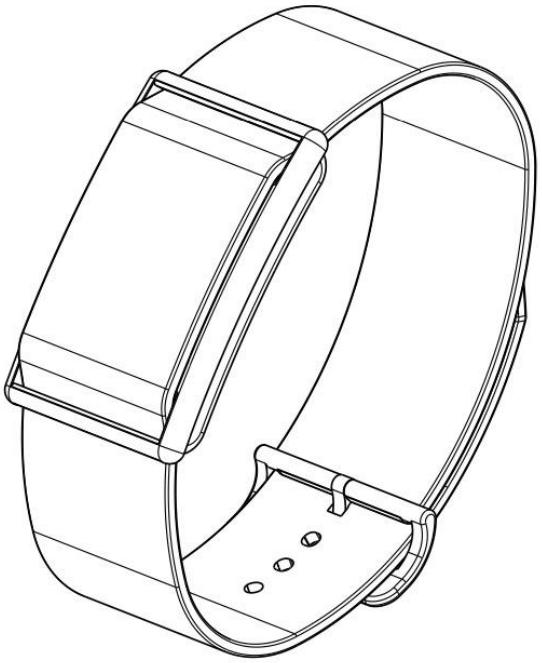
EN



CardioWatch 287-1B

Bracelet & Corsano Trials App

Instruction Manual

As of 2022-07-27 I Revision status: 10

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1 INTRODUCTION

Thank you for purchasing the Corsano CardioWatch 287-1B. The CardioWatch bracelet records raw PPG and ACC data, which is transferred to the application and cloud.

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 287-1B 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

This device is a digital bracelet intended for use in measuring pulse rate and activity in adult patient population.

Environments of Use: Hospital and Home Patient Population: Adult

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.
- 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.

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 287-1B 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.

2.9 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.

3 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

4 CONTENTS / PRODUCT INCLUDES

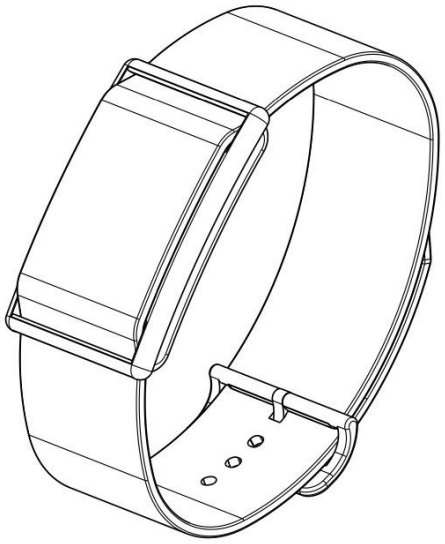


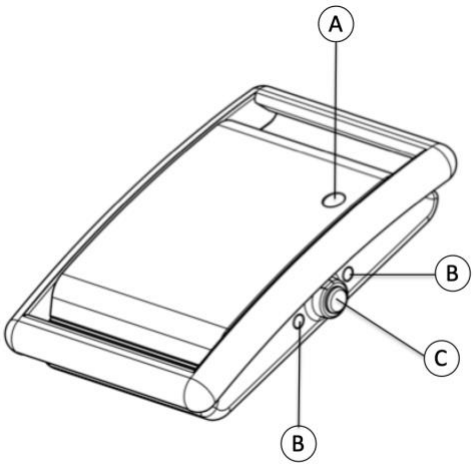
Figure 1 -Bracelet (CS-287-1B)

