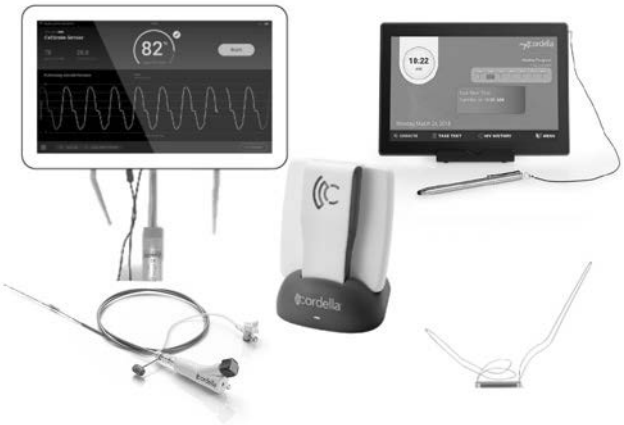
cordella™
HEART FAILURE SYSTEM

Cordella™ Pulmonary Artery Sensor System

Instructions for Use

Exclusively for Clinical Investigations.
To be used by Qualified Investigators Only.



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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 to better connect healthcare professionals and patients with tools for comprehensive heart failure management. The Cordella Heart Failure System consists of the patient-facing myCordella System Pack 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 innovative 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 System Pack may improve long-term outcomes in patients with New York Heart Association (NYHA) Class III heart failure.

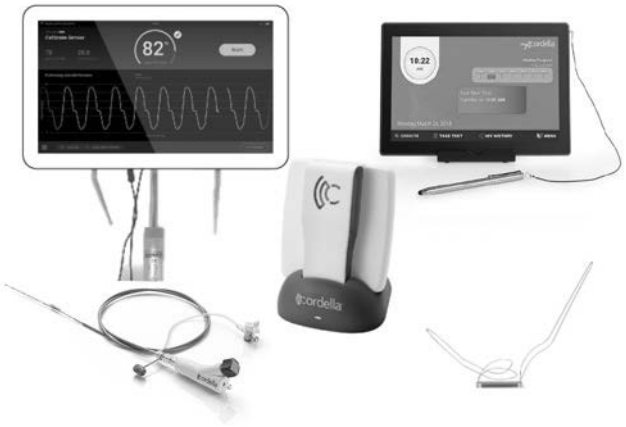
1.1 Intended Use

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.

1.3 Component Names



Cordella™ Pulmonary Artery Sensor System

This system is exclusively for clinical investigations.

An innovative 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 Hub
- Cordella Data Analysis Platform (CDAP) for cloud-based storage and analysis of home PA pressure readings (not pictured)

Cordella™ Heart Failure System

This system is commericially available.

myCordella™ Patient Management Portal (PMP)

A web-based application that displays patient data received from the myCordella Hub to the clinician. The PMP is intended to assist clinicians in efficiently and effectively managing patients and driving treatment changes when necessary.

myCordella™ Hub (Display Screen)

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™ System Pack

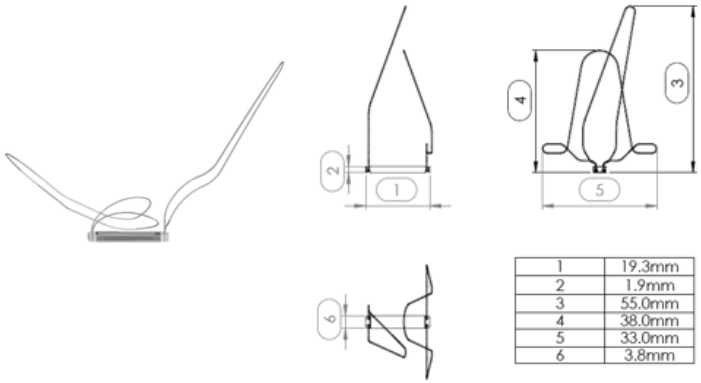
- myCordella Hub
- A&D Deluxe Connected Weight Scale
- A&D Deluxe Connected Blood Pressure Monitor
- Nonin Pulse Oximeter
- myCordella Hub Stand
- myCordella Carrying Case
- Stylus and Tether
- myCordella Patient Manual
- myCordella Quick Start Guide

2. Device Descriptions

The Cordella Pulmonary Artery Sensor System measures pulmonary artery (PA) pressure on demand to help clinicians identify pulmonary congestion suggestive of worsening heart failure through evaluation of trends of pulmonary artery pressure values. 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 Reader that allows patients to measure PA pressure at home, and Cordella Data Analysis Platform (CDAP), a cloud-based platform to store and analyse the PA pressure measurements.

2.1 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.



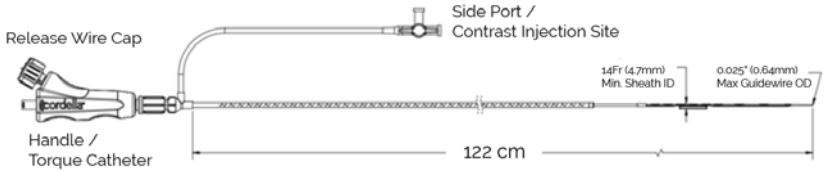
1	19.3mm
2	1.9mm
3	55.0mm
4	38.0mm
5	33.0mm
6	3.8mm

2.2 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 Hub. The raw data is converted into readable data and sent to the myCordella Patient Management Portal for the clinician to review.

