CARDIOMEMS™ HF SYSTEM

HOSPITAL ELECTRONICS SYSTEM QUICK REFERENCE GUIDE

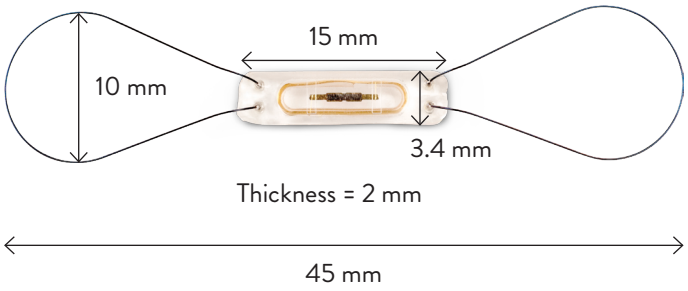
Abbott

CARDIOMEMS™ HF SYSTEM

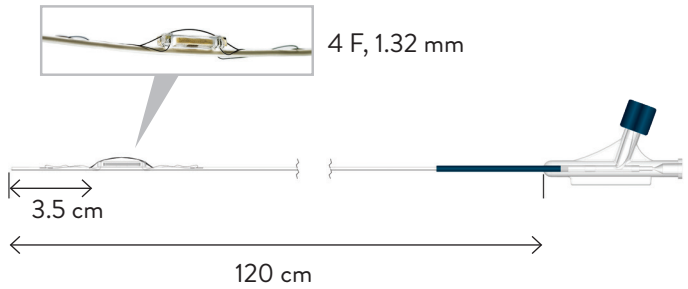
This quick guide is an abridged version of the full instructions. This guide is not intended to replace the User's Manual provided with the product. Read and understand the instructions for use, warnings and precautions specified within the User's Manual regarding the use of the CardioMEMS™ HF System.

PA SENSOR AND DELIVERY SYSTEM PRODUCT SPECIFICATIONS

CARDIOMEMS™ PA SENSOR



CARDIOMEMS PA SENSOR DELIVERY SYSTEM



PROCEDURAL AIDS

The accessories required to implant the device and set the sensor's pulmonary artery (PA) pressure baseline are listed in the following table. **These accessories are not packaged with the device.**

ITEM	SPECIFICATIONS
PA Catheter (PAC)	• 7 F × 110 cm Swan-Ganz‡ (SG) – If thermodilution (TD) is to be performed • 7 F × 110 cm Pulmonary Wedge Catheter – Large ID for contrast flow. Use for Modified Fick cardiac output (CO) — no TD
Introducer Sheath	12 F introducer sheath and dilators with access guidewire
Sensor Delivery Guidewire	0.018" × 260 to 300 cm fixed core guidewire with straight or angled tip (no J-tip), nitinol preferred

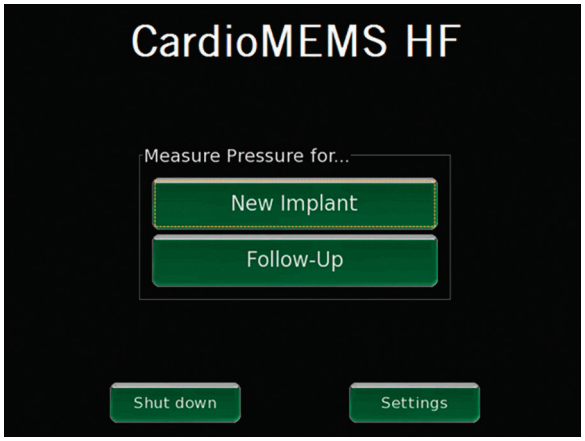
In addition to the specified accessories, the following cath lab equipment and supplies are required to implant and set the sensor's PA pressure baseline:

- Fluoroscope with digital angiography capabilities and ability to record and recall images (C-arm or fixed)
- Blood pressure monitoring equipment for a right heart catheterization (RHC) procedure
- Saline solution
- Radiopaque contrast media

STEP 1: **HOSPITAL ELECTRONICS SYSTEM SETUP AND PREPARATION**

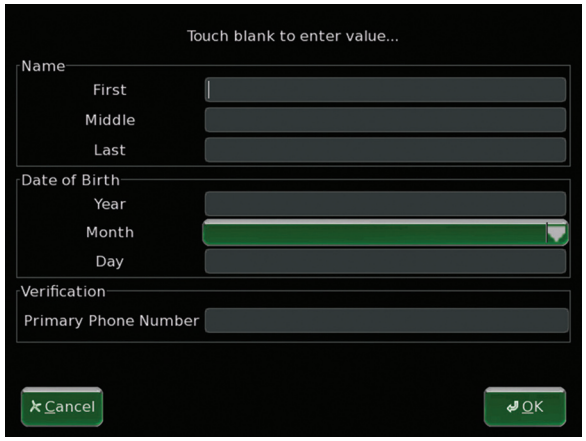
1A

- Turn on the Hospital Electronics System (HES) using the ON button that is located on the back of the unit above the power cord.
- Select **New Implant**.



