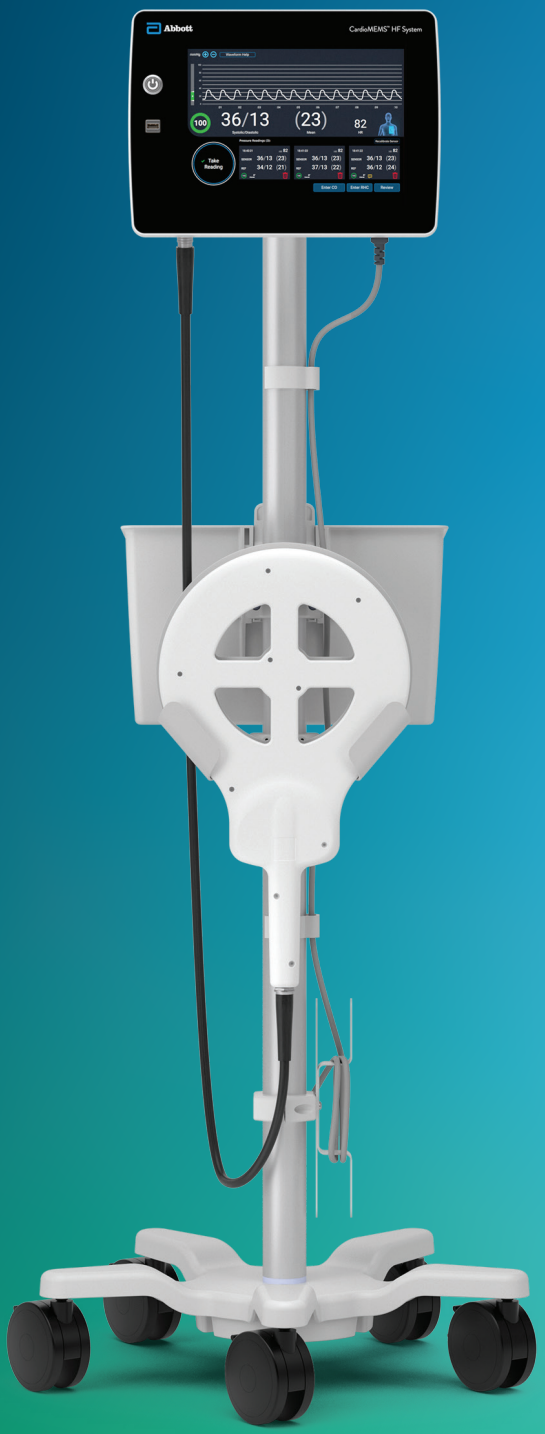
Abbott

CARDIOMEMS™ HOSPITAL SYSTEM

QUICK REFERENCE GUIDE



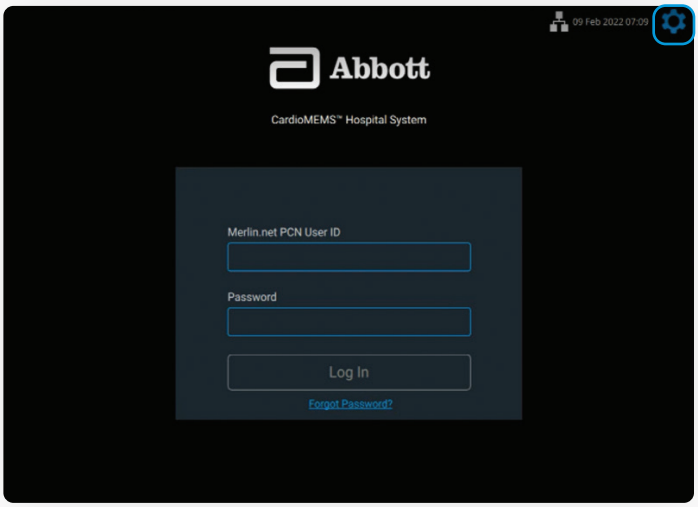
HOSPITAL SYSTEM SETUP AND PREPARATION

HOSPITAL SYSTEM SETUP AND PREPARATION

1 Turn on the Hospital System using the **Power On** button located on the front of the unit, to the left of the monitor's screen.

2 After logging in via the Merlin.net™ Patient Care Network (PCN) log-in mode, the default log-in option can be changed to **Password Only** or **No Password**.

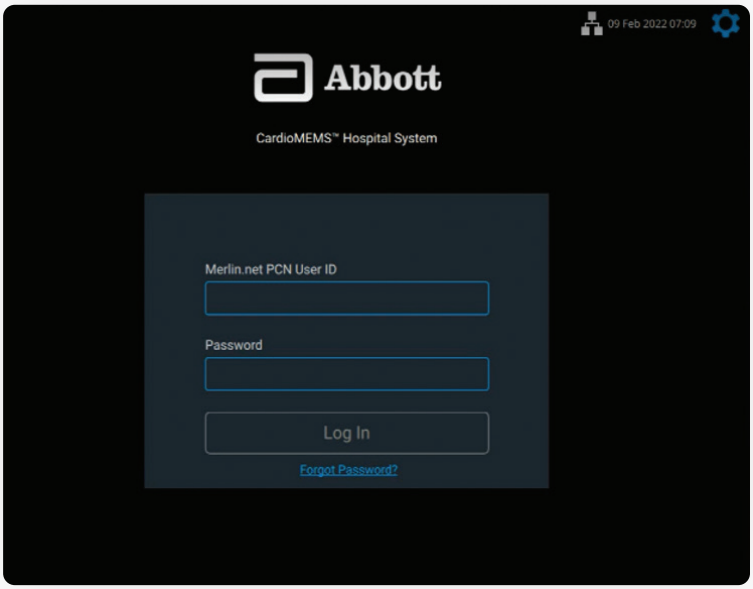
To change the default log-in option, access the Settings Menu by pressing the gear on the Home screen.



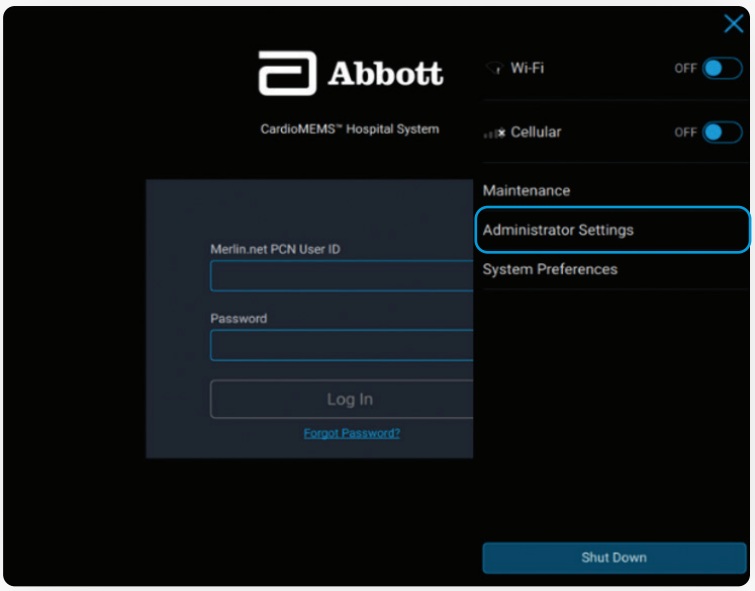
LOG IN TO THE SYSTEM

1 The default log-in option is the Merlin.net™ PCN login.

- Enter the credentials used to log in to the Merlin.net PCN.
- If Merlin.net PCN credentials are not known, call Technical Support at 1-844-692-6367.



2 Choose **Administrator Settings**.



LOG-IN OPTIONS

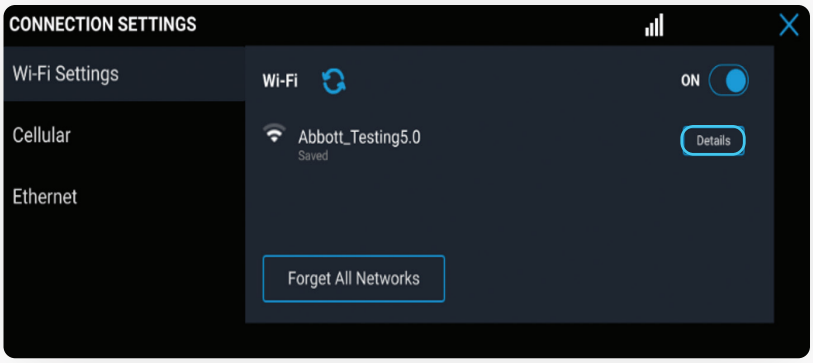
	MERLIN.NET™ PCN	PASSWORD ONLY	NO PASSWORD
Use Considerations	Allows full functionality for multiple clinics with connectivity. Preferred for hub-and-spoke	Allows full functionality for a single clinic	Allows limited functionality for a single clinic. The summary report cannot be emailed or exported to USB in this mode. The summary report is accessible only from the Merlin.net PCN
Security	Most secure	Less secure	Least secure
Connectivity	Requires connectivity, but clinical functions — with limited functionality — can be accessed without connectivity	Does not require connectivity	Does not require connectivity
Users	Individual and multiple users can log in. Users must have Merlin.net PCN account credentials	Multiple users must share a password	Multiple users are allowed access without a password
Clinic	Hospital System can share multiple clinics	Hospital System is associated with one clinic	Hospital System is associated with one clinic

CONSIDERATIONS

- No Password is not a recommended log-in mode. Use caution when using No Password login setting, as PHI data will be displayed.
- Use caution and secure the area when using the No Password log-in setting since PHI data is displayed.

CONFIGURE NETWORK CONNECTIVITY

The system can be configured to communicate with the Merlin.net™ PCN using local Wi-Fi‡, cellular or Ethernet‡ connections. Information sent is encrypted.

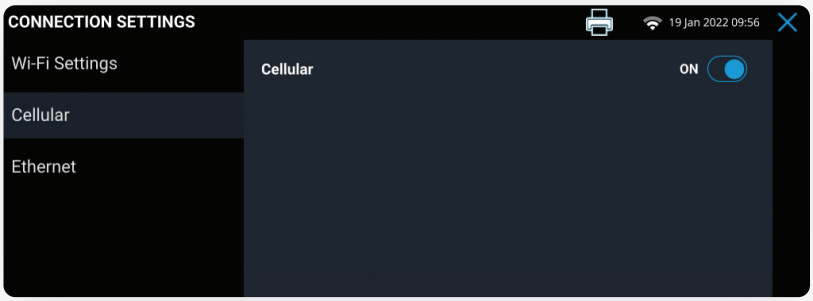


OPTION 1: WI-FI‡

- This only uses the Wi-Fi network at the facility to gain access to the Merlin.net PCN.
- Select **Details** to set up the local network and password.
- Network must be sufficiently encrypted.
- Network credentials are not sent to the Merlin.net PCN.

