCN, but can be changed by the patient if desired. In order to change the time, unclick the currently selected notification window and select the new desired time.

Tapping the back arrow twice will return the user to the home screen.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

HISTORY

Tapping **History** opens a monthly calendar that shows reading compliance at a glance. Any day on which a reading has been sent and received will display a green circle with a check mark.
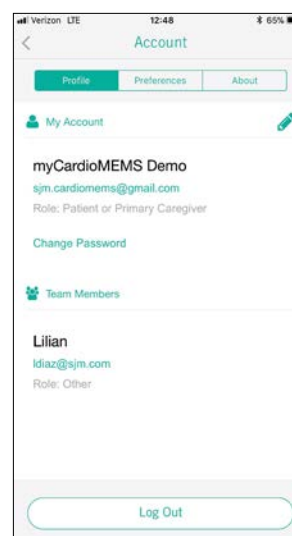
Days that have an orange or pink bubble indicate a message or medication was received from the clinic. To review that message or medication change, tap the date and swipe up on the screen to see the message.
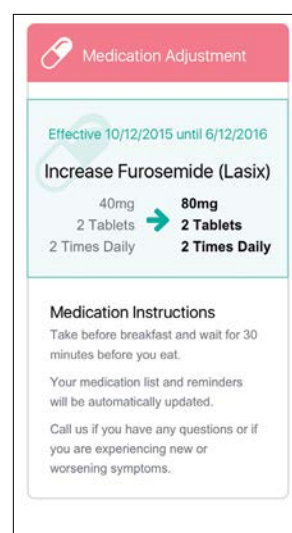
ACCOUNT

The account button displays the enrolled user's account information. At the top of the Account page, there are three menu options: Profile, Preferences and About.

Profile: From this screen, users can change their password. If their email address needs to be changed, they must call Technical Service at 1-844-MYCMEMS. This page also displays the other users in the patient's care profile. If, for any reason, the user wishes to log out of the app, they can tap **Log Out** at the bottom of the page. This will require them to log in again the next time they wish to view any content in the app.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

ACCOUNT (CONTINUED)

Preferences: On this screen, a patient can enter a past hospitalization date, but it is not required.
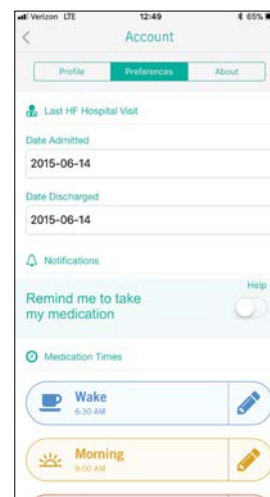
If Medication Management is turned on for the patient and the Patient/Caregiver user wants to receive notifications to be reminded when to take a medication, the user should turn on the reminders. If reminders are turned on, the app should remain open in the background at all times.
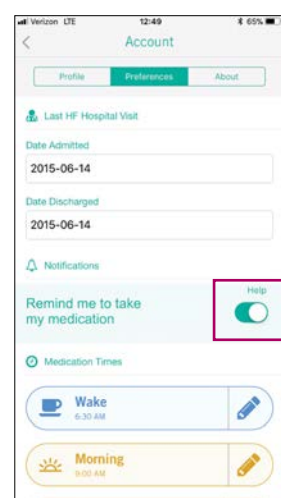
If the user would like to change any of the medication times to better correspond with their daily routing, they should tap the Medication Time they want to change (e.g., Wake).

Then the user taps in the **Time** field to enter a new time and taps **Save** to continue.

Once the changes have been made on the Preferences screen, swipe to the bottom and tap **Save** to apply changes.

About: This screen displays the Terms of Use and App Information.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT
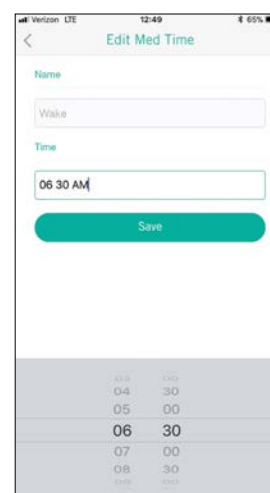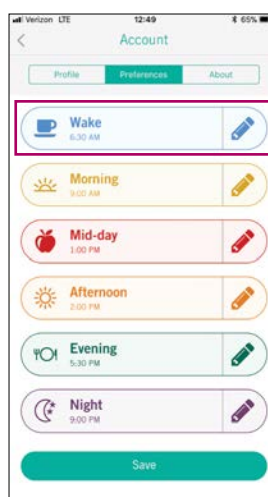
HELP

Visiting the help screen allows the user to view FAQs and watch help videos related to using the app.

