INSTRUCTIONS FOR USE

CARDI/O® [kar-dee-o]

(remote patient monitor)

for touchless, no-wearable use

Device Description

The Cardi/o® Sensor device is a component of the Cardi/o® remote patient monitoring (RPM) platform. The Cardi/o Sensor device is a wireless, no-touch/no-wearable vital signs sensor, set on a desktop or mounted to a wall to record heart rate, respiratory rate, and stress related to heart rate variability, and motion. The Cardi/o® Sensor continuously gathers physiological data from the person being monitored and then transmits encrypted data via WiFi to the Cardi/o®Cloud platform. The encrypted wireless data provided by the Cardi/o® Sensor may be accessed and viewed via Cardi/o®App for mobile phones or Cardi/o®Central Dashboard web app for desktop computers. The data from the Cardi/o Sensor may be downloaded from the Cardi/o®Cloud for storage or integrated into a Third-Party Relay Application via the APIs of the Cardi/o® Software Library. The data provided by the Cardi/o Sensor is intended to aid caregivers in making diagnoses by providing additional information.

During normal operation, data is collected via touchless radar sensing capability of the Cardi/o® Sensor and transmitted immediately to the Cardi/o®Cloud via WiFi. A continuous connection is needed between the Cardi/o® Sensor and the Internet to facilitate continuous physiological data transmission. The continuous wireless transmission of data occurs with an update rate of 2 seconds between data collection and transmission.

Patients may opt in to request assistance from healthcare providers through predefined alarm thresholds that, when exceeded, send alerts via a wall-mounted transceiver that is connected to the cloud.

Indications for Use

The Cardi/o® RPM is a wireless “no-wearable” remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in healthcare settings as well as in environments where healthcare is administered, such as home healthcare services, assisted living and skilled nursing facilities. This physiological data can include heart rate, respiratory rate, heart rate variability, and motion. The RPM may be used for synchronous or asynchronous for telemedicine consultations.

The Cardi/o® Sensor is intended for use on general care patients who are 18 years of age or older who may be susceptible to decubitus ulcers of the skins, such as the elderly, for use as a general patient monitor, to provide physiological information. The collection and transmission of data is performed on the device.

The data from the device is intended for use by healthcare professionals as an aid to remote diagnosis and treatment while preventing the spread of communicable diseases such as COVID-19.

The device can be used on patients unable or averse to wearable patient monitors, such as patients living with dementia or autism. The device is not intended for use on critical care patients.

The data provided by the Cardi/o® Sensor may also be intended for trained technicians at a remote site to review the data and determine if they concur with the analysis made by the algorithm in the Cardi/o® Sensor.

The data collected by the Cardi/o® Sensor is an adjunct to clinical assessment; clinician review of the data should precede any diagnosis or therapeutic intervention.

Contraindications

- The Cardi/o® Sensor is not intended as a stand-alone diagnostic monitor for vital signs, but the data may be applicable for use in diagnosis.

Warnings

- Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact continuous or real-time monitoring. Limited data will be stored on the device for transfer once connectivity is reestablished.
- The Cardi/o® Sensor is designed to monitor one individual at a time. Having more than one individual in the field of view of the sensor may produce skewed data that may not represent the parameters of the intended subject.
- Disturbances to cardiac-respiratory signals include distortions due to foreign interference and noise artifacts may occur when using the Cardi/o® Sensor. Do not rely entirely upon heart rate signals of the Cardi/o® Sensor. Keep patients under close surveillance.
- Automated interpretation of heart rate variability by the Cardi/o® Sensor is a valuable tool when used properly. However, no automated interpretation is completely reliable, and a qualified physician shall review the interpretations before treatment, or non-treatment, of any patient.
- Heart rate, respiratory rate, stress level (HRV), and motion data will not be transmitted or stored if the Sensor is not powered.
- The patient must be in the field of view of the Cardi/o® Sensor to collect physiological data.
- Clinical validation has not been performed on patients who are pregnant or breastfeeding.