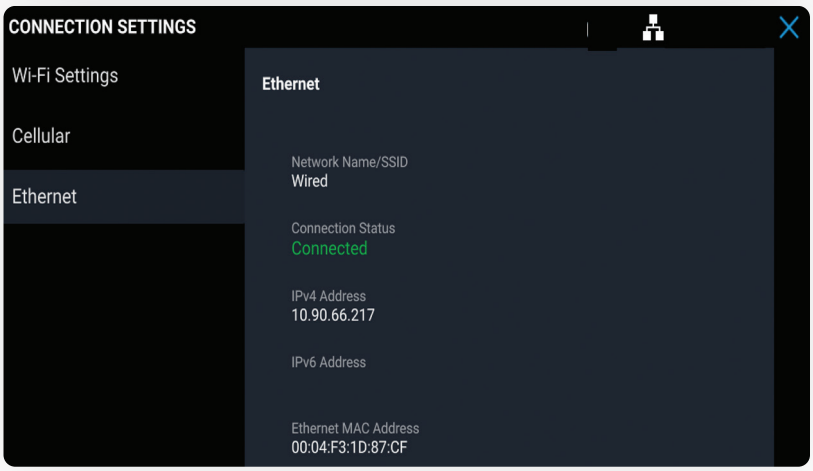
OPTION 2: CELLULAR

This is the default connectivity, with a 4G LTE‡ cellular modem.



OPTION 3: ETHERNET‡

- Ethernet port is located on the side of the unit.
- To ensure electrical safety, do not touch the Ethernet port and the patient simultaneously.
- Direct connection to a nonsecure network may interfere with system operation and/or result in unauthorized access to patient information.

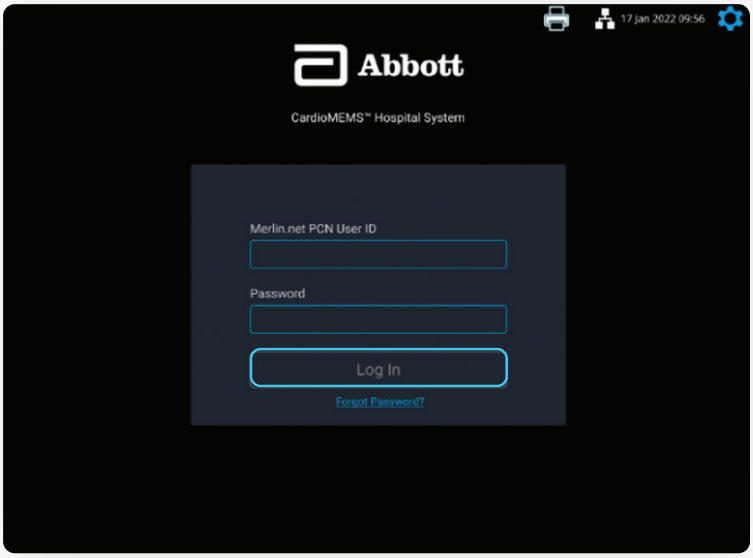


CARDIOMEMS™ PA SENSOR IMPLANT

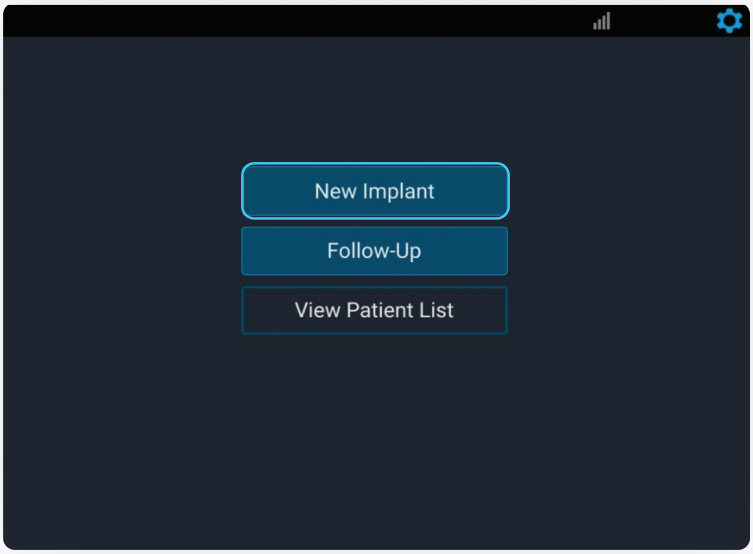
CARDIOMEMS™ PA SENSOR IMPLANT

LOG IN

1 Enter Merlin.net™ PCN user ID and password, then select **Log In**.

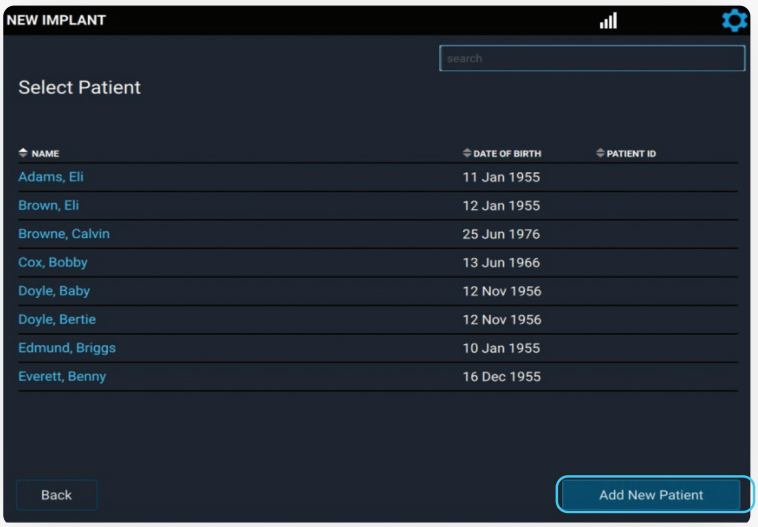


2 Select **New Implant** from the Main Menu.

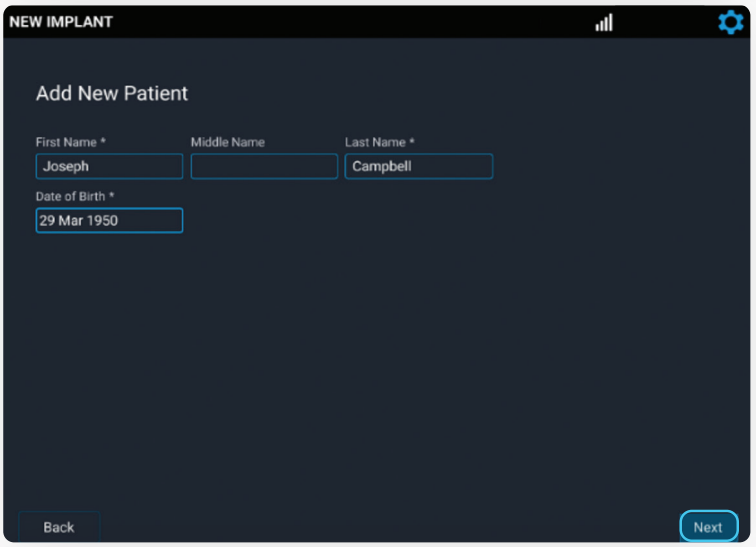


ENTER PATIENT INFORMATION

1 Select the patient from the list, or select **Add New Patient**.

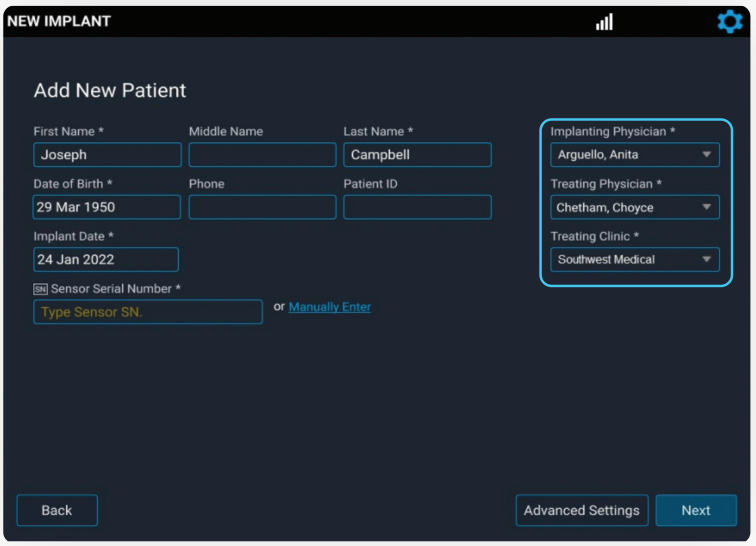


2 Enter new patient information, then select **Next**.



3 Select the implanting and treating physicians.

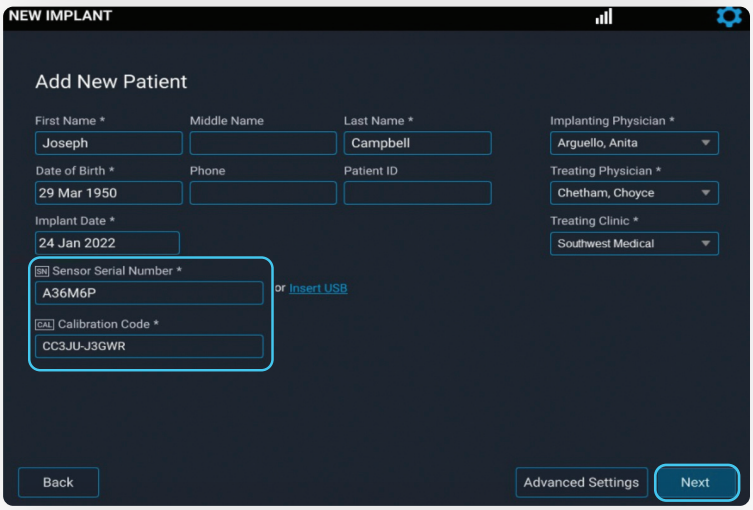
System automatically associates the corresponding Merlin.net™ PCN clinic in the Treating Clinic field.



