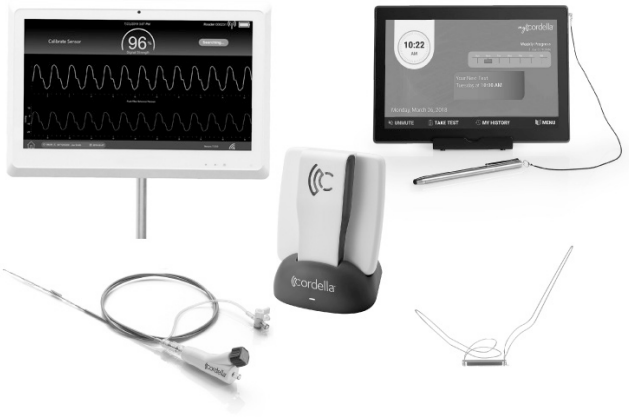
cordella™
HEART FAILURE SYSTEM

Cordella™ Pulmonary Artery Sensor System

Instructions for Use

CAUTION— Investigational device. Limited by Federal (or United States) law to investigational use.
Exclusively for clinical investigations.



ENDOTRONIX

815 Ogden Avenue
Lisle, IL 60532
USA
info@endotronix.com
Phone: 1 888 512 5595

EC REP **Endotronix Ireland Limited**

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

(page left blank intentionally)

Table of Contents

1. Introduction

The Cordella Pulmonary Artery (PA) Sensor System is intended to measure, record, and transmit PA pressure data from NYHA Class III heart failure patients at home to clinicians for assessment and patient-centered heart failure management. 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 pulmonary artery. With this Cordella Sensor, PA pressure can be wirelessly measured from the patient's home on demand. Changes in PA pressure may indicate fluid accumulation in the lungs. 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 PA Sensor System is intended to measure, record, and transmit pulmonary artery pressure data from NYHA Class III heart failure patients at home to clinicians for assessment and patient-centered heart failure management.

1.2 Contraindications

The Cordella PA Sensor System is contraindicated for patients that cannot tolerate anticoagulation or antiplatelet regimens. The Cordella Sensor is not recommended for patients with venous peripheral stents, inferior vena cava filters, or artificial valves in the path of the Delivery System.

2. Device Descriptions

2.1 Cordella™ Pulmonary Artery Sensor System

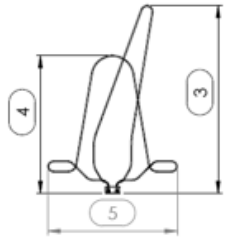
A myCordella Peripheral designed for on-demand measurement of pulmonary artery pressure from the patient's home.

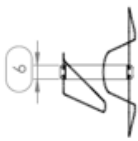
The system includes:

- 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 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 pulmonary artery. The Cordella Sensor does not contain batteries or active electrical components.

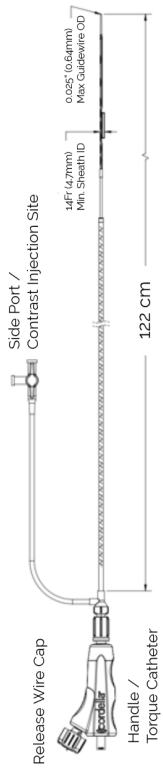




1	19.3mm
2	1.9mm
3	55.0mm
4	38.0mm
5	33.0mm
6	3.8mm

myCordella™ Patient Reader

The myCordella 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.



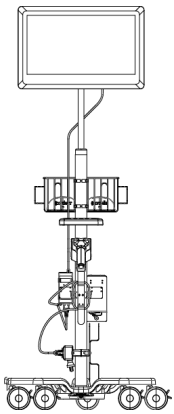
Delivery System

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 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.

Calibration Equipment

The Calibration Equipment (CalEQ) is hospital equipment that supports the implantation procedure.

- 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.
- For additional detail on operation of CalEQ, see Calibration Equipment Operator's Manual.



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

This system is commercially available.