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

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

5 KNOW YOUR BRACELET

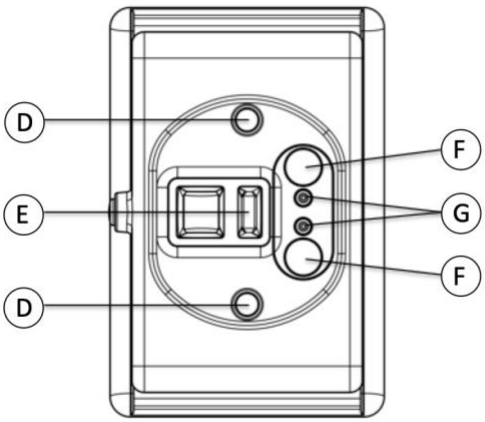
5.1 Front of the bracelet



(A) Ambient Temperature Sensor
(B) LEDs
(C) Pusher button

Figure 4 – Front view of Bracelet

5.2 Back and bottom of the bracelet



(D) Temperature Sensors
(E) PPG Sensor
(F) Magnets
(G) Charge Contacts

Figure 5 – Back view of Bracelet

5.3 Charging the bracelet

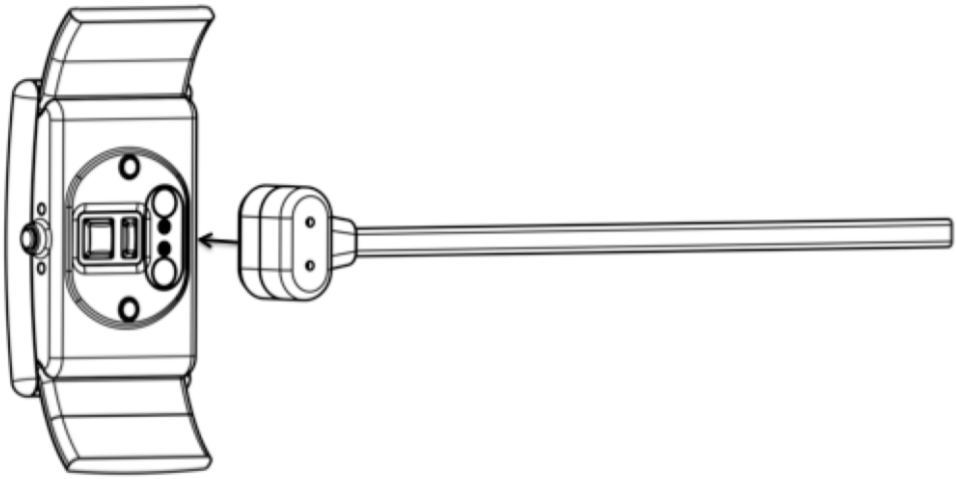


Figure 6 – Charging view

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

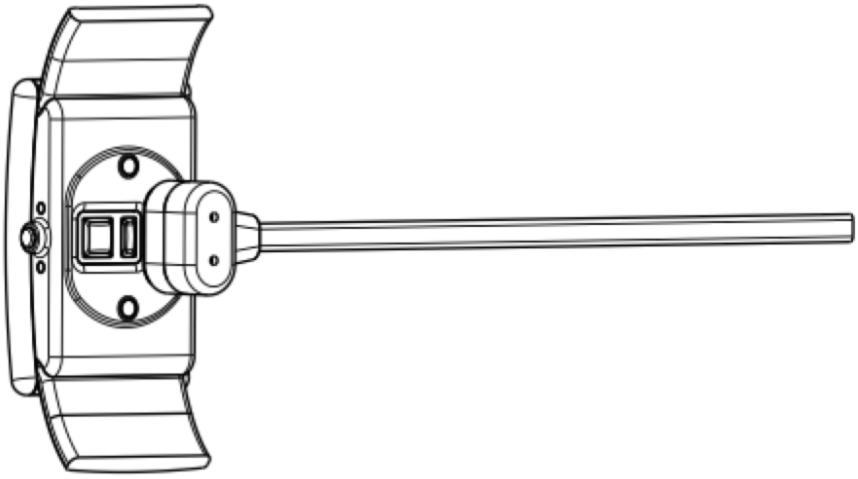


Figure 7 – Charging view – charger attached

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

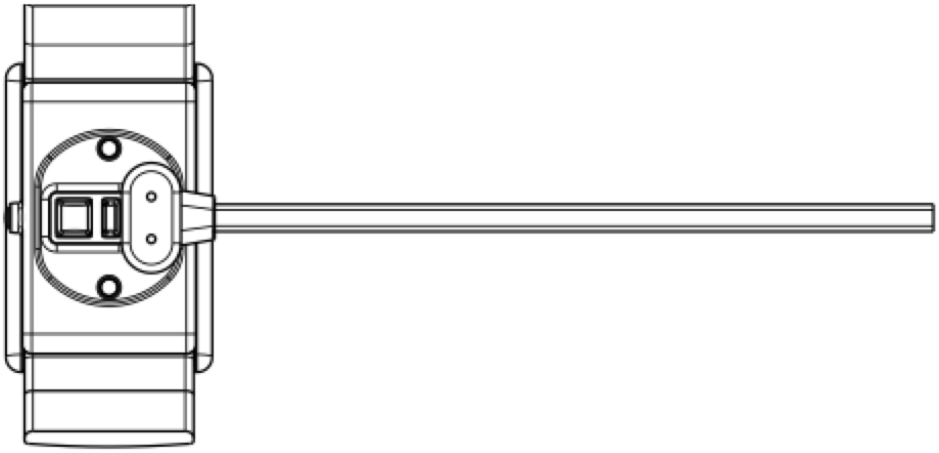


Figure 8 – Charging view – charger attached #2

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

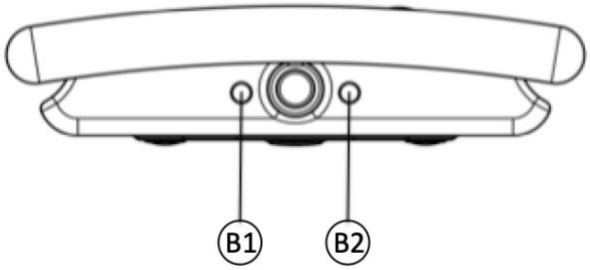


Figure 9 – Bracelet side view

LED	Pattern	State
Green (B1)	Flashing	Bracelet charging
Green (B1)	OFF	Bracelet fully charged or not on charger
Orange (B2)	Flashing for 5 sec	After the pusher is pressed, when the Bracelet is looking for the Bluetooth Low Energy connection
Orange (B2)	ON for 5 seconds	After the pusher is pressed, when the Bracelet is connected to a smartphone
Orange (B2)	ON for 10 seconds	After a successful pairing with the APP.