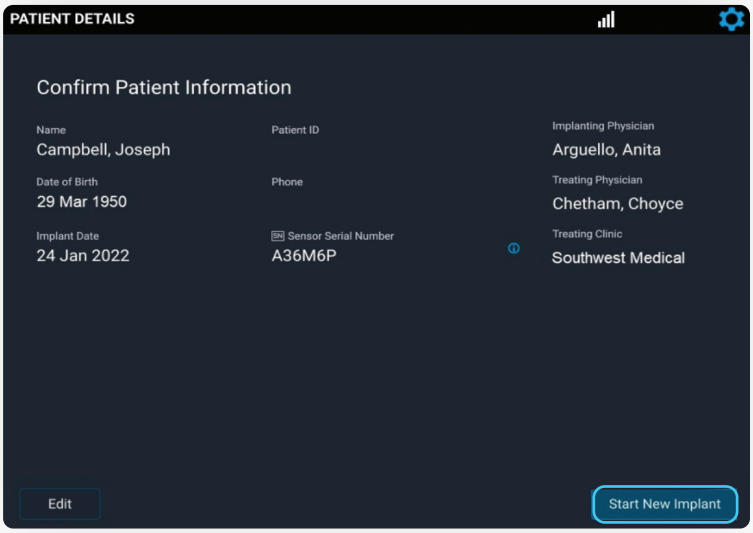
ENTER SENSOR INFORMATION

1 Locate the sensor serial number on the package, and enter it in the field.

2 The Calibration Code field will automatically populate if there is connectivity. Select **Next**.



3 Reconfirm the patient and sensor information, then select **Start New Implant**.

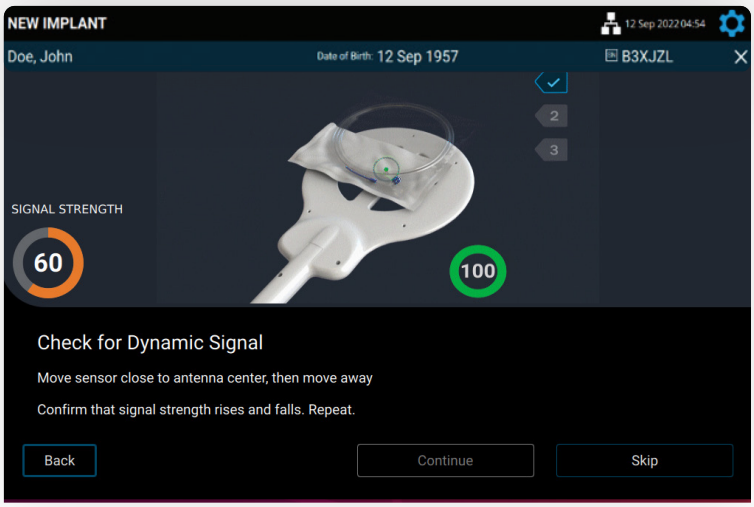


CHECK FOR DYNAMIC SIGNAL

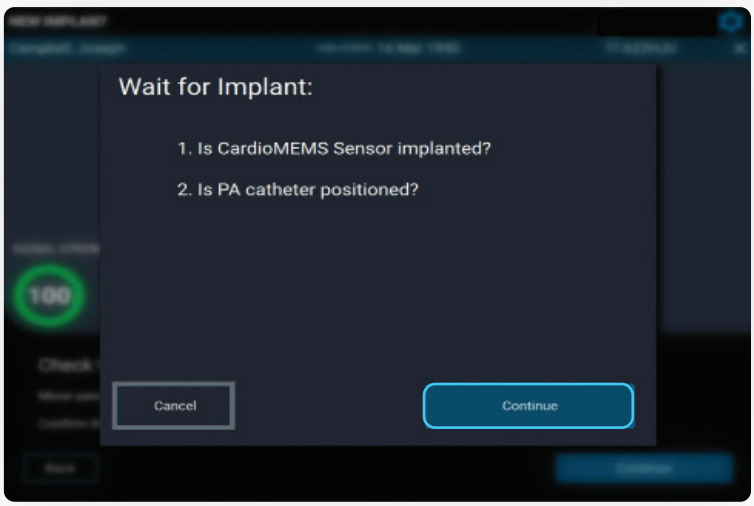
1 Move the antenna center close to the unopened sensor package, and verify the signal strength on the left is green and at 100%.

2 Move the antenna away from the sensor package, and confirm the signal strength on the left decreases.

Repeat two more times, then select **Continue**.

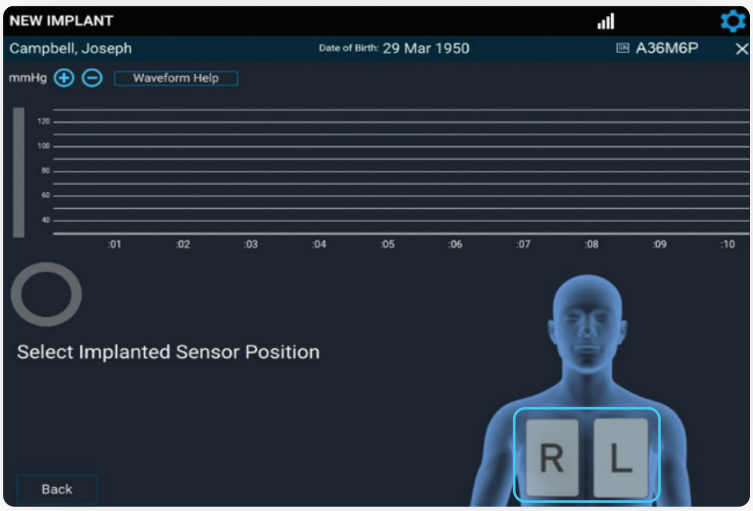


3 "Wait for Implant" message appears. Select **Continue** when the physician is ready to calibrate the implanted sensor.



PLACE THE ANTENNA UNDER THE PATIENT'S SHOULDER

On the Sensor Position screen, select the **R** or **L** button to indicate the sensor location.

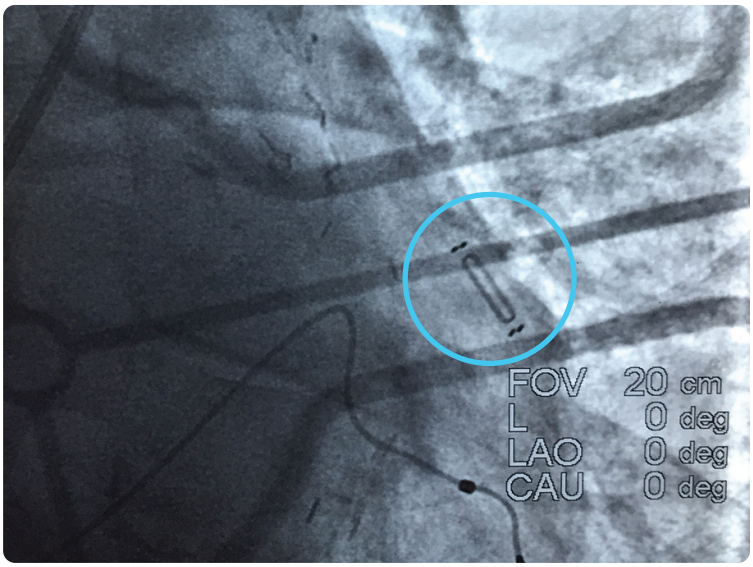


CONSIDERATIONS

- Conditions for safe contact: place a layer between the antenna and the patient's skin, for example, a sheet or a pillowcase.
- CAUTION: Do not place the antenna under the 3M‡ Bair Hugger‡ blanket or table pad.

Note: Fluoroscopy can be used to help position the antenna underneath the sensor. Once the antenna is positioned, it is recommended to move fluoroscopy equipment away from the patient.

- If, on fluoroscopy, the gold sensor coil can be seen as an oval, then the sensor should be centered on the antenna.
- If, on fluoroscopy, the gold sensor coil appears as an oval in the AP view, then the sensor should be nearer to the outside of the antenna.

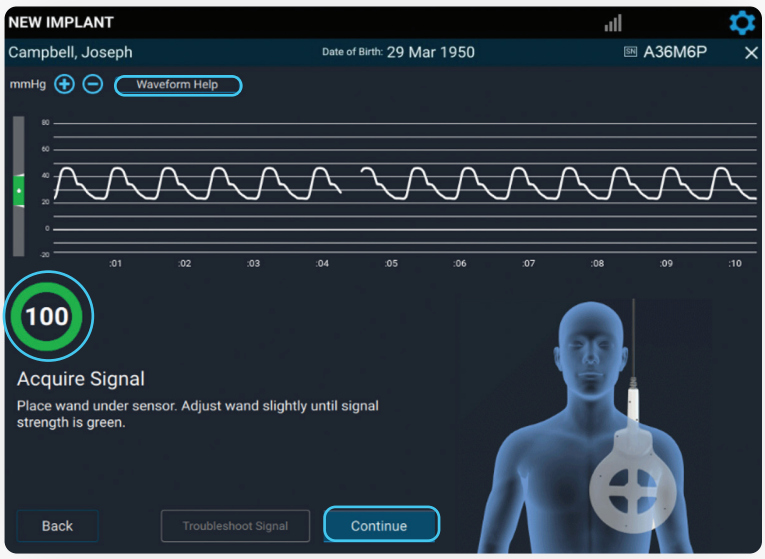


ACQUIRE CARDIOMEMS™ PA SENSOR SIGNAL

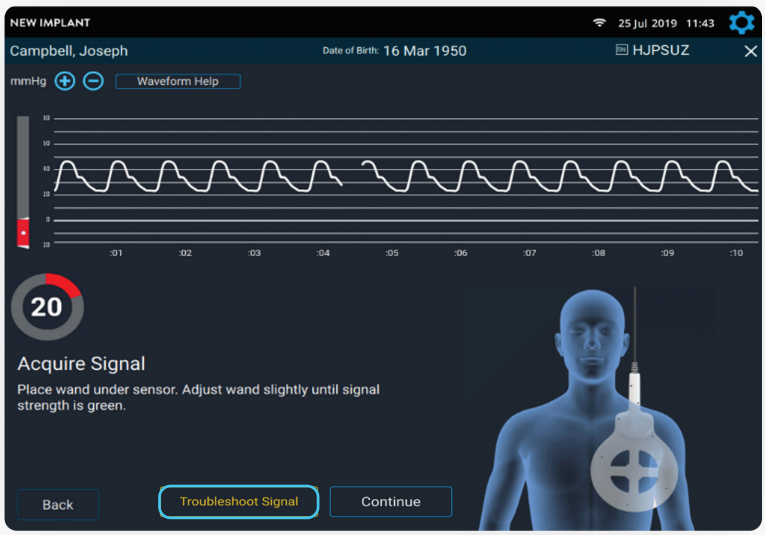
Once the antenna is in place, concentrate on the screen, looking for a physiologic PA waveform and a green signal strength indicator > 70%, indicating a strong, pulsatile signal.

- Stable signal strength > 90% is optimal.
- If the waveform does not fit these criteria, select **Waveform Help** to troubleshoot common issues.

