EN

CardioWatch 287-2

Bracelet Instruction Manual

1 Table of Contents

2 INTRODUCTION

Thank you for purchasing the Corsano CardioWatch 287-2. Corsano CardioWatch 287-2 not only analyses your heartbeat, but also your heart rhythm, oxygen saturation, respiratory rate, ECG, temperature and activity- simple and at any time. The bracelet has been validated in clinical studies and enables screening for irregular heartbeats (e.g. extrasystoles) as well as the presence of absolute arrhythmia with suspected atrial fibrillation (AF). However, irregular heartbeats (e.g. extrasystoles) and atrial fibrillation can only be diagnosed in accordance with the guidelines with an ECG of the thoracic wall, generally carried out by cardiologists.
If you are feeling unwell or experience other troubling symptoms, please seek medical advice immediately.

3 SAFETY INSTRUCTIONS

This instruction manual provides you with important information about the Corsano CardioWatch 287-2 Bracelet. To ensure the safe and proper use of this bracelet, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact support@corsano.com before attempting to use this bracelet. For specific information about your own heartbeats, consult with your physician.

3.1 Intended Use

The CardioWatch 287-2 System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals.

The CardioWatch 287-2 System is intended to provide visual and audible physiologic multi-parameter alarms.

The CardioWatch 287-2 System is intended for temperature monitoring of the patient.

The CardioWatch 287-2 System is intended for continuous monitoring of the following indices in adults:

- Pulse rate
- Oxygen saturation
- Respiration rate
- Temperature
- Movement

The CardioWatch 287-2 System is intended for intermittent or spot-check monitoring, in adults, of:

- Non-invasive blood pressure
- Weight
- ECG

The CardioWatch 287-2 System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The CardioWatch 287-2 System is not intended for use on acutely ill cardiac patients with

the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The CardioWatch 287-2 System is not a substitute for an ECG monitor.

The CardioWatch 287-2 System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

3.2 Receiving and Inspection

Remove this bracelet and other components from the packaging and inspect for damage. If this bracelet or any other components is damaged, DO NOT USE and contact support@corsano.com

Read the Important Safety Information in this instruction manual before using this bracelet. Follow this instruction manual thoroughly for your safety.

Keep for future reference. For specific information about your own heartbeats, CONSULT WITH YOUR PHYSICIAN.

- DO NOT use this bracelet on infants, toddlers, children or persons who cannot express themselves.
- DO NOT adjust medication based on readings from this bracelet. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high or irregular heartbeats.
- DO NOT use this bracelet on an injured arm or an arm under medical treatment.
- DO NOT use this bracelet in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the bracelet and/or cause an inaccurate reading.
- DO NOT take recordings in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).
- DO NOT use this bracelet in oxygen rich environments or near flammable gas.
- The device is intended to be worn on the wrist (left or right), DO NOT use on other parts of the body.
- Consult with your physician before using this bracelet if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- To help avoid strangulation, keep the charger cable away from infants, toddlers or children.

- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.
- The individual packaging contains important information, it should not be thrown away.

3.3 Data Transmission

This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off the Bluetooth® feature in this bracelet and remove batteries and/or unplug the charger when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

3.4 Handling and Usage

- Stop using this bracelet and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this bracelet on an arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow, which could result in injury.
- Consult with your physician before using this bracelet if you have severe blood flow problems or blood disorders.
- DO NOT use this bracelet for any purpose other than measuring heartbeats.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 12 inches (30 cm) of this bracelet. This may result in incorrect operation of the bracelet and/or cause an inaccurate reading.
- DO NOT disassemble or attempt to repair this bracelet or other components. This may cause an inaccurate reading.
- DO NOT drop or subject this bracelet to strong shocks or vibrations.
- DO NOT use this bracelet with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the bracelet and/or cause an inaccurate reading.
- Ensure that this bracelet has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading.
- Ensure the bracelet is well adjusted on the wrist to have the best performance of the heart rate sensor, and not too tight to avoid skin injuries

3.5 Charger Handling and Usage

- USE the charger cable with a CE marked adapter with the following characteristics:

  - Input voltage: 100/240 V - 50hz 60hz
  - Output voltage: DC 5V (+-5%)
  - Maximum current: 500 mA

- DO NOT use the charger if this bracelet or the charger cable is damaged. If this bracelet or the cable is damaged, unplug the charger immediately.

- Plug the charger into the appropriate USB outlet. DO NOT use in a multi-outlet plug.

- NEVER plug in or unplug the charger from the electric outlet with wet hands.

- DO NOT disassemble or attempt to repair the charger.

- Fully insert the USB plug at the end of the charger into the USB outlet.

- When unplugging the charger from the outlet, be sure to safely pull from the USB outlet. DO NOT pull from the charger cable.

- When handling the charger cable:

DO NOT damage it. DO NOT break it.
DO NOT tamper with it.
DO NOT forcibly bend or pull it. DO NOT twist it.
DO NOT use it if it is gathered in a bundle. DO NOT pinch it.
DO NOT place it under heavy objects.

- Wipe any dust off of the charger.

- Unplug the charger when not in use.

- Unplug the charger before cleaning this bracelet.

3.6 Warnings

Regardless of the measurement taken using this device, you should immediately consult your practitioner when you experience symptoms that could indicate a disease, such as chest pain, pressure, tightness, etc.

You may be experiencing a cardiac arrhythmia or other disease even in the absence of a notification from the APP. You should notify your practitioner at any changes of your health condition.

If a serious incident occurs in relation to the device, it must be reported to the manufacturer and the competent authority.

3.7 Residual risks

In rare cases, the device may detect arrhythmia while you experienced no cardiac problems. You should contact your practitioner to get a diagnostics confirmation.

3.8 Clinical benefit

The CardioWatch 287 provides a non-invasive and comfortable solution to continuously and accurately monitor vital signs and enables off-line analysis and screening of cardiac arrhythmia (AFib for instance) by third-party medial applications.

3.9 Cleaning and service life

Use a lint-free cloth moistened with warm water to clean the housing and casing of your device.

Use warm water and hypoallergenic soap to clean the strap.
Dry the wrist band with a soft cloth.
It is not necessary to sterilize the device.

The Smartwatch is an electronic device with rechargeable battery. The expected service life is 5 years.

4 SYMBOLS

These instructions for use contain the following symbols (color and size may vary):

Symbol	Meaning
CE 1912	This stand-alone software is a medical device classified as risk category IIa, in accordance with rule 10 of EU Directive 93/42/EEC, last amended by 2007/47/EC of the European Parliament and Council of 5 September 2007.
	Indicates the medical device manufacturer
	Warning Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions. A warning is always related to safety.
	Note Indicates the need for the user to consult the instructions for use
	Applied Part TYPE BF Applied Part (IEC 60417-5333)
REF	Indicates the manufacturer's catalogue number so the medical device can be identified
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified
CE	CE marking indicates that a product complies with applicable European Union regulations
FC	FCC marking indicates the electronic device, which sold in the United States, is certified and the electromagnetic interference from the device is under the limits that are approved by Federal Communications Commission
	Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005
	Refer to instruction manual/booklet.
	The wearable device does not generate alarms.
Rx	On prescription only.