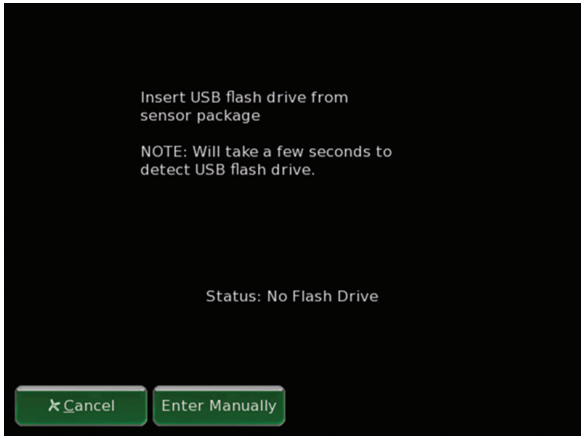
1B

- When unit attempts to connect to Merlin.net™ Patient Care Network (PCN) website, select **Cancel** to bring up the manual entry screen.
- Touch the fields to enter name and date of birth (DOB).



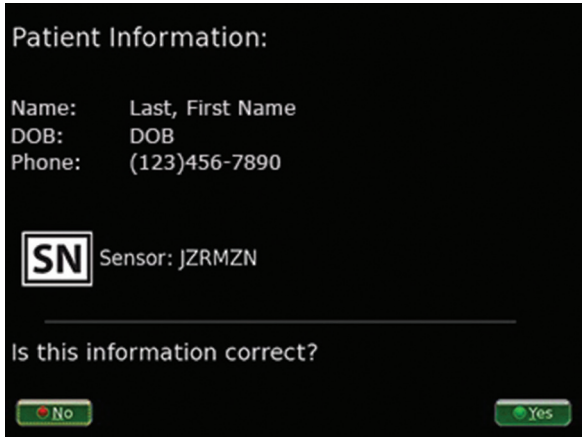
1C

- Retrieve the CardioMEMS™ HF System USB from the PA Sensor box and plug into the right side port with the green dot.



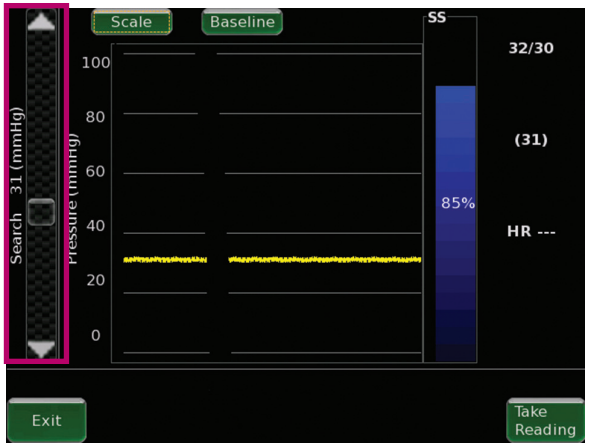
1D

- Confirm the serial number matches the tag attached to the USB. Press **Yes.**



1E CHECK CARDIOMEMS™ PA SENSOR FOR SIGNAL

- To check the unopened CardioMEMS™ PA Sensor for appropriate communication with the CardioMEMS™ hospital antenna before implant, first drop the Search Pressure to -20 mmHg.
- Hold the antenna close to the sensor package and watch the HES screen to confirm that the Signal Strength goes to 99%. Either a blue or a green bar is appropriate for this check.
- Move the antenna away from the sensor package and see that the Signal Strength drops.
- When the test is complete, move the Search Pressure back to 30 mmHg.

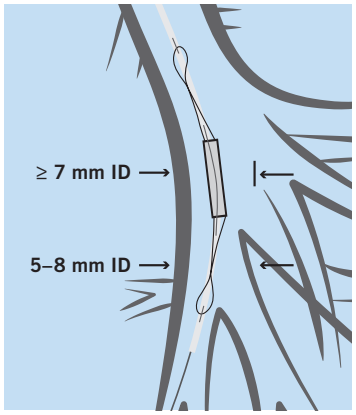


STEP 2: CARDIOMEMS™ PA SENSOR DELIVERY AND DEPLOYMENT

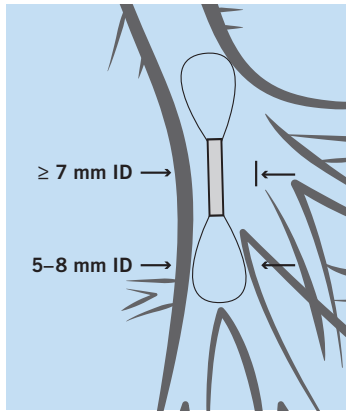
VESSEL SIZING FOR CARDIOMEMS™ PA SENSOR DEPLOYMENT

TARGETING THE PA 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 occasionally may be inserted into the right PA, depending on the patient's anatomy.