Select **Continue** once the waveform and the signal strength are acceptable.



If the system detects poor signal quality, the **Troubleshoot Signal** button turns yellow. Select **Troubleshoot Signal** to receive guidance on improving the sensor signal strength.

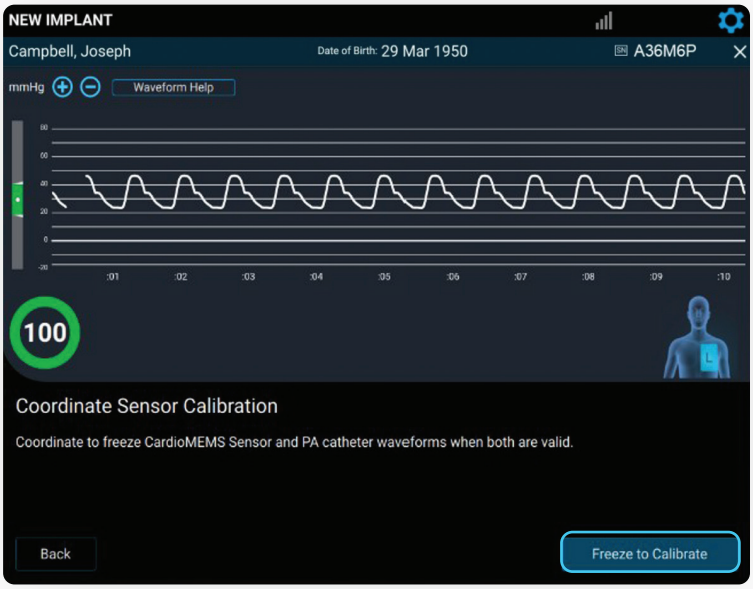


CALIBRATE PA SENSOR USING PA CATHETER MEAN PRESSURE

1 Obtain 10 seconds of valid pressure waveforms.

When a strong physiologic signal is acquired, **Freeze to Calibrate** will turn blue.

Capture mean PA pressures at the same time **Freeze to Calibrate** is selected.



2 Enter the mean PA pressure measured by the PA Catheter.

Sensor pressure values will appear, and the sensor will calibrate to the mean PA pressure entered.

VERIFY SENSOR CALIBRATION

If the sensor pressure values do not match the PA pressures in real time, select the **Recalibrate** button to capture a new waveform.

If the calibration is acceptable, select the **Save** button.

VALID READING CRITERIA

- The signal strength is > 70% with a green color.
  - A signal strength of > 90% and stable is preferred.
  - The **Take Reading** button will not be active if the signal strength is < 70% in the last 10 seconds.
- The heart rate (HR) must be accurate.
- There must be a good physiologic, pulsatile waveform.

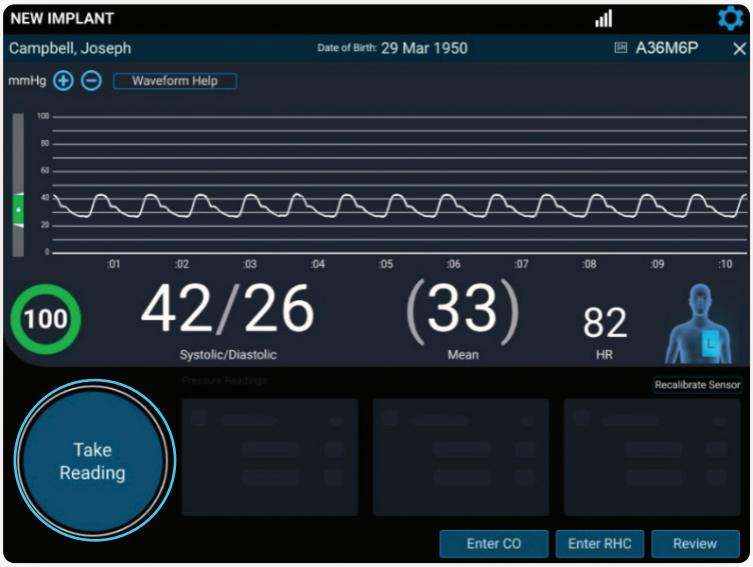
Note: Ultrasound equipment, ECG or defibrillator cables in the area may prevent valid readings. Ensure that possible sources of electrical interference are removed.

TAKING A READING DURING IMPLANT

1 Obtain 10 seconds of valid pressure waveforms.

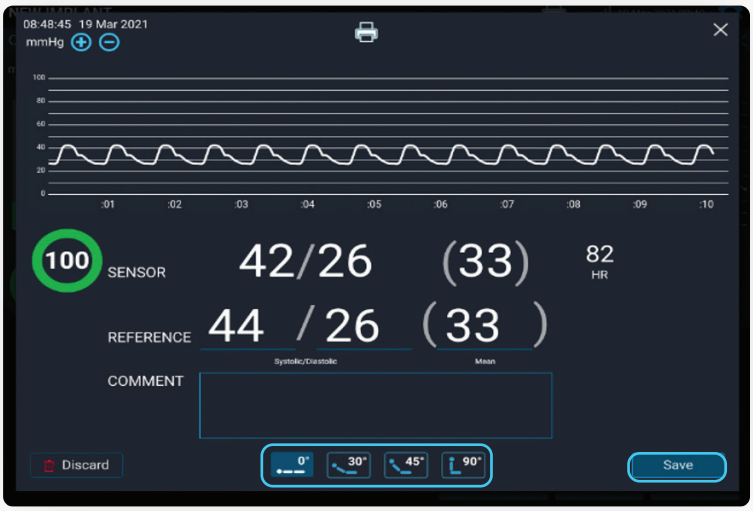
Record the pressures from the PA Catheter at the same time as you select **Take Reading**.

- Consider coordinating with the hemodynamic system operator and say out loud, "1, 2, 3 ... now" as you select the **Take Reading** button.



2 Enter systolic, diastolic and mean from the PA Catheter. Next, select the patient position. Then, select **Save**.

Repeat these steps for a total of **three readings**.

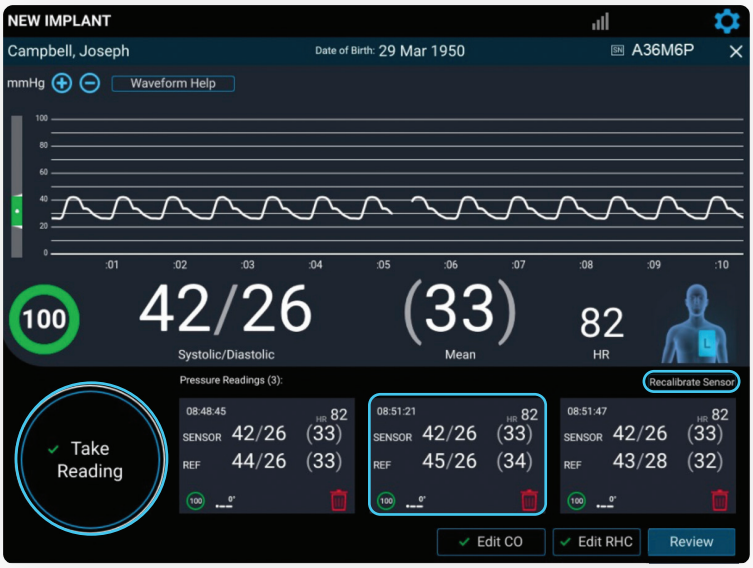


3 The summary of each reading appears on the screen. Verify that each sensor reading value correlates to the readings from the PA Catheter.

- Select the **Trash** icon to discard a reading.
- Select **Take Reading** to take another reading.

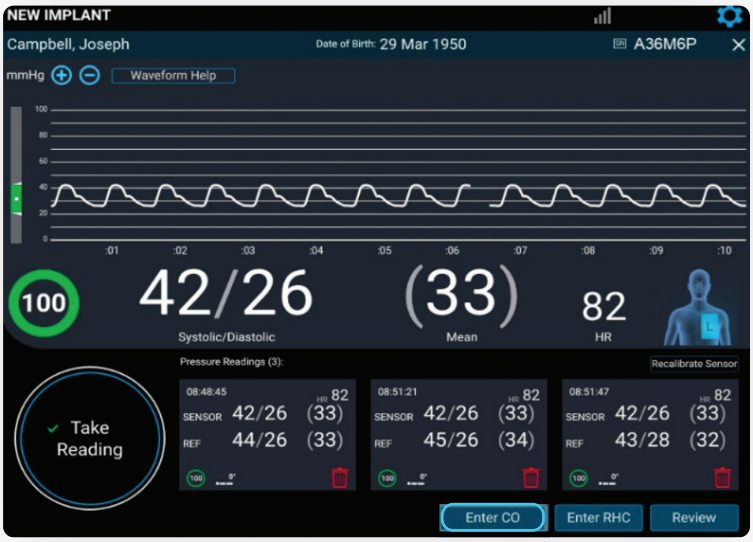
If the readings do not correlate to your satisfaction, recalibrate the sensor.

- Consider obtaining PA pressures during end expiration.



CALIBRATE CARDIAC OUTPUT (CO)

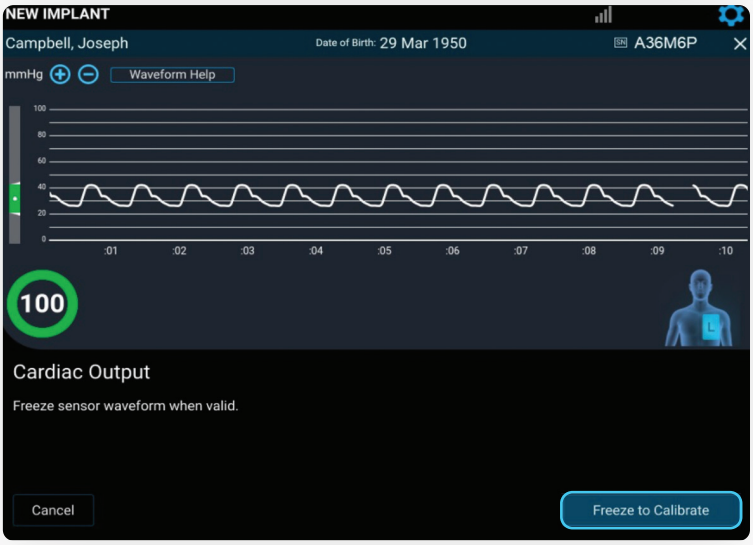
1 Select the **Enter CO** button.



