

EN

CardioWatch 287-2

Bracelet & Corsano App

Instruction Manual

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1 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.

2 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.

2.1 Intended Use

The CardioWatch 287-2 is a wireless remote monitoring intended for continuous collection of physiological data in home and healthcare settings. This includes heart rate, heart rate variability (R-R interval), respiration rate, activity, sleep, ECG, SpO2, Body Temperature and Blood Pressure. Data is transmitted wirelessly from the device via the application or gateway to a server or health cloud where it is stored and made available for further analysis.

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

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

2.2 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.

2.3 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.

2.4 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

2.5 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.

2.6 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.

2.7 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.

2.8 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 medical applications.

3 SYMBOLS

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

Symbol	Meaning
	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)
	Indicates the manufacturer's catalogue number so the medical device can be identified
	Indicates the manufacturer's serial number so that a specific medical device can be identified
	CE marking indicates that a product complies with applicable European Union regulations
	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.


4 CONTENTS / PRODUCT INCLUDES

4.1 Receiving and Inspection

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

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

Keep the Instructions for Use for future reference.

 **CAUTION:** The individual packaging contains important information, it should not be thrown away.

4.2 Contents

One bracelet CardioWatch 287-2B:



Bracelet - CW287-2B

One USB charging cable:



Charger (CS-287CH-1)

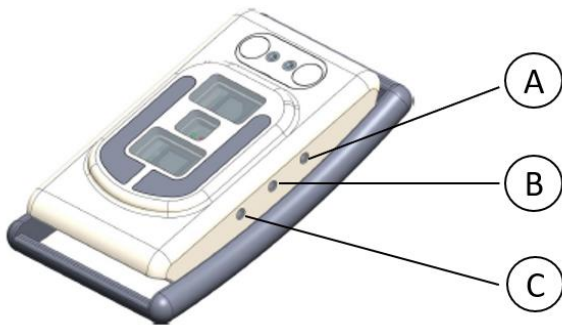
One package box with instructions:



Instruction Manual (CS-287IFUEN-2)

5 KNOW YOUR BRACELET

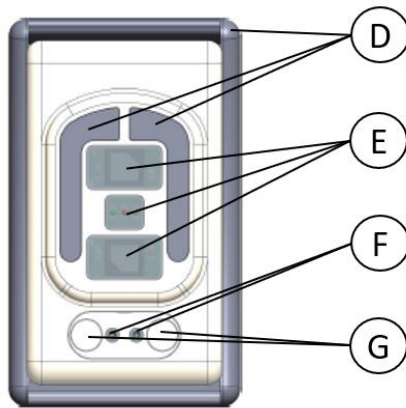
5.1 Back and Side of the bracelet



Back and Side view of Bracelet

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

5.2 Back and bottom of the bracelet



Back view of Bracelet

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

WARNINGS

- ⚠ Stop using this bracelet and consult with your Physician or Healthcare Practitioner if you experience skin irritation or discomfort.
- ⚠ To achieve the best performance of the heart rate sensor, ensure that the bracelet is well adjusted on the wrist and not too tight so as to avoid skin irritation or injury.
- ⚠ Regardless of the measurement(s) taken or the values of the measurements made using this device, you should immediately consult your Physician if you experience symptoms that could indicate a disease, such as chest pain, chest pressure, tightness, etc.

- ⚠ You should notify your Physician or Healthcare Practitioner of any changes of your health condition.
- ⚠ The device is intended to be worn on the wrist (left or right), DO NOT use on other parts of the body.
- ⚠ DO NOT apply the wearable device on open wounds, sores, or cuts.
- ⚠ For specific information about your own heartbeats, CONSULT WITH YOUR PHYSICIAN.
- ⚠ Ensure that this bracelet has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change may lead to an inaccurate reading.
- ⚠ The bracelet is IP66 water resistant, which means it is protected against dust and powerful water jets. Patients may shower with their bracelet.
- ⚠ Repair of the device may only be carried out by the manufacturer otherwise the correct functioning of the device may be compromised.
- ⚠ No modification of the equipment is allowed. Modification of this equipment may cause interference with other devices, injury to patient and user including electric shock, burns or death.
- ⚠ DO NOT use this bracelet for any purpose other than the intended uses.
- ⚠ This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers, or children.
- ⚠ To help avoid strangulation, keep the charger cable away from infants, toddlers, or children.

CAUTIONS

- ⚠ The device should not be placed over a tattoo - doing so may prevent calculation of an accurate SpO2 or pulse rate.
- ⚠ DO NOT drop or subject this bracelet to strong shocks or vibrations.

5.3 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. Turn off the Bluetooth® feature and/or unplug the charger when in RF restricted areas. For further information on potential restrictions, please refer to documentation on Bluetooth usage provided by the FCC.

- ⚠ **CAUTION:** If the device is removed from Bluetooth range, it will store signal data for a maximum of 24 hours. After 24 hours, the oldest data will be erased.

5.4 Charging the bracelet

Remove the device prior to charging.

Use the charger cable with a CE marked adapter with the following characteristics:

Input voltage: 100/240 V - 50hz 60hz

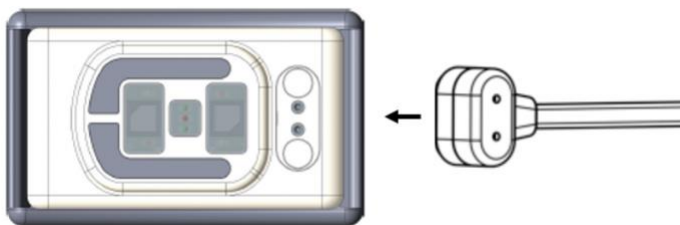
Output voltage: DC 5V (+/-5%)

Maximum current: 500 mA

Plug the charger into the appropriate USB outlet.