Precautions

- For data to be sent to a healthcare professional for review:
  - The Cardi/o® Sensor must be properly used by the patient.
  - The patient must remain in range of their Sensor device.
  - The Cardi/o® Sensor must have adequate power for data transmission. Notification of interruption in data collection of the Cardi/o® Sensor will be indicated on the Cardi/o®App when the Sensor device is offline and may also be sent via SMS Text if this feature is enabled.
  - The Sensor device must remain connected to the Internet and functional for data transmission. Wireless connectivity must be active for transmission of data from the Sensor deviceto the Cardi/o®.
- The healthcare professional can be notified when there are interruptions in data connectivity if this feature is enabled.
- Physiological data collected by the Cardi/o® Sensor for patients experiencing stress may indicate slightly higher or lower respiratory rate values, compared to visual observation.
- The Cardi/o® Sensor is for Individual Use Only. Do not monitor more than one patient at a time.
- Wireless electronic devices may cause signal interference during data transmission. Avoid close proximity with interfering devices.
- Do not use the Cardi/o® Sensor if the package has been opened, or appears used, damaged, or expired.

- Incorrect handling, excessive force, or dropping the Cardi/o® Sensor may cause malfunction or permanent damage.
- If the Cardi/o Sensor fails to operate, contact your healthcare provider immediately.
- Dispose of the Cardi/o® Sensor per local laws, care facility laws or hospital laws for routine/non-hazardous electronic waste.

Additional Warnings and Precautions for Emergency Use Authorization (EUA)

The following additional warning and precautions apply when using the Cardi/o® Sensor under the Emergency Use Authorization for general remote patient monitoring:

- The Cardi/o® Remote patient Monitor has neither been cleared or approved for remote monitoring and detection of vital signs such as heart rate, respiratory rate, and heart rate variability in patients who are undergoing treatment for COVID-19 or who have pre-existing conditions (such as hypertension or heart failure). Such remote monitoring may reduce health care personnel to exposure to SARS-CoV-2, the virus that causes COVID-19;
- The Cardi/o® Remote patient Monitor has been authorized for the above emergency use by FDA under an EUA;
- The Cardi/o® Remote patient Monitor has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- WARNING: When interpreting the Cardi/o® heart rate, respiratory rate and heart rate variability measurements, data recordings should be reviewed for interference artifacts. Heart rate, respiratory rate and heart rate variability measurements with the Cardi/o® Sensor may be unreliable in the presence of significant noise or artifacts. Relevant changes in these measurements should be further investigated using a standard 3-lead or 8-lead ECG.
- WARNING: Heart rate, respiratory rate and heart rate variability measurements with the Cardi/o® Sensor may be unreliable in cases of significant motion. Consider taking physiological measurements when the patient is at rest.
- The accuracy of the Cardi/o® Remote Patient Monitor for measuring heart rate, respiratory rate, heart rate variability and motion has only been tested for accuracy over 30-minute intervals.
- Using the Cardi/o® Remote Patient Monitor to measure heart rate, respiratory rate, heart rate variability and motion has only been tested with the recommended Sensor placements. The accuracy of these measurement with nonstandard Sensor placement is unknown.

Product Storage

- Storage temperature range: (-15) – 85º C
- Storage relative humidity range: 10 – 95% RH

System Interoperability

The Cardi/o® Remote Patient Monitor is compatible with Sensor devices and software developed with the Cardi/o® Application Programming Interface (API). Please contact Advanced Telesensors Inc. to obtain implementation information, including the *Cardi/o® Application Programming Interface (API) Instructions*.

Components Included with the Cardi/o Remote Patient Monitor System

The Cardi/o® Remote Patient Monitor System contains:

1. The Cardi/o® Sensor Device – a 3 x 3-inch device (desktop or wall-mounted) that detects and transmits the vital signs measured by the device, presenting this data locally or remotely for the patient and to healthcare personnel. The Cardi/o® device integrates remote radar cardio-pulmonary sensing technology and Wi-Fi data connection to collect physiological data. The patient keeps the Cardi/o® device on a desk top during remote telemedicine consultations or mounted in rooms where continuous remote monitoring is to occur, allowing continuous upload of vital signs data to the Cardi/o®Cloud platform while the patient remains within sensing range;
    - The Sensor device is designed to record physiological data of the patient sitting, laying prone or standing within the Sensor's 10-foot (3 meters) range and 30º field of view.
2. Cardi/o®App Application – a software Graphical User Interface on mobile phones and tablets intended for use by HCP to display physiological data collected by the Cardi/o® Sensor device;
3. The Cardi/o®Central Dashboard Application – a web application that runs in a computer web browser or mobile device. This allows healthcare personnel to monitor patients from multiple Internet-connected devices in a single user interface;
4. Cardi/o®Cloud – stores data uploaded by the Cardi/o® Sensor and makes it available to cloud-enabled monitoring and data analytics applications, such as the Cardi/o®Central Dashboard application.

