Patient Reader Manual

IMPORTANT

PLEASE READ THIS MANUAL BEFORE USING THE
CORDELLA™ PULMONARY ARTERY SENSOR SYSTEM

CAUTION--Investigational device. Limited by Federal
(or United States) law to investigational use.

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Introduction

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

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

Managing Heart Failure with Daily Cordella™ Sensor Readings

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

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

Intended Use

The Cordella 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.

The Cordella™ Pulmonary Artery Sensor System

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

Component Name

Cordella™ Pulmonary Artery Sensor (Cordella Sensor)

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

myCordella™ Patient Reader (Reader)

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

myCordella™ Docking Station (Docking Station)

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

Safety Information

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

Warnings	**This symbol indicates "the possibility of system damage or malfunction, delay in receipt of information to a doctor, inaccurate readings, or injury."**
Precautions	**This symbol indicates "the possibility of system damage, malfunction, or the delay in treatment."**

Warnings

- The Reader is suitable for home healthcare environments and professional healthcare facilities except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbance is high.
- The Reader and Docking Station should not be used adjacent to or stacked with other equipment. If it is necessary to operate the components adjacent to or stacked with other equipment, verify that the system is operating normally in the configuration in which it will be used. If necessary, contact customer service to help re-locate the system.
- DO NOT expose any power accessories to water or other liquids.
- DO NOT disassemble or modify any component of the Cordella™ PA Sensor System.
- DO NOT use 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.
- The Cordella™ PA Sensor System is not intended to be an emergency response device. In case of a medical emergency, call the local Emergency Medical Services and/or your healthcare provider.
- After the implantation procedure, it is critical to adhere to prescribed anticoagulation and other medications from the physician.
- Power cables may pose a tripping hazard. Be mindful of cords crossing walkways.
- myCordella™ Patient Reader may be interfered with by other equipment generating electromagnetic fields. When possible, avoid using the system while simultaneously using the equipment within ~5 feet/1.5 meters such as: laptop computers, tablets, e-readers, cell phones, cordless phones, wireless routers, hair dryers, electric shavers, refrigerators, home stereos, alarm-clock radios, air conditioners, electric ovens, washers, dryers, dishwashers, televisions, microwaves, or walkie talkies (450MHz devices) within ~10 feet/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, remove or stop using the interfering equipment.
- Use only the cables and accessories provided. The use of accessories, transducers or cables other than those specified or provided as replacement parts, may result in decreased immunity of the system, inaccurate readings, damage to the system, injury to user, or improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than ~5 feet/1.5 meters to any part of the Reader. Otherwise, degradation of the performance of the Reader could result.
- 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 service.

- If the skin becomes red, warm, or irritated, immediately stop using the Reader and contact customer service.
- Contact Endotronix customer service if more than 1 Cordella user resides in the same home. DO NOT use more than one Reader in the same general vicinity at one time, as use of multiple Readers at once may cause them to interfere with each other.
- The Reader contains Lithium Ion batteries. DO NOT place the Reader on a hot surface.

⚠ Precautions

- Avoid exposing any components of 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 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 compromised, contact Endotronix customer service.
- Accuracy of the Cordella™ PA Sensor System is affected by a change in body temperature (<-3mmHg/Δ°C).
- Accuracy of the Cordella™ PA Sensor System is slightly affected by large changes in elevation between the initial baseline calibration and subsequent measurements. Readings may lose accuracy when taken >2000m of elevation.
- The Cordella Sensor is a permanent implant. Removing the implant after implantation is not recommended.
- The Cordella Sensor may be affected by a change in elevation above or below sea level. If you plan to travel below sea level or SCUBA dive or extremely high altitudes without pressurization, please contact customer service.

