EN

CardioWatch 287-2
Bracelet & Mobile Patient App
Instruction Manual

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IMPORTANT

This Instruction Manual is subject to periodic review, update and revision, please consult the Corsano Website for the latest version.

The following Instruction Manuals are available with CardioWatch 287-2 System:

- Bracelet & Patient Mobile Application: for the Patient & Healthcare Practitioner

- HCP Mobile App Instruction Manual: for the Healthcare Practitioner only

- Web Portal Instruction Manual: for the Healthcare Practitioner only

PLEASE READ THE RELEVANT INSTRUCTION MANUALS BEFORE OPERATING THE SYSTEM. If any part of an Instruction Manual is not clear, contact Corsano Health for assistance.

This Instruction Manual is provided electronically, if you wish to obtain a paper copy please contact Corsano Health.

List of Abbreviations

Abbreviation	Meaning
EMC	Electromagnetic Compatibility
FCC	Federal Communications Commission
HF	High Frequency
ICU	Intensive Care Unit
ISED	Innovation, Science and Economic Development Canada
LED	Light Emitting Diode
MRI	Magnetic Resonance Image
RF	Radiofrequency
RPM	Respirations per Minute
RSS	Radio Standards Specifications
SpO2	Functional oxygen saturation
USB	Universal Serial Bus
WEEE	Waste Electrical and Electronic Equipment
HCP	Healthcare Practitioner

⚠️ **WARNING:** A WARNING statement provides information about a potentially hazardous situation which, if not avoided, could result in serious injury or damage.

⚠️ **CAUTION:** A CAUTION statement provides information about a potentially hazardous situation which, if not avoided, may result in injury to the user or patient, or in damage to

the equipment or other property.

RECOMMENDATION : A RECOMMENDATION statement provides a proposition or suggestion to user.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician or other practitioner licensed by U.S. state law to use or order the use of this device.

1 TABLE OF CONTENTS

2 INTRODUCTION

The Corsano CardioWatch 287-2 System is a Remote-Patient Monitoring System that consists of a monitoring bracelet device worn on the wrist by adult patients (aged 18 years old and over), a web-based browser platform and a user mobile application operable in either Patient Mode or Healthcare Practitioner (HCP) Mode.

Vital signs data both on mobile devices and web-based dashboard are available to the HealthCare Provider.

The following figure shows the Corsano CardioWatch 287-2 System:
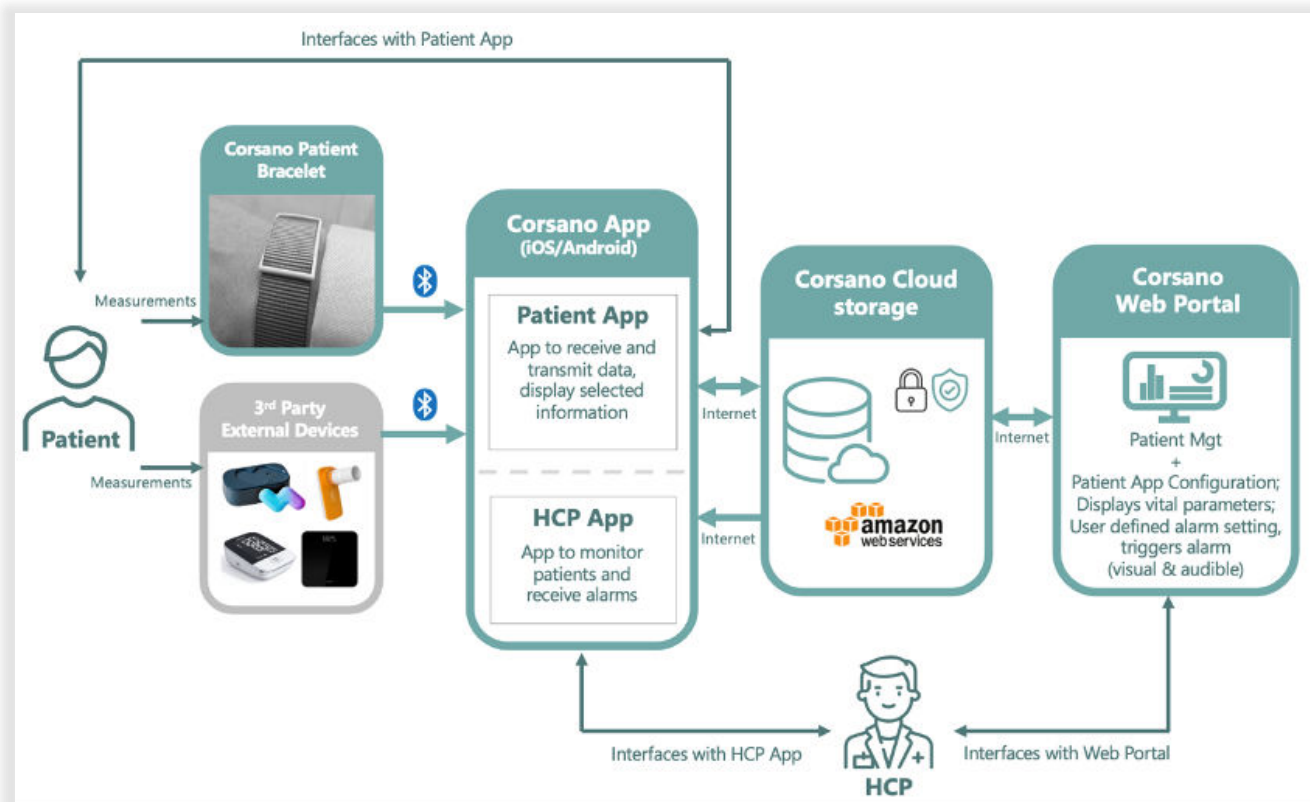
CardioWatch 287-2 System