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 and driving treatment changes when necessary.

myCordella™ Tablet

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

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

myCordella™ Patient Kit*

- myCordella Tablet
- Weight Scale
- Blood Pressure Monitor
- Pulse Oximeter
- myCordella Tablet Stand
- myCordella Carrying Case
- Stylus and Tether
- 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	Swan-Ganz thermodilution pulmonary artery catheter
Procedural Guidewire (for inserting the Delivery System)	Stiff Amplatz Guidewire, Hi-Torque Steelcore 18, Hi-Torque Steelcore 18LT, V-18 Control Wire (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 faciliate gaining distal vessel access.
Straight Flush 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

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 possibility of system damage or malfunction, delay in receipt of information to a healthcare provider, inaccurate readings, or injury.
Precautions	Precautions indicate the possibility of system damage, malfunction, or the delay in treatment.

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.

Warnings: Implantation Procedure (Cont.)

- 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.

- 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 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.

Warnings: Implantation Procedure (Cont.)

- 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 12).
- 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 250 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.

- 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.

- myCordella Patient Reader may be interfered with by other equipment generating electromagnetic fields. When possible, avoid using the Reader while simultaneously using other equipment such as: patient monitoring systems, chest EKG leads, motors on motorized beds, pagers, RFID tags, laptop computers, tablets, cell phones, cordless phones, wireless routers, air conditioners within ~5 feet (1.5m), UHF RFID tags within ~10 feet (3m), and RFID equipment operating at 2.45 GHz within ~14 feet (4.25m).

- 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 (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 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.

- Under certain conditions, the Reader's surface may exceed 41°C. If the Reader becomes too warm to hold comfortably, place it back in the Docking Station and wait several hours for it to cool. If the Reader remains too warm to hold comfortably for more than a day, contact Customer Service.

- 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 every three years using a RHC procedure.

3.3 Warnings: Calibration Equipment

- 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.
- Torqueing 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.

Precautions (Cont.)

- 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.
- 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.
- 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, cracked or any component becomes dislodged.
- If the Reader label becomes compromised, contact Endotronix Customer Service
- Accuracy of the Cordella Pulmonary Artery Sensor System is affected by a change in body temperature (<-3mmHg/Δ°C).
- CalEQ and the Reader contain a Lithium-ion battery.
- LVAD 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
- 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)
- 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

Non-clinical testing and MRI simulations were performed to evaluate the Cordella Sensor. Non-clinical testing demonstrated that the Cordella Sensor is MR Conditional. A patient with this implant can be scanned safely in an MR system under the following conditions:

MR Conditional

- Static magnetic field of 1.5 Tesla or 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning in the Normal Operating Mode

Under the scan conditions defined, the Cordella Sensor is expected to produce a maximum temperature rise of 4.5°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, 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.

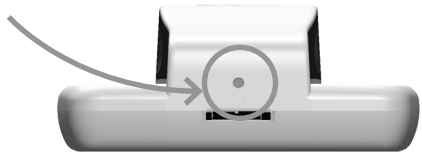
Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

4.1 Pre-Procedure Preparation

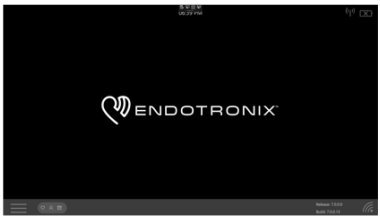
1. Within the myCordella Patient Management Portal on a separate computer, download and print the patient's QR Barcode Report through the Download Wizard in the patient's chart (for detailed instructions, see the myCordella Patient Management Portal Clinician Manual: PA Pressure).

2. At least 30 minutes before the procedure, transport the CalEQ and Delivery System unit box, including a backup Delivery System, to the catheterization lab (see Transport section). Ensure the CalEQ includes two Readers and Docking Stations and the Interconnect Cable (if applicable). If you will be operating CalEQ using battery power, ensure that the CalEQ and Readers are fully charged before the start of procedures for the day (i.e. the Docking Station LED should be solid white). See Section 9 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.



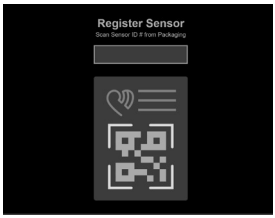
4. Turn on the CalEQ by pressing the power button on the bottom of the monitor and sign in as the CalEQ user.