5 CONTENTS / PRODUCT INCLUDES

Figure 1 -Bracelet (CS-287-1B)

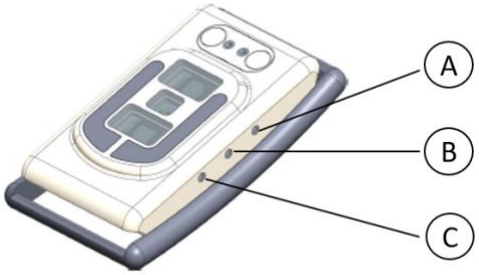
Figure 2 - Charger (CS-287CH-1)

Figure 3 - Instruction Manual (CS-287IFUEN-1)

NOTE: Follow instructions for use.

6 KNOW YOUR BRACELET

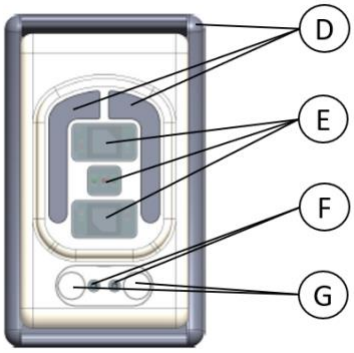
6.1 Back and side of the bracelet



(A) Green LED
(B) Orange LED
(C) Blue LED

Figure 4 – Front view of Bracelet

6.2 Back and bottom of the bracelet



(D) Electrodes for ECG
(E) PPG Sensor
(F) Charge contacts
(G) Magnets for charge cable holding

Figure 5 – Back view of Bracelet

6.3 Charging the bracelet

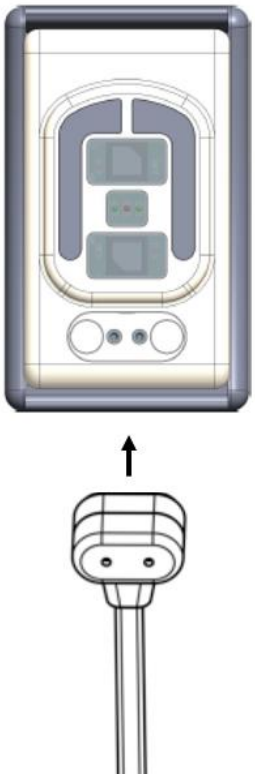


Figure 6 – Charging view

Attach the charger cable to the backside of the bracelet. The magnets will pull the charger head to the bracelet.

The Magnets will click the charger into position. The LED will light up to indicate that charging has started.
While charging, the Bracelet will not perform any measurement.

The polarity of the magnets in the bracelet and the charger will ensure that the charger contacts will align.

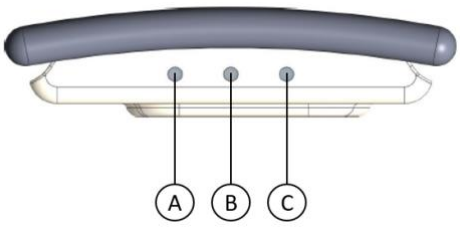


Figure 7 – Bracelet side view

LED	Pattern	State
Green (A)	Flashing	Bracelet charging
Green (A)	ON	Bracelet fully charged (when on charger)
Green (A)	OFF	Bracelet not on charger
Orange (B)	Flashing for 5 sec	Bracelet is initiating a

		Bluetooth Low Energy connection
Orange (B)	ON for 5 seconds	Bracelet connected to a Smartphone
Blue (C)	ON	Bracelet is performing an ECG measurement

When the bracelet is close to the end of its battery autonomy, the user gets a notification through the mobile APP (20% remaining).

7 USING YOUR BRACELET WITH A SMART DEVICE

7.1 Download and install the free “CORSANO” app onto your smart device.

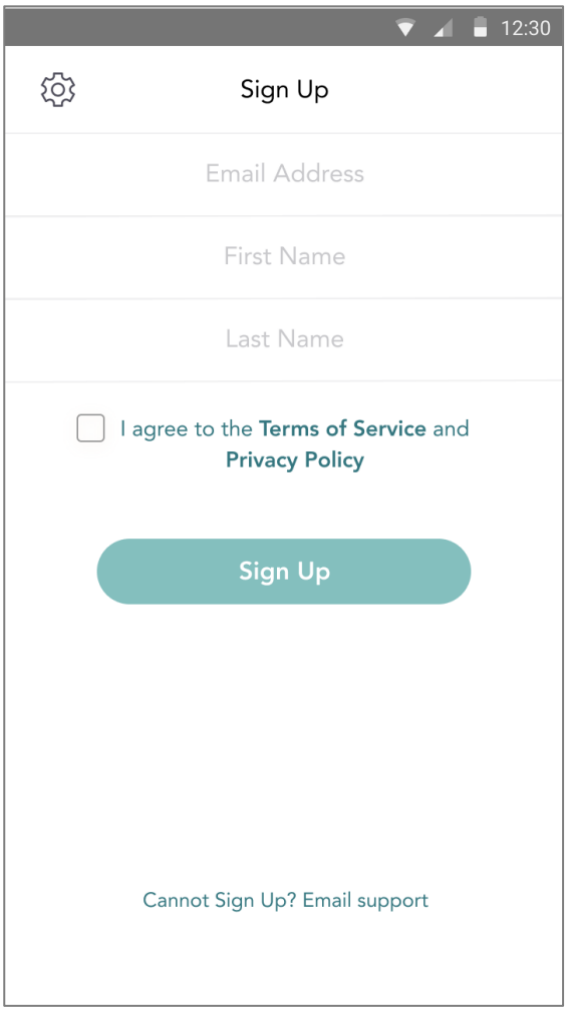
Download on the App Store

GET IT ON Google Play

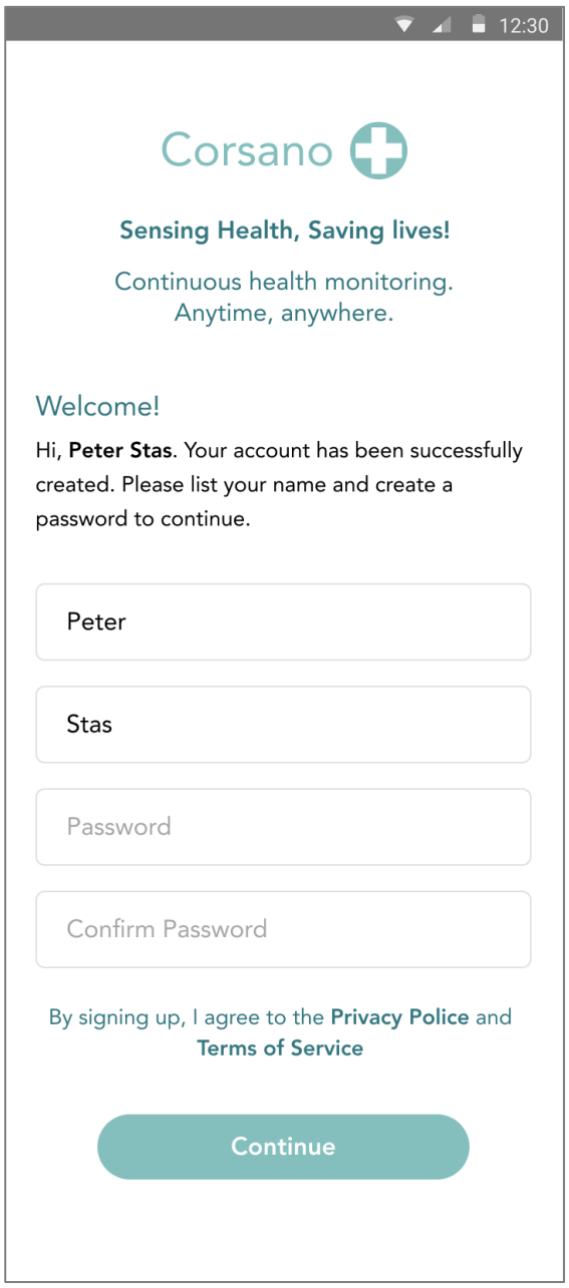
7.2 First time use

Select Sign Up (2) to create your account. If you have an account, select Sign In (1)

