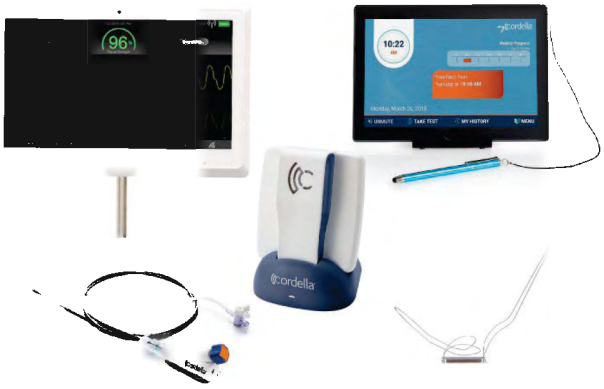
Cordella™ Pulmonary Artery Sensor System

Instructions for Use

Rx Only

Exclusively for clinical investigations in Europe.



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1. Introduction

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT), as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations. The Cordella PA Sensor System is for trend-based monitoring. The Cordella PA Sensor System is not intended for emergency use or real-time monitoring. It is designed to be used with the Cordella™ Heart Failure System (Cordella System) to better connect healthcare professionals and patients with tools for comprehensive heart failure management. The Cordella System consists of the patient-facing myCordella Kit and the clinic-facing myCordella™ Patient Management Portal (PMP).

The Cordella PA Sensor is an implantable blood pressure monitor that permanently resides in the patient's right pulmonary artery. With this Cordella Sensor, PA pressure can be wirelessly measured from the patient's home on demand. Active management of a patient using the Cordella Sensor and the other peripherals of the myCordella Kit may improve long-term outcomes in patients with New York Heart Association (NYHA) Class III heart failure.

1.1 Intended Use

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT), as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

1.2 Contraindications

The Cordella Pulmonary Artery Sensor System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

1.3 Clinical Considerations for Patient Selection

The following patients may not be appropriate for implantation of the Cordella PA Sensor System:

- Patients with an active infection
- Patients with a history of recurrent pulmonary embolism (≥2 episodes within 5 years) and/or recent deep vein thrombosis (within the past 3 months)
- Patients with known coagulation disorders
- Patients with a hypersensitivity or allergy to platelet aggregation inhibitors including aspirin, clopidogrel, prasugrel, and ticagrelor
- Patients with a known history of life threatening allergy to contrast dye
- Patients unable to tolerate a right heart catheterization
- Patients with a Glomerular Filtration Rate (GFR) <25 ml/min or who are on chronic renal dialysis
- Patients who have been implanted with a Cardiac Resynchronization Device (CRT)-Pacemaker (CRT-P) or CRT-Defibrillator (CRT-D) within the past 3 months.

2. Device Descriptions

2.1 Cordella™ Pulmonary Artery Sensor System

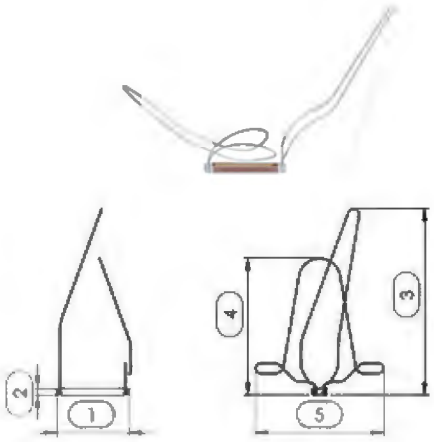
The Cordella Pulmonary Artery Sensor System is designed for on-demand measurement of pulmonary artery pressure from the patient's home.

The system includes:

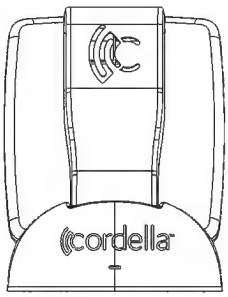
- A catheter-based Delivery System with a pre-loaded Cordella Sensor for implant in the pulmonary artery
- Calibration Equipment (CalEQ) for collecting relevant calibration information during implantation
- myCordella Handheld Patient Reader for patient use to measure PA pressure in the home, which communicates wirelessly to the myCordella Tablet
- Cordella Data Analysis Platform (CDAP) for cloud-based storage and analysis of home PA pressure readings (not pictured)

Cordella™ PA Sensor

The Cordella Sensor is a small implant that resides permanently in the patient's right pulmonary artery. The Cordella Sensor does not contain batteries or active electrical components. The Cordella Sensor is not made with natural rubber latex.

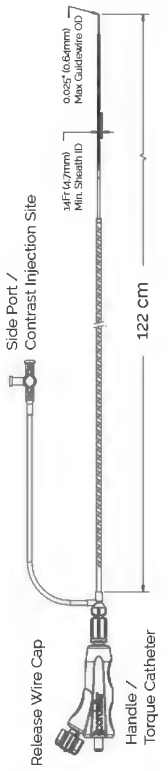


1	19.3mm
2	1.9mm
3	55.0mm
4	38.0mm
5	33.0mm
6	3.8mm



myCordella Handheld Patient Reader

The myCordella Handheld Patient Reader (Reader) is a handheld device that is provided to the patient for at-home use to measure PA pressure on demand. The Reader wirelessly transmits the raw data obtained from the Cordella Sensor to the myCordella Tablet. The raw data is converted into readable data and sent to the myCordella Patient Management Portal for the clinician to review.



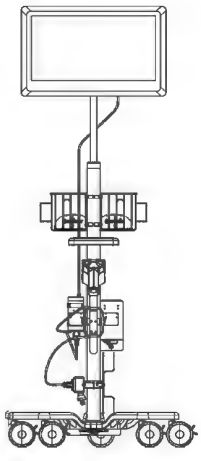
Delivery System

The Delivery System is a catheter with a pre-loaded Cordella Sensor at the distal end and is used to implant the Cordella Sensor into the right pulmonary artery. The Delivery System comprises a stability sheath, torque catheter, handle, torque luer, and side port. Implantation of the Cordella Sensor using the Delivery System is designed to be performed during right heart catheterization through venous access. The Stability Sheath contains a marker band at the distal end to aid in visualization under fluoroscopy. The Delivery System is not made with natural rubber latex.

Calibration Equipment

The Calibration Equipment (CalEQ) is hospital equipment that supports the implantation procedure. The main functions of Calibration Equipment include:

- Interrogates the Cordella Sensor to verify proper working condition.
- Facilitates linking of component serial numbers to patient IDs.
- Calibrates the Cordella Sensor to a reference pressure at the time of implantation.
- Trains patient on optimal Reader placement post-procedure.
- Recalibrates the Cordella Sensor to a reference pressure post-implant.
- CalEQ is operated by Endotronix personnel only.



Cordella Data Analysis Platform (CDAP)

The Cordella Data Analysis Platform (CDAP) is a secure, cloud-based, standalone application that collects and stores raw Reader data and processes it according to pre-defined algorithms to convert it into final-form pulmonary artery pressure data.

2.2 Cordella™ System

myCordella™ Patient Management Portal (PMP)

A web-based application that displays patient data received from the myCordella Tablet to the clinician. The PMP is intended to assist clinicians in managing patients.

myCordella™ Tablet

An intuitive, user-friendly display screen that assists patients with obtaining vital sign measurements.

- Collects & securely transmits daily health information to clinicians
- Facilitates review of past measurements
- Allows secure communication between patient and clinician

myCordella™ Patient Kit*

- myCordella Tablet
- Weight Scale
- Blood Pressure Monitor
- Pulse Oximeter
- myCordella Tablet Stand
- myCordella Carrying Case
- Stylus
- myCordella Patient Manual
- myCordella Quick Start Guide

*The set of components may be labeled as a system pack; however in this document it will be referred to as a patient kit.

2.3 Recommended Accessories

Cordella Pulmonary Artery Sensor System is recommended for use with the accessories listed in the following table. These accessories are not included in the Cordella Sensor and Delivery System packaging.

Item	Specifications
14F Introducer Sheath	Cook performer introducer, Item No. G08024 RCF 14.0-38J-14F - 13cm length
PA Catheter	Pulmonary artery catheter
Procedural Guidewire (for inserting the Delivery System)	Cook Extra Stiff Amplatz Guidewire, Hi-Torque Steelcore 18, Hi-Torque Steelcore 18LT, (260-300 cm; straight-tip; 0.025" or 0.018")
Guidewire for troubleshooting PA position, if necessary	Optional guidewire per operator's preference. Wires that are steerable or have a shaped or shapeable tip may facilitate gaining distal vessel access.
Guide Catheter	Guide catheter with marker bands per operator's preference compatible with power injection systems

Additionally, the following catheter lab equipment and supplies are required during Cordella Sensor implantation. They are the same items typically used during right heart catheterization procedures.

- Fluoroscope with digital angiography capabilities and ability to record and recall images
- Fluid-filled or electrical blood pressure monitoring equipment to obtain PA pressure measurement during right heart catheterization
- Hand injector and radiopaque contrast media for visualization.
- Power injector for angiograms
- Patient Monitor
- Hemodynamic module

3. Safety Information

Before use of the Cordella Pulmonary Artery Sensor System, thoroughly read and understand the instructions for use to avoid potential injury or death.

Warnings	Warnings indicate the potential for serious adverse reactions or safety hazards, and limitations in use imposed by them.
Precautions	Precautions indicate special care that should be taken to ensure safe and effective use of the device.

3.1 Warnings: Implantation Procedure

- Only trained personnel should use the Cordella Pulmonary Artery Sensor System.
- The implant procedure must be performed by trained clinical personnel with the appropriate interventional and endovascular skills, including but not limited to implantable device placement and deployment over a guidewire and in a location with the infrastructure to support right heart catheterizations.
- DO NOT reuse, reprocess, or re-sterilize the Cordella Sensor and Delivery System. The Cordella Sensor and Delivery System are for single use only. Any reuse, reprocessing, or re-sterilization may influence the structural integrity of the components of the device and could lead to transmission of infectious diseases, other types of infections from one patient to another, as well as many other serious adverse events including but not limited to injury, illness, or death of the patient.
- Use only the cables and accessories provided. The use of accessories, transducers, or cables other than those specified, with the exception of transducers and cables provided as replacement parts, may result in increased emissions, decreased immunity of the system, inaccurate readings, damage to the system, injury to user, or improper operation.

Warnings: Implantation Procedure (Cont.)

- Fluoroscopy is required to perform the implant procedure in order to visualize the target vasculature and to ensure proper device placement.
- The operator should be cautious not to dislodge or damage previously implanted medical devices including pacemaker and/or implanted cardiac defibrillator leads.
- Cordella Sensor should be placed into the patient's right pulmonary artery with diameter ≥12 mm and ≤26 mm at the right pulmonary artery downturn. Sensor placement in <12 mm vessel may result in vessel injury and Sensor placement in >26 mm vessel or Sensor placement outside of the right pulmonary artery downturn may result in Sensor instability.
- As much as possible, avoid contacting the Cordella Sensor with any subsequent catheters or wires. When contact is unavoidable (e.g. during Delivery System withdrawal), take care to avoid disrupting the Cordella Sensor.
- Excessively forceful movements of the Delivery System may result in vessel injury or perforation. DO NOT advance Delivery System if excessive resistance is felt.
- DO NOT advance or retract the Delivery System without a guidewire in place.
- Following device implantation, all future right heart catheterizations (RHCs) will require fluoroscopy to reduce the likelihood of catheter or guidewire contact with the Cordella Sensor. Future RHC should be done via left pulmonary artery.
- DO NOT pull the release wires prior to intended deployment. Any strain on the release wires may loosen the Cordella Sensor tie down mechanism.
- DO NOT mishandle the Delivery System or use it if the packaging or any components are not sterile, have been opened or are damaged (i.e. kinked or stretched), or the expiration date has elapsed. DO NOT attempt to repair a damaged Delivery System. Replace it with another Delivery System from inventory and return the device to Endotronix through the RMA process (see Section 14).

Warnings: Implantation Procedure (Cont.)

- DO NOT attempt to modify, disassemble, or otherwise alter the Cordella Pulmonary Artery Sensor System.
- A continuous heparin drip should be used to prevent clotting. The ACT should be at least 200 sec from the time of Delivery System insertion until the Stability Sheath is removed.
- DO NOT expose the Cordella Sensor to therapeutic levels of ultrasonic energy.
- After the procedure, it is critical for the patient to adhere to prescribed anticoagulation, antiplatelet, and other medications from the physician.
- DO NOT use an automated power injector through the Stability Sheath.
- DO NOT insert the Cordella Sensor by pushing the Delivery System without supporting the Cordella Sensor from behind as this may result in damage to the device.
- If gripping the Cordella Sensor is necessary, grab only by the sides and not the top surface as this may cause Sensor damage.

3.2 Warnings: Reader and Docking Station

- The Reader is suitable for home healthcare environments and professional healthcare facilities except near active heart failure hospital equipment and the radiofrequency (RF) shielded room of a medical electrical (ME) system for magnetic resonance imaging, where the intensity of electromagnetic (EM) disturbance is high.
- The Reader and Docking Station should not be used adjacent to or stacked with other equipment. If it is necessary to operate the components adjacent to or stacked with other equipment, verify that the system is operating normally in the configuration in which it will be used.
- DO NOT expose any power accessories, the Reader, or the Docking Station to food or liquids.
- DO NOT use myCordella in the presence of explosive or flammable anesthetic agents.
- Power cables may pose a tripping hazard. Be mindful of cords crossing walkways.
- DO NOT position power cables in any manner that may cause entanglement or strangulation.
- Other equipment generating electromagnetic fields may interfere with the Reader. When possible, avoid using the Reader while simultaneously using other equipment such as: patient monitoring systems, chest ECG leads, motors on motorized beds, pagers, RFID tags, laptop computers, tablets, cell phones, cordless phones, wireless routers, continuous glucose monitors on the right arm, air conditioners within ~5 feet (1.5m), UHF RFID tags within ~2 feet (0.6m), and RFID equipment operating at 2.45 GHz within ~4 feet (1.2m).
- The Reader requires special precautions regarding electromagnetic compatibility (EMC) and needs to be placed into service according to the EMC information provided. If interference is noted while taking a reading (e.g. if CalEQ and Reader continue to disconnect), remove or stop using the interfering equipment.

Warnings: Reader and Docking Station (Cont.)

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than ~5 feet (1.5 m) from any part of the Reader. Otherwise, degradation of the performance of the Reader could result.
- The patient should not have necklaces, jewelry, shirt pocket contents, metal objects, and near field communication objects in the vicinity of the reading location while taking a reading.
- If the skin becomes red, warm, or irritated, immediately stop using the Reader and contact Customer Service.
- DO NOT use more than one Reader in the same general vicinity at one time, as use of multiple Readers at once may cause them to interfere with each other.
- To ensure accuracy, the Sensor must be recalibrated approximately every three years using a RHC procedure.

3.3 Warnings: Calibration Equipment

- CalEQ must be operated by trained Endotronix personnel only.
- The CalEQ is suitable for professional healthcare facilities except for near active heart failure hospital equipment and the radiofrequency (RF) shielded room of a medical electrical (ME) system for magnetic resonance imaging, where the intensity of electromagnetic (EMI) disturbance is high.
- The CalEQ should not be used adjacent to or stacked with other equipment. If it is necessary to operate the components adjacent to or stacked with other equipment, verify that the system is operating normally in the configuration in which it will be used.
- Portable RF communications equipment (including components such as antenna cables and external antennas) should be used no closer than ~5 feet (1.5m) from any part of the CalEQ. Otherwise, degradation of the performance of the CalEQ could result.
- Only use CalEQ accessories, cables, and/or components that have been supplied by Endotronix. Using other unlabeled accessories, cables, and/or components may affect patient safety and measurement accuracy.
- The CalEQ should not be used to obtain pulmonary artery pressure and/or pulmonary artery pressure derived parameters for diagnostic purposes.
- Only connect CalEQ to 60601-1 compliant patient monitors. Using non-compliant patient monitors may affect patient safety and measurement accuracy.
- To avoid risk of electric shock, the CalEQ must only be connected to a supply main with protective earth.
- DO NOT plug additional devices into the CalEQ power strip.

3.4 Precautions

- Only use the side-port of the Stability Sheath for injection and aspiration. The guidewire lumen should not be used for aspiration or injection after initial flushing.
- The implant procedure is an adjunct to a standard (RHC) procedure. All standard protocols for the RHC should be followed.
- Explanting the Cordella Sensor after implantation is not recommended.
- If there is evidence of a change in device performance, please contact Customer Service.
- The Cordella Sensor and Delivery System are only compatible with a 14 French introducer or larger. Use of a smaller introducer may damage the Cordella Sensor or Delivery System product and may prevent introduction. The use of peel away introducers is not recommended.
- Torquing the Stability Sheath with the Torque Catheter removed may result in kinking of the Stability Sheath and may impact the reliability of a fluid-filled pressure measurement.
- Precaution should be taken to avoid damage to the Cordella Sensor prior to implantation. It is an all-glass enclosure and it is fragile. Only remove from packaging when ready to start a procedure. Take care to avoid shock or drop to the distal end of the Delivery System where the Cordella Sensor is pre-mounted. Care should be taken to limit contact with the Cordella Sensor prior to insertion through the introducer sheath.
- Avoid squeezing or pinching the body of the Cordella Sensor if at all possible.
- DO NOT place more than one Cordella Sensor in a patient. The two Cordella Sensors may interfere with each other and limit the ability to obtain accurate readings.
- Activities that may expose the patient to ambient pressure extremes may affect device performance. If the patient plans to SCUBA dive, please contact Customer Service.

Precautions (Cont.)

- Accuracy of the Cordella Pulmonary Artery Sensor System is slightly affected by large changes in elevation between the initial baseline calibration and subsequent measurements. Readings may lose accuracy when taken at >2000m of elevation. If a patient plans to travel or move to a location at >2000m of elevation, contact Customer Service.
- The CalEQ should not be used in the sterile field.
- DO NOT expose any components of myCordella to water or liquids. Contact Customer Service for a replacement if any components are exposed to liquids.
- DO NOT drop the Reader. Handle with care.
- If dropped, the Reader battery may be exposed. If the battery is exposed, contact Endotronix immediately for a replacement Reader. Any damage to the Reader may result in an inaccurate reading.
- DO NOT use the Reader if the plastic casing has been damaged or any component becomes dislodged.
- If the Reader label becomes compromised, contact Endotronix Customer Service
- CalEQ and the Reader contain a Lithium-ion battery.
- LVAD and Continuous Glucose Monitor compatibility with the Cordella System has not been assessed.
- Improper or rapid removal of the Delivery System may cause vessel damage.

3.5 Potential Adverse Events

Potential risks associated with the overall procedure include potential access complications associated with standard right heart catheterization, the potential risks of conscious sedation, and the use of angiography:

- Allergic reaction
- Arrhythmias
- Bleeding complications (which may require transfusion)
- Cardiac arrest
- Chest pain
- Death
- Device embolization/migration
- Device explant
- Emergent or urgent cardiac, vascular, and/or other surgery necessitated by the device or implant procedure (e.g., coronary sinus lead revision)
- Endocarditis or device infection
- Entry site complications (e.g., hematoma, dissection)
- Fracture of a component of the device/system that may or may not lead to serious injury or surgical intervention.
- Gastrointestinal bleed
- Hemoptysis
- Hypo or hypertension
- Infection or fever
- Lead dislodgement
- Peripheral embolism/thrombus
- Pulmonary embolism/pulmonary occlusion
- Pseudoaneurysm of the vein
- Radiation exposure
- Reaction to contrast media/medication
- Renal insufficiency or failure
- Respiratory distress or failure (breathing problems)
- Right atrial/ventricular and coronary sinus lead dislodgement
- Sepsis
- Valvular injury (tricuspid and/or pulmonary)
- Vascular complications (e.g., venous dissection, perforation, rupture, arteriovenous fistula,)
- Vessel trauma which may require surgical repair
- Worsening heart failure

3.6 MRI Safety Information

MRI simulations and non-clinical testing determined that the Cordella Pulmonary Artery Pressure Sensor is MR Conditional. A patient with the Cordella Pulmonary Artery Pressure Sensor may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MR Conditional

Parameter	Condition of Use/ Information
Nominal Values of Static Magnetic Field (T)	1.5-Tesla or 3.0-Tesla
Static Magnetic Field Orientation	Horizontal
Maximum Spatial Field Gradient T/m and gauss/cm)	40-T/m (4000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	There are no transmit RF coil restrictions
Receive RF Coil Information	There are no receive RF coil restrictions
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR (W/kg)	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 30 minutes of continuous RF exposure with a 5 min. cool down period before the next session
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

Under the scan conditions defined, the Cordella Sensor is expected to produce a maximum temperature rise of 5°C after 15 minutes of continuous scanning. If defined MRI conditions are not followed, there is increased risk of additional heating or movement of the Cordella Sensor or of damage to the Cordella Sensor.

Selecting the optimal MR imaging parameters may be necessary if the goal is to image close to the Cordella Sensor. In non-clinical testing, the image artefact caused by the Cordella Sensor extends approximately 6 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

NOTE: It is important that the patient understands they should inform clinical staff who will be performing an MRI scan that the patient has an implanted Cordella Sensor and to refer to these guidelines. The MR Conditional symbol is on the patient's implant card, which should be given to the patient after the implant and be carried with them at all times.
The Cordella Sensor is safe to use with ultrasound imaging, but DO NOT expose to therapeutic levels of ultrasonic energy.

Contact Customer Service for current MR Conditional labeling and the most up-to-date instructions for this device in the MR environment.

3.7 Sterilization

The Delivery System package contents have been sterilized with ethylene oxide before shipment. The system is for single use and is not intended to be re-sterilized. If the sterile package has been compromised or the expiration date has been reached, replace it with another Delivery System from inventory and contact Customer Service.

4. Instructions for Use

Implanting physicians are required to have completed the Cordella Pulmonary Artery Sensor System training, which includes didactic and clinical education material. CalEQ must be operated by trained Endotronix personnel.

Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

4.1 Pre-Procedure Preparation

1. Within the myCordella Patient Management Portal on a separate computer, download and print the patient's QR Barcode Report through the Download Wizard in the patient's chart (for detailed instructions, see the myCordella Patient Management Portal Clinician Manual: PA Pressure).

2. Before the procedure, transport the CalEQ and Delivery System unit box, including a backup Delivery System, to the catheterization lab (see Section 7 Transport). Ensure the CalEQ includes the Interconnect Cable (if applicable). Unpack and fully charge two Readers and place them on the CalEQ Docking Stations. If possible, keep CalEQ plugged in for the duration of the procedure. If you will be operating CalEQ using battery power, ensure that the CalEQ and Readers are fully charged and turned off before the start of procedures for the day (i.e. the Docking Station LED should be solid white). See Section 10 Reader Audio & Visual Cues.

3. Plug in the CalEQ power strip to an easily accessible outlet. Ensure the Readers are in the Docking Stations and the Docking Stations are plugged into the power strip. Always keep Readers docked when not in use. The light on the Docking Station will blink while charging and change to solid when the Reader is fully charged.

To turn a Reader on, press and hold the power button for several seconds. DO NOT use excessive force when pressing the power button to avoid potential damage to the device.

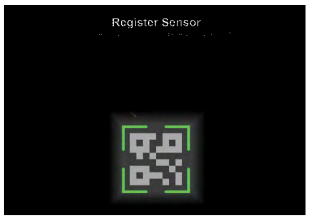
4. Turn on the CalEQ by pressing the power button on the bottom of the monitor and sign in as the CalEQ user.

5. To calculate reference pressure parameters necessary for calibration, the CalEQ may use hemodynamic data obtained from the analog output of the hospital's hemodynamic module. Follow the steps below to confirm proper set-up with the monitor. If an Interconnect Cable is not provided with CalEQ, calibration will be based on manually entered reference pressure values rather than hemodynamic data fed from the monitor.

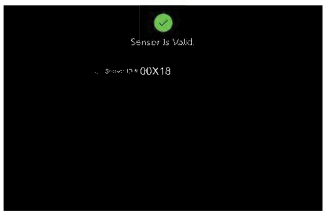
- The cable input is located on the rear of the stand. The Interconnect Cable's BNC connector should remain attached to the cable input on the CalEQ. Connect the other end of the Interconnect Cable to the hemodynamic module's analog output. This will provide a pulmonary artery pressure measure to the CalEQ for calibration measurements. For compatible Interconnect Cables, see the Calibration Equipment Operator's Manual.

- The analog invasive blood pressure signal from the hemodynamic module must be configured to the industry standard of 1V/100mmHg and 0V=0mmHg to be compatible with the CalEQ. For more information on configuring the hemodynamic module, contact Customer Service or review the operating instructions provided by the manufacturer of the patient monitor.
- The CalEQ is installed and configured by Endotronix based on the hemodynamic module to be used. Please notify Customer Service if there is a change in hemodynamic module as it may impact the compatibility and accuracy of the reference pressure signal obtained by CalEQ.

4.2 Pairing and Interrogating the Cordella Sensor in Packaging

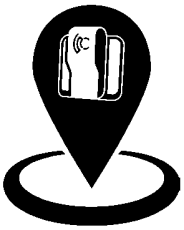


1. Press 'Calibrate.' Scan the QR code on the Delivery System unit box.

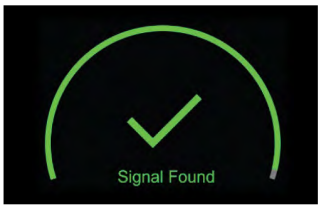


2. On the confirmation screen, ensure there is a green checkmark on the screen. Press the "Next" button if the information matches.

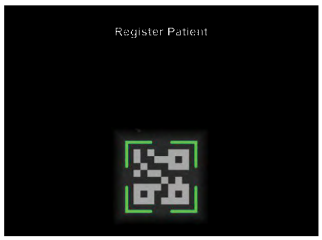
3. Undock the Reader when prompted. While searching for the Sensor, the Reader will display a solid blue light and will beep twice every few seconds.



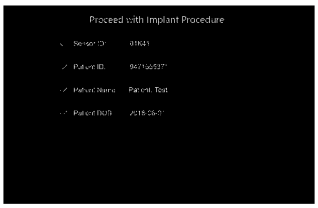
4. Position the Reader along the top of the Delivery System box near the location symbol shown here. Until a signal is found, reposition the Reader over the top and side of the box.



5. The CalEQ will search for a signal from the Sensor. If a signal cannot be found, DO NOT use the Delivery System. Repeat the procedure in Section 4.2 starting at step 1 with a new Delivery System package and contact Customer Service after the procedure.



6. When prompted to pair to the patient, scan the QR Barcode Report that was printed from the PMP. If the patient ID does not match, the PMP barcode report will need to be reprinted and rescanned.

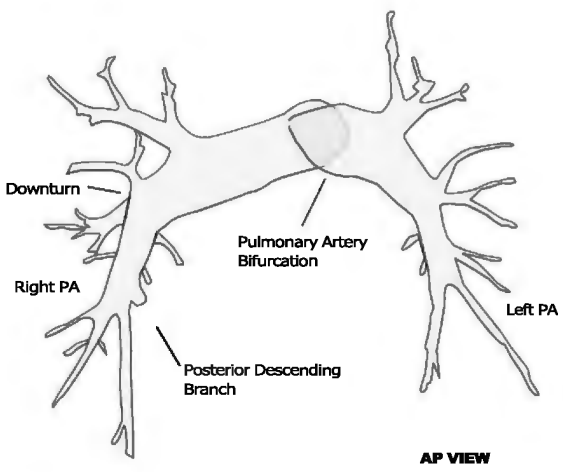


7. On the confirmation screen, ensure all Cordella Sensor and patient information is correct.

DO NOT scan visibly damaged barcodes; use a different Delivery System.

4.3 Vessel Mapping and Guidewire Placement

The Cordella Sensor is implanted in the patient's right pulmonary artery. The following image is provided for reference with useful anatomical landmarks indicated:



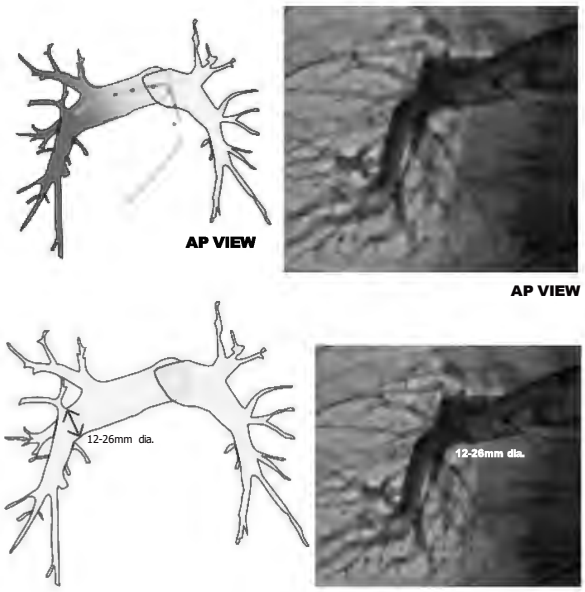
1. Set up the patient for venous access (femoral or right internal jugular) per standard protocol.

   Position ECG leads as far away from the right side of the patient's chest and side as possible. The use of limb ECG leads is recommended.

2. Gain access to the patient's vein and dilate to allow for a 14 French introducer. Perform a right heart catheterization.

3. Ensure the field of view of the right lung is centered and perform right pulmonary artery angiography in AP view and LAO-CAU 30/30 views. Use either power-injection with angiography catheters (such as pigtail or straight flush) or hand-injection with a PA catheter (or any other preferred catheters). The physician is responsible for selecting the type, amount, and concentration of contrast agent as well as the angiography settings and dose of ionizing radiation. Make sure the images visualize the RPA downturn and the posterior descending branch.

4. Assess RPA anatomy using the obtained images:

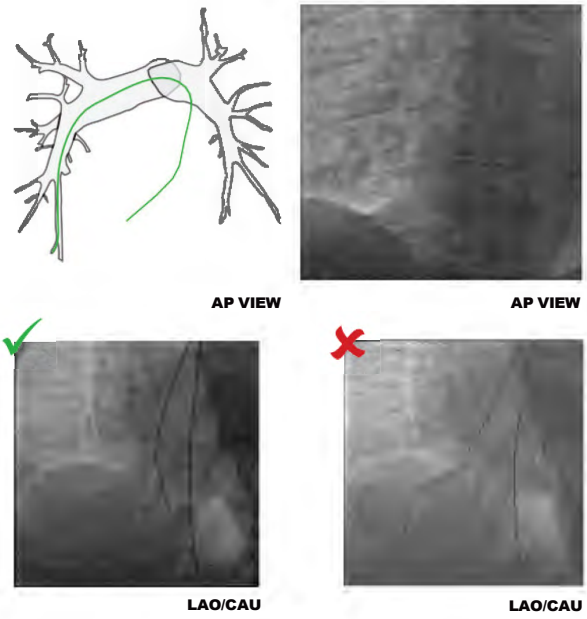


A. Use AP view to detect and measure the diameter of the downturn of the RPA (target location for the sensor). The vessel at this location must be between 12-26 mm. Quantitative Vascular Analysis (QVA) should be used if the vessel size is indeterminate. If the vessel appears to be either larger or smaller than the indicated range, abort the procedure and DO NOT implant the Cordella Sensor.

B. Use LAO-CAU view to visualize, detect and confirm the distal pathway of the posterior descending branch for the guidewire and the delivery system.

5. Introduce a guidewire (.018"-.025", 260cm-300cm) through the lumen of the catheter extending into the descending posterior branch of the right pulmonary artery. Ensure that the wire follows the following path:
   - In the AP view: Largest descending posterior vessel.
   - In the LAO/CAU (30/30) view: Largest descending posterior vessel.

   The wire should remain in this branch for 6 cm beyond the downturn.



6. Remove the catheter, leaving the guidewire in place.

> **WARNING:** Ensure that the guidewire is in the right pulmonary artery distal to the implant location and NOT in a side branch. Correct guidewire position should be confirmed in BOTH the AP and LAO/CAU 30/30 views.

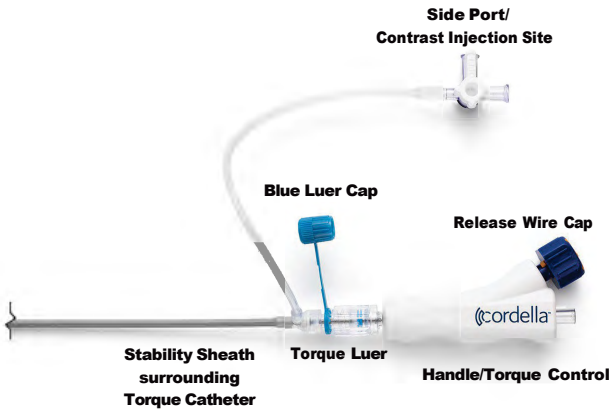
4.4 Delivery System Package Inspection

Inspect the Delivery System package carefully for any rips, tears, or other damage before opening. If the integrity of the sterile package has been compromised, or the product or package is defective, DO NOT use the product and contact Customer Service to initiate a Return Material Authorization (RMA) procedure.

The unit box contains one Cordella Sensor tied down to the distal end of the Delivery System and the product documentation.

4.5 Delivery System & Cordella Sensor Insertion

1. Remove the Delivery System from the sterile packaging and record the Sensor Serial Number in the patient's chart with the peel and stick label.
2. Inspect the entire effective length of the Delivery System carefully for any damage, including kinks, burrs, roughness, loose connections, handle rotation ability, and a correctly tied-down Sensor. The features of the Delivery System handle are labeled below:



3. The following image displays the tied-down Sensor, for reference.

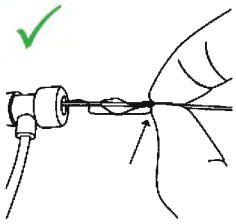
4. If the Delivery System or Cordella Sensor appears damaged or defective, DO NOT use the product and contact Customer Service to initiate an RMA procedure.

> **WARNING:** The Cordella Sensor should not be interrogated by the Reader after removal from the packaging until the Sensor is implanted.

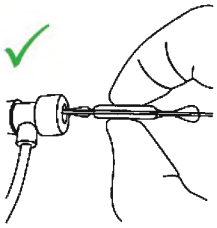
5. Remove the stylet from the distal end of the Delivery System and flush the side port and guidewire lumen with sterile saline.

6. Thread the Delivery System over the guidewire through the distal tip (front-end loading).

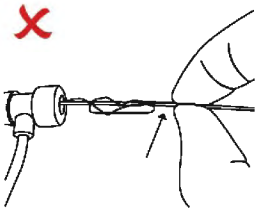
7. Grip the catheter directly behind the Cordella Sensor making contact and supporting the back end of the Sensor as shown, and gently push the Sensor through the introducer. Care should be taken to push from the back of the Cordella Sensor to minimize damage and changes to the tiedown configuration.



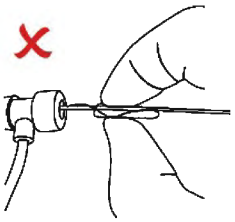
WARNING: DO NOT insert the Cordella Sensor by pushing the Delivery System without supporting the Cordella Sensor from behind as this may result in damage to the device.



WARNING: If gripping the Cordella Sensor is necessary, grab only by the sides and not the top surface as this may cause Sensor damage.



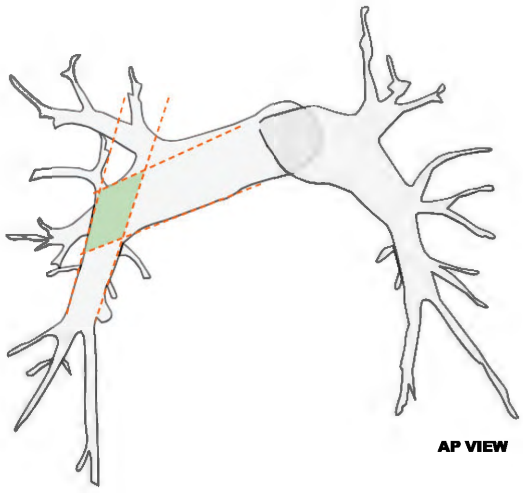
8. Slowly push the Cordella Sensor through the introducer. If severe resistance is encountered, stop pushing the Cordella Sensor and attempt to identify the source of resistance. Proceed cautiously.



9. Once inserted, the delivery system should be gently advanced using fluoroscopic guidance over a guidewire. If resistance is encountered (i.e. at heart valves or other anatomical structures), the delivery system should be rotated and/or pulled-back before being advanced further.

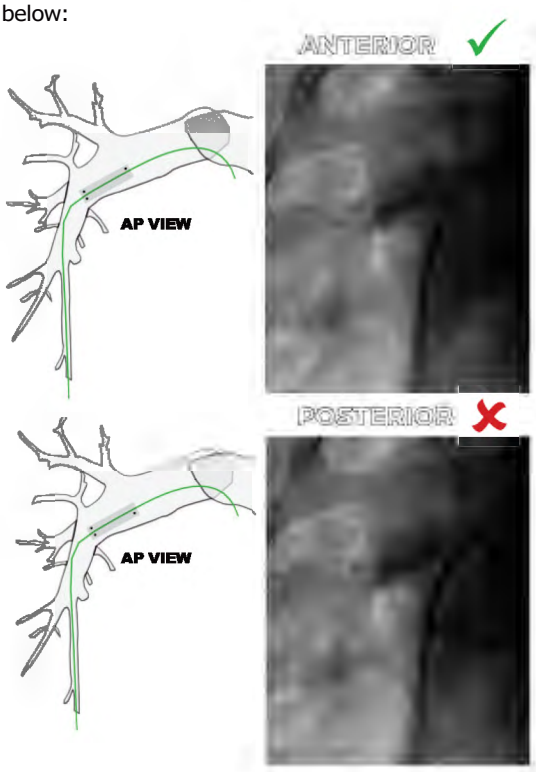
4.6 Cordella Sensor Implantation

1. The target location for the Cordella Sensor is at the downturn of the right PA (highlighted in the figure below for a representative typical PA anatomy). The location can be defined by the overlapping region of the right PA trunk and the downturn as illustrated below. The distal radiopaque marker bands on the Sensor should be within the highlighted area upon Sensor deployment. Anterior-Posterior imaging is required for proper anatomical visualization.

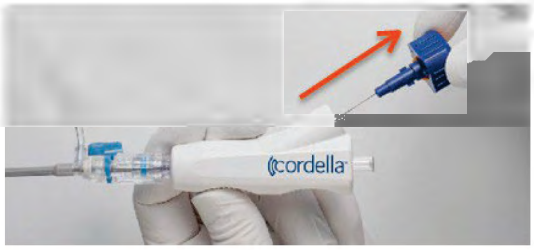


2. Advance the Cordella Sensor to the target area by gripping the handle and navigating through the heart to the right pulmonary artery.

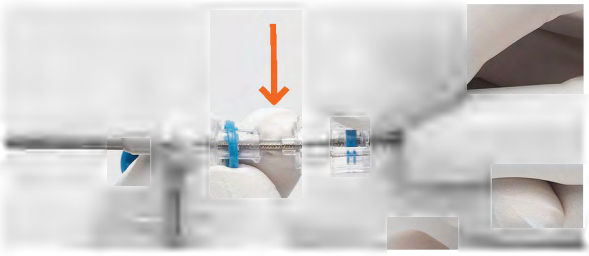
3. The Cordella Sensor has three (3) radiopaque marker bands to help identify rotational position of the Sensor. Once in the optimal position, rotate the Cordella Sensor using the handle as necessary to ensure the Sensor is anterior facing as shown below:



4. Once in target deployment position (distal end of Sensor body at RPA downturn, anterior facing), while stabilizing the handle, deploy the Cordella Sensor by rotating the release cap a quarter turn counterclockwise and slowly pulling the release wire cap parallel to the Delivery System, then fully removing the release wires. Release wire cap and wires should be discarded.



5. Once the Cordella Sensor is deployed, under fluoroscopic guidance, retract the guidewire into the Torque Catheter and gently withdraw the Delivery System and guidewire together approximately 2 cm away from the deployed Sensor. Assure that the Torque Catheter is not engaging with the Sensor. If this occurs, stop retraction immediately and rotate Torque Catheter before reattempting withdrawal of the sheath and catheter.
6. Unscrew the torque luer to disconnect. Hold the handle in a stable position within the palm of the hand.



7. While visualizing under fluoroscopy, gently and slowly withdraw the Torque Catheter past the Cordella Sensor, making sure not to disturb the Cordella Sensor location. Leave the Stability Sheath in place proximal to the newly deployed Cordella Sensor. Ensure that the Stability Sheath is not engaging with the Sensor.

> **WARNING:** If the Torque Catheter engages the Cordella Sensor, stop withdrawing the Torque Catheter, rotate approximately 90 degrees and resume slow, gentle retraction until clear of the Cordella Sensor.

8. Screw the tethered blue luer cap onto the Stability Sheath hub to prevent back-bleeding through the hemostasis valve.
9. Use the Stability Sheath as a fluid-filled column to obtain a reference pressure by attaching the side port to the pressure transducer, making sure to:
   - Adjust the pressure transducer height to mid-axillary height
   - Flush the catheter and fluid line to ensure there are no air bubbles

- Zero the measurement
- Check that the catheter tip is positioned within the PA and that the catheter does not cross the Sensor.

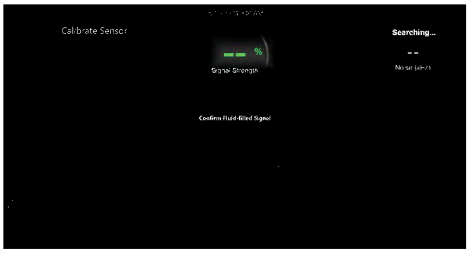
WARNING: Avoid torquing the Stability Sheath when used as a fluid-filled column. Torquing can result in kinks which inhibit accurate reference pressure measurements for Sensor calibration.

4.7 Calibrating the Sensor

NOTE: During Reader operation, electromagnetic interference (EMI) generating equipment may need to be temporarily moved away from the Reader's zone of operation. This may include temporarily repositioning other medical equipment such as any ECG leads, or patient monitoring systems, as well as other non-medical equipment such as pagers away from the Reader.

WARNING: DO NOT USE the Reader near radio transmitters such as Walkie Talkies or intercom systems.

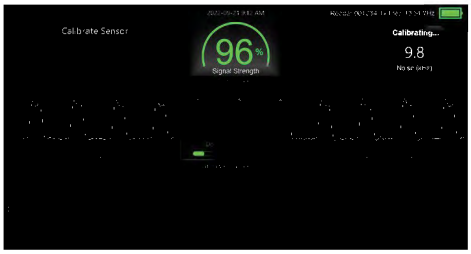
1. With the catheter placed and the Interconnect Cable connected to the patient monitor, the CalEQ will immediately display the fluid-filled reference pressure signal. Skip this step if the CalEQ is not set up to accept hemodynamic data fed from the hemodynamic module. Compare the fluid-filled reference pressure signal on CalEQ with that on the hemodynamic module. Press "Continue" button if signal is correctly displayed.



2. Undock the Reader when prompted. CalEQ will show the live, uncalibrated waveform of the Cordella Sensor. Adjust the position of the Reader over the patient's chest until the signal strength percentage is as high as possible (>80%). Ensure

the noise level is minimized by following the guidance and warnings regarding EMI. Once optimal signal percentage is achieved (>80%), hold the Reader still for 20 seconds and monitor the waveform until calibration automatically begins.

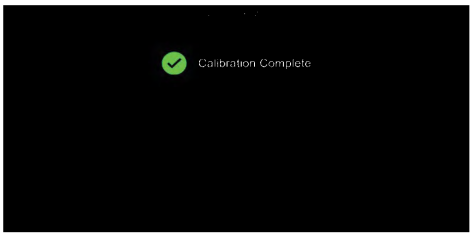
3. CalEQ will calibrate the Cordella Sensor for 18 seconds. DO NOT adjust the Reader position or patient monitor connections during this time. A progress bar displays the progress through calibration, and the live waveforms will be paused.



4. When prompted, dock the Reader.
5. If reference pressures will be manually entered, the CalEQ system will prompt the user to zero the reference pressure. Enter the systolic and diastolic values from the fluid-filled pressure measurements on the patient monitor. Press the "Next" button.

6. A report containing Cordella Sensor pressures, reference pressures, a comparison between them, and the corrected waveform will appear. If the results are acceptable, press the "Accept" button. If a recalibration seems necessary for any reason, press the "Calibrate Again" button and repeat the calibration steps.

7. After the procedure, save the calibration data. If the CalEQ is connected to the network, select the "Upload to Cloud" button and wait for verification that the upload was successful. If the CalEQ is not connected to the network or otherwise cannot upload, press "Upload Later." See Section 15.3 for instructions how to upload the calibration data once connection to the network is restored.



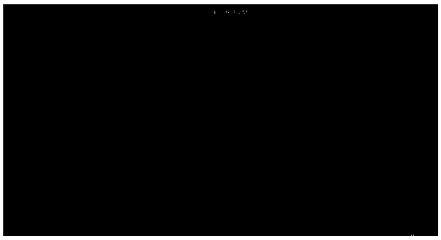
8. Remove the Stability Sheath. Close the venous access site per standard protocols.

5. Reader Training

Post-implant, patients should complete training to learn the best placement of the Reader. This training may be completed using CalEQ or the myCordella Tablet.

To initiate training using CalEQ, follow these steps:

1. From the CalEQ home screen, the user can press the "Training" button.



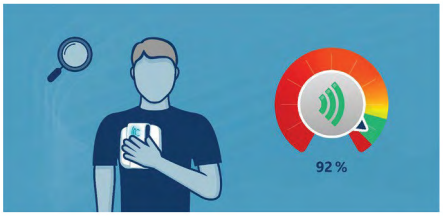
To initiate training using the myCordella Tablet, follow these steps:

1. Pair the Reader that was used for calibration to the patient in PMP. See myCordella Patient Management Portal Clinician Manual: PA Pressure for instructions.
2. Press "Refresh" on the patient's Tablet. The Reader will then be paired with the Tablet.
3. Choose the "Take Test" button and select "PA Pressure" on the Tablet.

As the patient moves the Reader around on their chest and side, the display will provide feedback on the signal strength. As signal strength changes, the pointer on the dial will move clockwise or counterclockwise and the signal symbol below will grow and shrink between one and three signal bars. The patient should be trained to consistently place the Reader in the position that maximizes the signal strength without entering the red section that indicates the Reader is too close.

When using the Tablet, a reading will begin once the Reader has reached its signal strength threshold.

When using the CalEQ, there is no limit to the number of times a patient can practice locating the optimal Reader position, as the Reader will not start taking a reading even when it has reached its signal strength threshold.