CARDI/O® USE INSTRUCTIONS

Note: It is recommended that healthcare providers advise users on correct placement of the Cardi/o® Sensor. To collect data the Cardi/o® Sensor must be connected to the Internet.

Cardi/o® Overview

Cardi/o® Remote Patient Monitor (RMP) may be use for synchronous telehealth consultations where real-time intermittent spot-checking of vital signs may be desired; and for asynchronous telehealth consultations where historical data can be viewed and downloaded. Follow ***Steps 1 through 2.B*** to configure the Sensor device for WiFi connection and proper set up/positioning of the Sensor device for usage. Follow ***Steps 3 through 5*** to access patient data via the Cardi/o® mobile app and Cardi/o®Central Dashboard web-app.

Step 1. Connect the Cardi/o® Sensor to the Internet via WiFi

Scan the barcode containing a unique ID that is located on the sensor device with a smart phone, then input the local WiFi passcode to complete the Sensor connection.

Determine whether the Cardi/o® RMP will be for intermittent use or long-term use and position the Sensor device according to ***Figure A*** or ***Figure B*** below.

Step 2.A Positioning Cardi/o® for *Intermittent* Use – tabletop option

Note: Orientation of the Logo Side is important when positioning the device to collect data on the patient.

See ***Figure A*** below for a view of the Cardi/o® Sensor set on a tabletop, showing the logo side in relation to the patient.

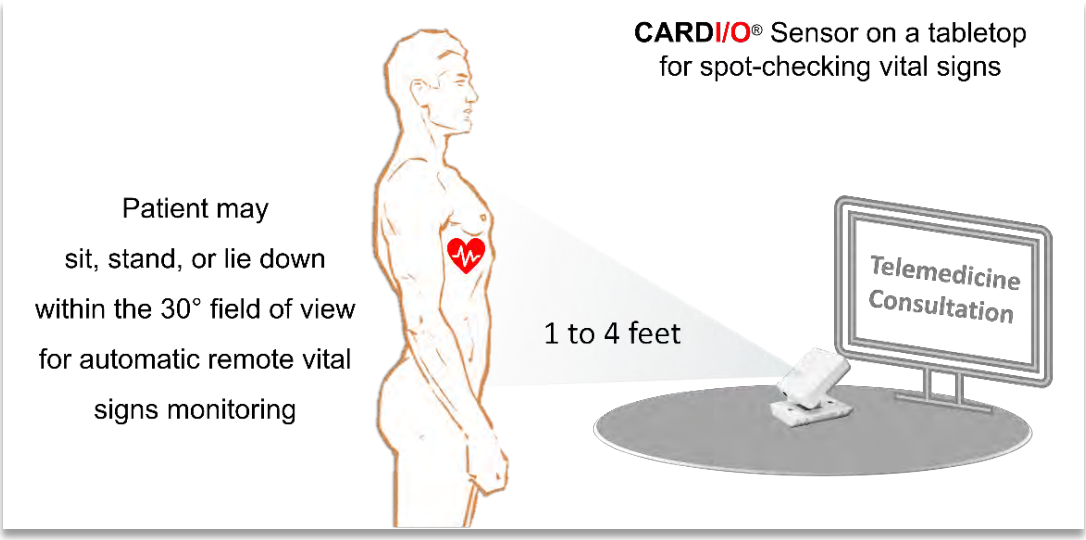

***Figure A**: Use Cardi/o® for sterile, no-contact vital signs capture. The data will automatically upload to the Cardi/o® patient record.*

Step 2.B Positioning Cardi/o® for *Long Term* Use – wall-mount option

See ***Figure B*** below for a view of the Cardi/o® Sensor wall placement in relation to patient. The sensor is placed between 6 to 8 feet vertical from the floor facing the bed where the patient spends most of their time at rest. The Sensor device is designed to record physiological data of the patient sitting, laying prone or standing within the Sensor's 10-foot range and 30º field of view.