Patient Privacy and Medical Privacy Standards

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

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

Implant procedure

Before the Implant Procedure

Prior to the implant procedure, you and your doctor will discuss the benefits and risks of the procedure and the Cordella PA Sensor

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

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

The Implant Procedure

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

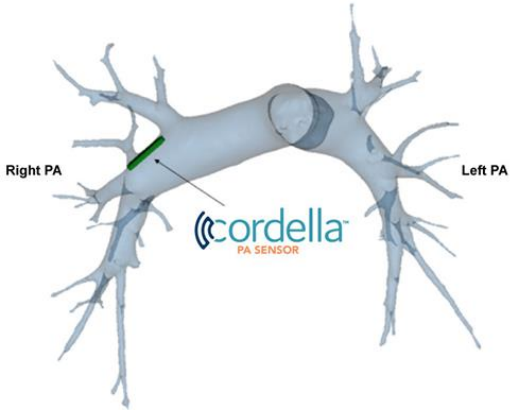
The Cordella Sensor is the length of a $0.01 coin (19.3mm x 3.8mm x 1.9mm) and has two wire loops extending off either end which hold it in place in the vessel. The Cordella Sensor is tied down on a catheter that is skillfully navigated to your PA by your doctor.

The steps of the implant procedure are:

1. You may be mildly sedated to start but your doctor will likely need you awake during certain parts of the procedure to follow instructions.
2. A nurse will clean the access site and will numb it with a local anesthetic.
3. You will be monitored by an electrocardiogram with sensors on different areas of your body to measure electrical activity of your heart. These patches will be attached to wires to monitor your heart during the procedure.
4. Once the anesthetic has numbed the access site, your doctor will make a small incision and insert a small tube called a pulmonary catheter. The pulmonary catheter will be threaded through your vein while your doctor looks at a screen with a live x-ray—called a fluoroscope—of your veins and heart. Your doctor will navigate this catheter through your veins to your heart and then to your PA.
5. Your doctor will take a few pictures with the fluoroscope at this point by injecting dye through the end of the catheter that is still outside your body. These pictures will give your

doctor a better idea of what the vessels in your pulmonary arteries look like and will help guide placement of the sensor to the best possible position. This is called angiography.

6. At this point the pulmonary catheter is removed, the catheter with attached Cordella Sensor replaces it, and the best possible position for the Sensor is confirmed.
7. Once the Sensor is in the best possible position, your doctor will implant it.
8. After the Cordella Sensor is implanted, the handheld Reader will be held over the right side of your chest and the Reader will begin reading the PA pressure. A pulmonary catheter will be used to take some simultaneous reference pressure measurements to calibrate the new Sensor.
9. Following the removal of all catheters, the access site will be closed, leaving the Cordella Sensor in the PA.



After the Implant Procedure

Once the procedure is complete, you will be brought to a recovery area. While in the recovery area, a staff person will come by to take some PA pressure measurements with the Reader. You may be kept overnight for observation.

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

Getting Started

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

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

The Reader is distributed in Travel Mode. Start the Reader for the first time by holding the travel button on the bottom for several seconds.

Reader Placement

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

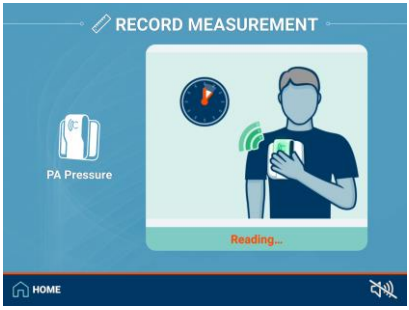
Position the Reader on the prescribed location (from training), most likely the upper right chest. A clinician may indicate that the Reader should be placed in a different location—for example on the side of the body. The Reader will wait for good signal strength before gathering information from the Sensor, so adjust the position until the Reader plays the “Sensor Located” tone and displays a quickly flashing blue light (see the Audio & Visual Cues section below).

Taking a Reading

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

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

Allow the Reader to charge fully before obtaining your first home reading.



Ensure that you are sitting upright comfortably and resting for a few minutes until breathing comfortably. To see the LED indicator on the Reader, use a mirror or ask a caregiver to describe it as you take the reading. The animation walks you through proper data collection using the Reader. Briefly:

1. Check to ensure the LED light on the front of the Docking Station indicates a battery charge that will allow for the reading to be completed. The LED on the Docking Station should be solid white when the Reader is fully charged and ready to take a reading.
2. Remove the Reader from the Docking Station with the ***left hand*** to make it easier to locate the Cordella Sensor in the ***right*** side of the chest. When the Reader is removed from the Docking Station it will begin beeping and the light on the Reader will be solid BLUE.
3. Hold the Reader to the prescribed place on the chest (that was designated during training) and listen for a quick series of beeps which means lock is achieved. The light on the Reader will blink BLUE in rapid succession.