NOTE: The Reader must be disconnected from the CalEQ before it can be used with the patient's Tablet. Follow prompts on CalEQ to disconnect the Reader.

6. Recalibration

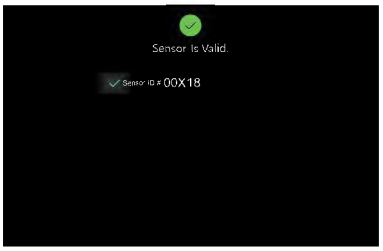
Post-implant, the Sensor may need to be recalibrated if there is anomalous PA pressure data and Endotronix Customer Service has recommended a recalibration. See Troubleshooting Section 15.4 for more information. Additionally, to ensure accuracy, the Sensor must be recalibrated approximately every three years. Recalibration is completed during a RHC procedure.

6.1 Pre-Procedure Preparation

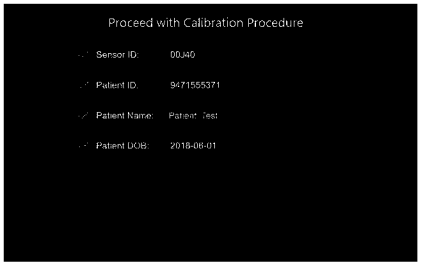
Complete the Pre-Procedure Preparation steps from Section 4.1. Contact Customer Service to obtain the Sensor QR Barcode and print.

6.2 Recalibration

1. On the CalEQ, press "Recalibrate." Scan the Sensor QR Barcode provided by Endotronix personnel. On the confirmation screen, ensure there is a green checkmark and press the "Next" button.



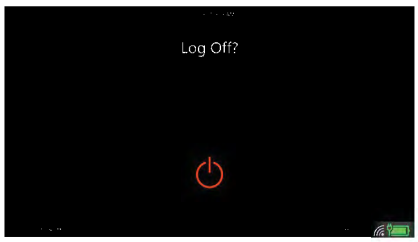
2. Scan the patient's QR Barcode Report. On the confirmation screen, ensure there is a green checkmark and press the "Next" button if the information matches.



3. Set up the patient for venous access (femoral or right internal jugular) per standard protocol. Position ECG leads as far away from the right side of the patient's chest and side as possible. Endotronix recommends limb ECG leads.
4. Gain access to the patient's vein. Advance the tip of a reference catheter into the main or left PA. Avoid advancing the catheter across the Sensor body or anchor wires in the right PA, as this may damage or disrupt stability of the Sensor. Obtain a reference pressure, making sure to:
   - Adjust the pressure transducer height to mid-axillary
   - Flush the catheter and fluid line to ensure there are no air bubbles
   - Zero the measurement
5. Follow the instructions in the Calibrating the Sensor steps (Section 4.7) to finish recalibration.

7. Transport

To transport the CalEQ, turn off the computer. To do this, press the "Menu" button (three horizontal lines), select "End Session", then select "Power Off".



Unplug the power strip and wrap up the power cord. Disconnect the Interconnect Cable from the patient monitor (if applicable). Do not disconnect the interconnect Cable from CalEQ. Wrap the Interconnect Cable around the hooks on the basket. The CalEQ computer and Docking Stations should remain plugged into the power strip.

If the button is depressed but the Reader doesn't respond, the battery is likely depleted; return the Reader to the Docking Station and allow the Reader to charge.

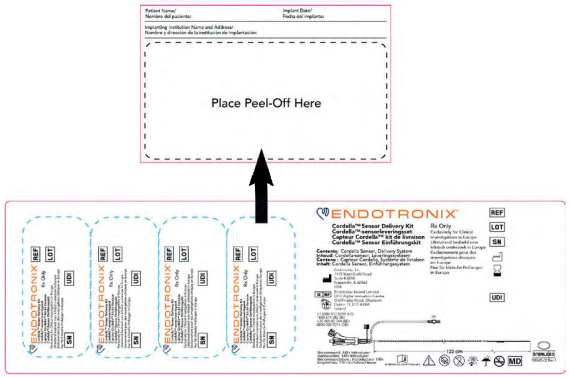
8. Peri-Procedural Anticoagulation and Antiplatelet Therapy

For patients who are not being treated with chronic anticoagulant therapy, it is recommended to use dual antiplatelet therapy with aspirin and clopidogrel, (or prasugrel, ticagrelor) for 30 days post implant. Patients who are currently on anticoagulant therapy, or those in which chronic anticoagulant therapy is indicated for HF treatment should discontinue use of anticoagulant therapy 1-2 days prior to the Cordella Sensor implant and restart treatment post-implant. An INR of <1.5 is recommended prior to Sensor implant for subjects who were previously on anticoagulant therapy. The standard of care per institutional protocol as bridge therapy to Cordella Sensor placement should be used in patients who were on anticoagulant therapy (e.g., IV heparin or low molecular weight heparin).

Post 30 days, for patients not on anticoagulant therapy, continuous antiplatelet therapy with aspirin is recommended indefinitely. It is important to resume or initiate antiplatelet or anticoagulant therapy post-implant to reduce the likelihood of thrombotic events.

9. Patient Implant Card

A patient identification card is provided. Apply one of the peel-off labels from the Delivery System box onto the card. The patient identification card should be given to the patient after implantation. Advise patients to keep this card in their possession at all times.



10. Audio & Visual Cues

Reader Audio Cues

Event	Sound	Required Action
Searching for Sensor	Several beeps increasing in speed	Reposition Reader to find stronger signal.
Sensor Located	Four quickly ascending, high pitched beeps, repeating three times	Strong signal found. Hold Reader in place.
Reading in Progress	Two quickly ascending beeps, repeating every ~3 seconds	Hold Reader in place (~18 seconds).
Successful Sensor Reading	Several quickly ascending, high pitched beeps	Measurement complete. Return Reader to Docking Station.
Failed Reading	Several slowly descending, low pitched beeps	Reposition Reader to find stronger signal.
Return to Docking Station	Successful Reading sound repeating periodically	Return to Docking Station. If Reader is there, check Docking Station visual cues.
Warmup	Several slowly ascending beeps	Return the Reader to the Docking Station to allow it to warm up.
Low Battery	Three quick, low pitched beeps, repeating every ~10 seconds	When accompanied by solid white light, return to Docking Station.
Contact Customer Service	Three quick, low pitched beeps, repeating every ~10 seconds	When accompanied by flashing purple light, call Customer Service.

Reader Visual Cues

Light	Event/Required Action
Solid Dark Blue	Searching for Sensor.
Slowly Flashing Dark Blue	Return to Docking Station.
Rapidly Flashing Dark Blue	Sensor located. Ready to begin reading.
Slowly Flashing Green	Reading in progress. Hold Reader in place until light becomes solid green.
Solid Green	Successful Sensor reading.
Rapidly Flashing White	Failed reading. Reposition Reader.
Solid White	Low battery. Return to Docking Station.
Alternating White, Blue, Dark Blue	Return the Reader to the Docking Station to allow it to warm up.
Rapidly Flashing Purple	Contact Endotronix Customer Service.
Light Off	Out of battery. Return to Docking Station.
Solid Blue	Reader is not paired to CalEQ. Reader is set up for home readings.

Docking Station Visual Cues

Light	Event/Required Action
Flashing White	The Reader is being charged.
Solid White	The Reader is fully charged and ready for use.
No Light	When the Reader is docked and no light is present, the Docking Station is not connected to a power source. Check that the Docking Station Power Cord is plugged into both Docking Station and the CalEQ power strip, the Reader is fully seated in the Dock, the Dock is sitting flush, and that the power strip is plugged into an outlet. If the light remains off, contact Customer Service.

11. Maintenance and Storage

11.1 Environmental Information

Store the Delivery System and Cordella Sensor in standard hospital storage conditions. Keep dry and out of sunlight.

The CalEQ computer, Docking Station, and backup Docking Station should remain plugged into the power strip. The power strip cord is to be used for mains disconnection. Reference the Equipment Specifications in Appendix B for specific storage conditions.

The Cordella Sensor and Delivery System are sterilized in a Tyvek pouch. Tyvek pouches are stored in unit boxes. The unit boxes containing the sterile Tyvek pouch should be stored in a clean, dry place with other sterile inventory.

Ensure all parts are clean and dry prior to storage.

11.2 Replacement and Repair

The Cordella Pulmonary Artery Sensor System does not require user maintenance and contains no user serviceable parts. If an issue with the system appears to require maintenance, contact Customer Service.

To maintain applicable warranties and function, Endotronix requires that only authorized personnel perform repairs. There are no user serviceable parts. Repairs made by unauthorized personnel will invalidate your warranty. For product warranty information, please contact Customer Service. Changes or modifications not expressly approved by Endotronix may void the user's authority to operate the system.

WARNING: DO NOT attempt to modify, disassemble, or otherwise alter any of the system components. If the system appears to be damaged, contact Endotronix Customer Service.

If there are defects or damage to any system component, including power accessories, request a

replacement from Endotronix and follow the RMA process (see Section 14) as requested by Customer Service.

Software configuration of the CalEQ can only be performed by Endotronix authorized personnel.

12. Inspection & Cleaning Instructions

Inspect the CalEQ system regularly. If any of the inspection checkpoints apply, please contact Customer Service.

Inspection Checklist

- Power cords are not frayed or connected to unauthorized equipment. If there is a frayed power cord or if the unit is attached to unauthorized equipment, unplug the unit and notify Customer Service to obtain a new one.
- Cables are properly attached and in good condition.
- All accessories are securely attached.
- Components are not in or near water.
- Components have not been moved to an unsuitable location.
- If any component has been dropped or damaged, call Customer Service. Qualified service personnel must inspect any dropped or damaged units before they are assigned for use.

Cleaning

- Shut down the CalEQ before cleaning or disinfecting.
- Turn off the Reader by pressing and holding the small switch at the base for several seconds.
- To clean, wipe the surfaces with Super Sani-Cloth wipes or equivalent cleaner.
- Clean the system components after each use.
- DO NOT disassemble. Clean only the surfaces of the Reader, Docking Station, and CalEQ.
- DO NOT immerse any component in any liquid.
- DO NOT spray liquids directly on any component – use a pre-moistened cloth.
- DO NOT autoclave.
- DO NOT sterilize with ethylene oxide.

13. Disposal

The Cordella Sensor and Delivery System are single use devices. Once the Cordella Sensor has been deployed from the Delivery System, dispose of the Delivery System following standard hospital protocols for disposal of biohazardous materials. If the Cordella Sensor is removed from the patient for any reason (death, adverse event, etc.), then it should be contained and shipped to Endotronix following standard protocols for biohazardous materials, taking care not to damage the device. If there is an adverse event or suspected device malfunction related to the Delivery System, contact Customer Service to initiate an RMA procedure.

It is not necessary to remove the Sensor prior to cremation. Do not implant an explanted Sensor in another patient as sterility, functionality, and reliability cannot be ensured.

The Reader, Docking Station and CalEQ devices contain lithium ion batteries, which should not be discarded with municipal waste. The Reader, Docking Station, and CalEQ should be discarded following applicable electronic waste procedures. If there is an adverse event or suspected device malfunction related to the Reader, Docking Station, or CalEQ, contact Customer Service to initiate an RMA procedure.

14. Return Materials Authorization (RMA)

If Customer Service requests that the equipment be returned, please follow the directions below.

1. Carefully pack the equipment in the original shipping box or equivalent with its original protective packaging materials or equivalent as instructed by Customer Service.
2. Include the RMA number given to you by Customer Service on the outside of the shipping container. Ship all equipment and signed equipment return list to:

   RMA#
   Customer Service Department, Repairs
   Endotronix, Inc.
   1415 West Diehl Road
   Suite #500W
   Naperville, IL 60563
   U.S.A

15. Troubleshooting

15.1 Implant Procedure & Delivery System

Delivery System Connection

- If the Stability Sheath becomes disconnected from the Torque Catheter during the procedure, reconnect the Stability Sheath to the Torque Catheter and hand tighten the torque luer connection to stabilize.

Advancing the Delivery System

- If difficulty is experienced advancing the Delivery System through the heart structures, retract the system proximal to the right atrium and apply torque to the handle to rotate the Cordella Sensor such that it is on the inner curve of the pathway to the right pulmonary artery.

Kinked Guidewire

- If the guidewire becomes kinked, the Delivery System may bind to it and prevent the Delivery System from being advanced or retracted.

Sensor Orientation before Deployment

- If rotational placement of the Cordella Sensor in the target segment is difficult to achieve (e.g. excessive rotation), try incremental application of torque (i.e. "ratcheting") rather than continuously increasing application of torque to the handle.
- If rotating the Cordella Sensor while in target vessel is difficult, you may retract the system into a larger vessel, then rotate to the desired orientation, then advance into position in the target segment.

Aborted Procedure

- If the decision is made not to deploy the Cordella Sensor after it has been inserted through the introducer sheath:
  - Slowly retract the Delivery System until the Cordella Sensor is in contact with the distal tip of the introducer. Almost the entire length of the Delivery System will be removed, and the Cordella Sensor will catch or snag on the introducer tip.

- At this point, while holding the introducer in place, rotate the handle of the Delivery System while keeping it in slight tension (DO NOT ACTIVELY PULL).
- After a minimum of 5 rotations of the handle, the Cordella Sensor should have corkscrewed into the distal portion of the introducer and it will be safe to retract the Delivery System and Cordella Sensor slowly until they are fully removed. If high resistance is met or the introducer is being dislodged, insert the Delivery System approximately 5 mm into the introducer and repeat the removal procedure steps listed above, rotating the handle in the opposite direction. If high resistance is still met or the introducer continues to dislodge, consider removing both the Delivery System and introducer sheath in tandem.
- DO NOT reuse the same Delivery System and Cordella Sensor after removal from the introducer. Return the used Delivery System and Sensor to Endotronix following the RMA process described above.

Reference Pressure Measurement

- After Sensor deployment and torque catheter removal, if the stability sheath becomes kinked and a pressure reading cannot be obtained, advance the sheath forward or backward 2-3 cm. Flush stability sheath to confirm kink has been resolved prior to performing the fluid filled calibration.
- If the reference pressure measurement through the stability sheath is suspected as being inaccurate, reinsert the PA catheter for use as the reference pressure measurement device.

15.2 Pairing and Interrogating the Cordella Sensor

Scanning Sensor or Patient QR Barcode

- If no information is displayed after attempting to scan the QR barcode:
    1. Check that the barcode aimer circle is illuminated. If the aimer is not illuminated,

check that the power cord for the barcode scanner is connected properly to the handle and the CalEQ. If the barcode scanner is not functioning properly, contact Endotronix Customer Service.

2. Check that the QR barcode is not smeared, rough, scratched, or exhibiting voids. If the QR barcode on the Delivery System packaging is damaged, contact Endotronix Customer Service for assistance. If the QR barcode from the QR Barcode Report is damaged, re-print the QR Barcode Report from PMP.

Reader-CalEQ Communication

- If the Reader is picked up from the Docking Station but the screen remains on "Undock Reader," wait a few minutes for the CalEQ to recognize that the Reader is undocked. If after a few minutes, the screen remains on "Undock Reader", turn off and redock the Reader, verify the Reader is paired to CalEQ, then repeat the procedure with the backup Reader and contact Endotronix Customer Service post-procedure.

Sensor Interrogation Check Failure

- If the Reader is unable to find the Cordella Sensor signal when placed on the Delivery System packaging, even after repositioning the Reader around and to the side of the box, DO NOT use the Delivery System and instead repeat the steps with a new Delivery System package and contact Endotronix Customer Service after the procedure.

15.3 Calibrating the Cordella Sensor

Reader Power

- If the Reader does not turn on, as indicated by audio and visual cues, after pressing and holding the power button for several seconds, place the Reader back on the Docking Station, ensuring that the Docking Station power cord is plugged into the power strip and the power strip is plugged into an outlet. If the Docking Station LED flashes, the Reader battery is likely depleted and must be charged; the backup Reader should be used. If the Reader does not turn on, even when

charged, use the backup Reader and contact Endotronix Customer Service after the procedure.

Difficulty Locating Sensor Signal

- If the Reader is having difficulty taking a reading or is unable to achieve >80% signal strength, move patient monitoring systems, cell phones, pagers, and other equipment that could cause interference as far away from the patient's chest as possible.

Repeated Calibration Errors or Reader Problems

- If the Reader continues to have difficulties, calibration can be completed after the implant procedure. Record the reference measurements during the procedure, then follow the calibration steps later. It is important that the patient's position during post-procedure calibration closely matches their position when the reference measurements were taken. Ensure that the patient's body, legs, and arm positions, as well as pillow use are the same. The patient should be breathing normally and should refrain from speaking.

Incorrect Reference Pressure

- If the wrong reference pressure measurement numbers are entered, press "Calibrate Again" and complete the calibration workflow again.

Reader Not Found

- If the Reader is picked up from the Docking Station and CalEQ says "Reader Not Found," repeat the procedure with the backup Reader and contact Endotronix Customer Service to initiate the RMA process.

Upload Calibration Data after Restoring Wireless Network Connection

- If the option to "Upload Later" is chosen instead of "Upload to Cloud," navigate to Calibration History to upload the calibration data as soon as connection to a wireless network is restored. To view Calibration History, press the "Menu" button in the bottom left corner, then the "Calibration History" button. Selecting "Upload to Cloud" will upload all data that has not been previously uploaded. If connection to a wireless network

cannot be restored, contact Endotronix Customer Service for assistance.

15.4 Anomalous PA Pressure Data

In the event that anomalous PA pressure data is observed in the PMP, the patient's Cordella Sensor may require recalibration.

Examples of anomalous PA pressure data may include:

- Gradual mean pressure changes without a corresponding proportional change in pulse pressure (systolic- diastolic pressure)
- Largely negative mmHg values for mean PA pressure
- Large, sustained one-time shifts in PA pressure
- Indiscernible PA pressure waveform
- Significant reduction in PA pulse pressure

If you suspect the patient's Cordella Sensor may require recalibration, contact Customer Service.

16. Useful Life

The useful life of the Cordella Sensor is tested to ten (10) years. The tested service life of the Reader and Docking Station is four (4) years, and the tested service life of CalEQ is five (5) years.

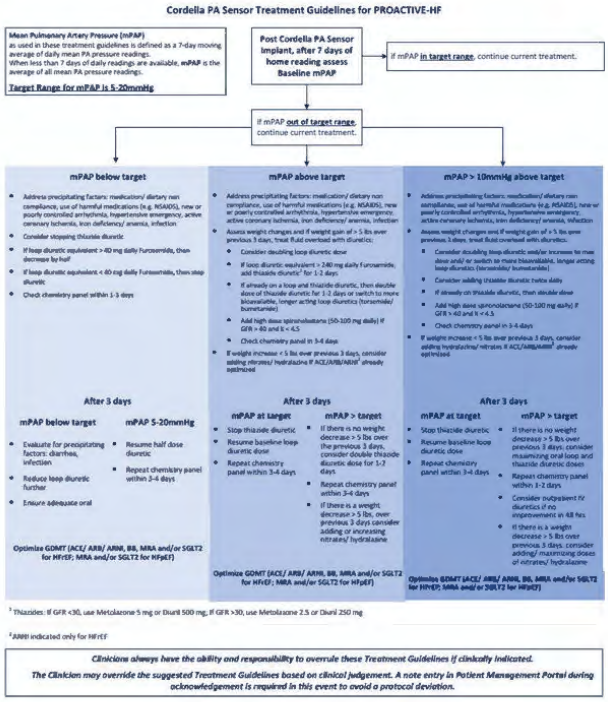
17. Clinical Study Information

17.1 Introduction

In its final design, the PROACTIVE-HF study was a prospective, single-arm, open-label, multi-center clinical trial to evaluate the safety and effectiveness of the Cordella PA Sensor System in NYHA functional class III HF patients. Adults with a diagnosis of HFrEF or HFpEF and NYHA functional class III symptoms were eligible for enrollment if they were treated with GDMT for a minimum of 3 months (stable doses at least 30 days prior to enrollment) and, within the past year, the patient had either 1) one HF hospitalization, or 2) HF treatment in a hospital day care setting, or 3) urgent outpatient clinic HF visit for IV diuretics, or 4) a persistently elevated NT-proBNP level at the time of screening. The Institutional Review Board of each participating center approved the study protocol, each patient provided written informed consent, and events were adjudicated by a Clinical Events Committee.

All patients enrolled into PROACTIVE-HF received the Cordella HF System (recording weight, BP, HR, and SpO_2). After demonstrating compliance with utilization, all patients underwent right heart catheterization and deployment of the Cordella PA pressure sensor into the interlobar right pulmonary artery, provided that the RPA downturn diameter is 12-26 mm for secure stabilization of the sensor. Patients were instructed to take their daily PAP measurements along with their weight, BP, HR, SpO_2, and HF symptoms by using Bluetooth-connected peripherals. Vital signs were visible to both clinicians and patients, while pulmonary artery pressures were visible to the clinicians only. All patients were then managed according to the trial specific seated mPAP treatment guidelines, with a target seated mean pulmonary artery pressure goal of 5-20 mmHg, achieved through titration of diuretics and GDMT via a trial specific treatment guideline as shown in Figure 1.

Figure 1: PROACTIVE-HF Treatment Guidelines for Seated Mean Pulmonary Artery Pressure



Of note, the aforementioned final study design resulted from a deviation of the original study design for the PROACTIVE-HF, which was initially designed by the manufacturer of this device to be a prospective, randomized, controlled, multi-center clinical trial. In the initial phases of this trial, patients were initially randomized 1:1 to either Control or Treatment groups. All readings (pulmonary artery pressure and vital signs) were visible to clinicians of patients within the treatment arm, while only the vital signs were visible to treatment arm patients themselves. However, once PROACTIVE-HF began enrolling subjects, prospective clinical evidence from CardioMEMS was published in 2019-2021, including the GUIDE-HF Trial in 2021. The GUIDE-HF Trial was a prospective, randomized, controlled, single-blind, multicenter, pivotal clinical trial whose purpose was to establish a reasonable assurance of safety and effectiveness of the CardioMEMS HF System to guide the treatment of patients with New York Heart Association (NYHA) Class II - IV heart failure. The GUIDE-HF Trial demonstrated a positive clinical benefit of PAP-guided heart failure management in NYHA functional class III patients using the CardioMEMS device. With this new evidence, in December 2021 the manufacturer of this

device petitioned to the Food and Drug Administration (FDA), to change the study design from a randomized controlled clinical trial to a single-arm trial (described above), with pre-specified safety and efficacy endpoints to provide objective evidence of a similar risk-benefit profile to the CardioMEMS HF System in NYHA functional class III subjects. At the time of crossover to a single-arm, patients in the randomized Control arm (Cohort #1) were unblinded and both clinicians and patients, who opted, in received immediate access to mPAP data and all patients were then managed according to the trial specific seated mPAP treatment guidelines. Cohort #1 subjects did not contribute to the primary safety and efficacy endpoints of PROACTIVE-HF but contributed to a patient engagement substudy. Patients in the randomized Treatment arm (Cohort #2) continued follow-up per protocol and, along with the newly enrolled single arm Treatment group (Cohort #3), contributed to the primary safety and efficacy endpoints of PROACTIVE-HF.

17.2 Study Objectives

The objectives of this study are to demonstrate the safety and efficacy of the Cordella PA Sensor System.

17.3 Study Design

Patients were treated between January 10, 2020 and September 30, 2023. The database for this PMA reflected data collected through September 30, 2023 and included 456 patients. There were 77 investigational sites.

This study was a prospective, multi-center, open-label, single-arm clinical trial to assess device safety and efficacy of the Cordella PA Sensor System in NYHA Class III Heart Failure patients compared to a Performance Goal (PG) of the rate of HF hospitalizations or all-cause mortality at 6 months based on a meta-analysis on the combined cohorts of CHAMPION-HF, CardioMEMS Post approval study, MEMS-HF, GUIDE-HF (NYHA Class III cohort), and LAPTOP-HF (control group only). This trial was conducted under the IDE# G190020. The patient population was composed of patients with a HF diagnosis of > 3 months with either preserved or reduced LVEF.

Subjects in this trial were categorized into three (3) different cohorts:

Cohort #1- Previously enrolled Control Arm subjects

- Upon change to single arm, subjects in this cohort were unblinded to their PAP measurements and informed about their previous group assignment and continue their Follow-up visit schedule.
- Additionally, subjects were asked, throughout the remaining Follow-up period, to complete a regular subject survey on their experience with PAP Measurements and PAP values.
- Upon change to single arm, clinicians were unblinded to PAP measurements and started managing the patients to target PA pressures per protocol/ CIP and according to Guideline Directed Medical Therapy (GDMT).
- Additionally, the clinical site was asked to contact the subject on a regular basis to discuss their PAP values.
- Separate subgroup analysis (safety and effectiveness) were performed.

Cohort #2- Previously enrolled Treatment Arm subjects

- As of month 12 subjects in this cohort were able to see their own PAP measurements for the remaining duration of the study.
- Clinicians continued to manage the patients to target PA pressures per protocol/CIP and according to GDMT.
- All primary and secondary safety and effectiveness analyses were performed.

Cohort #3- Newly enrolled subjects

- Subjects participated in the Screening/ Enrollment Visit, Cordella PA Sensor Implant Visit, and Follow-Up Visits.
- Clinicians managed the patients to target PA pressures per protocol/ CIP and according to GDMT.
- As of month 12, subjects in this cohort were able to see their own PAP measurements for the remaining duration of the study.
- All primary and secondary safety and effectiveness analyses were performed.

The Cordella PA Sensor was implanted in conjunction with a right heart catheterization (RHC) procedure. During this visit, the Cordella PA Sensor, which is pre-mounted on a catheter Delivery System, was introduced via percutaneous venous access to the pulmonary artery. Once deployed, the Sensor PAP was calibrated using the Delivery System's fluid-filled catheter for independent reference measurements. The calibration coefficients for that Sensor/Reader/ Subject were stored in a database, allowing for consistent PAP calculations throughout the study duration. Also, at the Screening Visit, eligible subjects were provided with the commercially available Cordella HF System to measure BP, HR, SpO_2 and weight.

Subjects were observed until stable and discharged home with instructions to take their PAP measurements daily in addition to their weight, BP, HR and SpO_2, which were all wirelessly transmitted to a secure website for review using the myCordella Patient Management Portal.

Visibility to patients' daily data trends enabled the clinician to proactively manage the patients to target PA pressures per protocol and according to GDMT. The clinician contacted all subjects on a regular basis to discuss their health status and all patients were treated according to GDMT. All Subjects will return for follow up visits at 1, 6, 12, 18, 24 months, as well as at Year 3, 4 and 5, after the Cordella PA Sensor implant, or until study termination. The 3 month follow-up visit was performed as a remote/ virtual telemonitoring visit.

All subjects who received a Cordella PA Sensor Implant were followed for 6 months for the Primary Efficacy and Primary Safety Endpoints and will be followed for up to 5 years post implant. Additional monitoring of safety and efficacy assessments will be performed throughout the study duration, including evaluation of subject functional and health status, adverse events, Heart Failure (HF) related hospitalizations or equivalent (e.g., intravenous (IV) diuretics).

A total of 75 sites (71 US/4 EU) enrolled a subject in this trial. A subject is considered enrolled if the subject signed the consent form, completes the screening visit, and is reviewed by the Eligibility Committee. A subject is considered to be a screen failure if the subject signed the consent form but was subsequently determined ineligible based on the trial inclusion and/ or exclusion criteria prior to implant.

The trial began in the USA with the first site for the trial initiated on November 8, 2019, and Enrollment into the trial started on January 10, 2020. After approval of protocol amendment V7.0 (November 21, 2021), the amendment not only increased the number of participating centers to one-hundred twenty (120) in the United States (US) and Europe (EU), as well as a change in trial design from a randomized to a single arm trial. After the approval of protocol amendment V7.0 (November 21, 2021) in December 2021 all sites were consequently converted to this single arm trial.

Enrollment was completed on March 8, 2023, and the last subject was implanted on March 31, 2023.

Out of the 738 enrolled subjects, 528 subjects received an implant (Figure 3). Five-hundred twenty-eight (528) are a combination of 72 subjects in Cohort# 1, the previously enrolled Control Arm subjects; 88 subjects in Cohort# 2, the previously enrolled Treatment Arm subjects; and 368 subjects in Cohort# 3, the newly enrolled subjects. One-hundred twenty-five (125) subjects failed screening and 85 subjects were withdrawn prior to implant. Thirty-seven (37) subjects had an aborted implant.

17.4 Clinical Inclusion and Exclusion Criteria

Enrollment in the PROACTIVE-HF study was limited to patients who met the following inclusion criteria:

1. Subject has given written informed consent
2. Male or female, at least 18 years of age
3. Diagnosis and treatment of HF (regardless of left ventricular ejection fraction (LVEF)) for ≥ 3 months and NYHA Class III HF at time of Screening
4. Subjects should be on stable, optimally titrated medical therapy for at least 30 days, as recommended according to current American Heart Association (AHA)/American College of Cardiology (ACC) guidelines as standard-of-care for HF therapy in the United States, or current European Society of Cardiology (ESC) guidelines for HF treatment in Europe, with any intolerance documented
5. Subjects who qualified for the following:
    a. HF related hospitalization in the past year i.e. one calendar day change
    b. HF treatment in a hospital day-care

setting

c. Or urgent outpatient clinic HF visit for IV diuretics within 12 month (last hospitalization should be 30 days before Screening /Enrollment)

d. Or N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) at time of Screening/ Enrollment defined as:

   - Subjects with LVEF ≤ 50%: NT-proBNP ≥ 1500 pg/mL.
   - Subjects with LVEF > 50%: NT-proBNP ≥ 800 pg/mL.

   Thresholds for NT-proBNP (for both LVEF ≤ 50% and LVEF > 50% will be corrected for body mass index (BMI) using a 4% reduction per BMI unit over 25 kg/m^2

6. Subjects should be on diuretic therapy
7. Subjects who are physically able to hold the myCordella™ Handheld Patient Reader unit (approximate weight 1.3lb) against the ventral thoracic surface for up to 2 minutes per day while in a seated position, as well as dock and undock the myCordella™ Handheld Patient Reader
8. Subjects with sufficient eyesight, hearing, and mental capacity to respond to the myCordella™ Handheld Patient Reader's audio/visual cues and operate the myCordella™ Handheld Patient Reader
9. Subject has sufficient Cellular and/ or Wi-Fi Internet coverage at home
10. Subject agrees to return to the treating Investigator for all scheduled follow up visits and can return to the hospital for follow up

Patients were not permitted to enroll in the PROACTIVE-HF study if they met any of the following exclusion criteria:

1. Intolerance to all neuro-hormonal antagonists (i.e., intolerance to ACE-I, ARB, ARNI, and beta-blockers) due to hypotension or renal dysfunction
2. ACC/AHA Stage D refractory HF (including having received or currently receiving pharmacologic circulatory support with inotropes)
3. Subjects with history of recurrent pulmonary embolism ≥ 2 episodes within 5 years prior to Screening Visit) and/or deep vein thrombosis within 3 months of the Screening Visit
4. Subjects who have had a major CV event (e.g., myocardial infarction, stroke) within 3 months of the Screening Visit
5. Unrepaired severe valvular disease
6. Subjects with significant congenital heart disease that has not been repaired and would prevent implantation of the Cordella PA Sensor or mechanical/tissue right heart valve(s)

7. Subjects with known coagulation disorders
8. Subjects with a hypersensitivity or allergy to platelet aggregation inhibitors including aspirin, clopidogrel, prasugrel, and ticagrelor; or patients unable to take dual antiplatelet or anticoagulants for one- month post implant
9. Known history of life threatening allergy to contrast dye.
10. Subjects whereby RHC is contraindicated
11. Subjects with an active infection at the Sensor Implant Visit
12. Subjects with a GFR <25 ml/min or who are on chronic renal dialysis
13. Implanted with CRT-P or CRT-D for less than 90 days prior to screening visit
14. Received or are likely to receive an advanced therapy (e.g., mechanical circulatory support or lung or heart transplant) in the next 12 months
15. Subjects who are pregnant or breastfeeding
16. Subjects who are unwilling or deemed by the Investigator to be unwilling to comply with the study protocol, or subjects with a history of non-compliance
17. Severe illness, other than heart disease, which would limit survival to <1 year
18. Subjects whose clinical condition, in the opinion of the Investigator, makes them an unsuitable candidate for the study
19. Subjects enrolled in another investigational trial with an active Treatment Arm
20. Subject who is in custody by order of an authority or a court of law

17.5 Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 1, 6, 12, 18, 24 months, as well as at Year 3, 4 and 5, after the Cordella PA Sensor implant, or until study termination. Adverse events and complications were recorded at all visits. The key timepoints and assessments are shown in the Table 1:

Table 1. PROACTIVE-HF / ETX-HFS-PA-03: Study Visit Schedule

Assessment	V1: Screening/ Enrollment (30 days)[15]	V2: Cordella PA Sensor Implant Visit	V3: Month 1 (±7 days)	V4 [11]: Month 3 (±7 days)	V5: Month 6 (±14 days)	V6: Month 12 (±30 days)	V7 to V8: Months 18, 24 (±30 days)	V9 to V11 Year 3, 4, 5 (±30 days)
Informed Consent	X							
Subject Demographics	X							
Study Eligibility Review and Committee Approval	X							
Cardiac/Medical & Surgical History	X							
Physical Exam, height, weight, and vital signs [1, 5]	X	X	X[12]		X	X	X	X
12-Lead ECG with Interpretation	X				X	X	X	X
Urinalysis [2]	X							
Safety Labs Chemistry/ Hematology/ aPTT/ INR)	X				X	X	X[4]	X
Serum NT-pro BNP	X		X	X[12]	X	X	X	X
aPTT/ INR (if indicated)								
Echocardiogram [3]	X					X		X
Subject Training: Cordella™ HF System [14]	X							
Subject Training: CorPASS		X						
Cordella™ PA Sensor Implant		X						
Cordella System Use (daily)	X	X	X	X	X	X	X	X
Cordella™ PAP – dia/sys/ mean/pulse		X[9]	X[5,6]	X[5,6]	X[5,6]	X[5,6]	X[5,6]	X[6]
RHC PAP / RAP/ PCWP/ CO/ CI/ RVP[8]		X						X[17]
Subject Status	X		X	X	X[10]	X[10]	X	X
6- Minute Walk Test	X				X	X[7]	X[4,7]	X[7]
NYHA Functional Classification	X[16]		X	X	X	X	X	X
KCCQ Quality of Life Questionnaires [5]	X		X	X	X	X	X	X
Concurrent/Cardiac Medications	X	X	X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X	X	X
Health Economic Questionnaire							X[4]	
Subject Survey (optional)/ **Cohort #1 only[13]**	1. Month 1 after Unblinding 2. Quarterly until V11 / Year 5							
Site Survey (optional)/ **Cohort #1 only[13]**	1. Month 1 after Unblinding 2. Quarterly until V11 / Year 5							

1. Full Physical Examination and Height performed at Screening Visit only
2. Urine (V1) pregnancy test for females
3. Echo may be obtained within 3 or 6 months of Screening details are in section 8.1.10
4. At Month 24 only
5. via myCordella™ Patient App at home prior to visit. Baseline KCCQ will be completed on myCordella tablet following Cordella System distribution at Screening Visit
6. via myCordella™ Patient App seated and supine
7. Additional PAP Measurements will be obtained before and after 6-minute walk test
8. Additional RHC as needed for Re-calibration purposes at the clinician's discretion
9. Via CalEQ
10. Incl. question on assigned treatment at Visit 5 and 6
11. Visit should be completed remote/ virtually
12. If available
13. After subject gets unblinded to PAP Pressures at V6 or cross-over whatever comes first
14. Subject training on and distribution of the commercial Cordella™ System (should occur at Screening Visit (Visit 1).
15. Some study procedures need to be repeated in case a subject is implanted >30 days after Visit 1, details are in section 8.3.1.
16. may be obtained within the 30 day Study Visit 1 window
17. At V9/ Year 3 only

17.6 Clinical Endpoints

With regards to safety, the study had primary and secondary safety endpoints which are discussed below:

17.6.1 Safety Endpoints

Primary Safety Endpoints:

1. Freedom from device or system-related complications (DSRC) at 6 months will be tested against the null rate of 90%. Based on a one sample test of a proportion, a sample size of 450 patients provides greater than 95% power assuming a population rate of 95% based on a two-sided Type I error rate of 5%.
2. Freedom from pressure sensor failure at 6 months will be tested against a null rate of 95%

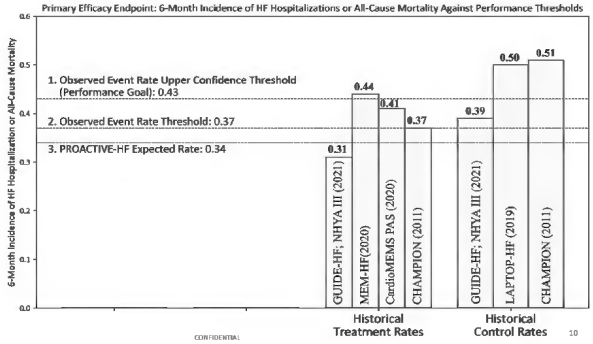
Secondary Safety Endpoints:

1. Frequency of serious adverse events (SAEs) throughout the study
2. Frequency of implant procedure and procedure related adverse events
3. Pressure sensor failure rate throughout the study

With regards to effectiveness, the study had primary and secondary efficacy endpoints which are discussed below.

With regard to success/failure criteria, results of individual CardioMEMS studies and an internally derived meta-analysis were considered in determining the Primary Endpoint Performance Goal (PG) for the re-designed study. The meta-analysis was performed on the combined cohorts of CHAMPION-HF, CardioMEMS Post approval study, MEMS-HF, GUIDE-HF (NYHA Class III cohort), and LAPTOP-HF (control group only) as shown in Figure 2.

Figure 2: Results of Individual CardioMEMS Studies and Meta Analysis For Determining the Primary Endpoint Performance Goal



To meet the new objectives of the study, observed event rates in the single-arm PROACTIVE- HF should be similar to observed event rates in the treatment arm of CardioMEMS studies and lower than observed event rates in the control arm of CardioMEMS studies. Therefore, we set the PG below the meta-analysis upper bound 95% confidence interval of CardioMEMS treated patients, and below the meta-analysis estimates of CardioMEMS control patients and adjusted the goal downwards to account for a potential impact of treatment with SGLT2i. Furthermore, we also require that the single-arm PROACTIVE-HF observed event rate be lower than both the meta-analysis estimate of CardioMEMS treatment patients, and the lowest observed event rates of CardioMEMS control patients, further adjusted down by potential impact of SGLT2i.

Primary Efficacy Endpoint:

The primary endpoint was the 6-month incidence of HF related hospitalizations (HFH) or all-cause mortality.

For the primary endpoint of HFH and all-cause mortality at 6 months, the PG is 0.43 events per patient 6-month and, for study success, the upper confidence bound of the observed event rate for the planned study must be less than the PG. Additionally, the observed event rate must be lower than 0.37 events per patient 6-month.

Evaluating the upper bound of the confidence interval for the rate, ensures:

1) the observed rate will be comparable to prior studies of active treatment (highest observed value = 0.44),
2) the observed rate will be less than the mean rate from meta- analysis of prior studies of treatment and control, and
3) the observed rate will be less than the lowest rate observed in the control studies (GUIDE-HF). The added requirement for the observed rate to be less than 0.37 provides further assurance that results are comparable to studies of prior treatment.

Based on this, the study will implant 450 subjects (single arm cohorts) leading to an expected evaluable cohort of 406 subjects. With a PG of 0.43 and a one-sided 0.025 alpha level, the study will have greater than 80% power assuming a population treatment rate of 0.34.

Secondary Efficacy Endpoints:

1. The first secondary efficacy endpoint is incidence of HF Hospitalizations or all-cause mortality at 12 months compared to a PG. The PG of 0.70 for the first secondary endpoint of 12-month incidence of HFH or all-cause mortality was derived from clinically relevant, contemporary studies of NYHA Class III HF subjects. Additionally, we require the observed event rate to be less than 0.59.
2. Number of HFH at 6 and 12 months post-implant compared to the number of HFH in the 6 and 12 months prior to implant
3. Comparison of the number of HFH or emergency department / hospital outpatient IV diuretic visits of Cohort #1 and Cohort #2 at 6 and 12 months post- implant

4. Change of NT-pro BNP from baseline through 6 and 12 months
5. Combined outcome of:
    a. First and recurrent HFH
    b. Emergency department / hospital outpatient IV diuretic visits
    c. All-cause mortality

At 6 months, added together with equal weighting into a total number of events

6. HFH or emergency department / hospital outpatient IV diuretic visits at 6 and 12 months
7. Cardiac and all-cause mortality
8. Days alive and out of the hospital (DAOH)
9. IV diuretic visits
10. Heart failure related medication changes
11. Change in PAP:
    a. From baseline through 6 and 12 months in subjects with a baseline mean PAP
        i. Above target range
        ii. Within or below target range
        iii. Overall
    b. Before and after 6-minute walk test (6MWT)
12. Percentage of device success as documented by ability of the system to successfully transmit PAP data
13. Patient outcome measures, measured by KCCQ
14. Functional status improvement, as measured by NYHA and 6MWT
15. Health economic analysis

17.6.2 Accountability of PMA Cohort

At the time of database lock, 738 patients had enrolled in the PROACTIVE-HF study (85.5% of screened patients) and a total of 528 patients (71.5% of enrolled patients) implanted with the device are available for analysis at the completion of the study on 29 September 2023. Implanted subjects were included in either the randomized Control Arm prior to the trial redesign (Cohort #1, N = 72 subjects), in the randomized Treatment Arm prior to the trial redesign (Cohort # 2, N=88 subjects), or in the Treatment Arm after the trial redesign (Cohort #3, N=368 subjects). Subjects in Cohorts #2 and #3 (N = 456) contribute to the primary safety and efficacy endpoints in PROACTIVE-HF. Subjects in Cohort #1 contribute to a substudy examining patient engagement with pulmonary artery pressures.

a. Intent-to-Treat Population (ITT), includes all enrolled subjects intended to receive the Cordella PA Sensor who entered the Cath Lab, including those in whom Implant

Procedure was not completed for whatever reason (e.g., Cordella PA Sensor Implant could not be performed due to anatomical reasons) from Cohort #2 and #3. The ITT was used for all analyses of safety endpoints.

b. Modified Intent-to-Treat Population (mITT), includes all implanted subjects form Cohort #2 and Cohort #3. All primary and secondary effectiveness analyses were performed on the mITT.

c. Per Protocol Population (PP), includes all mITT subjects without any major protocol deviations. All primary and secondary safety and effectiveness analyses were performed in addition on PP population. If PP and mITT populations were identical, analysis was performed based on mITT only.

d. Cohort #1- Previously enrolled Control Arm subjects- Population, this subgroup includes all Cohort #1 (previously enrolled Control Arm) subjects and was reported separately for all endpoints.

The trial enrollment and subject population are presented below in Figure 3.

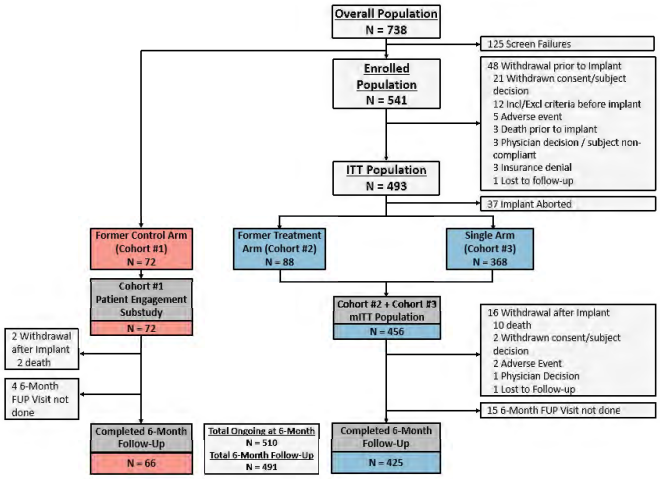


Figure 3: PROACTIVE-HF / ETX-HFS-PA-03: Patient Disposition

17.6.3 Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a single arm study performed in the US.

Study Population and Baseline Parameters

mITT & mITT Stratified by Cohort Number

There were some differences between the cohorts as illustrated in the Table below, for example the proportion of patients in Cohort #3 on SGLT2i at baseline was greater than that of Cohort #1 (64.1% vs. 29.2%) and Cohort #2 (64.1% vs. 33.0%). Table 2 presents the demographics and patient characteristics by the mITT population and stratified by Cohort assignment.