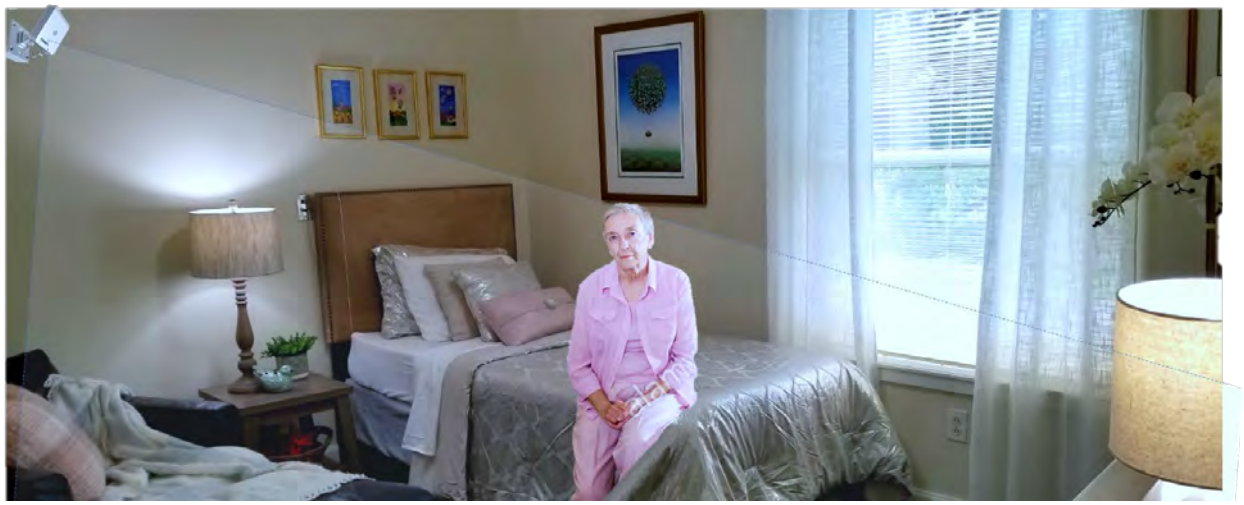

Figure B: *Position the Cardi/o Sensor device on a wall facing the bed for nighttime monitoring. Or, determine the best position according for daytime monitoring using the 30° field of view reference point. Call your healthcare provider or Cardi/o support for assistance with proper placement and installation.*

In ***Figure C*** below, follow ***steps 1 through 4*** to install the Sensor to a wall for long-term patient monitoring.