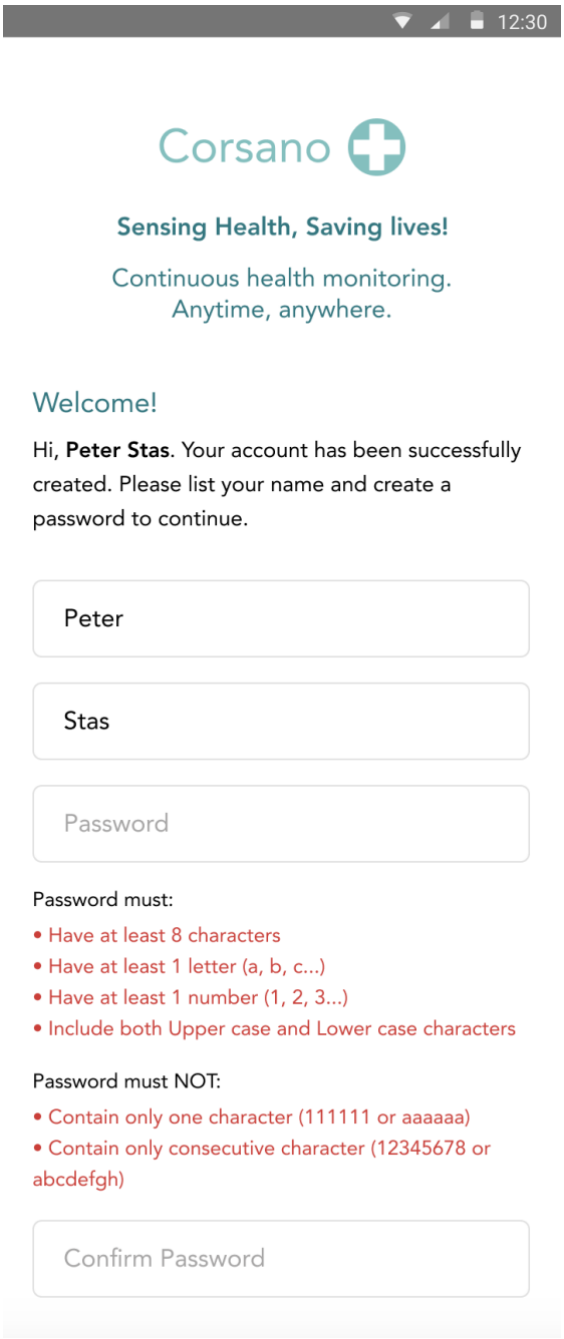
Sign Up



Enter your Email Address, First Name and Last Name. Agree to Terms of Service and Privacy Policy. Press the Sign Up button



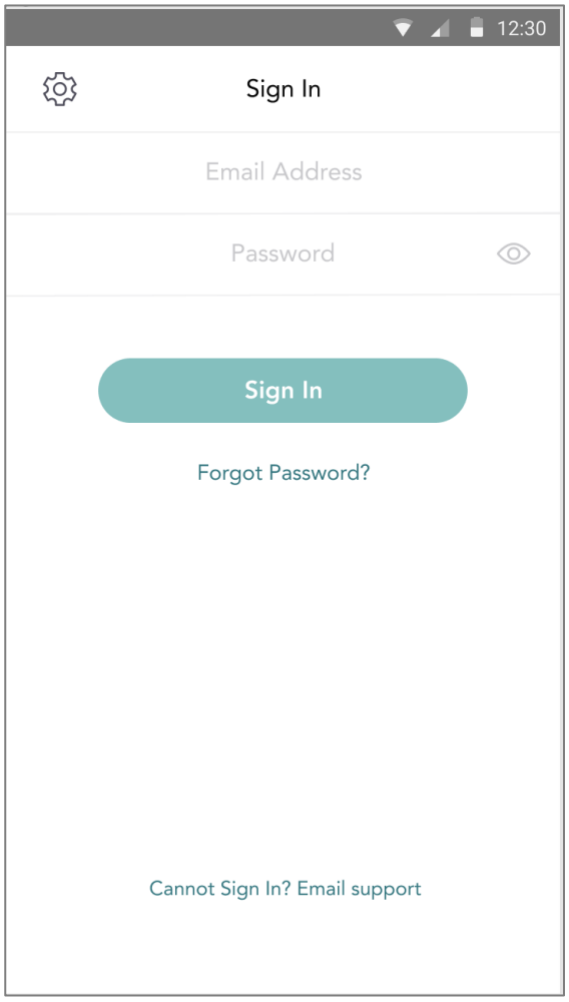
You will receive an email with a link to the confirmation page. Please fill your password and confirm password. When ready, press the Continue button.



A password should have at least 8 characters, at least one letter a, b, c…, at least one number, and both Upper and Lower case characters.

Password must NOT contain only numbers or consecutive characters

After you have signed up, you can Sign-In:



7.3 Pairing Your Bracelet with a Smart Device

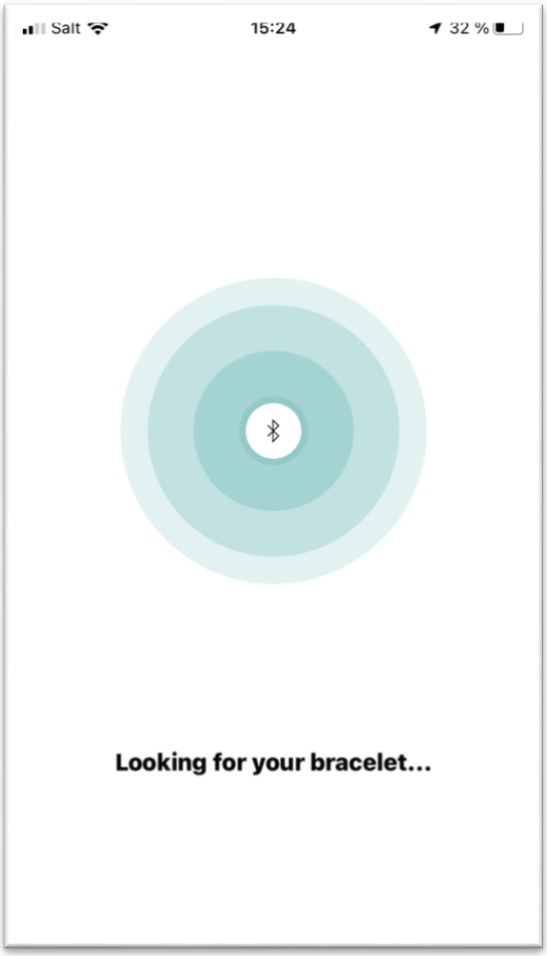
7.3.1 Pairing with the bracelet 287-2B

Upon first sign-in, user will be asked to pair a bracelet, follow the instructions:

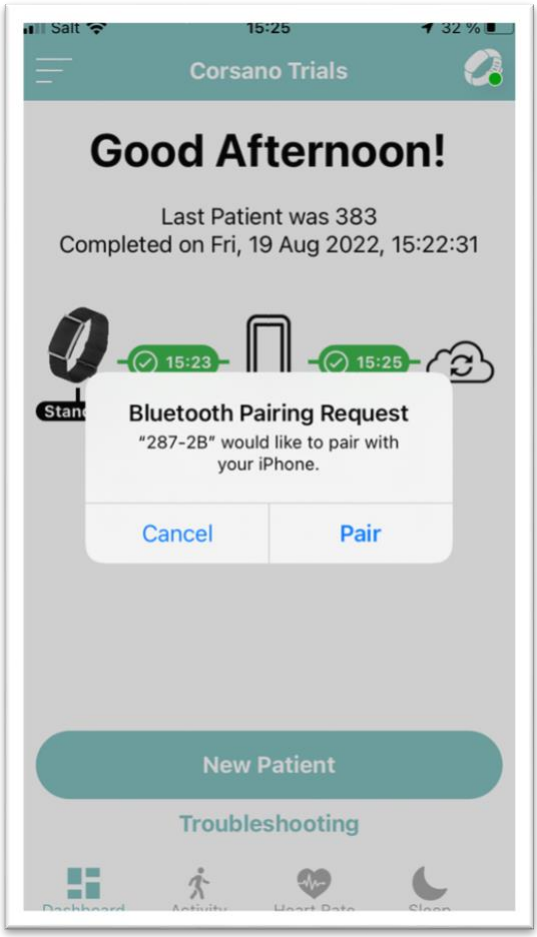
First, select “287-2B” in the list:

Press the pusher, the orange LED will flash, the bracelet is waiting for pairing.

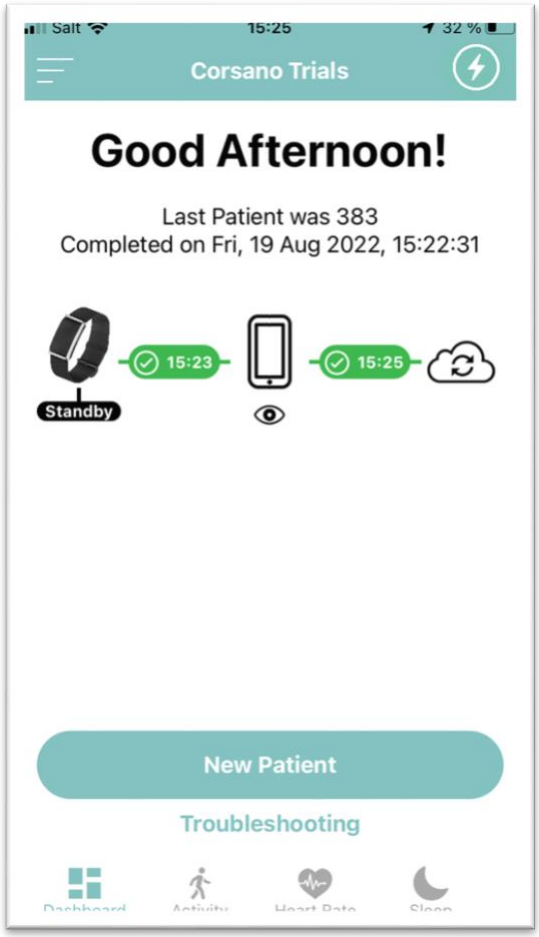
Press on button in the app to start pairing.



After button is pressed app will look for the bracelet



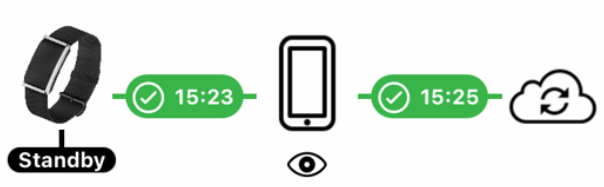
Once the device is found, confirm the pairing by pressing “Pair”. On successful pairing, the bracelet will light the orange LED up for 10 seconds and then turn it OFF.



The app is then ready to go.

Figure 8 – APP Pairing, complete

When your bracelet is connected successfully to your smart device, the green “V” symbol appears under Settings. The time of the last synchronization is also displayed.



7.4 Troubleshooting the Bluetooth Connection

If the connection between the bracelet and app is lost, a red “X” will appear:

Click on the button Please Reconnect and follow instructions:

1. Make sure your phone is nearby
2. Check if watch is charged
3. Check if GPS is on (Android only)
4. Force quit the app on your phone
5. Turn your phone’s Bluetooth off and on again
6. Re-open the app

If these steps did not reconnect, please proceed:

1. Shut down your phone (do not do restart; completely shut the phone off and turn it back on). This will fully reset the Bluetooth system in the phone
2. Turn your phone on again
3. Re-open the app

If none of the above did not resolve, you will need to re-pair your bracelet:

1. Go to watch settings: Remove/Clean old pairing
2. Go to Bluetooth settings, find 287, 286, 284 > Click Forget Device/Unpair
3. Force quit the app on your phone
4. Re-open the app
5. Press the (+) inside the watch icon in upper right corner
6. Follow pairing instructions

7.5 Troubleshooting the Cloud Connection

If the connection between the app and the cloud is lost, a red “X” will appear:

Click on the button Please Reconnect and follow instructions:

1. Make sure your phone is connected to internet
2. Force quit the app on your phone
3. Turn your phone’s Airplane Mode off and on again
4. Re-open the app

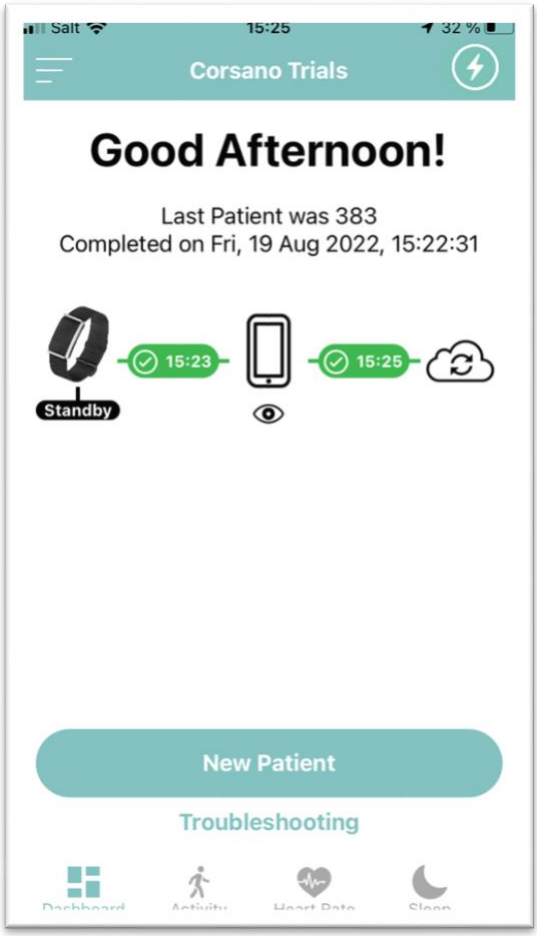
If these steps did not reconnect, please proceed:

1. Shut down your phone (do not do restart; completely shut the phone off and turn it back on). This will fully reset your phone
2. Turn your phone on again
3. Re-open the app