Table 2. Demographics for mITT, Cohort #1, Cohort #2, and Cohort #3

Characteristic	mITT (N=456)	Cohort #1 (N=72)	Cohort #2 (N=88)	Cohort #3 (N=368)
Demographics				
Age (years), Mean (SD)	63.5 (12.5)	65.9 (11.3)	64.5 (11.5)	63.3 (12.8)
Male, n (%)	276 (60.5%)	42 (58.3%)	56 (63.6%)	220 (59.8%)
Female, n (%)	180 (39.5%)	30 (41.7%)	32 (36.4%)	148 (40.2%)
Weight (kg), Mean (SD)	105.8 (25.8)	102.9 (22.8)	102.0 (23.3)	106.7 (26.4)
Height (cm), Mean (SD)	172.0 (10.6)	171.3 (11.3)	172.5 (9.9)	171.9 (10.8)
Body mass index (kg/m2 , Mean (SD)	35.9 (8.8)	35.3 (8.4)	34.4 (7.8)	36.2 (9.0)
Race				
White, n (%)	347 (76.1%)	56 (77.8%)	68 (77.3%)	279 (75.8%)
Black, n (%)	84 (18.4%)	11 (15.3%)	14 (15.9%)	70 (19.0%)
Asian, n (%)	7 (1.5%)	0 (0%)	3 (3.4%)	4 (1.1%)
Hawaiian or Pacific Islander, n (%)	3 (0.7%)	1 (1.4%)	1 (1.1%)	2 (0.5%)
American Indian/Alaskan native, n (%)	2 (0.4%)	1 (1.4%)	1 (1.1%)	1 (0.3%)
Other, n (%)	4 (0.9%)	0 (0%)	0 (0%)	4 (1.1%)
Race not reported, n (%)	9 (2.0%)	3 (4.2%)	1 (1.1%)	8 (2.2%)
Ethnicity				
Hispanic or Latino, n (%)	20 (4.4%)	5 (6.9%)	3 (3.4%)	17 (4.6%)
Not Hispanic or Latino, n (%)	401 (87.9%)	61 (84.7%)	81 (92.0%)	320 (87.0%)

Characteristic	mITT (N=456)	Cohort #1 (N=72)	Cohort #2 (N=88)	Cohort #3 (N=368)
Ethnicity not reported, n (%)	13 (2.9%)	2 (2.8%)	0 (0%)	13 (3.5%)
Unknown, n (%)	22 (4.8%)	4 (5.6%)	4 (4.5%)	18 (4.9%)
Smoking History				
Never, n (%)	210 (46.1%)	34 (47.2%)	33 (37.5%)	177 (48.1%)
Previous, n (%)	209 (45.8%)	31 (43.1%)	43 (48.9%)	166 (45.1%)
Smoker, n (%)	37 (8.1%)	7 (9.7%)	12 (13.6%)	25 (6.8%)
Heart Failure Ejection Fraction				
LVEF ≤ 40% (HFrEF), n (%)	208 (45.6%)	33 (45.8%)	40 (45.5%)	168 (45.7%)
LVEF ≥ 50% (HFpEF), n (%)	201 (44.1%)	31 (43.1%)	37 (42.0%)	164 (44.6%)
40% < LVEF < 50% (HFmrEF), n (%)	45 (9.9%)	8 (11.1%)	10 (11.4%)	35 (9.5%)
Medical History/Surgical History				
Diabetes mellitus, n (%)	161 (35.3%)	26 (36.1%)	30 (34.1%)	131 (35.6%)
Chronic kidney disease, n (%)	198 (43.4%)	37 (51.4%)	32 (36.4%)	166 (45.1%)
Chronic obstructive pulmonary disease, n (%)	92 (20.2%)	15 (20.8%)	21 (23.9%)	71 (19.3%)
Coronary artery bypass graft, n (%)	81 (17.8%)	12 (16.7%)	15 (17.0%)	66 (17.9%)
Percutaneous coronary intervention, n (%)	134 (29.4%)	23 (31.9%)	28 (31.8%)	106 (28.8%)
Valve repair / replacement, n (%)	21 (4.6%)	5 (6.9%)	6 (6.8%)	15 (4.1%)
Heart Failure History				
Time since first diagnosis of HF [months], Mean (SD)	58.1 (68.4)	66.3 (62.5)	54.0 (59.0)	59.1 (70.5)
Time since first diagnosis of HF [months], Median	33.08	46.98	31.67	33.53
Time since first diagnosis of HF [months], Min	2.97	0.03	2.97	3.03
Time since first diagnosis of HF [months], Max	454.37	257.73	309.43	454.37
Etiology of Heart Failure				
Ischemic, n (%)	143 (31.4%)	26 (36.1%)	33 (37.5%)	110 (29.9%)
Non-Ischemic, n (%)	313 (68.6%)	46 (63.9%)	55 (62.5%)	258 (70.1%)

Characteristic	mITT (N=456)	Cohort #1 (N=72)	Cohort #2 (N=88)	Cohort #3 (N=368)
Number of HFH in prior year, Count (%)				
0	90 (19.7%)	7 (9.7%)	17 (19.3%)	73 (19.8%)
1	208 (45.6%)	48 (66.7%)	45 (51.1%)	163 (44.3%)
2	88 (19.3%)	9 (12.5%)	19 (21.6%)	69 (18.8%)
3	46 (10.1%)	5 (6.9%)	3 (3.4%)	43 (11.7%)
4	9 (2.0%)	1 (1.4%)	1 (1.1%)	8 (2.2%)
5	8 (1.8%)	2 (2.8%)	1 (1.1%)	7 (1.9%)
5+	7 (1.5%)	0 (0%)	2 (2.3%)	5 (1.4%)
Number of HFH in prior year, Mean (SD)	1.4 (1.3)	1.3 (1.0)	1.3 (1.2)	1.4 (1.3)
Number of HFH in prior year, Min	0	0	0	0
Number of HFH in prior year, Max	8	5	6	8
Other Cardiovascular History				
Hypertension, n (%)	403 (88.4%)	65 (90.3%)	74 (84.1%)	329 (89.4%)
Coronary artery disease, n (%)	269 (59.0%)	45 (62.5%)	57 (64.8%)	212 (57.6%)
Myocardial infarction, n (%)	118 (25.9%)	16 (22.2%)	21 (23.9%)	97 (26.4%)
Atrial fibrillation, n (%)	236 (51.8%)	39 (54.2%)	43 (48.9%)	193 (52.4%)
Transient ischemic attack, n (%)	23 (5.0%)	4 (5.6%)	3 (3.4%)	20 (5.4%)
Stroke, n (%)	48 (10.5%)	7 (9.7%)	7 (8.0%)	41 (11.1%)
Peripheral vascular disease, n (%)	61 (13.4%)	14 (19.4%)	10 (11.4%)	51 (13.9%)
Carotid artery disease, n (%)	33 (7.2%)	8 (11.1%)	4 (4.5%)	29 (7.9%)
Ventricular tachycardia, n (%)	88 (19.3%)	16 (22.2%)	19 (21.6%)	69 (18.8%)
Ventricular fibrillation, n (%)	18 (3.9%)	2 (2.8%)	4 (4.5%)	14 (3.8%)
Atrial flutter, n (%)	58 (12.7%)	9 (12.5%)	9 (10.2%)	49 (13.3%)
Implantable cardioverter defibrillator, n (%)	160 (35.1%)	21 (29.2%)	36 (40.9%)	124 (33.7%)
Cardiac resynchronization therapy, n (%)	82 (18.0%)	15 (20.8%)	15 (17.0%)	67 (18.2%)
Laboratory				
Estimated glomerular filtration rate [mL/ min/1.73m^2], Mean (SD)	54.7 (18.7)	50.1 (19.7)	54.3 (18.2)	54.8 (18.8)

Characteristic	mITT (N=456)	Cohort #1 (N=72)	Cohort #2 (N=88)	Cohort #3 (N=368)
NT-proBNP [pg/mL], Mean (SD)	1731.4 (3012.8)	1768.8 (3809.4)	2061.0 (4401.6)	1655.1 (2590.4)
Hemodynamics (Right Heart Catheterization)				
Systolic pulmonary artery pressure (mmHg), Mean (SD)	43.3 (14.9)	40.9 (13.0)	43.9 (16.4)	43.2 (14.6)
Diastolic pulmonary artery pressure (mmHg), Mean (SD)	18.8 (7.9)	18.4 (6.4)	19.6 (8.9)	18.6 (7.7)
Mean pulmonary artery pressure (mmHg), Mean (SD)	28.2 (10.1)	26.7 (8.9)	29.1 (11.6)	28.0 (9.7)
Right atrial pressure (mmHg), Mean (SD)	9.7 (6.7)	9.0 (4.6)	10.1 (5.7)	9.6 (7.0)
Pulmonary capillary wedge pressure (mmHg), Mean (SD)	16.5 (8.7)	15.3 (6.8)	16.9 (9.9)	16.4 (8.3)
Cardiac output (L/min , Mean (SD)	5.3 (3.2)	5.6 (3.3)	5.0 (1.3)	5.4 (3.5)
Cardiac index (L/min/m2 , Mean (SD)	2.4 (0.6)	2.7 (1.4)	2.3 (0.5)	2.4 (0.6)
Vital Signs				
Systolic blood pressure, Mean (SD)	121.8 (19.1)	116.6 (18.7)	120.6 (17.6)	122.0 (19.5)
Diastolic blood pressure, Mean (SD)	72.9 (12.6)	67.9 (11.3)	72.7 (11.8)	73.0 (12.8)
Heart rate, Mean (SD)	77.2 (14.1)	77.7 (14.1)	77.6 (14.4)	77.1 (14.1)
Blood oxygen saturation, Mean (SD)	95.8 (2.8)	96.1 (2.5)	95.9 (2.9)	95.8 (2.8)
Heart Failure Medications				
Agents acting on the renin-angiotensin system, n (%)	310 (68.0%)	47 (65.3%)	61 (69.3%)	249 (67.7%)
Angiotensin receptor-neprilysin inhibitor, n (%)	199 (43.6%)	23 (31.9%)	36 (40.9%)	163 (44.3%)
Angiotensin II receptor blocker, n (%)	84 (18.4%)	21 (29.2%)	16 (18.2%)	68 (18.5%)
Angiotensin-converting enzyme inhibitor, n (%)	32 (7.0%)	4 (5.6%)	12 (13.6%)	20 (5.4%)
Beta blocker, n (%)	395 (86.6%)	61 (84.7%)	75 (85.2%)	320 (87.0%)
Diuretic, n (%)	454 (99.6%)	72 (100.0%)	88 (100.0%)	366 (99.5%)
Loop diuretic, n (%)	444 (97.4%)	72 (100.0%)	85 (96.6%)	359 (97.6%)
Thiazide diuretic, n (%)	2 (0.4%)	2 (2.8%)	2 (2.3%)	0 (0%)
Aldosterone antagonist, n (%)	310 (68.0%)	47 (65.3%)	54 (61.4%)	256 (69.6%)
Sodium-glucose transport protein 2 inhibitor, n (%)	265 (58.1%)	21 (29.2%)	29 (33.0%)	236 (64.1%)

Characteristic	mITT (N=456)	Cohort #1 (N=72)	Cohort #2 (N=88)	Cohort #3 (N=368)
Hydralazine, n (%)	35 (7.7%)	5 (6.9%)	6 (6.8%)	29 (7.9%)
Nitrates, n (%)	83 (18.2%)	12 (16.7%)	13 (14.8%)	70 (19.0%)
Functional Capacity & Quality of Life				
New York heart association functional class III, n (%)	456 (100.0%)	71 (98.6%)	88 (100.0%)	367 (99.7%)
Kansas City cardiomyopathy questionnaire overall summary score (points), Mean (SD)	52.8 (22.8)	49.7 (23.8)	52.4 (22.7)	52.8 (22.9)
Six-minute walk test (m), Mean (SD)	259.5 (121.1)	281.5 (133.6)	270.7 (120.7)	256.9 (121.2)
Enrollment Type				
Enrollment Type: HFH, n (%)	150 (32.9%)	31 (43.1%)	37 (42.0%)	113 (30.7%)
Enrollment Type: NT-proBNP, n (%)	89 (19.5%)	6 (8.3%)	16 (18.2%)	73 (19.8%)
Enrollment Type: HFH and NT-proBNP , n (%)	216 (47.4%)	34 (47.2%)	34 (38.6%)	182 (49.5%)
Enrollment Type: Does Not Meet Criteria, n (%)	1 (0.2%)	1 (1.4%)	1 (1.1%)	0 (0%)
LVEF = Left Ventricular Ejection Fraction, HF = Heart Failure, HFH = Heart Failure Hospitalization				

17.7 Safety and Effectiveness Results

17.7.1 Safety Results

Primary Safety Results

Primary Safety Endpoints: Main Analysis

The analysis of safety was based on the Intention to Treat population (ITT) from Cohort #2 and Cohort #3, comprising 493 patients available for the 6-month evaluation. The key safety outcomes for this study are presented below in Tables 3 to 5. Adverse effects are reported in Tables 6 to 7.

First Primary Safety Endpoint

The first primary safety endpoint describes freedom from a Device/System Related Complications DSRC) through 6 months and was tested against the null rate of 90%. In the ITT population a total of four (4) DSRCs occurred. The probability of being free from a DSRC at 6 months post implant procedure was 99.2% [95% CI: 97.9%, 99.7%]. The lower bound of the confidence interval, based on the Kaplan-Meier (KM) method, is higher than the null rate of 90%. (Table 3 and KM plot Figure 4).

The first primary safety endpoint was met.

None of the DSRCs resulted in permanent subject impairment or death and all subjects recovered without sequelae. Clinical details of all DSRCs (four (4) events in ITT and one (1) event in Cohort#1) are shown in Table 4.

Table 3: PROACTIVE-HF / ETX-HFS-PA-03: Freedom From Device / System Related Complications – Results Through 6 months for ITT Population

Item	Result	ITT (N=493)
Subject with any DSRC	n (%)	4 (0.8%)
Censored	n (%)	489 (99.2%)
Subjects completed 6 months and without any DSRC	n (%)	439 (89.0%)
Subjects withdrew prior to 6 months and without any DSRC	n (%)	50 (10.1%)
Time to first DSRC (days)**		
25% percentile [95% CI]	181.0	
Median [95% CI]	181.0	
75% percentile [95% CI]	181.0	
Minimum	0.0	
Maximum	181.0	
Probability of being free from DSRC	rate [95% CI]	99.2 [97.9 – 99.7]

** With a very small proportion of subjects who have experienced an event, the median time is likely to be shorter than the actual time to event in the population; based on the limited number of events observed there is an underestimate of the true underlying time to event.

Probability of being free from DSRC at 6 months was estimated using the Kaplan-Meier method.

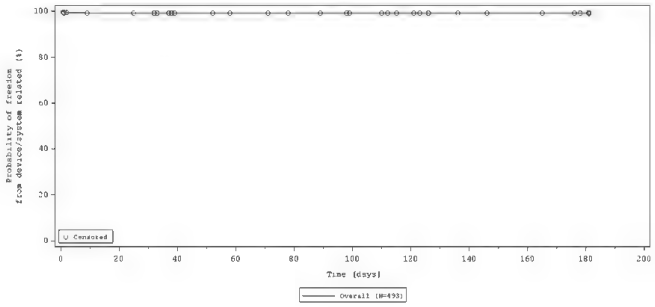


Figure 4: First Primary Safety Endpoint Analysis: Freedom From Device / System Related Complications Kaplan-Meier Plot*

* In case of event, time to event = [(Date of event – date of Implant visit) + 1]; In case of no event, time to event = [(Date of last available date – date of Implant visit) + 1], this data will be censored.

Table 4: Summary of DSRCs as Adjudicated by the CEC (ITT Population and Cohort #1)

Event Description and Term	**N (%)**	**Outcome**
Further Migration of the Cordella Sensor / Device Dislocation	1 (0.2%)	Recovered
Right internal jugular blood vessel complications secondary to device insertion attempt / Procedure Complication	1 (0.2%)	Recovered
Implant Device Complication/ Complication associated with device	1 (0.2%)	Recovered
Device breakage/ Pressure sensor fracture	1 (0.2%)	Recovered
Total Subjects Experiencing a DSRC in ITT population	4 (0.8%)	
Event Description and Term	**N (%)**	**Outcome**
LV-Lead dislodgement/ Lead Dislodgement	1 (1.4%)	Recovered
Total Subjects Experiencing a DSRC in Cohort #1	1 (1.4%)	

Second Primary Safety Endpoint

The second primary safety endpoint describes freedom from Pressure Sensor Failure (PSF) through 6 Months, which was tested against the null rate of 95%. With one (1) event the Freedom from Pressure Sensor Failure rate was 99.8% (Table 5). The probability of being free from a Pressure Sensor Failure event at 6 months post implant procedure was 99.8 % [95% CI: 98.6%, 100%]. The lower bound of the confidence interval, based on the KM method (Figure 5), is higher than the null rate of 95%.

The second primary safety endpoint was met.

The event of PSF is ongoing with the device implanted and without any further related events.

Table 5: Second Primary Safety Endpoint Analysis: Freedom from Pressure Sensor Failure

Item	Result	ITT (N=493)
Subject with any PSF	n (%)	1 (0.2%)
Censored	n (%)	492 (99.8%)
Subjects completed 6 months and without any PSF	n (%)	440 (89.2%)
Subjects withdrew prior to 6 months and without any PSF	n (%)	52 (10.5%)
Time to first PSF (days)		
25% percentile [95% CI]	181.0	
Median [95% CI]	181.0	
75% percentile [95% CI]	181.0	
Minimum	0.0	
Maximum	181.0	
Probability of being free from PSF	rate [95% CI]	0.998 [0.986 - 1.0]

Probability of being free from PSF at 6 months was estimated using the Kaplan-Meier method

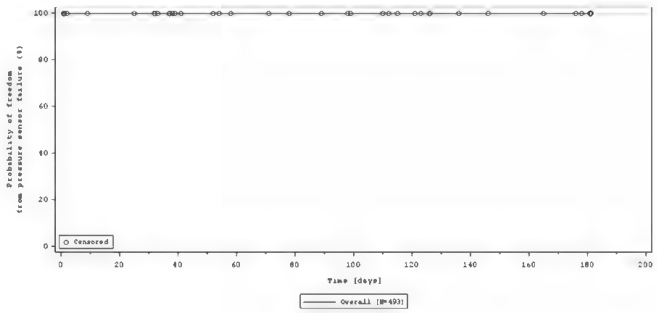


Figure 5: Second Primary Safety Endpoint Analysis: Freedom from Pressure Sensor Failure Kaplan-Meier Plot*

* In case of event, time to event = [(Date of event – date of Implant visit) + 1]; In case of no event, time to event = [(Date of last available date – date of Implant visit) + 1], this data will be censored.

Secondary Safety Results

Secondary safety endpoints were based on mITT population for (1) Pressure Sensor Failure rate throughout the study, and ITT population for (2) frequency of site reported SAEs throughout the study and (3) frequency of CEC adjudicated implant procedure and procedure-related AEs and SAEs.

Pressure Sensor Failure Rate throughout the Study

Up to the 6-month FU visit only (1) Pressure Sensor Failure has been reported.

Frequency of Serious Adverse Events (SAEs) throughout the Study

Table 6 presents a summary of serious adverse events as reported by investigators.
There were no unanticipated adverse device effects (UADEs).

Table 6: Predefined Serious Adverse Events by Category Through 6 Months for ITT and Cohort #1 Populations

Item	Result	ITT (N=493)	Cohort #1 (N=72)	ITT + Cohort 1 (N=565)	Cohort 1 vs ITT p-value
Subjects with at least one predefined SAE	n (%) n*	196 (39.8%) 425.0	31 (43.1%) 85.0	227 (40.2%) 510.0	0.5938
Heart Failure	n (%) n*	79 (16.0%) 100.0	16 (22.2%) 31.0	95 (16.8%) 131.0	0.189
ED Visit	n (%) n*	4 (0.8%) 4.0	0 (0%)	4 (0.7%) 4.0	0.4431
Hospitalization	n (%) n*	72 (14.6%) 90.0	16 (22.2%) 31.0	88 (15.6%) 121.0	0.0959
Urgent, Unscheduled Outpatient Office/ Practice	n (%) n*	2 (0.4%) 2.0	0 (0%)	2 (0.4%) 2.0	0.5882
Acute Kidney Injury (AKIN)	n (%) n*	22 (4.5%) 26.0	7 (9.7%) 8.0	29 (5.1%) 34.0	0.0589
Bleeding	n (%) n*	6 (1.2%) 6.0	4 (5.6%) 4.0	10 (1.8%) 10.0	0.0091
Conduction Disturbances and Arrhythmias	n (%) n*	28 (5.7%) 35.0	4 (5.6%) 4.0	32 (5.7%) 39.0	0.9661
Hemoptysis	n (%) n*	12 (2.4%) 13.0	1 (1.4%) 1.0	13 (2.3%) 14.0	0.5806
Myocardial Infarction (MI)	n (%) n*	3 (0.6%) 3.0	1 (1.4%) 1.0	4 (0.7%) 4.0	0.4607
Pulmonary Embolism	n (%) n*	6 (1.2%) 7.0	0 (0%)	6 (1.1%) 7.0	0.3467
Pulmonary Occlusion	n (%) n*	0 (0%)	0 (0%)	0 (0%)	NE
Renal Dysfunction	n (%) n*	8 (1.6%) 9.0	1 (1.4%) 1.0	9 (1.6%) 10.0	0.8823
Stroke and Trans Ischemic Attach (TIA)	n (%) n*	0 (0%)	1 (1.4%) 1.0	1 (0.2%) 1.0	0.0088
Vascular Access Site and Access-Related Complications	n (%) n*	4 (0.8%) 4.0	2 (2.8%) 2.0	6 (1.1%) 6.0	0.1284
Vessel Trauma	n (%) n*	4 (0.8%) 4.0	0 (0%)	4 (0.7%) 4.0	0.4431
Other	n (%) n*	123 (24.9%) 215.0	17 (23.6%) 30.0	140 (24.8%) 245.0	0.8059
Item	**Result**	**ITT (N=493)**	**Cohort #1 (N=72)**	**ITT + Cohort 1 (N=565)**	**Cohort 1 vs ITT p-value**
Subjects with at least one OTHER SAE	n (%) n*	123 (24.9%) 215.0	17 (23.6%) 30.0	140 (24.8%) 245.0	0.8059
Blood and lymphatic system disorders	n (%) n*	4 (0.8%) 6.0	0 (0%)	4 (0.7%) 6.0	0.4431
Cardiac disorders	n (%) n*	6 (1.2%) 7.0	1 (1.4%) 2.0	7 (1.2%) 9.0	0.902
Ear and labyrinth disorders	n (%) n*	1 (0.2%) 1.0	0 (0%)	1 (0.2%) 1.0	0.7021
Gastrointestinal disorders	n (%) n*	12 (2.4%) 14.0	1 (1.4%) 1.0	13 (2.3%) 15.0	0.5806
General disorders and administration site conditions	n (%) n*	8 (1.6%) 9.0	2 (2.8%) 4.0	10 (1.8%) 13.0	0.4875
Hepatobiliary disorders	n (%) n*	6 (1.2%) 7.0	0 (0%)	6 (1.1%) 7.0	0.3467
Immune system disorders	n (%) n*	1 (0.2%) 1.0	0 (0%)	1 (0.2%) 1.0	0.7021
Infections and Infestations	n (%) n*	46 (9.3%) 63.0	9 (12.5%) 11.0	55 (9.7%) 74.0	0.3967
Injury, poisoning and procedural complications	n (%) n*	10 (2.0%) 11.0	0 (0%)	10 (1.8%) 11.0	0.2227
Investigations	n (%) n*	2 (0.4%) 2.0	0 (0%)	2 (0.4%) 2.0	0.5882
Metabolism and nutrition disorders	n (%) n*	9 (1.8%) 9.0	3 (4.2%) 4.0	12 (2.1%) 13.0	0.1981
Musculoskeletal and connective tissue disorders	n (%) n*	4 (0.8%) 4.0	0 (0%)	4 (0.7%) 4.0	0.4431
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%) n*	1 (0.2%) 1.0	0 (0%)	1 (0.2%) 1.0	0.7021
Nervous system disorders	n (%) n*	13 (2.6%) 16.0	1 (1.4%) 1.0	14 (2.5%) 17.0	0.5245
Product issues	n (%) n*	6 (1.2%) 6.0	2 (2.8%) 2.0	8 (1.4%) 8.0	0.2951
Psychiatric disorders	n (%) n*	2 (0.4%) 2.0	1 (1.4%) 1.0	3 (0.5%) 3.0	0.2836
Renal and urinary disorders	n (%) n*	2 (0.4%) 2.0	0 (0%)	2 (0.4%) 2.0	0.5882
Respiratory, thoracic and mediastinal disorders	n (%) n*	25 (5.1%) 32.0	3 (4.2%) 4.0	28 (5.0%) 36.0	0.7412
Skin and subcutaneous tissue disorders	n (%) n*	4 (0.8%) 4.0	0 (0%)	4 (0.7%) 4.0	0.4431
Surgical and medical procedures	n (%) n*	1 (0.2%) 1.0	0 (0%)	1 (0.2%) 1.0	0.7021
Vascular disorders	n (%) n*	16 (3.2%) 17.0	0 (0%)	16 (2.8%) 17.0	0.121
Item	**Result**	**ITT (N=493)**	**Cohort #1 (N=72)**	**ITT + Cohort 1 (N=565)**	**Cohort 1 vs ITT p-value**
Subjects with at least one Unanticipated SAE	n (%) n*	151 (30.6%) 297.0	24 (33.3%) 45.0	175 (31.0%) 342.0	0.6429
Blood and lymphatic system disorders	n (%) n*	4 (0.8%) 5.0	0 (0%)	4 (0.7%) 5.0	0.4431
Cardiac disorders	n (%) n*	59 (12.0%) 82.0	10 (13.9%) 13.0	69 (12.2%) 95.0	0.6419
Ear and labyrinth disorders	n (%) n*	1 (0.2%) 1.0	0 (0%)	1 (0.2%) 1.0	0.7021
Gastrointestinal disorders	n (%) n*	13 (2.6%) 14.0	2 (2.8%) 3.0	15 (2.7%) 17.0	0.9446
General disorders and administration site conditions	n (%) n*	7 (1.4%) 7.0	2 (2.8%) 4.0	9 (1.6%) 11.0	0.39
Hepatobiliary disorders	n (%) n*	4 (0.8%) 5.0	0 (0%)	4 (0.7%) 5.0	0.4431
Immune system disorders	n (%) n*	1 (0.2%) 1.0	0 (0%)	1 (0.2%) 1.0	0.7021
Infections and Infestations	n (%) n*	41 (8.3%) 51.0	8 (11.1%) 9.0	49 (8.7%) 60.0	0.4312
Injury, poisoning and procedural complications	n (%) n*	12 (2.4%) 12.0	2 (2.8%) 2.0	14 (2.5%) 14.0	0.8609
Investigations	n (%) n*	1 (0.2%) 1.0	0 (0%)	1 (0.2%) 1.0	0.7021
Metabolism and nutrition disorders	n (%) n*	14 (2.8%) 15.0	2 (2.8%) 2.0	16 (2.8%) 17.0	0.9764
Musculoskeletal and connective tissue disorders	n (%) n*	3 (0.6%) 3.0	1 (1.4%) 1.0	4 (0.7%) 4.0	0.4607
Nervous system disorders	n (%) n*	11 (2.2%) 14.0	3 (4.2%) 3.0	14 (2.5%) 17.0	0.3237
Product issues	n (%) n*	3 (0.6%) 4.0	3 (4.2%) 3.0	6 (1.1%) 7.0	0.0059
Psychiatric disorders	n (%) n*	2 (0.4%) 2.0	1 (1.4%) 1.0	3 (0.5%) 3.0	0.2836
Renal and urinary disorders	n (%) n*	18 (3.7%) 23.0	2 (2.8%) 2.0	20 (3.5%) 25.0	0.7079
Respiratory, thoracic and mediastinal disorders	n (%) n*	30 (6.1%) 37.0	1 (1.4%) 1.0	31 (5.5%) 38.0	0.1021
Skin and subcutaneous tissue disorders	n (%) n*	4 (0.8%) 4.0	0 (0%)	4 (0.7%) 4.0	0.4431
Surgical and medical procedures	n (%) n*	2 (0.4%) 2.0	0 (0%)	2 (0.4%) 2.0	0.5882
Vascular disorders	n (%) n*	13 (2.6%) 14.0	1 (1.4%) 1.0	14 (2.5%) 15.0	0.5245

Of note, with an event rate of 3.0% for all-cause hemoptysis, the event rate of this safety endpoint in the early experience with this new device is

numerically higher than prior studies completed to date with similar PAP-measuring devices, such as in CHAMPION (0.2%), GUIDE-HF (0.3%) and MONITOR-HF (2.3%).

Frequency of Implant Procedure and Procedure-Related Adverse Events and Serious Adverse Events

Table 7 presents a summary of CEC adjudicated implant procedure and/or Cordella PA Sensor System related AEs and SAEs.

Table 7: Summary of CEC adjudicated Non-DSRC related AEs or SAEs

Item	Result n=Number of subjects (%) n*=Number of events	ITT (N=493)
Subjects with at least one predefined AE or SAE with study device or implant procedure relationship	n (%) n*	37* (7.5%) 39
Bleeding	n (%) n*	3 (0.6%) 3
Conduction Disturbances and Arrhythmias	n (%) n*	4 (0.8%) 4
Heart Failure	n (%) n*	2 (0.4%) 2
Hemoptysis	n (%) n*	15 (3.0%) 16
Pulmonary Embolism	n (%) n*	1 (0.2%) 1
Vascular Access Site and Access-Related Complications	n (%) n*	12 (2.4%) 13
Other	n (%) n*	16 (3.2%) 16
TOTAL	n (%) n*	52 (10.5%) 54
*Subjects may overlap in Predefined AE/SAE Categories and Category Other		

17.7.2 Effectiveness Results

The analysis of effectiveness was based on the 456 evaluable patients at the sixth month time point. Key effectiveness outcomes are presented in Tables 8 to 9.

Primary Effectiveness Results

Primary Efficacy Endpoint: Main Analysis

The historical composite event rates of HF hospitalization and all-cause mortality obtained from CardioMEMS literature and an internally derived meta-analysis for patients managed with PAP-guided HF management ranged from 0.31-0.44 events per patient 6-month and the historical composite event rates for the control arm patients ranged from 0.39-0.51.

The primary endpoint was based on all mITT subjects. The 6-month incidence of HF related hospitalizations or all-cause mortality was 0.1589 [95% CI: 0.1200, 0.2106] events per patient 6-month. The observed rate of 0.1589 was significantly less than PG (0.1589 vs 0.43; $p<0.0001$). Given that the upper confidence bound of the observed event

rate was less than PG (0.1589 vs 0.43), the observed rate was significantly lower than PG, and the observed rate was less than 0.37, all criteria for the primary efficacy were satisfied and the primary efficacy endpoint was met.

Of note, while the PROACTIVE-HF aimed to enroll NYHA class III HF patients, the final event rate for the primary effectiveness endpoint (0.1589) was numerically much lower than the average event rate derived from published results from clinically relevant, contemporary studies of NYHA class III HF subjects (as evidenced by an historical performance goal originally set at 0.43). While supportive of the overall benefit of the device, the benefit profile was not compared against concurrent standard of care subjects which should be taken into account when considering this device for a patient until additional data is available.

The primary efficacy endpoint summary statistics are shown in Table 8.

Table 8: Primary Endpoint Analysis and Components

Overall Primary Efficacy Endpoint Analysis and Components	Result	mITT (N=456)
6-month incidence of HF hospitalization or all-cause mortality	Event rate*	0.1589
	[95% CI]*	0.1200-0.2106
	p-value	<0.0001**
6-month incidence of HF hospitalization	Event Rate *	0.1334
	[95% CI]*	0.0989-0.1798
6-month incidence of all-cause mortality	Event Rate*	0.0221
	[95% CI]*	0.0119-0.0411
Number of HF hospitalization	n	60
Number of all-cause mortality	n	10
Total number of HF hospitalization or all-cause mortalities	n	70
HF hospitalization or all-cause mortalities subject event rate	n	456
	mean (SD)	0.1793 (0.5403)
	median	0.0
	min	0.0
	max	3.46
	missing (%)	0 (0%)
HF hospitalization or all-cause mortalities number of events per subject	n	456
	mean (SD)	0.15 (0.45)
	median	0.0
	min	0
	max	3
	missing (%)	0 (0%)
* Event rates with 95% confidence intervals were calculated using a negative binomial model **A one-sided p-value < 0.025 indicates that the 6 month incidence of HF hospitalizations or all-cause mortality < 0.43		
HF = Heart Failure Hospitalization, CI = Confidence Interval		

Primary Efficacy Endpoint: Stratified by Cohort Number

The main analysis was repeated on the individual cohort numbers and interpretation of p-values is done in a descriptive manner only. In the Cohort #1 population, the 6-month incidence of HF related hospitalizations or all-cause mortality was 0.3106 [95% CI: 0.1341, 0.7195] events per patient 6-month. The observed rate was not significantly less than PG (0.3106 vs 0.43; p=0.2214).

Comparison of the 6-month incidence of HF hospitalization or all-cause mortality event rates between subgroups was done with a negative binomial model. An alpha level of 0.15 is used for subgroup comparisons to balance type I and II error concerns given the study is not prospectively powered for such statistical hypothesis tests. The subgroup comparisons are generally considered to be exploratory and hypothesis generating. There is no adjustment for multiple comparisons.

The 6-month incidence of HF related hospitalizations or all-cause mortality was significantly different between Cohort #1 and the mITT population (Cohort #2 plus Cohort #3) (0.3106 vs. 0.1589, p=0.0858). Differences between Cohort #2 and Cohort #3 event rates (0.1557 vs. 0.1595, p=0.8979) were not significant. The primary efficacy endpoint summary statistics for Cohort #1, Cohort #2, and Cohort #3 are shown in Table 9.

Table 9: Primary Endpoint Analysis and Components Stratified by Cohort Number

Efficacy Endpoint Analysis and Components	Result	Cohort #1 (N=72)	Cohort #2 (N=88)	Cohort #3 (N=368)
6-month incidence of HF hospitalization or all-cause mortality	Event rate*	0.3106	0.1557	0.1595
	[95% CI]*	0.1341-0.7195	0.0731-0.3313	0.1180-0.2156
	p-value	0.2214	0.0042**	<0.0001**

6-month incidence of HF hospitalization	Event Rate*	0.269	0.1279	0.1347
	[95% CI]*	0.1234-0.5867	0.0590-0.2770	0.0975-0.1861
6-month incidence of all-cause mortality	Event Rate*	0.0279	0.023	0.0219
	[95% CI]*	0.0070-0.1114	0.0057-0.0919	0.0110-0.0438
Number of HF hospitalization	n	18	11	49
Number of all-cause mortality	n	2	2	8
Total number of HF hospitalization or all-cause mortalities	n	20	13	57
HF hospitalization or all-cause mortalities subject event rate	n	72	88	368
	mean (SD)	0.3351 (1.1326)	0.1643 (0.5516)	0.1829 (0.5383)
	median	0	0	0
	min	0	0	0
	max	6.84	3.03	3.46
	missing (%)	0 (0%)	0 (0%)	0 (0%)
HF hospitalization or all-cause mortalities number of events per subject	n	72	88	368
	mean (SD)	0.28 (0.86)	0.15 (0.49)	0.15 (0.44)
	median	0	0	0
	min	0	0	0
	max	5	3	3
	missing (%)	0 (0%)	0 (0%)	0 (0%)
Cohort #1 vs. mITT (Cohort #2 & Cohort #3) Event Rate p-value		0.0859†		
Cohort #1 vs. Cohort #2 Event Rate p-value		0.2378†		
Cohort #2 vs. Cohort #3 Event Rate p-value		0.8979†		

*Event rates with 95% confidence intervals were calculated using a negative binomial model
**A one-sided p-value < 0.025 indicates that the 6 month incidence of HF hospitalizations or all-cause mortality < 0.43
† alpha =0.15 for subgroup comparisons

HF = Heart Failure Hospitalization, CI = Confidence Interval

Secondary Effectiveness Results

All secondary efficacy endpoints were based on the mITT population and are applicable to 6-month follow-up. At 12-month follow-up, key secondary efficacy endpoints covered include 1) the incidence of HF hospitalization and all-cause mortality at 12 months, 2) The number of HF hospitalizations at 12 months post-implant compared to the number of HF hospitalizations in the 12 months prior to implant, 3) Comparison of the number of HF Hospitalizations or Emergency Department/ Hospital Outpatient IV diuretic visits of Cohort #1 and Cohort #2 + Cohort #3 at 12 months post implant, 4) change of N-terminal pro B-type Natriuretic Peptide (NT-proBNP) from Baseline through 12 months, 5) heart failure hospitalization or HF Emergency Department / Hospital Outpatient IV diuretic visits at 12 months, and 6) Change in pulmonary artery pressure from baseline through 12 months. 6-month results are presented below.

- The number of HF hospitalizations per subject at 6 months post-implant was significantly fewer than the number of HF hospitalizations per subject in the 6 months prior to implant in the mITT (0.6 ± 0.7 vs 0.1 ± 0.4; $p<0.0001$).
- For every HF hospitalizations or emergency department/ hospital outpatient IV diuretic visit event in Cohort #2 and Cohort #3 there were 1.4725 events in Cohort #1. The rate of events in Cohort #1 compared to the rate of events in Cohort #2 and Cohort #3 (0.2508 vs. 0.1703, $p=0.0697$) was significant (alpha level of 0.15).
- Mean NT-proBNP decreased from Screening to 6 months, however the change was not significant (1731.4 ± 3012.8 vs. 1632.5 ± 2742.4 pg/ml, $p=0.0628$).
- In the mITT population, 63 (13.8%) subjects had at least one of the combined outcomes of first and recurrent HF hospitalizations, emergency department/ hospital outpatient IV diuretic visits, and all-cause mortality with an event rate of 0.1925 [95% CI: 0.156, 0.2375]. These were primarily made up of first and recurrent HF hospitalization (N=60, 84% of total events), followed by emergency department / hospital outpatient IV diuretic visits (N = 17, 19.5% of total events) and all-cause mortality (N=10, 11.5% of total events).
- In the mITT population, 56 (12.3%) subjects had at least one of the combined outcomes of HF hospitalization of HF emergency/ outpatient IV diuretic visits with an event rate of 0.1703 [95% CI: 0.1362, 0.213]. These were primarily made up

of HF hospitalization (N=60, 78% of total events), followed by emergency department / hospital outpatient IV diuretic visits (N = 17, 22% of total events).

- In the mITT population, there were 10 all-cause deaths, 6 of which were cardiac related. All-cause mortality event rate was 0.0221 [95% CI: 0.0119, 0.0411] and cardiac mortality event rate was 0.0133 [95% CI: 0.006, 0.0295].

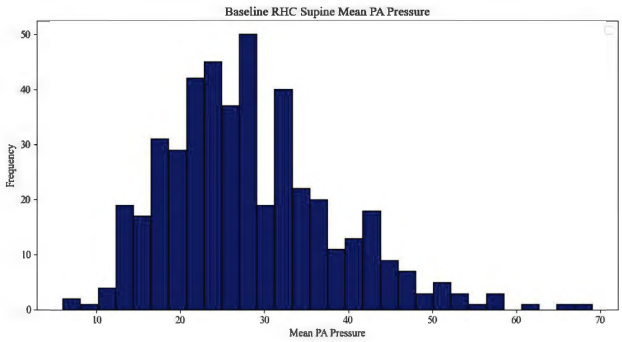
- Patients in the mITT population spent an average 172.0 ± 27.2 days alive and out of hospital.
- In the mITT population, 14 (3.1%) subjects had 17 outpatient IV diuretic visits with an event rate of 0.0376 [95% CI: 0.0234, 0.0605]. These were primarily made of hospital outpatient IV diuretic visits (N=10, 59% of total events) followed by HF emergency department IV diuretic visits (N=7, 41% of total events).
- For the mITT population, 234 (51.3%) subjects had a HF related medication change from implant to Month 1, 227 (49.8%) subjects had a HF related medication change from Month 1 to Month 3, and 260 (57.0%) had a HF related medication change from Month 3 to Month 6.
- Overall, the device successfully transmitted PAP data in 67651 out of 68232 days of data collection (>99%).

Change in PAP

Mean pulmonary artery pressure (mPAP) is summarized at all study visits by 'Above Target range', 'Within/Below Target range', and 'Overall' for subjects with a baseline mPAP. Target range is seated trend mPAP 5-20 mmHg.

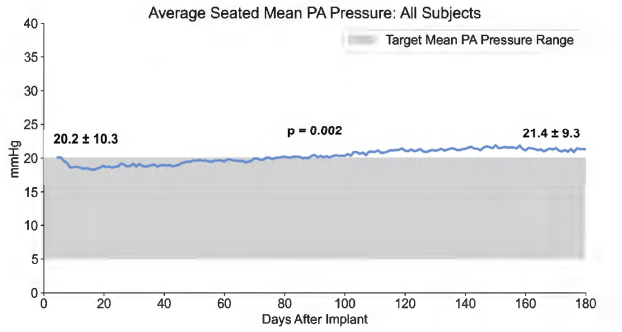
Seated trend mPAP and supine mPAP are external data collected by Endotronix, as measured by the Cordella System, and transmitted by the patients from home. Baseline is defined as the first trend seated mPAP transmitted from the patient within 14 days of the Implant Visit, V3 – Month 1 is defined as the last seated trend within 7 days prior to the visit, V4 – Month 3 is defined as the last seated trend within 7 days prior to the visit, and V5 – Month 6 is defined as the last seated trend within 14 days prior to and 14 days after the visit. Figure 6 shows the baseline distribution of RHC Supine Mean PA Pressure.

Figure 6: Histogram of Baseline Right Heart Catheterization Supine Mean Pulmonary Artery Pressure



In the overall mITT population, the seated trend mPAP increased significantly over 6 months (20.2 ± 10.3 vs. 21.4 ± 9.3 mmHg, p=0.002) as shown in Figure 7.

Figure 7: Average Trend Seated Mean Pulmonary Artery Pressure in the mITT Population



In the Above Target population, the seated trend mPAP decreased significantly over 6 months (29.2 ± 7.7 vs. 26.8 ± 9.2 mmHg, p=0.0006). In the Below/Within Target population, the seated trend mPAP increased significantly over 6 months (12.8 ± 4.9 vs. 17.0 ± 6.8 mmHg, p<0.0001). Summary statistics for the mITT population are shown in Table 10.

Table 10: Change in Seated Trend mPAP from Baseline through 6 months for mITT Population

Category	Time	Result	mITT (N=456)	Above Target* (N = 206)	Below/ Within Target* (N = 247)
Seated Trend mPAP (mmHg)	Baseline	n	437	197	240
		Missing, n (%)	19 (4.0%)	9 (4.0%)	7 (3.0%)
		mean (SD)	20.2 (10.3)	29.2 (7.7)	12.8 (4.9)
		median	19.12	27.43	13.7
	V3 - Month 1	n	432	199	233
		Missing, n (%)	24 (5.0%)	7 (3.0%)	14 (6.0%)
		mean (SD)	18.9 (11.5)	26.0 (8.8)	12.9 (10.0)
		median	17.62	25.22	12.5
	V4 - Month 3	n	426	194	232
		Missing, n (%)	30 (7.0%)	12 (6.0%)	15 (6.0%)
		mean (SD)	20.3 (9.6)	26.4 (9.2)	15.2 (6.6)
		median	18.83	25.84	15.07
	V5 - Month 6	n	388	171	210
		Missing, n (%)	68 (15%)	35 (17%)	37 (15%)
		mean (SD)	21.4 (9.3)	26.8 (9.2)	17.0 (6.8)
		median	20.4	16.2	17.3
Mean Implant Visit vs. Mean V5 - Month 6		p-value	0.0016	0.0006†	<0.0001†

mPAP = mean pulmonary artery pressure; * Target = seated trend mPAP 5-20mmHg as first transmitted from home. Baseline cut-off is 14 days from implant; †Repeated-measures-test

Change in Medication

Pulmonary artery pressure before and after changes in medication are also provided for the mITT cohort in Table 11. For the mITT cohort, an average increase in pulmonary artery pressures over 2-3 weeks preceded a medication increase. Following the medication increase, there was an average decrease in pulmonary artery pressures over 1-3 weeks for most medication classes.

Table 11: Mean and Standard Deviation of Trend Mean Seated Pulmonary Artery Pressures by Day of Dosage Increases of Various Medication Classes in the mITT Population (N=456)

Med Class	Number Patients	Number Increases	21 Days Before	14 Days Before	7 Days Before	Day Before	3 Days After	7 Days After	14 days After	21 Days After
Diuretic	276	1119	23.0 (8.6)	23.4 (8.5)	23.8 (8.7)	24.3 (8.7)	24.5 (8.6)	23.9 (8.6)	23.7 (8.6)	23.6 (8.4)
RASI	90	134	20.7 (10.5)	20.8 (10.0)	21.1 (10.1)	21.6 (10.0)	21.5 (9.9)	21.1 (9.5)	20.7 (9.0)	21.0 (9.2)
Beta Blocker	88	123	17.9 (9.0)	18.6 (8.7)	18.7 (9.1)	19.4 (8.8)	19.3 (8.6)	19.7 (9.1)	19.8 (9.2)	19.9 (8.8)
SGLT2-I	45	55	22.5 (8.7)	22.7 (9.0)	22.6 (9.1)	22.9 (8.2)	22.9 (7.8)	22.7 (8.1)	22.4 (8.5)	22.2 (8.6)
MRA	90	118	21.5 (8.6)	21.0 (8.5)	22.1 (10.0)	22.3 (9.5)	22.2 (9.1)	22.0 (9.4)	21.8 (9.2)	21.2 (8.6)
Nitrate	25	38	20.4 (11.2)	20.1 (10.7)	21.1 (10.3)	20.9 (9.6)	20.7 (9.5)	20.5 (9.7)	20.7 (9.8)	19.3 (9.6)
HHC	21	36	19.7 (9.2)	20.8 (8.7)	21.5 (10.2)	22.0 (10.2)	22.0 (9.5)	21.4 (10.2)	21.8 (11.1)	22.0 (12.4)

RASI = renin-angiotensin system inhibitor; SGLT2-I = sodium-glucose cotransporter 2 inhibitor; MRA = Minerlocorticoid receptor antagonist; HHC = hydralazine hydrochloride

Subject outcome measures, measured by Kansas City Cardiomyopathy Questionnaire (KCCQ)

In the mITT population, the KCCQ Overall Summary Score (OSS) improved over 6 months (52.8 ± 22.8 vs. 57.8 ± 24.2 points). Descriptive statistics for the KCCQ-OSS for the mITT population are shown in Table 12.

Table 12: Kansas City Cardiomyopathy Questionnaire OSS Score for the mITT Population

KCCQ Score	Time	Result	mITT (N=456)
Overall Summary Score	Screening	n	421
		missing (%)	35 (8.0%)
		mean (SD)	52.8 (22.8)
		median	52.6
		min	0.0
		max	100.0
	V3 - Month 1	n	407
		missing (%)	49 (11.0%)
		mean (SD)	55.8 (23.3)
		median	55.73
		min	2.6
		max	100.0
	V4 - Month 3	n	392
		missing (%)	64 (14.0%)
		mean (SD)	56.1 (24.6)
		median	56.68
		min	0.0
		max	100.0
	V5 - Month 6	n	379
		missing (%)	77 (17.0%)
		mean (SD)	57.8 (24.2)
		median	58.33
		min	0.0
		max	100.0
Screening vs. V5 - Month 6		p-value	<0.0001†
†Paired t-test			

Functional status improvement, as measured by six-minute walk test (6MWT)

In the mITT population, 6MWT distance increased, although not significantly, through 6 months (259.5 ± 121.1 vs. 283.2 ± 123.9 meters, p=0.001). Summary statistics for the mITT populations are shown in Table 13.