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

6 USING YOUR BRACELET WITH A SMART DEVICE

6.1 Download and install the free “Corsano Trials” app onto your smart device.

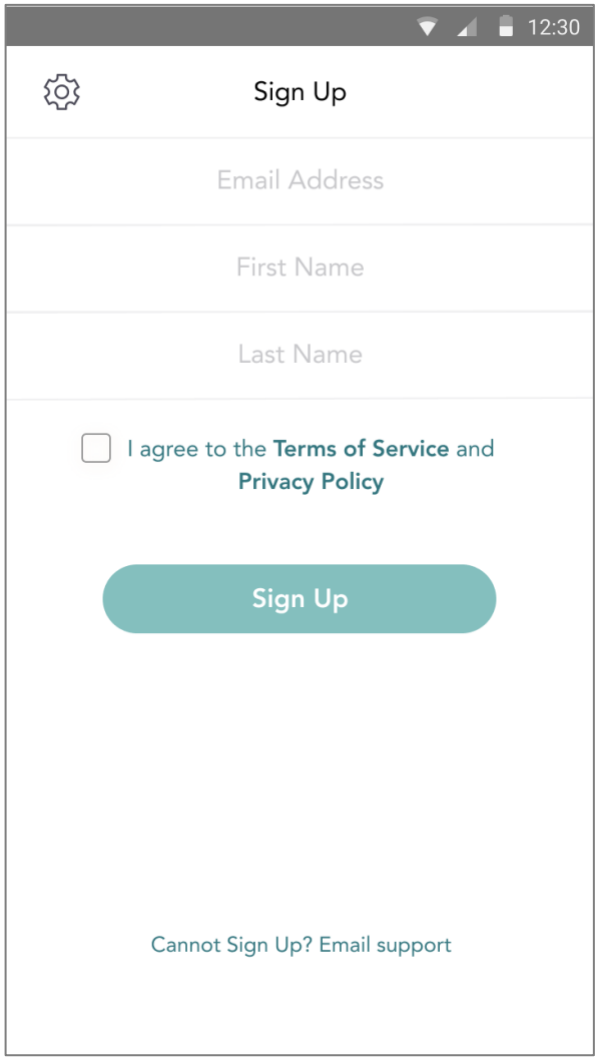
Download on the App Store

GET IT ON Google Play

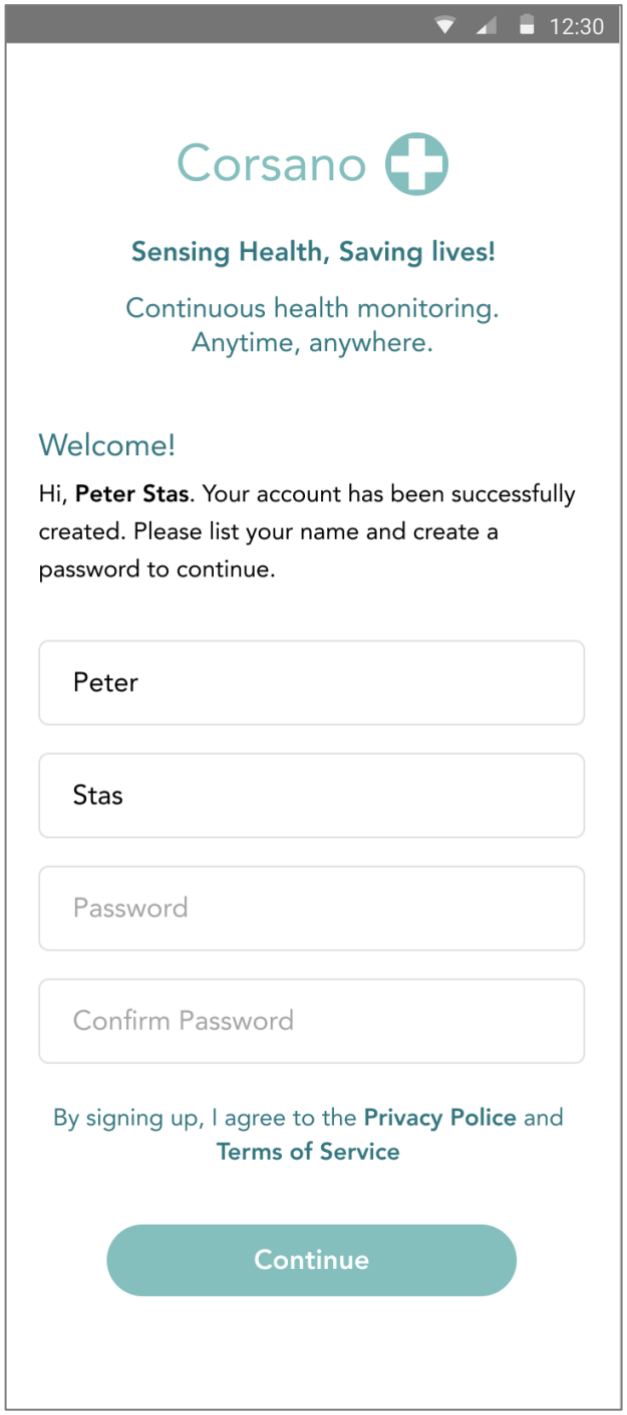
6.2 First time use

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