If none of the above did not resolve, you will need to to logout and login again to the cloud:

1. Go to profile settings and log out
2. Force quit the app on your phone
3. Re-open the app
4. Enter user and password
5. Follow instructions

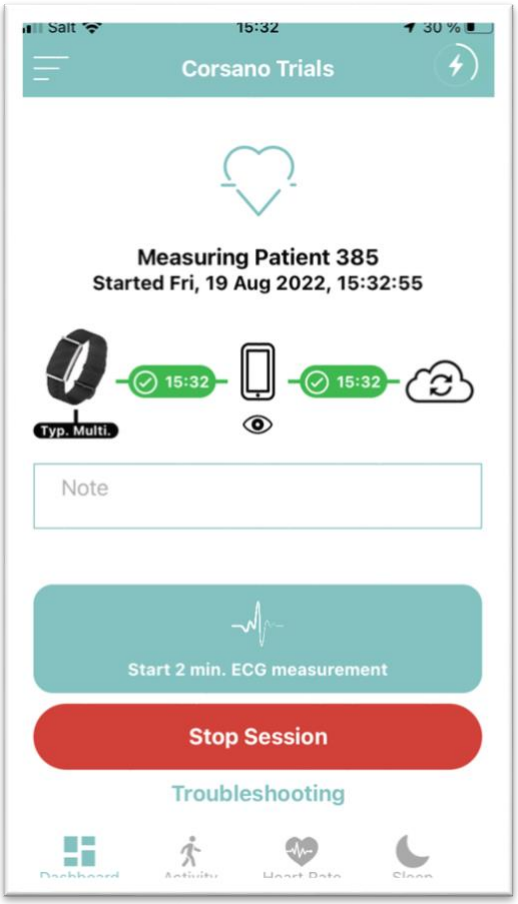
8 RECORD PATIENTS



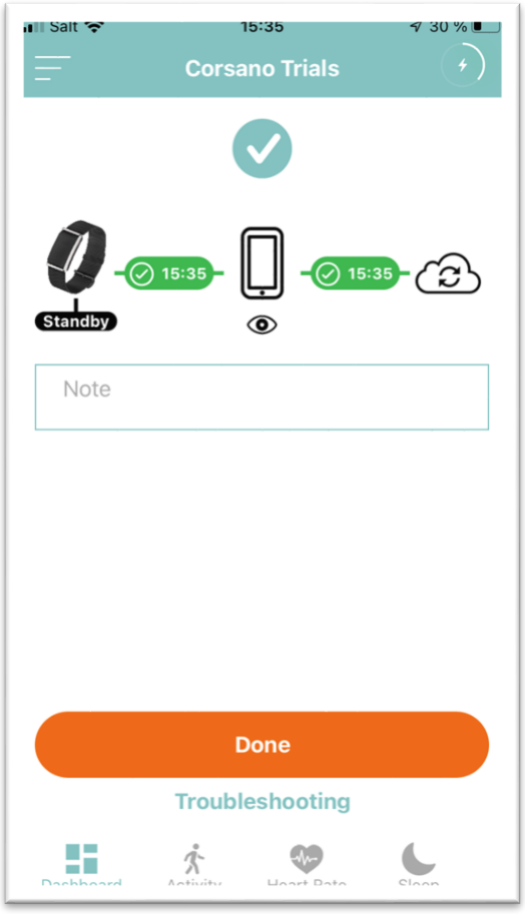
Click on “New Patient”

Click on “Start Session”

During the measurement, please do not remove the app from multitasking. The screen of the phone can be locked. Please keep an internet connection on the phone while measuring. Please keep the phone close to the bracelet (few meters maximum) when measuring.



When you want to stop the measurement, click on “Stop Measurement”



The app will stop the measurement and synchronize the remainng data present in the device.

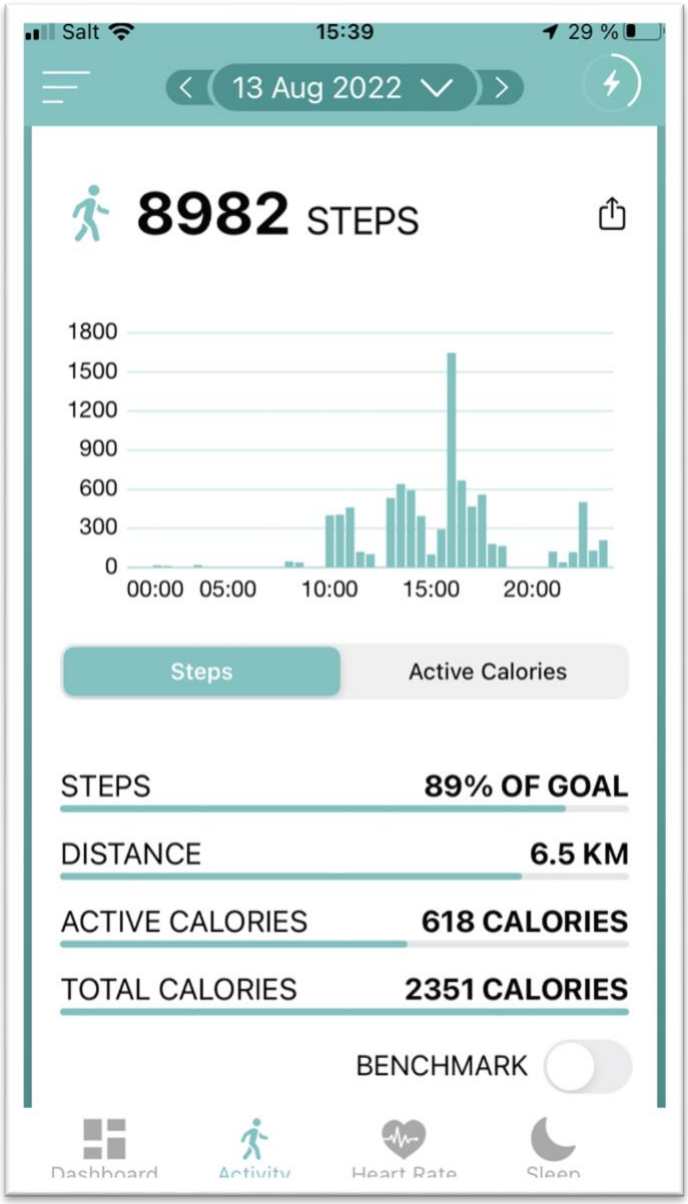
Click on “Done”

You can start these steps again to record other patients.