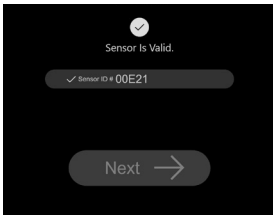
5. To calculate reference pressure parameters necessary for calibration, the CalEQ uses hemodynamic data obtained from the analog output of the hospital's hemodynamic monitor. Follow the steps below to confirm proper set-up with the monitor. If an Interconnect Cable is not provided with CalEQ, calibration 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 on 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 monitor's analog output. This will provide a pulmonary artery pressure measure to the CalEQ for calibration measurements. For compatible Interconnect Cables, contact Customer Service.
- 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 monitor to be used. Please notify Customer Service if there is a change in hemodynamic monitor as it may impact the compatibility and accuracy of the reference pressure signal obtained by CalEQ.

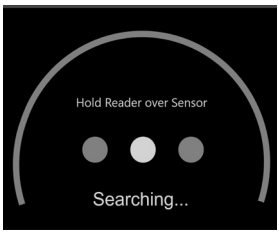
4.2 Pairing and Interrogating the Cordella Sensor in Packaging



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

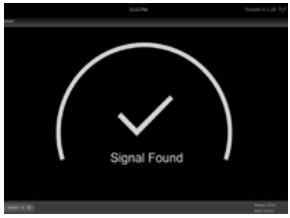


2. On the confirmation screen, ensure there is a green checkmark on the screen. Press the "Next" button if the information matches.

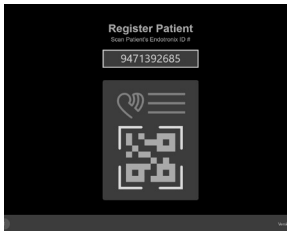


3. Undock the Reader when prompted. While searching for the Sensor, the Reader will display a solid blue light and will beep twice every few seconds.

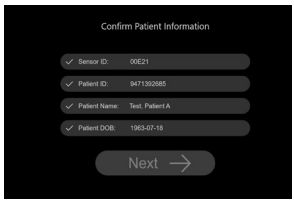
4. Position the Reader along the top of the Delivery System box near the location symbol shown here. Until a signal is found, reposition the Reader over the top and side of the box.



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 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.

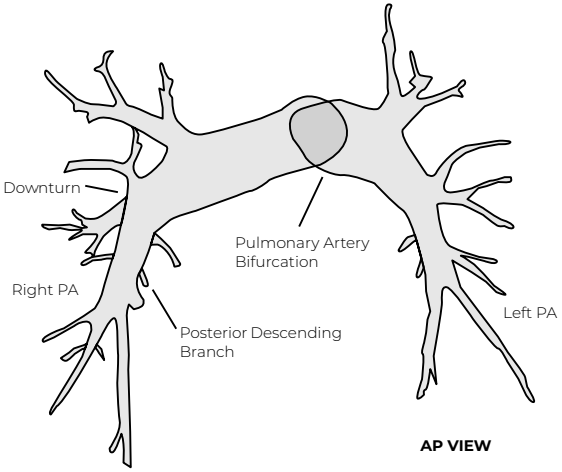
4.3 Delivery System Package Inspection

1. Inspect the Delivery System package carefully for any damage before opening.

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

4.4 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:

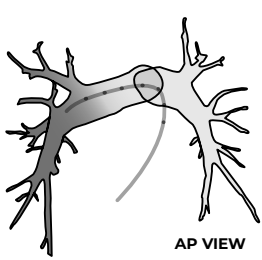


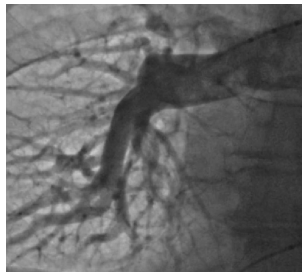
1. Set up the patient for venous access (femoral or right internal jugural). Position the sterile drape to allow for non-sterile access to the patient's chest. Position ECG leads as far away from the right side of the patient's chest and side as possible. The use of limb ECG leads is recommended.