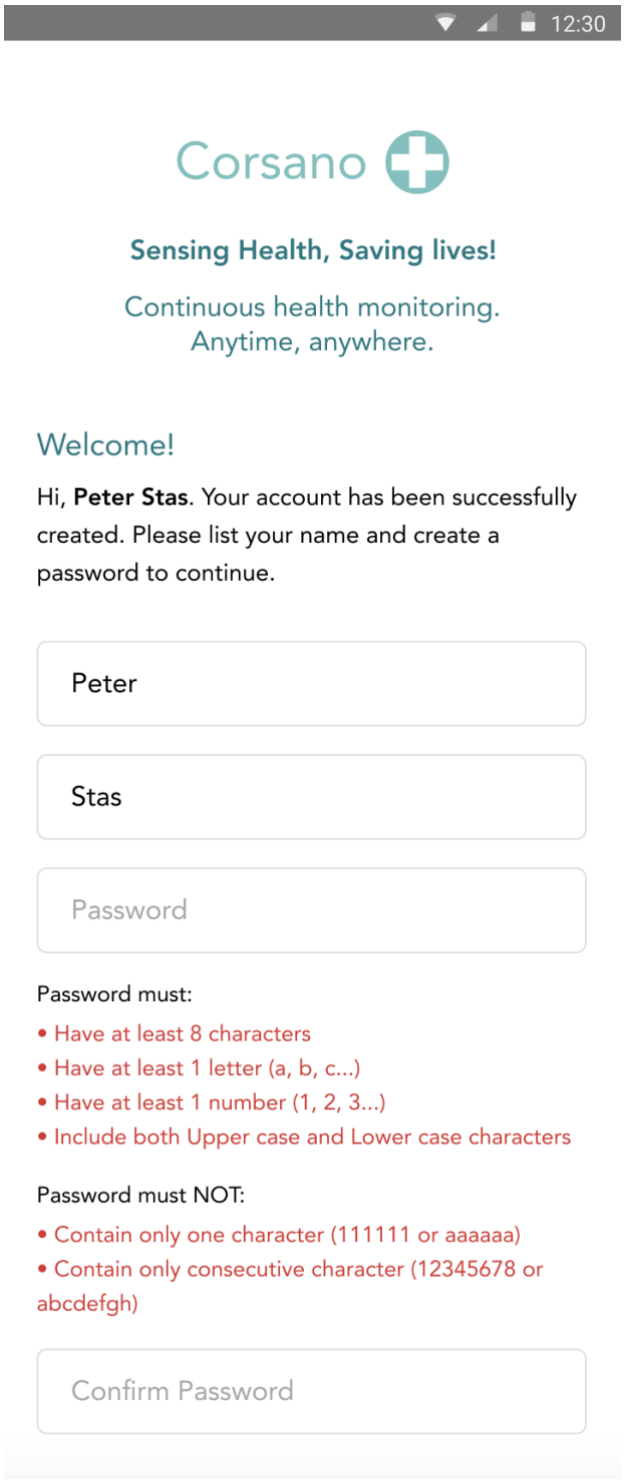
Sign Up



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



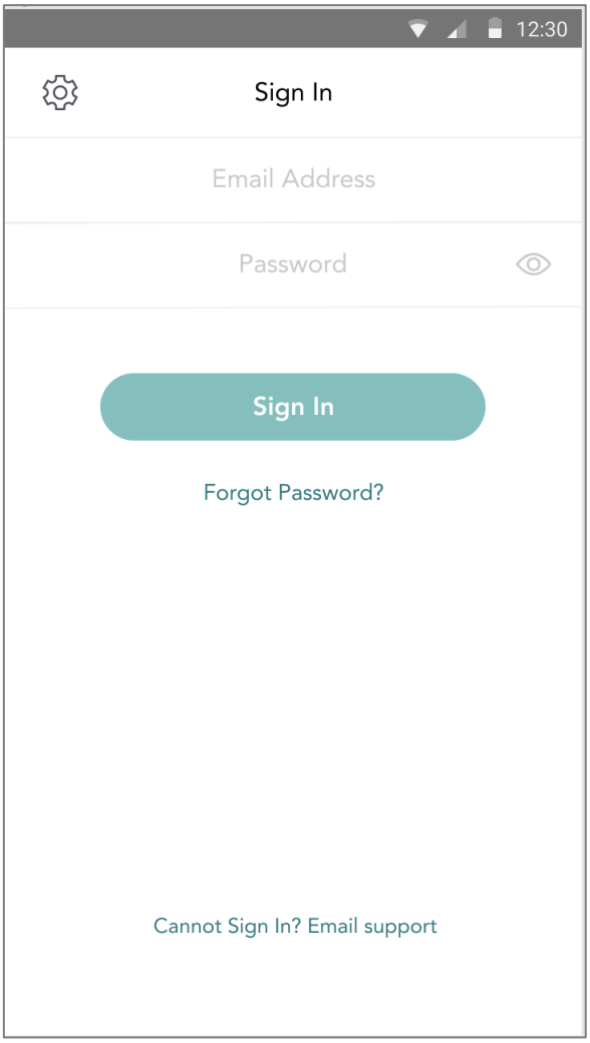
You will receive an email with a link to the confirmation page. Please fill your password and confirm password. When ready, press the Continue button.



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:

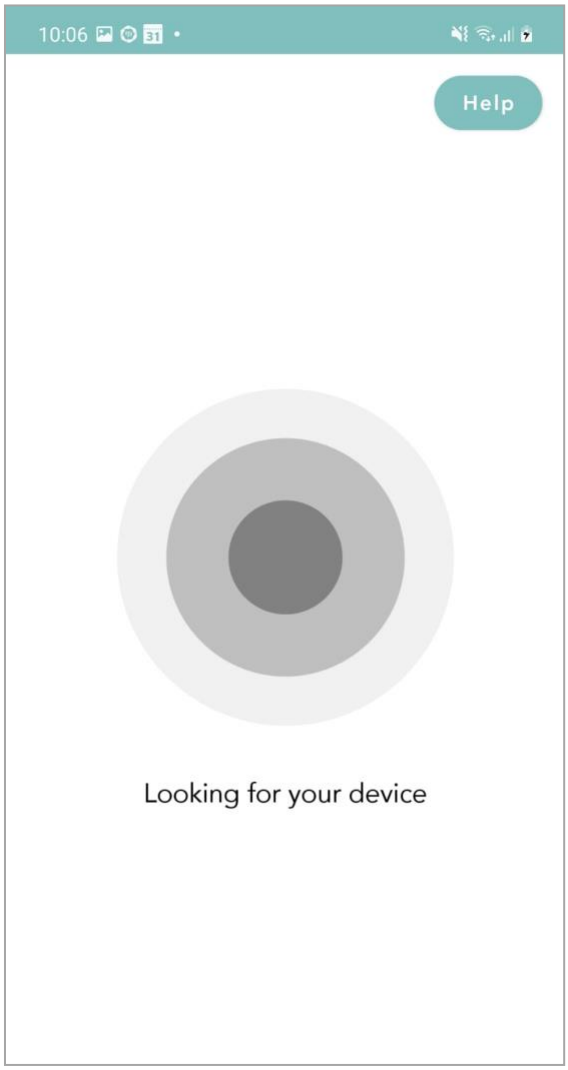


6.3 Pairing Your Bracelet with a Smart Device

Upon first sign-in, user will be asked to pair a bracelet, follow the instructions.
First, select “287-1B” in the list:

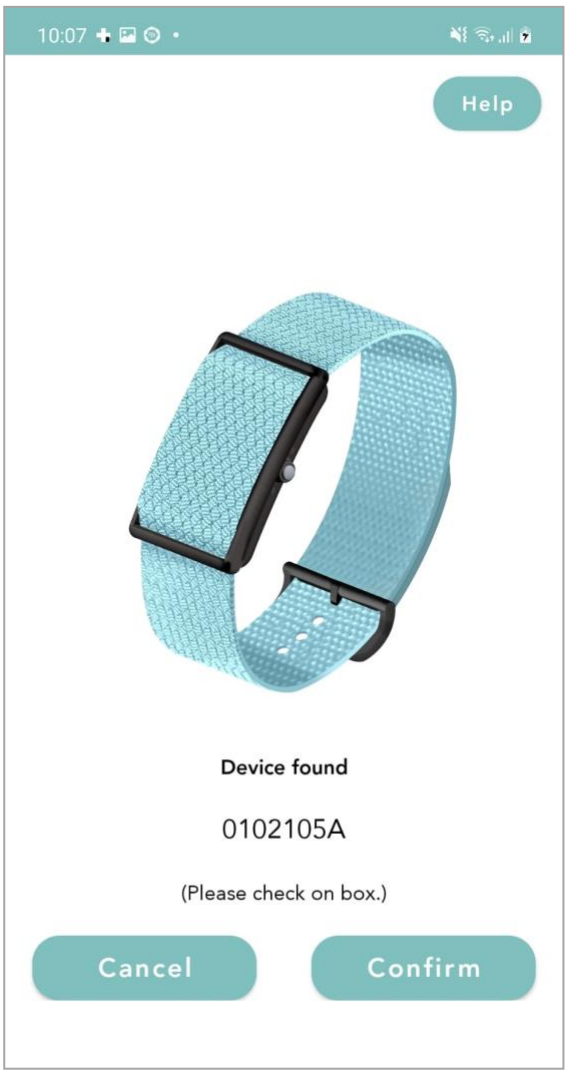
Press the pusher, the orange LED will flash, the bracelet is waiting for pairing.

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 by pressing on the pusher. On successful pairing, the bracelet will light the orange LED up for 10 seconds and then turn it OFF.



The app will display the Serial Number found. Please double check the S/N on the device and click Confirm. The devices is now paired to the app.

Figure 10 – APP Pairing, complete

When your bracelet is connected successfully to your smart device, the green “V” symbol appears under Settings:

6.4 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

6.5 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

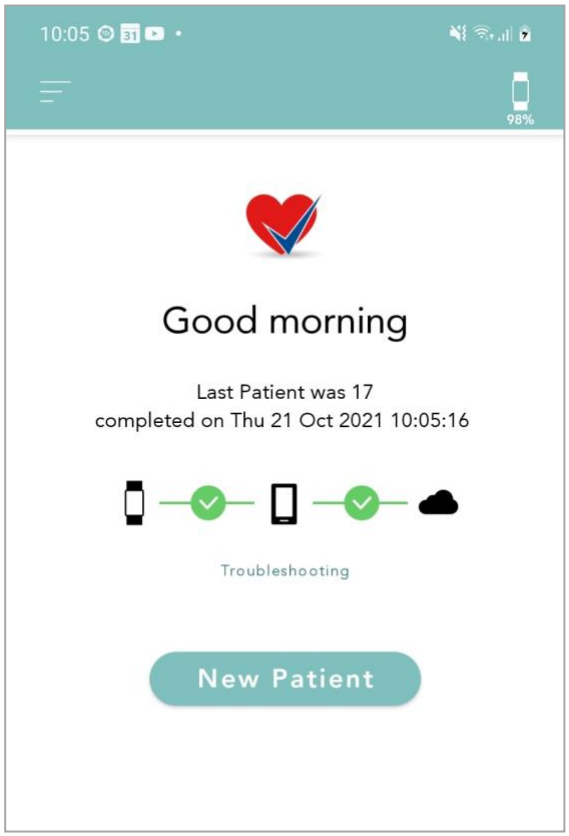
If these steps did not reconnect, please proceed:

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

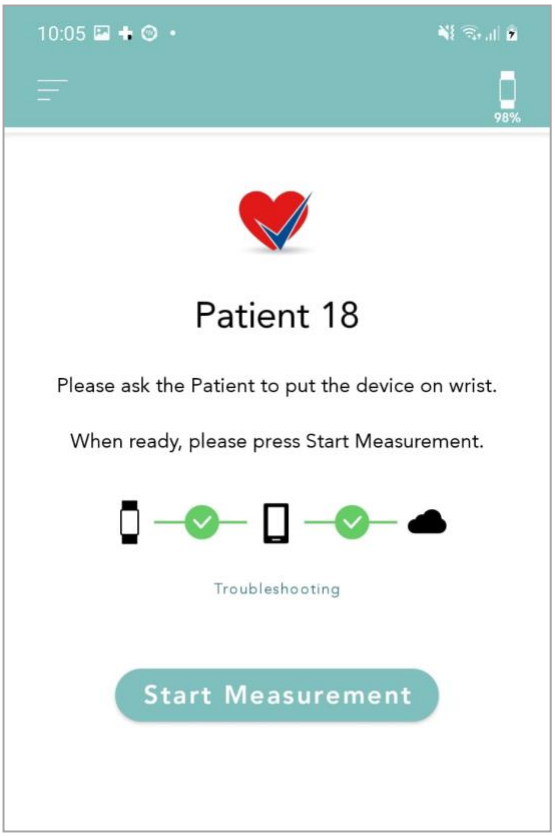
If none of the above did not resolve, you will need to to logout and login again to the cloud:

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

7 RECORD PATIENTS

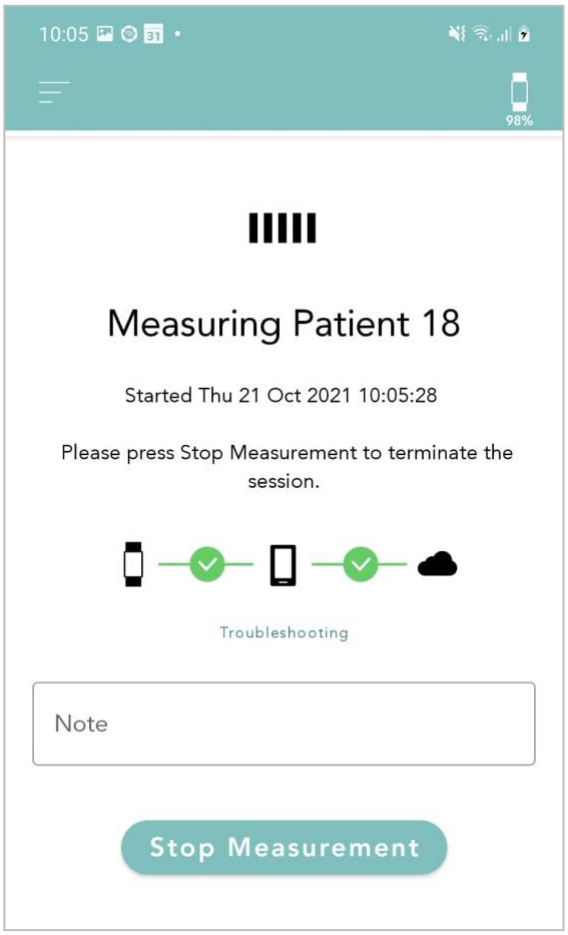


Click on “New Patient”

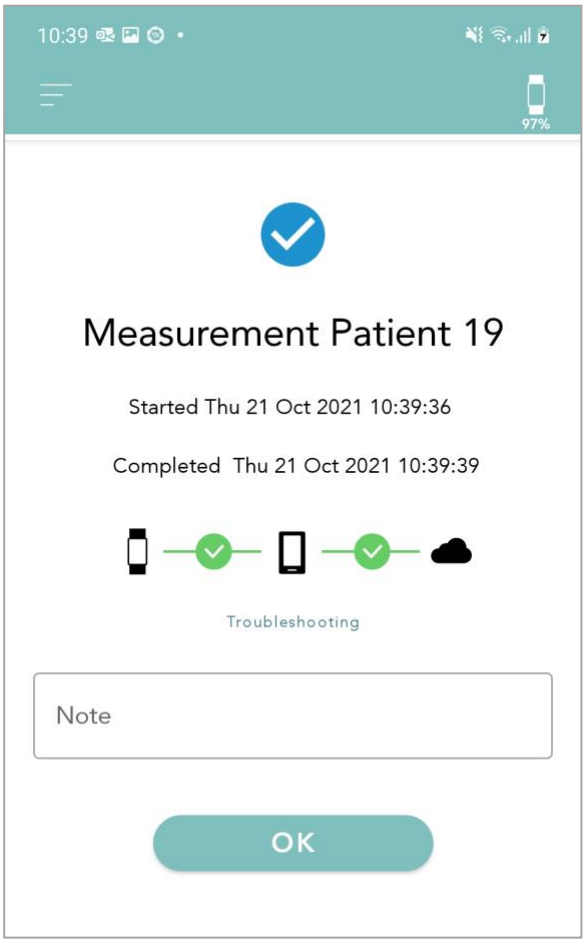


Click on “Start Measurement”

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. At this stagethe note is still editable.