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

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



Charging view

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.

When unplugging the charger from the outlet, be sure to pull from the USB outlet safely without pulling on the charger cable.

Keep the charger clean and wipe any dust off of the charger with a dry, soft cloth.

Unplug the charger when not in use.

Unplug the charger before cleaning the bracelet.

WARNINGS:



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



To avoid electrical shock, inspect all cables before use. Never use cables that appear cracked, worn, or damaged in any way.

CAUTIONS:



Prevent liquid spillages onto the Charger. If the Charger is immersed in liquid, or has liquid spilled on it, disconnect it and return it for service.



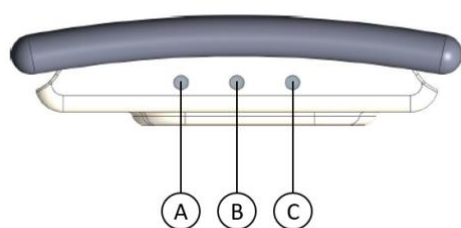
The battery charge level displayed in the user interface is only accurate if the batteries are in normal working condition.

- ⚠ Worn out or defective batteries can significantly reduce battery capacity or the operating time.
- ⚠ DO NOT use the charger if the bracelet or the charger cable is damaged. If the bracelet or the cable is damaged, unplug the charger immediately.
- ⚠ DO NOT charge the device from a multi-outlet plugs.
- ⚠ DO NOT disassemble or attempt to repair the charger.
- ⚠ DO NOT pull from the charger cable.

When handling the charger cable:

- ⚠ DO NOT damage, break, tamper with, forcibly bend, twist, or pull the charger cable.
- ⚠ DO NOT gathered the charger cable into a bundle or pinch it.
- ⚠ DO NOT place it under heavy objects.

5.5 LED Explanation



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

LED Explanation

When the bracelet is close to the end of its battery autonomy, the Patient and Healthcare Practitioner will receive a notification through the mobile APP (20%, 10% remaining). The battery level is also displayed on the Web Portal, including low level alarm.

5.6 Cleaning

The CardioWatch 287-2B Bracelet and USB Charge Cable are re-usable and may be used for more than one patient. The strap is single use and should be disposed of in clinical waste or according to local guidelines and regulations.

The re-usable components must be decontaminated following each and every episode of use and prior to being sent for service or repair. This is to ensure the safety of both patients and staff.


The term decontamination refers to a process that removes or destroys contamination. Consequently, micro-organisms and other contaminants are prevented from reaching a susceptible site in sufficient numbers to initiate infection or any harmful response.

Standard infection control precautions should be adhered to as per your local operating institution's guidelines, policies and procedures. It is the responsibility of the user to ensure that correct decontamination has been carried out.

To clean the re-usable components they should be completely wiped with detergent wipes, paying attention to all surfaces.

If there is evidence of blood or other bodily fluids, then disinfection wipes should be used. Additional precautions should be taken, and personal protection equipment used, as per your local operating institution guidelines, policies and procedures.

During usage, users should regularly check the condition of the CardioWatch 287-2B Bracelet and USB Charge Cable and clean as necessary. 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.

 **WARNING:** Do not autoclave or sterilize the wearable device or any part of the CardioWatch 287-2 monitoring system.

6 USING YOUR BRACELET WITH THE CORSANO APP

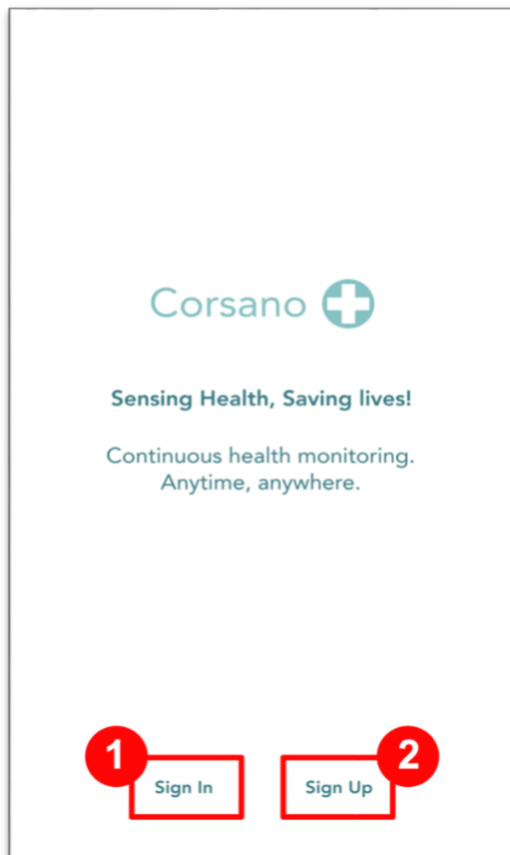
6.1 Download and install the Corsano App onto your smart device.