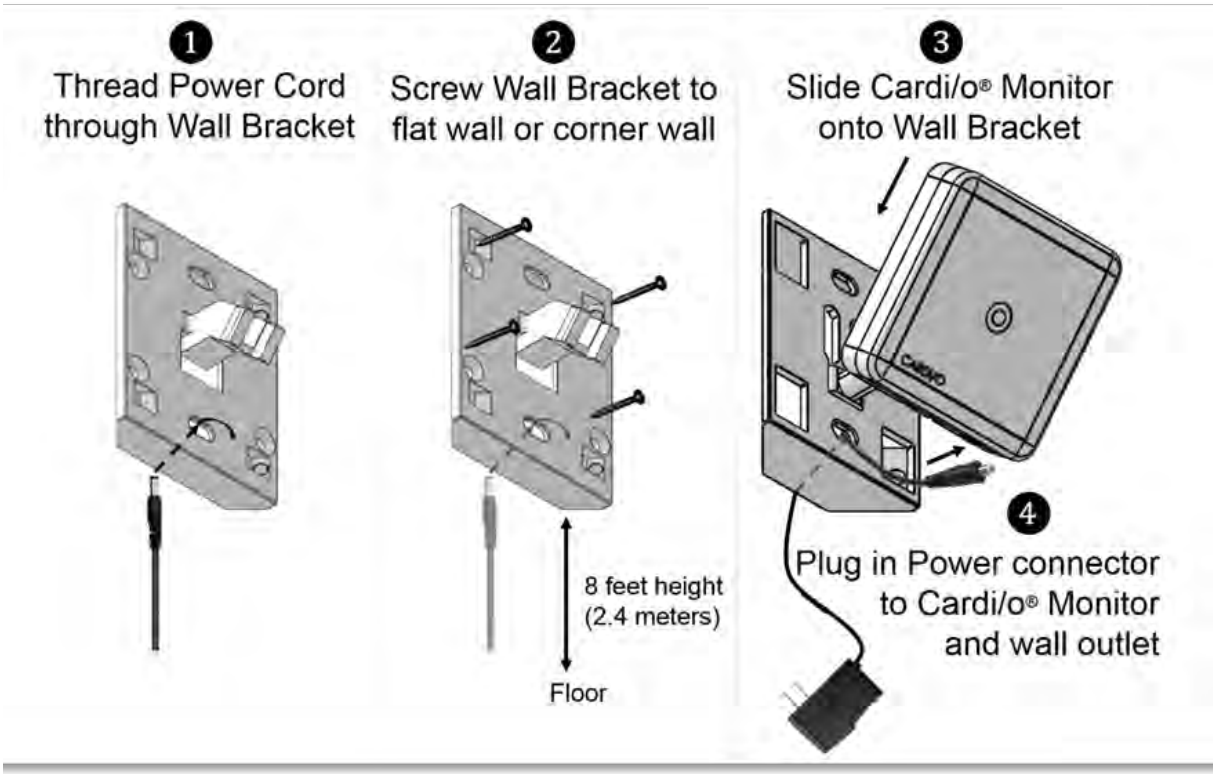

Figure C: *The dual-mount wall bracket can be used in a corner or flat wall for optimal positioning.*

Step 3. Accessing Patient Data

See ***Figure D*** below for five (5) steps to access patient data collected by the Cardi/o® remote monitor system.