2.3 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 is comprised of a stability sheath, torque catheter, 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 Cordella Sensor and Delivery System are packaged together and sterilized with ethylene oxide before shipment. The Delivery System is designed for single use and should not be reused or re-sterilized. If the sterile package has been compromised, do not use the Cordella Sensor and Delivery System, and contact Customer Support.



2.4 Calibration Equipment

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

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

2.5 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.

2.6 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
Vascular Access Kit	14 Fr Introducer Sheath (see recommendation) and dilators with preferred access guidewire (no Endotronix recommendation)
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	Stiff Amplatz Guidewire (260cm; straight-tip; 0.025" or 0.018")
Pigtail catheter	6F pigtail catheter (ID>0.06")

Additionally, Endotronix recommends use of the following catheter lab equipment and supplies 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 a PA pressure measurement during a right heart catheterization procedure
- Hand injector and radiopaque contrast media for visualization. DO NOT use an automated injector through the Stability Sheath.
- 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 surgical 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.
- Cordella Sensor should be placed into the patient's right pulmonary artery with diameter ≥12 mm and ≤30 mm at the right pulmonary artery downturn.
- 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.
- Avoid vessel wall contact with the Delivery System whenever possible. Too much or too forceful contact may perforate the vessel.
- 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.
- 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.
- After Cordella Sensor deployment, take care to remove the Delivery System slowly and gently to avoid moving the Cordella Sensor.
- DO NOT attempt to modify, disassemble, or otherwise alter the Cordella Pulmonary Artery Sensor System.

- During the implant procedure, there should be a continuous heparin drip to prevent clotting.
- DO NOT expose the Cordella Sensor to therapeutic levels of ultrasonic energy.
- To avoid risk of electric shock, 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.
- After the implatation procedure, it is critical for the patient to adhere to prescribed anticoagulation and other medications from the physician.

3.2 Warnings: Reader and Docking Station

- The Reader is suitable for home healthcare environments and 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 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 anaesthetic 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.

Warnings: Reader and Docking Station (Cont.)

- myCordella Patient Reader may be interfered with by other equipment generating electromagnetic fields. When possible, avoid using the Reader while simultaneously using other equipment within ~1.5 meters such as: patient monitoring systems, chest EKG leads, motors on motorized beds, pagers, laptop computers, tablets, cell phones, cordless phones, wireless routers, air conditioners, or walkie talkies (450MHz devices) within ~3 meters.
- 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than ~1.5 meters to any part of the Reader. Otherwise, degradation of the performance of the Reader could result.
- The patient should not have necklaces, jewellery, 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 for several hours for it to cool. If the Reader remains too warm to hold comfortably for more than a day, contact Customer Support.
- If the skin becomes red, warm, or irritated, immediately stop using the Reader and contact Customer Support.
- 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.

3.3 Precautions

- The Delivery System should only be used with a guidewire. Do not aspirate or infuse the Delivery System guidewire lumen during use.
- The implant procedure is an adjunct to a standard (RHC) procedure. All standard protocols for the RHC should be followed.
- The Cordella Sensor is attached to the distal end of the Delivery System; care should be taken to limit contact with the Sensor prior to insertion through the introducer sheath.
- Ensure all Luer connections are secure (but not over-tightened) prior to insertion through the introducer. If at any time during the procedure the Stability Sheath comes loose from the Torque Catheter, reconnect and tighten the Luer connection to secure until after Sensor deployment.
- Removing the Cordella Sensor after implantation is not recommended.
- If there is evidence of a change in device performance, please contact Customer Support.
- 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. Endotronix does not recommend use of peel away introducers.
- Precaution should be taken to avoid disruption of the Cordella Sensor position after deployment with the Delivery System or any subsequent devices used during right heart catheterization procedures.
- 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.

Precautions (Cont.)

• 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.
• The mean pressure measurement accuracy of the system may be affected by various factors. Signs of mean pressure measurement error include: gradual mean pressure changes without a corresponding proportional change in pulse pressure (systolic-diastolic pressure), negative mean pressures, acute shift in mean pressures, and non-physiologic acute shift in mean pressures persistent over multiple measurements. If any of these signs are observed, temporarily suspend use of the pressure information for management of the patient and contact Customer Support for further assistance. Baseline (mean pressure) recalibration may be necessary to continue use of the system.
• Activities that may expose the patient to pressure extremes may affect device performance. If the patient plans to SCUBA dive, please contact Customer Support.
• 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 Support for a replacement if any components are exposed to liquids.
• DO NOT drop the Reader. Handle with care.
• If dropped, the Reader may expose the battery. 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 comprimised, contact Endotronix Customer Support
• Accuracy of the Cordella Pulmonary Artery Sensor System is affected by a change in body temperature (<-3mmHg/Δ°C).

3.4 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
- Emergent or urgent cardiac surgery necessitated by the device or procedure
- Endocarditis or device infection
- Entry site complications (e.g., hematoma, dissection)
- Gastrointestinal bleed
- Haemoptysis
- 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

3.5 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 10,000 gauss/cm (100 T/m)
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) 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 (i.e. per pulse sequence). 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 Endotronix Customer Support (see Contact Us section) for current MR Conditional labelling and the most up-to-date instructions for this device in the MR environment.

3.6 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 Support.