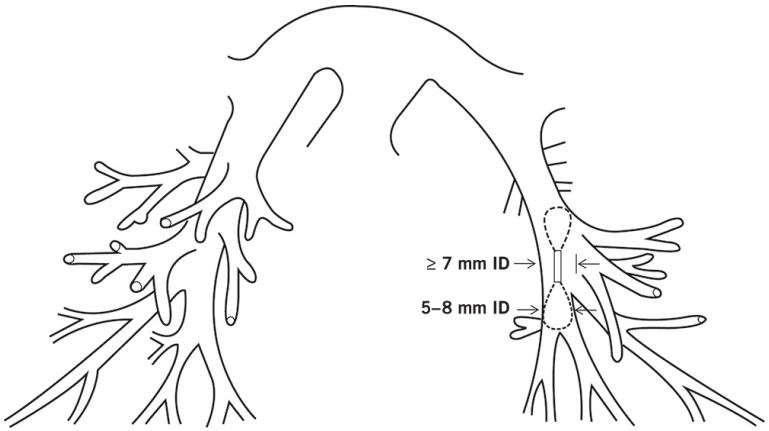
PRE-SENSOR RELEASE



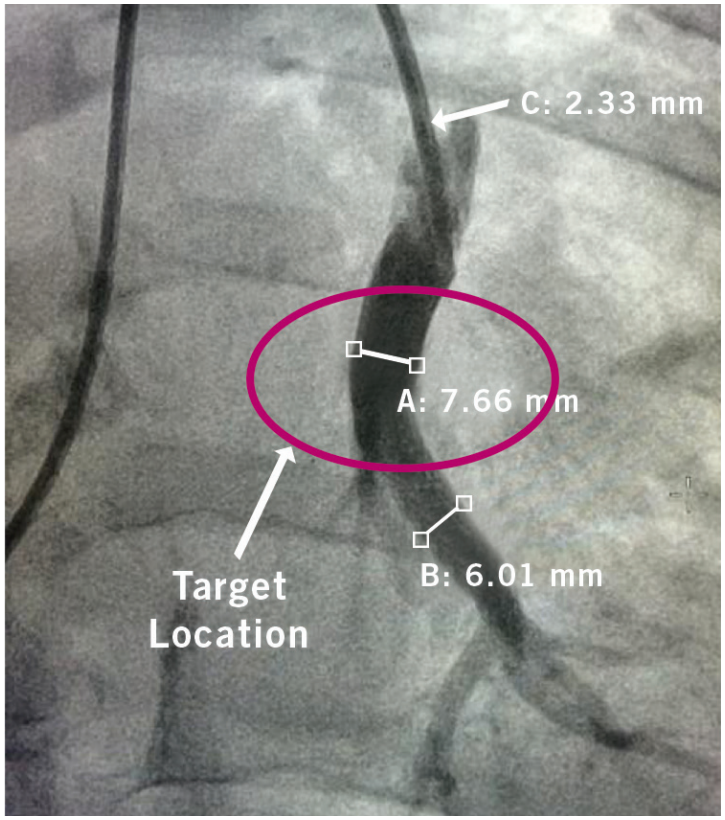
POST-SENSOR RELEASE

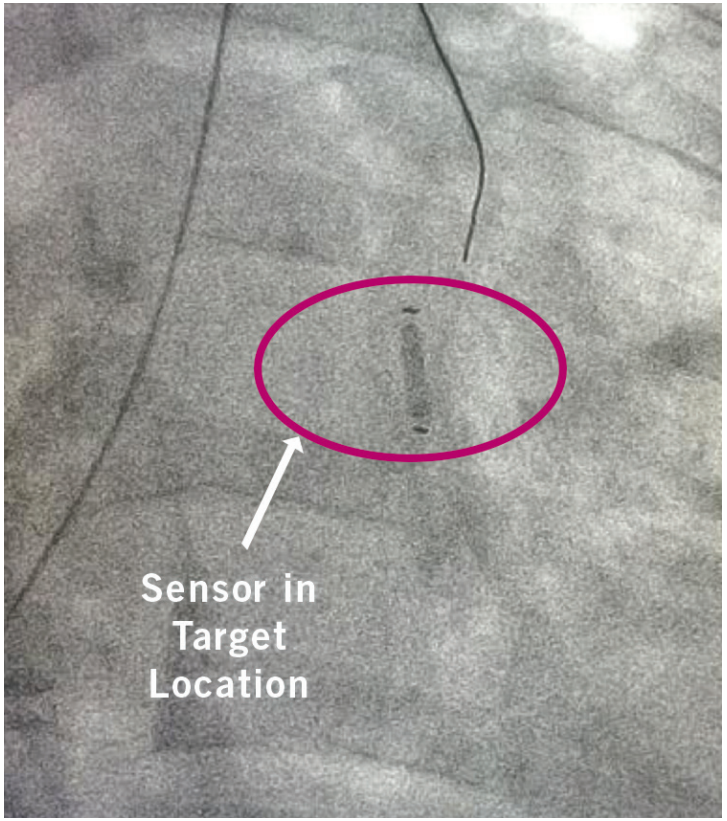
DEPLOYMENT TARGET GUIDE

- Target vessel should be at least three times as wide as recommended 7F PA catheter (2.33mm), with <30 degrees of angulation.
- Deploy in large aspect of the left descending PA (right PA is acceptable).
- Place the sensor as medial and posterior as possible, whether in the left or right PA.
  - Sensor Body: ≥ 7 mm internal diameter (ID) target vessel
  - Distal Loop: 5 to 8 mm ID target vessel
- Keep the guidewire positioned distal to the sensor throughout deployment and catheter retraction.