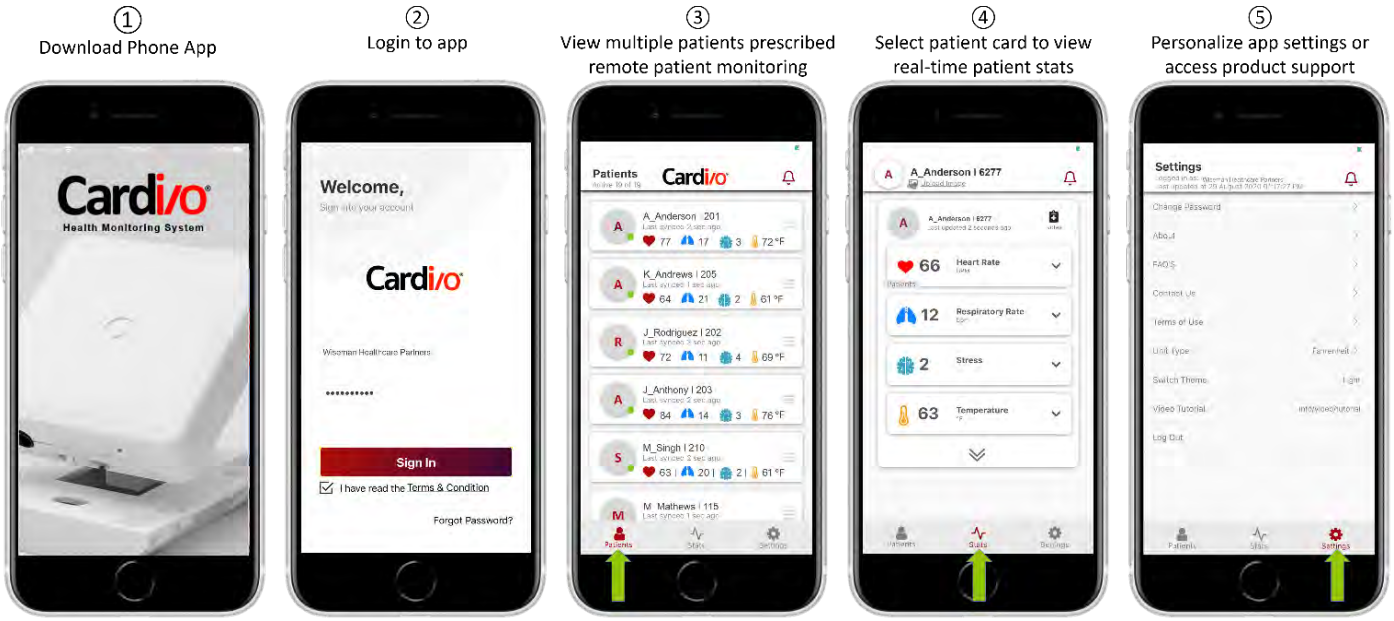

Figure D *represents the top-level navigation screens. After login, navigate between the* ***Patients*** *list,* ***Stats*** *and* ***Settings****.*

Note:

Step 1: "Download Phone App is performed once

Step 2: "Login to app" may accept biometric fingerprint login if the feature is enabled on the phone.

Step 3: Displays the scrollable list of patients which have been prescribed Remote Patient Monitoring, and their respective vital signs.

Step 4: Click on a bar to access individual patient data and histogram information.

Step 5: Displays a menu of settings for viewing preference and app support.

See *Figure E* below for five (5) primary steps to navigate patient data collected by the Cardi/o® Sensor.

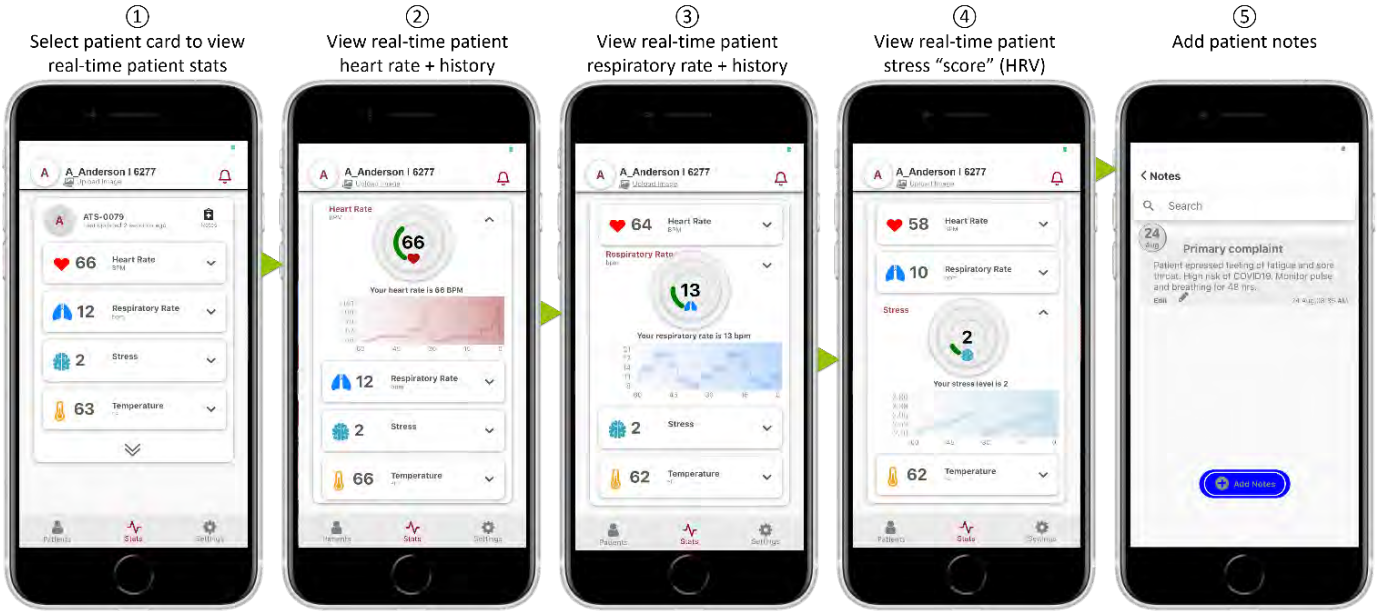

***Figure E**: Investigate patient data by clicking the respective bars. Access historical data trends for analysis by clicking the down arrow located on the bar of each parameter.*

Note:

Step 1: Displays a patient dashboard

Step 2: Click the heart rate bar to view a graph indicating data trending over time.