4. Instructions for Use

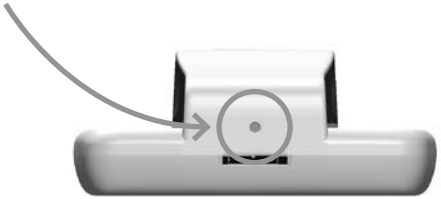
Implanting physicians are required to have completed the Cordella Pulmonary Artery Sensor System training, which includes didactic and clinical education material.

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 box, including a backup Delivery System, to the catheterization lab (see Transport section). Ensure the CalEQ includes two Readers and Docking Stations.

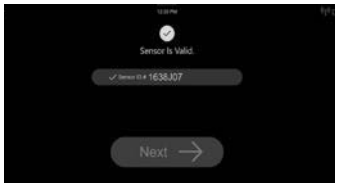
3. Plug in the CalEQ power strip to an easily accessible outlet. Ensure the Readers are in the Docking Stations and the Docking Stations are plugged into the power strip. Always keep Readers docked when not in use. The light on the Docking Station will blink while charging and change to solid when the Reader is fully charged. To turn a Reader on, press and hold the small button at the base of the Reader for several seconds.



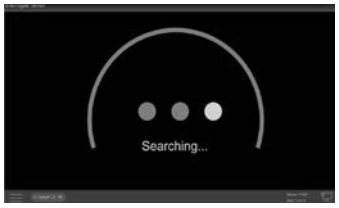
4. Turn on the CalEQ by pressing the power button on the bottom of the monitor and sign in as the CalEQ user.

4.2 Pairing and Interrogating the Cordella Sensor in Packaging

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

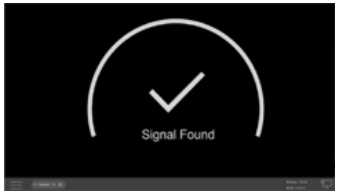


2. On the confirmation screen, ensure there is a green checkmark on the screen. Press the "Next" button if the information matches.

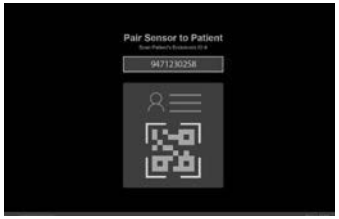


3. Undock the Reader when prompted. While searching for the Sensor, the Reader will display a solid blue light and will beep twice every few seconds. Wait until the CalEQ advances to the searching screen, holding the Reader away from the Delivery System packaging.

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 Support after the procedure.



6. When prompted to pair to the patient, remove the scanner and 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.

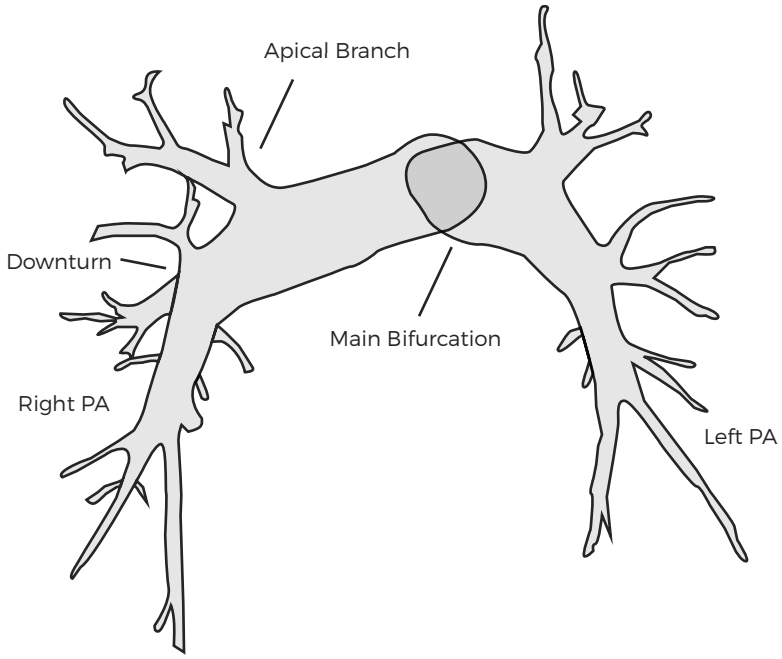
DO NOT scan visibly damaged barcodes; use a different Delivery System package.

4.3 Delivery System Package Inspection

1. Inspect the Delivery System package carefully for any damage before opening.
2. Ensure the "Use By" Date on the product label has not passed. The implant of the Cordella Sensor is not permitted after its expiration date.
3. The primary box contains one Cordella Sensor tied down to the distal end of the Delivery System and the product documentation.