TARGET IMPLANT SITE





Sensor = 2 × 3.4 mm

THINGS TO CONSIDER

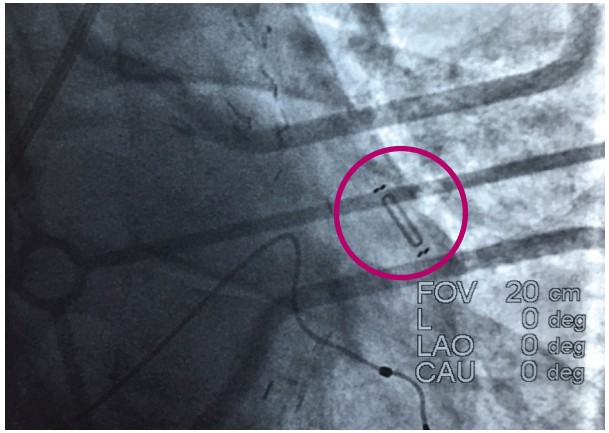
- Prior to inserting the CardioMEMS PA Sensor, swirl the distal end of the catheter (at least 20 cm from the tip) in a bowl of saline to activate the hydrophilic coating.
- Use AP and LAO views to confirm posterior branch.
- During removal, while under fluoro, remove the catheter first, then the wire, using the best view to see sensor/catheter separation.
- Do everything slowly and deliberately.
- If the sensor pulls back, STOP, re-introduce the PA Catheter (PAC) alongside the delivery catheter and use the balloon as a backstop.
- Ensure the distal tip of the guidewire is straight before removing the delivery system.

AP = anterior-posterior
LAO = left anterior oblique

STEP 3: CARDIOMEMS™ PA SENSOR CALIBRATION

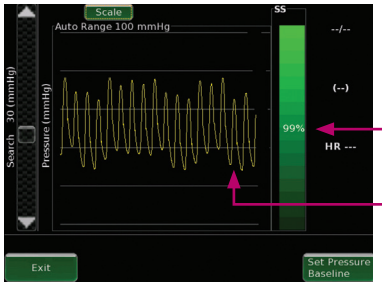
3A PLACE THE ANTENNA

- Once the CardioMEMS™ PA Sensor has been deployed in the patient's PA, reposition the PAC in the pulmonary vasculature and place the antenna under the patient's shoulder, coming down from the head. ***Do not*** place the antenna beneath the table pad or a Bair Hugger‡ pad or cross over or under ECG leads.
- Fluoroscopy can be used to help target the antenna beneath the sensor.
  - If, in AP view, the gold sensor coil can be seen as an oval, then the sensor should be centered on the antenna.
  - If, in AP view, the sensor coil appears as a line, then the sensor should be aligned with the outer circle of the antenna.

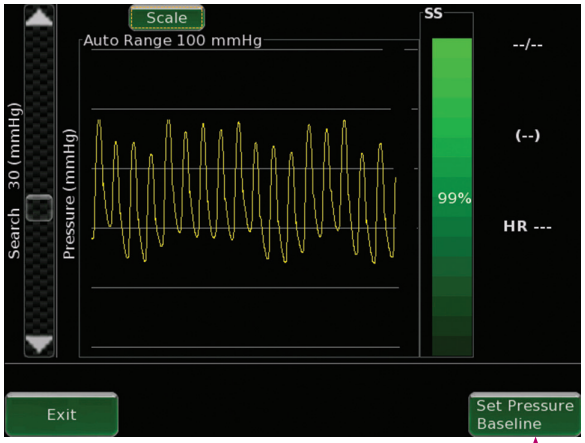


3B ACQUIRE SIGNAL

- Once the antenna wand is in place, concentrate on the HES screen, looking for a physiologic PA waveform ***and*** a green Signal Strength bar, indicating a strong, pulsatile signal.



3C CALIBRATE PA SENSOR USING PA MEAN PRESSURE FROM PAC



- Obtain 10 seconds of valid pressure waveform.
- Select **Set Pressure Baseline.**

3C CALIBRATE PA SENSOR USING PA MEAN PRESSURE FROM PAC (CONTINUED)

VALID CALIBRATION CRITERIA:

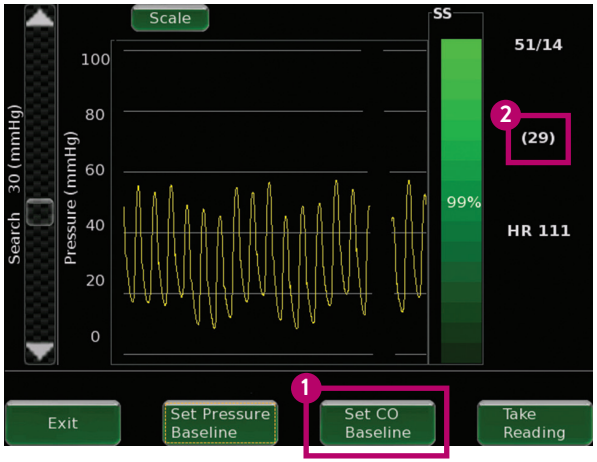
- > 70% Signal Strength with a green bar color
- Good physiologic, pulsatile waveform
- > 90% and stable is preferred
- **Do not proceed without a valid calibration**
- **Electrocardiogram (ECG) and defib cables in the area may prevent valid calibration**

- Enter the mean PA measured by the corresponding waveform on the PAC.
- Sensor-calculated heart rate (HR) and PA pressures will register after sensor calibration.