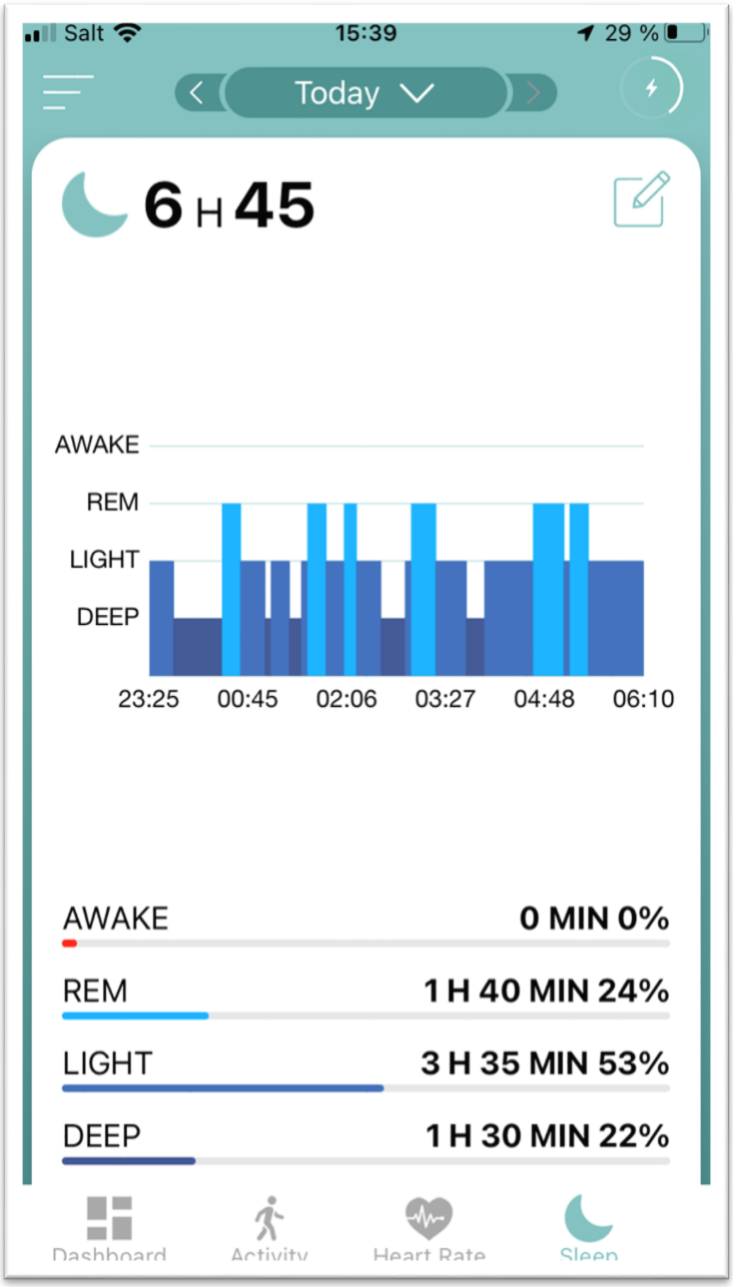
Confirm the stopping of the measurement by clicking on “Yes”:

9 NON-MEDICAL INFORMATION

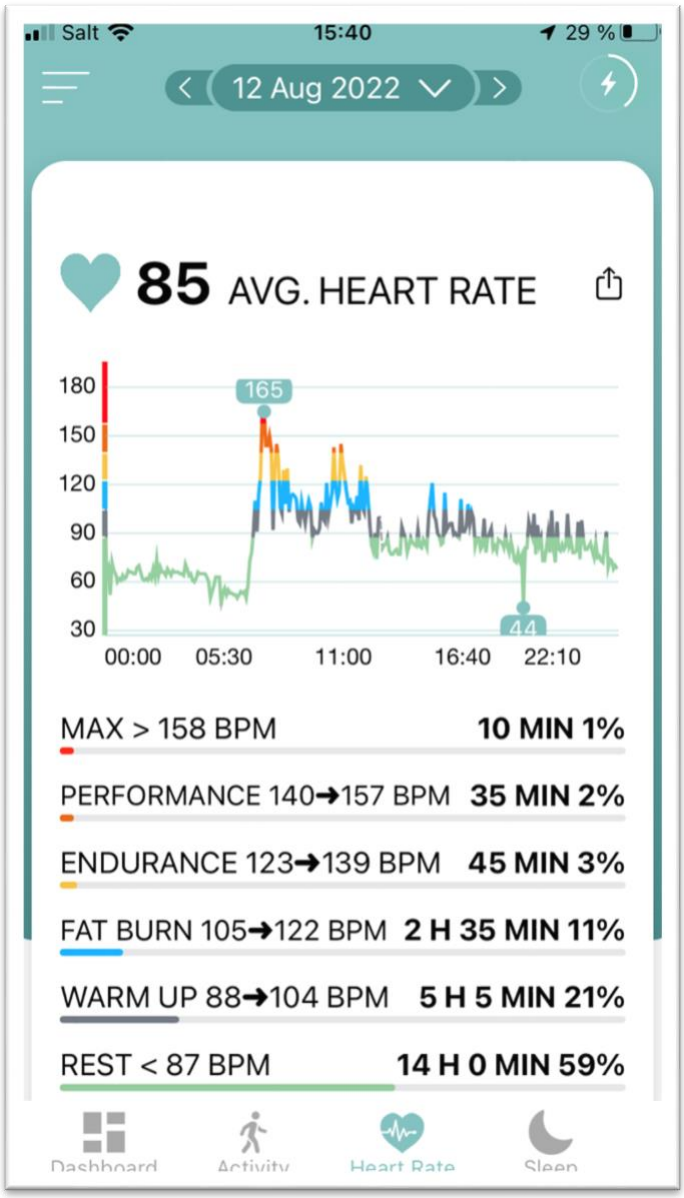
The CORSANO app provides non-medical information like Activity:



Sleep:


Salt
15:39
29 %
Today
6 H 45
AWAKE
REM
LIGHT
DEEP
23:25
00:45
02:06
03:27
04:48
06:10
AWAKE 0 MIN 0%
REM 1 H 40 MIN 24%
LIGHT 3 H 35 MIN 53%
DEEP 1 H 30 MIN 22%
Dashboard
Activity
Heart Rate
Sleep

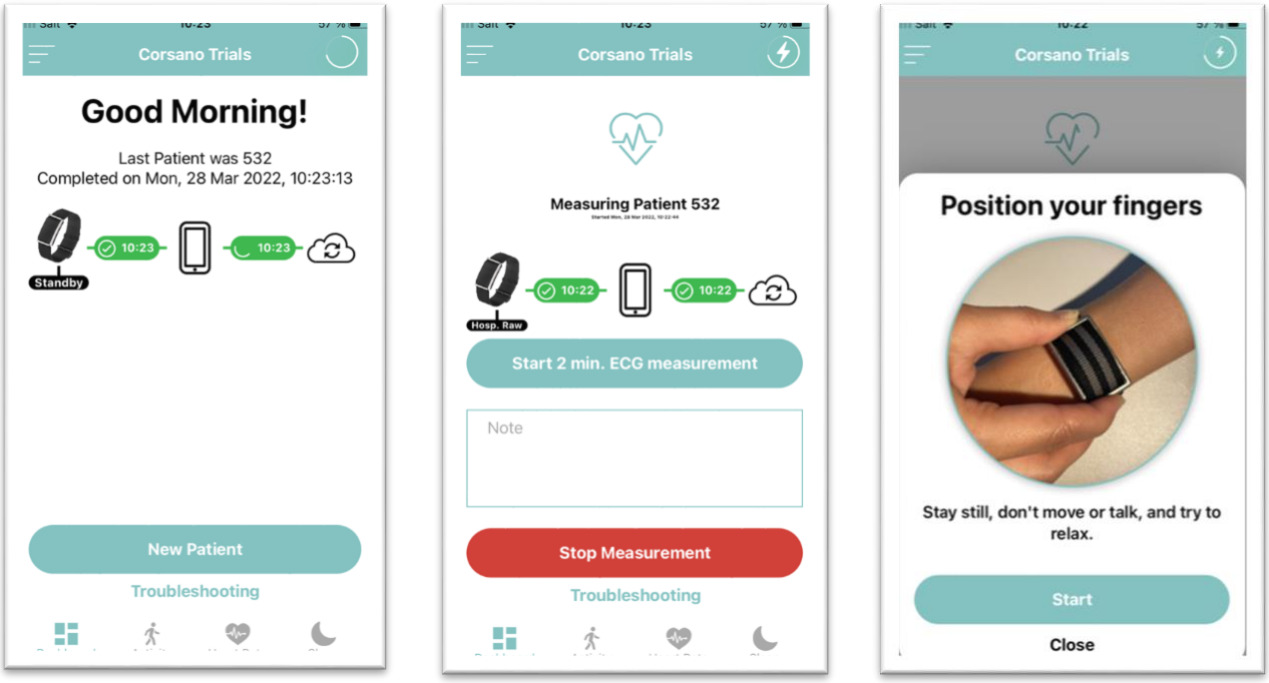
Heart Rate:



ECG:

To record an ECG, launch the measurement from the APP:

- Tap “New Patient”
- Tap “Start 2 min. ECG measurement”
- At the end of the measurement, that data is available in the cloud



The CardioWatch 287-2B is not intended for infants weighing less than 10 kg.