MEDICATION RECONCILIATION

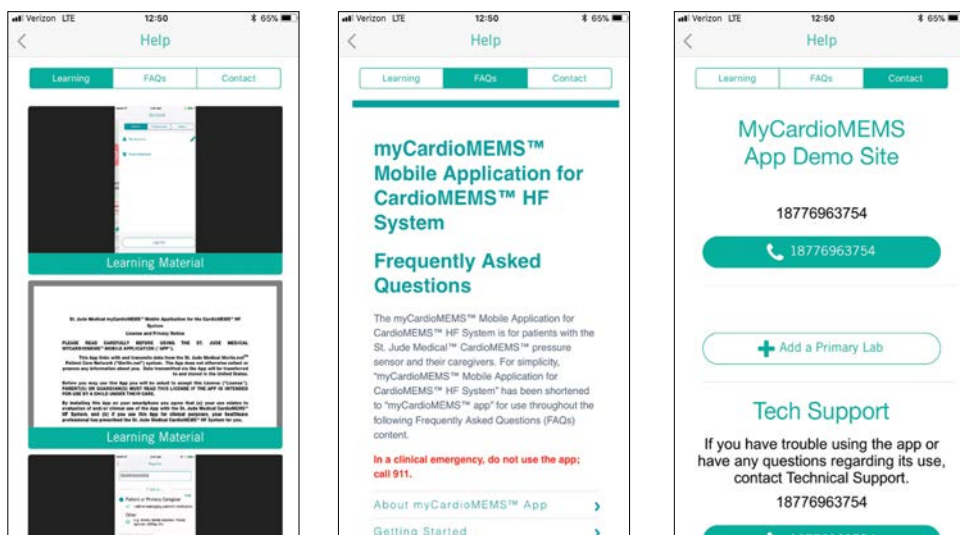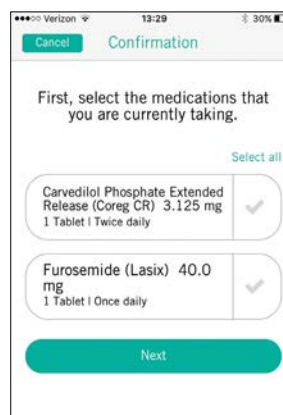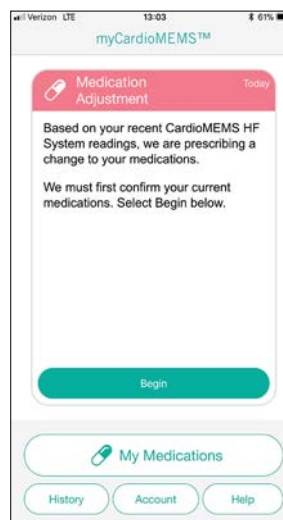If a patient has Medication Management turned on and the clinician selects **Acknowledgement requested from the patient**, the Patient/Caregiver user will have to complete the medication reconciliation process when a medication change or addition is sent from the Merlin.net™ PCN.

Notification: After a patient is enabled for Medication Management, medication changes made in Merlin.net PCN will be sent to the Patient/Caregiver user through the app. The patient will see a Medication Adjustment card and will select **Begin** to indicate they are taking their medications appropriately.

Virtual Medication Reconciliation: The patient should select the currently prescribed medications that they are taking correctly. Tap **Next**.

PROGRAM PRACTICE GUIDE

—

PATIENT SELECTION

—

PATIENT EDUCATION

—

IMPLANT CONSIDERATIONS

—

PATIENT MANAGEMENT

—

MERLIN.NET™ PCN

—

BILLING AND REIMBURSEMENT

—

MEDICATION RECONCILIATION (CONTINUED)

Reconciliation Confirmation: The user will be asked to confirm their entries from the last page. If the patient does not indicate they are taking their medication appropriately, they will be requested to contact their clinic. In this case, the medication change will display **Pending** on the patient list column.
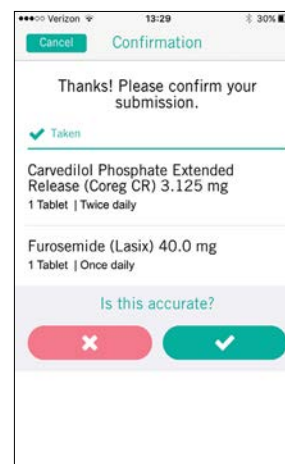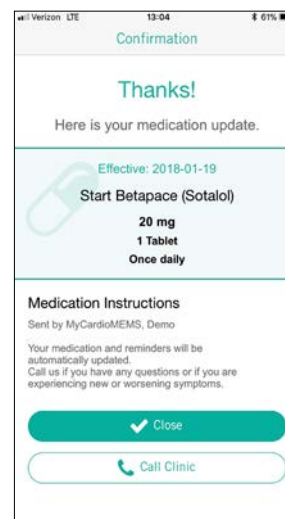
Titration Instruction: If the patient indicates they are taking their medication appropriately, they will receive details of the new update. The medication will be updated in their medications list in the app. The user can change the time of day they receive notifications if desired. The medication changes will also display as **Confirmed** on the patient list.