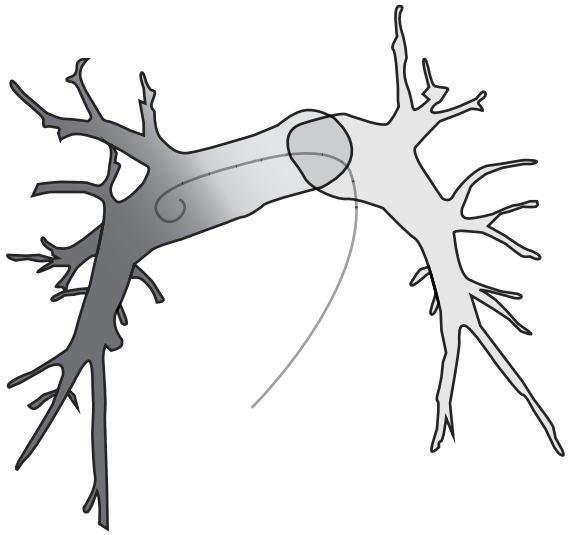
4.4 Vessel Mapping and Guidewire Placement

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

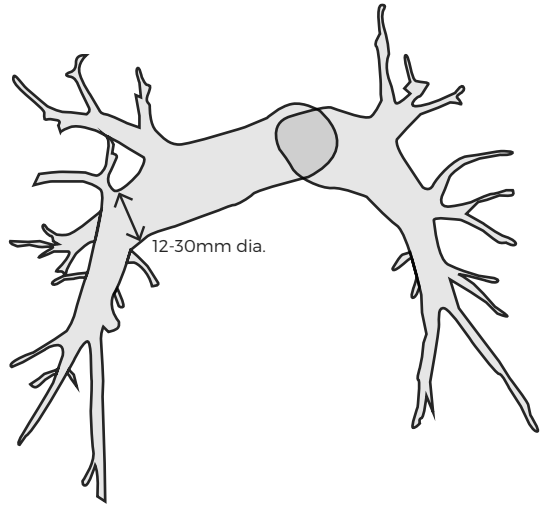


1. Set up the patient for venous access. Position the sterile drape to allow for non-sterile access to the patient's chest. Position ECG leads as far away from the right side of the patient's chest and side as possible. Endotronix recommends limb ECG leads.
2. Gain access to the patient's vein and expand to allow for a 14 French introducer. Begin a typical right heart catheterization by floating a pulmonary artery catheter (PAC) or steering a guide catheter to the right pulmonary artery.
3. Introduce a 0.018" or 0.025" diameter guidewire through the lumen of the catheter and place the distal tip of the guidewire distal to the target implant location.

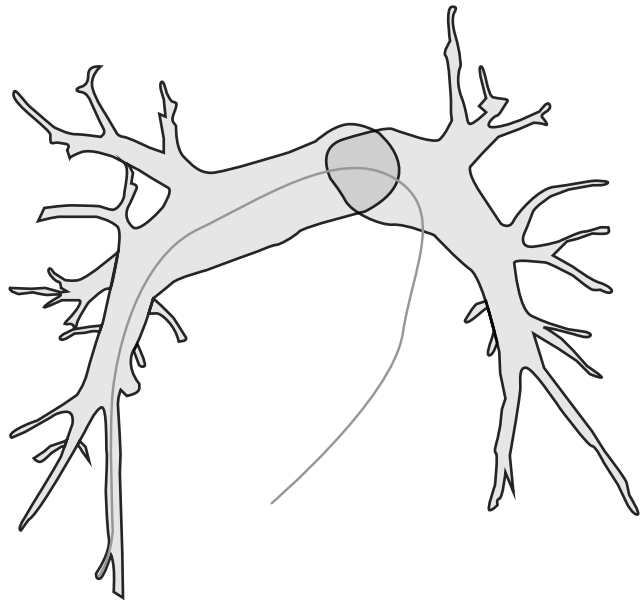
4. Exchange the catheter for a pigtail catheter and remove the guidewire. Ensure the pigtail catheter extends into the right PA as shown.



5. Inject contrast agent through the pigtail catheter to illuminate the right pulmonary artery and provide a roadmap for identifying proper Sensor deployment location. Using the markers on the pigtail (10mm spacing) estimate the diameter of the right PA main vessel at the downturn. The vessel at this location must be between 12-30mm. If the vessel appears to be either larger or smaller than the indicated range, abort the procedure and DO NOT implant the Cordella Sensor.



6. Introduce a guidewire (.018"-.025", 260cm-300cm) through the lumen of the pigtail catheter extending into the right pulmonary artery. Ensure that the wire follows the main branch of the right pulmonary artery and remains in the main branch for appx. 6cm beyond the downturn.



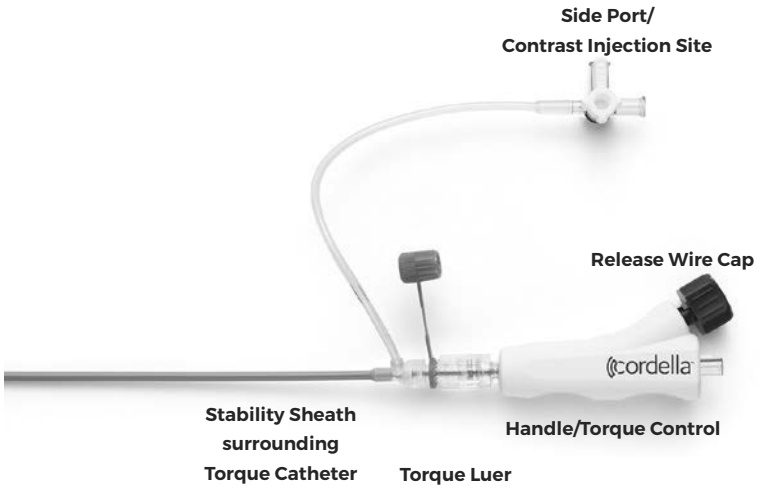
7. Remove the pigtail catheter, leaving the guidewire in place.