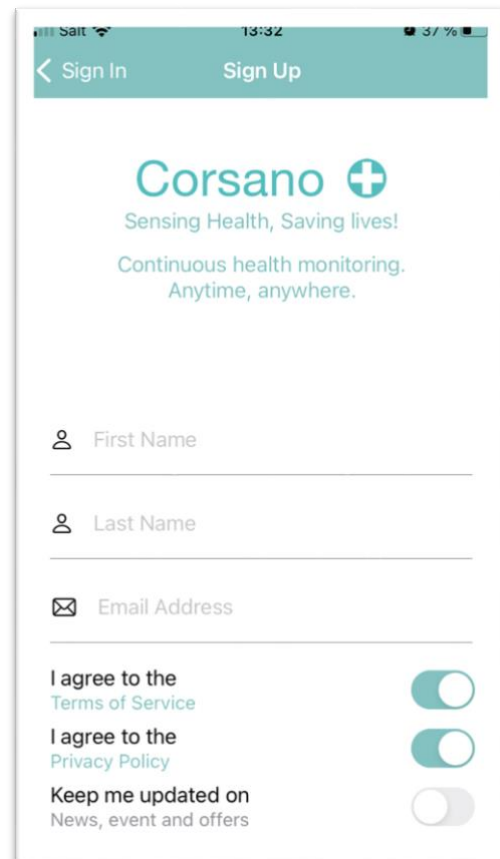
6.2 First time use – Sign Up

Select “Sign Up” to create a user account (2)

Enter First Name, Last name, Email



Choose Sign-Up



Sign-Up

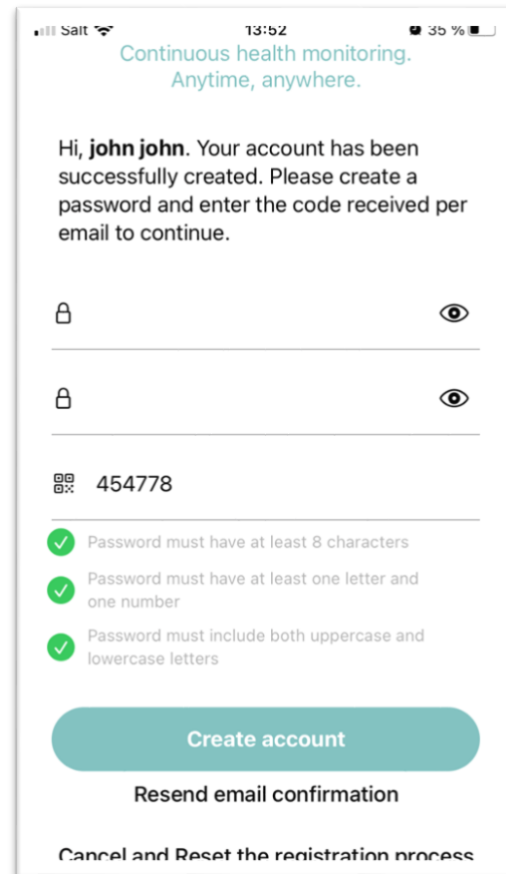
Agree on Terms of Service and Privacy Policy

An email is sent to you with a 6-digit code.

Enter:

- Your password
- Your password again
- The received code

Press "Create account"

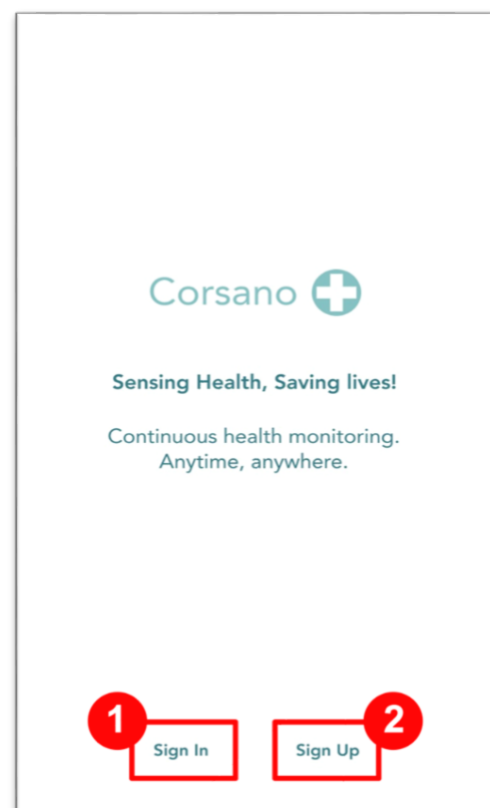


Create account

6.3 Sign In

Once you have created a user account, you can sign-in in the APP.

Select "Sign In" (1)

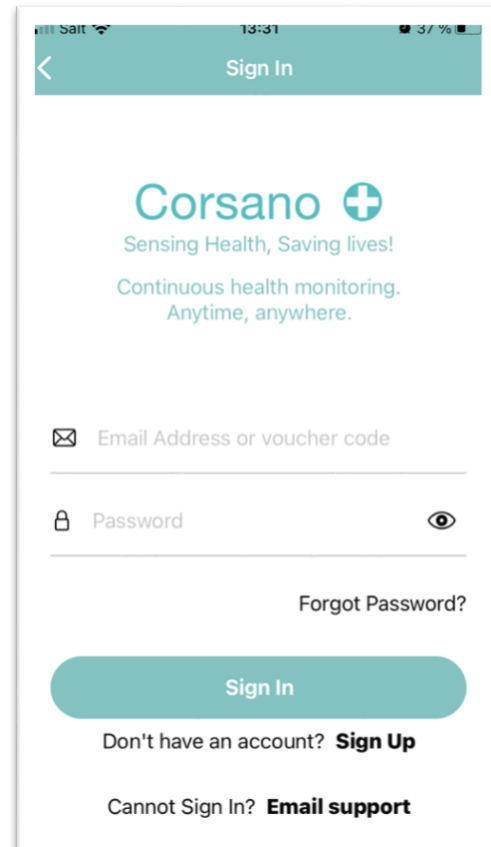


Choose Sign-In

Enter:

- Email
- Password

Press **“Sign In”**



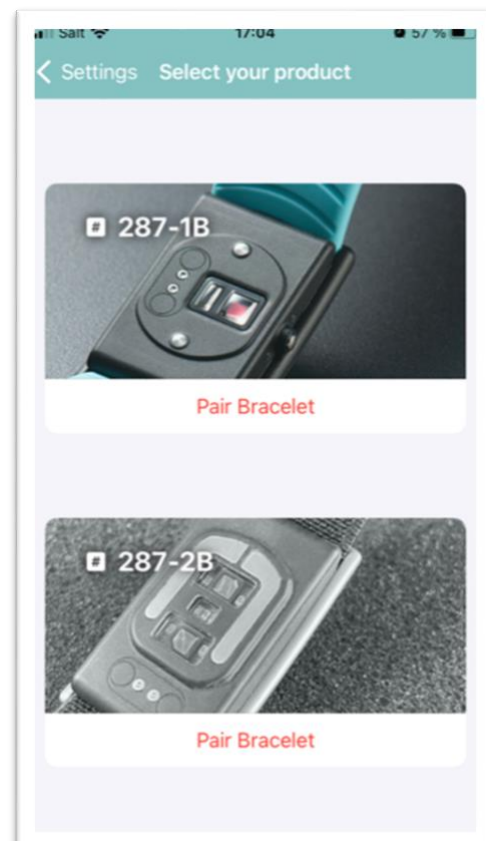
Sign-In

6.4 Pairing Your Bracelet

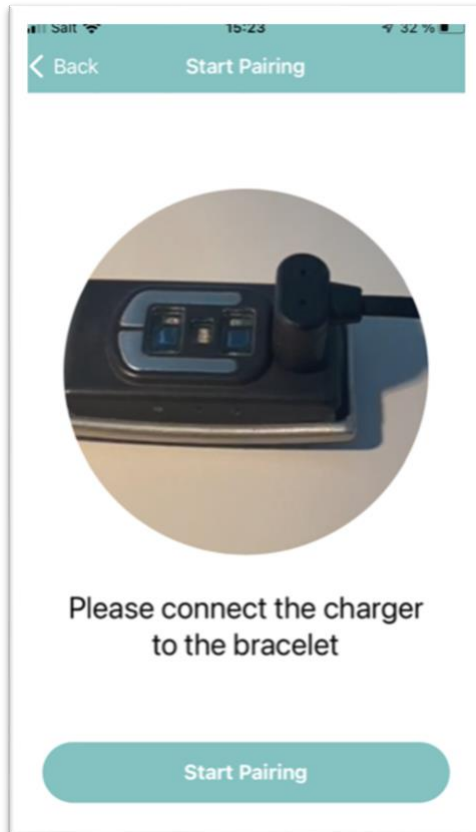
Upon first sign-in, user will be asked to pair a bracelet, follow the instructions:

First, select your bracelet in the list:

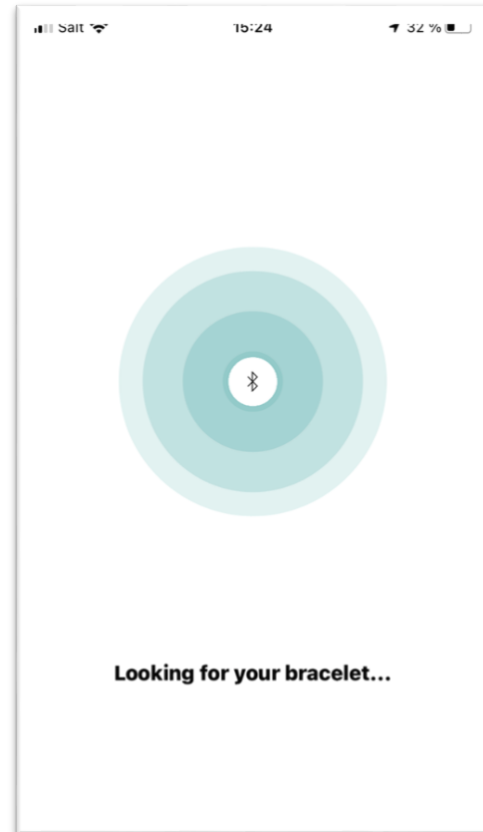
- 287-2B



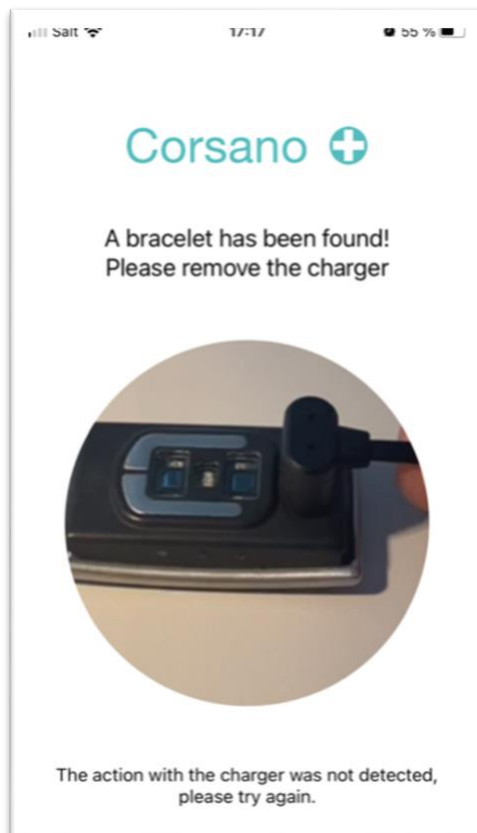
Pair Bracelet



Connect the charger and press Start Pairing



Wait for the app to find the bracelet



Remove charging cable to complete pairing

6.5 Troubleshooting the Bluetooth Connection

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



Please follow instructions:

1. Make sure your phone is nearby
2. Check if watch is charged
3. Check if GPS is on (for Android)
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 287-1B, 287-2B > 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

6.6 Troubleshooting the Cloud Connection

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



Please 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

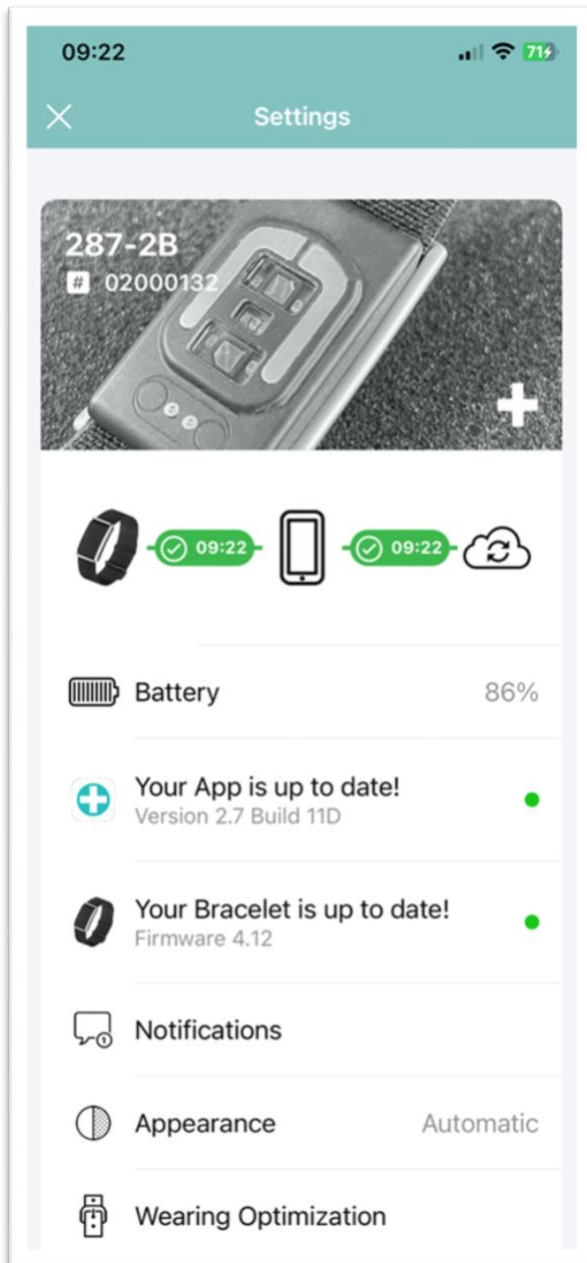
6.7 Corsano App Settings (Patient Mode)

In the App, you can open the Settings Menu by clicking on the icon on the top left corner.

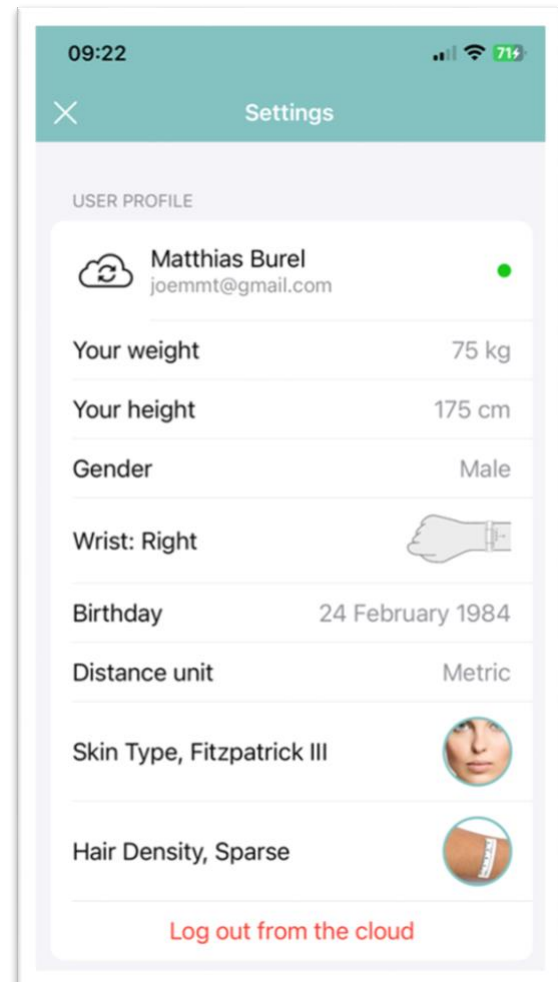
You can see the information about the app and device.

You can see your profile data and modify if needed.

These parameters are important for the measurement accuracy.



App and Bracelet Status




Profile Settings

7 APP SCREENS


By default, the Corsano App in Patient Mode does not display information.

In particular cases, the HCP may decide based on therapy, that, the Patient Mode should display trending information, for instance Patient Activity Levels (Motion & Steps) Information can be displayed to encourage the patient to be more active.