The bracelet is intended to continuously monitor physiological vital sign data (Pulse Rate (PR), oxygen saturation (SpO2), body temperature (TEMP), blood pressure (NIBP) and activity levels (MOTION / STEP) from the person being monitored and securely transmit the encrypted data via the Patient App to the secure server.

The bracelet is intended for Electrocardiography spot measurements (ECG).

The bracelet is intended for use in professional healthcare facilities, such as hospitals or skilled nursing facilities, or the home.

The Corsano CardioWatch 287-2 System is also integrated with third-party devices for displaying and monitoring physiological signs (spot monitoring of: non-invasive blood pressure (CuffBP), lung function & spirometry (SPIRO), weight (WEIGHT) as well as continuous monitoring of axillary temperature (aTEMP).

The Healthcare Practitioner can securely access the patient physiological signs remotely via the mobile application HCP Mode or via a browser web-interface which are also intended to provide visual and audible physiologic multi-parameter alarms.

This instruction manual provides you with important information about the Corsano CardioWatch 287-2 Bracelet and App. These instructions are intended for both the Patient and the Healthcare Practitioner.
The CardioWatch 287-2 System should only be used by and under the supervision of trained Healthcare Practitioners.

You may check the Knowledge Base under Settings within the App with answers to Frequently Asked Questions.

You may also contact your Healthcare Practitioner if you need assistance with using the CardioWatch 287-2 Bracelet and App.

You may also contact Corsano for Technical Questions via support@corsano.com.

3 SAFETY INSTRUCTIONS

To ensure the safe and proper use of the CardioWatch 287-2 Bracelet and App, READ and UNDERSTAND all of the safety and operating instructions.
If you do not understand these instructions or have any questions, contact your Healthcare Practitioner or support@corsano.com before attempting to use the system.

3.1 Warnings

⚠ To maintain patient safety, adhere to all WARNINGS and CAUTIONS listed in this Instruction Manual.

⚠ The CardioWatch 287-2 System is intended for use by qualified medical personnel only; Please always follow instructions from your Healthcare Practitioner.

⚠ The CardioWatch 287-2 System is not intended for use in high-acuity environments, such as an 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, a continuous ECG monitor should be used. The CardioWatch 287-2 System is not a substitute for an ECG monitor.

⚠ Consult with your Healthcare Practitioner before using this bracelet and app 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. Any of these conditions, in addition to motion, trembling, or shivering may affect the measurement made by this device.

⚠ NEVER diagnose or treat yourself based on the physiological parameters readings.

⚠ DO NOT adjust medication based on readings from this system. You should take medication as prescribed by your Physician. ONLY a Physician is qualified to diagnose and treat illness of a patient. ALWAYS consult with your Physician.

⚠ The Bracelet is intended for use on a single patient, DO NOT use the Bracelet on anyone else during patient monitoring.