Table 13: 6-Minute Walk Test through 6 Months for the mITT Population

Category	Time	Result	mITT (N=456)
6MWT Total Distance Walked	Screening	n	436
		missing, (%)	20 (4.0%)
		mean (SD)	259.5 (121.1)
		median	267.74
		min	0.0
		max	780.0
	V5 - Month 6	n	347
		missing, (%)	109 (24.0%)
		mean (SD)	283.2 (123.9)
		median	290.0
		min	0.0
		max	640.0
Screening vs. V5 - Month 6		p-value	0.001†
†Paired t-test			

17.7.3 Subgroup Analyses

Main Analysis: Subgroups

Further analyses were undertaken to provide additional information of interest. The study was not specifically powered for the subgroups of the listed baseline characteristics. All p-values are for descriptive purposes only. The p-values are considered nominal. The following baseline characteristics were evaluated for potential association with safety and effectiveness outcomes:

1. male vs. female
2. HFpEF vs. HFrEF vs. HFmrEF
3. White vs. Non-White race
4. Hispanic vs. Non-Hispanic ethnicity
5. above median BMI vs. below median BMI
6. NT-proBNP > 1500 pg/mL vs NT-proBNP ≤ 1500 pg/mL
7. above median eGFR vs. below median eGFR
8. ischemic vs. non-ischemic HF

9. cardiac resynchronization therapy vs. no cardiac resynchronization therapy
10. enrollment type: all HFH vs. enrollment type: HFH criteria only vs. enrollment type: NT-proBNP criteria only vs. enrollment type: HFH & NT-proBNP criteria
11. pulmonary hypertension vs. no pulmonary hypertension
12. above target range vs. within/below target range
13. on SGLT2i at any time in 6-month follow-up vs. not on SGLT2i at any time in 6-month follow-up
14. on ARNI at any time in 6-month follow-up vs. not on ARNI at any time in 6-month follow-up
15. on MRA at any time in 6-month follow-up vs. not on MRA at any time in 6-month follow-up.

The 6-month incidence of HF related hospitalizations or all-cause mortality in all subgroups analyzed was significantly lower than the performance goal (0.43). The only subgroup comparisons that had significantly different event rates were those associated with pulmonary hypertension: pulmonary hypertension vs. no pulmonary hypertension (0.2349 vs. 0.0529, $p<0.0001$) and Above Target range vs. Below/Within Target Range (0.2540 vs. 0.0734, $p=0.0001$) and associated with high NT-proBNP: NT-proBNP > 1500 vs. NT-proBNP ≤ 1500 (0.2503 vs. 0.1053, $p=0.0026$). Results for each subgroup and subgroup comparison are shown in Table 14.

Table 14: Primary Efficacy Analysis: Subgroups

Subgroup	Event rate*	95% CI*
White (N=347)	0.1555	0.1114-0.2171
Non-White (N=109)	0.1704	0.1012-0.2866
Hispanic (N=20)	0.1036	0.0259-0.4142
Non-Hispanic (N=436)	0.1608	0.1208-0.2141
Below Median BMI (N=228)	0.1739	0.1159-0.2610
Above Median BMI (N=228)	0.1456	0.0985-0.2151
NT-proBNP > 1500 (N=148)	0.2503	0.1651-0.3796
NT-proBNP <= 1500 (N=298)	0.1053	0.0723-0.1532
Above Median eGFR (N=223)	0.1375	0.0897-0.2109
Below Median eGFR (N=231)	0.1795	0.1247-0.2630
Ischemic HF (N=143)	0.1857	0.1035-0.3333

Non-Ischemic HF (N=313)	0.1453	0.1085-0.1946
Cardiac Resynchronization Therapy (N=82)	0.1276	0.0593-0.2746
No Cardiac Resynchronization Therapy (N=374)	0.1658	0.1259-0.2242
Enrollment Type: All HFH (N=366)	0.1722	0.1271-0.2335
Enrollment Type: HFH criteria only (N=150)	0.103	0.0552-0.1920
Enrollment Type: NT-proBNP criteria only (N=89)	0.1047	0.0509-0.2151
Enrollment Type: HFH & NT-proBNP criteria (N=216)	0.2204	0.1562-0.3109
PH (baseline RHC mPAP > 20 mmHg) (N=264)	0.2349	0.1731-0.3188
No PH (baseline RHC mPAP ≤ 20 mmHg) (N=190)	0.0529	0.0284-0.0983
Above Target (seated mPAP > 20 mmHg) (N=206)†	0.254	0.1815-0.3555
Within Target (seated mPAP 5-20 mmHg) (N=247)†	0.0734	0.0462-0.1166
On SGLT2i at any time in 6-month follow-up (N=297)	0.1591	0.1149-0.2204
Not on SGLT2i at any time in 6-month follow-up (N=159)	0.1585	0.0919-0.2734
On ARNI at any time in 6-month follow-up (N=212)	0.16	0.1061-0.2415
Not on ARNI at any time in 6-month follow-up (N=224)	0.1579	0.1074-0.2322
On MRA at any time in 6-month follow-up (N=336)	0.1631	0.1187-0.2243
Not on MRA at any time in 6-month follow-up (N=120)	0.1475	0.0808-0.2691

*Event rates with 95% confidence intervals were calculated using a negative binomial model

† From baseline defined as the first trend seated mPAP transmission

SGLT2i = Sodium-Glucose Transport Protein 2 Inhibitors; ARNI = Angiotensin Receptor/Neprilysin Inhibitor; MRA = Mineralocorticoid Receptor Antagonist; BMI = Body Mass Index; HFH = Heart Failure Hospitalization; NT-proBNP = N-terminal Prohormone of Brain Natriuretic Peptide; HF = Heart Failure; PH = Pulmonary Hypertension; RHC = Right Heart Catheterization; mPAP = Mean Pulmonary Artery Pressure

17.7.4 Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

17.8 Conclusions

17.8.1 Effectiveness Conclusions

The benefits of the device are based on data collected in a single arm clinical study conducted to support PMA approval as described above.

The primary efficacy endpoint of the 6-month incidence of HF related hospitalizations or all-cause mortality in the modified Intent-to-Treat (mITT) population was met. For study success, the upper confidence bound of the observed event rate in the mITT population was required to be less than the performance goal (PG) which was 0.43 events per patient 6-month, or equivalently, that the corresponding p-value from the hypothesis test (6-month primary event rate < PG) was less than 0.025. Furthermore, the observed rate must be less than 0.37. Given that the upper confidence bound of the observed event rate was less than PG (0.2106 vs 0.43), the observed rate was significantly lower than PG (0.1589 vs 0.43; p<0.0001), and the observed rate was less than 0.37, all criteria for the primary efficacy endpoint were satisfied. The primary efficacy endpoint was tested in a number of subpopulations as prespecified by the PROACTIVE-HF protocol. These analyses were separate from the primary efficacy outcomes and were not endpoint contributing and so the findings here are hypothesis generating. All subgroups of the mITT population analyzed (Male, Female, HFpEF, HFrEF, HFmrEF) met the criteria for primary endpoint success with low rates of HF hospitalizations and mortality across all subgroups.

However, the population initially enrolled into PROACTIVE-HF as the control group in the randomized arm (Cohort #1) did not meet the criteria for efficacy endpoint success although the 6-month incidence of HFH or all-cause mortality was low (0.31 [95% CI: 0.13, 0.72]). Furthermore, the 6-month incidence of HF related hospitalizations or all-cause mortality was higher in Cohort #1 compared to the mITT population (Cohort #2 and Cohort #3) (0.3106 vs. 0.1589, p=0.0859; alpha=0.15) but lower than historical control groups. There was no difference between Cohort #1 and Cohort #2 (0.3106 vs. 0.1557, p=0.2378) event rates. There was an absence of difference between Cohort #2 and Cohort #3 (0.1557 vs. 0.1595, p=0.8979). Recall, the study was not prospectively powered for these analyses, p-values are nominal, and the results are hypothesis generating. However, the differences between Cohort #1 and both Cohort #2 and Cohort #3 may be attributed to the fact that the Cohort #1 population did not have access to PAP

(neither did their clinicians) for a median of 170 days in the 6 month follow-up but had access to vital signs for the entire duration of follow-up. Once PROACTIVE-HF was changed to a single arm trial, subjects and their clinicians in Cohort #1 were unblinded to PAP. In the 6 months following unblinding, the rate of HF hospitalization or all-cause mortality was 0.13 events per patient 6-month and at 12 months post-unblinding, the rate was 0.34 events per patient 12-month.

The primary 6-month incidence of HF related hospitalizations requiring one calendar day change or all-cause mortality was primarily made up of HF related hospitalizations, which occurred with an incidence of 0.1334 [95% CI: 0.0989, 0.1798] events per patient 6-months. The incidence of all-cause mortality was 0.0221 [95% CI: 0.0119, 0.0411] events per patient 6-month. These incidence rates were composed of 60 HF related hospitalizations and 10 all-cause deaths. These results compare favorably with the first randomized trial in PAP-guided HF management (CHAMPION), which reported 6-month incidences of HF related hospitalizations or all-cause mortality of 0.37. More contemporary trials only report 12-month incidences but estimating the 6-month rates via an exponential distribution result in 6-month incidences of HF related hospitalizations or all-cause mortality of 0.31 in GUIDE-HF NYHA III and 0.31 in MONITOR-HF. While PROACTIVE-HF did not include emergency department / hospital outpatient IV diuretic visits in the primary efficacy endpoint, these data are reported in the secondary outcomes. Including emergency department / hospital outpatient IV diuretic visits along with HF related hospitalizations and all-cause mortality results in an event rate of 0.1925 [95% CI: 0.156, 0.2375]. Of the 10 all-cause deaths, six were cardiac related resulting in a 6-month incidence of cardiac mortality of 0.0133 [95% CI: 0.006, 0.0295].

In the mITT population, the average seated trend mPAP increased over 6 months (20.2 ± 10.3 vs. 21.4 ± 9.3 mmHg, paired t-test p=0.0016). However, the target range for seated mPAP was 5-20 mmHg and, for those subjects who were above target range at baseline (i.e. congested), there was a significant decrease in seated mPAP over 6 months (29.2 ± 7.7 vs. 26.8 ± 9.2 mmHg, paired t-test p=0.0006 . For those subjects below / within target range at baseline (≤20 mmHg), there was significant increase in seated mPAP over 6 months (12.8 ± 4.9 vs. 17.0 ± 6.8 mmHg, paired t-test p<0.0001). It should be noted that, on average, these patients were still in target range at 6 months. The Cordella System is the first PAP-guided HF management system to incorporate seated PAP readings for HF management. As subjects spend most of their waking hours in an

upright position, seated measurements may be more relevant for monitoring in ambulatory HF subjects.

When subjects move from the supine to seated position, volume shifts may occur leading to venous pooling and seated PAP may be more representative of a subject's volume status under gravitational loading. The Cordella System is also the first PAP-guided HF management system to incorporate daily vital signs with seated PAP readings for HF management. For systolic blood pressure, both in-office (121.8 ± 19.1 vs. 115.9 ± 18.9, paired t-test p-value<0.0001) and home (118.4 ± 20.0 vs. 115.6 vs. 18.1 mmHg, paired t-test p-value 0.0056) readings were significantly lower at 6 months.

In the mITT population, the KCCQ Overall Summary Score improved over 6 months (52.8 ± 22.8 vs. 57.8 ± 24.2 points). Importantly, a change in 5 points is considered to be a small but clinically important change.15 Functional capacity, as measured by 6MWT improved in the mITT population (259.5 ± 121.1 vs. 283.2 ± 123.9 m).While NT-proBNP did not decrease significantly (p=0.06), the trend was favorable.

Much of the success of PAP-guided HF management relies on subjects sending in their data and clinicians responding in a timely and appropriate manner to those data. In PROACTIVE-HF, patient compliance was defined as transmitting at least 5 days of Cordella clinical data per week (did not need to be consecutive days). Subject compliance was very good with an average of 88% compliance over 6 months. Put another way, subjects submitted, on average, 6.2 days every week through 6 months. For the sites, compliance was defined as A) acknowledgements of all subjects' vital signs at least two times a week with a maximum of 4 days between data reviews and B) documentation of patient treatment decisions within the PMP system for each notification generated by the system. Here again, compliance was very good with an average of 93% acknowledging of subjects' PAP and vital signs within 4 days of transmission with an average of 2.2 days between transmission and acknowledgment. Furthermore, 93% of the notifications generated by the Cordella System had the related patient treatment decision entered into the system.

17.8.2 Safety Conclusions

The risks of the device are based on data collected in a clinical study conducted to support PMA approval as described above.

The study's first primary safety endpoint was the freedom from a Device/System-Related Complication (DSRC) through 6 months. Four adjudicated DSRC events were observed in the ITT population during the follow-up and the probability of being free from a DSRC at 6 months post-implant procedure was 99.2%.

None of the DSRCs resulted in permanent subject impairment or death and all subjects recovered without sequelae. The outcomes for DSRCs support an acceptable safety profile for Cordella PA Sensor implantation procedures and follow up, suggesting that even when DSRCs occurs, they can be managed effectively without long-term negative impacts on the patient. The first primary safety endpoint was met. However, with an event rate of 3.0% for all-cause hemoptysis, the event rate of this safety endpoint in the early experience with this new device is numerically higher than prior studies completed to date with similar PAP-measuring devices, such as in CHAMPION (0.2%), GUIDE-HF (0.3%) and MONITOR-HF (2.3%). The study's second primary safety endpoint was the freedom from Pressure Sensor Failure through 6 months. One event of Pressure Sensor Failure was reported and adjudicated and the probability of being free from a Pressure Sensor Failure event at 6 months post-implant procedure was 99.8%. Again, this is similar to what has been reported for the currently approved device. The second primary safety endpoint was met. Throughout the study thus far, there are no other reports on implanted PA sensors failing to provide readings indicating very good sensor stability and system performance.

There were comparable incidences of HF adverse events in the different subject populations, including hospitalizations, emergency department visits, and outpatient office or practice visits. Similar incidences of acute kidney injury and renal dysfunction were observed, along with vascular access site complications and vessel trauma. Peri-procedural hemoptysis was noted in 15 cases and all subjects with hemoptysis recovered.

In ITT and Cohort #1 populations, CEC adjudicated prespecified related Non-DSRC AEs/SAEs summed to seventy total events with (possible) relationship to procedure and/or study device. Ten of the (possibly)

procedure related events were also related to study device and two events were related to study device only.

Fifty-four (54) of related events occurred in ITT population, thirty-eight (38) in prespecified SAE categories and sixteen (16) in category "Other". The most common were Hemoptysis (n=15, 3%; number of events =15) and Vascular Access Site Complications (n =12, 2.4%; number of events =13). Further related events were Conduction Disturbances and Arrhythmias (n =4, 0.8%; number of events =4), Bleeding (n =3, 0.6%; number of events =3), Heart Failure (n =2, 0.4%; number of events =2) and Pulmonary Embolism (n =1,0.2%; number of events =1). In Cohort #1, a total of nine (serious) adverse events related to the procedure and/or study device were adjudicated. These included two instances of bleeding, two events of conduction disturbances and arrhythmias, one of each of vascular access site complication, and vessel trauma. Three procedure related category "Other" events were adjudicated. None of the AEs or SAEs related to the procedure or study device resulted in permanent impairment or death of any subject. With the exception of two instances, all subjects recovered without any lasting effects. One event of "Recovery with Sequelae" pertains to a device explant followed by the subject's full recovery. The second event of "Recovery with Sequelae" was succeeded by an event from which the subject has fully recovered. All subjects who experienced related events have not experienced any further events associated with the Cordella PA Sensor System during the study follow-up.

Observed hemoptysis events were mild or moderate, with most requiring no treatment beyond observation or medication. Interventions were limited to imaging during the RHC, chest X-ray, or CT Angiography. In two cases, intubation was necessary for airway protection, but both instances resulted in patient extubation and patient discharge. However, the occurrence of all-cause hemoptysis was numerically higher (3.0%) than prior studies completed to date with similar PAP-measuring devices, such as in CHAMPION (0.2%), GUIDE-HF (0.3%) and MONITOR-HF (2.3%). Based on internal clinical evaluation and event adjudication during the trial, IFU and physician training documents were updated to address the risks, lowering the Activation Clotting Time (ACT) requirement for the procedure and adding cautionary statements regarding guidewire insertion, all with the objective to decrease the residual risk of hemoptysis.

17.8.3 Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The primary and secondary safety and efficacy endpoints of PROACTIVE-HF were met. The safety profile showed 99.2% freedom from DSRC and 99.8% freedom from pressure sensor failure, with a 3.0% rate of all cause hemoptysis which was numerically higher than prior studies completed to date with similar PAP-measuring devices. In terms of effectiveness, the 6-month incidence of heart failure hospitalization and mortality were low across all populations analyzed. The incidence rate of 0.1589 [95% CI: 0.1200, 0.2106] events per patient 6-month met all criteria for primary endpoint success. While the PROACTIVE-HF aimed to enroll NYHA class III HF patients, the final event rate for the primary effectiveness endpoint (0.1589) was numerically much lower than the average event rate derived from published results from clinically relevant, contemporary studies of NYHA class III HF subjects (as evidenced by an historical performance goal originally set at 0.43). While supportive of the overall benefit of the device, the benefit profile was not compared against concurrent standard of care subjects which should be taken into account when considering this device for a patient until additional data is available.

There was an improvement in quality of life by five points and 6MWT through 6 months. There was high compliance in both subject transmission of daily data and clinician acknowledgement of those transmissions. Of note, these secondary analyses are purely exploratory, not powered and not adjusted for multiple comparisons.

18. Contact Us

The user should contact Competent Authority and Endotronix Customer Service to report any serious incident that has occurred in relation to the medical device.

For technical assistance setting up or using the Delivery System, Reader and/or Dock, or CalEQ, contact Endotronix Customer Service.

Questions or concerns regarding unexpected operation or events, serious incidents, and general inquiries can be directed to the contact information below:

Endotronix Customer Service

Endotronix, Inc.
1415 West Diehl Road
Suite #500W
Naperville, IL 60563
U.S.A

+1 888 512 5595 (US)
1800 814 282 (IE)
0800 000 9241 (DE)
+32 800 82 244 (BE)

support@endotronix.com

Appendices

Appendix A: Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Reader and Docking Station are devices that comply with IEC 60601-1-2 Ed. 4.1. CalEQ is a device that complies with IEC 60601-1-2 Ed. 4.0.

The Reader and Docking Station and CalEQ are intended for use in the electromagnetic environment specified below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
Conducted Emissions CISPR 11	Reader: Class B, Group 1 CalEQ: Class A, Group 1	The Reader must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The Reader is suitable for use in professional healthcare facility and home healthcare environments. The Calibration Equipment is suitable for use in professional healthcare facility.
Radiated Emissions CISPR 11	Reader: Class B, Group 1 CalEQ: Class A, Group 1	
Harmonic Current Emissions IEC 61000-3-2	Reader: Class A CalEQ: Class A	
Voltage changes, Fluctuations/ Flicker Emissions IEC 61000-3-3	Reader: Compliant CalEQ: Compliant	

The operator of the Reader and Docking Station and CalEQ should assure that it is used in such an environment.

NOTE: The EMISSIONS characteristics of CalEQ make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to

radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Reader and Docking Station are devices that comply with IEC 60601-1-2 Ed. 4.1. CalEQ is a device that complies with IEC 60601-1-2 Ed. 4.0.

The Reader and Docking Station are intended for use in the electromagnetic environment specified below:

Immunity Test	Test Level	Compliance	Electromagnetic Environment Guidance
Electrostatic Discharge Immunity IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst Immunity IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical professional healthcare facility or home healthcare environments.
Surge IEC 61000-4-5	±1 kV line to line	±1 kV line to line	
	±0.5 kV line to line	±0.5 kV line to line	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT (100% dip in UT) for 0.5 cycle	0% UT (100% dip in UT) for 0.5 cycle	
	0% UT (100% dip in UT) for 1 cycle	0% UT (100% dip in UT) for 1 cycle	
	70% UT (30% dip in UT) for 25 cycles(50Hz) and 30 cycles(60Hz)	70% UT (30% dip in UT) for 25 cycles(50Hz) and 30 cycles(60Hz)	
	0% UT (100% interruption in UT) for 250 cycles(50Hz) and 300 cycles(60Hz)	0% UT (100% interruption in UT) for 250 cycles(50Hz) and 300 cycles(60Hz)	

Power Frequency Magnetic Field IEC 61000-4-8	30A/m 50Hz and 60Hz	30A/m 50Hz and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical professional healthcare facility or home healthcare environments.
Radiated RF Immunity IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz	10V/m	Portable and mobile RF communication equipment should be no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Refer to the Recommended Separation Distances table for guidance on required separation distances based on the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF Immunity IEC 61000-4-6	3 Vrms Outside the ISM Bands 6 Vrms In the ISM and amateur radio bands 150kHz to 80MHz	3 Vrms Outside the ISM Bands 6 Vrms In the ISM and amateur radio bands	
Electromagnetic compatibility (EMC) IEC 61000-4-39	8A/m at 30kHz	8A/m at 30kHz	
	65A/m at 134.2kHz	65A/m at 134.2kHz	
	7.5A/m at 13.56MHz	7.5A/m at 13.56MHz	
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

CalEQ is intended for use in the electromagnetic environment specified below:

Immunity Test	Test Level	Compliance	Electromagnetic Environment Guidance
Electrostatic Discharge Immunity IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst Immunity IEC 61000-4-4	±1 kV for signal leads ±2 kV for power supply lines	±1 kV for signal leads ±2 kV for power supply lines	Mains power quality should be that of a typical professional healthcare facility environments.
Surge IEC 61000-4-5	±1 kV line to line	±1 kV line to line	
	±2 kV line to ground	±2kV line to ground	
Power Frequency Magnetic Field IEC 61000-4-8	30A/m 50Hz	30A/m 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical professional healthcare facility environments.
Radiated RF Immunity IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz	3V/m	Portable and mobile RF communication equipment should be no closer than 20cm to any part of the system, including cables specified by Endotronix. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF Immunity IEC 61000-4-6	3 Vrms Outside the ISM Bands 6 Vrms In the ISM and amateur radio bands 150kHz to 80MHz	3 Vrms Outside the ISM Bands 6 Vrms In the ISM and amateur radio bands	
NOTE: UT is the a.c. mains voltage prior to application of the test level. **NOTE 1:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Reader

The Reader is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Reader can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Reader as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (M)			
	174 MHz to 216 MHz $d = 1.2\sqrt{P}$	335 MHz to 450 MHz $d = 2\sqrt{P}$	809 MHz to 849 MHz $d = 0.3\sqrt{P}$	2.35 GHz to 2.65 GHz $d = 3.8\sqrt{P}$
1	1.20	2.00	0.30	1.20
10	3.79	6.32	0.95	3.79
100	12.00	20.00	3.00	12.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: For frequencies which may be described by two equations in the table above, the larger separation distance applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Reader Frequency Band

The Reader receives RF electromagnetic energy and includes RF transmitters that perform within the frequency range of 12.88MHz to 14.12MHz.

The Reader includes RF transmitters that perform at center bands (13.09MHz, 13.34MHz, 13.62MHz, and 13.90MHz).

BT Transceiver frequency

BT Smart Ready Module - FCC ID QOQBT121
Operating Frequency Range: 2402MHz – 2480MHz

Intel WiFi/Bluetooth Module FCC ID PD97265NG
Operating Frequency Range: 5.15GHz - 5.85GHz (dependent on country); 2.400 - 2.4835GHz (dependent on country).

FCC Statement

The Reader is approved for wireless transmission under FCC ID 2AR87ETXCPAS01. It has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult Customer Service.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

RF Exposure Compliance Information

This device meets the U.S. FCC's requirements for exposure to radio waves and is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy.

Appendix B: Equipment Specifications

Cordella™ PA Sensor System

Manufacturer: Endotronix

Method of measurement: Wireless interrogation of implanted Cordella Sensor

Pulmonary artery pulse pressure maximum range: 40-100 mmHg

Pulmonary artery pressure range at sea level: 0-100 mmHg

System Accuracy (short-term under typical environmental conditions): +/- 2 mmHg at baseline (740 mmHg) and +/- 3% across the pressure range compared to a reference pressure measurement for a pressure range of 600- 860mmHg (absolute).

Note: Accuracy of the Cordella PA Sensor System is affected by a change in body temperature, drift over time, positional variation of the Reader relative to the Sensor, and changes in ambient temperature and humidity. Error after combining all sources of variation is specified below.

Worst Case System Error: System Root Sum Square (RSS) error after combining all sources of variation must remain within +/- 7.8 mmHg over 10 years.

Patient safety/use: Typical reading time is 30 seconds.

Calibration: At implant and recalibration, approximately every 3-years, or when deemed necessary by a medical professional

myCordella™ Handheld Patient Reader

Manufacturer: Endotronix

Expected service life: Four years

Safety standards: Meets all relevant parts of IEC 60601-1 Ed. 3.2 and 60601-1-11 Ed. 2.1

EMC standards: Meets all relevant parts of IEC 60601-1-2 Ed. 4.1

Essential Performance: Error is less than 3 mmHg

Operating frequency: 12.88-14.12 MHz, 2.45 GHz

Physical

Approximate dimensions

- Width: 6.44 in / 16.35 cm
- Height: 2.0 in / 5.1 cm
- Depth: 5.63 in / 14.3 cm
- Weight: 1.2 lbs. / 0.54 kg

Power

Input of 4.2V/16.8V ⎓ 667mA/142mA

Environment

The Reader may not meet its performance specifications if stored or used outside the environmental ranges listed below.

Temperature

- Operation: 5 – 35 °C (41 – 95 °F)
- Transport: -10 – 55 °C (14 – 131 °F)
- Storage: -10 – 55 °C (14 – 131 °F)

Relative humidity

- Operation: 6 – 93% (non-condensing)
- Transport: 6 – 93% (non-condensing)
- Storage: 6 – 93% (non-condensing)

Atmospheric Pressure

- Operation: 800 – 1066 hPa

myCordella™ Docking Station

Manufacturer: Endotronix

Expected service life: Four years

Physical

Approximate dimensions
- Width: 5.5 in / 14.0 cm
- Height: 2.5 in / 6.4 cm
- Depth: 5.5 in / 14.0 cm
- Weight: 0.4 lbs. / 181.4 g

Environment

The Docking Station may not meet its performance specifications if stored or used outside the environmental ranges listed below.

Temperature
- Operation: 5 – 35 °C (41 – 95 °F)
- Transport: -25 – 70 °C (-13 – 158 °F)
- Storage: -25 – 70 °C (-13 – 158 °F)

Relative humidity
- Operation: 6 – 93% (non-condensing)
- Transport: 0 – 90% (non-condensing)
- Storage: 0 – 90% (non-condensing)

Atmospheric Pressure
- Operation: 800 – 1066 hPa

Power Cord

Cord length: ~ 5 feet / 1.5 m

AC Power: Wall mount style power supply
- Input of 100-240V ~, 50-60 Hz
- Output of 5V ⎓ @ 3A

Manufacturer: SL Power Electronics

Part No: ME20A0503B01

Docking Station
- Input: +5V ⎓ 3.0 A

Output: 4.2V/16.8V, 667mA/142mA

Calibration Equipment

Manufacturer: Endotronix

Expected service life: Five years

Mechanical Characteristics

Approximate dimensions
- Width: 27 in / 69 cm
- Adjustable Height: 55 in – 66 in / 140 cm – 168 cm
- Depth: 27 in / 69 cm
- Total Weight of Fully Loaded Equipment: 82 lbs / 37 kg
- Maximum Allowed Basket Load: 11 lbs/5 kg
- Display: 21.5" LCD, 1920 x 1080 (16:9)

Environment

The CalEQ may not meet its performance specifications if stored or used outside the temperature and humidity ranges listed below.

Temperature
- Operation: 5 – 35 °C (59 – 86 °F)
- Transport: -20 – 45C °C (-4 – 113 °F)
- Storage: 0 – 25 °C (32 – 77 °F)

Relative humidity
- Operation: 10 – 90% (non-condensing)
- Transport: 10 – 90% (non-condensing)
- Storage: 10 – 90% (non-condensing)

Classification:
- Class I Equipment
- IP Rating
  - Computer Monitor: IP65 Front Panel, IPX1 Back Cover
  - Barcode Scanner: IP42
  - NI 9215 DAQ: IP40
  - Docking Station: IP21
- Continuous Use

Safety standards: Meets all relevant parts of IEC 60601-1 Ed. 3.1

EMC standards: Meets all relevant parts of IEC 60601-1-2 Ed. 4.0

Essential Performance: Reference pressure error is less than 4mmHg

Electrical Characteristics

Power

- Computer Monitor
  - System Input: 12 – 48V ⎓
  - AC Adapter
    - Input: 100 – 240V ~ , 50/60 Hz, 2.0 – 1.0A
    - Output: 19V ⎓ 6.31A, 120W MAX
    - Cord Length: approx. 6 feet (2m)
  - Total Battery Capacity: 4700mAh
  - Battery Life (based on normal usage and environmental conditions): 3 hours
  - Charging Time (based on normal environmental conditions): 6.5 hours

- Multiple Socket Outlet (MSO)
  - REF: 100622-00
    - Input: 120V ~ , 60Hz, 12A
    - Output: 120V ~ , 60Hz, 12A
    - Cord Length: approx. 15 feet
  - REF: 100622-01
    - Input: 230V ~ , 50Hz, 13A
    - Output: 230V ~ , 50Hz, 13A
    - Cord Length: approx. 3m
  - REF: 100622-02, 100622-04
    - Input: 230V ~ , 50Hz, 16A
    - Output: 230V ~ , 50Hz, 16A
    - Cord Length: approx. 3m

Definition of Symbols

The following symbols are used on the labels of the Cordella Pulmonary Artery Sensor System:

Symbol	Standard	Clause Number	Explanatory Text
Rx Only	N/A	N/A	Caution: Federal law restricts this device to sale by or on the order of a physician.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.7.10	Unique Device Identifier
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.7.7	Medical Device
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.12	Single Patient Multiple Use
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.2.13	Single Sterile Barrier System with protective packaging inside
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.6	Manufacturer's catalogue or part number so that the medical device can be identified.

Symbol	Standard	Clause Number	Explanatory Text
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.5	Manufacturer's batch code so that the batch or lot can be identified.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.7	Manufacturer's serial number so that a specific medical device can be identified.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.8	Importer
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.2	Authorized representative in the European Community.
	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.2, Symbol 10	Need for the user to consult the instructions for use.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.2	Medical device that needs protection from light sources or heat.

Symbol	Standard	Clause Number	Explanatory Text
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.7	Temperature limits to which the medical device can be safely exposed.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.8	Humidity limits to which the device can be safely exposed.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.9	Atmospheric pressure limits to which the device can be safely exposed.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.4	Device that needs to be protected from moisture.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.1	Device that can be broken or damaged if not handled carefully.
	Federal Communications Commission	N/A	Federal Communication Commission Number.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.1	Device manufacturer.

Symbol	Standard	Clause Number	Explanatory Text
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.3	Date when the device was manufactured.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.4	Expiration date.
	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.1, Symbol 4	Device should be attached to direct current source.
	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.1, Symbol 8	Device should be attached to alternating current source.
	IEC 60417 Graphic symbols for use on electrical equipment	Table D.1, Symbol 9	Equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.2, Symbol 20	Type BF applied part complying with IEC 60601-1.

Symbol	Standard	Clause Number	Explanatory Text
	N/A	UN 3841	The myCordella Handheld Patient Reader and Calibration Equipment operate using lithium-ion batteries. Lithium-ion batteries should not be crushed or burned.
IPn$_1$n$_2$	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.3, Code 2	Manufacturer-determined degree of particle and water ingress protection, where... N1 = degree of protection from particulates (scale of 0-6); and N2 = degree of protection from water (scale of 0-8)
IP21	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.3, Code 2	Protected against solid foreign objects of 12.5 mm and greater, and against the effects of dripping water.
IP22	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.3, Code 2	Protected against solid foreign objects of 12.5 mm and greater, and against the effects of dripping water when tilted at 15°.
IP42	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.3, Code 2	Protected against solid foreign objects of 1.0 mm or greater, and against the effects of dripping water when tilted at 15°.

Symbol	Standard	Clause Number	Explanatory Text
IP65	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Table D.3, Code 2	Protected against total dust ingress, and against the effect of low pressure water jets from any direction.
	ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	7.3.2	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.4	General warning.
	N/A	N/A	On/Standby button.
	IEC 60417 Graphic symbols for use on electrical equipment	7000-5140	IEC 60417-5140 - Equipment includes RF Transmitter.

Symbol	Standard	Clause Number	Explanatory Text
	EN 50419 Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2009/96/EC (WEEE)	N/A	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.2	Do not re-use.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.2.3	Sterilized with ethylene oxide.
	IEC 60417 Graphic symbols for use on electrical equipment	7000-1321B	Mass.

Symbol	Standard	Clause Number	Explanatory Text
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.2.6	Do not re-sterilize.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.2.8	Do not use if package is damaged.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.3	Refer to Instructions for Use
 www. endotronix.com/ manuals	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.3	Refer to electronic Instructions for Use on this website.
	ISO 15233-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.5, Reference Annex B for the general negation symbol	Not made with natural rubber latex

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cordella™
HEART FAILURE SYSTEM

Cordella® Pulmonary Artery Sensor System

Calibration Equipment Operator's Manual

Rx Only
Exclusively for Clinical Investigations in Europe.

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Table of Contents

1. Introduction

1.1 System Overview

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT), as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations. The Cordella PA Sensor System consists of a catheter-based Delivery System with a pre-loaded Cordella PA Sensor (Cordella Sensor), Calibration Equipment (CalEQ), a myCordella Handheld Patient Reader (Reader) that allows patients to measure PA pressure at home, and Cordella Data Analysis Platform (CDAP), a cloud- based platform to store and analyze the PA pressure measurements. These Instructions for Use only describe the use of the Calibration Equipment. The Cordella Sensor and Reader have separate Instructions for Use. CDAP is not user-facing and does not have Instructions for Use.

The Calibration Equipment is hospital equipment that supports the implantation procedure. The main functions of Calibration Equipment include:

- Interrogates the Cordella Sensor to verify proper working condition prior to implant.
- Facilitates linking of component serial numbers to patient IDs.
- Calibrates the Cordella Sensor to a reference pressure at the time of implantation.
- Trains patient on optimal Reader placement post-procedure.
- Recalibrates the Cordella Sensor to a reference pressure post-implant.

1.2 Environment

The Calibration Equipment is intended for use in cardiac catheterization laboratories and pre-procedure and post-procedure holding areas. Use the system only for Cordella Sensor calibration. It does not perform diagnosis.

1.3 Equipment Training

Training is required prior to use of the system. Operation of the Calibration Equipment is limited to trained Endotronixâ personnel only. If you require information about this product, please contact Customer Service.

1.4 Installation

System installation and testing is performed on site by Endotronix Field Service Technicians. During initial installation of the equipment, the Calibration Equipment is assembled and connected to the hospital wireless network by Endotronix personnel. System testing may require access to the catheterization laboratory and/or connection to the hemodynamic monitoring system. After Endotronix performs the initial installation, it is the responsibility of the hospital to move the Calibration Equipment to its storage and use locations. Movement of the Calibration Equipment does not require Endotronix to reverify installation performance.

WARNING: No modification should be made to the installation without prior consent of Endotronix. Changes or modifications not expressly approved by Endotronix may void the customer's warranty on the system.

1.5 Conventions Used in this Manual

The following conventions are used in this manual.

Warning

Warnings indicate the potential for serious adverse reactions or safety hazards, and limitations in use imposed by them.

Precaution

Precautions indicate special care that should be taken to ensure safe and effective use of the device.

Note

Provide additional user information.

NOTE The Calibration Equipment may be used in conjunction with equipment not manufactured by Endotronix, including but not limited to patient monitors, whose operation may not be fully described within this manual. This manual should not supersede the operating instructions provided by the equipment manufacturer.

NOTE Pictures of the Calibration Equipment appearing throughout this manual are for illustration purposes only. Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

2. Safety

2.1 Important Safety Directions

These Instructions for Use are intended to assist users in the safe and effective operation of the products described. Before attempting to operate the product, users must read and understand the Instructions for Use.

2.2 Warnings and Precautions

Adhere to the following warnings, precautions, and notes. Additional warnings and cautions specific to a particular feature are provided in the appropriate sections of these instructions.

⚠ Warnings

- DO NOT expose any power accessories to food or liquids.
- DO NOT use the Cordella System in the presence of explosive or flammable anesthetic agents.
- The Cordella PA Sensor System is not intended for emergency use or real-time monitoring.
- Power cables may pose a tripping hazard. Be mindful of cords crossing walkways.
- The CalEQ is suitable for professional healthcare facilities except for near active heart failure hospital equipment and the radiofrequency (RF) shielded room of a medical electrical (ME) system for magnetic resonance imaging, where the intensity of electromagnetic (EM) disturbance is high.
- The CalEQ should not be used adjacent to or stacked with other equipment. If it is necessary to operate the components adjacent to or stacked with other equipment, verify that the system is operating normally in the configuration in which it will be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than ~5 feet (1.5m) to any part of the CalEQ. Otherwise, degradation of the performance of the CalEQ could result.

⚠ Warnings, cont.

- Only use the CalEQ accessories, cables, and/or components that have been supplied by Endotronix. Using other unlabeled accessories, cables, and/or components may affect patient safety and measurement accuracy.
- The CalEQ should not be used to obtain pulmonary artery pressure and/or pulmonary artery pressure derived parameters for diagnostic purposes.
- Only connect the CalEQ to 60601-1 compliant patient monitors. Using non-compliant patient monitors may affect patient safety and measurement accuracy.
- DO NOT place the CalEQ near a radiator, fireplace, stove, or any source of heat. Temperatures over 60˚C (140˚F) might cause the battery pack to explode, leak chemical fluids, or cause a fire. Operating the battery at a higher temperature increases the risk of a battery explosion.
- To avoid risk of electric shock, the CalEQ must only be connected to a supply main with protective earth.
- DO NOT plug additional devices into the CalEQ power strip.
- DO NOT use more than one CalEQ in the same general vicinity at one time, as use of multiple CalEQs at once may cause them to interfere with each other.
- DO NOT use more than one Reader in the same general vicinity at one time, as use of multiple Readers at once may cause them to interfere with each other.

Precautions

- The CalEQ should not be used in the sterile field.
- DO NOT expose any components of the Calibration Equipment to water or liquids. Contact Customer Service for a replacement if any components are exposed to water or liquids.
- The CalEQ contains a Lithium-Ion battery.

• Disconnect the CalEQ from mains connection while in storage if the CalEQ will not be used for more than two weeks.
• Since the battery will discharge over time in storage, it is best practice to charge every three months to extend cycle capacity or else the battery may fail to charge or hold power in the future.
• Systems that have been in storage for over 9 months without charge have a chance to fall into a failed battery state where the battery is unrecoverable. It is best practice to periodically charge unused equipment.
• For long term storage, the computer should be stored at a temperature range between 0°C and 25°C. You must take into account that the computer's internal temperature is higher than the outside temperature. Any temperature outside of this range would decrease battery performance.
• If the DAQ is expired, DO NOT use CalEQ and contact Customer Service.

2.3 Emissions and Immunity

This is a class A product. The use of accessories and cables other than those specified may result in increased emissions and/or decreased immunity of the Calibration Equipment.

The CalEQ has been tested and found to comply with the conducted and radiated RF emission requirements of the FCC "Code of Federal Regulations" Title 47, Part 15, Subpart B Sections 15.107 and 15.109 for Class A digital devices and with the limits for medical devices specified by IEC 60601-1-2. These limits are designed to ensure RF devices operate effectively without causing harmful interference and to provide reasonable protection against harmful interference in a typical medical installation. See Electromagnetic Compatibility section for more details.

2.4 Electrical Connection

The CalEQ is powered from AC current and has an internal battery.
The CalEQ does not require any special shut-down process. In the event of total power loss (including battery power) the device stops receiving and displaying patient data. Use the normal start-up procedure when power is restored.
The CalEQ is a Class 1 device that does not require a separate connection to a Potential Equalization Conductor. The power strip cord is to be used for mains disconnection. Plug the CalEQ into an easily accessible outlet.

3. Operation

The CalEQ is used to perform the initial calibration of the Cordella Sensor and perform recalibration when necessary. In addition, the CalEQ has a feature that can be used to train the patient on the optimal Reader placement. Operation of the Calibration Equipment is limited to trained Endotronix personnel only.

3.1 Computer Start-Up

Press the power button at the bottom right corner of the screen to turn on the computer. See Appendix A.2: Front Panel for location of power button.

Upon first login, the user will be prompted to change the password. The new password must meet the following complexity requirements:

- Not contain the user's account name ("CalEQ") or parts of the user's full name that exceed two consecutive characters
- Be at least seven characters in length
- Contain characters from three of the four categories:
  - English uppercase characters (A through Z)
  - English lowercase characters (a through z)
  - Base 10 digits (0 through 9)
  - Non-alphabetic characters (for example, !, $, #, %)

NOTE: Complexity requirements are enforced when passwords are changed or created. The user will be prompted to change the password every 90 days. If you forget your password or have difficulties logging in, contact Customer Service.

3.2 CalEQ Set-Up

3.2.1 Cable Connection

To calculate reference pressure parameters necessary for calibration, the CalEQ uses hemodynamic data fed to it from the analog output of the hospital's hemodynamic monitor. Follow the below steps to confirm proper setup with the monitor. If an Interconnect Cable is not provided with the CalEQ, calibration will be based on manually-entered reference pressure values rather than hemodynamic data from the monitor.

The cable input is located on the rear of the stand. See Appendix A.7: Data Acquisition System for a diagram of the CalEQ with location of cable input. The Interconnect Cable's BNC connector should remain attached to the cable input on the CalEQ. Connect the other end of the Interconnect Cable to the hemodynamic monitor's analog output. This will provide a pulmonary artery pressure measure to the CalEQ for calibration measurements. For compatible Interconnect Cables, see Appendix B: Interconnect Cables.

The analog invasive blood pressure signal from the hemodynamic monitor must be configured to the industry standard of 1V/100mmHg and 0V=0mmHg to be

compatible with the CalEQ. For more information on configuring the hemodynamic monitor, contact Customer Service or review the operating instructions provided by the manufacturer of the patient monitor.

The CalEQ is installed and configured by Endotronix based on the hemodynamic module to be used. Please notify Customer Service if there is a change in hemodynamic monitoring equipment as it may impact the compatibility and accuracy of the reference pressure signal obtained by the CalEQ.

3.2.2 Reader Pairing

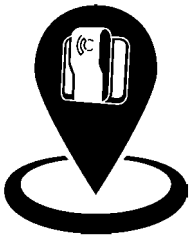
To pair a new Reader, undock and turn on the Reader, so that it is transmitting. Select the "Search for Readers" button. Available Readers will appear in the list. Select the desired Reader from the list. If the desired Reader does not appears, select the refresh button. If the Reader is also paired to a myCordella Tablet, ensure that the myCordella Tablet is turned off prior to starting to use the Reader with the CalEQ or the paired Reader may fail to connect to the CalEQ. To disconnect a Reader from the CalEQ, select the Reader from the list of paired Readers and follow the prompts. The Reader will need to be turned on and undocked.

NOTE: If you will be operating the CalEQ using battery power, ensure that the CalEQ and the Reader are fully charged before the start of the procedure.

3.3 Calibrate / Recalibrate

From the Main Menu, the user can begin a Calibration or Recalibration. See Cordella Pulmonary Artery Sensor System IFU (100663-04) for details on when to perform a Recalibration.

3.3.1 Interrogating the Cordella Sensor in Packaging



When prompted, scan the barcode on the Delivery System unit box. If performing a Recalibration, scan the Recalibration QR report provided by Endotronix. Ensure the information matches before continuing. If performing a Calibration, you will be prompted to undock the Reader to perform the Sensor Interrogation check. The Reader will start searching for the Sensor. Position the Reader along the top and side of the Delivery System box near the location symbol shown here. If a signal cannot be found, DO NOT use the Delivery System. Repeat with a new Delivery System package and contact Customer Service after the Calibration procedure.

- If the Reader is having difficulty connecting to the CalEQ, exit the Calibration and check that the Reader is on the 'Paired Readers' list.

3.3.2 Pairing the Sensor to the Patient

When prompted, scan the QR Barcode Report that was printed from the Patient Management Portal. If the patient ID does not match, the QR Barcode Report will need to be reprinted and rescanned. Ensure that all the Cordella Sensor and patient information is correct before proceeding with the implant procedure .

NOTE See Cordella Pulmonary Artery Sensor System IFU for details on:

- Delivery System Package Inspection
- Vessel Mapping and Guidewire Placement
- Delivery System & Cordella Sensor Insertion
- Cordella Sensor Implantation
- Obtaining a Reference Pressure

3.3.3 Searching – Fluid-Filled Reference Pressure Signal

Obtain a reference pressure, making sure to:

- Adjust the pressure transducer height to half of the patient's chest height
- Flush the catheter and fluid line to ensure there are no air bubbles
- Zero the measurement
- Check that the catheter tip is positioned within the PA and that the catheter does not cross the Sensor

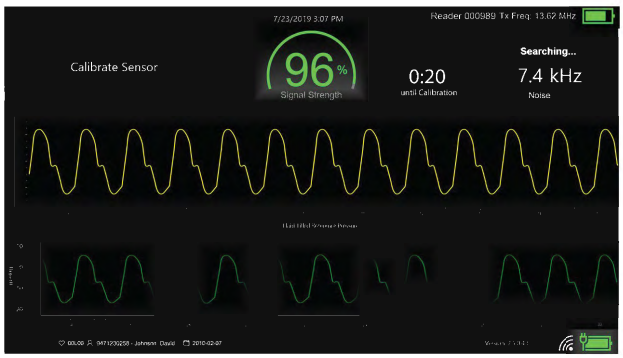
Compare the live fluid-filled reference pressure signal on the CalEQ with that on the patient monitor. Press "Continue" if the signal is correctly displayed.

NOTE: Signal strength and noise will populate when the Reader is undocked and connected.

- If the fluid-filled reference pressure signal displayed by CalEQ differs significantly from that displayed by the patient monitor or the fluid-filled reference pressure signal is not available, follow the steps in the on-screen Troubleshooting Guide.
- If the fluid-filled reference pressure signal displayed by the CalEQ has a similar shape as the reference pressure waveform on the patient monitor but the pulse pressure is significantly different, check the patient monitor settings. Confirm that the transducer is placed into the correct invasive blood pressure channel as instructed by the Clinical Specialist.
- If the fluid-filled reference pressure signal received by the CalEQ is lost during a calibration, the CalEQ will notify the user and require that the user resolve the connection issues to restore the signal.
- If issues persist, select "Manual Entry" and continue the procedure. You will be prompted to enter the pulmonary artery pressure measurements from the patient monitor. Contact Customer Service post-procedure.

3.3.4 Searching – Cordella Sensor Signal

Adjust the Reader position on the patient's chest to optimize the Signal Strength while keeping noise low. Reader ID, Reader Transmit Frequency, Reader Battery indicator, Signal Strength and Noise, and the live uncalibrated Cordella Sensor signal will appear when the Reader is connected to the CalEQ. After 20 consecutive seconds of a strong Sensor signal, the CalEQ will automatically advance to Calibrating and start collecting data for the calibration. The countdown at the top of the screen shows how many seconds until the screen will advance.