WARNING: Ensure that the guidewire is in the main right pulmonary artery distal to the implant location and NOT in a side branch.

4.5 Delivery System & Cordella Sensor Insertion

1. Catheterization lab staff should assist the implanter in sterile removal of the Cordella Sensor and 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 tight connections. The features of the Delivery System handle are labeled below:



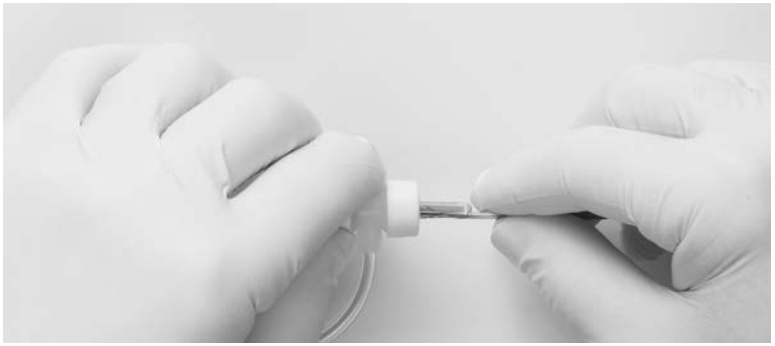
3. Ensure the Cordella Sensor is tied down correctly by comparing to the image below.

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

> **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 using a hand syringe.

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



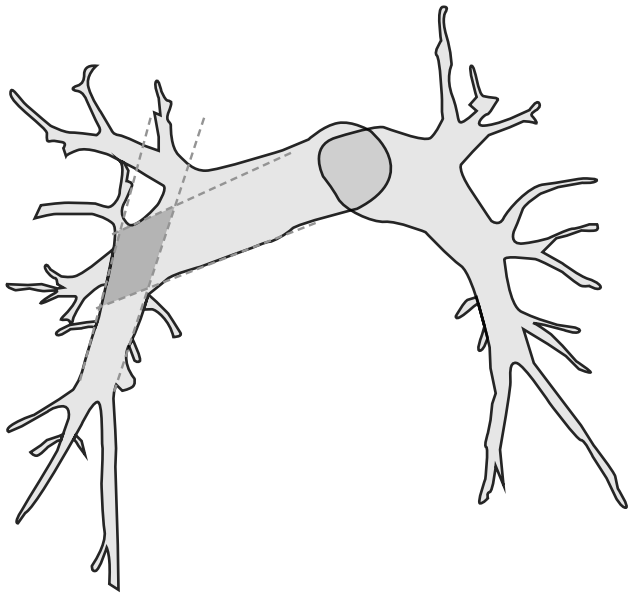
7. Grip the catheter directly behind the Cordella Sensor as shown and gently push the Cordella Sensor through the introducer. Care should be taken to push from the back of the Cordella Sensor to minimize damage and changes to the tiedown configuration.

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

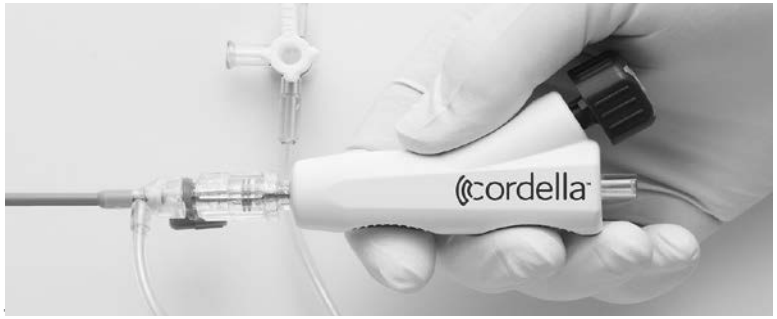
8. Slowly push the Cordella Sensor through the introducer. If severe resistance is encountered, stop pushing the Cordella Sensor and attempt to identify the source of resistance. Proceed cautiously.

4.6 Cordella Sensor Implantation

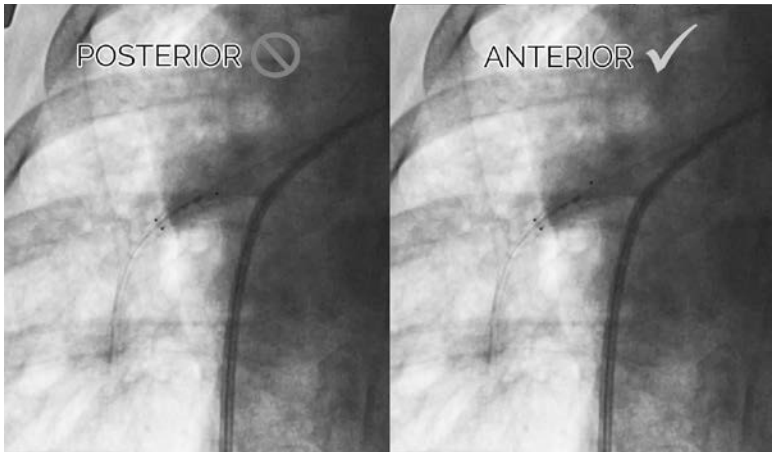
1. The target location for the Cordella Sensor is at the downturn of the right PA (highlighted in the figure below for a representative typical PA anatomy). The location can be defined by the overlapping region of the main right PA trunk and the downturn as illustrated below. The distal radiopaque marker 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 using the Torque Handle to navigate through the heart to the right pulmonary artery.