4. During the reading, it is important to remain still and hold the Reader as still as possible. The light on the Reader will blink GREEN during a reading. Continue to breathe normally during the reading.
5. After ~18 seconds the Reader will play a "Success" tone if the reading worked properly. The light on the Reader will become a solid GREEN.
   a. In the event the reading obtained was not good enough due to movement or improper Reader placement, the Reader will play a "Fail" tone. The light on the Reader will blink YELLOW rapidly. Immediately after, the Reader will return to "Search" mode described in step 2.
6. Once a good reading is obtained, the Reader will be a solid GREEN and will continue to play the "Success" tone until it is returned to the Docking Station. The Reader should always remain docked unless it is being used or transported.

Submit Results

The tablet screen will either return to the "Take A Test" screen or you may tap the "Continue" button, which will appear at the bottom center of the screen. Tap the "Review Results" button to advance to the "Test Summary" screen. The PA pressure reading will display as taken. Press the "Submit" button.

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

Audio & Visual Cues

Reader Audio Cues

Event	Sound	Required Action
Searching for Sensor	Two descending beeps, repeating every ~2 seconds	Reposition Reader to find stronger signal.
Sensor Located	Four quickly ascending, high pitched beeps, repeating three times	Great job finding strong signal! Hold Reader in place.
Reading in Progress	Two quickly ascending beeps, repeating every ~3 seconds	Hold Reader in place (~18 seconds).
Successful Sensor Reading	Several quickly ascending, high pitched beeps	Measurement complete! Return Reader to Docking Station.
Failed Reading	Several slowly descending, low pitched beeps	Reposition Reader to find stronger signal.
Return to Docking Station	Successful Reading sound repeating periodically	Return to Docking Station. If Reader is there, check Docking Station visual cues.
Low Battery	Three quick, low pitched beeps, repeating every ~10 seconds	When accompanied by solid 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.
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 electrical outlet. If the light remains off, contact customer service. To turn off audio and visual cues from the Reader during this time, put the Reader into Travel Mode (see Traveling with the myCordella System below).

Traveling with the myCordella Patient Reader and Docking Station

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

To travel with the Reader, remove the Reader from the Docking Station and press and hold the travel button on the Reader for several seconds to initiate Travel Mode. The travel button is a small button located on the bottom of the Reader, at the base of the handle and adjacent to the power connector. Depressing the button will disable the audio and visual cues on the Reader and prevent damage to the batteries. This same process can be used to Power Off the Reader at any time. To restart the Reader after travel, press and hold the button again. If you are unable to charge the Reader during your travels continue taking your scheduled readings by restarting the Reader, taking a reading, and powering the Reader back off.

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 fully.

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

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

Wait 5 minutes to take a reading after disabling Travel Mode to allow the Reader to warm-up.

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 Service

Toll-free: 1-888-512-5595

Support@endotronix.com

Repairing Equipment

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

Return Materials Authorization (RMA)

If customer service requests that the equipment be returned, please follow the directions below.

1) 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.
   Endotronix, Inc.
   815 Ogden Ave
   Lisle, IL 60532
   USA

Inspection & Cleaning Instructions

Inspect the system regularly. No maintenance is required. If any of the inspection checkpoints apply, please contact customer service.

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

Cleaning

- Clean the systems components as needed.
- UNPLUG the Docking Station and remove the Reader before cleaning or disinfecting.
- Put the Reader in “Travel Mode” to minimize audio signals while cleaning.
- To clean, wipe the surfaces with a lint-free cloth lightly moistened in water.
- DO NOT disassemble. Clean only the surfaces of the Reader and Docking Station.
- DO NOT immerse the Reader or Docking Station in any liquid.
- DO NOT spray liquids directly on the Reader or Docking Station – use a pre-moistened cloth.
- DO NOT autoclave.
- DO NOT sterilize with ethylene oxide.