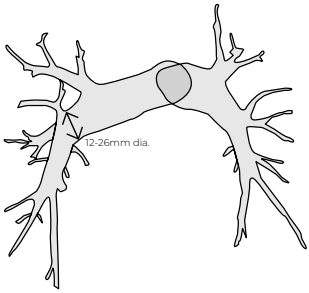
2. Gain access to the patient's vein and dilate to allow for a 14 French introducer. Perform a right heart catheterization.

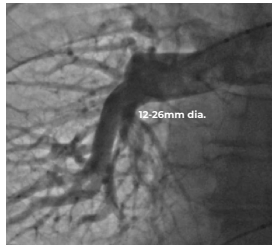
3. Ensure the field of view the right lung centered and perform right pulmonary artery angiography in AP view and LAO-CAU 30/30 views. Use either power-injection with angiography catheters (such as pigtail or straight flush) or hand-injection with a PA catheter (or any other preferred catheters). Make sure the images visualize the RPA downturn and the posterior descending branch.

4. Assess RPA anatomy using the obtained images:









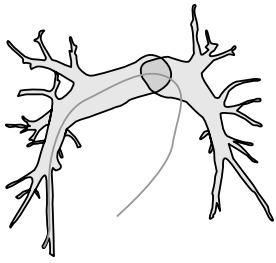
A. Use AP view to detect and measure the diameter of the downturn of the RPA (target location for the sensor). The vessel at this location must be between 12-26 mm. Quantitative vascular analysis (QVA) should be used if the vessel size is indeterminate. If the vessel appears to be either larger or smaller 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.

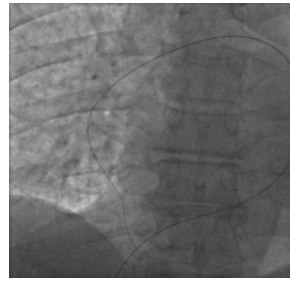
5. Introduce a guidewire (.018”-.025”, 260cm-300cm) through the lumen of the straight flush catheter extending into the descending posterior branch of the right pulmonary artery. Ensure that the wire follows the following path:

   - In the AP view: Largest descending posterior artery.
   - In the LAO/CAU (30/30) view: Largest vessel which is most medial and straightest (“straight down the page to the patient’s left”).

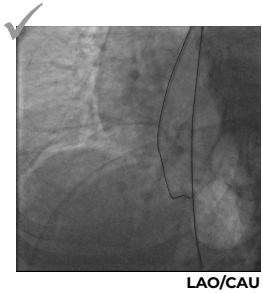
   The wire should remain in this branch for 6 cm beyond the downturn.



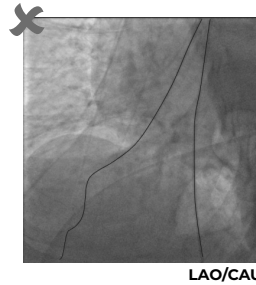
AP VIEW



AP VIEW



LAO/CAU



LAO/CAU

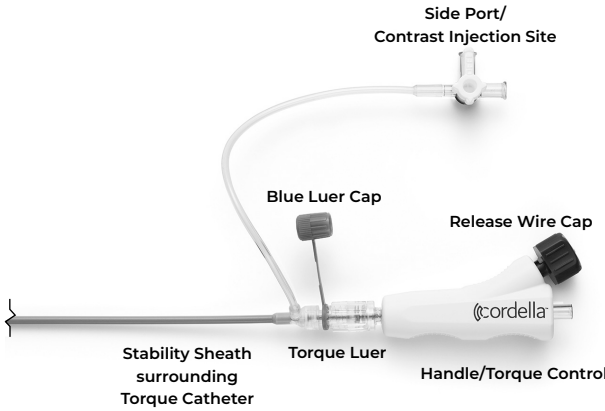
6. Remove the straight flush catheter, leaving the guidewire in place.

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.

4.5 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, or loose connections. The features of the Delivery System handle are labeled below:



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

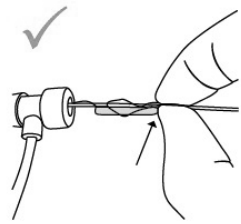
4. If the Delivery System or Cordella Sensor appears damaged or defective, do not use the product and contact Customer Service.