- To lower the noise level, relocate electromagnetic interference (EMI) generating equipment such as: patient monitoring systems, chest ECG leads, motors on motorized beds, C-arms, pagers, RFID tags, laptop computers, tablets, cell phones, cordless phones, wireless routers, air conditioners at least ~5 feet (1.5m), UHF RFID tags at least ~2 feet (0.6m), and RFID equipment operating at 2.45 GHz at least ~4 feet (1.2m) away from the Reader.

3.3.5 Calibrating

The CalEQ will collect Cordella Sensor and Fluid-Filled Reference Pressure data for 18 seconds. Do not adjust the Reader position or the patient monitor connections during this time. During Calibration, several indicators will not update in real time, including the Cordella Sensor and Fluid-Filled Reference Pressure waveforms, Signal Strength and Noise, Reader Transmit Frequency and Reader Battery capacity. The CalEQ will remain displaying the last 10 seconds of collected data. A progress bar displays the progress through the data collection.

- If the Reader signal is compromised during a calibration, the CalEQ will provide an error message with information on next steps.
- If fluid-filled reference pressure signal is lost during a calibration, the CalEQ will notify the user and require that the user resolve the connection issues to restore the signal.

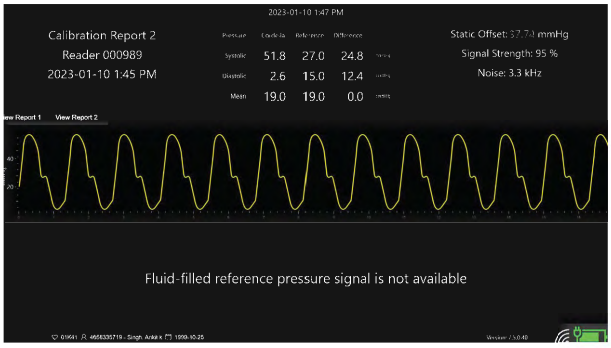
3.3.6 Reference Pressure Entry

If the reference pressures will be manually entered, the CalEQ will provide a keypad to enter the Systolic and Diastolic PA Pressures. The Mean PA Pressure is automatically calculated. Select "Next" to continue. The CalEQ will complete the calibration using the entered information.

NOTE: This information cannot be corrected without re-collecting the Cordella Sensor data. If you are completing this step after choosing to Calibrate Again and wish to use previously entered reference pressure values, use the restore button to recall the Systolic and Diastolic PA Pressures entered during the previous calibration.

3.3.7 Calibration Report

The report shows the collected Cordella Sensor pressures, reference pressures, a comparison between them, and the corrected waveforms. The report also shows the signal strength, noise, and Reader ID used during the calibration. If the results are acceptable, press the "Accept" button. If a recalibration seems necessary, press "Calibrate Again" and repeat the calibration steps. Toggle between each calibration attempt by selecting from the buttons at the top. The optimal calibration will have high signal strength, low noise, agreement between reference pressure and Cordella pressure, and no error messages. After the optimal calibration is accepted, you will be directed to a screen where you can upload the calibration data to the Endotronix Cloud. If the CalEQ is in a location without wireless network connectivity, select "Upload Later." Calibration data should be uploaded to the Endotronix Cloud as soon as connection to a wireless network is restored. See Section 3.4.5: Upload to Cloud.



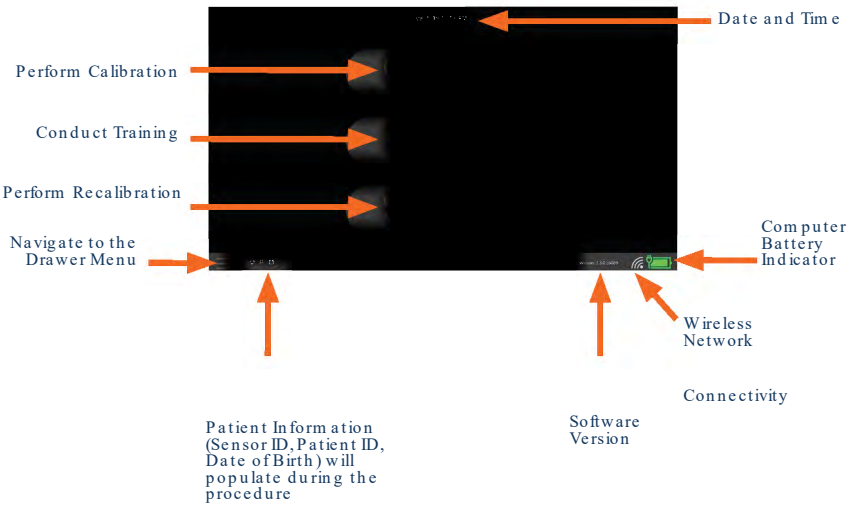
NOTE: The Reader must be disconnected from the CalEQ before it can be used by the patient at home. If you exit the Recalibration without disconnecting the Reader, you will need to navigate to the Reader Pairing page to disconnect the Reader.

3.4 Display Navigation

CalEQ includes a touchscreen that displays calibration reading information and step-by-step prompts to guide the user through the calibration, training, and recalibration process.

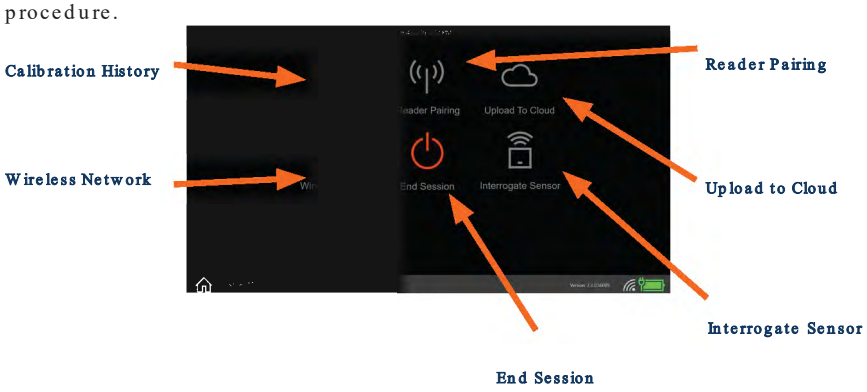
3.4.1 Main Menu

Following computer log in, the Main Menu is displayed. From the Main Menu, the user can begin Calibration, Training, or Recalibration. Navigate by pressing the buttons on the touchscreen.



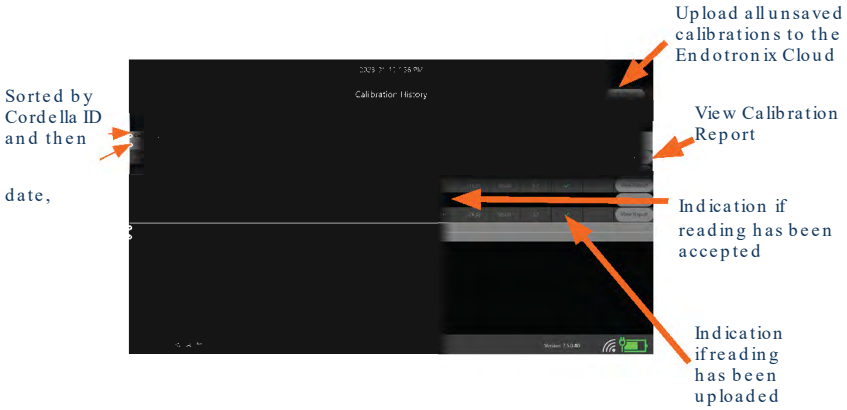
3.4.2 Drawer Menu

From the Main Menu, the user can navigate to the Drawer Menu. The Drawer Menu shows settings and additional information that can be viewed outside of the procedure.



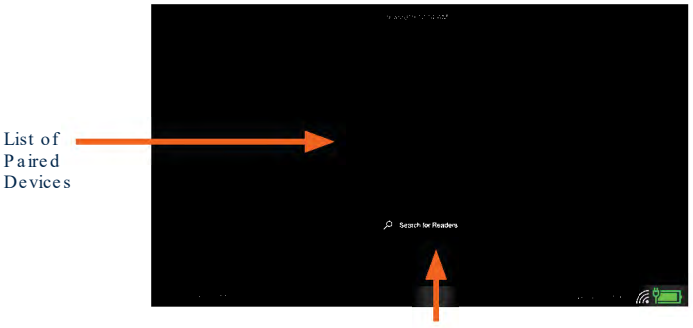
3.4.3 Calibration History

From the Drawer Menu, the user can navigate to the Calibration History page. The Calibration History displays a log of all calibration readings completed on the CalEQ and is organized by Cordella ID and calibration date. From the Calibration History page, the user can review a Calibration Report, choose to accept the calibration if being viewed on the day it was taken and has not yet been uploaded to the Endotronix Cloud, and upload new data to the Endotronix Cloud. The CalEQ must be connected to WiFi in order for the data to successfully upload. If the CalEQ is used in a location where connection to a wireless network is impossible, data will need to be transferred to the Endotronix Cloud manually. Please contact Customer Service for assistance.



3.4.4 Reader Pairing

From the Drawer Menu, the user can navigate to the Reader Pairing page. Once paired, the CalEQ can communicate to the Reader over Bluetooth. In addition to the raw data that is processed and displayed on the CalEQ, the Reader sends the CalEQ status update messages and error code messages over Bluetooth. The Reader Pairing page displays a list of the paired Readers. From the Reader Pairing page, the user can verify that a specific Reader is paired to the CalEQ. The Reader must be paired with the CalEQ in order for it to connect and transmit data to the CalEQ. Multiple Readers can be paired to each CalEQ. Readers can be identified by the Reader Serial Number on the product label.



NOTE: Wireless Network Connectivity is required to initially set up the Reader for use. See Wireless Network for instructions on how to connect. If the CalEQ is used in a location where connection to a wireless network is impossible, please contact Customer Service for assistance.

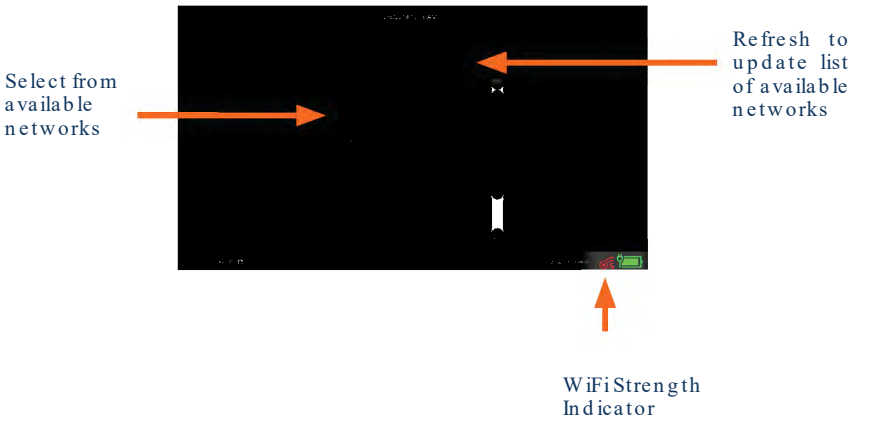
3.4.5 Upload to Cloud

From the Drawer Menu, the user can navigate to the Upload to Cloud page. From the Upload to Cloud page, the user can upload new data to the Endotronix Cloud. Selecting Upload to Cloud will upload all data that has not been previously uploaded. If the CalEQ is used in a location where connection to a wireless network is impossible, data will need to be transferred to the Endotronix Cloud manually. Please contact Customer Service for assistance.

3.4.6 Wireless Network

From the Drawer Menu, the user can navigate to the Wireless Network page wherein the user can see a list of available networks. If the desired network is not displayed, select the refresh button. After selecting the desired network, enter the network password using the on-screen keyboard.

WiFi is required to initially set up Readers for use during a procedure. Technical data is downloaded from the Endotronix Cloud. WiFi is also required to upload data to the Endotronix Cloud following a Calibration or Recalibration procedure. Connect the CalEQ to private, secured wireless networks only. If the CalEQ cannot be connected to a private, secured wireless network, contact Customer Service to transfer technical data manually or for an alternate method of accessing the Endotronix Cloud. If the CalEQ is connected to a wireless network that does not meet the security requirements, there may be increased cybersecurity risk. If the CalEQ is connected to a wireless network that includes other equipment, it is the responsibility of the hospital to identify, evaluate, and control the additional cybersecurity risks that could result.

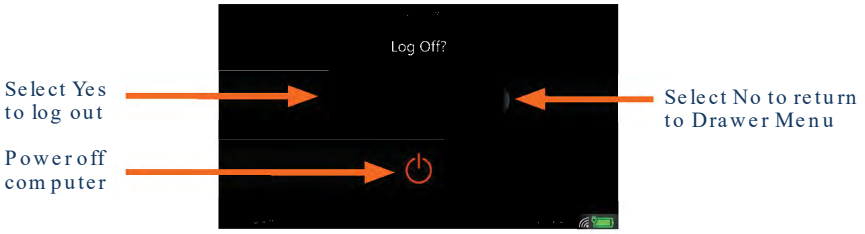


3.4.7 Interrogate Sensor

From the Drawer Menu, the user can navigate to the Interrogate Sensor page. From the Interrogate Sensor page, the user can complete the same Interrogate Sensor check from the Calibration procedure.

3.4.8 End Session

From the Drawer Menu, the user can navigate to the End Session page. The End Session page allows the user to sign out and shut off the computer.



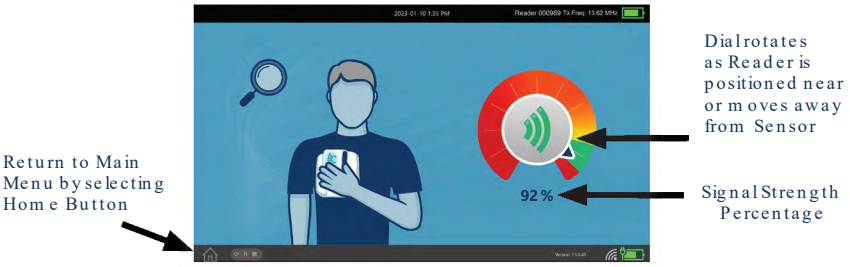
3.5 Reader Training Module

From the Main Menu, the user can begin Reader Training. The CalEQ will prompt the user to undock the Reader. The patient will pick up the Reader by its handle. When the Reader connects, the CalEQ will automatically advance to the Training screen. The patient will then place the Reader on their chest and move it towards their reading location (right side of the chest).

As the Reader is moved around, Signal Strength feedback is given in approximately real time. As signal strength changes, the pointer on the dial will move clockwise or counter clockwise and the signal symbol will grow and shrink between one and three signal bars. The patient should be trained to consistently place the Reader in the position that maximizes the signal strength without entering the red section that indicates the Reader is too close. There is no limit to the number of times a patient can complete the training.

When training is complete, dock the Reader or press the Home button to exit. The CalEQ will provide prompts to disconnect the Reader to prepare the Reader for use at the patient's home.

> **NOTE:** The Reader must be disconnected from the CalEQ before it can be used by the patient at home. If you exit the Training without disconnecting the Reader, you will need to navigate to the Reader Pairing page to disconnect the Reader.



4. Messages and Troubleshooting

4.1 Troubleshooting

For troubleshooting information about the implanting procedure, see the Cordella Pulmonary Artery Sensor System Instructions for Use.

4.2 Interrogating the Sensor and Pairing The Sensor to the Patient

If no information is displayed after attempting to scan the QR barcode:

- Check that the red barcode aiming dot is illuminated. If the aimer is not illuminated, check that the interface cable for the barcode scanner is connected properly to the handle and the CalEQ. If the barcode scanner is not functioning properly, contact Customer Service.
- Check that the QR barcode is not smeared, rough, scratched, exhibiting voids, or coated with frost or water droplets. If the QR barcode on the Delivery System packaging is damaged, contact Customer Service for assistance. If the QR barcode from the QR Barcode Report is damaged, re-print the QR Barcode Report from Patient Management Portal.

4.3 Messages

NOTE: Messages in this manual are intended for reference only and may not be an exact replication of the wording on the screen as a result of continuous software improvements. For any questions about a message on the CalEQ, please contact Customer Service for explanation.

Message	Explanation and/or Possible Solution
GENERAL	
Are you sure you want to leave this page? All unsaved data will be lost.	Message may appear when attempting to return to the Main Menu after starting a calibration.
Reader Error: Please dock Reader and try again.	Error message may appear due to Reader-CalEQ communication issue. Dock Reader and try again.

Messages, cont.

READER PAIRING	
Success: Reader ###### has been disconnected and is ready for home use.	Reader was successfully disconnected from the CalEQ. Reader will no longer communicate with the CalEQ. You must pair the Reader again in order to transmit data to the CalEQ.
Technical Data Not Downloaded. Reader ###### was not paired. Check wireless connection and try again. If issue persists, contact Endotronix to transfer technical data manually and try again.	Error message may appear when attempting to pair a new Reader to the CalEQ. Wireless network connection is required to set up a new Reader. Check wireless network connection and try again. If issue persists, contact Customer Service to transfer technical data manually and try again.
Error: The Reader you selected does not match the Reader that connected.	Error message may appear when attempting to disconnect Reader from Reader Pairing Menu. The Reader selected from the Paired Readers list did not successfully disconnect from the CalEQ. Verify that the Reader Serial Number selected from the Paired Readers list is the Reader that has been undocked. Reader Serial Number is listed on the product label.
Error: Failed to connect to Reader	Error message may appear when attempting to pair a new Reader. The CalEQ was unable to pair with the Reader selected from the available Readers list. Please try again.
Error: Failed to set up Reader for home use. Please dock Reader.	Error message may appear when attempting to disconnect Reader. The CalEQ was unable to set up the Reader for home use. Please try again.
Error: Failed to set up Reader for calibration.	Error message may appear when attempting to pair a new Reader. The CalEQ was unable to set up the Reader for use with CalEQ. Please try again.
Reader Communication Error. Please Dock the Reader. Ensure MyCordella tablet is powered off and try again	Error message may appear when attempting to pair the Reader or connect the Reader to CalEQ throughout the calibration workflow. Locate and turn off the patient's tablet before continuing

Messages, cont.

WIRELESS NETWORK	
Login failed. Check your credentials and try again.	Incorrect password entered. Wireless network cannot connect. Please try again.
INTERROGATING THE SENSOR AND PAIRING IT TO THE PATIENT	
Please scan the Sensor QR barcode from the Delivery System unit box	Error message may appear after attempting to scan the Sensor QR code. Verify that the Delivery System label is not damaged. Verify that the correct QR is being scanned.
Please scan the Recalibration QR barcode	Error message may appear after attempting to scan the Recalibration QR code. Verify the Recalibration QR is not damaged. Verify that the correct QR is being scanned.
Sensor is NOT Valid.	Error message may appear after scanning Sensor QR code. Verify that the Delivery System label is not damaged.
Sensor/patient mismatch. Recalibration cannot continue. Please confirm the barcodes are correct and try again.	Error message may appear during Recalibration. Confirm the barcodes are correct and try again.
SEARCHING FLUID FILLED REFERENCE PRESSURE SIGNAL	
Fluid-filled reference pressure signal is not available.	Error message may appear if no reference pressure signal is received or if the signal received is not showing signs of a typical PA pressure waveform. Check cable connections and hemodynamic module settings to restore signal. The user may continue onto calibration using manually entered PA pressure values if signal cannot be restored.
Fluid-filled reference pressure signal is out of range.	Error message may appear if the reference pressure signal is outside the range: -5mmHg to 120mmHg. Check the cable connections and hemodynamic module settings to restore the signal. Ensure the reference pressure catheter is in the correct location and the transducer is zeroed and at the correct height. The user may continue onto calibration using manually entered PA pressure values if signal cannot be restored.

Messages, cont.

Fluid-filled signal warning. Fluid-filled signal was lost.	Error message may appear if the CalEQ is not receiving reference pressure signal while searching for the optimal Reader position. Check cable connections and hemodynamic module settings to restore signal. The user may continue onto calibration using manually entered PA pressure values if signal cannot be restored.
Fluid-filled signal warning. Fluid-filled signal was lost during calibration	Error message may appear if the CalEQ stops receiving reference pressure signal during the calibration. Check cable connections and hemodynamic module settings to restore signal. The user may complete calibration using manually entered PA pressure values taken from a patient monitor or repeat calibration to calibrate with a restored signal.
CALIBRATING	
Sensor data collection in progress. Do NOT move Reader.	Message appears while the Reader is taking a calibration reading. Maintain the position with optimal signal strength determined during Searching phase.
Sensor data calibration in progress. Do NOT dock Reader.	Message appears immediately after the Reader finishes taking the calibration reading. Do not dock the Reader until prompted.
CALIBRATION REPORT	
Warning: Pulse Pressure Difference. Recommendation: Ensure the fluid-filled catheter is in the correct location, zero the pressure transducer, and repeat the calibration procedure.	Error message may appear after calibration reading data is collected. Ensure the fluid-filled catheter is in the correct location, zero the pressure transducer, and repeat the calibration procedure. Dismiss warning if the fluid filled catheter is in the correct location.
Something went wrong. An unexpected error has occurred. Please try again and contact Customer Service post-procedure.	Error message may appear after calibration reading data is collected. Repeat calibration and contact Customer Service post-procedure.

Messages, cont.

Signal Strength Error. The Reader moved too far or too close to the Cordella Sensor. Ensure Reader signal strength color is green and do not move Reader during calibration.	Error message may appear after calibration reading data is collected. Select "show details" for more information. Repeat the calibration procedure with the Reader in the optimal position.
Low Pulse Pressure Error. Low pulse pressure detected. If pulse pressure appears normal on patient monitor, reposition sources of electromagnetic interference (C-Arm, monitors, ECG leads, etc.)	Error message may appear after the calibration reading data is collected. Calibration was not able to be completed.
Interference Error. Interference detected. Reposition sources of electromagnetic interference (C-arm, monitors, ECG leads, etc.) and calibrate again or accept the calibration if waveform and noise value appear to indicate a good reading.	Error message may appear after calibration reading data is collected. Move patient monitoring systems, cell phones, pagers, ECG leads, C-arms, and other equipment that could cause interference at least 1.5m (5ft) away from the patient's chest and calibrate again. Alternatively, if the CalEQ continues to display the Interference Detected message, calibration can be completed after the implant procedure. Record the reference measurements during the procedure, then follow the calibration steps later. It is important that the patient's position during post-procedure calibration closely matches their position when the reference measurements were taken. Ensure that the patient's body, legs, and arm positions, as well as pillow use are the same. The patient should be breathing normally and should refrain from speaking.

Messages, cont.

Warning: Offset out of expected Range. Recommendation: Reposition sources of electromagnetic interference (C-arm, monitors, ECG leads, etc.), and repeat the calibration procedure.	Error message may appear after calibration reading data is collected if the calculated offset is outside the range: 20 mm Hg to 60 mm Hg. It is recommended to ensure the reference pressure and Cordella signals are correct by ensuring the fluid-filled catheter is in the correct location, zeroing the pressure transducer, moving patient monitoring systems, cell phones, pagers, ECG leads, C-arms, and other equipment that could interfere with the Reader at least 1.5m (5ft) away from the patient's chest and calibrate again.
Calibration Again will restart the calibration workflow. Are you sure you want to Calibrate Again? Select Yes to Calibrate Again	Message may appear when selecting Calibrate Again after a successful calibration.
Are you sure you want to accept the calibration? Select Yes to continue.	Message may appear when selecting Accept after a successful calibration
Are you sure you want to leave this page? Select Yes to go to Home. Select No to return to the Calibration Report	Message may appear when selecting Home after a successful calibration without accepting.
PATIENT TRAINING MODULE	
Would you like to disconnect this Reader and set up for home use?	Message may appear when exiting Training. If the user selects Yes, the CalEQ will provide prompts to disconnect the Reader. If the user selects No, the user will be brought to the Main Menu.
Success: Reader ###### has been disconnected and is ready for home use.	The Reader will no longer communicate with the CalEQ. You must pair the Reader again in order to transmit data to the CalEQ.

Messages, cont.

UPLOAD TO CLOUD	
No Calibration Data Found	Message may appear when attempting to Upload to Cloud but there is no unsaved data on the CalEQ to upload. The Calibration History will show a check mark under Uploaded to Cloud or Saved to USB columns.
Failed to connect to Endotronix Cloud	Error message may appear when attempting to Upload to Cloud either immediately following a procedure or through the Upload to Cloud button on the Drawer Menu. If the CalEQ is connected to a wireless network and the issue persists, contact Customer Service for assistance.

5. Maintenance

5.1 Inspection

Inspect the CalEQ system regularly. If any of the inspection checkpoints fail, please contact Customer Service.

5.2 Inspection Checklist

- Power cords are not frayed or connected to unauthorized equipment. If there is a frayed power cord or if the unit is attached to unauthorized equipment, unplug the unit and notify Customer Service to obtain a new one.
- Cables are properly attached and in good condition.
- All accessories are securely attached.
- Components are not in or near water.
- Components have not been moved to an unsuitable location.
- The CalEQ power supply should not be covered by any plastic protection cover.
- If any component has been dropped or damaged, contact Customer Service. Qualified service personnel must inspect any dropped or damaged units before they are assigned for use.

5.3 Cleaning

- Clean the system components after each use.
- Shut down the CalEQ before cleaning or disinfecting.
- To clean, wipe the surfaces with Super Sani-Cloth wipes or equivalent cleaner.
- DO NOT disassemble. Clean only the surfaces of the CalEQ.
- DO NOT immerse any component in any liquid.
- DO NOT spray liquids directly on any component – use a pre-moistened cloth.
- DO NOT autoclave.
- DO NOT sterilize with ethylene oxide.

5.4 Transport

To transport the CalEQ, turn off the computer. To do this, press the Drawer Menu, select "End Session," then select "Power Off." Unplug the power strip and wrap up the power cord. Disconnect the Interconnect Cable from the hemodynamic module (if applicable). Do not disconnect the Interconnect Cable from the CalEQ. Wrap the Interconnect Cable around the hooks on the basket. The CalEQ computer should remained plugged into the power strip. To unlock the casters, lift the locking mechanism. To lock the caster, push the locking mechanism down. See Appendix A.9: Roll Stand Base for a diagram with the location of the locking mechanism on the Roll Stand casters.

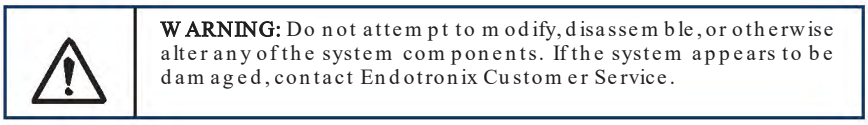
5.5 Maintenance and Replacement

To maintain applicable warranties and function, Endotronix requires that only authorized personnel perform repairs and preventative maintenance. There are no user serviceable parts. Repairs made by unauthorized personnel will invalidate your warranty. For product warranty information, please contact Endotronix. Changes or modifications not expressly approved by Endotronix may void the customer's warranty on the system.

To help ensure the equipment remains in proper operational and functional order, adhere to a good maintenance schedule. Endotronix requires that the following be performed by authorized service personnel at least every 12 months after installation, and every time the unit is serviced:

- Inspection
- Cleaning
- Replacement of parts when applicable, for example parts which:
    - Have reached their end of useful life or their calibration due date
    - Have been identified as available for upgrade
- Software update when applicable.
- The battery will discharge over time in storage, therefore it is best practice to charge the battery every three months to extend cycle capacity or else it may fail to charge or hold power in the future. Systems that have been in storage for over 9 months without charge have a chance to fall into a failed battery state where the battery is unrecoverable. It is important to periodically charge unused equipment.

The CalEQ does not require customer maintenance. If an issue with the system appears to require maintenance, contact Customer Service.



WARNING: Do not attempt to modify, disassemble, or otherwise alter any of the system components. If the system appears to be damaged, contact Endotronix Customer Service.

If there are defects or damage to any system component, including power accessories, request a replacement from Endotronix and follow the RMA process (described below) as requested by Customer Service.

Software configuration of the CalEQ can only be performed by Endotronix authorized personnel.

5.6 Disposal

The CalEQ contains Lithium-ion batteries, which should not be discarded with the municipal waste.

5.7 Return Material Authorization (RMA)

If Customer Service requests that the equipment be returned, please follow the directions below.

1. Carefully pack the equipment in the original shipping box or equivalent with protective packaging materials or equivalent as instructed by Customer Service.

2. Include the RMA number given to you by Customer Service on the outside of the shipping container. Ship all equipment and signed equipment return list to:

   RMA#
   Customer Service Department, Repairs
   Endotronix, Inc.
   1415 West Diehl Road
   Suite #500W
   Naperville, IL 60563 U.S.A

6. Specifications

NOTE: The Calibration Equipment may not meet performance specifications if stored or used outside temperature and humidity specifications. When moving the device from such a location, wait at least one hour prior to use to allow it to adjust to room temperature.

6.1 Requirements

System Technical Description	Calibration Equipment (CalEQ)
Address users can refer to	1415 West Diehl Road Suite #500W Naperville, IL 60563 U.S.A
Type of protection against electric shock	Class I externally powered equipment
Degree of protection against ingress of water	Computer Monitor: IP65 Front Panel, IPX1 Back Cover Barcode Scanner: IP42 DAQ: IP40 Dock: IP21
Mode of operation	Continuous
Type of use/reuse	Multiple patient multiple use
Useful Life	Expected service life of 5 years

6.2 General – System

Pulmonary artery pulse pressure maximum range	40-100 mmHg
Pulmonary artery pressure range at sea level	0-100 mmHg
Operating Temperature Range	5 – 35 °C (41 – 95 °F)
Storage Temperature Range	0 – 25 °C (32 – 77 °F)
Transport Temperature Range	-20 - 45 °C (-4 - 113 °F)
Operating Relative Humidity Range	10 – 90% (non-condensing)

Transport &Storage Relative Humidity Range	10 – 90% (non-condensing)
Safety and Performance Standards Compliance	IEC 60601-1:2012 Edition 3.1; IEC 60601-1-2:2014 Edition 4.0
Signal Input from Hemodynamic Monitor:	1V/100mmHg
Dimensions (as assembled)	Width: 27in / 69cm Adjustable Height: 55in – 66in / 140cm – 168cm Depth: 27in / 69cm Display: 21.5" LCD, 1920 x 1080 (16:9)
Current	AC
Voltage range, type of current, frequency, power input (watts, amps, VA)	Multiple Socket Outlet (MSO) ➔ REF: 100622-00 • Input: 120V ~, 60Hz, 12A • Output: 120V ~, 60Hz, 12A • Cord Length: approx. 15 feet ➔ REF: 100622-01 • Input: 230V ~, 50Hz, 13A • Output: 230V ~, 50Hz, 13A • Cord Length: approx. 3 meters ➔ REF: 100622-02, 100622-04 • Input: 230V ~, 50Hz, 16A • Output: 230V ~, 50Hz, 16A • Cord Length: approx. 3 meters
Total Battery Capacity	4700 mAh
Battery Life (based on normal usage and environmental conditions)	3 hours
Charging Time (based on normal environmental conditions)	6.5 hours
Standard Operator Position	1m
Maximum Allowable Basket Load	11 lbs / 5 kg
Total Weight of Fully Loaded Equipment	82 lbs / 37 kg

NOTE: The battery on the computer has a lifespan of between 300 and 500 cycles under normal usage and operating conditions. Using the computer in a higher or lower ambient temperature affects the total number of cycles in the battery's service life.

NOTE: Avoid frequently plugging and unplugging the power adapter to extend the battery's lifetime.

NOTE: Please notify Customer Service if you start noticing shorter and shorter battery run times as this may mean the batteries are nearing their end of life.

NOTE: It is recommended to keep the Calibration Equipment connected to wall power (supply mains) while in use. If the Calibration Equipment is being operated using battery power, the Readers should be powered off when not in use.

6.3 Electromagnetic Compatibility

6.4 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The CalEQ complies with FCC rules and IEC 60601-1-2 Ed. 4.0. The Calibration Equipment is intended for use in the electromagnetic environment specified below.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
FCC Title 47, Part 15, Subpart B		
Conducted limits Section 15.107	Class A digital device	The Calibration Equipment is suitable for use in commercial environment.
Radiated emission limits Section 15.109	Class A digital device	
60601 1 2 Ed. 4.0		
Conducted Emissions CISPR 11	Class A Group 1	The Calibration Equipment is suitable for use in professional healthcare facility.
Radiated Emissions CISPR 11	Class A Group 1	
Harmonic Current Emissions IEC 61000-3-2	Class A	
Voltage changes, Fluctuations/Flicker Emissions IEC 61000-3-3	Compliant	

The operator of the CalEQ should assure that it is used in such an environment.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

6.5 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CalEQ complies with IEC 60601-1-2 Ed. 4.0. The Calibration Equipment is intended for use in the electromagnetic environment specified below.

Immunity Test	Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic Discharge Immunity IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst Immunity IEC 61000-4-4	±1kV for signal leads ±2 kV for power supply lines	±1kV for signal leads ±2 kV for power supply lines	Mains power quality should be that of a typical professional healthcare facility.
Surge IEC 61000-4-5	±1kV line to line	±1kV line to line	
	±2 kV line to ground	±2 kV line to ground	
Power Frequency Magnetic Field IEC 61000-4-8	30A/m 50Hz	30A/m 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical professional healthcare facility.

Radiated RF Immunity IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz	3V/m	Portable and mobile RF communication equipment should be no closer than 20cm. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF Immunity IEC 61000-4-6	3 Vrms Outside the ISM Bands 6 Vrms In the ISM and amateur radio bands 150kHz to 80MHz	3 Vrms Outside the ISM Bands 6 Vrms In the ISM and amateur radio bands	
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Portable and Mobile RF Communications Equipment and the Reader

The Reader is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Reader can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Reader as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)			
	174 MHz to 216 MHz $d = 1.2\sqrt{P}$	335 MHz to 450 MHz $d = 2\sqrt{P}$	809 MHz to 849 MHz $d = 0.3\sqrt{P}$	2.35 GHz to 2.65 GHz $d = 2\sqrt{P}$
0.01	0.12	0.20	0.03	0.20
0.1	0.38	0.63	0.09	0.63
1	1.20	2.00	0.30	2.00
10	3.79	6.32	0.95	6.32
100	12.00	20.00	3.00	20.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: For frequencies which may be described by two equations in the table above, the larger separation distance applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Reader Frequency Band

The Reader receives RF electromagnetic energy and includes RF transmitters that perform within the frequency range of 12.88MHz to 14.12MHz.

The Reader includes RF transmitters that perform at center bands (13.09MHz, 13.34MHz, 13.62MHz, and 13.90MHz).

BT Transceiver frequency

Intel WiFi/Bluetooth Module FCC ID PD9AX210NG
Operating Frequency Bands: includes 2.4GHz / 5GHz / 6GHz

FCC Statement

The equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

6.6 Essential Performance

- The Essential Performance defined for the CalEQ is: the reference pressure error is less than 4mmHg.

7. Summary of PROACTIVE-HF Pivotal Study

Objectives/Purpose

The objective of the PROACTIVE-HF study was to demonstrate the safety and efficacy of the Cordella PA Sensor System. The patient population consisted of male and female patients, ≥ 18 years of age with a diagnosis of NYHA Class III HF who were eligible for enrollment if they were treated with GDMT for a minimum of 3 months (stable doses at least 30 days prior to enrollment) and, within the past year, the patient had either 1) one HF hospitalization, or 2) HF treatment in a hospital day care setting, or 3) urgent outpatient clinic HF visit for IV diuretics, or 4) a persistently elevated NT-proBNP level at the time of screening. After obtaining written informed consent and screening, eligible patients underwent a device Implant Visit in conjunction with a right heart catheterization procedure. Post-procedure follow-ups were scheduled at 1-Month, 3-Month, 6-Month, 12-Month, 18-month, 24-Month, 36-Month, 48- Month, and 60-Month (final follow-up).

Study Design

The PROACTIVE-HF study was a prospective, multi-center, open-label, single-arm clinical trial to assess device safety and efficacy of the Cordella PA Sensor System

in NYHA Class III Heart Failure patients compared to a Performance Goal (PG) based on a meta-analysis on the combined cohorts of CHAMPION-HF, CardioMEMS Post approval study, MEMS-HF, GUIDE-HF (NYHA Class III cohort), and LAPTOP-HF (control group only). The PROACTIVE-HF study was originally designed as a prospective, randomized controlled multi-center clinical trial but converted to a single-arm, open-label clinical trial in December 2021.

Intended Use

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT), as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

Contraindications

The Cordella Pulmonary Artery Sensor System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

Safety Endpoints

Primary Safety Endpoints:

1. Freedom from device or system-related complications (DSRC) at 6 months is tested against a null rate of 90%

2. Freedom from pressure sensor failure at 6 months is tested against a null rate of 95%

Secondary Safety Endpoints:

1. Frequency of serious adverse events (SAEs) throughout the study

2. Frequency of implant procedure and procedure related adverse events and serious adverse events

3. Pressure sensor failure rate throughout the study

Efficacy Endpoints

Primary Efficacy Endpoint:

The primary endpoint was the 6-month incidence of HF related hospitalizations (HFH) or all-cause mortality. Six (6) months data were compared to a Performance Goal (PG) based on treatment outcomes for CardioMEMS data.

The statistical PG of 0.43 was derived from published results from clinically relevant, contemporary studies of NYHA Class III HF subjects. For study success, the upper confidence bound of the observed event rate for the planned study must be less than the PG. Additionally, the observed event rate was required to be less than 0.37. Evaluating the upper bound of the confidence interval for the observed rate, ensures that 1) the observed rate is comparable to prior studies of active treatment (highest observed value = 0.44), 2) the observed rate is less than the mean rate from meta-analysis of prior studies of treatment and control, and 3) the observed rate is less than the lowest rate observed in the control studies

(GUIDE-HF). The added requirement for the observed rate to be less than 0.37 provides further assurance that results are comparable to studies of prior treatment.

*Please refer to the Instructions for Use in the Implant Manual or Summary of Safety and Effectiveness Data (SSED) for a listing of all secondary endpoints, inclusion/exclusion criteria.

Results

The data results from the PROACTIVE-HF study support the reasonable assurance of safety and effectiveness of the Cordella PA Sensor System when used in accordance with the indications for use. The primary and secondary safety and efficacy endpoints of PROACTIVE-HF were met. The safety profile was excellent with 99.2% freedom from DSRC and 99.8% freedom from pressure sensor failure. The event rate for all-cause hemoptysis (coughing up blood) was 3.0% for which this safety endpoint in the early experience with this new device is numerically higher than prior studies completed to date with similar PAP-measuring devices, such as in CHAMPION (0.2%), GUIDE-HF (0.3%) and MONITOR-HF (2.3%). Overall, the 6-month incidence of heart failure hospitalization and mortality were low across all populations analyzed. The incidence rate of 0.1589 [95% CI: 0.1200, 0.2106] events per patient 6-month met all criteria for primary endpoint success. While PROACTIVE-HF aimed to enroll NYHA Class III HF patients, the final event rate for the primary effectiveness endpoint (0.1549) was numerically lower than the average event rate derived from published results from clinically relevant, contemporary studies of NYHA Class III HF subjects. This unexpected finding may warrant further evaluation in future studies.

There was an improvement in quality of life by five points, and 6MWT through 6 months. Subjects with mean PAP (mPAP) above target range (seated mPAP > 20 mmHg) at baseline saw a reduction in mPAP (2.4 mmHg) and subjects with normal/below normal PAP saw an increase in mPAP (4.2 mmHg), although, on average, these subjects remained within target range at 6 months. Of note, these secondary analyses are purely exploratory, not powered and not adjusted for multiple comparisons. There was high compliance in both subject transmission of daily data and clinician acknowledgement of those transmissions.

In NYHA Class III patients at risk of congestive events, the Cordella PA Sensor and HF System was safe, improved quality of life and functional capacity. The markedly low event rates may relate to high subject and clinician compliance, high rates of GDMT at baseline, and integration of daily vital signs with seated PAP, which may be more relevant for monitoring of ambulatory HF patients. However, the lower event rate compared to clinically relevant, contemporary studies of NYHA Class III HF patients may need to be explored in future studies.

*Please refer to the Instructions for Use in the Implant Manual or Summary of Safety and Effectiveness Data (SSED) for a comprehensive summary of the study.

8. Contact Us

The user should contact Competent Authority and Endotronix to report any serious incident that has occurred in relation to the medical device.

For technical assistance setting up or using the Delivery System, Reader and/or Dock, or CalEQ, contact Endotronix.

Questions or concerns regarding setup, use, unexpected operation or events, serious incidents, and general inquiries can be directed to the contact information below:

Endotronixâ Customer Service

Endotronix, Inc.
1415 West Diehl Road
Suite #500W
Naperville, IL 60563
U.S.A

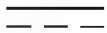
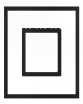
+1 888 512 5595 (US)
1800 814 282 (IE)
0800 000 9241 (DE)
+32 800 82 244 (BE)
support@endotronix.com

9. Symbols

The following safety symbols and messages may appear in your manual, on the equipment labels or shipping carton. Please read carefully:

Symbol	Standard Number	Standard Title	Clause Number	Explanatory Text
Rx Only	N/A	N/A	N/A	Caution: Federal law restricts this device to sale by or on the order of a physician.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.7.10	Unique Device Identifier
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.7.7	Medical Device
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.12	Single Patient Multiple Use
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.6	Manufacturer's catalogue or part number so that the medical device can be identified.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.5	Manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.7	Manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.8	Importer

Symbol	Standard Number	Standard Title	Clause Number	Explanatory Text
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.2	Caution: Federal law restricts this device to sale by or on the order of a physician.
	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.2, Symbol 10	Need for the user to consult the instructions for use.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.2	Medical device that needs protection from light sources or heat.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.7	Temperature limits to which the medical device can be safely exposed.
	ISO 15223-2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.8	Humidity limits to which the device can be safely exposed.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.9	Range of atmospheric pressure to which the device can be safely exposed.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.4	Device that needs to be protected from moisture.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.1	Device that can be broken or damaged if not handled carefully.
	N/A	Federal Communications Commission	N/A	Federal Communication Commission Number.

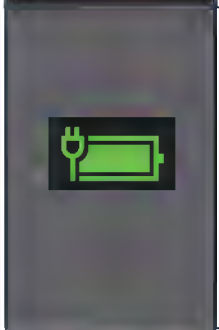
Symbol	Standard Number	Standard Title	Clause Number	Explanatory Text
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.1	Device manufacturer.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.3	Date when the device was manufactured.
	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.1, Symbol 4	Device should be attached to direct current source.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.4	Expiration Date.
	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.1, Symbol 8	Device should be attached to alternating current source.
	N/A	N/A	UN 3481	The Reader and Calibration Equipment operates using lithium ion batteries. Lithium-ion batteries should not be crushed or burned.
	IEC 60417	Graphic symbols for use on electrical equipment	Table D.1, Symbol 9	Equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	IEC 60601-1	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance.	Table D.2, Symbol 20	Type BF applied part complying with IEC 60601-1.

Symbol	Standard Number	Standard Title	Clause Number	Explanatory Text
IPN_1N_2	IEC 60601-1	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance.	Table D.3; Code 2	Manufacturer-determined degree of particle and water ingress protection, where... N1 = degree of protection from particulates (scale of 0-6); and N2 = degree of protection from water (scale of 0-8)
IP21	IEC 60601-2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.3; Code 2	Protected against solid foreign objects of 12.5 mm and greater, and against the effects of dripping water.
IP40	IEC 60601-3	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.3; Code 2	Protected from tools and small wires greater than 1mm, and not protected from liquids.
IP42	IEC 60601-4	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.3; Code 2	Protected against solid foreign objects of 1.0 mm or greater, and against the effects of dripping water when tilted at 15°.
IP65	IEC 60601-5	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.3; Code 2	Protected from total dust ingress, and against the effects of low-pressure water jets from any direction.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.4	General warning.
	N/A	N/A	N/A	On/Standby button.
	IEC 60417	Graphic symbols for use on electrical equipment	7000-5140	IEC 60417-5140 - Equipment includes RF Transmitter.

Symbol	Standard Number	Standard Title	Clause Number	Explanatory Text
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	N/A	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste.
	IEC 60417	Graphic symbols for use on electrical equipment.	7000-1321B	Mass.

The following safety symbols and messages may appear in the user interface. Please read carefully:

	Navigate to Drawer Menu
	Navigate to Main Menu. Exits Calibration/ Recalibration. If selected prior to accepting Calibration, data will be lost.
Version ##.#.####	Calibration Equipment Software Version. Appears in lower right corner.
Reader######	Reader serial number. Appears in the upper right corner when Reader is connected to the CalEQ.
	Wireless pairing unavailable. Contact Endotronix Customer Service.
	No wireless network connectivity. See instructions for Wireless Network.
	No wireless network connectivity. Additional actions required. See instructions for Wireless Network.
	Wireless network connectivity. Strength of network connection shown with number of bars.

	Sensor ID
	Patient ID and Name
	Patient Date of Birth
	Battery Level (Reader) – High (green, solid), Empty (red, blinking) Reader battery indicator appears when the Reader is connected to the CalEQ. The Reader battery indicator is located in the upper right corner, to the right of the Reader serial number. Do not begin a calibration procedure if Reader battery is Empty.
	Battery Level (Computer) – High (green, solid), Empty (red, blinking) The CalEQ battery indicator appears in the lower right corner, to the right of the Software Version. The CalEQ battery indicator appears with the plug when the power strip is plugged in and the computer is charging. The CalEQ battery indicator appears without the plug when the computer is not charging and running off of the battery. Start a calibration procedure with the CalEQ fully charged if performing the procedure with the CalEQ running off of the battery,
	Signal Strength Indicator - Red. Signal strength is low. The CalEQ will not transition to calibration. Adjust the position of the Reader to increase the signal strength until the signal strength indicator turns Green.
	Signal Strength Indicator - Yellow. Signal strength is medium. Adjust the position of the Reader to further optimize the signal until the signal strength indicator turns Green. The CalEQ will transition to calibration after several seconds in this signal strength zone.
	Signal Strength Indicator - Green. Signal strength is in the target range. The CalEQ will transition to calibration after several seconds in this signal strength zone.
	Signal Strength Indicator - Too Close. Signal strength is too high. The CalEQ will not transition to calibration. Adjust the position of the Reader to return to the target range.