The CardioWatch 287-2B is not able to display pacemaker pulses.

The Heart Rate from ECG is calculated by counting the number of R peaks in 6 seconds and multiply by 10.

A pause in ECG is determined when baseline is stabilized and there is no R peak for more than 3 seconds.

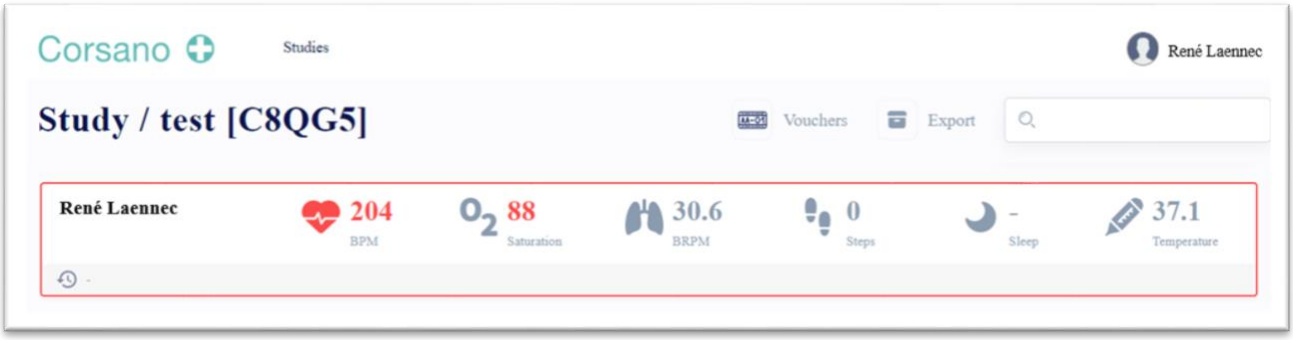
The CardioWatch 287-2B can measure ST segment shifts:

- Analysis is performed on the single lead
- No operator selectable detection criteria
- Information is displayed episode by episode
- Heart rate and displacement are reported for each episode

10 ALARMS IN PORTAL

The CORSANO TRIALS app collects metrics from the device and synchronizes to the cloud. When alarm conditions are met, data are highlighted in the patient summary page, available for the physicians to check the patients.

The delay in alarm generation depends on the synchronization time of the device data with the cloud. When the connection from the device up to the cloud is maintained, this can take up to 10 minutes. The data and alarm indication are available for the physician on the Corsano portal.

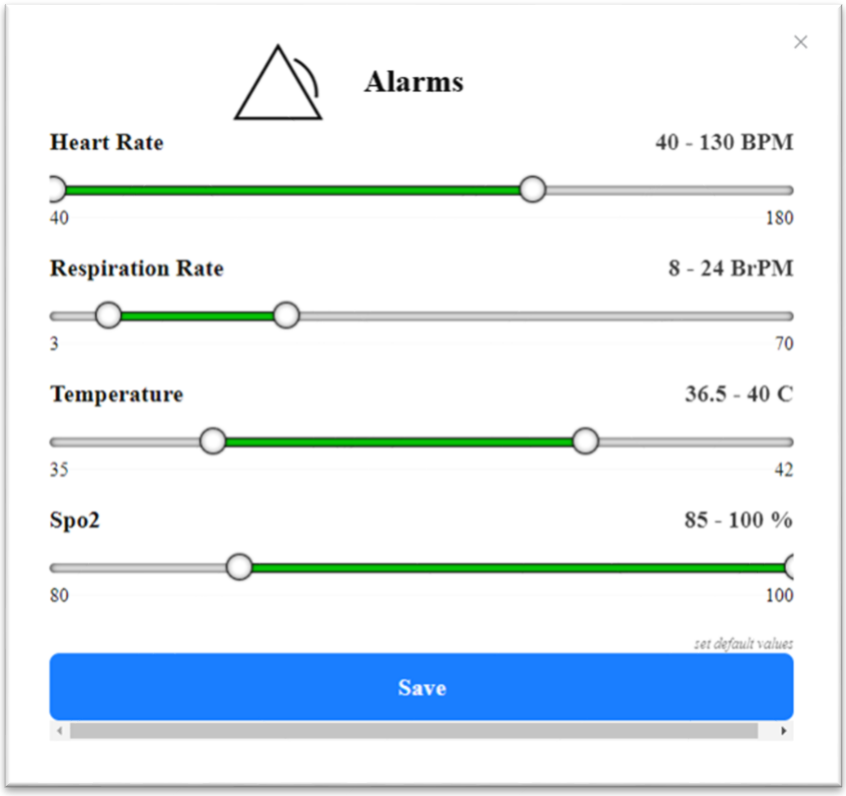


On the portal, the physicians can define the alarm levels conditions. The delay to trigger the alarm condition depends on the synchronization time of the data collection chain and can go up to 10 minutes. More if the data transmission link is broken.

Alarm limits can be defined for the following metrics:

- Heart rate
- Temperature
- Respiratory rate
- SpO2

Caution: The alarms are information to help the physicians to see if the metrics are in a pre-defined range. The system is not intended to be used in high acuity environments where the condition of the patient may require immediate action.



Caution: setting the limit values to extreme can render the alarm system useless.

Alarms and audible signals are displayed according to the priority level:

- High priority: red

Setting the alarm limits is protected by password. Only responsible persons can adjust.