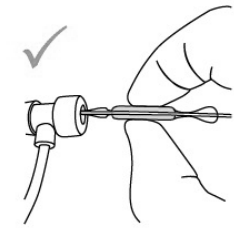
WARNING: The Cordella Sensor should not be interrogated by the Reader after removal from the packaging until the Sensor is implanted.

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

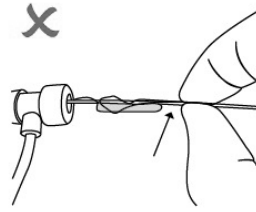
6. Thread the Delivery System over the guidewire through the distal tip (front-end loading).

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.

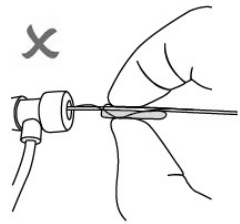




WARNING: Do not insert the Cordella Sensor by pushing the Delivery System without supporting the Cordella Sensor from behind as this may result in damage to the device.



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

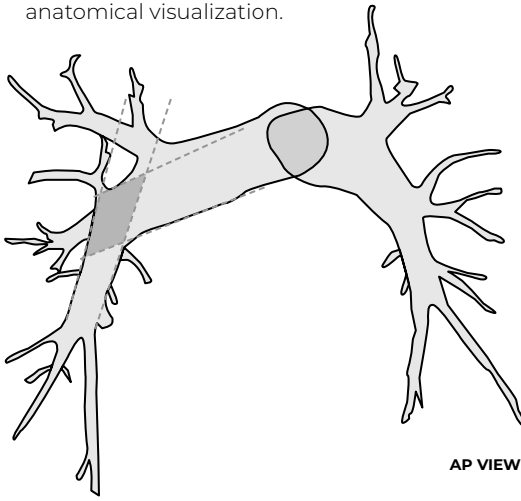


8. Slowly push the Cordella Sensor through the introducer. If severe resistance is encountered, stop pushing the Cordella Sensor and attempt to identify the source of resistance. Proceed cautiously.

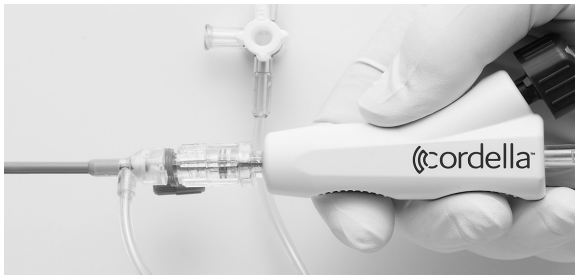
9. Once inserted, the delivery system should be gently advanced using fluoroscopic guidance over a guidewire. If resistance is encountered (i.e. at heart valves or other anatomical structures), the delivery system should be rotated and/or pulled-back before being advanced further.

4.6 Cordella Sensor Implantation

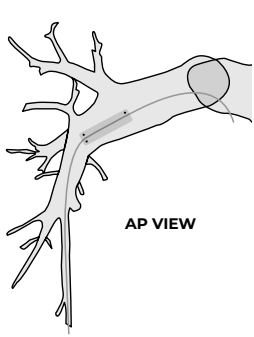
1. The target location for the Cordella Sensor is at the downturn of the right PA (highlighted in the figure below for a representative typical PA anatomy). The location can be defined by the overlapping region of the right PA trunk and the downturn as illustrated below. The distal radiopaque marker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

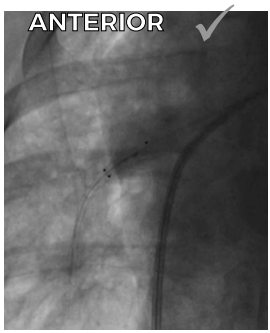


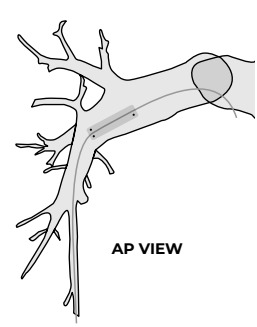
2. Advance the Cordella Sensor to the target area to the target area by gripping the handle and navigating through the heart to the right pulmonary artery.