⚠ The Bracelet and any other applied device parts should be removed before patient defibrillation.

⚠ DO NOT use this Bracelet on infants, toddlers, children, or persons who cannot express themselves. This device has not been validated in a pediatric population.

⚠ DO NOT use this Bracelet on an injured arm or an arm used as part of other medical treatment (e.g., on an arm with an arterio-venous shunt for dialysis). Wearing the bracelet could temporarily interfere with blood flow, which could result in injury.

⚠ DO NOT use this Bracelet if you have severe blood flow problems or blood disorders.

⚠ DO NOT use this Bracelet if you have damaged or irritated skin.

⚠ DO NOT use this bracelet with other medical electrical (ME) equipment simultaneously other than those authorized by Corsano. This may result in incorrect operation of the bracelet and/or cause an inaccurate reading.

⚠ DO NOT use this bracelet in areas containing high-frequency (HF) surgical equipment or hyperbaric chambers, or computerized tomographic (CT) scanners. This may result in incorrect operation of the bracelet and/or cause an inaccurate reading.

⚠ DO NOT take recordings in the close vicinity of strong electromagnetic fields (e.g., electromagnetic anti-theft systems, metal detectors).

⚠ DO NOT use this bracelet in oxygen-rich environments or near flammable gas. This equipment is neither approved nor certified for use in areas where oxygen concentrations are greater than 25% or where combustible or explosive gas mixtures are likely to occur.

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

⚠ This Bracelet is MR-unsafe!

⚠ DO NOT expose the Bracelet to a magnetic resonance (MR) environment.

⚠ This Bracelet may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.

⚠ Thermal injury and burns may occur due to the metal components of the Bracelet that can heat during MR scanning.

⚠ The Bracelet may generate artifacts in the MR image.

⚠ The Bracelet may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

3.2 Cautions

⚠ Please inform your Healthcare Practitioner if you are at risk for respiratory crises; you should be observed closely.

⚠ Movement, ambient light, and low perfusion may affect SpO2 and pulse rate calculation and accuracy. Corsano 287-2 System is not intended for use in calculating accurate SpO2 during periods of high motion, high ambient light, and low perfusion conditions.

⚠ SpO2 measurements are particularly sensitive to the pulsations in the artery and the arteriole. Measurements may not be accurate if you are experiencing shock, hypothermia, anemia or has received certain medications that reduce the blood flow in the arteries.

⚠ Ensure that this bracelet has acclimated to operating temperatures (+10 to +40 ºC) before taking a measurement. Taking a measurement after an extreme temperature change may lead to an inaccurate reading.

⚠ Motion levels are provided for information purposes only. They should not be relied upon to inform patient care.

⚠ 3rd party external devices shall not be used outside their intended use, including

intended patients nor operating conditions.

⚠ The Bracelet is provided non-sterile.

3.3 Notes

Keep this manual where it can be easily located when needed.

3.4 Indications for 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 System is not intended for use in high-acuity environments, such as an 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, continuous ECG monitor should be used. 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.

3.5 Clinical Benefit

The CardioWatch 287-2 System provides a non-invasive, comfortable monitoring of vital signs with visual and audible physiological multi-parameter alerts. Data is transmitted to the Corsano Web Portal where it is reviewed by Healthcare Practitioners (HCP).
The principal clinical benefit of the CardioWatch 287-2 System is to provide patient monitoring of non-invasive vital signs data with patient adjustable visual & audible physiological alerts to the Healthcare Practitioner.

A secondary clinical benefit is that the Healthcare Practitioner may decide, based on the patients therapy, that the Corsano App in Patient Mode should display patient trending information, for instance Patient Activity (Motion Levels & Steps) to encourage the patient to be more active or to better adhere to Healthcare Practitioner instructions.

3.6 Essential Performance

The essential performance in accordance with the IEC 60601-1:2005+AMD1:2012+AMD2:2020 for CardioWatch 287-2 System has been established as the ability of the system to maintain precision measurements on SpO2, PR, Body temperature, Respiration Rate as well as data transmission.

The precision measurements have been established as per IEC collateral standards and where appropriate product specification.