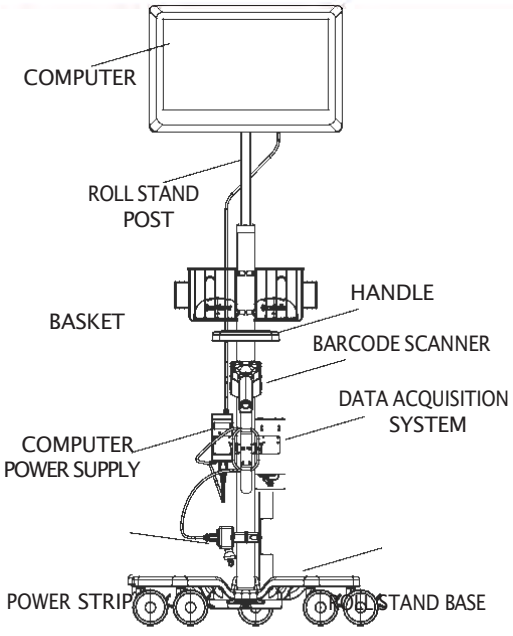
Appendices

Appendix A: Parts Identification

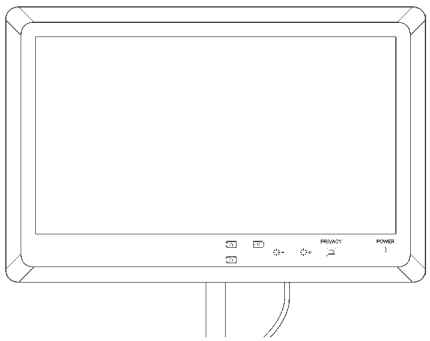
NOTE: Pictures of parts and equipment are for illustration purposes only. Figures in this appendix are intended for reference only and may not be an exact replication of the equipment as a result of continuous system improvements.

A.1 System Overview

Box	Contents
1	• Computer • Basket • Handle • Power Strip and Mount • Barcode Scanner and Mount • Power Supply and DAQ Mount • Calibration Equipment Operator's Manual
2	• Roll Stand



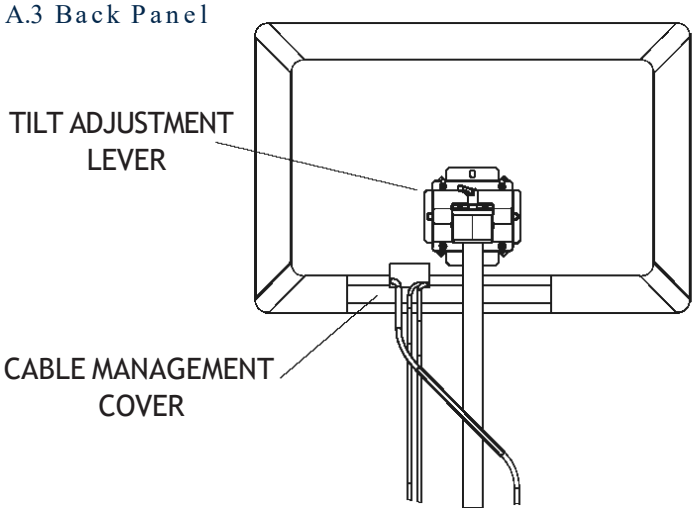
A.2 Front Panel



There are four buttons on the lower bezel of the screen. In addition, there are three battery indicator lights. From left to right, they are:

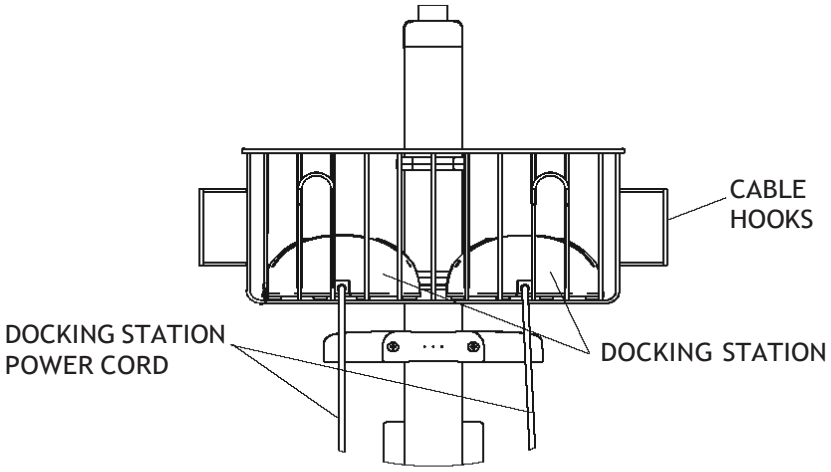
Button	Response Time	Function
Ready to Use Power button	Delay 1.5 sec	On/off System Power
Privacy button	N/A	N/A – button has been disabled
Brightness/-	Immediately	Turn on the brightness adjustment on the display. By continuously pressing the button, the screen brightness will continue to decrease.
Brightness/+	Immediately	Turn on the brightness adjustment on the display. By continuously pressing the button, the screen brightness will continue to increase.
Battery Indicator Light	N/A	When there is a battery installed, the light will turn ON. When the battery charge level drops below 15%, the light will change from green to orange to alert the user that battery is running low and to plug in the unit.

A.3 Back Panel



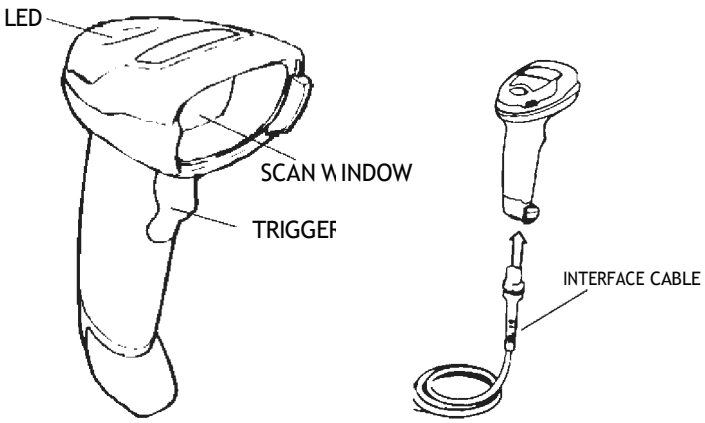
Component	Description
Tilt Adjustment Lever	Loosen the Tilt Adjustment Lever by rotating clockwise. Grasp the top and/or bottom of the Touchscreen Computer and tilt to the desired angle. Once positioned, tighten the Tilt Adjustment Lever.
Cable Management Cover	Do not remove Cable Management Cover

A.4 Basket



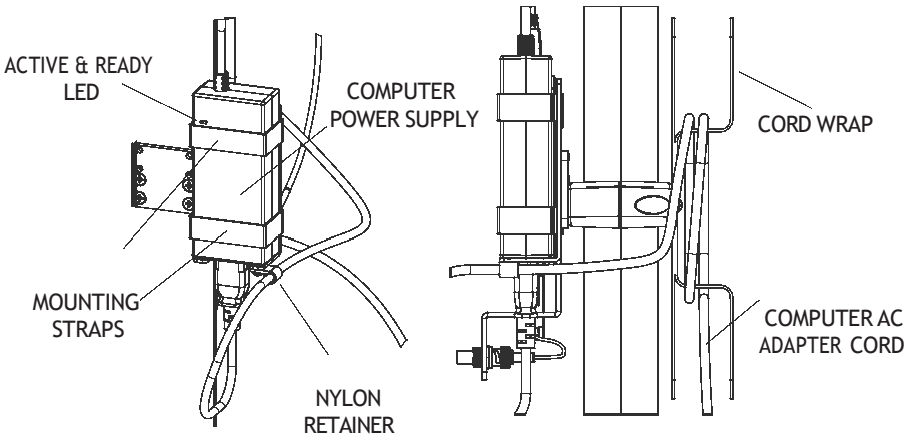
Component	Description
Cable Hooks	Wrap the Interconnect Cable around the Cable Hooks when not in use
Docking Station	Charges Readers during the implantation procedure

A.5 Barcode Scanner



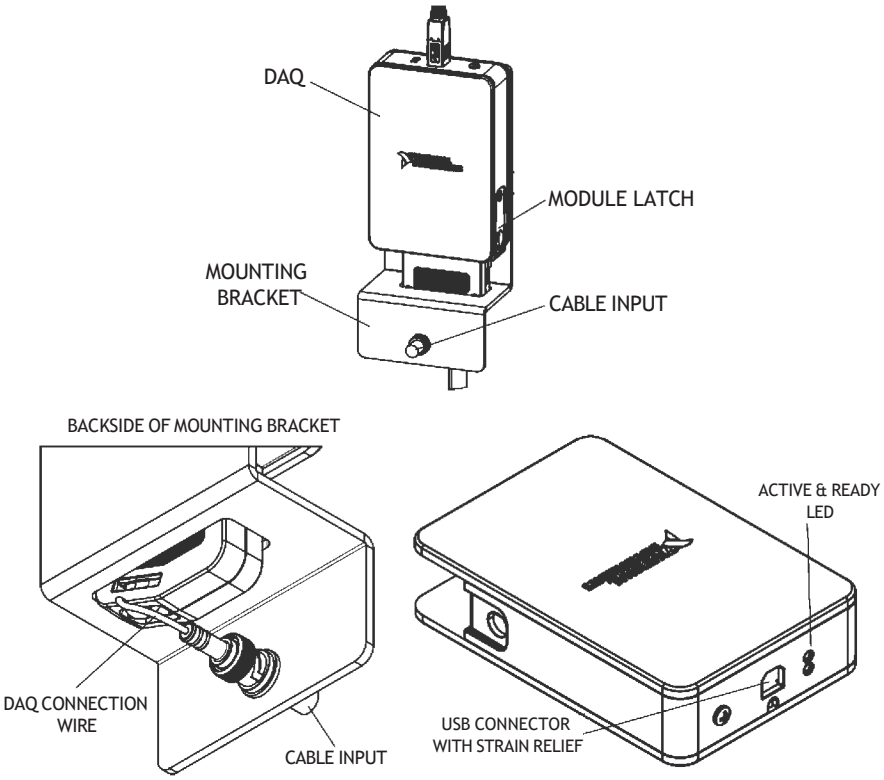
Component	Description
Trigger	Press and release trigger to scan barcode
LED	Indicates scan status. LED Green means a successful scan. LED Red means a transmission error
Scan Window	The aiming dot is smaller when the digital scanner is closer to the symbol and larger when it is farther from the symbol. The digital scanner beeps to indicate that it successfully decoded the barcode.
Interface Cable	Cable is inserted into the interface cable port on the rear of the scanner. Provides power to Barcode Scanner

A.6 Power Supply



Component	Description
Active &Ready LED	LED will illuminate when Power Supply is receiving power
Mounting Straps	Secures the Power Supply in the mounting bracket
Nylon Retainer	Secures Computer AC Adapter Cord to the mount
Computer AC Adapter Cord	This end of the Power Supply is plugged into the power strip
Cord Wrap	Wrap Computer AC Adapter Cord around the cable hooks

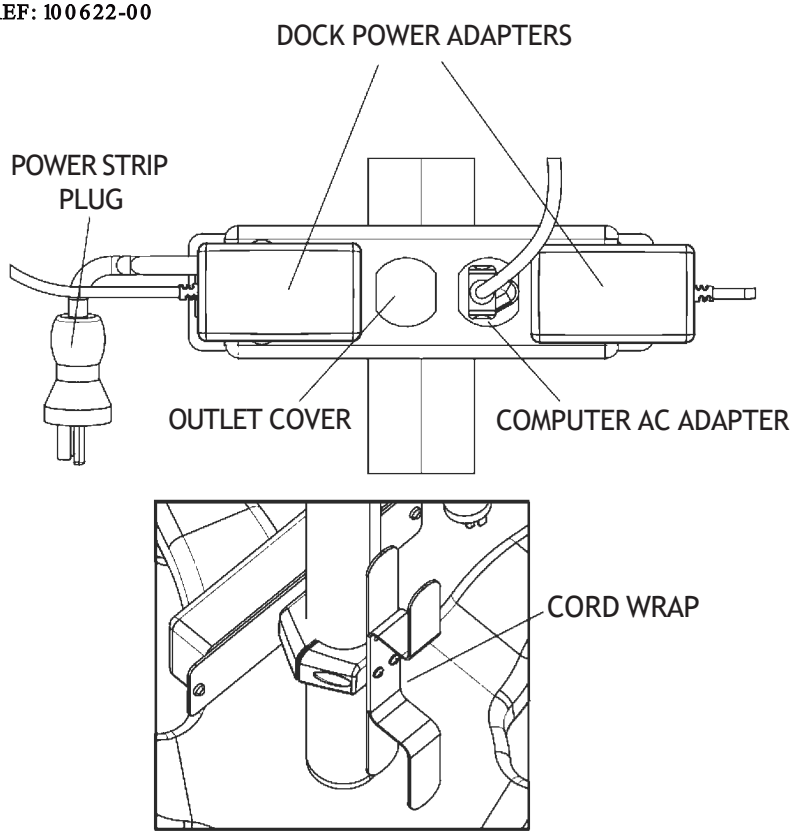
A.7 Data Acquisition System (DAQ)



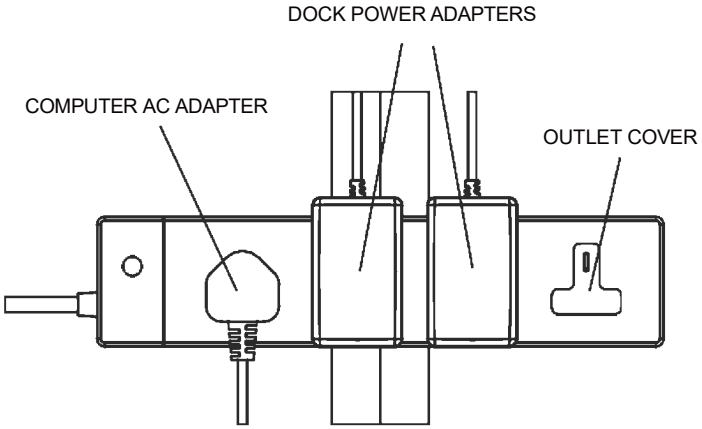
Component	Description
Cable Input	Location for Interconnect Cable
DAQ	Data Acquisition System
Active &Ready LED	The Active LED indicates DAQ USB communication. The Ready LED lights when the DAQ is ready for use.
USB Connector with Strain Relief	Provides power to the DAQ. Do not disconnect the cable unless the Computer is powered off.
Module Latch	Secures DAQ in its housing. Do not unlatch the DAQ.
DAQ Connection Wire	Connects from DAQ to mounted connector for Cable Input

A.8 Power Strip

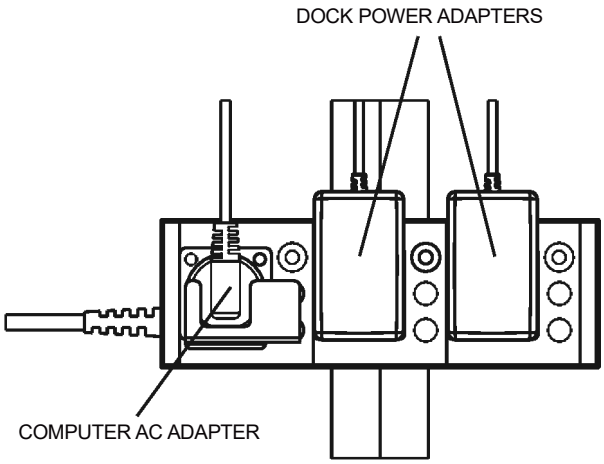
REF: 100622-00



REF: 100622-01

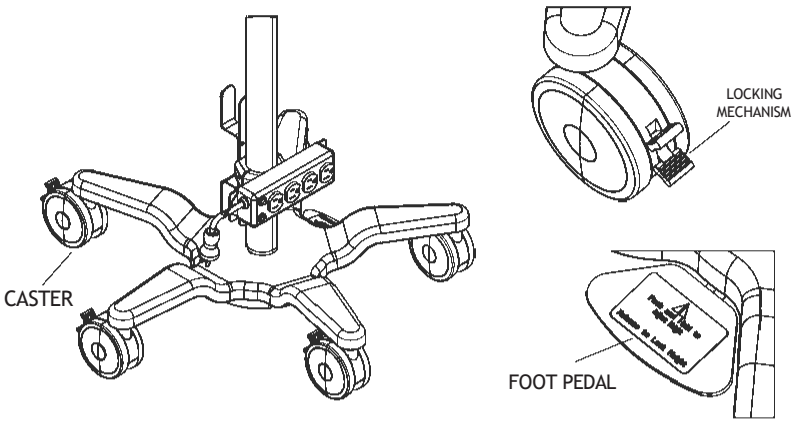


REF: 100622-02, 100622-04



Component	Description
Power Strip Plug	Used to connect the CalEQ to hospital electricity
Computer AC Adapter Cord	Provides power to Computer
Dock Power Adapter	Provides power to Dock
Outlet Cover	Covers unused power outlet and/or secures plug in outlet
Cord Wrap	Wrap Power Strip cord when the CalEQ is in transport

A.9 Roll Stand Base



Component	Description
Foot Pedal	Height of Computer can be adjusted by pushing and holding Foot Pedal.
Caster	Roll Stand Base has five locking casters.
Locking Mechanism for Caster	Press down on the plastic toggle to lock wheels. Lift the plastic toggle to unlock wheels.

Appendix B: Interconnect Cables

Interconnect Cable Endotronix Part Number	Compatible Hemodynamic Modules
100585-00	• GE TRAM-Rac 4a [Slot 2 Waveform A or TRAM ART1 or BP1]
100585-01	• GE TRAM-Rac 4a [Slot 2 Waveform B or TRAM BP2]
100585-02	• GE TRAM 100A • GE TRAM 200A & 200SL • GE TRAM 250SL • GE TRAM 400A • GE TRAM 450SL • TRAM 500A • GE TRAM 600A & 600SL • GE TRAM 650SL • MARQUETTE EAGLE 3000 • MARQUETTE EAGLE 4000
100585-03	• GE TRAM 451 • GE TRAM 451M • GE TRAM 451N • GE DASH 3000 • GE DASH 4000 • GE DASH 5000
100585-04	• GE HEALTHCARE Carescape Patient Data Module (PDM)
100586-00	• PHILIPS MEDICAL Xper Flex Cardio Physiomonitoring System • REF FC2010 & FC2020
100586-01	• PHILIPS MEDICAL M1006A Module [or equivalent]

100586-02	• PHILIPS MEDICAL M1006B Option C#01 Module [or equivalent] • Amicas Hemodynamics PDM v2 • CAMTRONICS PhysioLog PDM • CAMTRONICS PhysioLog PDM v2 • EMAGEON HeartSuite Hemodynamics PDM • EMAGEON HeartSuite Hemodynamics PDM v2 • Merge Hemo Hemodynamics PDM v1 • Merge Hemo Hemodynamics PDM v2 • McKesson Horizon Cardiology Hemo PDM v1 • McKesson Horizon Cardiology Hemo PDM v2 • Schiller Argus PB-1000 • Schiller Argus PB-2000 • Schiller Argus PB-2200
100617-00	• Draeger Infinity Delta • Draeger Infinity Kappa • Draeger Infinity Kappa XLT • Siemens SC7000 • Siemens SC9000XL • Siemens SC9000 • Siemens Axiom Sensis using SC9000 module
100616-00	• Spacelabs 90470 HLO2 • Spacelabs 90470 Command Module (-04,-05,-06,-10) • Spacelabs Command Module 91496 (B,C,L) • Spacelabs Command Module 90496 (B,C)

Patents: www.endotronix.com/patents

Handheld Patient Reader Manual

Manual del
Lector de Mano del paciente

IMPORTANT/IMPORTANTE

PLEASE READ THIS MANUAL BEFORE USING THE CORDELLA® PULMONARY ARTERY SENSOR SYSTEM
LEA ESTE MANUAL ANTES DE UTILIZAR EL SISTEMA CORDELLA® CON SENSOR DE LA ARTERIA PULMONAR

Rx Only

ENDOTRONIX
1415 West Diehl Road
Suite #500W
Naperville, IL, 60563
www.endotronix.com
1 888 512 5595

Endotronix Ireland Limited
DCU Alpha Innovation Centre
Old Finglas Road, Glasnevin
Dublin 11, D11 KXN4
Ireland

100469-03 Rev. 3

Language Guide / Guía de Lenguaje

Table of Contents

Introduction

The Cordella Pulmonary Artery (PA) Sensor System is intended to connect healthcare professionals and patients with tools designed to improve comprehensive heart failure management. This guide provides basic information about instructions for use of the Cordella Pulmonary Artery Sensor System in the home.

NOTE: The information provided in this patient manual does not attempt to define any intervention, health care policy, or procedures. Clinical procedures and policies are the responsibility of your doctor.

Managing Heart Failure with Daily Cordella® Sensor Readings

The Cordella Sensor is designed to provide your care team with information about the pressure in your PA in order to view and act on changes in PA pressure or trends over time. The wireless Cordella Sensor is permanently implanted in the right pulmonary artery, which is a vessel between the heart and lungs. When you take a measurement, the Cordella Sensor sends a signal which indicates the pressure in the artery. Changes in PA pressure may indicate fluid accumulation in the lungs.

By watching the trends in your PA pressure, your healthcare providers may intervene to address the increasing pressure before you have symptoms. This information, along with your other vital signs such as blood pressure, heart rate, blood oxygen, weight and responses to health-related questions provides your care team with a snapshot of your health status on the secure website, myCordella Patient Management Portal (PMP). Based on the trends, your healthcare provider can manage your heart failure proactively and remotely, potentially preventing hospitalizations.

Intended Use

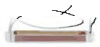
The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT), as well as have been stable for 30 days on GDMT. The device output is meant to aid

clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

The Cordella® Pulmonary Artery Sensor System

Cordella Pulmonary Artery Sensor System is designed for on-demand measurement of PA pressure from your home. This may help your healthcare providers identify pulmonary congestion suggestive of worsening heart failure through trends in PA pressures.

Component Name



Cordella® Pulmonary Artery Sensor System (Cordella Sensor)

Small implant that resides permanently in the right pulmonary artery. The Cordella Sensor will enable PA pressure measurements with the myCordella Handheld Patient Reader while at home. The Reader will collect and securely transmit PA pressure readings to the clinician. Measurements from this device are equivalent to those obtained by trained clinical personnel using invasive, fluid-filled catheter-based products.

myCordella® Handheld Patient Reader (Reader)

Device that collects pulmonary artery pressure data from the Cordella Sensor. Each day, you will hold the wireless Reader against your chest for approximately 18 seconds, guided by audio and visual cues on the myCordella Tablet and Reader. The Reader sends data to the Tablet, which provides daily PA pressure readings to your clinician on the myCordella Patient Management Portal, enabling a more complete picture of your health status.

myCordella® Docking Station (Docking Station)

Small stand that conveniently holds and charges the Patient Reader while you are not using it. The Docking Station should always remain plugged in. The Reader should always remain in the Docking Station unless it is in use or it is packed for traveling. The power supply cord is to be used to disconnect the Docking Station from AC power. LED lights on the front will indicate if the Reader is charging or fully charged.

Safety Information

To prevent personal injury or damage to any equipment, please read and observe all safety information.

Warnings	**Warnings indicate the potential for serious adverse reactions or safety hazards, and limitations in use imposed by them.**
Precautions	**Precautions indicate special care that should be taken to ensure safe and effective use of the device.**

Warnings

- The Reader is suitable for home healthcare environments and professional healthcare facilities except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbance is high.
- The Reader and Docking Station should not be used adjacent to or stacked with other equipment. If it is necessary to operate the components adjacent to or stacked with other equipment, verify that the system is operating normally in the configuration in which it will be used. If necessary, contact Customer Service to help re-locate the system.
- DO NOT expose any power accessories to water or other liquids.
- DO NOT disassemble or modify any component of the Cordella PA Sensor System.
- DO NOT use Cordella PA Sensor System in the presence of explosive or flammable anesthetic agents.
- The Cordella PA Sensor System is not intended for emergency use or real-time monitoring.
- The Cordella PA Sensor System is not intended to be an emergency response device. In case of a medical emergency, call the local Emergency Medical Services and/or your healthcare provider.
- After the implantation procedure, it is critical to adhere to prescribed anticoagulation and other medications from the physician.
- Power cables may pose a tripping hazard. Be mindful of cords crossing walkways.
- DO NOT position power cables in any manner that may cause entanglement or strangulation.
- Reader may be interfered with by other equipment generating electromagnetic interference (EMI). When using the Cordella PA Sensor System, avoid using the following items which generate EMI and keep them at least ~5 feet/1.5 meters away: CPAP machines, laptop computers, tablets, e-readers, hair dryers, electric shavers, refrigerators, metal furniture, electrical or adjustable beds, home stereos, alarm-clock radios, air conditioners, electric ovens, washers, dryers, dishwashers, televisions, and microwaves.
- Avoid using the Reader in the same room or within ~13 feet (3.8 meters) of wireless routers.
- When taking a reading with the Reader, avoid simultaneous communication via walkie talkie.

- When possible, turn off and unplug possible EMI sources within your home during Cordella PA Sensor System use.
- When possible, take readings using the Reader at least 5 feet (1.5 meters) away from walls as metal supports and electrical wiring may cause electromagnetic interference.
- The frequencies used for wireless power transfer (WPT) and 5G cellular networks are significantly different from the operating frequency of the Reader. Testing for immunity to WPT and 5G has not been performed. These are potential EMI sources that may be present in your home and could interfere with the performance of the Reader. Signs that the Reader may be impacted by EMI and potentially performing abnormally include having trouble completing a reading, requiring multiple reading attempts, or receiving a message from your physician that readings are not available. If any of the above signs are observed, move the Reader away from the WPT or 5G cellular devices to restore the Reader intended function.
- The Reader performance may be impacted by EMI across the following ranges emitted from other electronics which are not listed above in the common household items list:
    - 174 MHz – 216 MHz
    - 335 MHz – 450 MHz
    - 809 MHz – 849 MHz
    - 2.35 GHz – 2.65 GHz

  Signs that the Reader may be impacted by EMI and performing abnormally include having trouble completing a reading, requiring multiple reading attempts, or receiving a message from your physician that readings are not available. Impact on Reader performance can be prevented by maintaining the minimum separation distances between portable and mobile RF communications equipment (transmitters) and the Reader as recommended in Appendix C. These separation distances have been tested to ensure that any frequencies which may impact Reader performance within the listed ranges have been accounted for. Additional measures may be necessary, such as removing the source of interference or completing daily readings in a different room.
- The Reader requires special precautions regarding electromagnetic compatibility (EMC) and needs to be placed into service according to the EMC information provided. If interference is noted, remove or stop using the interfering equipment.
- Use only the cables and accessories provided. The use of accessories, transducers or cables other than those specified or provided as replacement parts, may result in decreased immunity of the system, inaccurate readings, damage to the system, injury to user, or improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than ~5 feet (1.5 meters) to any part of the Reader. Otherwise, degradation of the performance of the Reader could result.
- If the skin becomes red, warm, or irritated, immediately stop using the Reader and contact Customer Service.
- Contact Endotronix Customer Service if more than 1 Cordella user resides in the same home. DO NOT use more than one Reader in the same general vicinity at one time, as use of multiple Readers at once may cause them to interfere with each other.
- The Reader contains Lithium Ion batteries. DO NOT place the Reader on a hot surface.

⚠ Precautions

- Avoid exposing any components of Cordella PA Sensor System to water or liquids. Contact Customer Service for a replacement if any components are exposed to liquids.
- DO NOT drop the Reader. Handle with care.
- If dropped, the Reader battery may be exposed. If the battery is exposed, contact Endotronix immediately for a replacement Reader. Any damage to the Reader may result in an inaccurate reading.
- DO NOT use the Reader if the plastic casing has been damaged, cracked or any component becomes dislodged.
- If the Reader label becomes compromised, contact Endotronix Customer Service.
- Accuracy of the Cordella PA Sensor System is slightly affected by large changes in elevation between the initial baseline calibration and subsequent measurements. Readings may lose accuracy when taken >2000m of elevation. If you plan to travel or move to a location at >2000m of elevation, please contact Customer Service.
- The Cordella Sensor is a permanent implant. Removing the implant after implantation is not recommended.
- The Cordella Sensor may be affected by a change in elevation above or below sea level. If you plan to travel below sea level or SCUBA dive or extremely high altitudes without pressurization, please contact Customer Service.
- DO NOT attempt to pair the Reader to any devices except myCordella Tablet.
- Electromagnetic interference from theft detection systems, airport security systems, etc., could make it difficult to take sensor measurements. However, it is highly unlikely that you would be taking measurements when you are close to these devices.
- The Docking Station and power adapter can be sensitive to electrostatic discharge (ESD) at high levels which may cause the Docking Station to lose function. To reduce the potential for ESD discharge to the Docking Station, disconnect the power cable from the wall outlet prior to disconnecting the cable from the Docking Station.
- If the Docking Station or power adapter becomes inoperable due to ESD, the LED light on the front of the Docking Station will not illuminate when the Reader is placed on the Docking Station, and the Reader battery will not charge. Contact Endotronix Customer Service for return and replacement of the Docking Station.

Patient Privacy and Medical Privacy Standards

All components of the Cordella PA Sensor System have been designed to comply with patient privacy regulations. Your healthcare providers organization as well as Endotronix will ensure that they are also in complete compliance with privacy and security statutes, as well as the organization's policies, procedures, and protocols to respect patient information and ensure patient privacy at all times.

Endotronix is not responsible for the use or abuse of patient information by health care providers.

Implant procedure

Before the Implant Procedure

Prior to the implant procedure, you and your doctor will discuss the benefits and risks of the procedure and the Cordella PA Sensor System. You will be given a detailed description of the procedure, your doctor will discuss the risks associated with the procedure and the Sensor, your doctor will respond to any questions you have, and you will be asked to sign an informed consent.

Inform your doctor of any infections, arrhythmias, or bleeding that occurs before the implant procedure.

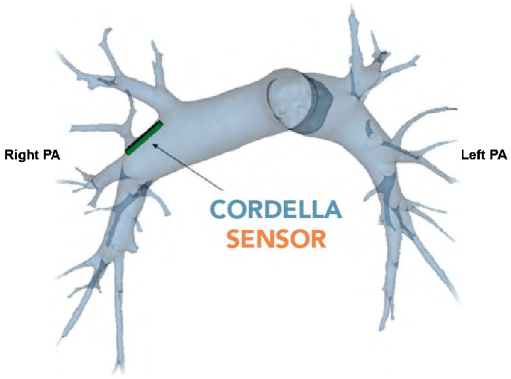
The Implant Procedure

During a right heart catheterization, the Cordella Sensor is permanently implanted in the right pulmonary artery, which is a blood vessel that carries blood from the heart to the lungs. This catheterization is a standard procedure used to measure the pressures in the heart and PA.

The Cordella Sensor is the length of a $0.01 coin (19.3mm x 3.8mm x 1.9mm) and has two wire loops extending off either end which hold it in place in the vessel. The Cordella Sensor is tied down on a catheter that is skillfully navigated to your PA by your doctor.

The steps of the implant procedure are:

1. Your doctor will make a small incision and insert a small tube called an introducer. A pulmonary artery catheter will be inserted through the introducer and into your vein while your doctor looks at a screen with a live x-ray—called a fluoroscope—of your veins and heart. Your doctor will navigate this catheter through your veins to your heart and then to your PA.
2. Your doctor will take a few pictures with the fluoroscope at this point by injecting dye through the end of the catheter. These pictures will give your doctor a better idea of what the vessels in your pulmonary arteries look like and will help guide placement of the sensor. This is called angiography.
3. A wire is inserted to provide support and the pulmonary artery catheter is removed. The catheter with attached Cordella Sensor is inserted and positioned in the right pulmonary artery.
4. Once the Sensor is in the best possible position, your doctor will implant the Cordella Sensor.
5. After the Cordella Sensor is implanted, the handheld Reader will be held on the right side of your chest to calibrate the Sensor.
6. After calibration, the pulmonary artery catheter will be removed and you will be brought to the recovery area.



After the Implant Procedure

While in the recovery area, an Endotronix representative will come by to take some PA pressure measurements with the Reader. You may be kept overnight for observation.

You will be trained on proper use of the Reader and the optimal (prescribed) location for the Reader for readings taken at home. You will also be given an implant card (about the size of a business card) and discharged to go home. The implant card must always be kept with you to alert medical and security personnel to important information about your Sensor.

Getting Started

The Reader will automatically pair with the myCordella Tablet on start-up. No additional user input is required. Upon returning home with the Reader and Docking Station, connect the Docking Station Power Cord to the power port on the back of the Docking Station and the other end into the wall outlet. Place the Docking Station on a flat surface near the myCordella Tablet with a minimum two-inch/five-centimeter clearance from surrounding objects or walls.

Place the Reader in the Docking Station. The LED light on the front of the Docking Station will blink while charging and change to solid white when the Reader is charged. Call Endotronix Customer Service if this does not occur within 24 hours of setup.

Start the Reader for the first time by holding the power button on the bottom for several seconds.

Reader Placement

Reliably and repeatedly finding proper Reader location is essential to collecting valid PA pressure measurements.

With your left hand, grip the handle and pick up the Reader from the Docking Station. Place the Reader against your chest so the lighted symbol is at the top, in the direction of your head. An Endotronix representative may indicate that the Reader should be placed in a different location—for example on the side of the body. Adjust the Reader position to maximize signal strength based on the displayed signal strength gauge on the tablet screen and the changing audio cue speed from the Reader. When optimal position is achieved, the Reader plays the "Sensor Located" tone and displays a quickly flashing blue light (see the Audio & Visual Cues section below) as it proceeds to collect data.

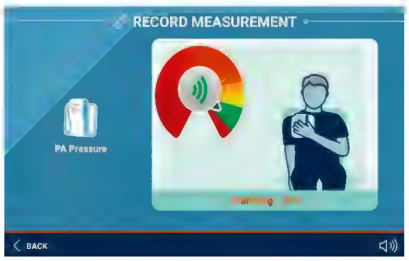
Taking a Reading

The handheld Reader should be removed from the Docking Station using the left hand for ease of locating the Cordella Sensor in the right PA (right side of the chest). It is essential for proper operation of the Reader to maintain a metal free zone in the area where the reading will take place and to take each reading in a consistent body position.

Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

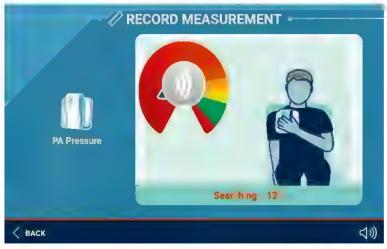
Remove all necklaces, watches and jewelry prior to beginning the measurement within 3 inches/8 cm of your prescribed reading location.

Power the Reader on and place it in the Docking Station to charge fully before taking your first home reading.



Taking a PA Pressure Reading

Taking a Lying Flat PA Pressure Reading



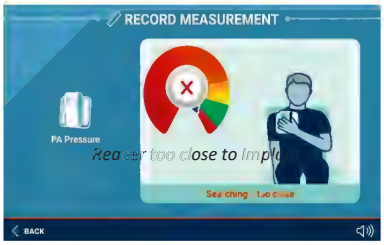
Reader too far from Implant

If you are taking a PA Pressure reading, ensure that you are **sitting** upright comfortably and resting for a few minutes until breathing comfortably.

If you are taking a Lying Flat PA Pressure reading (if prescribed), pick up the Reader and then lie down completely flat, placing your right arm at your side and breathing normally.

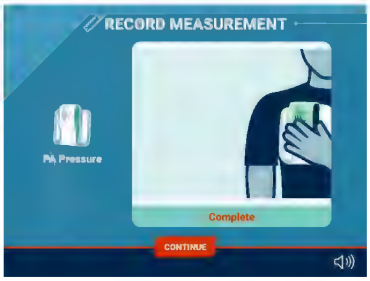
To see the LED indicator on the Reader, use a mirror or ask a caregiver to describe it as you take the reading. The animation walks you through proper data collection using the Reader.

1. Remove the Reader from the Docking Station with the ***left hand*** to make it easier to locate the Cordella Sensor in the ***right*** side of the chest. When the Reader is removed from the Docking Station it will begin beeping and the light on the Reader will be solid BLUE.
2. Hold the Reader to the prescribed place on the chest (that was designated during training) and observe the signal strength indications on the screen. Adjust the Reader position to maximize the signal strength within the indicated green zone. Sound cues from the Reader will change in speed as the Reader gets closer or farther from the Sensor. If the Reader is either too close or too far from the implant it will be unable to take a reading. Once optimal Reader position is achieved, the light on the Reader will blink BLUE in rapid succession and data capture will begin.



Reader too close to Implant

3. During the reading, it is important to remain still and hold the Reader as still as possible. The light on the Reader will blink GREEN during a reading. Continue to breathe normally during the reading.
4. After ~18 seconds the Reader will play a "Success" tone if the reading worked properly. The light on the Reader will become a solid GREEN.
   a. In the event the reading obtained was not good enough due to movement or improper Reader placement, the Reader will play a "Fail" tone. The light on the Reader will blink WHITE rapidly. Immediately after, the Reader will return to "Search" mode described in step 1.
5. Once a good reading is obtained, the Reader LED will be a solid GREEN and will continue to play the "Success" tone until it is returned to the Docking Station. The Reader should always remain docked unless it is being used or transported.



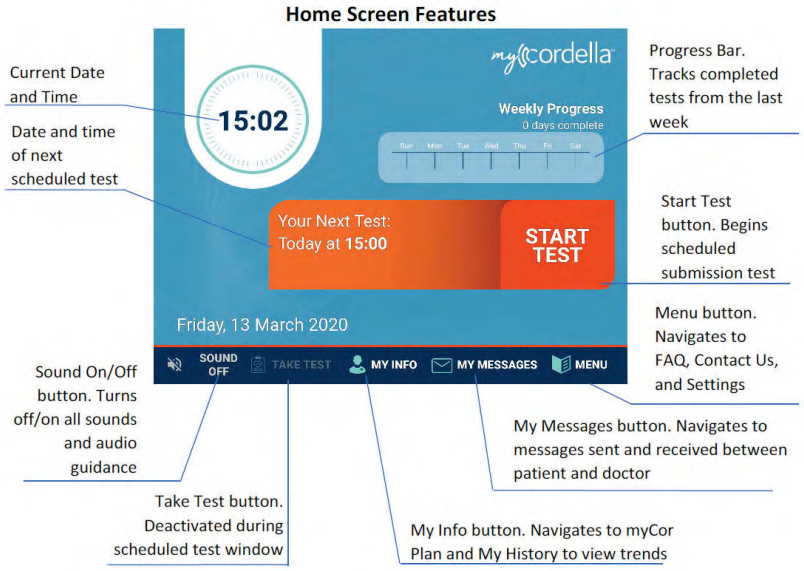
Submit Results

The tablet screen will return to the "Take A Test" screen. Tap the "Review Results" button to advance to the "Test Summary" screen. The PA pressure reading will display as taken. Press the "Submit" button.

NOTE: Once at the "Test Summary" screen, if all tests have been completed, the application will automatically submit the measurements after 30 seconds if no action is taken, regardless if the test was scheduled or unscheduled.

Accessing Your History

The myCordella Tablet allows the patient to review previous submissions by day or by measurement type. Press the “My Info” button on the home screen to access the “My History” page and review daily submissions or trends created from weekly and monthly submissions. Navigate between daily measurements history or trends by tapping their respective tabs at the bottom of the myCordella Tablet.



Audio & Visual Cues

Reader Audio Cues

Event	Sound	Required Action
Searching for Sensor	Several beeps increasing in speed	Reposition Reader to find stronger signal.
Sensor Located	Four quickly ascending, high pitched beeps, repeating three times	Strong signal found. Hold Reader in place.
Reading in Progress	Two quickly ascending beeps, repeating every ~3 seconds	Hold Reader in place (~18 seconds).
Successful Sensor Reading*	Several quickly ascending, high pitched beeps	Measurement complete. Return Reader to Docking Station.
Failed Reading	Several slowly descending, low pitched beeps	Reposition Reader to find stronger signal.
Return to Docking Station	Successful Reading sound repeating periodically	Return to Docking Station. If Reader is there, check Docking Station visual cues.
Low Battery	Three quick, low pitched beeps, repeating every ~10 seconds	When accompanied by solid white light, return to Docking Station.
Warmup	Several slowly ascending beeps	Return the Reader to the Docking Station to allow it to warm up.
Contact Customer Service	Three quick, low pitched beeps, repeating every ~10 seconds	When accompanied by flashing purple light, call Customer Service.

*To prevent the Cordella System from displaying erroneous data to healthcare providers, data analysis is performed on all readings. If erroneous information is detected, this will be shown to the clinician as a bad reading, and a clinician may request another reading even if the Reader indicated success. To prevent bad readings, ensure the signal strength is as high as possible in the dial's green zone and position the Reader away from equipment generating electromagnetic interference (EMI). In addition, ensure you take seated or lying flat readings as instructed by the Cordella System. See "Warnings" and Appendix C for more detailed information about interference.

Reader Visual Cues

Light	Event/Required Action
Solid Blue	Searching for Sensor.
Slowly Flashing Blue	Return to Docking Station.
Rapidly Flashing Blue	Sensor located. Ready to begin reading.
Slowly Flashing Green	Reading in progress. Hold Reader in place until light becomes solid green.
Solid Green	Successful Sensor reading.
Alternating White, Blue, and Darker Blue	Return the Reader to the Docking Station to allow it to warm up.
Rapidly Flashing White	Failed reading. Reposition Reader.
Solid White	Low battery. Return to Docking Station.
Rapidly Flashing Purple	Contact Endotronix Customer Service.
Light Off	Out of battery. Return to Docking Station.

Docking Station Visual Cues

Light	Event/Required Action
Flashing White	The Reader is being charged.
Solid White	The Reader is fully charged and ready for use.
No Light	When the Reader is docked and no light is present, the Docking Station is not connected to a power source. Check that the Docking Station Power Cord is plugged into both Docking Station and electrical outlet. If the light remains off, contact Customer Service. To turn off audio and visual cues from the Reader during this time, put the Reader into Travel Mode (see Traveling with the Reader and Docking Station below).

Traveling with the Reader and Docking Station

Cordella PA Sensor System is designed to be portable and should be taken with you on personal or business travel. Endotronix recommends carefully packing the Patient Reader in a carry-on suitcase by wrapping the Reader in bubble wrap or clothing and storing in the center of the suitcase. The Docking Station and power cord should be wrapped separately and also be stored in a suitcase where it will be under the least amount of stress.

To travel with the Reader, remove the Reader from the Docking Station and press and hold the power button on the Reader for several

seconds to initiate Travel Mode. The power button is a small button located on the bottom of the Reader, at the base of the handle and adjacent to the power connector. Depressing the button will disable the audio and visual cues on the Reader and prevent damage to the batteries. This same process can be used to power off the Reader at any time.

To restart the Reader after travel, press and hold the button again. The Reader will need to be warmed up and charged on the Docking Station before it can take a reading. Place the Reader on the Docking Station for approximately 10 minutes to allow it to warm up. While docked, the Reader will not emit audio or visual cues. If you are unable to charge the Reader during your travels, you may see and hear the warmup cues described above when you restart the Reader. After the Reader warms up, those cues will end and search cues will begin, signaling that you can begin taking your reading. When the reading is finished, power the Reader back off.

If the button is depressed but the Reader does not respond, the battery is likely discharged; return the Reader to the Docking Station and allow the Reader to charge fully.

Ensure you carry your implant ID card with you at all times.

The Reader contains lithium ion batteries. DO NOT transport in checked luggage.

NOTE: Wait approximately 10 minutes to take a reading after disabling Travel Mode to allow the Reader to warm up.

Contact Us

The user should contact Competent Authority and Endotronix to report any serious incident that has occurred in relation to the medical device.

Questions or concerns regarding setup, use, unexpected operation or events, serious incidents, and general inquiries can be directed to the contact information below:

Endotronix Customer Service

Endotronix, Inc.
1415 West Diehl Road
Suite #500W
Naperville, IL 60563
U.S.A

Toll-free: 1-888-512-5595
Support@endotronix.com

Repairing Equipment

To maintain applicable warranties and function, Endotronix requires that only authorized personnel perform repairs. There are no user serviceable parts. Repairs made by unauthorized personnel will invalidate your warranty. For product warranty information, please contact Endotronix. Changes or modifications not expressly approved by Endotronix may void the customer's warranty on the system. Do not dispose of any system components; contact Customer Service and follow the RMA procedure below to return materials to Endotronix. The useful life of the Cordella Sensor is ten (10) years.

Return Materials Authorization (RMA)

If Customer Service requests that the equipment be returned, please follow the directions below.

1) Carefully pack the equipment in the original shipping box or equivalent with its original protective packaging materials or equivalent as instructed by Customer Service.
2) Include the RMA number given to you by Customer Service on the outside of the shipping container. Ship all equipment and signed equipment return list to:

   RMA #
   Customer Service Department, Repairs Endotronix, Inc.
   Endotronix, Inc.
   1415 West Diehl Road
   Suite #500W
   Naperville, IL 60563
   U.S.A

Inspection & Cleaning Instructions

Inspect the system before each use. No maintenance is required. If any of the inspection checkpoints apply, please contact Customer Service.

Inspection Checklist
○ Power cord is not frayed or connected to unauthorized equipment. If there is a frayed power cord or if the unit is attached to unauthorized equipment, unplug the unit and notify Customer Service to obtain a new one. ○ Cables are properly attached and in good condition. ○ All accessories are securely attached. ○ Components are not in or near water or other liquids. ○ Components have not been moved to an unsuitable location. ○ If Reader or Docking Station have been dropped or damaged, DO NOT use and call Customer Service.
 Cleaning
○ Clean the systems components as needed. ○ UNPLUG the Docking Station and remove the Reader before cleaning or disinfecting. ○ Put the Reader in “Travel Mode” to minimize audio signals while cleaning. ○ To clean, wipe the surfaces with a lint-free cloth lightly moistened in water. ○ DO NOT disassemble. Clean only the surfaces of the Reader and Docking Station. ○ DO NOT immerse the Reader or Docking Station in any liquid. ○ DO NOT spray liquids directly on the Reader or Docking Station – use a pre-moistened cloth. ○ DO NOT autoclave. ○ DO NOT sterilize with ethylene oxide.

MRI Conditions

MRI Information
○ You can have an MRI scan under certain conditions. Talk with the clinician ordering your MRI scan to ensure that he or she knows that you have a Cordella PA Sensor. ○ If defined MRI conditions are not followed, there is increased risk of additional heating or movement of the Cordella Sensor or of damage to the Cordella Sensor. ○ MRI Conditions are described in your physician's Cordella PA Sensor System Instructions for Use. ○ Ensure you always carry your implant ID card with you.