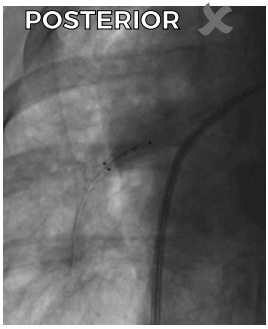


3. The Cordella Sensor has three (3) radiopaque marker bands to help identify rotational position of the Sensor. Once in the optimal position, rotate the Cordella Sensor using the handle as necessary to ensure the Sensor is anterior facing as shown below:



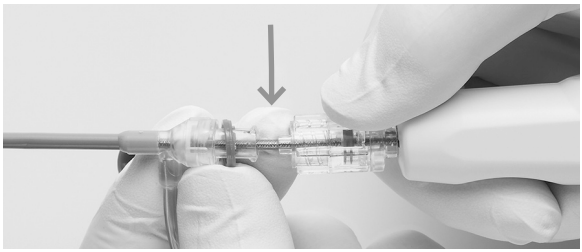






4. Once in target deployment position (distal end of Sensor body at RPA downturn, anterior facing), while stabilizing the sheath, deploy the Cordella Sensor by rotating the release cap a quarter turn counter clockwise and slowly pulling the release wire cap parallel to the Delivery System, then fully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

5. Once the Cordella Sensor is deployed, under fluoroscopic guidance, retract the guidewire into the Torque Catheter and gently withdraw the Stability Sheath and Torque Catheter together approximately 2 cm away from the deployed Sensor. Assure that the Torque Catheter is not getting hung up on the Sensor. If this occurs, stop retrieval immediately and turn 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 near the newly deployed Cordella Sensor. Once the Torque Catheter is fully removed, separate the guidewire and discard the Torque Catheter.

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 any ECG leads, pagers, or patient monitoring systems away from the Reader.

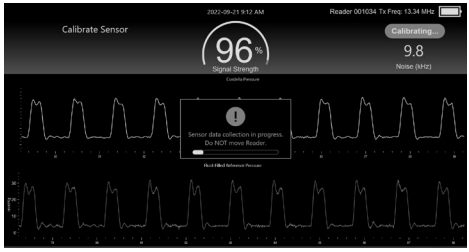
WARNING: DO NOT USE the Reader near radio transmitters such as Walkie Talkies or intercom systems.

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 patient monitor. Compare the fluid-filled reference pressure signal on CalEQ with that on the patient monitor. 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.

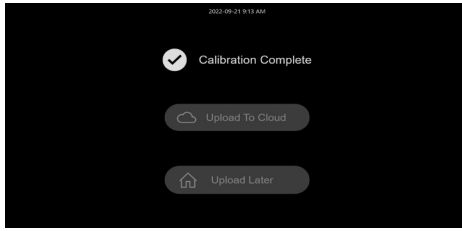


4. When prompted, dock the Reader.

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 cannot upload, press “Upload Later.”

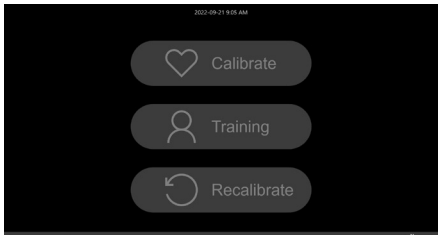


8. Remove the Stability Sheath and introducer sheath. Close the venous access site per standard protocols.

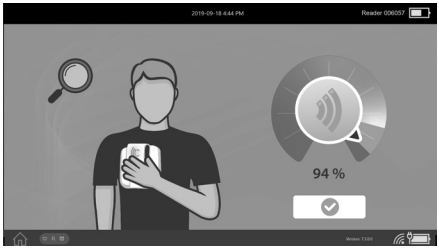
5. Patient Reader Training

Post-implant, patients should complete training on CalEQ to learn the best placement of the Reader.

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



2. As the patient moves the Reader around on their chest and side, they will receive feedback on the signal strength from CalEQ. As signal strength changes, the pointer on the dial will move clockwise or counter clockwise 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. There is no limit to the number of times a patient can complete this training.



NOTE: The Reader must be disconnected from the CalEQ before it can be used by the patient at home. Follow prompts on CalEQ to disconnect the Reader.