3D CALIBRATE CO (OPTIONAL)

After calibrating the PA sensor, obtain 10 seconds of valid waveform.

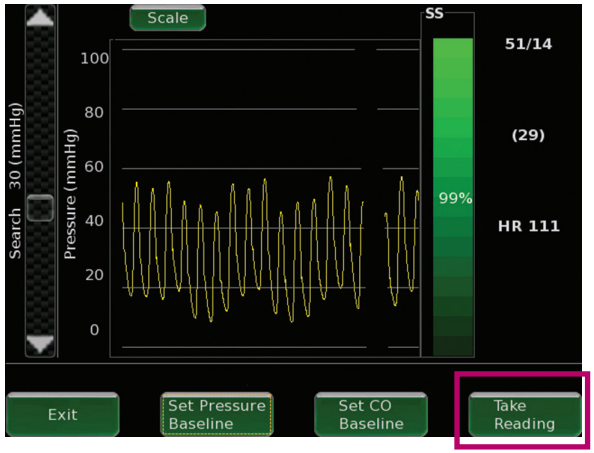
- Select **Set CO Baseline** (Box 1).
- Enter CO obtained during the RHC.



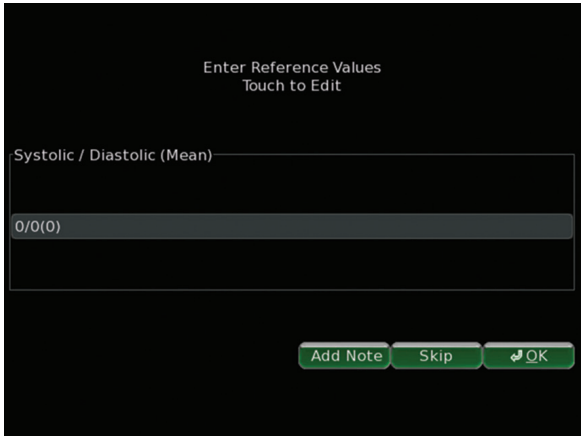
Next, wait until there is a full screen of displayed data (after setting CO baseline), and then check that the PA mean pressure on the HES screen correlates to the PA mean from the PAC, within 1–2 mmHg (Box 2). If you do not have a close match, return to Step 3C and recalibrate.

STEP 4: **TAKE READINGS, UPLOAD AND SHUT DOWN**

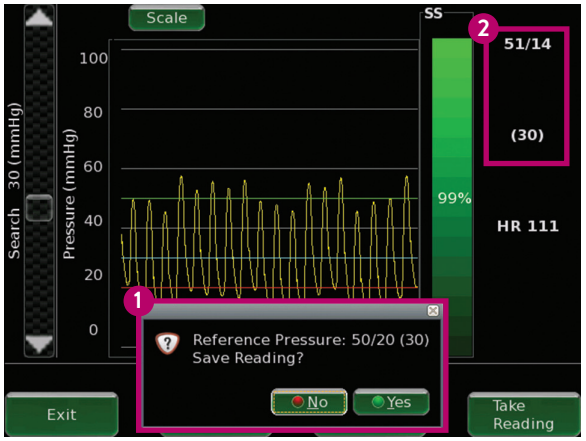
4A Obtain 10 seconds of valid pressure waveforms and then select **Take Reading.** Record the pressures from the PAC ***at the same time as you press the button*** (it may be helpful to coordinate with the control room operator and say out loud "1, 2, 3 ... now" as you press this button).



4B Enter systolic, diastolic and mean from the PAC, then select **OK**.



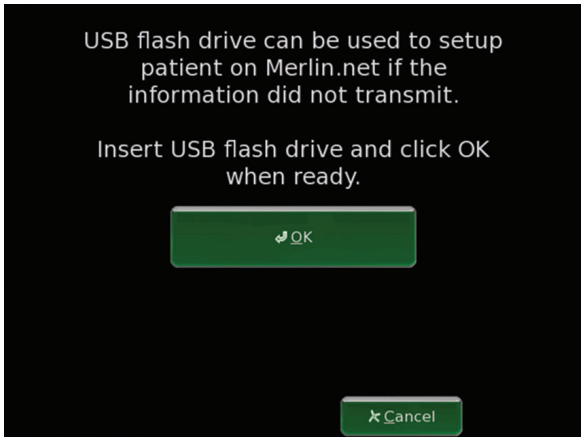
4C Verify that the sensor pressure correlates to the PAC pressures. If the reference catheter pressures (Box 1) do not correlate to the sensor pressures (Box 2) and there is a lot of respiration variation, consider setting a new pressure baseline.