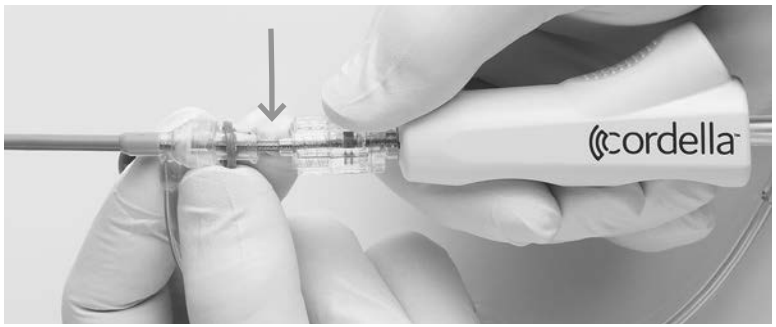


3. Once in the optimal position, the Cordella Sensor has three (3) radiopaque marker bands to help identify rotational position of the Sensor. Rotate the Cordella Sensor using the Torque Handle as necessary to ensure the Sensor is anterior facing as shown below:



4. Once in target deployment position (Sensor body at RPA downturn, anterior facing), deploy the Cordella Sensor by detaching and pulling the release wire cap, then fully removing the release wires. Release wire cap and wires may be discarded.

5. Once the Cordella Sensor is deployed, unscrew the torque luer to disconnect. Hold the handle in a stable position within the palm of the hand.



6. 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.

7. 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 half of 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.
8. Screw the tethered blue luer cap onto the Stability Sheath hub to prevent back-bleeding through the hemostasis valve.

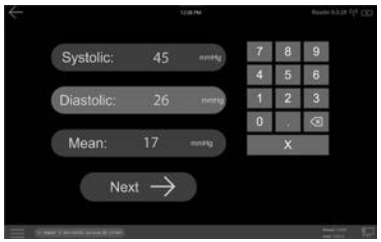
WARNING: Avoid torquing the Stability Sheath when used as a fluid-filled column. Torquing can result in kinks which inhibit accurate reference pressure measurements for Sensor calibration.

4.7 Calibrating the Sensor

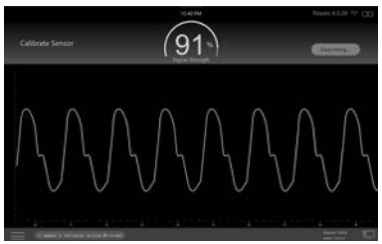
NOTE: During Reader operation, electromagnetic interference (EMI) generating equipment may need to be temporarily moved away from the Reader's zone of operation. This may include temporarily repositioning any ECG leads, pagers, or patient monitoring systems away from the Reader.

WARNING: DO NOT USE 450MHz devices, such as Walkie Talkies or intercom systems, near the Reader.

1. The CalEQ system will prompt the user to zero the reference pressure.

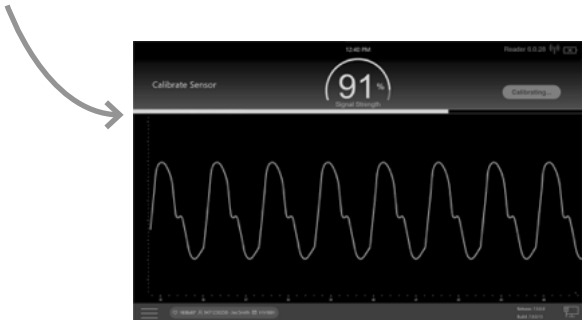


2. Enter the systolic and diastolic values from the fluid-filled pressure measurements on the patient monitor. Press the "Next" button.



3. Undock the Reader when prompted. CalEQ will proceed to the Calibrate Sensor screen, where it will show a live, uncalibrated waveform. Adjust the position of the Reader over the patient's chest until the signal percentage is as high as possible (>75%). Once signal percentage above 75% is achieved, hold the Reader still for 20 seconds and monitor the waveform in preparation for calibration.

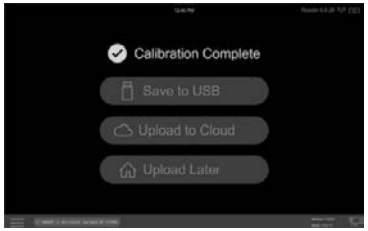
4. Imediately after, CalEQ will calibrate the Cordella Sensor for 18 seconds. Do not adjust the Reader position during this time. A progress bar above the waveform displays the progress through calibration, and the live waveform will be paused.



5. When prompted, dock the Reader.

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 the data, press "Upload Later" and notify Customer Support.



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

5. 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. The CalEQ computer, Docking Station, and backup Docking Station should remained plugged into the power strip. The Reader and backup Reader should remain in the Docking Stations during transport. Lower the CalEQ screen as far as possible by depressing the foot pedal.

The Reader should be powered off before transport. To transport the Reader, press and hold the small button located on the bottom of the Reader, at the base of the handle and adjacent to the power connector, for several seconds. 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 transport, press and hold the button again. If the button is depressed but the Reader doesn't respond, the battery is likely discharged; return the Reader to the Docking Station and allow the Reader to charge.