Step 3: Click the respiratory rate bar to view a graph indicating data trending over time.

Step 4: Click the stress bar to view a graph indicating data trending over time.

Step 5: Click the notes icon [ ] in the main patient dashboard (seen in **Step 1**) to type notes pertaining to patient data or consultation.

Step 4. Managing Patient Alerts

See ***Figure F*** to the right to locate alerts on the main Residents Dashboard screen of the Cardi/o®App. The number on the bell indicates the number of patients that have exceeded one or more predefined thresholds related to heart rate, respiratory rate, and stress level.

Clear alerts by swiping left on each highlighted bar on the Patient list and click "clear alert".

You may also enable the mobile phone SMS Text Alerts feature in the Cardi/o®Central Dashboard administrator portal by assigning telephone numbers to respective caregivers.

***Figure F:** The number of active alerts is indicated in the red dot.*

Personalize Alarm Thresholds via the Cardi/o®Central Dashboard Administrator Portal

Adjust the high and low thresholds of the alarm parameters in the Cardi/o®Central Dashboard administrator portal to personalize alert settings for individual patients. **Table 1** below indicates the default values for the high and low thresholds for each parameter.

PARAMETERS	Range	Low Threshold	High Threshold
Heart Rate	20 – 180 BPM	50	100
Respiratory Rate	0 – 60 bpm	9	29
Stress Score (HRV-related)	0 – 10 score	0	5

***Table 1**: Default thresholds for Alarm settings are indicated above, and may be adjusted according to guidance by the healthcare professional*

Step 5. Downloading and Reporting Data

Note: Recorded patient data is intended to automatically uploaded data via the cloud to the unique patient Cardi/o® record on a continuing basis.

Download data via the Cardi/o®Central Dashboard web-application installed on a desktop computer. Select date ranges and time periods to view data trends and values on a pdf report. Email the report to an email you designate; set reporting for as many times a day or week as needed for treatments. Refer to the applicable guide for the Cardi/o®Central Dashboard web-application to navigate reporting features.

Cardi/o® Sensor Return or Disposal

Follow instructions given by your healthcare provider to return the Cardi/o® sensor. If directed to dispose of the Sensor, please observe local laws for disposal of electronic products.

Note: The Cardi/o® Sensor is a re-usable device. Use standard sterilization practices before re-issuing the device to another user. The device will need to be reconfigured for WiFi connectivity to the Internet if reissued to a user at a different location.

Troubleshooting

For issues related to a user interface application and for additional troubleshooting guidance, refer to separate Instructions for Use for the interface.

Contact Information

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Austin, TX 78728 USA
Phone: (888) 292-2208
www.cardio.io

Customer Support
support@cardio.io
888-292-2208, option 4

Product Specifications

Measurements	Heart Rate Dynamic Range	Not available for patients with pacemakers. 20 – 180 Beats Per Minute (BPM) Accuracy tested +/- 2 BPM of 3-lead ECG
	Respiration Rate Dynamic Range	Not available for patients with pacemakers. 0 – 60 breaths per minute (bpm) Accuracy tested +/- 2 BPM of 3-lead ECG
	Stress ~ Heart Rate Variability (stationary and ambulatory)	Not available for patients with pacemakers. Ratio of Low Frequency to High Frequency (LF/HF); also known as “HRV Score”
	Dynamic sensing range	10-feet (3-meter) max separation between subject and Cardi/o® Sensor o 2-inch (5 cm) minimum separation
Communications	WiFi WLAN Standard	IEEE 802.11b/g/n, Wi-Fi compliant
	Serial WiFi (eS-WiFiTM)	ISM43362-M3G-L44
	Radio Frequency Range	24.0 – 24.497 GHz ISM
	Modulation	802.11 g/n : OFDM /64-QAM,16-QAM, QPSK, BPSK 802.11b : CCK, DQPSK, DBPSK
	Max Power Output	802.11n /72Mbps: 18* dBm ± 1.5 dB
	Security	Wi-Fi authentication WEP-128, WPA-PSK (TKIP), WPA2-PSK.
Power	AC Adapter Input	110V – 240V – 50/60 Hz 0.4A max
	Output	5.9V 2.0A max
Operating Conditions	Humidity	10 – 95% RH (noncondensing)
	Altitude	<3000 m
	Barometric Pressure	70 kPa to 102 kPa
	Ambient Temperature	0 – 70°C

Electromagnetic Emission Declaration

The Cardi/o® Sensor is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	The Cardi/o® Sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Cardi/o® Sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

FCC Compliance (FCC ID: To be determined)

The Cardi/o® Sensor 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 (FCC Title 47, Subpart C, Part 15.249).