4D Following these steps, take two additional readings, waiting 10 seconds between each reading. After completing the readings, remove the antenna. The case is now complete. Select **Exit** at the bottom left of the HES screen, and the HES will automatically attempt to connect to the Merlin.net™ PCN website and send the implant data.

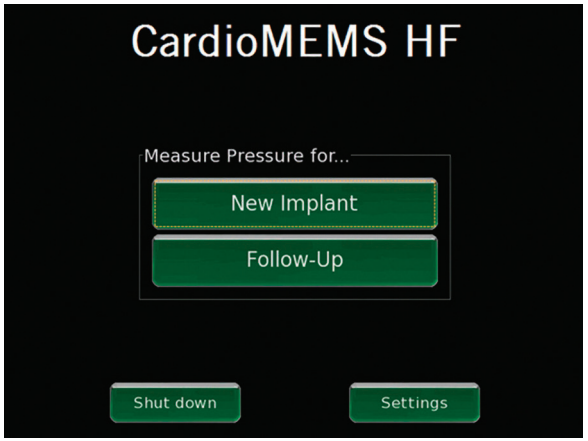
4E Once the data transfer is complete, a prompt on the HES screen will appear asking to save the data. The USB flash drive should still be inserted into the HES. Select **OK**.

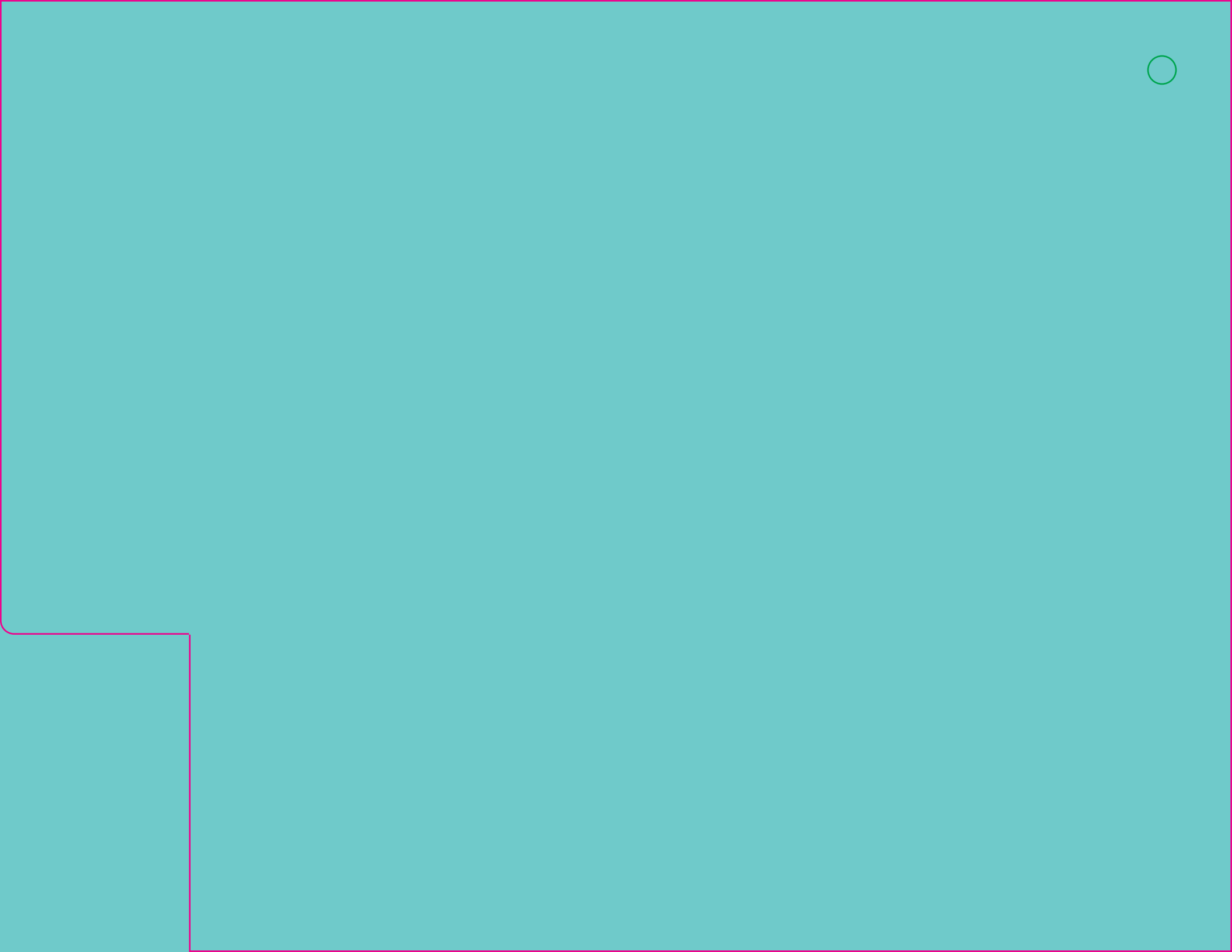
In almost ***all*** cases, the USB flash drive will no longer be needed, unless network connectivity is a challenge. If so, see the instructions on the next page for "Associating the Patient on the Merlin.net PCN without Connectivity."