 **CAUTION:** All information displayed in the Patient App is not for diagnostics use.

The HCP can select:

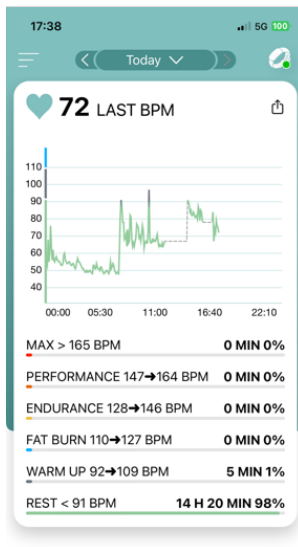
- Pulse rate (PR)
- Oxygen saturation (SpO2)
- Temperature (sTemp / aTemp)
- Activity (MOTION / STEPS)
- Respiration Rate (RR)
- Non-Invasive Blood Pressure (NIBP)
- Weight (Weight)

 **CAUTION:** the information provided to the Patient is intended to provide trending data to assist the HCP in providing patient motivation. HCP decides which information is shown to the patient based on therapy.

Such examples may include:

- Activity (Steps) to motivate patient to move sufficiently
- Tracking Temperature and take medicine on instruction of HCP in case of fever
- Non-invasive blood pressure spot-measurements data to ensure that patient:
 - has properly done spot-measurements
 - has taken medicine based on instructions of HCP
- Pulse rate to motivate the patient to exercise to an increased pulse rate (fat burn)

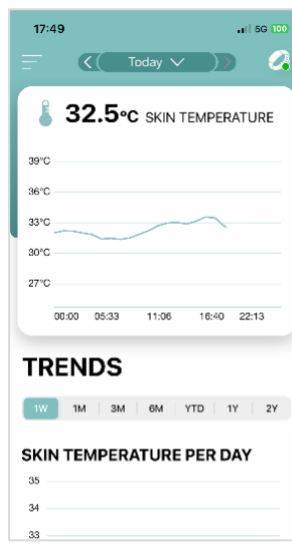
The following figure gives a summary view of the available Patient Mode Screens:



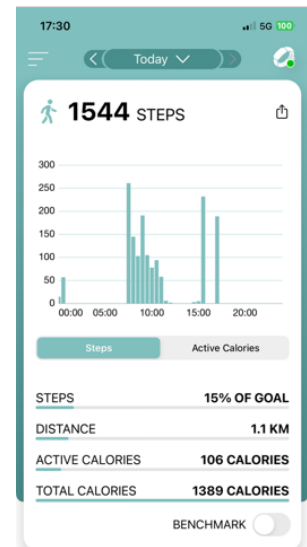
Pulse rate



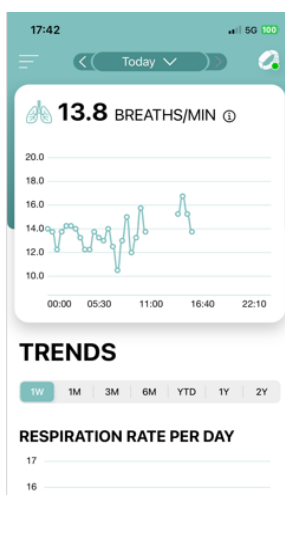
SpO2



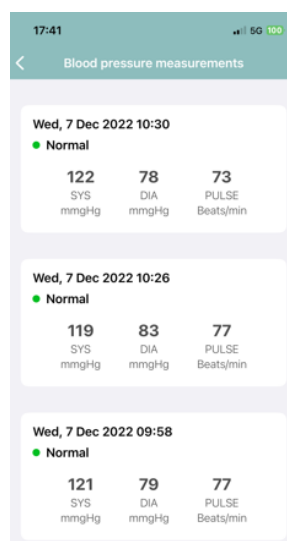
Temperature



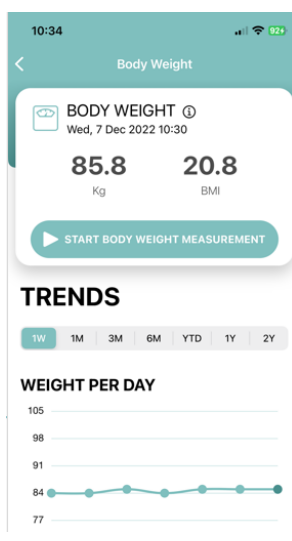
Activity



Respiration rate



NIBP



Weight



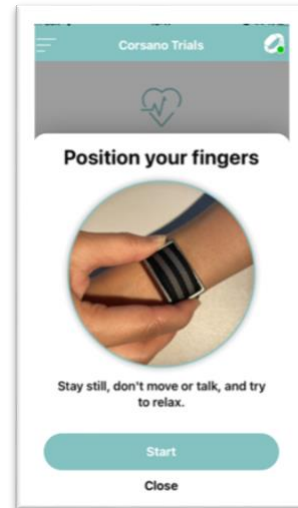
NOTE: The HCP determines which screens will be seen in the Patient App via the Configuration Panel in the Web Portal.

8 PERFORM AN ECG

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

1. Press “Start”

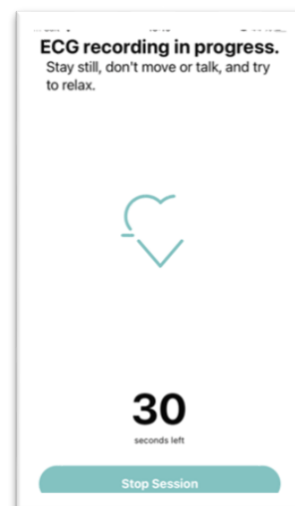
Touch the metal frame with your opposite hand, according to the picture.



2. Sit down, stay still, don't move or talk, try to relax.

The measurement lasts for 30s.