4 SYMBOLS

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

Symbol	Meaning
	Indicates the medical device manufacturer
	A WARNING statement provides information about a potentially hazardous situation which, if not avoided, could result in serious injury or damage.
	A CAUTION statement provides information about a potentially hazardous situation which, if not avoided, may result in injury to the user or patient, or in damage to the equipment or other property.
	Indicates the need for the User to consult the instructions for use
	Applied Part (Corsano Bracelet) 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.
	Wearable device (Bracelet) does not generate alarms.
Rx	For prescription use only (USA)

	Device is MR-unsafe

5 CONTENTS / PRODUCT INCLUDES

5.1 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 this Instruction Manual where it can be easily located when needed for future reference.

The Bracelet packaging contains important information, it should not be thrown away.

5.2 Contents

One bracelet CardioWatch 287-2:

Bracelet - CW287-2

One USB charging cable:

Charger (CS-287CH-1)

One package box with instructions:

Instruction Manual (IFU Corsano CardioWatch 287-2 Bracelet)

IMPORTANT : the USB AC / DC Power Supply (USB Adapter) is not provided.
Refer to §16.3 - AC-DC Power Supply (USB Adapter) for the minimum specification.

6 KNOW YOUR BRACELET

6.1 Back and Side of the bracelet
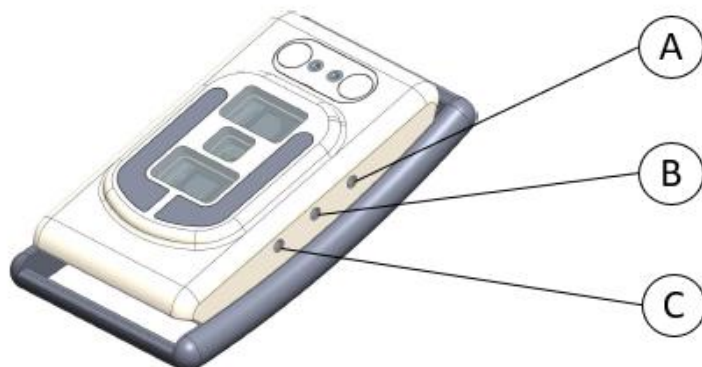
Back and Side view of Bracelet

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

6.2 Back and bottom of the bracelet
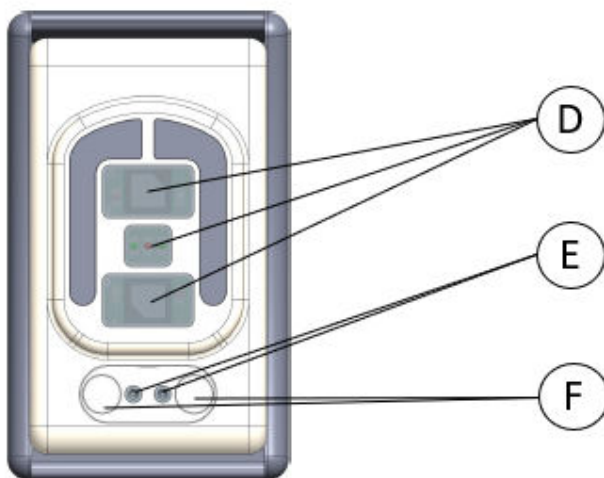
Back view of Bracelet

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

6.3 WARNINGS / CAUTIONS / RECOMMENDATIONS

⚠️ Stop using this bracelet and consult with your Physician or Healthcare Practitioner if you experience skin irritation or discomfort.

⚠️ DO NOT apply the wearable device on open wounds, sores, or cuts; the device is only intended for contact with intact skin.

ⓘ To achieve the best performance of the pulse rate sensor, ensure that the bracelet is well-adjusted on the wrist and not too tight to avoid skin irritation or injury.

⚠️ The Bracelet should not be placed over a tattoo - doing so may prevent calculation of an accurate SpO2 or pulse rate.

⚠️ Regardless of the measurement(s) taken or the values of the measurements made using this device, you should immediately consult your Physician or Healthcare Practitioner 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 Bracelet is intended to be worn on the wrist (left or right), DO NOT use on other parts of the body.

⚠️ For specific information about your own pulse rate, CONSULT WITH YOUR PHYSICIAN.

⚠️ The Bracelet is IP66 water resistant, which means it is protected against dust and powerful water jets only. You may take a shower with the Bracelet but should not be used during swimming.

⚠️ Repair of the Bracelet may only be carried out by the manufacturer otherwise the correct functioning of the device may be compromised.