Summary of PROACTIVE-HF Pivotal Study

Objectives/Purpose

The objective of the PROACTIVE-HF study was to demonstrate the safety and efficacy of the Cordella PA Sensor System. The patient population consisted of male and female patients, ≥ 18 years of age with a diagnosis of NYHA Class III HF who were eligible for enrollment if they were treated with GDMT for a minimum of 3 months (stable doses at least 30 days prior to enrollment) and, within the past year, the patient had either 1) one HF hospitalization, or 2) HF treatment in a hospital day care setting, or 3) urgent outpatient clinic HF visit for IV diuretics, or 4) a persistently elevated NT-proBNP level at the time of screening. After obtaining written informed consent and screening, eligible patients underwent a device Implant Visit in conjunction with a right heart catheterization procedure. Post-procedure follow-ups were scheduled at 1-Month, 3-Month, 6-Month, 12-Month, 18-month, 24-Month, 36-Month, 48- Month, and 60-Month (final follow-up).

Study Design

The PROACTIVE-HF study was a prospective, multi-center, open-label, single-arm clinical trial to assess device safety and efficacy of the Cordella PA Sensor System in NYHA Class III Heart Failure patients compared to a Performance Goal (PG) based on a meta-analysis on the combined cohorts of CHAMPION-HF, CardioMEMS Post approval study, MEMS-HF, GUIDE-HF (NYHA Class III cohort), and LAPTOP-HF (control group only). The PROACTIVE-HF study was originally designed as a prospective, randomized controlled multi-center clinical trial but converted to a single-arm, open-label clinical trial in December 2021.

Intended Use

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT), as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

Contraindications

The Cordella Pulmonary Artery Sensor System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

Safety Endpoints

<u>Primary Safety Endpoints:</u>

1. Freedom from device or system-related complications (DSRC) at 6 months is tested against a null rate of 90%

2. Freedom from pressure sensor failure at 6 months is tested against a null rate of 95%

<u>Secondary Safety Endpoints:</u>

1. Frequency of serious adverse events (SAEs) throughout the study

2. Frequency of implant procedure and procedure related adverse events and serious adverse events

3. Pressure sensor failure rate throughout the study

Efficacy Endpoints

Primary Efficacy Endpoint:

The primary endpoint was the 6-month incidence of HF related hospitalizations (HFH) or all-cause mortality. Six (6) months data were compared to a Performance Goal (PG) based on treatment outcomes for CardioMEMS data.

The statistical PG of 0.43 was derived from published results from clinically relevant, contemporary studies of NYHA Class III HF subjects. For study success, the upper confidence bound of the observed event rate for the planned study must be less than the PG. Additionally, the observed event rate was required to be less than 0.37. Evaluating the upper bound of the confidence interval for the observed rate, ensures that 1) the observed rate is comparable to prior studies of active treatment (highest observed value = 0.44), 2) the observed rate is less than the mean rate from meta-analysis of prior studies of treatment and control, and 3) the observed rate is less than the lowest rate observed in the control studies (GUIDE-HF). The added requirement for the observed rate to be less than 0.37 provides further assurance that results are comparable to studies of prior treatment.

* Please refer to the Instructions for Use in the Implant Manual or Summary of Safety and Effectiveness Data (SSED) for a listing of all secondary endpoints, inclusion/exclusion criteria.

Results

The data results from the PROACTIVE-HF study support the reasonable assurance of safety and effectiveness of the Cordella PA Sensor System when used in accordance with the indications for use. The primary and secondary safety and efficacy endpoints of PROACTIVE-HF were met. The safety profile was excellent with 99.2% freedom from DSRC and 99.8% freedom from pressure sensor failure. The event rate for all-cause hemoptysis (coughing up blood) was 3.0% for which this safety endpoint in the early experience with this new device is

numerically higher than prior studies completed to date with similar PAP-measuring devices, such as in CHAMPION (0.2%), GUIDE-HF (0.3%) and MONITOR-HF (2.3%). Overall, the 6-month incidence of heart failure hospitalization and mortality were low across all populations analyzed. The incidence rate of 0.1589 [95% CI: 0.1200, 0.2106] events per patient 6-month met all criteria for primary endpoint success. While PROACTIVE-HF aimed to enroll NYHA Class III HF patients, the final event rate for the primary effectiveness endpoint (0.1549) was numerically lower than the average event rate derived from published results from clinically relevant, contemporary studies of NYHA Class III HF subjects. This unexpected finding may warrant further evaluation in future studies.

There was an improvement in quality of life by five points, and 6MWT through 6 months. Subjects with mean PAP (mPAP) above target range (seated mPAP > 20 mmHg) at baseline saw a reduction in mPAP (2.4 mmHg) and subjects with normal/below normal PAP saw an increase in mPAP (4.2 mmHg), although, on average, these subjects remained within target range at 6 months. Of note, these secondary analyses are purely exploratory, not powered and not adjusted for multiple comparisons. There was high compliance in both subject transmission of daily data and clinician acknowledgement of those transmissions.

In NYHA Class III patients at risk of congestive events, the Cordella PA Sensor and HF System was safe, improved quality of life and functional capacity. The markedly low event rates may relate to high subject and clinician compliance, high rates of GDMT at baseline, and integration of daily vital signs with seated PAP, which may be more relevant for monitoring of ambulatory HF patients. However, the lower event rate compared to clinically relevant, contemporary studies of NYHA Class III HF patients may need to be explored in future studies.

* Please refer to the Instructions for Use in the Implant Manual or Summary of Safety and Effectiveness Data (SSED) for a comprehensive summary of the study.

APPENDICES

Appendix A: Cordella® Pulmonary Artery Sensor System Components

Use only supplies authorized by Endotronix, as other equipment may result in increased electromagnetic emissions, decreased immunity to emissions, or damage to the system. To order supplies, contact Customer Service and include the part number and name.

1415 West Diehl Road
Suite #500W
Naperville, IL 60563
U.S.A
support@endotronix.com

Cordella Pulmonary Artery Sensor System Component List	
100102-01	myCordella Handheld Patient Reader
100274-01	myCordella Docking Station
100264-00	Docking Station AC/DC Wall Mount Adapter

Appendix B: Equipment Specifications
myCordella® Handheld Patient Reader

Manufacturer	Endotronix
Method of measurement	Wireless interrogation of implanted Cordella Sensor.
Pulmonary artery pulse pressure maximum range	40-100 mmHg
Pulmonary artery pressure range at sea level	0-100 mmHg
System Accuracy (short term under typical environmental conditions)	+/- 2 mmHg at baseline (740 mmHg) and +/- 3% across the pressure range compared to a reference pressure measurement for a pressure range of 600-860mmHg (absolute) *Note: Accuracy of the Cordella PA Sensor System is affected by a change in body temperature, drift over time, positional variation of the Reader relative to the Sensor, and changes in ambient temperature and humidity. Error after combining all sources of variation is specified below.*
Worst Case System Error	System Root Sum Square (RSS) error after combining all sources of variation must remain within +/- 7.8 mmHg over 10 years.
Patient safety/use	Typical reading time is 30 seconds.
Calibration	At implant and recalibration, approximately every 3-years, or when deemed necessary by a medical professional.
Expected service life (of Reader only)	Four years
Safety standards	Meets all relevant parts of IEC 60601-1 Ed. 3.2
EMC standards	Meets all relevant parts of IEC 60601-1-2 Ed. 4.1
Operating frequency	12.88-14.12 MHz, 2.45 GHz
Physical	
Approximate Dimensions	• Width: 6.44 in / 16.35 cm • Height: 2.0 in / 5.1 cm • Depth: 5.63 in / 14.3 cm • Weight: 1.2 lbs / 0.54 kg
Power	
Input	4.2V/16.8V ⎓ 667mA/142mA
Environment	

The Reader may not meet its performance specifications if stored or used outside the environmental ranges listed below.	
Temperature	• Operation: 5 – 35°C (41 - 95°F) • Transport: -10 – 55°C (14 – 131°F) • Storage: -10 – 55°C (14 – 131°F)
Relative Humidity	• Operation: 6 – 93% (non-condensing) • Transport: 6 – 93% (non-condensing) • Storage: 6 – 93% (non-condensing)
Atmospheric Pressure	• Operation: 800 - 1066 hPa

Essential performance is maintained for the service life of the product. For additional information regarding essential performance contact Endotronix Customer Service.

myCordella® Docking Station

Manufacturer	Endotronix
Expected service life (of Docking Station only)	Four years
Safety standards	Meets all relevant parts of IEC 60601-1 Ed. 3.2
EMC standards	Meets all relevant parts of IEC 60601-1-2 Ed. 4.1
Physical	
Approximate Dimensions	• Width: 5.5 in / 14.0 cm • Height: 2.5 in / 6.4 cm • Depth: 5.5 in / 14.0 cm • Weight: 0.4 lbs. / 181.4 g
Environment *The Docking Station may not meet its performance specifications if stored or used outside the environmental ranges listed below.*	
Temperature	• Operation: 5 – 35°C (41 - 95°F) • Transport: -25 – 70°C (-13 – 158°F) • Storage: -25 – 70°C (-13 – 158°F)
Relative Humidity	• Operation: 6 – 93% (non-condensing) • Transport: 0 – 90% (non-condensing) • Storage: 0 – 90% (non-condensing)
Atmospheric Pressure	• Operation: 800 - 1066 hPa
Power Cord	
Manufacturer	SL Power Electronics
Part Number	ME20A0503F01

Cord Length	~ 8 feet / 2.4 m
AC Power	Wall mount style power supply • Input of 100-240V~, 50-60 Hz • Output of 5V⎓ @ 3A
Docking Station	• Input: +5V ⎓ 3.0 A • Output: 4.2V/16.8V, 667mA/142mA

Appendix C: Electromagnetic Guidance

Guidance and Manufacturer's Declaration – Electromagnetic Emissions & Immunity

The Reader and Docking Station comply with IEC 60601-1-2 Ed. 4.1. The Reader and Docking Station are Class II ME Equipment and the Reader is a BF Applied Part.

The Reader and Docking Station are intended for use in the electromagnetic environment specified below.

The operator of the Reader and Docking Station should assure that it is used in such an environment.

Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
Conducted Emissions CISPR 11	Class B, Group 1	The Reader must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The Reader is suitable for use in professional healthcare facility and home healthcare environments.
Radiated Emissions CISPR 11	Class B, Group 1	
Harmonic Current Emissions IEC 61000-3-2	Class A	
Voltage changes, Fluctuations/Flicker Emissions IEC 61000-3-3	Compliant	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Reader and Docking Station are investigational devices that comply with IEC 60601-1-2 Ed. 4.1.

The Reader and Docking Station are intended for use in the electromagnetic environment specified below.

Immunity Test	**Test Level**	**Compliance**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge Immunity IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst Immunity IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical professional healthcare facility or home healthcare environment.
Surge IEC 61000-4-5	±1 kV line to line	±1 kV line to line	
	±0.5 kV line to line	±0.5 kV line to line	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% *U*T (100% dip in *U*T) for 0.5 cycle	0% *U*T (100% dip in *U*T) for 0.5 cycle	
	0% *U*T (100% dip in *U*T) for 1 cycle	0% *U*T (100% dip in *U*T) for 1 cycle	
	70% *U*T (30% dip in *U*T) for 25 cycles(50Hz) and 30 cycles(60Hz)	70% *U*T (30% dip in *U*T) for 25 cycles(50Hz) and 30 cycles(60Hz)	
	0% *U*T (100% interruption in *U*T) for 250 cycles(50Hz) and 300 cycles(60Hz)	0% *U*T (100% interruption in *U*T) for 250 cycles(50Hz) and 300 cycles(60Hz)	
Power Frequency Magnetic Field IEC 61000-4-8	30A/m 50Hz and 60Hz	30A/m 50Hz and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical professional healthcare facility or home healthcare environment.
Radiated RF Immunity IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz	10V/m	Portable and mobile RF communication equipment should be no closer to any part

Conducted RF Immunity IEC 61000-4-6	3 Vrms Outside the ISM Bands 6 Vrms In the ISM and amateur radio bands 150kHz to 80MHz		of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Refer to the Recommended Separation Distances table for guidance on required separation distances based on the frequency of the transmitter. Minimum recommended separation distance d=5 feet (1.5 meters) Interference may occur in the vicinity of equipment marked with the following symbol: 
Electromagnetic compatibility (EMC) IEC 61000-4-39	8A/m at 30kHz	8A/m at 30kHz	
	65A/m at 134.2kHz	65A/m at 134.2kHz	
	7.5A/m at 13.56MHz	7.5A/m at 13.56MHz	
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Reader

The Reader is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Reader can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Reader as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (ft)**			
	174 MHz to 216 MHz $d = 3.9\sqrt{P}$	**335 MHz to 450 MHz** $d = 6.6\sqrt{P}$	**809 MHz to 849 MHz** $d = 1\sqrt{P}$	**2.35 GHz to 2.65 MHz** $d = 6.6\sqrt{P}$
0.01	0.39	0.66	0.10	0.66
0.1	1.23	2.09	0.32	2.09
1	3.90	6.60	1.00	6.60
10	12.33	20.87	3.16	20.87
100	39.00	66.00	10.00	66.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in feet (ft) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: For frequencies which may be described by two equations in the table above, the larger separation distance applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Reader Frequency Band

The Reader receives RF electromagnetic energy and includes RF transmitters that perform within the frequency range of 12.88MHz to 14.12MHz.

The Reader includes RF transmitters that perform at center bands (13.09MHz, 13.34MHz, 13.62MHz, and 13.90MHz).

BT Transceiver frequency

BT Smart Ready Module – FCC ID QOQBT121
Operating Frequency Range: 2402MHz – 2480MHz

FCC Statement

The equipment is approved for wireless transmission under FCC ID 2AR87ETXCPAS01. It has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult Customer Service.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

RF Exposure Compliance Information

This device meets the U.S. FCC's requirements for exposure to radio waves and is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy.

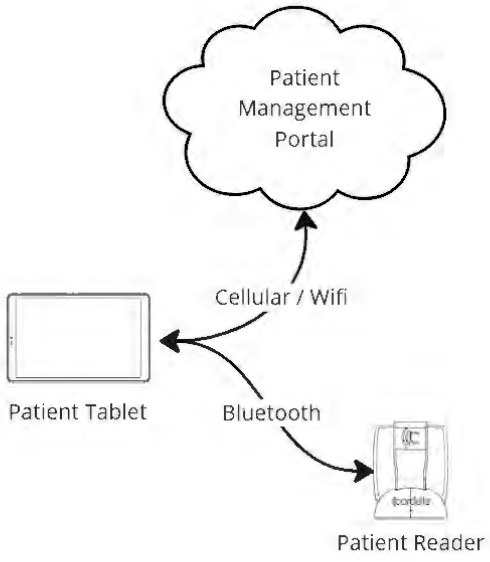
Appendix D: Wireless Communication – Quality of Service & Wireless Coexistence

About wireless communication

The Cordella Pulmonary Artery Sensor System (CorPASS) transmits data to a web hosted Patient Management Portal (PMP) enabling proactive heart failure management. Data is collected and transmitted using the following methods:

- **Bluetooth** - The device has a pre-configured Bluetooth feature enabling the collection of data from peripheral devices including the Handheld Reader.
- **Cellular** - The device has a pre-configured cellular wireless feature enabling the transmission of data from the Patient Tablet to the Patient Management Portal for clinicians review.
- **WiFi** - Transmission of data to the Patient Management Portal is also available via Wifi if cellular connectivity is not available/possible. Contact Customer Support for configuration of Tablet for device Wifi.

The wireless connections are pre-configured and ready for immediate use, no user interaction is required to collect or transmit the data. If any problems are encountered, please contact Endotronix Customer Service.



Overview of the device data transmission processes and wireless technologies.

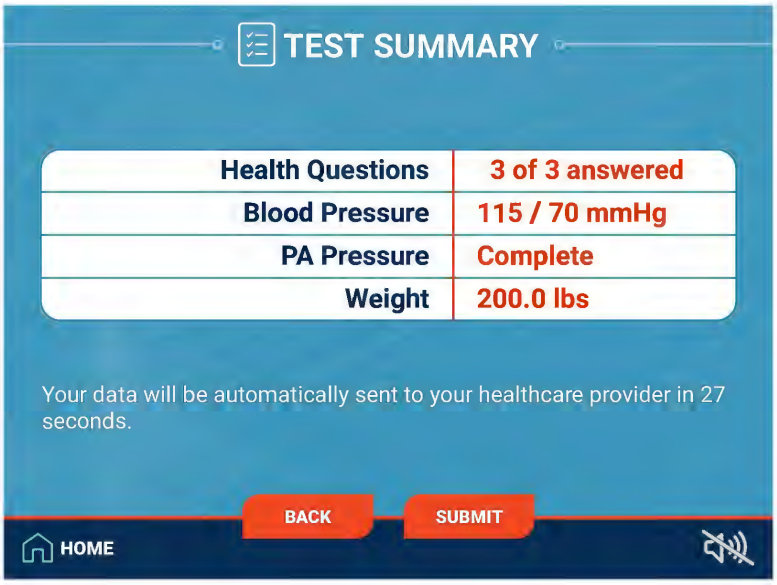
Wireless Quality of Service (QoS)

Wireless Quality of Service (QoS) is the ability of a wireless network to prioritize certain types of traffic over others to ensure a consistent level of service based on the criticality of an application. The device incorporates the use of wireless networks, therefore QoS plays a role in delivering a consistent and reliable user experience. The device's functionality has been designed to ensure the level of QoS services provided are consistent with its intended use.

Data Collection and Transmission Status

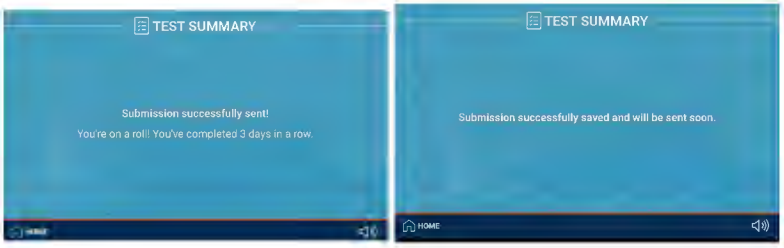
The device provides visual notifications regarding the status of data collection and transmission when any of the wireless methods are in use.

- **Bluetooth** - During the data collection process the user is visually notified of successful data collection as seen in the example below:



- **Cellular/WiFi** - After the data has been collected it is transmitted, and the user is visually notified of the

transmission's success or failure as seen below. If the data transmission was unsuccessful, the device will automatically attempt to resend the data, user interaction is not required.



If problems are encountered during the process of wireless collection or transmission, please contact Endotronix Customer Service.

Considerations When Transmitting Data

Successful collection and transmission of data depends on wireless services that may or may not always be available. Wireless communication can be influenced by many factors, such as geography, location, weather and other wireless devices in the area. It is important to take into account the fact that data transfer cannot always be assured using wireless communication. Please inform your healthcare provider in case of interruptions in data transmission of more than 3 days.

Please review the Safety Information section of this manual for Warnings and Precautions regarding the operation of this device (pg. 6).

Wireless Coexistence

Wireless coexistence issues can occur when different wireless devices operate in the same environment. Wireless coexistence issues can include:

- Frequency Interference: Wireless devices operating on similar frequencies can interfere with each other, leading to degraded performance or dropped connections.

- Signal Degradation: Proximity to other wireless products can result in signal degradation due to overlapping coverage areas or electromagnetic interference.

Recommendation to avoid Wireless coexistence issues:

- Physical Separation: Follow the warning relevant to EMI on page 6 and 7 and recommended distances on page 28 as needed. This will help you maintain safe physical separation between wireless devices to reduce interference and mitigate coexistence issues.

By following these precautions, Wireless coexistence issues can be mitigated to ensure optimal performance of wireless networks. If

additional problems are encountered during the process of wireless transmission, please contact Endotronix Customer Service.

Definition of Symbols

The following symbols are used on the labels of the Cordella Pulmonary Artery Sensor System.

Symbol	Standard number	Standard Title	Clause number	Explanatory text
UDI	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.7.10	Unique Device Identifier
MD	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.7.7	Medical Device
RxOnly	N/A	N/A	N/A	Caution: Federal law restricts this device to sale by or on the order of a physician.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.12	Single Patient Multiple Use
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.8	Importer
REF	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.6	Manufacturer's catalogue or part number so that the medical device can be identified.

Symbol	Standard number	Standard Title	Clause number	Explanatory text
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.5	Manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.7	Manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.2	Authorized representative in the European Community.
	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.2, Symbol 10	Need for the user to consult the instructions for use.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.2	Medical device that needs protection from light sources or heat.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.7	Temperature limits to which the medical device can be safely exposed.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.9	Range of atmospheric pressure to which the device can be safely exposed.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.4	Device that needs to be protected from moisture.

Symbol	Standard number	Standard Title	Clause number	Explanatory text
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.3.1	Device that can be broken or damaged if not handled carefully.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.1	Device manufacturer.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.3	Date when the device was manufactured.
	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.1, Symbol 4	Device should be attached to direct current source.
	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.1, Symbol 8	Device should be attached to alternating current source.
	N/A	N/A	UN 3481	The Reader operates using lithium ion batteries. Lithium-ion batteries should not be crushed or burned.
	IEC 60417	Graphic symbols for use on electrical equipment.	Table D.1, Symbol 9	Equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.

Symbol	Standard number	Standard Title	Clause number	Explanatory text
	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.2, Symbol 20	Type BF applied part complying with IEC 60601-1.
IPN_1N_2	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.3; Code 2	Manufacturer-determined degree of particle and water ingress protection, where... N1 = degree of protection from particulates (scale of 0-6); and N2 = degree of protection from water (scale of 0-8)
IP21	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.3; Code 2	Protected against solid foreign objects of 12.5 mm and greater, and against the effects of dripping water.
IP22	IEC 60601-1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Table D.3; Code 2	Protected against solid foreign objects of 12.5 mm and greater, and against the effects of dripping water when tilted at 15°.
	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	7.3.2	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.

Symbol	Standard number	Standard Title	Clause number	Explanatory text
	ISO 7010	Graphical symbols - Safety colours and safety signs - Registered safety signs.	7010-W001	General warning.
	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	5.4.4	Possibility of system damage, malfunction, or the delay in treatment.
	N/A	N/A	N/A	On/Standby button.
	IEC 60417	Graphic symbols for use on electrical equipment.	7000-5140	IEC 60417-5140 - Equipment includes RF Transmitter.
	N/A	Federal Communications Commission	N/A	Federal Communication Commission Number.

Índice

Introducción

El sistema Cordella con sensor de la arteria pulmonar (AP) está indicado para conectar a los profesionales médicos y los pacientes con herramientas diseñadas para mejorar el tratamiento integral de la insuficiencia cardíaca. Esta guía proporciona información básica sobre las instrucciones de uso del sistema Cordella con sensor de la arteria pulmonar en el hogar.

NOTA: La información proporcionada en este manual del paciente no tiene como propósito definir ninguna intervención, política de atención médica o procedimiento. Las políticas y procedimientos clínicos son responsabilidad de su médico.

Control de la insuficiencia cardíaca usando lecturas diarias del Sensor Cordella®

El sensor Cordella está diseñado para proporcionar a su equipo de atención información sobre la presión en su AP, resaltando los cambios en la presión de la AP o las tendencias a lo largo del tiempo, y facilitar una intervención terapéutica eficaz y oportuna. El sensor inalámbrico Cordella se implanta de manera permanente en la arteria pulmonar derecha, que es el vaso que se encuentra entre el corazón y los pulmones. Cuando usted obtiene una medición, el sensor Cordella envía una señal que indica la presión en la arteria. Los cambios en la presión de la AP pueden indicar acumulación de líquido en los pulmones.

Al vigilar las tendencias en su presión de la AP, sus profesionales médicos pueden intervenir para establecer un cambio de tratamiento para prevenir el aumento de la presión antes de que tenga síntomas. La información, junto con otros signos vitales como la presión arterial, la frecuencia cardíaca, el oxígeno en sangre, el peso y las respuestas a preguntas relacionadas con la salud, proporciona a su equipo de atención médica un panorama de su estado de salud por la red informática segura en el portal de manejo del paciente (PMP) myCordella. Basándose en las tendencias, el profesional médico puede controlar su insuficiencia cardíaca de forma proactiva y remota y, posiblemente, prevenir hospitalizaciones.

Uso previsto

El sistema Cordella con sensor de la AP está previsto para medir, registrar y transmitir datos de la presión de la AP en pacientes con insuficiencia cardíaca de clase III de la NYHA (Asociación Cardíaca de Nueva York) desde su hogar a los médicos, para la evaluación y el tratamiento de la insuficiencia cardíaca enfocándose en el paciente, con el objetivo de reducir las hospitalizaciones por esta afección.

El sistema Cordella® con sensor de la arteria pulmonar

El sistema Cordella con sensor de la arteria pulmonar está diseñado para la medición a demanda de la presión de la AP en su hogar. Esto puede ayudar a sus profesionales médicos a identificar, a través de las tendencias observadas en las presiones de la AP, una congestión pulmonar indicativa de un empeoramiento de la insuficiencia cardíaca.

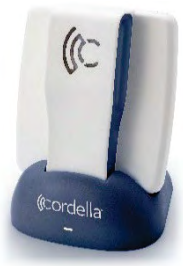
Nombre del componente

Sistema Cordella® con sensor de la arteria pulmonar (sensor Cordella)

Pequeño implante que reside permanentemente en la arteria pulmonar derecha. El sensor Cordella permite realizar las mediciones de la presión de la AP con el lector de mano del paciente myCordella mientras está en su casa. El lector recoge y transmite de forma segura las lecturas de la presión de la AP al médico. Las mediciones de este dispositivo son equivalentes a las obtenidas por personal clínico capacitado mediante el uso de productos invasivos basados en un catéter lleno de líquido.

Lector de mano del paciente myCordella® (lector)

Dispositivo que obtiene datos sobre la presión de la arteria pulmonar del sensor Cordella. Todos los días, debe sostener el lector inalámbrico contra el pecho durante aproximadamente 18 segundos, guiándose por las indicaciones auditivas y visuales de la tableta y el lector myCordella. El lector envía datos a la tableta, que proporciona lecturas diarias de la presión de la AP a su médico en el portal de manejo del paciente myCordella, lo que posibilita disponer de una evaluación más completa de su estado de salud.



Base de carga myCordella®
(base de carga)

Pequeño soporte que sujeta y carga cómodamente el lector del paciente mientras no está en uso. La base de carga siempre debe mantenerse enchufada. El lector siempre debe permanecer en la base de carga salvo que esté en uso o en su estuche cuando se viaja. El cable de alimentación debe utilizarse para desconectar la base de carga de la alimentación de CA. Las luces LED de la parte delantera indican si el lector se está cargando o está completamente cargado.

Información de seguridad

Para evitar lesiones personales o daños a cualquier equipo, lea y cumpla con toda la información de seguridad.

⚠ **Advertencias**	**Las advertencias indican la posibilidad de reacciones adversas graves o riesgos para la seguridad, y las limitaciones de uso que imponen.**
⚠ **Precauciones**	**Las precauciones indican que debe tenerse especial cuidado para garantizar el uso seguro y eficaz del dispositivo.**

⚠ Advertencias

- El lector es apto para entornos de atención médica en el hogar y centros de atención médica profesionales, excepto en la cercanía de equipos quirúrgicos de alta frecuencia activos y en cabinas blindadas contra la radiofrecuencia de un sistema eléctrico de uso médico para la obtención de imágenes por resonancia magnética, donde la intensidad de la perturbación electromagnética es elevada.
- El lector y la base de carga no se deben usar adyacentes a otros equipos ni apilados con otros equipos. Si es necesario operar los componentes apilados con otros equipos o a su lado, verifique que el sistema funcione normalmente en la configuración en la que se utilizará. En caso necesario, comuníquese con el servicio al cliente para obtener ayuda para reubicar el sistema.
- NO exponga ningún accesorio eléctrico al agua ni a otros líquidos.
- NO desarme ni modifique ningún componente del sistema Cordella con sensor de la AP.
- NO utilice el sistema Cordella con sensor de la AP en presencia de productos anestésicos explosivos o inflamables.
- El sistema Cordella con sensor de la AP no está previsto para usarse en emergencias ni en monitoreo en tiempo real.

- El sistema Cordella con sensor de la AP no está previsto como dispositivo de respuesta ante emergencias. En caso de una emergencia médica, llame a los servicios médicos de emergencia locales o a su profesional médico.
- Tras el procedimiento de implantación, es esencial cumplir con las indicaciones del médico respecto de los anticoagulantes y otros medicamentos recetados.
- Los cables de alimentación pueden generar el riesgo de tropezar. Preste atención a los cables que crucen pasillos.
- NO coloque los cables de alimentación de ninguna manera que pueda causar enredo o estrangulación.
- El lector puede recibir interferencias de otros equipos generadores de interferencia electromagnética (IEM). Cuando utilice el sistema Cordella con sensor de la AP, evite utilizar los siguientes elementos que generan IEM y manténgalos a una distancia mínima de ~5 pies (1.5 metros): aparatos de CPAP, computadoras portátiles, tabletas, lectores electrónicos, secadores de pelo, afeitadoras eléctricas, refrigeradores, mobiliario metálico, camas eléctricas o ajustables, equipos estereofónicos domésticos, radiodespertadores, aires acondicionados, hornos eléctricos, lavadoras, secadoras, lavaplatos, televisores y microondas.
- Evite utilizar el lector en la misma habitación o a menos de unos 13 pies (3.8 metros) de los enrutadores inalámbricos.
- Cuando realice una lectura con el lector, evite la comunicación simultánea a través de walkie talkie.
- Cuando sea posible, apague y desenchufe posibles fuentes de IEM en su casa durante el uso del sistema Cordella con sensor de la AP.
- Cuando sea posible, realice las lecturas con el lector a una distancia mínima de 5 pies (1.5 metros) de las paredes, ya que los soportes metálicos y el cableado eléctrico pueden causar interferencias electromagnéticas.
- El lector requiere precauciones especiales relacionadas con la compatibilidad electromagnética (CEM) y debe ponerse en servicio de acuerdo con la información sobre CEM proporcionada. Si se perciben interferencias, retire o deje de utilizar el equipo que causa la interferencia.
- Utilice solo los cables y accesorios suministrados. El uso de accesorios, transductores o cables distintos de los especificados o suministrados como piezas de repuesto puede provocar una disminución de la inmunidad del sistema, lecturas inexactas, daños al sistema, lesiones al usuario o un funcionamiento inadecuado.
- Los equipos de comunicaciones por RF portátiles (incluidos los periféricos como cables de antena y antenas externas) no se deben usar a una distancia inferior a aproximadamente 5 pies (1.5 metros) de ninguna parte del lector. De lo contrario, podría producirse una degradación en el rendimiento del lector.
- Si la piel se pone roja, caliente o irritada, deje de usar el lector inmediatamente y comuníquese con el servicio al cliente.
- Comuníquese con el servicio al cliente de Endotronix si más de 1 usuario de Cordella reside en el mismo hogar. NO utilice más de un lector al mismo tiempo en el mismo entorno general, dado que el uso de varios instrumentos de lectura a la vez puede causar que interfieran entre sí.
- El lector contiene baterías de iones de litio. NO coloque el lector sobre una superficie caliente.

⚠ Precauciones

- Evite exponer cualquier componente del sistema Cordella con sensor de la AP al agua u otros líquidos. Comuníquese con el servicio al cliente para obtener un repuesto si alguno de los componentes queda expuesto a líquidos.
- NO deje caer el lector. Manipúlelo con cuidado.
- Si lo deja caer, la batería del lector podría quedar expuesta. Si la batería resultase expuesta, comuníquese de inmediato con Endotronix para obtener un lector de repuesto. Cualquier daño en el lector puede provocar una lectura inexacta.
- NO utilice el lector si la cubierta de plástico ha sufrido daños o tiene grietas o si se ha desprendido algún componente.
- Si la etiqueta del lector se ve alterada, comuníquese con el servicio al cliente de Endotronix.
- La exactitud del sistema Cordella con sensor de la AP se ve ligeramente afectada por grandes cambios en la altitud entre la calibración inicial y las mediciones posteriores. Las lecturas pueden perder la exactitud cuando se toman a más de 2000 m de altitud. Si tiene previsto viajar o trasladarse a una ubicación a más de 2000 m de altitud, póngase en contacto con el servicio al cliente.
- El sensor Cordella es un implante permanente. No se recomienda retirarlo tras la implantación.
- El sensor Cordella puede verse afectado por un cambio en la altitud por encima o por debajo del nivel del mar. Si tiene previsto viajar por debajo del nivel del mar o bucear o subir a altitudes extremadamente elevadas sin presurización, comuníquese con el servicio al cliente.
- NO intente emparejar el lector con ningún dispositivo que no sea la tableta myCordella.

Normas de privacidad médica y privacidad del paciente

Todos los componentes del sistema Cordella con sensor de la AP se han diseñado para cumplir con las normas sobre la privacidad del paciente. La organización de profesionales médicos que le brindan atención y Endotronix se asegurarán de cumplir por completo las leyes de privacidad y seguridad, así como las políticas, procedimientos y protocolos de la organización con respecto a la información del paciente, y asegurar la privacidad del paciente en todo momento.

Endotronix no es responsable del uso o abuso de la información del paciente por parte de profesionales médicos.

Procedimiento de implante

Antes del procedimiento de implante

Antes del procedimiento de implante, usted y su médico hablarán sobre los beneficios y riesgos del procedimiento y el sistema Cordella con sensor de la AP. Se le dará una descripción detallada del procedimiento, su médico le explicará los riesgos asociados con el procedimiento y el sensor y responderá cualquier pregunta que tenga, y se le pedirá que firme un consentimiento informado.

Informe a su médico de cualquier infección, arritmia o sangrado que se produzca antes del procedimiento de implante.

El procedimiento de implante

Durante un cateterismo del lado derecho del corazón, el sensor Cordella se implanta permanentemente en la arteria pulmonar derecha, el vaso sanguíneo que transporta la sangre del corazón a los pulmones. Ese cateterismo es un procedimiento estándar utilizado para medir las presiones en el corazón y en la AP.

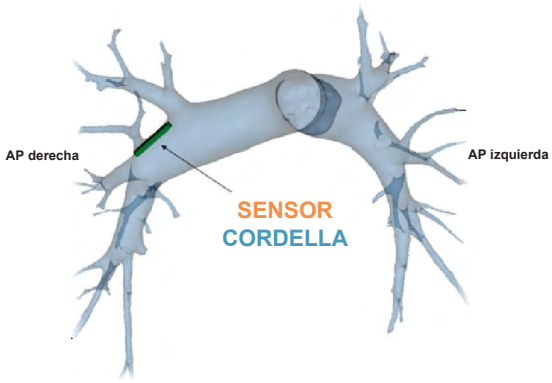
El sensor Cordella tiene la longitud de una moneda de $0.01 (19.3 mm x 3.8 mm x 1.9 mm) y tiene dos bucles de alambre que se extienden desde cada extremo y que lo fijan en su sitio en el vaso. El sensor Cordella está sujeto a un catéter que el médico desplaza hábilmente hasta la AP.

Los pasos del procedimiento de implante son los siguientes:

1. El médico realizará una pequeña incisión e introducirá un pequeño tubo llamado “introductor”. Un catéter para la arteria pulmonar se pasará por el introductor hasta el interior de la vena mientras el médico mira una pantalla con una radiografía en vivo (en un dispositivo que se llama “radioscopio”) de sus venas y corazón. El médico pasará este catéter por sus venas hasta llegar al corazón y luego a la AP.
2. En ese momento, el médico tomará unas cuentas imágenes con el radioscopio, para lo cual inyectará un tinte por el extremo del catéter. Estas imágenes le aportarán al médico una mejor idea del aspecto de sus arterias pulmonares y ayudarán a guiar la colocación del sensor. Este procedimiento

se llama “angiografía”.

3. Se introduce un alambre guía para proporcionar soporte, y se retira el catéter de la arteria pulmonar. El catéter con el sensor Cordella acoplado se introduce y se coloca en la arteria pulmonar derecha.
4. Una vez que el sensor esté en la mejor posición posible, el médico implantará el sensor Cordella.
5. Después de que el sensor Cordella esté implantado, el lector de mano se sostendrá en el lado derecho del pecho para calibrar el sensor.
6. Después de la calibración, se le retirará el catéter de la arteria pulmonar, y usted será llevado a la sala de recuperación.



Después del procedimiento de implante

Mientras esté en la sala de recuperación, pasará un representante de Endotronix para tomar algunas mediciones de la presión de la AP con el lector. Es posible que pase la noche allí en observación.

Se le enseñará cómo usar correctamente el lector y la ubicación óptima (prescrita) del lector para tomar las lecturas en casa. También se le entregará una tarjeta del implante (de aproximadamente el tamaño de una tarjeta de presentación), y le darán el alta para que vuelva a casa. Debe llevar siempre con usted la tarjeta del implante para avisar al personal médico y de seguridad de información importante sobre su sensor.

Cómo empezar a usar el sistema

El lector se emparejará automáticamente con la tableta myCordella cuando se encienda la tableta. No es necesario que el usuario haga nada más. Al regresar a casa con el lector y la base de carga, conecte el cable de alimentación de la base de carga al puerto de alimentación que se encuentra en la parte posterior de la base de carga y el otro extremo a una toma de pared. Coloque la base de carga sobre una superficie plana cerca de la tableta myCordella con un espacio libre mínimo de dos pulgadas (cinco centímetros) respecto a los objetos o las paredes circundantes.

Coloque el lector en la base de carga. La luz LED de la parte delantera de la base de carga parpadeará mientras se esté cargando y pasará a una luz blanca fija cuando el lector esté cargado. Llame al servicio al cliente de Endotronix si esto no ocurre en las 24 horas siguientes a la configuración.

Inicie el lector por primera vez pulsando el botón de encendido de la parte inferior durante varios segundos.

Colocación del lector

Encontrar de forma fiable y repetida la ubicación adecuada del lector resulta esencial para obtener mediciones válidas de la presión de la AP.

Con la mano izquierda, agarre el lector por el asa y retírelo de la base de carga. Coloque el lector contra el pecho de forma que el símbolo iluminado esté en la parte superior, en la dirección de la cabeza. Un representante de Endotronix podría indicar que el lector se debe colocar en una ubicación diferente; por ejemplo, en el costado del cuerpo. Ajuste la posición del lector para maximizar la intensidad de la señal según el indicador de intensidad de la señal que se muestra en la pantalla de la tableta y la velocidad de cambio de la señal de aviso acústica del lector. Cuando se logra la posición óptima, el lector reproduce el tono que indica “Sensor encontrado” y muestra una luz azul que parpadea rápido (consulte “Indicaciones auditivas y visuales” a continuación) a medida que procede a obtener datos.

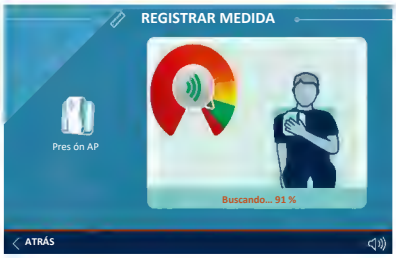
Obtención de una lectura

El lector de mano se debe retirar de la base de carga con la mano izquierda para que sea más fácil encontrar el sensor Cordella en la AP derecha (lado derecho del pecho). Es esencial para el funcionamiento adecuado del lector mantener una zona libre de metales donde se va a realizar la lectura y obtener cada lectura en una posición corporal uniforme.

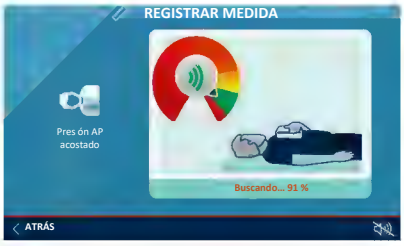
Las figuras de este manual están indicadas solo como referencia y posiblemente no sean una réplica exacta de las pantallas que usted tiene en su sistema debido a las mejoras continuas que se implementan en el software.

Antes de comenzar la medición, quítese todos los collares, relojes y alhajas que se encuentren a menos de 3 pulgadas (8 cm) de su ubicación de lectura prescrita.

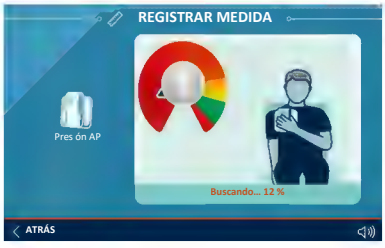
Encienda el lector y colóquelo en la base de carga para cargarlo por completo antes de tomar su primera lectura en casa.



Tomando una lectura de la presión AP



Tomando una lectura de la presión AP acostado



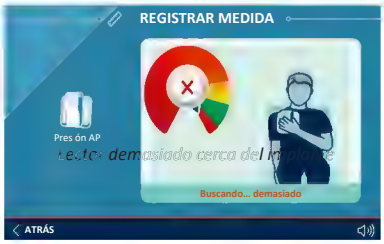
Lector demasiado lejos del implante

Si va a tomar una lectura de la presión de la AP, asegúrese de **sentarse** de manera erguida en una posición cómoda y de descansar unos minutos hasta respirar de forma cómoda.

Si va a tomar una lectura de la presión de la AP acostado (si se le ha prescrito), tome el lector y, a continuación, acuéstese por completo, coloque el brazo derecho a su lado y respire normalmente.

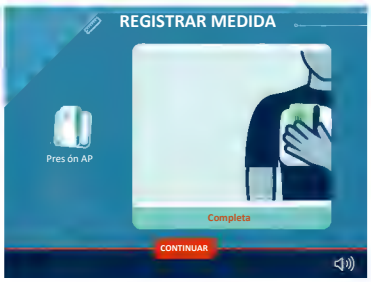
Para ver el indicador LED del lector, utilice un espejo o pida a un familiar que se lo describa mientras toma la lectura. La animación lo guía a través de una adecuada obtención de datos utilizando el lector.

1. Retire el lector de la base de carga con la ***mano izquierda*** para que sea más fácil encontrar el sensor Cordella en el lado ***derecho*** del pecho. Cuando se retire el lector de la base de carga, empezará a pitar, y la luz del lector se volverá fija y de color AZUL.
2. Sostenga el lector en el lugar prescrito sobre el pecho (que se designó durante su entrenamiento) y observe las indicaciones de la intensidad de la señal en la pantalla de la tableta. Ajuste la posición del lector para maximizar la intensidad de la señal dentro de la zona verde indicada. Las indicaciones auditivas del lector cambiarán de velocidad a medida que el lector se acerque o se aleje del sensor. Si el lector está demasiado cerca o demasiado lejos del implante, no podrá obtener una lectura. Una vez que se logre una posición óptima del lector, la luz del lector parpadeará en color AZUL con una rápida sucesión, y comenzará la obtención de datos.



Lector demasiado cerca del implante

3. Durante la lectura, es importante mantenerse quieto y sostener el lector lo más inmóvil que resulte posible. La luz del lector parpadeará de color VERDE durante la lectura. Siga respirando normalmente durante la lectura.
4. Después de unos 18 segundos, el lector emitirá un tono de “éxito” si la lectura se realizó correctamente. La luz del lector se volverá fija y de color VERDE.
   a. En caso de que la lectura obtenida no fuese lo suficientemente precisa debido al movimiento o la colocación indebida del lector, el lector emitirá un tono de “falla”. La luz del lector parpadeará rápidamente en color BLANCO. Inmediatamente después, el lector volverá al modo de “búsqueda” descrito en el paso 1.
5. Una vez que se obtenga una lectura precisa, el LED del lector pasará a ser una luz fija de color VERDE y seguirá emitiendo el tono de “éxito” hasta que se vuelva a colocar en la base de carga. El lector debe permanecer siempre en la base de carga salvo que se esté utilizando o transportando.



Envío de los resultados

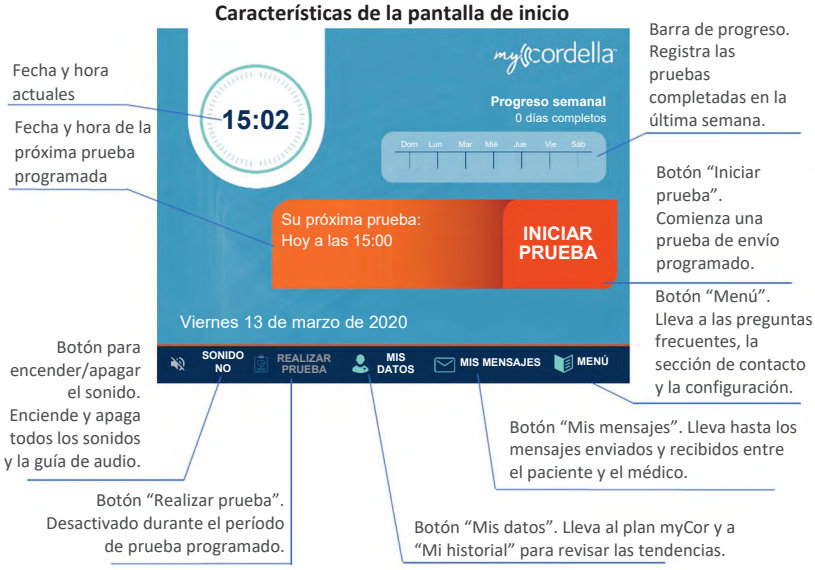
La pantalla de la tableta volverá a la pantalla “Realizar una prueba”. Pulse el botón “Revisar resultados” para avanzar a la pantalla “Resumen de las pruebas”. La lectura de la presión de la AP se mostrará mientras se obtenga. Pulse el botón “Enviar”.

NOTA: Una vez en la pantalla “Resumen de las pruebas”, si se han completado todas las pruebas, la aplicación enviará automáticamente las mediciones después de 30 segundos si no se realiza ninguna acción, independientemente de si la prueba estaba programada o no estaba programada por su médico.

Acceso a su historial

La tableta myCordella permite que el paciente revise los envíos previos por día o por tipo de medición. Pulse el botón “Mis datos” en la pantalla de inicio para acceder a la página “Mi historial” y revisar los envíos diarios o las tendencias creadas a partir de los envíos semanales y mensuales. Desplácese entre el historial de mediciones diarias o las tendencias pulsando sus respectivas pestañas en la parte inferior de la tableta myCordella.