CONCLUSION

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. Patient selection is a key to success with the app. In the hands of the right patients and caregivers, the myCardioMEMS Patient Application can enhance patient engagement in their own care.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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.

Abbott

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM

BILLING AND REIMBURSEMENT

CARDIOMEMS™ HF SYSTEM

BILLING AND REIMBURSEMENT

TABLE OF CONTENTS

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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.

- Local Medicare contractors implicitly cover, except for First Coast Services Options (FCSO) and Novitas Solutions, Inc., who have a non-covered service and a hemodynamic monitoring local decision.

- 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 CY2019 Medicare national average payment rate for comprehensive ambulatory payment classification (C-APC) 5200 is $29,341 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 FY2019 Medicare base payment rate of $19,297.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

REIMBURSEMENT LANDSCAPE
FOR THE CARDIOMEMS™ HF SYSTEM (CONTINUED)

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

CARDIOMEMS™ HF SYSTEM CODING
WHAT'S NEW?

The American Medical Association (AMA) created new CPT‡ 1 codes to further describe services related to PA pressure implantation and remote monitoring effective on January 1, 2019. These CPT codes will make it easier for documenting and reporting the CardioMEMS HF System procedures as well as providing defined physician payment.

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 requirements, physicians should not report 93297 or 93299 with 93264. This code is billable every 30 days when the requirements of the CPT code are met.

Physicians and qualified healthcare professionals may have additional questions about the new 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 2019 Abbott Reimbursement Guide and FAQ for additional information on the CPT code instructions for these codes and supporting resources for these services.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

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 Solutions, Inc. Please check with your local MAC if you are administered by FCSO or Novitas Solutions, Inc. 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
https://www.cardiovascular.abbott/us/en/hcp/reimbursement/heart-failure.html
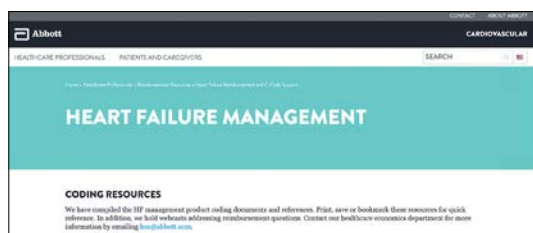
CARDIOMEMS HF SYSTEM 2019 ABBOTT REIMBURSEMENT GUIDE AND FAQ
available for download at Cardiovascular.Abbott/CardioMEMSWorkflow

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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 2019 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.

- Do not report 93264 in conjunction with 93297 or 93299.

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 2019 Medicare physician national payment rate for 93264?

The 2019 national physician payment rate for 93264 is $52 when performed in the physician's office and $37 when performed in the hospital.[2]

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 CY2019 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.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

FAQ

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 CPT‡ code 93299, they should be able to bill with this code based on medical appropriateness and documentation. CPT code 93299 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.

93299: Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results.

CPT code 93299 is reimbursed under C-APC 5741 with a 2019 Medicare National Average Payment rate of $37 when provided in the outpatient hospital.[3]

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 93297/93299, respectively?

According to the CPT instructions, it states, "Do not bill 93264 in conjunction with 93297 or 93299." Therefore, if the same provider is monitoring for both PA pressures and intrathoracic impedance, they cannot bill for both monitoring periods. CPT instructions indicate, "For remote monitoring of an implantable wireless pulmonary artery pressure sensor, use 93264."

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

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

REFERENCES

1. Bad debts, Charity, and Courtesy Allowances: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html

2. CY2019 Medicare Physician Final Rule. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-F.html

3. CY2019 Medicare Hospital Outpatient and ASC Final Rule. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC.html

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.

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

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

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

Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: Infection, Arrhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death, and Device embolization.

PROGRAM PRACTICE GUIDE

PATIENT SELECTION

PATIENT EDUCATION

IMPLANT CONSIDERATIONS

PATIENT MANAGEMENT

MERLIN.NET™ PCN

BILLING AND REIMBURSEMENT

PROGRAM
PRACTICE GUIDE

PATIENT
SELECTION

PATIENT
EDUCATION

IMPLANT
CONSIDERATIONS

PATIENT
MANAGEMENT

MERLIN.NET™ PCN

BILLING AND
REIMBURSEMENT

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.

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

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

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

Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: Infection, Arrhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death, and Device embolization.

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.

Abbott