MRI Conditions

MRI Information

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

APPENDICES

Appendix A: Cordella™ Pulmonary Artery Sensor System Components

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

Endotronix, Inc.
815 Ogden Ave
Lisle, IL 60532
USA
Info@endotronix.com

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

Appendix B: Equipment Specifications
myCordella™ Patient Reader

Manufacturer: Endotronix®
CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use.
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 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 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

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

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

Relative humidity

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

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

myCordella™ Docking Station

Manufacturer: Endotronix®
CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use.
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: ~ 8 feet / 2.4 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: ME20A0503F01

Docking Station

- Input: +5V ⎓ 3.0 A
- Output: 4.2V/16.8V, 925mA/250mA

Appendix C: Electromagnetic Guidance

Guidance and Manufacturer's Declaration – Electromagnetic Emissions & 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 Class II ME Equipment and the Reader is a BF Applied Part.

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

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

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The 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, ±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%.

<table>
<tr><td>Electrical Fast Transient/Burst Immunity
IEC 61000-4-4</td><td>±2 kV for power supply lines</td><td>±2 kV for power supply lines</td><td rowspan="6">Mains power quality should be that of a typical professional healthcare facility or home healthcare environment.</td></tr>
<tr><td rowspan="2">Surge
IEC 61000-4-5</td><td>±1 kV line to line</td><td>±1 kV line to line</td></tr>
<tr><td>±0.5 kV line to line</td><td>±0.5 kV line to line</td></tr>
<tr><td rowspan="4">Voltage dips, short interruptions and voltage variations on power supply input lines
IEC 61000-4-11</td><td>0% UT (100% dip in UT) for 0.5 cycle</td><td>0% UT (100% dip in UT) for 0.5 cycle</td></tr>
<tr><td>0% UT (100% dip in UT) for 1 cycle</td><td>0% UT (100% dip in UT) for 1 cycle</td></tr>
<tr><td>70% UT (30% dip in UT) for 25 cycles(50Hz) and 30 cycles(60Hz)</td><td>70% UT (30% dip in UT) for 25 cycles(50Hz) and 30 cycles(60Hz)</td></tr>
<tr><td>0% UT (100% interruption in UT) for 250 cycles(50Hz) and 300 cycles(60Hz)</td><td>0% UT (100% interruption in UT) for 250 cycles(50Hz) and 300 cycles(60Hz)</td></tr>
<tr><td>Power Frequency Magnetic Field
IEC 61000-4-8</td><td>30A/m
50Hz and 60Hz</td><td>30A/m
50Hz and 60Hz</td><td>Power frequency magnetic fields should be at levels characteristic of a typical professional healthcare facility or home healthcare environment.</td></tr>
<tr><td>Radiated RF Immunity
IEC 61000-4-3</td><td>10V/m
80MHz-2.7GHz
80% AM at 1kHz</td><td>10V/m</td><td rowspan="2">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.

Recommended separation distance
d= 1.5 meters

Recommended separation distance for Rated Maximum Output Power of Transmitter above 20W:
<table><tr><td>d = 0.35√P</td><td>150 kHz to 80 MHz</td></tr><tr><td>d = 0.35√P</td><td>80MHz to 800 MHz</td></tr></table></td></tr>
<tr><td>Conducted RF Immunity
IEC 61000-4-6</td><td>3 Vrms
Outside the ISM Bands

6 Vrms
In the ISM and amateur radio bands

150kHz to 80MHz</td><td></td></tr>
</table>

			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 range4. Interference may occur in the vicinity of equipment marked with the following symbol: 
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 separation distance of 1.5meters for frequencies from 150kHz to 800MHz.

Reader Frequency Band

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

The myCordella 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

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 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.

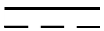
Testing

- 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

Definition of Symbols

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

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.
	Range of atmospheric pressure 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.
	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 operates 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°.
	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
	General warning.
	Possibility of system damage, malfunction, or the delay in treatment.
	On/Standby button.
	IEC 60417-5140 - Equipment includes RF Transmitter.
	Federal Communication Commission Number.