⚠️ No modification of the Bracelet is allowed. Modification 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 use.

⚠️ The Bracelet contains small parts that may cause a choking hazard if swallowed by infants, toddlers, or children.

⚠️ To avoid strangulation, keep the charger cable away from infants, toddlers, or children.

⚠️ DO NOT drop or subject this bracelet to strong shocks or vibrations.

6.4 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.

⚠ 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.

6.5   Charging the bracelet

Remove the Bracelet from the wrist prior to charging.

Fully insert the USB plug at the end of the Charger Cable into the USB Adapter.

Attach the other end of the Charger Cable to the rear side of the bracelet. The magnets will pull the charger head to the bracelet.
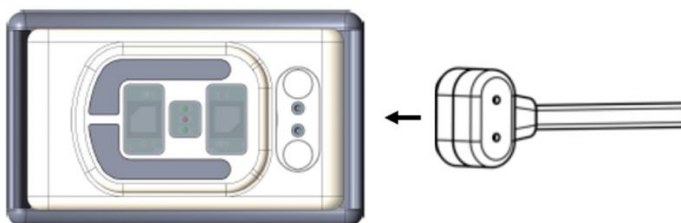
Charging view

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

The polarity of the magnets in the Bracelet and the Charger Cable will ensure that the charger contacts will align.

When unplugging the Charger Cable from the USB Adapter, be sure to remove from the USB Adapter 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 Cable when not in use.

Unplug the Charger Cable before cleaning the bracelet.

6.5.1   WARNINGS:

⚠ NEVER allow the Bracelet nor the mobile phone to become discharged.

⚠ NEVER plug in or unplug the Charger Cable from the USB Adapter with wet hands.

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

6.5.2   CAUTIONS:

⚠ Prevent liquid spillages onto the USB charger cable. If the charger cable 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 cable.

⚠ 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.

6.6 LED Explanation
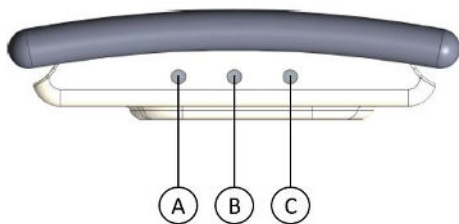
Bracelet side view

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 a 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 (at 20% and at 10% remaining). The battery level is also displayed on the Web Portal, including low level alarm.

6.7   Cleaning & Disinfection

The CardioWatch 287-2 Bracelet and USB Charger Cable are re-usable and may be used for more than one patient.

The strap is considered as single-patient use (for the duration of the monitoring period) and should be disposed of in clinical waste or according to local guidelines and regulations at the end of a patient monitoring period.

During patient use, users (Patients & HCP) should regularly check the condition of the CardioWatch 287-2 Bracelet, USB Charger Cable & Strap and clean and / or disinfect as necessary.

Prior to cleaning / disinfection, dissemble the strap from the bracelet, and remove the USB charge cable.

To clean the Strap, 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. Dry with a soft cloth.

To clean & disinfect the Bracelet & USB charge cable use a cleaning & disinfection wipe recommended by your HCP; suitable for Low Level cleaning & disinfection of medical devices. Consult the instructions on the selected cleaning & disinfection wipes for correct methodology.

These re-usable components may be cleaned & disinfected any time by the patient or HCP ; and must be systematically cleaned & disinfected :

- at the end of each patient monitoring period

    and

- prior to being returned to Corsano for repair.

In case of blood or fluid contamination immediately clean & disinfect.

Note : cleaning and disinfection of the bracelet have been validated using:
   o   Wip'Anios Excel
   o   Cidalkan.
The use of any other cleaning and disinfection wipes should be first tested & validated under the responsibility of the HCP.

⚠   Do not autoclave or sterilize the wearable device or any part of the CardioWatch 287-2 System.

⚠   After Cleaning & Disinfection, inspect visually the Bracelet and cable for damage and do not use in case of damage.