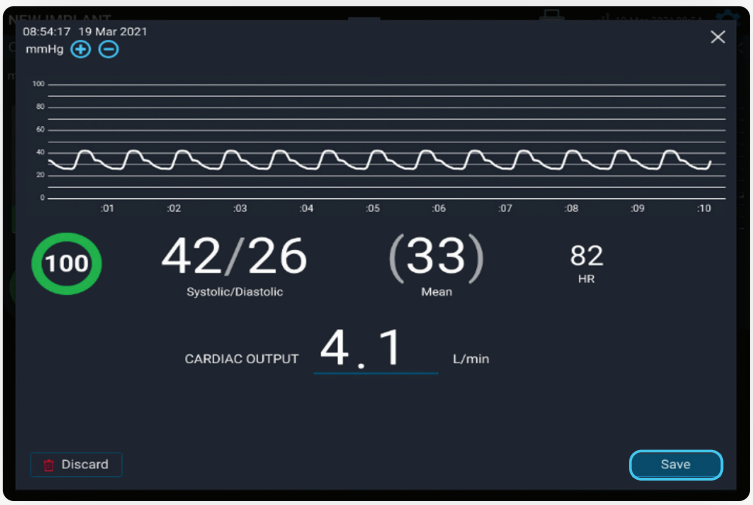
2 The Cardiac Output screen appears.

Signal strength should be green and > 70%, and PA waveform physiologic.

Select the **Freeze to Calibrate** button.



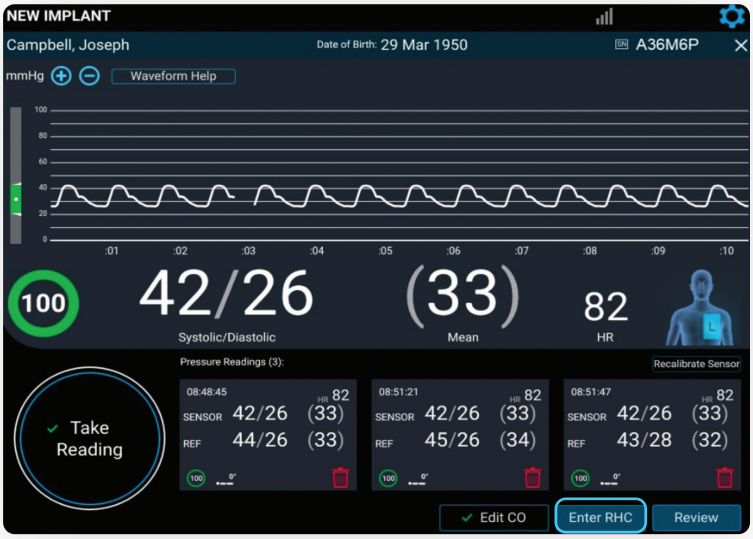
3 Enter the CO, select the **Right Arrow** button on the keyboard and then select **Save**.



ENTER RIGHT HEART CATHETER (RHC) VALUES

1 Select the **Enter RHC** button.

The RHC Pressures screen appears.

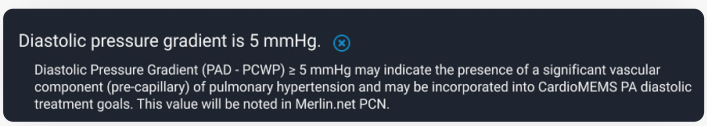


2 Enter the RA, RV, PA and PCWP pressures, then select **Save**.

RHC information entered on the Hospital System will be displayed in the Merlin.net™ PCN.

NOTE

If a diastolic pressure gradient is present, a notification message appears on the screen and will appear in the Merlin.net PCN.

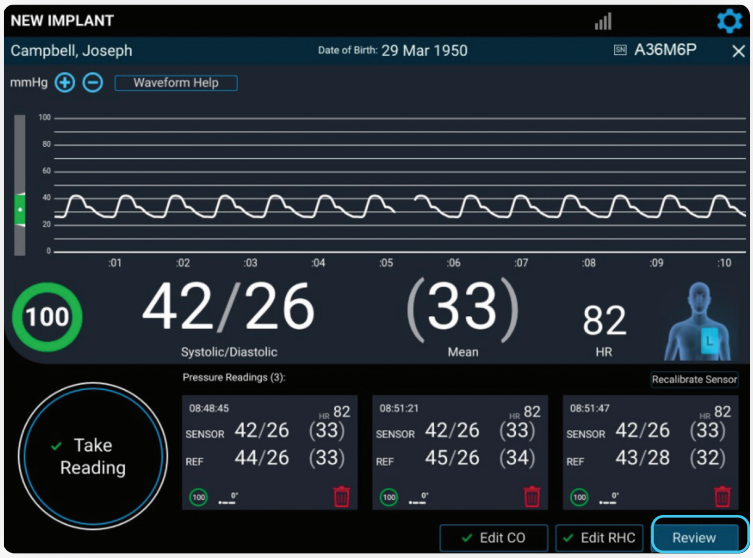


REVIEW AND CONFIRM ACCURACY OF ALL CAPTURED DATA

1 Select the **Review** button.

On this screen, users can:

- Discard PA pressure calibration.
- Edit or discard readings and CO calibration.
- Edit RHC values and sensor position.



2 Remove the antenna from the patient's back. The case is now complete.

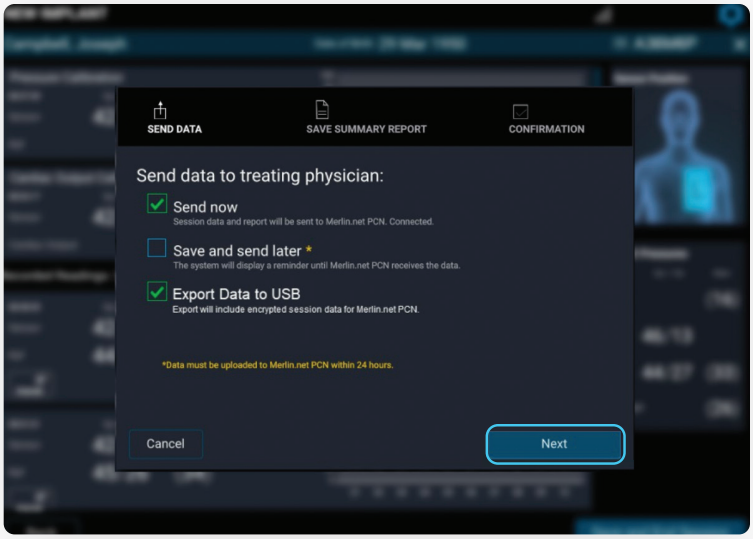
Select **Save and End Session**.

TRANSFER DATA

1 Select from the following options:

- **Send now** to automatically connect to the Merlin.net™ PCN website and send the implant data; requires network connection
- **Save and send later** to store in the Unsent Sessions section of the Main Menu screen
- **Export Data to USB** to save implant information to the USB drive for backup
  - The USB can be used to transfer implant data to the Merlin.net PCN if connectivity is an issue.

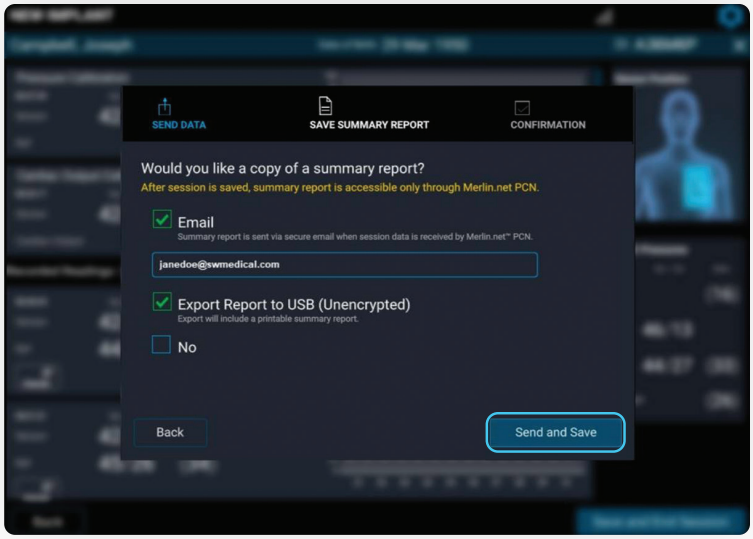
Select **Next**.



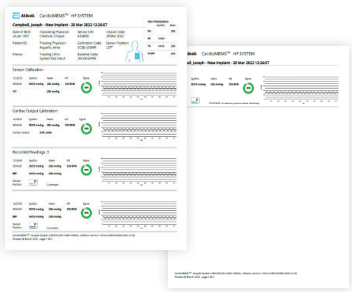
2 A summary report can be emailed or exported to the USB. Then select **Send and Save**.

Note: Session data can no longer be edited.

Note: It is critical to send or upload data within 24 hours of implant. The patient will not be able to take their readings until this step is completed.



SESSION SUMMARY REPORT

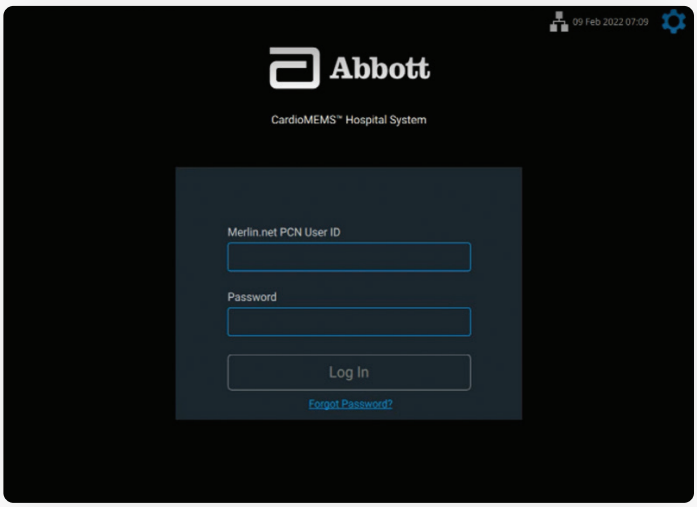


TAKING A FOLLOW-UP READING

TAKING A FOLLOW-UP READING

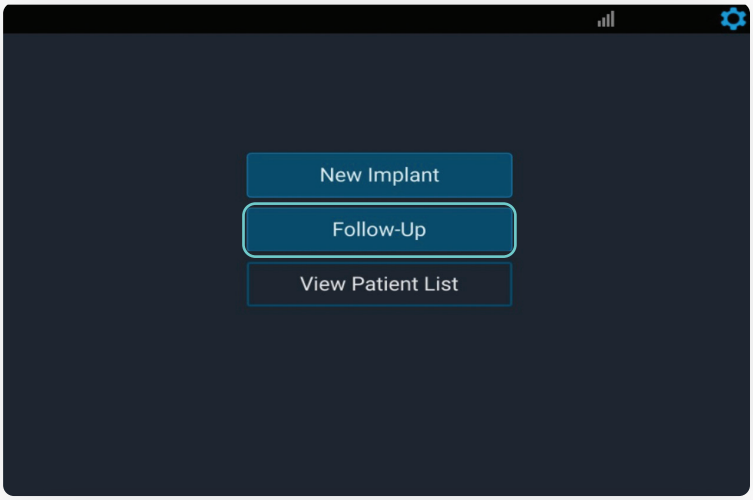
1 Turn on the Hospital System using the **Power On** button located on the front of the unit, to the left of the monitor's screen.