11 HEALTH APP AND GOOGLE FIT INTEGRATION

The CORSANO app is integrated with the Apple Health and Google Fit apps. Information about your activities and vitals helps us provide you with a monthly (premium) personal report. You have the option of turning off the integration within the Apple Health and Google Fit apps; however, doing so will limit the information available in your personal report. The CORSANO app shares the following pieces of information with the Apple Health and Google Fit app:

- Heart Rate
- Blood pressure
- Height
- Weight

The CORSANO app collects the following pieces of information from the Apple Health and Google Fit apps:

- Active Energy
- Blood Glucose
- Diastolic Blood Pressure
- Flights Climbed
- Heart Rate
- Height
- Oxygen Saturation
- Resting Energy
- Sleep Analysis
- Steps
- Systolic Blood Pressure
- Walking + Running Distance
- Weight
- Workouts

12 CLINICAL PERFORMANCE

	Definition	Unit	Range	Acquisition Time	Update interval	Accuracy *
Heart Rate*	Number of beats of the heart per minute	beats/minute (bpm)	30-220	5-10 sec	1 sec	HR is ±4 bpm MAD, ±5% MARD (at rest)
RR Interval	Elapsed time between two consecutive heart beats	msec	300-2000 ms	5-10 sec	1 sec	RR Interval ±50 ms MAD, ±5% MARD (at rest)
Heart Rate Variability	Beat to beat (RR interval) variations	msec	0-200 ms	5-10 sec	1 sec	HRV ±10 ms MAD, ±5% MARD (at rest)
Respiration Rate	Number of breaths (inhalation - exhalation cycles) per minute	breaths/minute (brpm)	5-45 brpm	20-30 sec	1 sec	Respiration Rate ±1 bprm MAD, ±5% MARD (at rest)
Sleep Stages	Detection of specific sleep stages & sleep HR	awake, light sleep, deep sleep, REM	sleep stage	upon end of the entire sleep event	1 min	Sleep Stage ±10 % MAD
Sleep Score	Sleep performance and sleep consistency with equal weight	%	0-100%	10 sec	1 sec	Sleep Score ±5 % MAD
SpO2*	Functional oxygen saturation	% saturation	70-100%	1 min	1 sec	±4% RMSE (excl. motion and low perfusion)
Body Temperature	Temperature of the body at the measurement site	Degree Celsius	35-45°C	30 min	1 min	+/- 0.3°C

***NOTES:**

MAD=Mean absolute difference, MARD=Mean absolute relative difference, RMSE=Root Mean Square Error

Because the CardioWatch287-2 measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within Arms of the value measured by a co-oximeter.

SpO2 is calculated on a 30 second period and updated every second.

Heart rate and SpO2 measurements cannot be considered as current data because of the synchronization delay. The synchronization usually takes less than 1 minute to the APP but may take more than 10 minutes to appear in the Cloud.

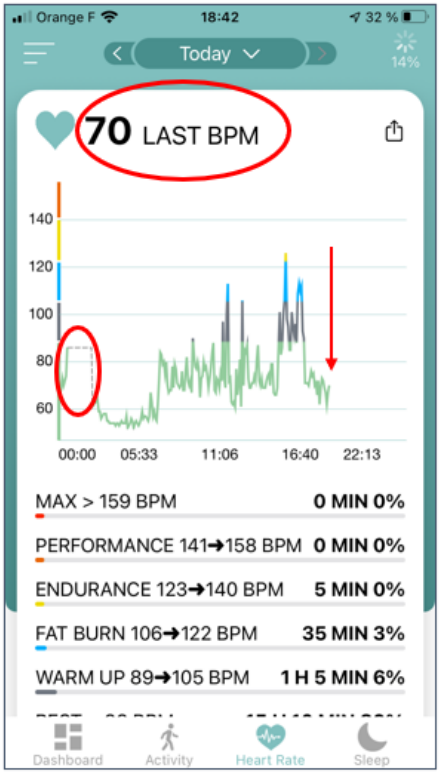
Heart rate and SpO2 alarms may be delayed and are not intended for high acuity conditions like ICUs or severe pathologies.

Heart rate and SpO2 are not normalized. They are measured with quality factor. When the values are potentially incorrect, they are not displayed. In this case, gaps may appear in the plots.

Heart rate and SpO2 was clinically validated on adults with informed consent. Functional testers cannot be used to assess accuracy. Modified Bland Altmann plots can be provided to healthcare

professional upon request.

The pulse oximeter measures the pulse rate signal and computes a quality factor. When it is not able to perform a good measurement, it cannot display a heart rate value and displays a dotted line on the Heart Rate graph.



The operation of the pulse oximeter can also be verified by using a simulator device (like the *WhaleTeq HRS200* for example).

1. Place the CardioWatch 287-2B device on the simulator device
2. Select the simulation heart rate (70 bpm for example)
3. Read the value in the Corsano Trials APP, on the heart rate graph, “LAST BPM”. (The error shall be less than ±1 bpm)

13 SPECIFICATION

Minimum requirements for mobile device Operating Systems:

- iO 12.2 or higher
- Android 8.0 or higher

PPG Sensor Characteristics*

PPG	Red, IR, Green
PPG LED/Photodiode number	7/2
PPG LEDs Peak wavelength	500-900 nm
PPG LEDs max current	128 mA
PPG sampling resolution	20 bits
Radiant Intensity 525nm*	47mW/sr
Radiant Intensity 660nm*	44mW/sr
Radiant Intensity 880nm*	35mW/sr

Motion Sensor Characteristics

Type	3-axis
Acquisition noise	1.3 mg RMS
Sensor range	±16 g full scale

Data Acquisition

PPG sampling rate	32 Hz
Motion sampling rate	32 Hz
Flash Memory Size	256 Mbit
Recording	Continuous

ECG

Sampling rate	256 Hz
Bandwidth	0.05 - 55 Hz

Power Requirements

Average current	1.2 mA
Max current consumption	100 mA
Average current	1.2
Battery type	Rechargeable
Technology	Lithium Polymer
Battery capacity (Bracelet)	140 mAh
Autonomy (Bracelet)	up to 1 week

Dimensions

Length x Width x Height	24.4 x 40.4 x 9.8 mm

Environmental Specifications

Ingress Protection*	IP66
Operational Temperature	+10 to +40 degrees C
Ambient Temperature when charging	+10 to +35 degrees C
Transport and storage Temperature	-20 to +60 degrees C
Operational Humidity	20% to 80%
Transport and storage Humidity	20% to 90%

Interface

Wireless Communication	BLE 5.0

Display LEDs .....green, orange, blue

***NOTES:**
PPG sensor are exposed on the back of the Corsano bracelet. The PPG sensor makes contact with the user's skin.
IP66: Totally protected against dust. Protected against strong jets of water.
Information about wavelength range can be especially useful to clinicians.

14 ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration - electromagnetic emissions		
The Corsano Bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano Bracelet should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Corsano Bracelet uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Corsano Bracelet is suitable for use in all establishments other than domestic and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

	IEC 60417-5333	TYPE BF APPLIED PART

Guidance and manufacturer's declaration—electromagnetic immunity			
Corsano racelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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%.
Electrical fast transient/burst IEC 61000-4-5	±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 commercial or hospital environment.
Surge IEC 61000-4-6	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration—electromagnetic immunity			
Corsano bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	NA NA	Portable and mobile RF communications equipment should be used no closer to any part of Corsano bracelet, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (m)** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz 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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	NA	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
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, an electromagnetic site survey should be considered. If the measured field strength in the location in which Corsano bracelet is used exceeds the applicable RF compliance level above, Corsano bracelet should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Corsano Bracelet. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and Corsano Bracelet

Corsano Bracelet is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Corsano bracelet can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Corsano bracelet 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 $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined 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.

15 DISPOSAL OF THE DEVICE

Once your bracelet has reached its end of life it has to be properly recycled so that the material can be reused and will not end up in the environment. Preferably bring your device to a recycling service for Waste Electrical and Electronic Equipment.

16 LEGAL NOTICE FOR FCC AND ISED

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:

- 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 technician for help.

NOTICE: This device complies with Part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s). 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.

The device can be operated at a distance of 0-20 cm or higher.

NOTICE: Changes or modifications made to this equipment not expressly approved by Corsano Health B.V. may void the FCC authorization to operate this equipment.

NOTE: L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage ;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

17 CORSANO CONTACT INFORMATION

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