Características de la pantalla de inicio



Indicaciones auditivas y visuales

Indicaciones auditivas del lector

Evento	Sonido	Acción necesaria
Buscando el sensor	Varios pitidos cada vez más rápidos	Reubique el lector para encontrar una señal más intensa.
Sensor encontrado	Cuatro pitidos agudos que ascienden rápidamente y se repiten tres veces	Se ha encontrado una señal intensa. Sostenga el lector en su ubicación.
Lectura en curso	Dos pitidos que ascienden rápidamente y se repiten cada 3 segundos aproximadamente	Sostenga el lector en su ubicación (18 segundos aproximadamente).
Lectura del sensor exitosa*	Varios pitidos agudos que ascienden rápidamente	Medición completa. Vuelva a colocar el lector en la base de carga.
Medición fallida	Varios pitidos graves que descienden lentamente	Reubique el lector para encontrar una señal más intensa.
Vuelta a la base de carga	Sonido de lectura exitosa que se repite periódicamente	Vuelva a colocar el sensor en la base de carga. Si el lector está allí, compruebe las indicaciones visuales de la base de carga.
Batería baja	Tres pitidos graves y rápidos que se repiten cada 10 segundos aproximadamente	Cuando estén acompañados de una luz fija blanca, vuelva a colocar el sensor en la base de carga.
Calentamiento	Varios pitidos que ascienden lentamente	Vuelva a colocar el lector en la base de carga para que se caliente.
Comunicarse con el servicio al cliente	Tres pitidos graves y rápidos que se repiten cada 10 segundos aproximadamente	Cuando estén acompañados de una luz parpadeante morada, llame al servicio al cliente.

*Para evitar que el sistema Cordella muestre datos erróneos a los profesionales médicos, se realiza un análisis de los datos de todas las lecturas. Si se detecta información errónea, se mostrará al médico como una lectura incorrecta, y un médico puede solicitar otra lectura incluso si el lector indica que es correcta. Para evitar lecturas incorrectas, asegúrese de que la intensidad de la señal sea lo más alta posible en la zona verde del dial y coloque el lector lejos del equipo que genere interferencia electromagnética (IEM). Además, asegúrese de tomar las lecturas sentado o acostado según las instrucciones del sistema Cordella. Consulte “Advertencias” y el Apéndice C para obtener información más detallada sobre las interferencias.

Indicaciones visuales del lector

Luz	Evento/acción necesaria
Fija azul	Buscando el Sensor.
Azul que parpadea lentamente	Vuelva a colocar el sensor en la base de carga.
Azul que parpadea rápidamente	Sensor encontrado. Listo para comenzar la lectura.
Verde que parpadea lentamente	Lectura en curso. Sostenga el lector en su ubicación hasta que la luz se vuelva fija de color verde.
Fija verde	Lectura del sensor exitosa.
Alterna entre blanco, azul y azul oscuro	Vuelva a colocar el lector en la base de carga para que se caliente.
Blanco que parpadea rápidamente	Lectura fallida. Reubique el lector.
Fija blanca	Batería baja. Vuelva a colocar el sensor en la base de carga.
Morado que parpadea rápidamente	Comuníquese con el servicio al cliente de Endotronix.
Luz apagada	Sin batería. Vuelva a colocar el sensor en la base de carga.

Indicaciones visuales de la base de carga

Luz	Evento/acción necesaria
Blanca que parpadea	El lector se está cargando.
Fija blanca	El lector está completamente cargado y listo para usarse.
Sin luz	Cuando el lector está en la base y no hay ninguna luz, la base de carga no está conectada a una fuente de alimentación. Compruebe que el cable de alimentación de la base de carga esté conectado tanto a la base de carga como a una toma eléctrica. Si la luz sigue apagada, comuníquese con el servicio al cliente. Para apagar las indicaciones auditivas y visuales del lector durante este tiempo, ponga el lector en “Modo viaje” (consulte “Cómo viajar con el lector y la base de carga” a continuación).

Cómo viajar con el lector y la base de carga

El sistema Cordella con sensor de la AP está diseñado para que sea portátil y debe llevarse consigo en viajes personales o laborales. Endotronix recomienda empacar con cuidado el lector del paciente en el equipaje de mano, envolviéndolo en plástico de burbujas o ropa y

guardándolo en el centro de la maleta. La base de carga y el cable de alimentación deben envolverse por separado y guardarse también en una maleta donde vayan a someterse a la menor cantidad de tensión.

Para viajar con el lector, retire el lector de la base de carga y pulse durante varios segundos el botón de encendido del lector para iniciar el "Modo viaje". El botón de encendido es pequeño y está ubicado en la parte inferior del lector, en la base del asa y junto al conector de alimentación. Al presionar el botón, se desactivan las indicaciones auditivas y visuales del lector y se evita que se dañen las baterías. Este mismo proceso se puede utilizar para apagar el lector en cualquier momento.

Para reiniciar el lector después de un viaje, pulse y mantenga pulsado el botón de nuevo. El lector deberá calentarse y cargarse en la base de carga antes de que pueda tomar una lectura. Coloque el lector en la base de carga durante aproximadamente 10 minutos para que se caliente. Mientras esté en la base de carga, el lector no emitirá indicaciones auditivas ni visuales. Si no puede cargar el lector durante los viajes, es posible que vea y escuche las indicaciones de calentamiento descritas anteriormente cuando reinicie el lector. Una vez que el lector se caliente, esas indicaciones terminarán, y comenzarán las indicaciones de búsqueda, lo que indicará que puede empezar a tomar la lectura. Cuando la lectura haya terminado, vuelva a apagar el lector.

Si el botón se presiona pero el lector no responde, es probable que la batería esté descargada; vuelva a colocar el lector en la base de carga y deje que se cargue por completo.

Asegúrese de llevar con usted su tarjeta de identificación del implante en todo momento.

El lector contiene baterías de iones de litio.
NO lo transporte en el equipaje facturado.

NOTA: Espere aproximadamente 10 minutos para tomar una lectura después de desactivar el "Modo viaje" para permitir que el lector se caliente.

Contáctenos

El usuario debe ponerse en contacto con la autoridad competente y con Endotronix para informar acerca de cualquier incidente grave que haya ocurrido en relación con el dispositivo médico.

Las preguntas o inquietudes relacionadas con la configuración, el uso, el funcionamiento o eventos imprevistos, incidentes graves y las consultas generales se pueden dirigir a la siguiente información de contacto:

Servicio al cliente de Endotronix

Endotronix, Inc.
1415 West Diehl Road
Suite #500W
Naperville, IL 60563
EE. UU.

Número gratuito: 1-888-512-5595
Support@endotronix.com

Reparación de equipos

Para mantener las garantías aplicables y el funcionamiento, Endotronix exige que solo realice reparaciones el personal autorizado. No hay piezas que puedan ser reparadas por el usuario. Las reparaciones realizadas por personal no autorizado invalidarán su garantía. Para obtener información sobre la garantía del producto, comuníquese con Endotronix. Los cambios o modificaciones no aprobados expresamente por Endotronix pueden anular la garantía del usuario en relación con el sistema. No deseche ningún componente del sistema; comuníquese con el servicio al cliente y siga el procedimiento de autorización de devolución de materiales que se describe a continuación para devolver los materiales a Endotronix. La vida útil del sensor Cordella es de diez (10) años.

Autorización de devolución de materiales (Return Materials Authorization, RMA)

Si el servicio al cliente solicita la devolución del equipo, siga las instrucciones que se detallan a continuación.

1) Embale con cuidado el equipo en la caja de envío original o una equivalente con sus materiales de embalaje protectores originales o equivalentes según las instrucciones del servicio al cliente.
2) Incluya el número de RMA que le proporcione el servicio al cliente en el exterior del contenedor de envío. Envíe todo el equipo y la lista de devolución del equipo firmada a:

   RMA #
   Customer Service Department, Repairs Endotronix, Inc.
   Endotronix, Inc.
   1415 West Diehl Road
   Suite #500W
   Naperville, IL 60563
   EE. UU.

Instrucciones de inspección y limpieza

Inspeccione el sistema antes de cada uso. No se necesita ningún mantenimiento. Si alguno de los puntos de la lista de inspección es válido, comuníquese con el servicio al cliente.

Lista de inspección
○ El cable de alimentación no está dañado ni conectado a un equipo no autorizado. Si hay un cable de alimentación dañado o si la unidad está conectada a un equipo no autorizado, desenchufe la unidad y notifique al servicio al cliente para obtener una nueva. ○ Los cables están conectados correctamente y en buen estado. ○ Todos los accesorios están conectados de forma segura. ○ Los componentes no están dentro ni cerca de agua u otros líquidos. ○ Los componentes no se han movido a una ubicación inadecuada. ○ Si el lector o la base de carga se han caído o se han dañado, NO los use y llame al servicio al cliente.
 Limpieza
○ Limpie los componentes del sistema según sea necesario. ○ DESENCHUFE la base de carga y retire el lector antes de la limpieza o desinfección. ○ Ponga el lector en “Modo viaje” para minimizar las señales auditivas durante la limpieza. ○ Para limpiar el dispositivo, pase por las superficies un paño que no genere pelusas ligeramente humedecido con agua. ○ NO desarme el equipo. Limpie solo las superficies del lector y de la base de carga. ○ NO sumerja el lector o la base de carga en ningún líquido. ○ NO rocíe líquidos directamente sobre el lector o la base de carga; utilice un paño previamente humedecido. ○ NO esterilice en autoclave. ○ NO esterilice con óxido de etileno.

Condiciones relacionadas con la RM

 Información sobre la RM
○ Puede someterse a una exploración por RM bajo determinadas condiciones. Hable con el médico que ordena la exploración por RM para asegurarse de que sepa que usted tiene un sensor Cordella de la AP. ○ Si no se siguen las condiciones definidas en relación con la RM, existirá un mayor riesgo de calentamiento o movimiento adicional del sensor Cordella o de daño al sensor Cordella. ○ Las condiciones relacionadas con la RM se describen en las instrucciones de uso del sistema Cordella con sensor de la AP de su médico. ○ Asegúrese de llevar siempre con usted su tarjeta de identificación del implante.

APÉNDICES

Apéndice A: Componentes del sistema Cordella® con sensor de la arteria pulmonar

Utilice solo suministros autorizados por Endotronix, dado que otro equipo puede resultar en un aumento de las emisiones electromagnéticas, una disminución de la inmunidad a las emisiones o un daño al sistema. Para pedir suministros, comuníquese con el servicio al cliente e incluya el nombre y el número de pieza.

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Lista de componentes del sistema Cordella con sensor de la arteria pulmonar	
100102-01	Lector de mano del paciente myCordella
100274-01	Base de carga myCordella
100264-00	Adaptador de montaje en pared de CA/CC para la base de carga

Apéndice B: Especificaciones del equipo
Lector de mano del paciente myCordella®

Fabricante	Endotronix
Método de medición	Interrogación inalámbrica del sensor Cordella implantado.
Intervalo máximo de presión de pulsos de la arteria pulmonar:	40-100 mmHg
Intervalo de presión de la arteria pulmonar a nivel del mar:	0-100 mmHg
Exactitud del sensor	+/- 2 mmHg al inicio y +/- 3 % en todo el intervalo de presión en comparación con una medición de la presión de referencia para un intervalo de presión de 600-860 mmHg (absoluto). *Nota: La exactitud del Sistema Cordella con Sensor de la AP se ve afectada por un cambio en la temperatura corporal (<-3 mmHg/Δ °C).*
Seguridad/uso del paciente	El tiempo de lectura típico es de 30 segundos.
Calibración	En el momento del implante y cuando lo considere necesario un profesional médico.
Vida útil prevista (solo del lector)	Cuatro años
Normas de seguridad	Cumple todas las partes relevantes de IEC 60601-1 Ed. 3.2.
Normas de CEM	Cumple todas las partes relevantes de IEC 60601-1-2 Ed. 4.1.
Frecuencia de funcionamiento	12.88-14.12 MHz, 2.45 GHz
Características físicas	
Dimensiones aproximadas	• Ancho: 6.44 pulg./16.35 cm • Altura: 2.0 pulg./5.1 cm • Profundidad: 5.63 pulg./14.3 cm • Peso: 1.2 lb/0.54 kg
Alimentación	
Entrada	4.2 V/16.8 V ⎓ 667 mA/142 mA
Entorno *Es posible que el lector no cumpla sus especificaciones de rendimiento si se almacena o utiliza fuera de los intervalos ambientales mencionados a continuación.*	
Temperatura	• Funcionamiento: 5–35 °C (41–95 °F) • Transporte: -10–55 °C (14–131 °F) • Almacenamiento: -10–55 °C (14–131 °F)

Humedad relativa	• Funcionamiento: 6–93 % (sin condensación) • Transporte: 6–93 % (sin condensación) • Almacenamiento: 6–93 % (sin condensación)
Presión atmosférica	• Funcionamiento: 800–1066 hPa

El rendimiento esencial se mantiene durante la vida útil del producto. Para obtener información adicional sobre el rendimiento esencial, comuníquese con el servicio al cliente de Endotronix.

Base de carga myCordella®

Fabricante	Endotronix
Vida útil prevista (solo de la base de carga)	Cuatro años
Normas de seguridad	Cumple todas las partes relevantes de IEC 60601-1 Ed. 3.2.
Normas de CEM	Cumple todas las partes relevantes de IEC 60601-1-2 Ed. 4.1.
Características físicas	
Dimensiones aproximadas	• Ancho: 5.5 pulg./14.0 cm • Altura: 2.5 pulg./6.4 cm • Profundidad: 5.5 pulg./14.0 cm • Peso: 0.4 lb/181.4 g
Entorno *Es posible que la base de carga no cumpla sus especificaciones de rendimiento si se almacena o utiliza fuera de los intervalos ambientales mencionados a continuación.*	
Temperatura	• Funcionamiento: 5–35 °C (41–95 °F) • Transporte: -25–70 °C (-13–158 °F) • Almacenamiento: -25–70 °C (-13–158 °F)
Humedad relativa	• Funcionamiento: 6–93 % (sin condensación) • Transporte: 0–90 % (sin condensación) • Almacenamiento: 0–90 % (sin condensación)
Presión atmosférica	• Funcionamiento: 800–1066 hPa
Cable de alimentación	
Fabricante	SL Power Electronics
Número de pieza	ME20A0503F01
Longitud del cable	~ 8 pies / 2.4 m
Alimentación de CA	Fuente de alimentación de montaje en pared

	• Entrada de 110-250 V~, 50-60 Hz • Salida de 5 V⎓ a 3 A
Base de carga	• Entrada: +5 V ⎓ 3.0 A • Salida: 4.2 V/16.8 V, 667 mA/142 mA

Apéndice C: Guía electromagnética

Guía y declaración del fabricante: Inmunidad y emisiones electromagnéticas

El lector y la base de carga cumplen la norma IEC 60601-1-2 Ed. 4.1. El lector y la base de carga son equipos eléctricos de uso médico de clase II, y el lector es una pieza aplicada BF.

El lector y la base de carga están previstos para usarse en el entorno electromagnético especificado a continuación.

El usuario del lector y la base de carga debe asegurarse de que se utilice en dicho entorno.

Prueba de emisiones	Cumplimiento	Entorno electromagnético: Guía
Emisiones conducidas CISPR 11	Clase B, Grupo 1	El lector debe emitir energía electromagnética para realizar su función prevista. Los equipos electrónicos cercanos se pueden ver afectados. El lector es apto para usarse en centros de atención médica profesionales y en entornos de atención médica en el hogar.
Emisiones radiadas CISPR 11	Clase B, Grupo 1	
Emisiones de corrientes armónicas IEC 61000-3-2	Clase A	
Cambios de voltaje, fluctuaciones/emisiones de parpadeo IEC 61000-3-3	Conforme	

Guía y declaración del fabricante: Inmunidad electromagnética

El lector y la base de carga son dispositivos en fase de investigación clínica que cumplen con la norma IEC 60601-1-2 Ed. 4.1.

El lector y la base de carga están previstos para usarse en el entorno electromagnético especificado a continuación.

Prueba de inmunidad	**Nivel de prueba**	**Cumplimiento**	**Entorno electromagnético: Guía**
Inmunidad a descargas electrostáticas IEC 61000-4-2	±8kV con contacto ±2 kV, ±4 kV, ±8 kV, ±15 kV en aire	±8kV con contacto ±2 kV, ±4 kV, ±8 kV, ±15 kV en aire	Los suelos deben ser de madera, cemento o losetas de cerámica. Si los suelos están cubiertos con un material sintético, la humedad relativa debe ser de, al menos, el 30 %.
Inmunidad a los transitorios eléctricos rápidos y ráfagas IEC 61000-4-4	±2 kV para líneas de suministro de energía	±2 kV para líneas de suministro de energía	La calidad de la red eléctrica debe ser la típica de un centro de atención médica profesional o de un entorno de atención médica en el hogar.
Sobretensión IEC 61000-4-5	±1 kV línea a línea	±1 kV línea a línea	
	±0.5 kV línea a línea	±0.5 kV línea a línea	
Caídas de voltaje, interrupciones breves y variaciones de voltaje en las líneas de entrada de suministro eléctrico IEC 61000-4-11	0 % *U*T (caída del 100 % en *U*T) durante 0.5 ciclo	0 % *U*T (caída del 100 % en *U*T) durante 0.5 ciclo	
	0 % *U*T (caída del 100 % en *U*T) durante 1 ciclo	0 % *U*T (caída del 100 % en *U*T) durante 1 ciclo	
	70 % *U*T (caída del 30 % en *U*T) durante 25 ciclos (50 Hz) y 30 ciclos (60 Hz)	70 % *U*T (caída del 30 % en *U*T) durante 25 ciclos (50 Hz) y 30 ciclos (60 Hz)	
	0 % *U*T (interrupción del 100 % en *U*T) durante 250 ciclos (50 Hz) y 300 ciclos (60 Hz)	0 % *U*T (interrupción del 100 % en *U*T) durante 250 ciclos (50 Hz) y 300 ciclos (60 Hz)	
Campo magnético de frecuencia eléctrica IEC 61000-4-8	30 A/m 50 Hz y 60 Hz	30 A/m 50 Hz y 60 Hz	Los campos magnéticos de frecuencia eléctrica deben estar a los niveles característicos de un típico centro de atención médica profesional o de un entorno de atención médica en el hogar.
Inmunidad de RF radiada IEC 61000-4-3	10 V/m 80 MHz-2.7 GHz 80 % AM a 1 kHz	10 V/m	Los equipos de comunicaciones por RF portátiles y móviles no deben estar a menor distancia de

Inmunidad frente a RF conducida IEC 61000-4-6	3 Vrms Fuera de las bandas ISM 6 Vrms En las bandas ISM y de radioaficionados De 150 kHz a 80 MHz		cualquier pieza del sistema, incluidos los cables, que la distancia de separación recomendada calculada a partir de la ecuación aplicable a la frecuencia del transmisor. Consulte la tabla sobre distancias de separación recomendadas para conocer las distancias de separación necesarias en función de la frecuencia del transmisor. Distancia de separación mínima recomendada d = 5 pies (1.5 metros) Pueden producirse interferencias en las proximidades de equipos marcados con el siguiente símbolo: 
Compatibilidad electromagnética (CEM) IEC 61000-4-39	8 A/m a 30 kHz 65 A/m a 134.2 kHz 7.5 A/m a 13.56 MHz	8 A/m a 30 kHz 65 A/m a 134.2 kHz 7.5 A/m a 13.56 MHz	
NOTA: UT es el voltaje de la red de CA antes de la aplicación del nivel de prueba.			

Distancias de separación recomendadas entre equipos de comunicaciones por RF portátiles y móviles y el lector

El lector está previsto para usarse en un entorno electromagnético en el que las perturbaciones de RF radiadas estén controladas. El usuario del lector puede ayudar a prevenir las interferencias electromagnéticas manteniendo una distancia mínima entre los equipos de comunicaciones por RF portátiles y móviles (transmisores) y el lector, según se recomienda a continuación, de acuerdo con la potencia de salida máxima de los equipos de comunicaciones.

Potencia nominal de salida máxima del transmisor (W)	**Distancia de separación de acuerdo con la frecuencia del transmisor (pies)**			
	De 174 MHz a 216 MHz $d = 3{,}9\sqrt{P}$	**De 335 MHz a 450 MHz** $d = 6{,}6\sqrt{P}$	**De 809 MHz a 849 MHz** $d = 1\sqrt{P}$	**De 2.35 GHz a 2.65 MHz** $d = 6{,}6\sqrt{P}$
0,01	0,39	0,66	0,10	0,66
0,1	1,23	2,09	0,32	2,09
1	3,90	6,60	1,00	6,60
10	12,33	20,87	3,16	20,87
100	39,00	66,00	10,00	66,00

En el caso de transmisores con una potencia nominal de salida máxima no mencionada anteriormente, la distancia de separación recomendada (d) en pies (pies) se puede calcular utilizando la ecuación aplicable a la frecuencia del transmisor, donde (P) es la potencia nominal de salida máxima del transmisor en vatios (W) de acuerdo con el fabricante del transmisor.

NOTA 1: En el caso de frecuencias que pueden describirse mediante dos ecuaciones en la tabla anterior, se aplica la mayor distancia de separación.

NOTA 2: Es posible que estas normas no se apliquen en todas las situaciones. La propagación electromagnética se ve afectada por la absorción y el reflejo de estructuras, objetos y personas.

Banda de frecuencia del lector

El lector recibe energía electromagnética de RF e incluye transmisores de RF que funcionan dentro del intervalo de frecuencias de 12.88 MHz a 14.12 MHz.

El lector incluye transmisores de RF que funcionan en las bandas centrales (13.09 MHz, 13.34 MHz, 13.62 MHz y 13.90 MHz).

Frecuencia del transceptor BT

Módulo BT Smart Ready: ID de la FCC QOQBT121
Intervalo de frecuencia operativa: 2402 MHz–2480 MHz

Declaración de la Comisión Federal de Comunicaciones (FCC)

El equipo está aprobado para la transmisión inalámbrica en virtud de la ID de la FCC 2AR87ETXCPAS01. Se ha probado y se ha demostrado que cumple con los límites para un dispositivo digital de Clase B, conforme a la parte 15 de las normas de la FCC. Estos límites están diseñados para proporcionar una protección razonable frente a interferencias nocivas en una instalación residencial. Este equipo genera, utiliza y puede radiar energía de radiofrecuencia y, si no se utiliza de acuerdo con las instrucciones, puede provocar interferencias nocivas en las comunicaciones de radio. Sin embargo, no existe ninguna garantía de que no vayan a producirse interferencias en una instalación en concreto. Si este equipo provoca una interferencia nociva en la recepción de radio o televisión, que puede determinarse apagando y encendiendo el equipo, se alienta al usuario a tratar de corregir la interferencia adoptando una o más de las siguientes medidas:

- Reorientar o reubicar la antena receptora.
- Aumentar la separación entre el equipo y el receptor.
- Conectar el equipo a una toma en un circuito diferente de aquel al que está conectado el receptor.
- Consultar al servicio al cliente.

Este dispositivo cumple con la parte 15 de las normas de la FCC. El funcionamiento está sujeto a las dos condiciones siguientes: (1) este dispositivo no puede provocar interferencias nocivas y (2) este dispositivo debe aceptar cualquier interferencia recibida, incluida una interferencia que pueda causar un funcionamiento no deseado.

Información de cumplimiento de la exposición a RF

Este dispositivo cumple con los requisitos de la FCC con respecto a la exposición a ondas de radio y está diseñado y fabricado para no superar los límites de emisión para la exposición a energía de radiofrecuencia (RF).

Definición de los símbolos

Los siguientes símbolos se utilizan en las etiquetas del sistema Cordella con sensor de la arteria pulmonar.

Símbolo	Número de la norma	Título de la norma	Número de cláusula	Texto explicativo
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.7.10	Identificador único de dispositivo
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.7.7	Dispositivo médico
RxOnly	N/C	N/C	N/C	Aviso: La ley federal restringe la venta de este dispositivo por orden o por parte de médicos.
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.4.12	Múltiples usos en un solo paciente
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.1.8	Importador

Símbolo	Número de la norma	Título de la norma	Número de cláusula	Texto explicativo
REF	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.1.6	Número de pieza o catálogo del fabricante, de modo que se pueda identificar el dispositivo médico.
LOT	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.1.5	Código de lote del fabricante, de modo que se pueda identificar el lote.
SN	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.1.7	Número de serie del fabricante, de modo que se pueda identificar un dispositivo médico específico.
EC REP	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.1.2	Representante autorizado en la Comunidad Europea.
	IEC 60601-1	Equipos electromédicos. Parte 1: Requisitos generales para la seguridad básica y el rendimiento esencial.	Tabla D.2, símbolo 10	Es necesario que el usuario consulte las instrucciones de uso.
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.3.2	Dispositivo médico que necesita protección frente a las fuentes de luz o calor.

Símbolo	Número de la norma	Título de la norma	Número de cláusula	Texto explicativo
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.3.7	Límites de temperatura a los que se puede exponer de forma segura el dispositivo médico.
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.3.9	Intervalo de presión atmosférica al que se puede exponer de forma segura el dispositivo.
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.3.4	Dispositivo que debe protegerse de la humedad.
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.3.1	El dispositivo se puede romper o dañar si no se manipula con cuidado.
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.1.1	Fabricante del dispositivo.
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.1.3	Fecha de fabricación del dispositivo.

Símbolo	Número de la norma	Título de la norma	Número de cláusula	Texto explicativo
	IEC 60601-1	Equipos electromédicos. Parte 1: Requisitos generales para la seguridad básica y el rendimiento esencial.	Tabla D.1, símbolo 4	El dispositivo se debe conectar a una fuente de corriente continua.
	IEC 60601-1	Equipos electromédicos. Parte 1: Requisitos generales para la seguridad básica y el rendimiento esencial.	Tabla D.1, símbolo 8	El dispositivo se debe conectar a una fuente de corriente alterna.
	N/C	N/C	UN 3481	El lector funciona con baterías de iones de litio. Las baterías de iones de litio no se deben aplastar ni quemar.
	IEC 60417	Símbolos gráficos para uso en equipos eléctricos.	Tabla D.1, símbolo 9	El equipo cumple los requisitos de seguridad especificados para los equipos de Clase II según la norma IEC 61140.
	IEC 60601-1	Equipos electromédicos. Parte 1: Requisitos generales para la seguridad básica y el rendimiento esencial.	Tabla D.2, símbolo 20	Parte aplicada tipo BF en cumplimiento de la norma IEC 60601-1.

Símbolo	Número de la norma	Título de la norma	Número de cláusula	Texto explicativo
IPN_1N_2	IEC 60601-1	Equipos electromédicos. Parte 1: Requisitos generales para la seguridad básica y el rendimiento esencial.	Tabla D.3; Código 2	Grado determinado por el fabricante de protección frente al ingreso de partículas y agua, donde… N1 = grado de protección frente a partículas (escala de 0-6) y N2 = grado de protección frente al agua (escala de 0-8)
IP21	IEC 60601-1	Equipos electromédicos. Parte 1: Requisitos generales para la seguridad básica y el rendimiento esencial.	Tabla D.3; Código 2	Protegido frente a objetos sólidos de 12.5 mm y mayores y frente a los efectos del goteo de agua.
IP22	IEC 60601-1	Equipos electromédicos. Parte 1: Requisitos generales para la seguridad básica y el rendimiento esencial.	Tabla D.3; Código 2	Protegido frente a objetos sólidos de 12.5 mm y mayores y frente a los efectos del goteo de agua cuando está inclinado a 15°.
	ASTM F2503	Práctica estándar para marcar dispositivos médicos y otros elementos para la seguridad en el entorno de resonancia magnética.	7.3.2	Se ha demostrado que el dispositivo no plantea riesgos conocidos en un entorno de RM especificado con las condiciones de uso especificadas.
	ISO 7010	Símbolos gráficos - Colores y señales de seguridad - Señales de seguridad registradas.	7010-W001	Advertencia general.

Símbolo	Número de la norma	Título de la norma	Número de cláusula	Texto explicativo
	ISO 15223-1	Dispositivos médicos: símbolos que se deben utilizar en las etiquetas del dispositivo, en la ficha técnica y en la información que se debe suministrar.	5.4.4	Posibilidad de daños o mal funcionamiento del sistema o de retrasos en el tratamiento.
	N/C	N/C	N/C	Botón de encendido/en espera.
	IEC 60417	Símbolos gráficos para uso en equipos eléctricos.	7000-5140	IEC 60417-5140 - El equipo incluye un transmisor de RF.
	N/C	Comisión Federal de Comunicaciones	N/C	Número de la Comisión Federal de Comunicaciones.

myCordella™ Patient Management Portal

Clinician Manual: PA Pressure

The Cordella Pulmonary Artery Sensor System is Exclusively for Clinical Investigations in Europe.
Rx Only

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Contents

Introduction

The Cordella™ Pulmonary Artery (PA) Sensor System is used with the commercial Cordella Heart Failure System to better connect healthcare professionals and patients with tools for comprehensive heart failure management.

This manual contains instructions for use for functionality specific to managing patients with PA pressure data in the myCordella™ Patient Management Portal (PMP). For information on the operation of other parts of the Cordella System, please refer to the respective instructions for use. Complete instructions on the PMP, including warnings and precautions, can be found in the myCordella PMP Clinician Manual and the myCordella PMP Quick Start Guide, which includes the basics of PMP use and the patient enrollment process. For information on using the PMP with PA pressure data and the Cordella PA Sensor System, use this manual.

Intended Use

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT), as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

Cordella™ Pulmonary Artery Sensor System

Component Names

The system includes:

- **A catheter-based Delivery System with a pre-loaded Cordella Sensor** for implant in the pulmonary artery
- **Calibration** Equipment (CalEQ) for collecting relevant calibration information during implantation
- **myCordella Patient Reader** for patient use to measure PA pressure in the home, which communicates wirelessly to the myCordella Tablet
- Cordella Data Analysis Platform (CDAP) for cloud-based storage and analysis of home PA pressure readings (not pictured)

The system includes:
- A catheter-based Delivery System with a pre-loaded Cordella Sensor for implant in the pulmonary artery
- Calibration Equipment (CalEQ) for collecting relevant calibration information during implantation
- myCordella Patient Reader for patient use to measure PA pressure in the home, which communicates wirelessly to the myCordella Tablet
- Cordella Data Analysis Platform (CDAP) for cloud-based storage and analysis of home PA pressure readings (not pictured)

Safety Information

Before use of the Cordella PA Sensor System, read and understand the instructions for use contained in this manual.

⚠ Warnings	**Warnings indicate the potential for serious adverse reactions or safety hazards, and limitations in use imposed by them.**

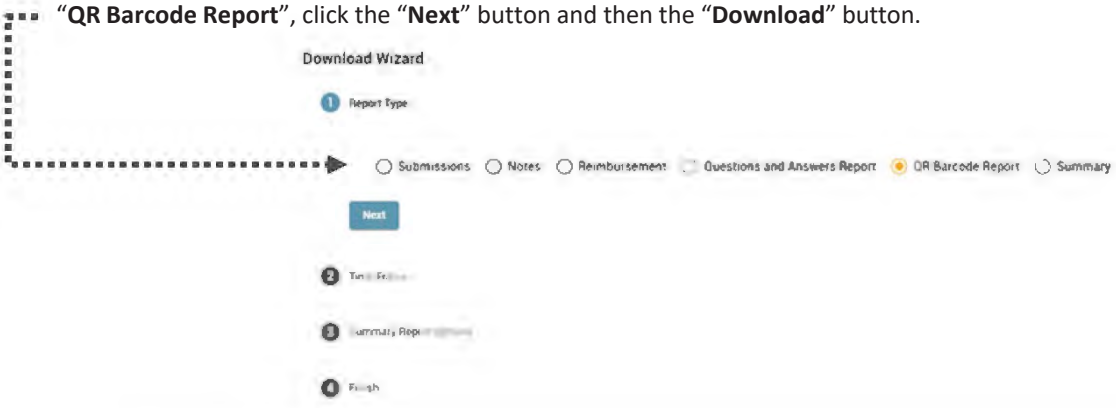
⚠ Warnings

- A healthcare professional should evaluate each patient to ensure that the decision to use the Cordella Pulmonary Artery Sensor System is appropriate for that patient.
- Each Reader is unique. If a patient needs to receive a replacement Reader, their baseline PA pressure values may shift up or down. It is important that care decisions are not made based on any baseline shift that occurs; instead, the new PA pressure values should be reviewed without treatment updates for 7 days of readings with the new Reader to account for any differences in the devices. Endotronix will provide notification if a Reader is replaced.

NOTE: Pictures of the Patient Management Portal appearing throughout this manual are for illustration purposes only. Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

Pre-Implant: Download the QR Barcode Report for the Implant Procedure

During the Cordella Sensor implant procedure, the QR barcode report needs to be scanned with the Calibration Equipment to match the Cordella Sensor with the appropriate patient. The QR barcode report for a patient can be created through the Download Wizard. Click on the Download Wizard icon in the patient's chart. After selecting "**QR Barcode Report**", click the "**Next**" button and then the "**Download**" button.

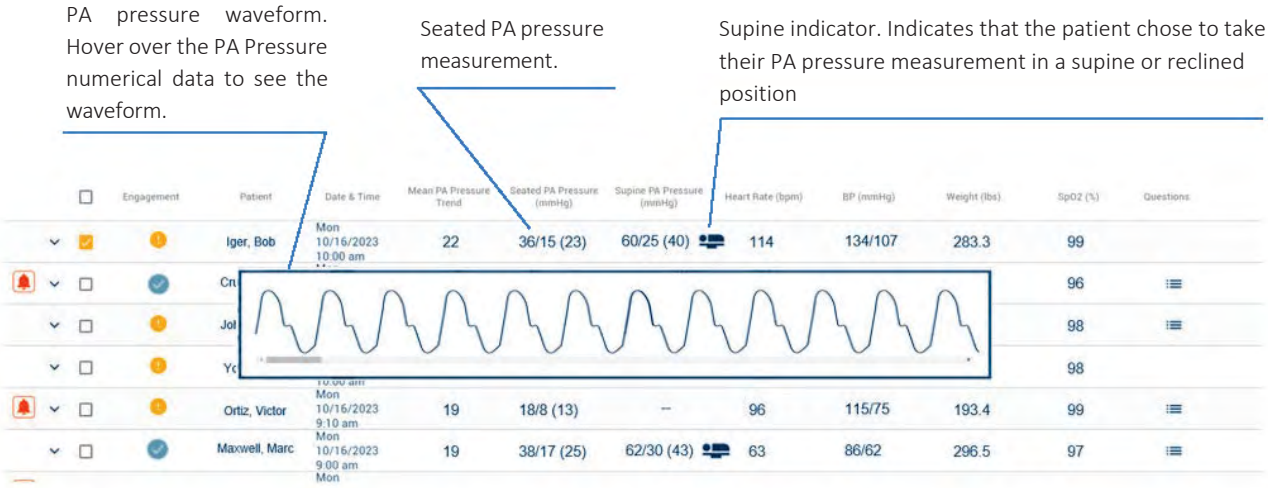


Getting Started

After the patient has received the Cordella Sensor, the patient's schedule and information must be adjusted to include the PA Pressure and Reader Serial Number.

Dashboard Overview

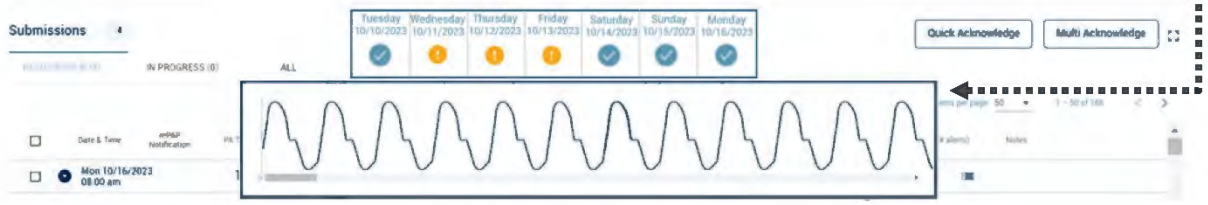
The PMP dashboard displays PA pressure data alongside all other data from patients' submissions.



Reading flagged as suspect. A reading can be flagged as suspect by right clicking and selecting "Mark as Suspect". Flagged readings do not appear on trend graphs.

View PA Pressure Data in the Patient Chart

Within the Submissions table, display the PA pressure waveform by hovering over a PA pressure value.

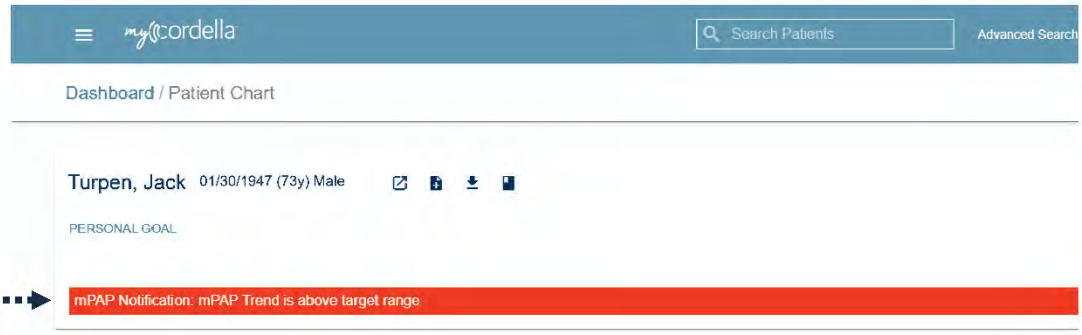


On the Trends chart, click the Expansion arrow to view 7-day moving average trends and daily values of mean, diastolic, and systolic PA pressure. Supine PA pressure, if available, can be viewed here as well. By default, mPAP daily and moving average trend values are displayed. Select and deselect options are available for notations to be visible on the graph. Check the "Highlight PA Trend Ranges" box to view how trends compare to trend ranges.

If any data is suspect, flag the reading and see “Patient Management Portal Help” below.

mPAP Notifications

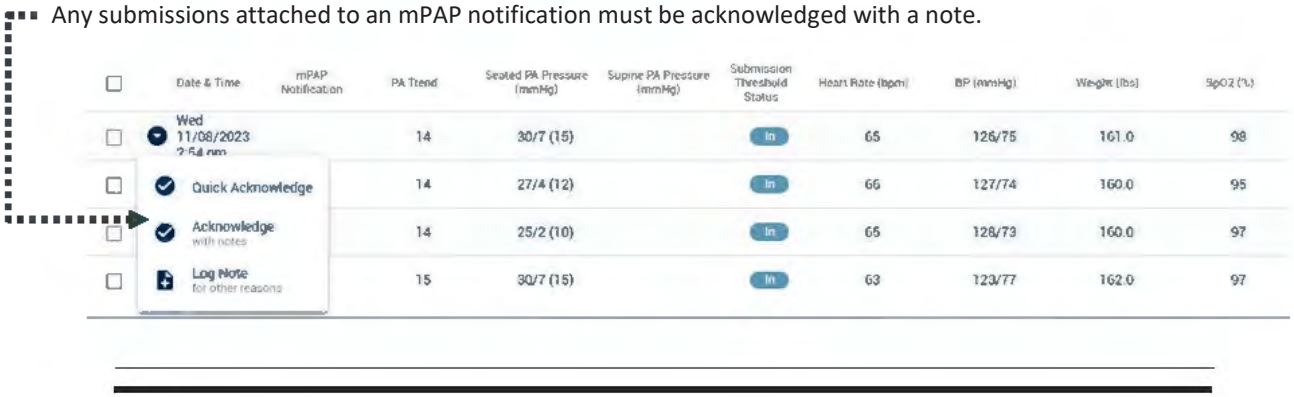
If the patient’s 7-day moving average trend falls outside of the system target range, an mPAP notification banner may appear.



A notification will only be triggered for mPAP trends outside the target range if the patient has been implanted for at least seven (7) days and it has been at least three (3) days since the previous notification. A notification will not be triggered for mPAP trends outside the target range if the patient appears to be responding to treatment.

The bell icon on the dashboard next to a patient's name indicates a notification for that patient, and all unacknowledged notifications are grouped under the Notifications tab. The date column in the Notifications tab will specify which submission triggered the mPAP notification.

Any submissions attached to an mPAP notification must be acknowledged with a note.



Patient Management Portal Help

Clinicians can access the myCordella PMP Clinician Manual, the myCordella PMP Quick Start Guide, a copy of this manual, and additional help videos from the dashboard menu in the PMP. Click on the three horizontal lines at the top left corner of the menu bar to view the "Help" drop down menu. Selecting the document will open the PDF in a new tab (internet browser settings for pop-up blocking may need to be disabled).

If suspect PA pressure data is observed, the patient's Cordella Sensor may require troubleshooting. Examples of suspect PA pressure data may include:

- Gradual mean pressure changes without a corresponding proportional change in pulse pressure (systolic-diastolic pressure)
- Largely negative mmHg values for mean PA pressure
- Large, sustained one-time shifts in PA pressure
- Indiscernible PA pressure waveform
- Significant reduction in PA pulse pressure

If you suspect the patient's Cordella Sensor may require troubleshooting or recalibration, contact Customer Service.

For additional help, call Endotronix Customer Service.

Summary of PROACTIVE-HF Pivotal Study

Objectives/Purpose

The objective of the PROACTIVE-HF study was to demonstrate the safety and efficacy of the Cordella PA Sensor System. The patient population consisted of male and female patients, ≥ 18 years of age with a diagnosis of NYHA Class III HF who were eligible for enrollment if they were treated with GDMT for a minimum of 3 months (stable doses at least 30 days prior to enrollment) and, within the past year, the patient had either 1) one HF hospitalization, or 2) HF treatment in a hospital day care setting, or 3) urgent outpatient clinic HF visit for IV diuretics, or 4) a persistently elevated NT-proBNP level at the time of screening. After obtaining written informed consent and screening, eligible patients underwent a device Implant Visit in conjunction with a right heart catheterization procedure. Post-procedure follow-ups were scheduled at 1-Month, 3-Month, 6-Month, 12-Month, 18-month, 24-Month, 36-Month, 48- Month, and 60-Month (final follow-up).

Study Design

The PROACTIVE-HF study was a prospective, multi-center, open-label, single-arm clinical trial to assess device safety and efficacy of the Cordella PA Sensor System in NYHA Class III Heart Failure patients compared to a Performance Goal (PG) based on a meta-analysis on the combined cohorts of CHAMPION-HF, CardioMEMS Post approval study, MEMS-HF, GUIDE-HF (NYHA Class III cohort), and LAPTOP-HF (control group only). The PROACTIVE-HF study was originally designed as a prospective, randomized controlled multi-center clinical trial but converted to a single-arm, open-label clinical trial in December 2021.

Intended Use

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT), as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

Contraindications

The Cordella Pulmonary Artery Sensor System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

Safety Endpoints

Primary Safety Endpoints:

1. Freedom from device or system-related complications (DSRC) at 6 months is tested against a null rate of 90%
2. Freedom from pressure sensor failure at 6 months is tested against a null rate of 95%

Secondary Safety Endpoints:

1. Frequency of serious adverse events (SAEs) throughout the study
2. Frequency of implant procedure and procedure related adverse events and serious adverse events
3. Pressure sensor failure rate throughout the study

Efficacy Endpoints

Primary Efficacy Endpoint:

The primary endpoint was the 6-month incidence of HF related hospitalizations (HFH) or all-cause mortality. Six (6) months data were compared to a Performance Goal (PG) based on treatment outcomes for CardioMEMS data.

The statistical PG of 0.43 was derived from published results from clinically relevant, contemporary studies of NYHA Class III HF subjects. For study success, the upper confidence bound of the observed event rate for the

planned study must be less than the PG. Additionally, the observed event rate was required to be less than 0.37. Evaluating the upper bound of the confidence interval for the observed rate, ensures that 1) the observed rate is comparable to prior studies of active treatment (highest observed value = 0.44), 2) the observed rate is less than the mean rate from meta-analysis of prior studies of treatment and control, and 3) the observed rate is less than the lowest rate observed in the control studies (GUIDE-HF). The added requirement for the observed rate to be less than 0.37 provides further assurance that results are comparable to studies of prior treatment.

* Please refer to the Instructions for Use in the Implant Manual or Summary of Safety and Effectiveness Data (SSED) for a listing of all secondary endpoints, inclusion/exclusion criteria.

Results

The data results from the PROACTIVE-HF study support the reasonable assurance of safety and effectiveness of the Cordella PA Sensor System when used in accordance with the indications for use. The primary and secondary safety and efficacy endpoints of PROACTIVE-HF were met. The safety profile was excellent with 99.2% freedom from DSRC and 99.8% freedom from pressure sensor failure. The event rate for all-cause hemoptysis (coughing up blood) was 3.0% for which this safety endpoint in the early experience with this new device is numerically higher than prior studies completed to date with similar PAP-measuring devices, such as in CHAMPION (0.2%), GUIDE-HF (0.3%) and MONITOR-HF (2.3%). Overall, the 6-month incidence of heart failure hospitalization and mortality were low across all populations analyzed. The incidence rate of 0.1589 [95% CI: 0.1200, 0.2106] events per patient 6-month met all criteria for primary endpoint success. While PROACTIVE-HF aimed to enroll NYHA Class III HF patients, the final event rate for the primary effectiveness endpoint (0.1549) was numerically lower than the average event rate derived from published results from clinically relevant, contemporary studies of NYHA Class III HF subjects. This unexpected finding may warrant further evaluation in future studies.

There was an improvement in quality of life by five points, and 6MWT through 6 months. Subjects with mean PAP (mPAP) above target range (seated mPAP > 20 mmHg) at baseline saw a reduction in mPAP (2.4 mmHg) and subjects with normal/below normal PAP saw an increase in mPAP (4.2 mmHg), although, on average, these subjects remained within target range at 6 months. Of note, these secondary analyses are purely exploratory, not powered and not adjusted for multiple comparisons. There was high compliance in both subject transmission of daily data and clinician acknowledgement of those transmissions.

In NYHA Class III patients at risk of congestive events, the Cordella PA Sensor and HF System was safe, improved quality of life and functional capacity. The markedly low event rates may relate to high subject and clinician compliance, high rates of GDMT at baseline, and integration of daily vital signs with seated PAP, which may be more relevant for monitoring of ambulatory HF patients. However, the lower event rate compared to clinically relevant, contemporary studies of NYHA Class III HF patients may need to be explored in future studies.

* Please refer to the Instructions for Use in the Implant Manual or Summary of Safety and Effectiveness Data (SSED) for a comprehensive summary of the study.

Contact Us

The user should contact Competent Authority and Endotronix to report any serious incident that has occurred in relation to the medical device.

Questions or concerns regarding the myCordella Patient Management Portal can be directed to the contact information below:

Endotronix™ Customer Service

US: 1 888 512 5595
Belgium: +32 800 82 244
Ireland: 1800 814 282
Germany: 0800 000 9241

Support@endotronix.com