You can stop the measurement anytime, by pressing “Stop”



Notice:

- 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.

9 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

10 CLINICAL PERFORMANCE

Clinical Function	Definition	Unit	Range	Acquisition time	Update time	Accuracy *
Pulse Rate	Number of beats of the heart per minute	beats/minute (bpm)	25-250	5-10 s	1 s	1.95 bpm Arms
RR Interval	Elapsed time between two consecutive heart beats	msec	300-2000 ms	5-10 s	1 s	RR Interval ± 50 ms MAD, $\pm 5\%$ MARD (at rest)
Heart Rate Variability	Beat to beat (RR interval) variations	msec	0-200 ms	5-10 s	1 s	HRV ± 10 ms MAD, $\pm 5\%$ MARD (at rest)
Respiration Rate	Number of breaths (inhalation - exhalation cycles) per minute	breaths/minute (brpm)	4-60 brpm	20-30 s	1 s	0.91 bprpm Arms
Sleep Stages	Detection of specific sleep stages & sleep HR	awake, light sleep, deep sleep, REM	sleep stage	At the end of sleep session	1 min	Sleep Stage $\pm 10\%$ MAD
Sleep Score	Sleep performance and sleep consistency with equal weight	%	0-100%	10 s	1 s	Sleep Score $\pm 5\%$ MAD
SpO2	Functional oxygen saturation	% saturation	70-100%	1 min	1 s	1.39% Arms
Body Temperature	Temperature of the body at the measurement site	Degree Celsius	34-42°C	30 min	1 min	+/- 0.3°C

*NOTES:

MAD=Mean absolute difference, MARD=Mean absolute relative difference, RMSE=Root Mean Square Error, Arms=Accuracy root mean square

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

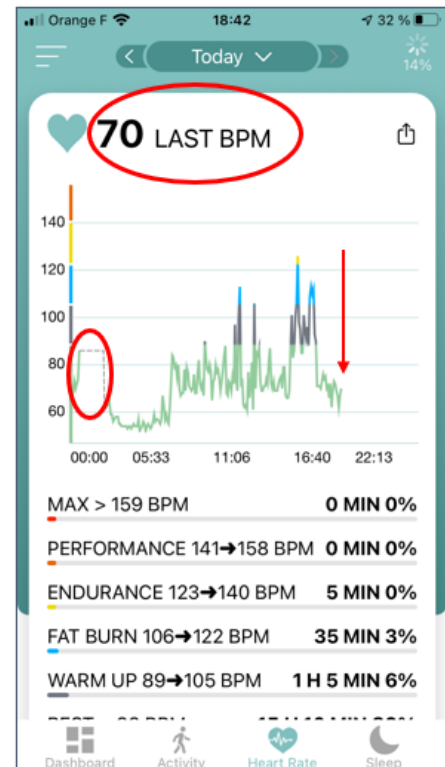
Heart rate and SpO2 are not normalized. They are measured with quality factor. When the values are potentially incorrect, they are not displayed. In this case, gaps may appear in the plots.

Heart rate and SpO2 was clinically validated on adults with informed consent. Functional testers cannot be used to assess accuracy. Modified Bland Altman 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)



11 CYBERSECURITY

11.1 Information Security Management System

Corsano Health has established an Information Security Management System (“ISMS”) in accordance with ISO/IEC 27001 (“ISO 27001”) that governs the processes required to protect company and information assets. Corsano Health utilizes the ISO 27001 Information Security (“InfoSec”) frameworks in order to identify and maintain the assets, technologies, and processes needed to protect customer information and to help ensure the confidentiality, integrity, availability, and privacy of customer data and supporting services.

To enable this, Corsano Health:

1. Aligns its InfoSec policies and procedures to the global industry standard ISO 27001
2. Achieves a robust InfoSec framework for the efficient functioning of the organization

While Corsano Health has taken significant steps to protect the CardioWatch 287-2 System from cyberattacks, the user has a crucial role in maintaining cybersecurity. The guidelines in this section must be followed.

The Corsano Bracelet communicates with the Corsano App through a secure Bluetooth 5.0 communication link with a state-of-the-art encryption layer. The Corsano App transmits the data to the Corsano Cloud. Communications between the Corsano Bracelet, App and Cloud are encrypted to an industry-standard.


The Corsano App can be installed on an iOS device running iOS version 14.5 or greater, or an Android device running Android version 8 (Oreo) or greater. As Apple review every application before it is allowed on the Apple App Store, the iPhone is very resilient to cyberattacks. The Google Play store reviews applications for the Android platform. The Corsano Web Portal is accessible via the Safari, Google Chrome or Microsoft Edge web browser. All communications between the Web Portal and the Corsano Cloud are encrypted to an industry-standard, using TLS1.2+.

11.2 About password policies, password expiration and auto-logout

A combination of username and password are used to control access to the Corsano App. The App requires that the user creates a strong password (More than eight characters, containing letters, digits, capital and small letters, at least one special character). It is the responsibility of the user to apply the appropriate password policies e.g. password complexity, renewal intervals.

Follow these general recommendations on password:

- Use a minimum password length of 8 characters
- Include lowercase and uppercase alphabetic characters, numbers and symbols
- Generate passwords randomly where feasible
- Passwords should be renewed after 90 days.

 The phone screen lock protection should be activated on your mobile phone to protect your personal health data.

11.3 About periodical software updates and patches

The Corsano App should be updated as soon as a new version becomes available. When a new version does become available, the Apple App Store in the case of iOS or the Google Play Store in the case of Android, will automatically update the app in-place. When accessing the Corsano Web Portal via the web interface, the HCP user will always have access to the most up to date version. The Corsano Bracelet firmware may require updates, if this is so you will be notified of its update as an integrated part of an update to the Corsano App.