6. Recalibration

Post-implant, the Sensor may need to be recalibrated occasionally if there is anomalous PA pressure data and Endotronix customer service has recommended a recalibration. See Troubleshooting section 15.4 for more information. Recalibration is completed during an 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. 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). Position the sterile drape to allow for non-sterile access to the patient's chest. 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, 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. Post-Procedure 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 as bridge therapy to Cordella Sensor placement should be used in patients who were on anticoagulant therapy.

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 and 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 yellow light, return to Docking Station.
Contact Customer Service	Three quick, low pitched beeps, repeating every ~10 seconds	When accompanied by flashing red light, call Customer Service.

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.
Rapidly Flashing Yellow	Failed reading. Reposition Reader.
Solid Yellow	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 Red	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 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 Reader and backup Reader should remain in the Docking Stations when not in use. 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 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 Endotronix. 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 Support. Qualified service personnel must inspect any dropped or damaged units before they are assigned for use.

Cleaning

- Clean the system components after each use.
- Shut down the CalEQ, and remove the Reader

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.
- 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. If there is an adverse event or device failure related to the Delivery System, the affected component should be shipped to Endotronix.

The Reader, Docking Station and CalEQ devices may contain lithium ion batteries, which should not

be discarded with the municipal waste. The Reader and Docking Station should not be disposed of and instead should be returned to Endotronix through the RMA process (see section 14).

14. Return Materials Authorization (RMA)

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

1. Check off each item on the equipment return list and carefully pack the equipment in the original shipping box or equivalent with its original protective packaging materials.

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.
   815 Ogden Ave.
   Lisle, IL 60532
   U.S.A.

15. Troubleshooting

15.1 Implant Procedure & Delivery System

- 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.
- 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.

- 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.
- 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.

- If the guidewire becomes kinked, the Delivery System may bind to it and prevent the Delivery System from being advanced or retracted.
- 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 reference pressure measurement catheter for use as the reference pressure measurement device.

15.2 Pairing and Interrogating the Cordella Sensor

- 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, exhibiting voids, or coated with frost or water droplets. 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.
- 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, then repeat the procedure with the backup Reader and contact Endotronix Customer Service post-procedure.

- 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, repeat the steps with a new Delivery System package and contact Endotronix Customer Service after the procedure.

15.3 Calibrating the Cordella Sensor

- 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.
- If the wrong reference pressure measurement numbers are entered, press “Calibrate Again” and complete the calibration workflow another time.
- 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.
- If the option to “Upload Later” is chosen instead of “Upload to Cloud,” navigate to Calibration History to upload the calibration data when desired. To view Calibration History, press the “Menu” button in the bottom left corner, then the “Calibration History” button. Alternatively, the next time a calibration is done, selecting “Upload to Cloud” will upload all data that has not been previously uploaded.
- If the Reader is having difficulty taking a reading, move patient monitoring systems, cell phones, pagers, and other equipment that could cause interference as far away from the patient’s chest as possible.

- o 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.

15.4 Reviewing 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)
- 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. Contact Us

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

+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

These are investigational devices that comply 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 myCordella™ Patient Reader and Docking Station and CalEQ are investigational devices that comply 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	
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 myCordella™ Reader

The myCordella Reader is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the myCordella Reader can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the myCordella 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 $d = 3.4\sqrt{P}$	216 MHz to 222 MHz $d = 1.7\sqrt{P}$	222 MHz to 450 MHz $d = 8\sqrt{P}$	450 MHz to 600 MHz $d = 3\sqrt{P}$	2.35 GHz to 2.65 GHz $d = 3.8\sqrt{P}$
0.01	0.34	0.17	0.80	0.30	0.38

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (M)				
	174 MHz to 216 MHz d = 3.4√P	216 MHz to 222 MHz d = 1.7√P	222 MHz to 450 MHz d = 8√P	450 MHz to 600 MHz d = 3√P	2.35 GHz to 2.65 GHz d = 3.8√P
0.1	1.08	0.54	2.53	0.95	1.20
1	3.4	1.7	8	3	3.8
10	10.75	5.38	25.30	9.49	12.02
100	34	17	80	30	38

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.

myCordella 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:

- 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.