7 USING YOUR BRACELET WITH THE CORSANO APP

7.1 Download and install the Corsano App onto your smart phone.

7.2 First time use – Sign Up

Select "Sign Up" to create a user account (2)   Enter First Name, Last name, Email
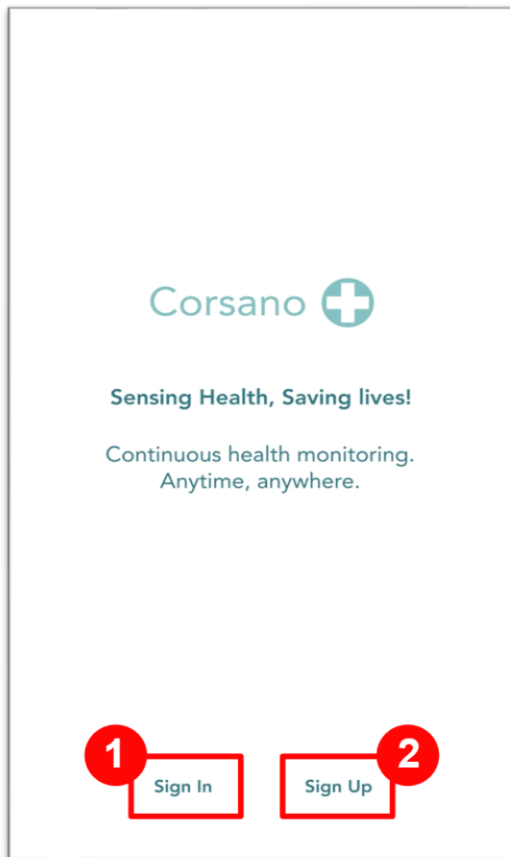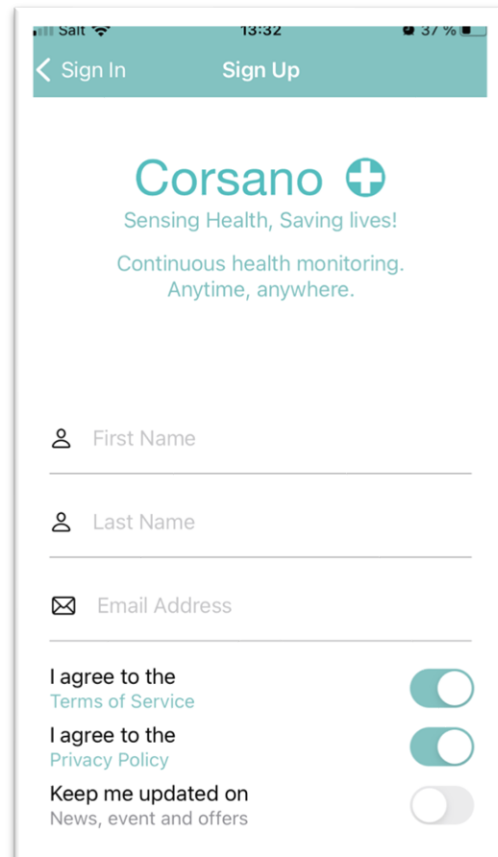
Choose Sign-Up   *Sign-Up*

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"
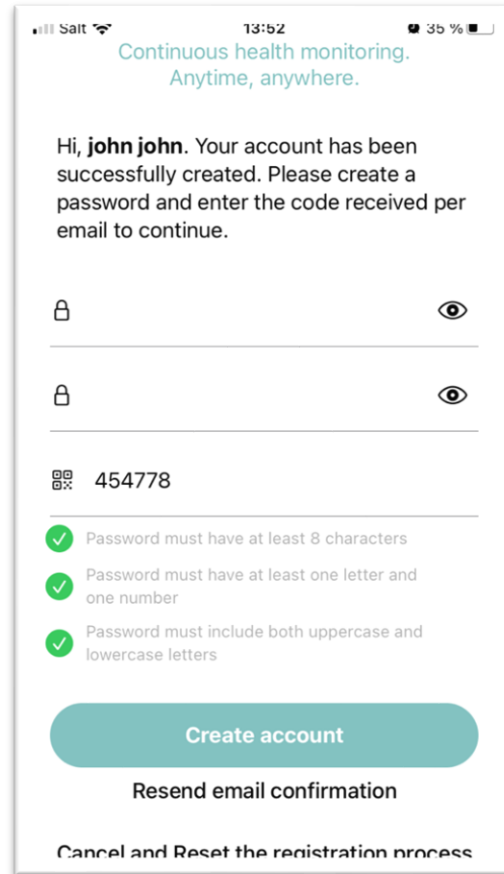
Create account