6. Post-Procedure Antiplatelet Therapy

It is recommended to use dual antiplatelet therapy as per the site's standard of care anticoagulation protocol for 30 days post-implant. Endotronix recommends aspirin and clopidogrel, though prasugrel or ticagrelor can be used in replacement of clopidogrel. After 30 days, single antiplatelet therapy with aspirin is recommended indefinitely or until other directives are provided by the cardiologist.

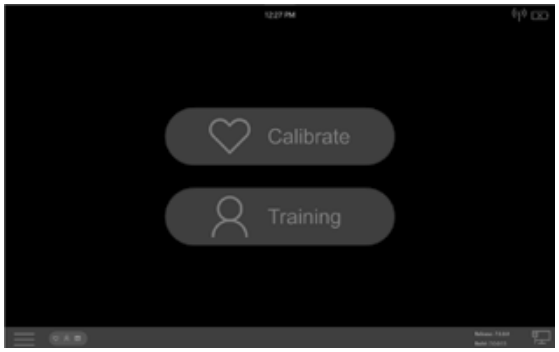
7. Patient Implant Card

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.

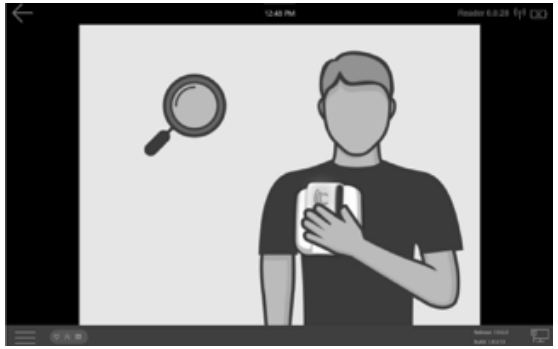
8. Patient Reader Training

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. CalEQ will display an animation that walks through the steps of taking a reading.



3. After the training video, the trainer or patient can press the “Start Training” button, undock the Reader when prompted, and automatically move into the Training screens.

4. 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. After several seconds of strong signal, as indicated by the dial pointer remaining in the green section on the right side of the dial, training will end and the patient will be prompted to dock the Reader. There is no limit to the number of times a patient can complete this training.

9. Reader/Docking Station Audio & Visual Cues

Reader Audio Cues

Event	Sound	Required Action
Searching for Implant	Two descending beeps, repeating every ~2 seconds	Reposition Reader to find stronger signal.
Implant 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 Implant 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 yellow light, return to Docking Station.
Contact Customer Support	Three quick, low pitched beeps, repeating every ~10 seconds	When accompanied by flashing red light, call Customer Support.

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 implant reading.
Rapidly Flashing Yellow	Failed reading. Reposition Reader.
Solid Yellow	Low battery. Return to Docking Station.
Rapidly Flashing Red	Contact Endotronix Customer Support.
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 and that the power strip is plugged into an outlet. If the light remains off, contact Customer Support. To turn off audio and visual cues from the Reader during this time, press and hold the small button at the base of the Reader for several seconds.

10. Maintenance and Storage

10.1 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 primary boxes. The primary 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.

10.2 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 Endotronix Customer Support.

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.

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 Support.

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 Support.

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

11. 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 detailed below.

12. Return Materials Authorization (RMA)

If Customer Support 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 Support on the outside of the shipping container. Ship all equipment and signed equipment return list to:

   RMA #
   Customer Support Department, Repairs Endotronix, Inc.
   Endotronix, Inc.
   815 Ogden Ave.
   Lisle, IL 60532
   U.S.A.

13. Inspection & Cleaning Instructions

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

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 Support 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.
- CalEQ power supply should not be covered.
- 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.

14. Troubleshooting

14.1 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, 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.
- 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 Torque 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.

14.2 Pairing and Interrogating the Cordella Sensor

- If no information is displayed after attempting to scan the QR barcode:
    1. Check that the red 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 not functioning properly, contact Endotronix Customer Support.

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 Support 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 Support 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 Support after the procedure.

14.3 Calibrating the Cordella Sensor

- If the Reader does not turn on, as indicated by audio and visual cues, after pressing and holding the travel 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 is not fully 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 Support after the procedure.
- If the wrong reference pressure measurement numbers are entered, go back to the Home Screen and start the calibration workflow from the beginning.
- 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 Support.
- 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 computer application starts getting choppy or lags, log out of the program and log back in. Log out by navigating to the Menu, pressing the "End Session" button, then pressing "Yes" to confirm.
- If the CalEQ finds a signal strength above 75% but does not transition to calibration, dock the Reader and undock when prompted. CalEQ will proceed to the Calibrate Sensor screen, where calibration can begin again.
- If the Reader is having difficulty taking a reading, move patient monitoring systems, cell phones, pagers, and other equipment that could cause interference at least 1m away from the patient's chest.
    - 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.

15. Useful Life

The tested useful life of the Cordella Sensor is ten (10) years. The tested service life of the Reader and Docking Station is one year, and the tested service life of CalEQ is five years.

16. Contact Us

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

Endotronix Customer Support
1800 814 282 (IE)
+44 (800) 3688346 (UK)
+32 800 82 244 (BE)

support@endotronix.com

Appendices

Appendix A: Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions & Immunity

These 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:

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	

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The myCordella™ Patient Reader and Docking Station 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, ±4V, ±8kV, +15kV air	±8kV contact ±2kV, ±4V, ±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 ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/ output 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. Minimum separation distance at all times: d= 1.5 meters Recommended separation distance for Rated Maximum Output Power of Transmitter above 20W: d = 0.35√P 150 kHz to 80 MHz d = 0.35√P 80MHz to 800 MHz d = 0.70√P 800MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[a]. 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: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the myCordella is used exceeds the applicable RF compliance level above, the myCordella should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the myCordella.