Essential Performance

- Cordella PA Sensor System must not display erroneous diagnostic data to the treating physician which may result in improper intervention.
- Acceptance Criteria: The error is less than 3mmHg, or the error is more than 81.4mmHg, which is not actionable by the physician, or Cordella PA Sensor System identifies the data as inaccurate and does not display it to the physician.
- If the Essential Performance is lost or degraded, the user should continue to take a reading as per usual and the Patient Management Portal would indicate a bad reading. Cordella PA Sensor System did not display erroneous diagnostic data which may have resulted in improper intervention.
- The Essential Performance defined for the CalEQ is: the reference pressure error is less than 4mmHg.
-

Appendix B: Equipment Specifications

myCordella™ 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: +/- 7.8 mmHg over full scale range, for operating conditions between 15° C and 30° C and relative humidity between 6% and 93%.

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

Calibration: At implant and recalibration 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. 3.1 and 60601-1-11 Ed. 2.0

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

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 temperature and humidity ranges listed below.

Temperature

- Operation: 15 – 30 °C (59 – 86 °F)
- Storage: -10 – 55 °C (14 – 131 °F)

Relative humidity

- Operation: 6 – 93% (non-condensing)
- Storage: 15 – 90% (non-condensing)

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

Power Cord

Cord length: ~ 5 feet / 1.5 m

AC Power: Wall mount style power supply

- Input of 110-250V , 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: 15 – 30 °C (59 – 86 °F)
- Storage: 0 – 25 °C (32 – 77 °F)

Relative humidity
- Operation: 10 – 90% (non-condensing)
- Storage: 15 – 90% (non-condensing)

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

Electrical Characteristics

Power
- Computer Monitor
    - o System Input: 12 – 48V ⎓
    - o AC Adapter
        - Input: 100 – 240V ~ , 50/60 Hz, 2.0 – 1.0A
        - Output: 19V ⎓ 6.31A, 120W MAX
        - Cord Length: approx. 6 feet (2m)
    - o Total Battery Capacity: 6000mAh
    - o Battery Life (based on normal usage and environmental conditions): 5 hours
    - o Charging Time (based on normal environmental conditions): 7 hours

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

UDI	Unique Device Identifier
MD	Medical Device
1	Single Patient Use
	Single Sterile Barrier System with protective packaging inside
REF	Manufacturer's catalogue or part number so that the medical device can be identified.
LOT	Manufacturer's batch code so that the batch or lot can be identified.
SN	Manufacturer's serial number so that a specific medical device can be identified.
EC REP	Authorized representative in the European Community.
	Need for the user to consult the instructions for use.
	Medical device that needs protection from light sources or heat.
	Temperature limits to which the medical device can be safely exposed.
	Humidity limits to which the device can be safely exposed.
	Atmospheric pressure limits to which the device can be safely exposed.
	Device that needs to be protected from moisture.
	Device that can be broken or damaged if not handled carefully.
FC	Federal Communication Commission Number.
	Device manufacturer.
	Date when the device was manufactured.
	Expiration date.

⎓	Device should be attached to direct current source.
~	Device should be attached to alternating current source.
⧈	Equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	Type BF applied part complying with IEC 60601-1.
	The myCordella Patient Reader and Calibration Equipment operate using lithium-ion batterries. Lithium-ion batteries should not be crushed or burned.
IPN_1N_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	Protected against solid foreign objects of 12.5 mm and greater, and against the effects of dripping water.
IP22	Protected against solid foreign objects of 12.5 mm and greater, and against the effects of dripping water when tilted at 15°.
IP42	Protected against solid foreign objects of 1.0 mm or greater, and against the effects of dripping water when tilted at 15°.
IP65	Protected against total dust ingress, and against the effect of low pressure water jets from any direction.
	Box quantity.
	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
	General warning.
	On/Standby button.
	IEC 60417-5140 - Equipment includes RF Transmitter.

	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.
	Do not re-use.
	Sterilized with ethylene oxide.
	Mass.
	Do not re-sterilize.
	Do not use if package is damaged.
	Refer to Instructions for Use

Rx Only