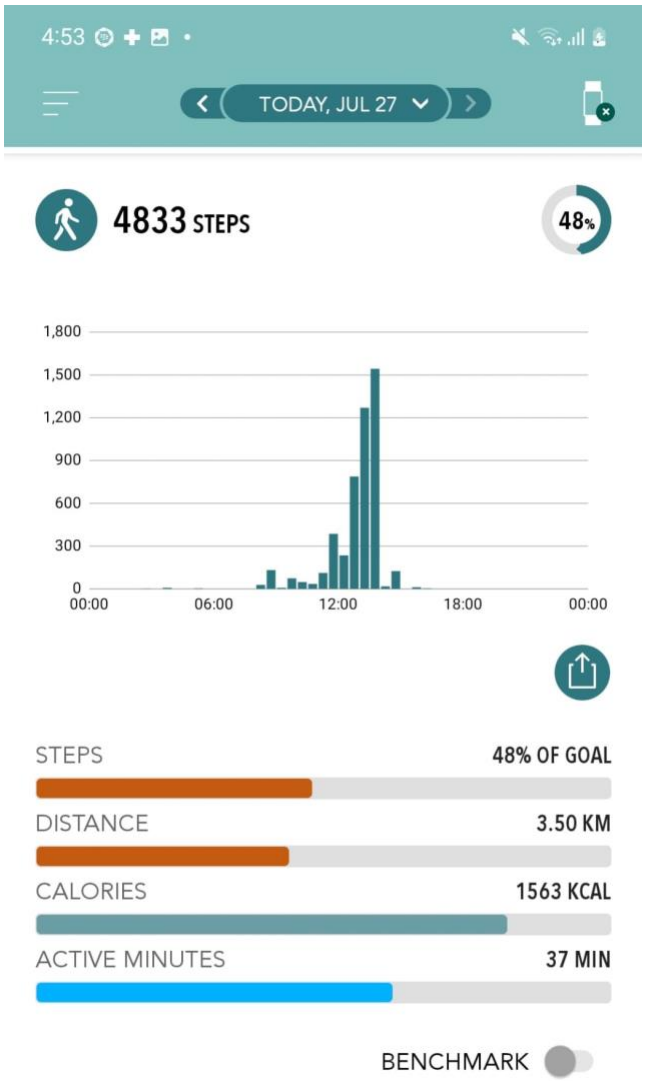
Click on “Done”

You can start these steps again to record other patients.

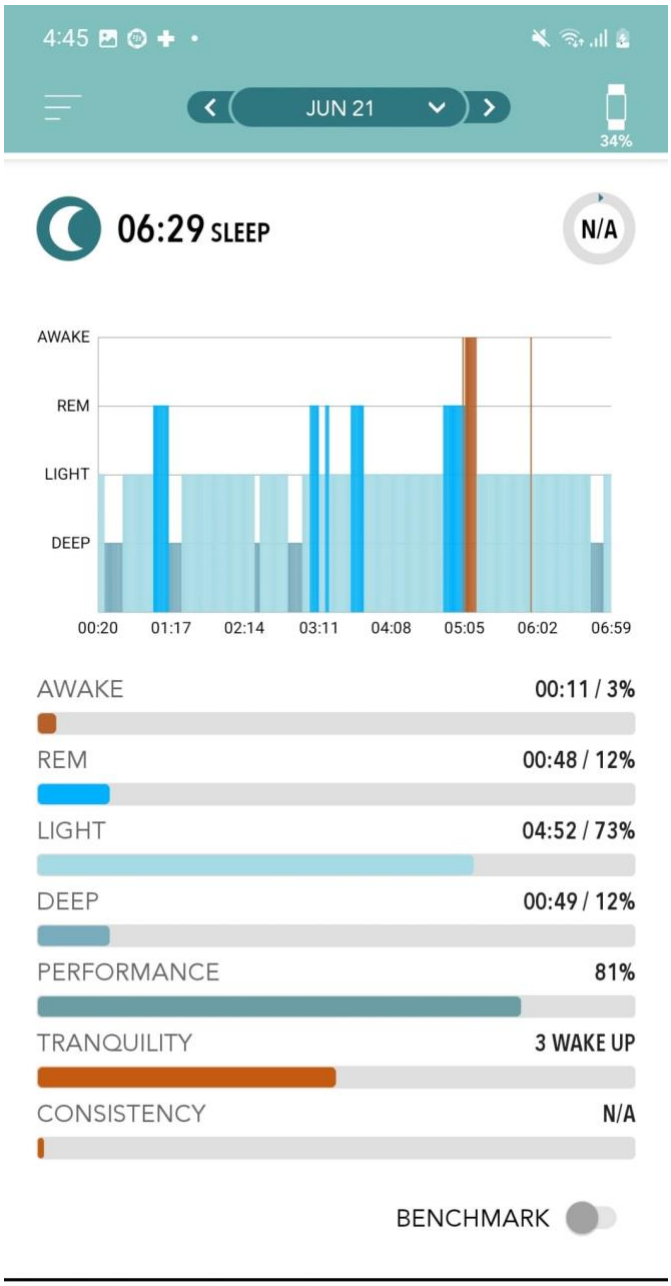
Confirm the stopping of the measurement by clicking on “Yes”