2 Log in to the system.



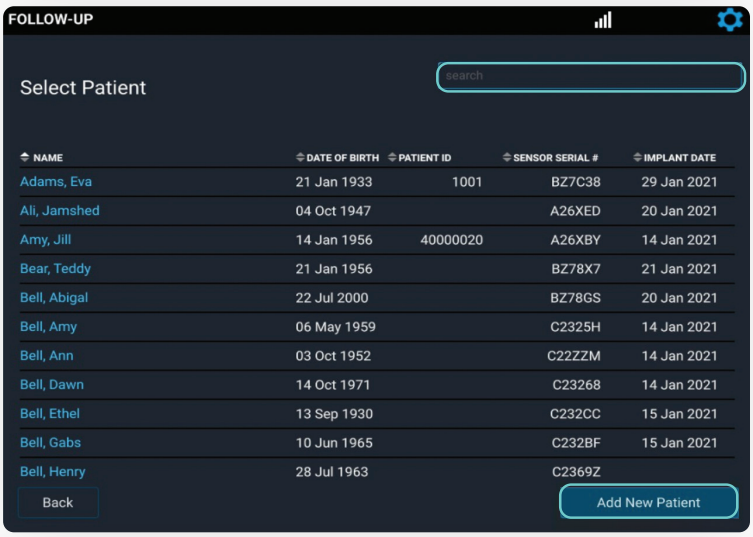
SETUP FOR PATIENT IMPLANTED WITH THIS HOSPITAL SYSTEM

1 After logging in, select **Follow-Up**.

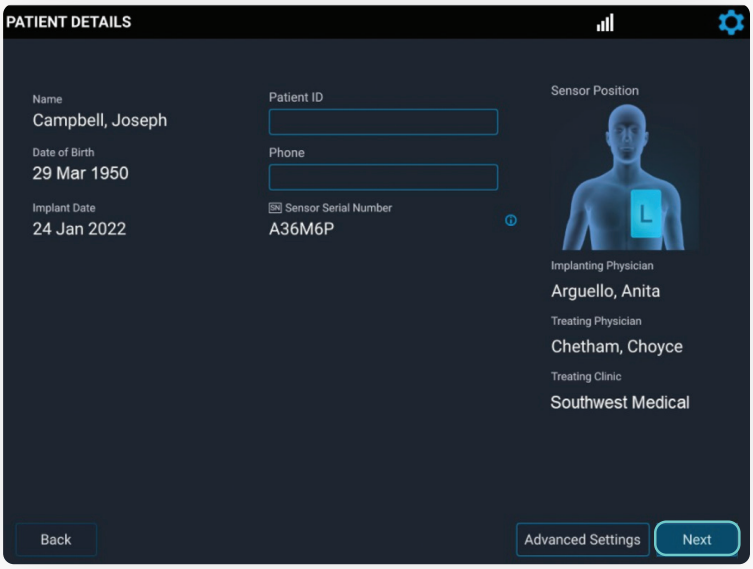


2 Select the patient from the list.

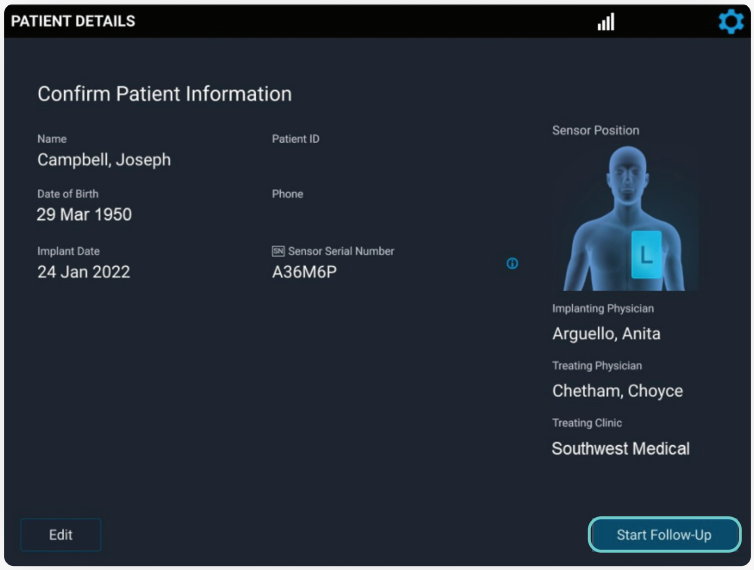
- If the patient is not on the list, use the search function.
- **Make sure the unit has connectivity to pull data from the Merlin.net™ PCN website.**
- If the patient is still not found, select **Add New Patient** to enter manually. Refer to the "Setup for Patient **Not** Implanted With This Hospital System" section for directions.



3 Review the information, then select **Next**.

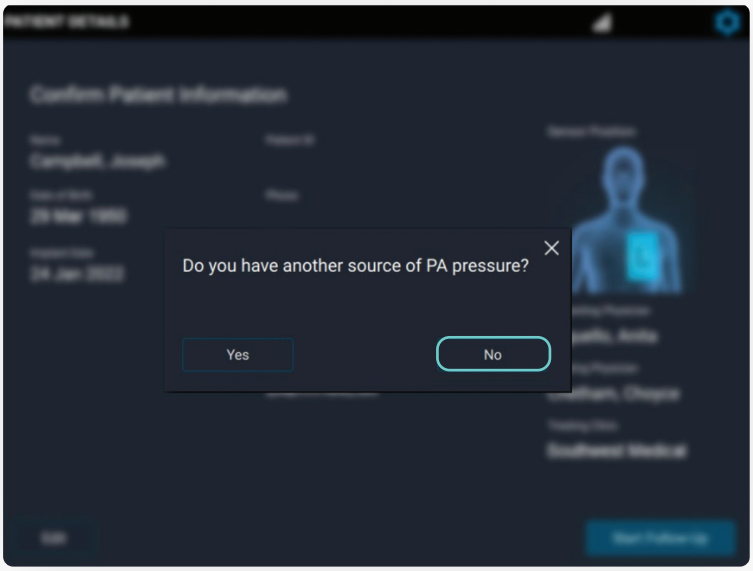


4 Confirm the patient information, then select **Start Follow-Up**.



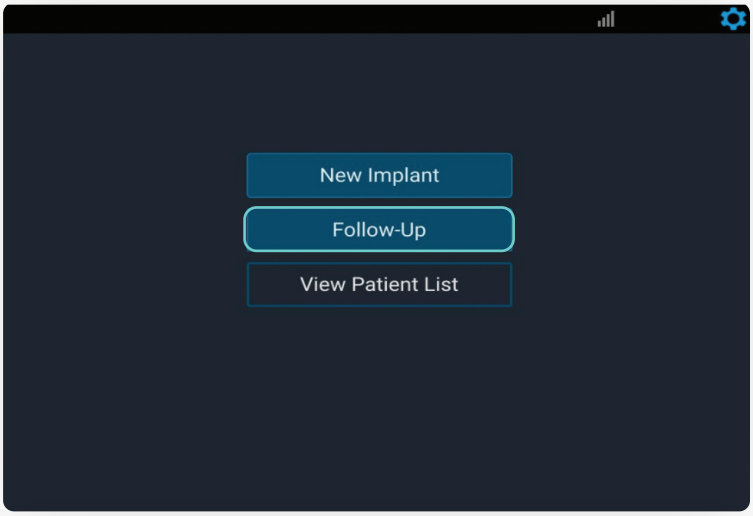
5 When the system asks, "Do you have another source of PA pressure?" select **No**.

- Select Yes if a sensor recalibration is required. See Sensor Accuracy Check and Recalibration section for more details.

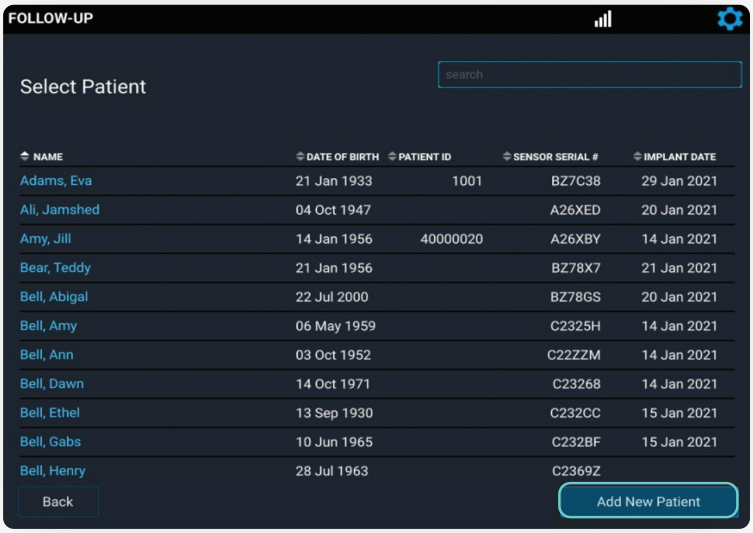


SETUP FOR PATIENT **NOT** IMPLANTED WITH THIS HOSPITAL SYSTEM

1 Select **Follow-Up**.



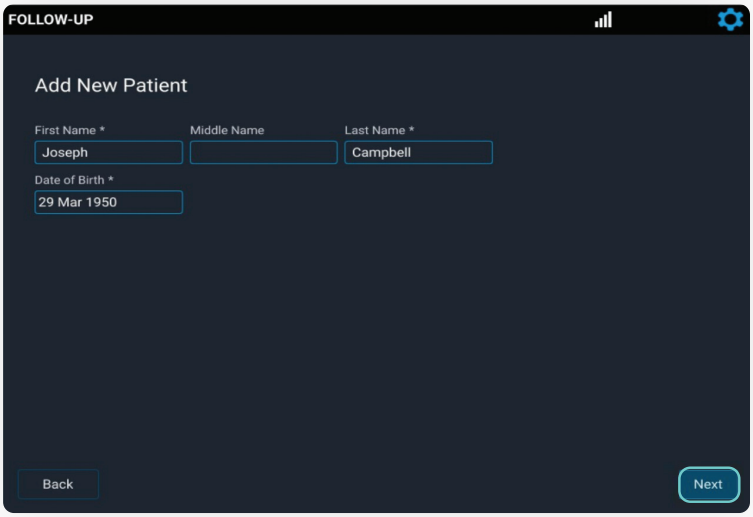
2 Select **Add New Patient**.