4F **SHUT DOWN**

- Select the on-screen **Shut Down** button.
- Do not unplug until shut down is complete (rear button is not designed to power down the system).

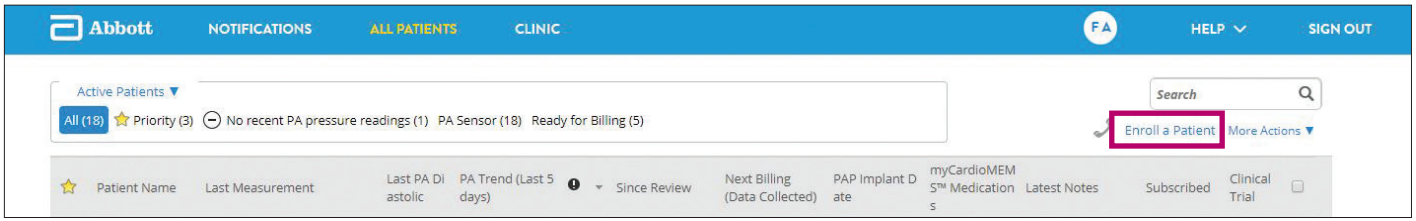




ASSOCIATING THE PATIENT IN THE MERLIN.NET™ PCN WITHOUT HES CONNECTIVITY

If network connectivity is a challenge, there is a manual upload process that may be easier than attempting to find an area with some connectivity options after the procedure. Steps 1–10 must be completed regardless of whether the site is an implant-only site 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 the sensor USB drive into the computer.
3. On the main patient list, click **Enroll a Patient.**



4. Select **PA Sensor.**
5. Enter the patient's name and DOB. Click **Enroll.**
6. In the new patient profile page, 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 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.

TROUBLESHOOTING

SUSPECT WAVEFORM WITH HIGH SIGNAL STRENGTH

- **Situation:** Technically suspect readings with high Signal Strength. The PA pressure waveform is non-pulsatile (Box 1), with no inflection for the heartbeat. The Signal Strength bar is blue (Box 2).

- **Recommended Action:** Slowly move the Search Pressure bar ***up*** 30mmHg whilst continually looking for a stronger signal (the Signal Strength bar will turn green). If no improvement, move the Search Pressure bar ***down*** 30mmHg below the starting point while looking for a stronger signal (the Signal Strength bar will turn green), while retaining a physiologic waveform.

PHYSIOLOGIC WAVEFORM WITH POOR SIGNAL STRENGTH

- **Situation:** Physiologic-appearing waveform (Box 3) but poor Signal Strength (Box 4). May result when locked on to a secondary signal, or "sideband."

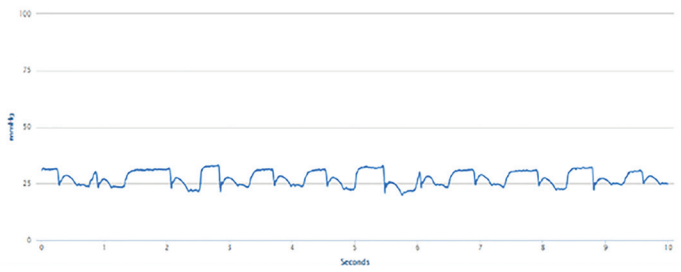
- **Recommended Action:** Remove potential sources of electromagnetic interference (EMI). Move the Search Pressure *up* 30 mmHg, looking for a stronger signal (the Signal Strength bar will turn green). If no improvement results, move the Search Pressure 30 mmHg below the starting point, and again look for a strong signal (the Signal Strength bar will turn green), while retaining the physiologic waveform.

OTHER EXAMPLES OF "FALSE LOCK" (NON-PHYSIOLOGIC WAVEFORM)

FALSE LOCK DUE TO EMI

- **Situation:** Antenna "locked" on signal from a device other than the CardioMEMS™ PA Sensor. This could be the patient's implantable cardioverter defibrillator (ICD) or pacemaker.
- **Recommended Action:** Reposition the antenna wand to localize the PA sensor signal.

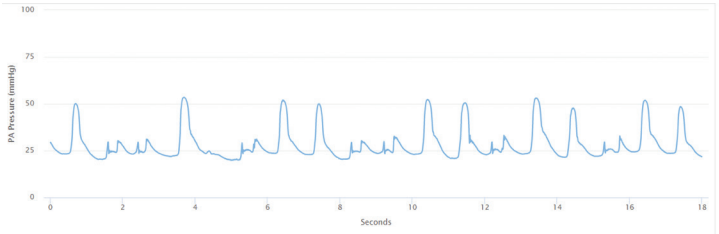
WAVEFORM



INTERMITTENT LOSS OF SIGNAL

- **Situation:** Interference "breaking in" on the correct PA sensor signal. This could be from a C-arm fluoroscopy unit, a Bair Hugger‡ pad, a monitor boom or ECG electrodes.
- **Recommended Action:** Reposition the antenna wand. Consider moving the C-arm as far away from the patient as possible, removing the Bair Hugger pad and ECG leads, etc.