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21)

Note: This equipment 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 installed and 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 (FCC Title 47, Subpart B, Part 15.105(b)):

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Guidance and Declaration – Electromagnetic Immunity

(For ME equipment ME system that are not life-supporting)

The Cardi/o® Sensor is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Immunity test	Compliance level	Electromagnetic environment- guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF [24.0 – 24.25 GHz] IEC 61000-4-3	5 mW/cm^2 (uncontrolled) 1 mW/cm^2 (uncontrolled)	Portable and mobile RF communications equipment should be used no closer to any part of the Cardi/o® Sensor device than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: Pd = (Pout*G) / (4*pi*r^2 Where: Pd = power density in mW/cm2 Pout = output power to antenna in mW G = gain of antenna in linear scale Pi = 3.1416 R = distance between observation point and center of the radiator in cm) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines	Mains power quality should be that of a typical home healthcare environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the N507 requires continued operation during power mains interruptions, it is recommended that the Cardi/o® Sensor device be powered from an uninterruptible power supply.

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. **Note 2:** Over the frequency range 1,500 MHz to 1,500-100,000 MHz, field strengths should be less than 5 mW/cm^2 for uncontrolled environments and less than 1 mW/cm^2 for controlled environments**. Note 3:** UT is the a.c. mains voltage prior to application of the test level. **(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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

Recommended separation distance between portable and mobile RF communications equipment and Cardi/o® Sensor.

(For ME equipment ME system that are not life-supporting)

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

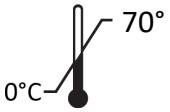
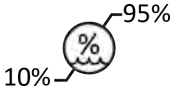
Maximum Permissible Exposure (MPE) Limits (§1.1310)

Frequency range (MHz)	Electric field strength	Magnetic field strength	Power density	Averaging time
	(V/m)	(A/m)	(mW/cm^2)	(minutes)
(i) Limits for Occupational/Controlled Exposure				
0.3-3.0	614	1.63	*(100)	≤6
3.0-30	1842/f	4.89/f	*($900/f^2$)	<6
30-300	61.4	0.163	1	<6
300-1,500			f/300	<6
1,500-100,000			5	<6
(ii) Limits for General Population/Uncontrolled Exposure				
0.3-1.34	614	1.63	*(100)	<30
1.34-30	824/f	2.19/f	*($180/f^2$)	<30
30-300	27.5	0.073	0.2	<30
300-1,500			f/1500	<30
1,500-100,000			1	<30

f = frequency in MHz. * = Plane-wave equivalent power density.

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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. **Note 2:** Cardi/o is intended to operate at ≥ 20 cm from persons during normal use. **Note 3**: Over the frequency range 1,500 MHz to 1,500-100,000 MHz, field strengths should be less than 5 mW/cm^2 for uncontrolled environments and less than 1 mW/cm^2 for controlled environments.

General Symbols

Symbol	Title	Symbol	Title
IP24	Protected against splashing water		Read usage instructions
	Properly dispose of EEE (Electrical and Electronic Equipment)		Non-ionizing radiation
	Prescription only		FCC Marking
	Manufacturer		Manufacture Date YYY-MM-DD
	Caution, consult documents		Not to be used in case package is damaged
	Catalogue number		Batch code
	Serial number		Temperature limits (Storage)
	Humidity limits (Storage)		Contents (Numeral represents quantity of units inside)
	Underwriters Laboratories MEDICAL — PATIENT MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; ANSI/AAMI/IEC 60601-2-25, "Medical Electrical Equipment - Part 2-25: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographs" E358758		

Document History

Revision	Description
Rev. 01	Initial release of this document.

This “Instructions for Use” has been approved by the U.S. Food and Drug Administration.