[b]See examples of calculated separation distances in next table

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and myCordella™

The myCordella Reader is intended for use in an electromagnetic environment where radiated radio frequency (RF) signals are controlled. The user of myCordella can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and myCordella 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)		
	150 kHz to 80 MHz d = 0.35√P	80 MHz to 800 MHz d = 0.35√P	800 MHz to 2.5 GHz d = 0.70√P
20	1.6	1.6	3.2
100	3.5	3.5	7.0

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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
NOTE 3: For a rated maximum output power of transmitter below 20W use a minimum separatation distance of 1.5 meters for frequencies from 150kHz to 800MHz.

myCordella Reader Frequency Band

The Reader receives RF electromagnetic energy and includes RF transmitters that perform within the frequency range of 12.8MHz to 14.13MHz.

The Reader includes RF transmitters that perform at center bands (13.09MHz, 13.34MHz, 13.62MHz, and 13.9MHz).

BT Transceiver frequency

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

FC 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:
—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 Support.

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.

Testing

- IEC 60601-1
- ANSI ES 60601-1
- IEC 60601-1-11
- CENELEC EN 60601-1
- CAN/CSA-C22.2 No. 60601-1
- CENELEC EN 60601-1-2
- ETSI EN 301 489-1
- ETSI EN 301 489-17
- ETSI EN 300-330
- CISPR 11

Development and testing for the Cordella Pulmonary Artery Sensor System has been conducted with the guidance of the following standards and regulations:

- **ISO 10993-1** - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- **EN-45502-1** - Active Implantable Medical Devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
- **IEC 60601-1** - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2** - Fourth Edition, Medical electrical equipment – Part 1: General Requirements for Safety – Part 2: Collateral Standard: Electromagnetic compatibility – Requirements and test
- **ISO 14708-1** - Implants for Surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer
- **ISTA 2A** - Packaged Products: 150lb (68kg) or Less
- **ISO 11607-1** - Packaging for Terminally Sterilized Medical Devices
- **ISO 11135-1** - Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Appendix B: Equipment Specifications

myCordella™ Reader

Manufacturer: Endotronix

Exclusively for Clinical Investigations.

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

Pressure Transducer Accuracy: +/- 7.8 mmHg over full scale range, for operating conditions between 5˚ C and 40˚ C and relative humidity between 15% and 93%.

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

Calibration: At implant and when deemed necessary by a medical professional

Expected service life (of Reader only): One year

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

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: 1.1 lbs. / 0.5 kg

Power

Input of 4.2V/16.8V ⎓ 925mA/250mA

Environment

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

Temperature

- Operation: 5 – 35 ˚C (32 – 95 ˚F)
- Storage: -10 – 55 ˚C (-40 – 167 ˚F)

Relative humidity

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

EMC: Meets all relevant parts of IEC 60601-1-2

myCordella™ Docking Station

Manufacturer: Endotronix

Exclusively for Clinical Investigations

Expected service life: One year

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, 925mA/250mA

Calibration Equipment

Manufacturer: Endotronix

Exclusively for Clinical Investigations.

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: 77 lbs / 35 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 (41 – 95 ˚F)
- Storage: -20 – 60 ˚C (-4 – 140 ˚F)

Relative humidity

- Operation: 25 – 85% (non-condensing)
- Storage: 25 – 85% (non-condensing)

Classification

- Class I Equipment
- IP Rating
  - Computer Monitor: IP54 Front Panel
  - Barcode Scanner: IP42
  - Reader: IP22
  - Docking Station: IP21
- Continuous Use

Safety Testing

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

Electrical Characteristics

Power

- Multiple Socket Outlet (MSO)
  - Input: 230V~, 50Hz, 13A (UK) or 16A (EU)
  - Output: 230V~, 50Hz, 13A (UK) or 16A (EU)
  - Cord Length: approx. 3 meters
- Computer Monitor
  - System Input: 12 – 48V⎓
  - AC Adapter
- Input: 100 – 240V~, 50/60 Hz, 1.3 – 0.6A
- Output: 19V⎓4.74A, 90W MAX
- Cord Length: approx. 2 meters

Definition of Symbols

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

	Manufacturer's catalogue or part number so that the medical device can be identified.
	Manufacturer's batch code so that the batch or lot can be identified.
	Manufacturer's serial number so that a specific medical device can be identified.
	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.
	Range of atmospheric pressure to which the device can be safely exposed.

	Device that needs to be protected from moisture.
	Federal Communication Commission Number
	Device that can be broken or damaged if not handled carefully.
	Device manufacturer.
	Date when the device was manufactured.
	Device should be attached to direct current source.
	Device should be attached to alternating current source.
	The myCordella Patient Reader and Calibration Equipment operate using lithium-ion batteries. Lithium-ion batteries should not be crushed or burned.
	Equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	Type BF applied part complying with IEC 60601-1.
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˚.
IP54	Limited protection against dust ingress, and against splash water from any direction.
	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.
	Wireless connectivity.
	Do not re-sterilize.
	Sterilized with ethylene oxide.
	Mass.