WAVEFORM



NO CONNECTIVITY IN CATH LAB FOR WI-FI‡ OR CELLULAR SIGNAL FOR HES

- **Situation:** The Wi-Fi‡ connection or cellular signal in the lab is too weak for the HES to connect with the Merlin.net™ PCN to transfer data and patient information from the case.
- **Recommended Actions:** When the HES attempts to connect to the Merlin.net PCN website (in the prior section, see "Associating the Patient in the Merlin.net PCN without HES Connectivity"), select **Cancel** to bring up the manual entry screen. Use the USB flash drive that is packaged with the CardioMEMS PA Sensor to store procedure and calibration information to upload manually to the Merlin.net PCN.

PA SENSOR WILL NOT RELEASE AND DEPLOY FROM THE DELIVERY SYSTEM

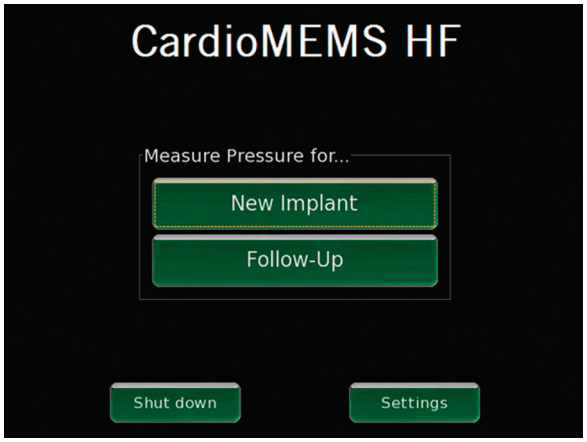
- **Situation:** The sensor appears to still be attached to the delivery system after removing the blue cap and tethering wires.
- **Recommended Actions:** Retract the delivery system 1-2cm very slowly to confirm if the sensor is stationary or moving with the delivery system. If the sensor is moving with the delivery system, advance back into its original position. Pull the wire back into the delivery system, wait 5-10 seconds then advance the wire back into the target vessel. If the sensor has still not released, re-introduce the PA Catheter (PAC) alongside the delivery catheter and use the balloon as a backstop. Another option is to remove the hub from the end of the delivery system and advance a 6F Guideliner catheter over the delivery system to break sensor contact.

PA SENSOR RECALIBRATION

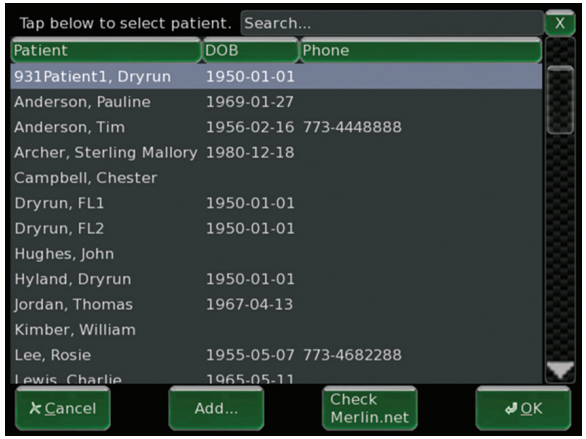
- It is rarely necessary, but there are straightforward options if you decide to recalibrate. Contact our Clinical Support Team for sensor evaluation and troubleshooting guidance.

TAKING A FOLLOW-UP READING

A Power on using the rear button. Select **Follow-Up.**



B
- Select **Patient Name,** then select **OK**.
- The system will ask if PA pressure readings are available. Unless you will be performing a RHC procedure, select **No** to take a sensor reading.



C

ACQUIRE SIGNAL

- Place the antenna under the patient's back, approaching from the side where the sensor was placed.
- Position the center of the antenna under the tip of the patient's shoulder blade on the side of the torso where the sensor is located.

VALID READING CRITERIA

- > 70% Signal Strength with a green bar
- Accurate HR
- Good physiologic, pulsatile waveform

D

- Select **Take Reading**, and if reading is acceptable, then select **Yes**.
- Repeat Step D as desired. Select **Exit** after all desired readings are saved.
- Ensure readings have uploaded to the Merlin.net™ PCN and the system is powered down before unplugging.

E

SHUT DOWN

- Select the on-screen **Shut Down** button.
- Do not unplug until shut down is complete (rear button is not designed to power down the system).

TECHNICAL SUPPORT

If you have questions on the CardioMEMS™ HF System, please contact Technical Support (support available in English only):

Belgium: +32 2 200 66 95

Denmark: +45 44 50 03 88

France: +33 1 41 46 50 03 88

Germany: +49 619 6771 1220

Italy: +39 02 3596 1180

Netherlands: +31 318 583 240

Switzerland: +41 442 757 180

UK/Ireland: +44 121 306 0550

International: +46 8 474 4756

In Europe, Middle East and Africa, Telephone Technical Support is available Monday through Friday (8:00 to 17:00 Central European Time).

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Cardiovascular.abbott

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.

MAT-2100384 v2.0 | Item approved for EMEA audiences only.

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