3 Enter the patient information, then select **Next**.

Call Technical Support to obtain the sensor serial number, calibration code and baseline code. Then enter the information manually.

Note: The patient's implant card only has the sensor serial number and calibration code.



4 Once entered, select the sensor position (**R** or **L**). Then select **Next** and follow the remaining steps.

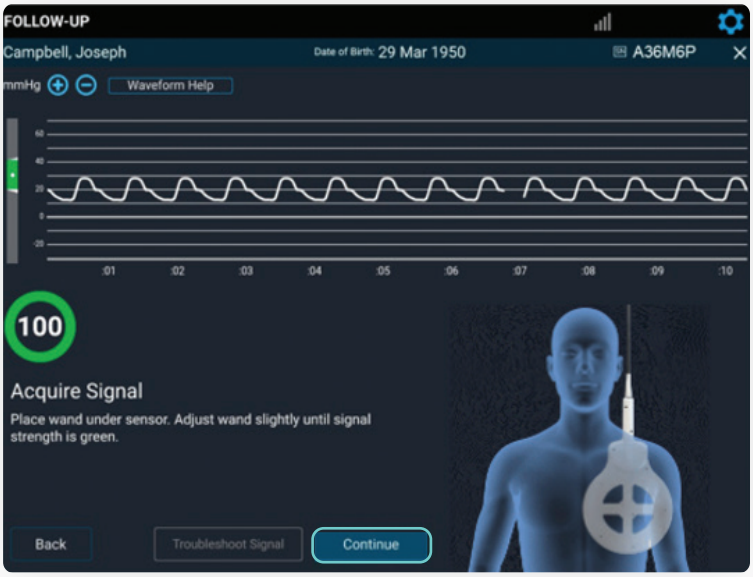
ACQUIRE SIGNAL

1 Slide the antenna under the patient's back on the side of their sensor, similar to the method at implant.

Look for a strong, stable signal that is > 70% and green.

- Signal strength > 90% is optimal.
- Verify the waveform is physiologic.

Select **Continue**.

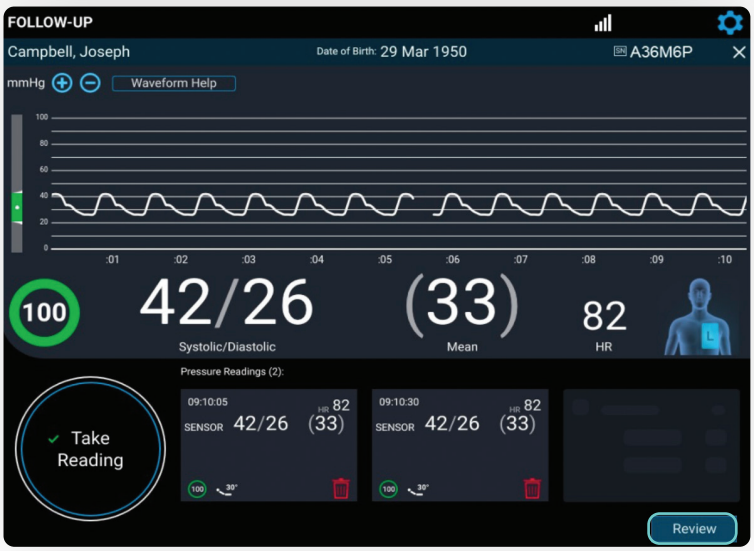


READING WITHOUT REFERENCE VALUES

1 Select **Take Reading** to initiate a reading from the Hospital System.

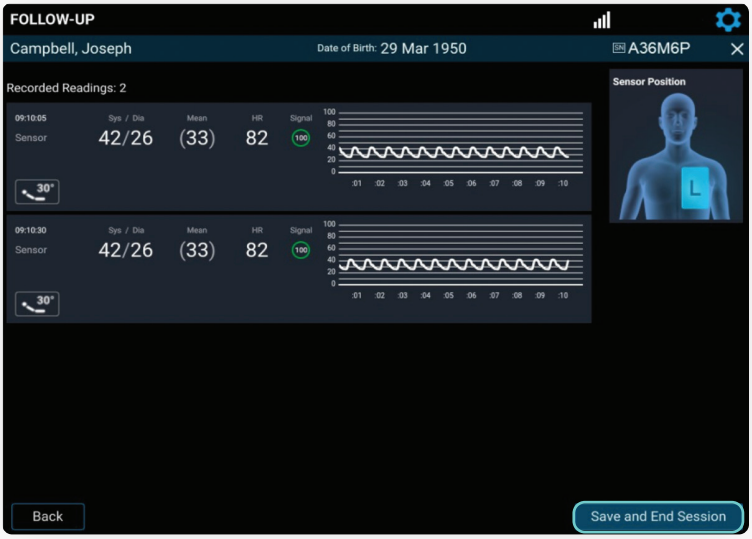
2 If the reading is acceptable, select the patient position and then select **Save** to save the reading.

3 After taking all readings, select **Review**.

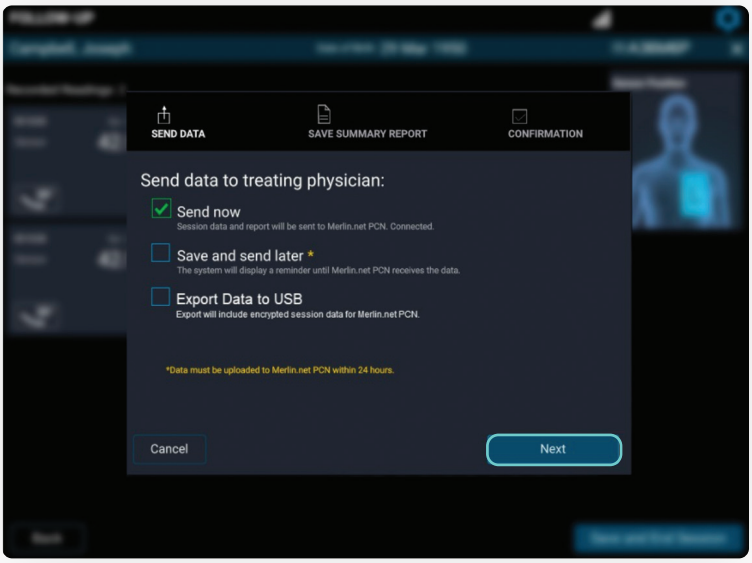


4 Review and confirm the accuracy of the captured data.

Select **Save and End Session** to transmit the data, or save for future upload.

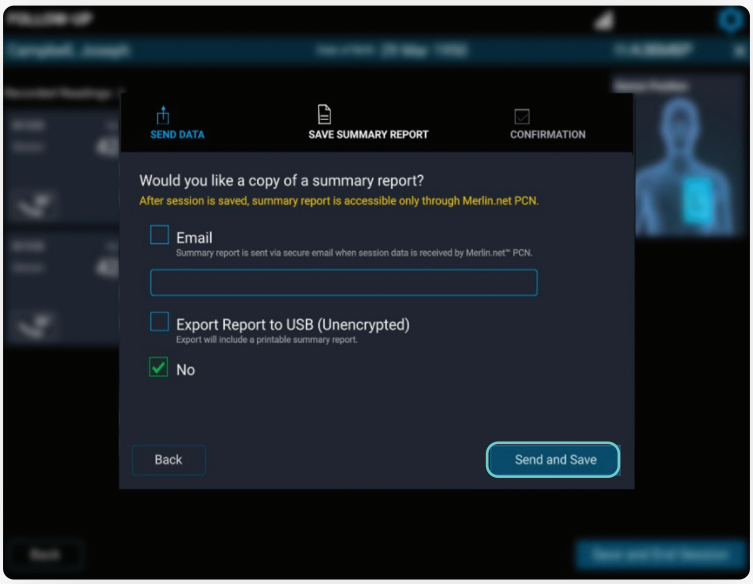


5 Select from the on-screen options to send, save or export the data, then select **Next**.



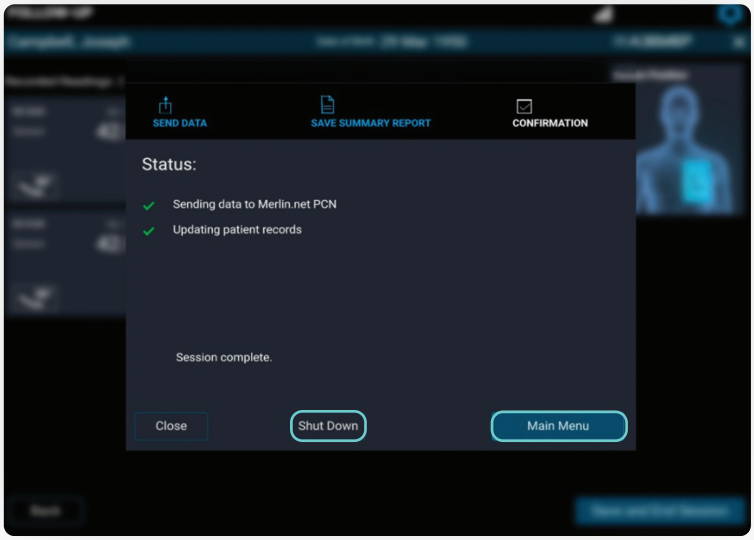
6 If needed, the summary report may be emailed or exported to the USB. Otherwise, select **No** and then select **Send and Save**.

Note: The summary report can always be obtained later on from the Merlin.net™ PCN.



7 The transfer status and "Session complete" message will be displayed. Select **Shut Down** or **Main Menu**.

Do not unplug the system until it is completely powered down.



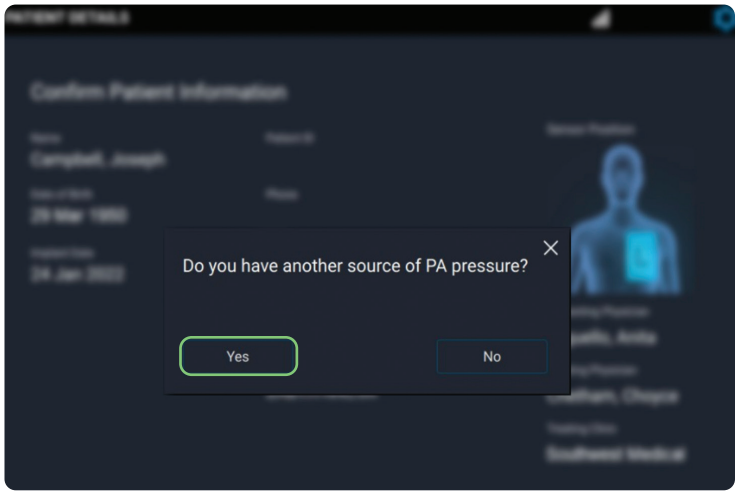
SENSOR ACCURACY CHECK AND RECALIBRATION

TO CONFIRM THE ACCURACY OF A CARDIOMEMS™ PA SENSOR'S CALIBRATION

- An alternate source of PA pressure (e.g., PA Catheter) is required.
- The system will prompt taking one pressure reading to confirm accuracy.
- After the confirmation reading, recalibration may be completed if necessary.