8 NON-MEDICAL INFORMATION

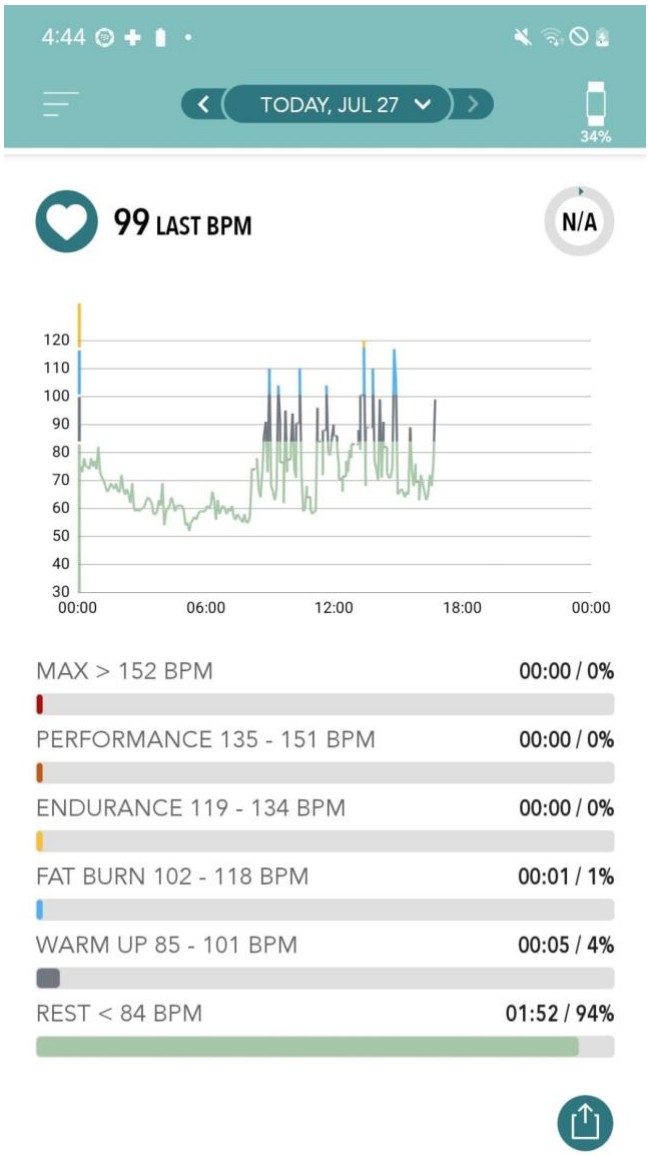
The Corsano Trials app provides non-medical information like Activity:



Sleep:


4:45
JUN 21
34%
06:29 SLEEP
N/A
AWAKE
REM
LIGHT
DEEP
00:20
01:17
02:14
03:11
04:08
05:05
06:02
06:59
AWAKE 00:11 / 3%
REM 00:48 / 12%
LIGHT 04:52 / 73%
DEEP 00:49 / 12%
PERFORMANCE 81%
TRANQUILITY 3 WAKE UP
CONSISTENCY N/A
BENCHMARK

Heart Rate:


4:44
TODAY, JUL 27
34%
99 LAST BPM
N/A
120
110
100
90
80
70
60
50
40
30
00:00
06:00
12:00
18:00
00:00
MAX > 152 BPM
00:00 / 0%
PERFORMANCE 135 - 151 BPM
00:00 / 0%
ENDURANCE 119 - 134 BPM
00:00 / 0%
FAT BURN 102 - 118 BPM
00:01 / 1%
WARM UP 85 - 101 BPM
00:05 / 4%
REST < 84 BPM
01:52 / 94%

9 HEALTH APP AND GOOGLE FIT INTEGRATION

The Corsano Trials 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 Trials app shares the following pieces of information with the Apple Health and Google Fit app:

- Heart Rate
- Blood pressure
- Height
- Weight

The Corsano Trials 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

	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

Remarks: * MAD=Mean absolute difference & MARD=Mean absolute relative difference under motion

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 Pruisenweg 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	Single Channel
PPG LEDs number	2
PPG LEDs Peak wavelength	525 nm
PPG LEDs max current	30 mA
PPG sampling resolution	19 bits

Motion Sensor Characteristics

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

Data Acquisition

PPG sampling rate	25 Hz
Motion sampling rate	100 Hz
Flash Memory Size	64 Mbit
Recording	Continuous

Power Requirements

Average current	1 mA
Max current consumption	45 mA
Battery type	Rechargeable
Technology	Lithium Polymer
Battery capacity (Bracelet)	93 mAh
Autonomy (Bracelet)	up to 1 week

Dimensions

Length x Width x Height	25mm x 37mm x 9mm

Environmental Specifications

Ingress Protection	IP66
Operational Temperature	+10 to +40 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	1 green, 1 orange
User action	pusher button

PPG sensor are exposed on the back of the Corsano bracelet. The PPG sensor makes contact with the user's skin.

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 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**
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.

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration—electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted

Conducted RF IEC 61000-4-6

Radiated RF IEC 61000-4-3</td><td>3 Vrms

150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>NA

NA

NA</td><td>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).
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:
 </td></tr>
<tr><td colspan="4">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</td></tr>
<tr><td colspan="4">[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.</td></tr>
</table>

[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 CORSANO CONTACT INFORMATION

Corsano Health B.V.
Wilhelmina van Pruisenweg 35
2595 AN The Hague
The Netherlands

www.corsano.com