11.4 Dealing with a lost or stolen Corsano Bracelet

In case a Corsano Bracelet is lost or stolen, please notify your Healthcare Practitioner and Corsano Health with the Serial Number of the lost bracelet.

11.5 General Guidelines for Security

1. Any mobile device with the Corsano App installed must also have a device passcode set
2. You should never disclose your Corsano username or password. No Corsano Health staff will ever ask you for these details
3. You should never write your Corsano username or password down
4. You should never provide an unauthorized user access to the Corsano App
5. You should never leave the Corsano App logged in and unattended. Please log out when you have finished using the app
6. You should never disclose protected health information within a support message to Corsano Health. This includes details like a patient's name or date of birth.

12 WARRANTY

Corsano Health warrants that components within its products will be free from defects in workmanship and materials for a period of one year from the date of purchase.

This warranty does not cover consumable items such as, but not limited to, straps.

Corsano Health shall not be liable for any incidental, special, or consequential loss, damage, or expense directly or indirectly arising from the use of its products. Liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing the affected products, at Corsano Health's option, at the factory or at an authorized distributor, for any product which shall under normal use and service appear to Corsano Health to have been defective in material or workmanship.

No agent, employee, or representative of Corsano Health has any authority to bind Corsano Health to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer or user.

THIS WARRANTY IS EXPRESSLY IN LIEU OF, AND CORSANO HEALTH EXPRESSLY DISCLAIMS, ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF CORSANO HEALTH.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments, or by any customer modification voids this warranty.

Corsano Health makes no warranty whatsoever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that the equipment or accessories which are claimed to be defective be returned when authorized, freight prepaid to Corsano Health, Wilhelmina van Pruysenweg 35, 2595 AN The Hague, The Netherlands or its authorized representative. Corsano Health shall not have any responsibility in the event of loss or damage in transit.

Corsano Health's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Corsano Health.

This warranty shall not extend to a) malfunction or damage caused by improper use or man-made failure; b) malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people; c) malfunction or damage caused by unstable or out-of-range power input; d) damage or wear and tear of straps; e) malfunction or damage of third party external devices ; f) malfunction or erroneous data provided in through any third party applications.

13 SPECIFICATION

Minimum requirements for mobile device Operating Systems:

- iOS 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
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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
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Display LEDsgreen, 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

The Corsano Bracelet and Charging cable have been tested for electrical safety and meet IEC 60601-1:2005/AMD2:2020 and IEC 60601-1-11:2015/AMD 1:2020 for devices used in the home environment.

The Corsano Bracelet and Charging cable have been tested to and meet IEC 60601-1-2:2014/AMD1:2020, are FCC qualified as a portable device and comply with the Radio Equipment Directive (2014/53/EU).


- ⚠ Portable RF communications equipment (including antenna cables, external antennas, wireless home network devices, mobile phones, and cordless phones) should be used no closer than 30cm (12 inches) to any part of the Corsano Bracelet, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- ⚠ All components and accessories are Magnetic Resonance (MR) unsafe and can pose a projectile hazard in the MR environment, and therefore, must be kept out of the Magnetic Resonance Imaging (MRI) scanner room.
- ⚠ Diathermy and electrocautery may affect the performance of the device. The device shall be removed during treatments.
- ⚠ Security systems (e.g., electromagnetic anti-theft systems (EAS), metal detectors), near-field communications (NFC) systems, wireless power transfer (WPT), Cellular 5G, may temporarily affect the performance of the device. Do not use the Corsano Bracelet and accessories in permanent close vicinity of such systems.
- ⚠ The use of accessories and cables other than those specified by Corsano, with the exception of cables sold by Corsano as replacement, may result in increased emission or decreased immunity of the device.
- ⚠ The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- ⚠ The Corsano Bracelet is a battery powered device and is not intended to be used while charging. Thus, the performance of the Corsano Bracelet was not assessed under conducted EMC event.
- ⚠ Refer to further guidance below regarding the EMC environment in which the device should be used.
- ⚠ The Corsano Bracelet uses Bluetooth Low Energy to communicate with the Corsano App to transmit the physiological parameters and has an effective RF radiated power output of 0dBm.

	IEC 60417-5333	TYPE BF APPLIED PART
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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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable (power < 50W)	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.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable (No power fluctuation)	

Guidance and manufacturer's declaration—electromagnetic immunity			
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.			
Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Compliant	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 61000-4-4	±2 kV for power supply lines	Compliant	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV, ±2 kV Line-to-line	Compliant	Portable and mobile RF communications equipment should be used no closer to any part of Corsano bracelet, including cables and accessories, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50-60 Hz	Compliant	Recommended separation distance (m) $d = 1.2 \sqrt{P}$
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	60Hz 110Vac 60Hz 230Vac 50Hz 110Vac 50Hz 230Vac	Compliant	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 6 GHz
Conducted RF IEC 61000-4-6	10Vrms 150 kHz to 80 MHz	Compliant	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 ^a , should be less than the compliance level in each frequency range ^b .
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 6 GHz, 10 V/m 80 MHz to 2.7 GHz, 28 V/m 450 MHz to 6 GHz	Compliant	Interference may occur in the vicinity of equipment marked with the following symbol: 
<p>NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people</p>			

^a Field strength 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

Corsano Health B.V.

Wilhelmina van Pruisenweg 35
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The Netherlands

www.corsano.com