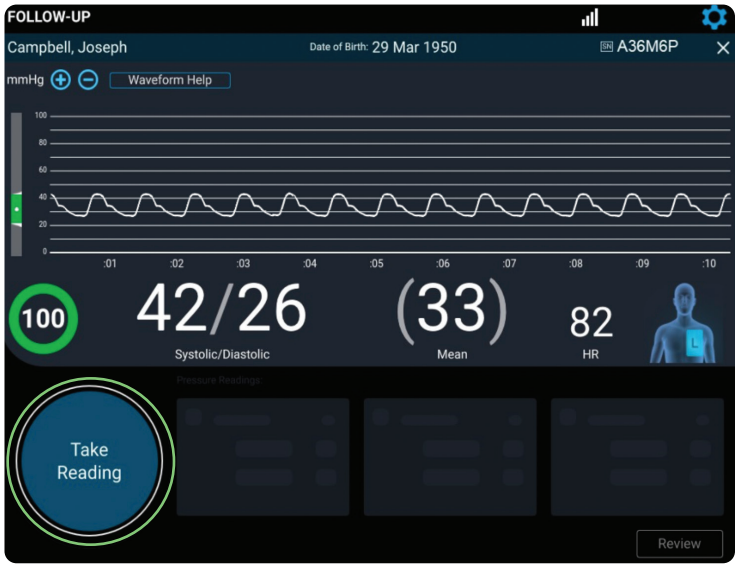
TAKE A CONFIRMATION READING

1 During a follow-up reading, when the system asks, "Do you have another source of PA pressure?" select **Yes**.



2 Obtain 10 seconds of valid pressure waveform and then select **Take Reading**.

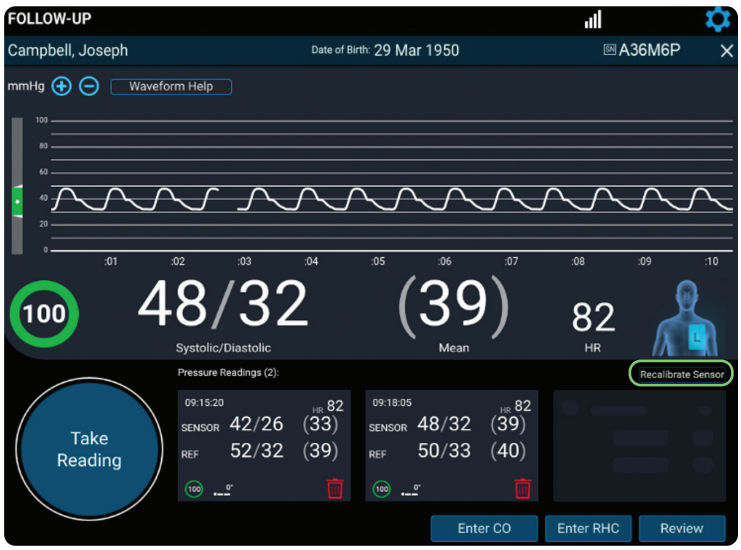
Coordinate to record the pressures from the PA Catheter at the same time **Take Reading** is pressed.



3 Enter systolic, diastolic and mean from the PA Catheter. Next, select the patient position. Then, select **Save**.

CONFIRM AND RECALIBRATE IF NECESSARY

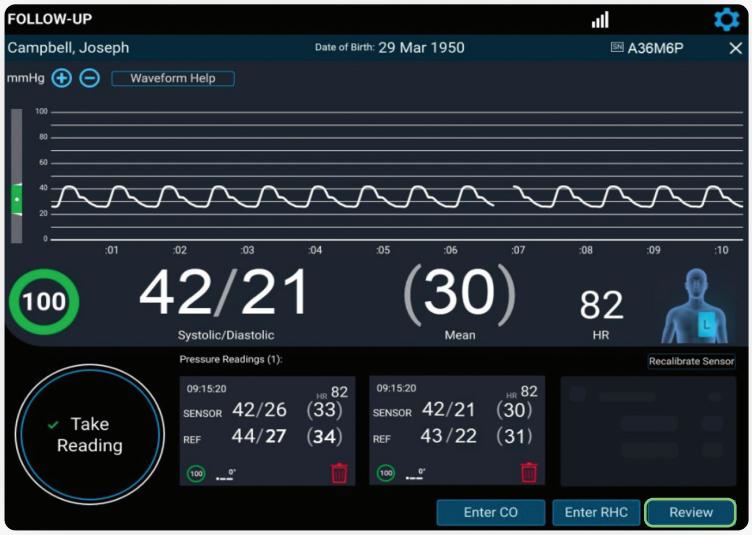
1 Verify that each sensor reading correlates to the readings from the PA Catheter.



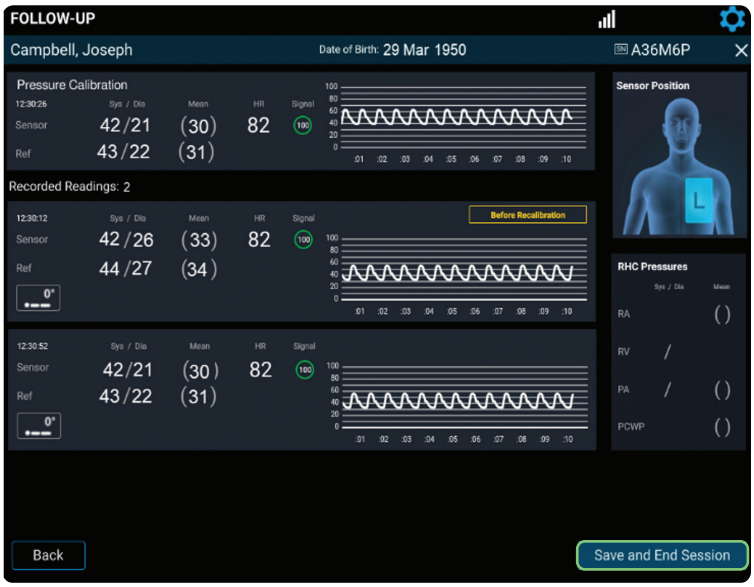
2 If the readings do not correlate to your satisfaction, recalibrate the sensor.

- Consider obtaining PA pressures during end expiration.
- Enter the PA Catheter mean pressure, select the recalibrating physician and then select **Save**.

3 Once recalibration is complete and additional readings are obtained, select **Review** to review for accuracy.

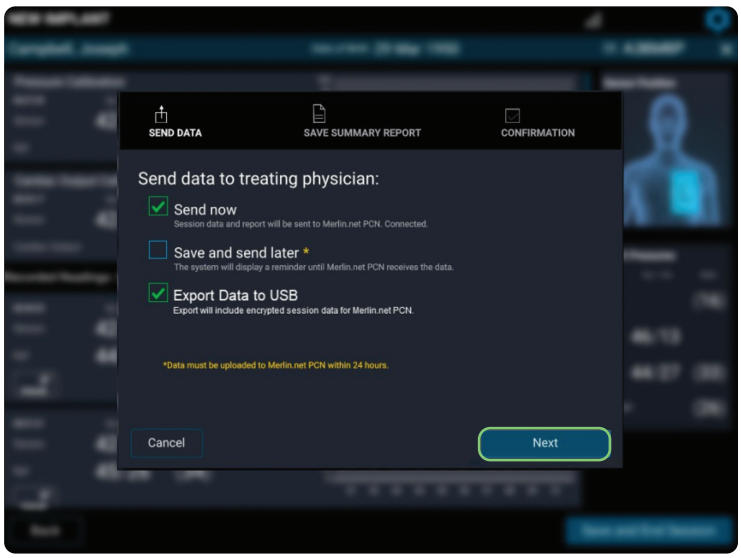


4 Select **Save and End Session**.



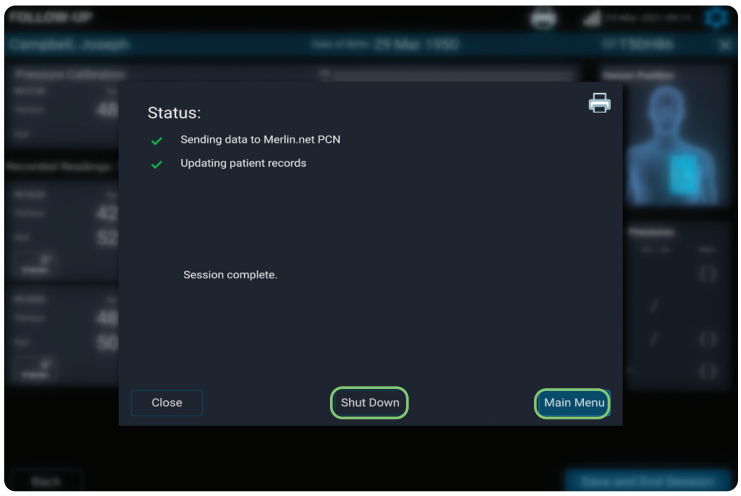
TRANSFER DATA AND SHUT DOWN

1 Select from the on-screen options to send, save or export the data, then select **Next**.



2 The transfer status and "Session complete" message will be displayed. Select **Shut Down** or **Main Menu**.

- Do not unplug the system until it is completely powered down.
- Pre- and post-calibration readings will be available in the summary report and on the Merlin.net™ PCN.



TECHNICAL SUPPORT

1-844-692-6367

FOR MORE INFORMATION ON THE CARDIOMEMS™ HF SYSTEM, VISIT

Cardiovascular.Abbott/CardioMEMS

Abbott
6101 Stoneridge Dr., Pleasanton, CA 94588 USA, Tel: 1 925 847 8600
Cardiovascular.Abbott/CardioMEMS

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.

CardioMEMS™ HF System Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.

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

CardioMEMS™ HF System Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: air embolism, allergic reaction, infection, delayed wound healing, arrhythmias, bleeding, hemoptysis, hematoma, nausea, cerebrovascular accident, thrombus, cardiovascular injury, myocardial infarction, death, embolization, thermal burn, cardiac perforation, pneumothorax, thoracic duct injury and hemothorax.

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