7.3   Sign In

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

Select "Sign In" (1)
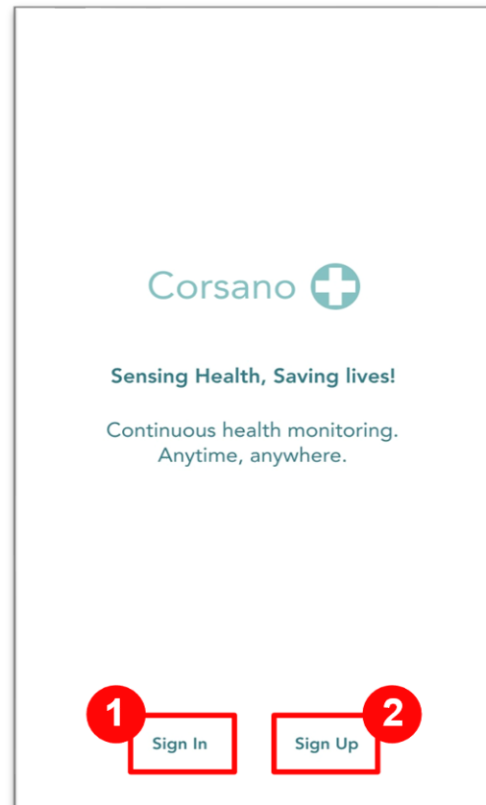
Choose Sign-In

Enter:
- Email
- Password

Press **"Sign In"**
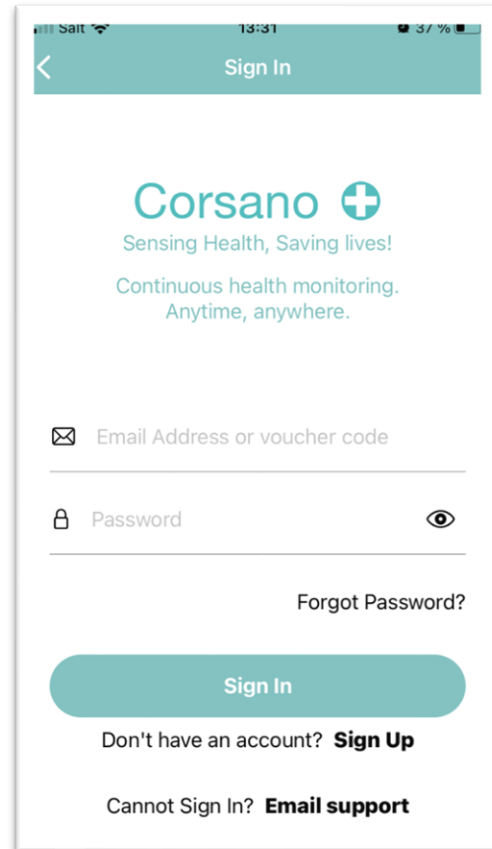
Sign-In

7.4 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:
- 287-2
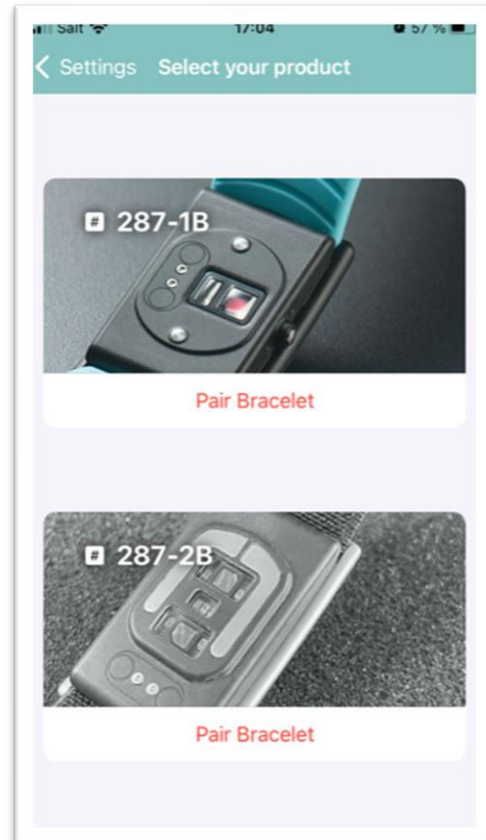
Pair Bracelet
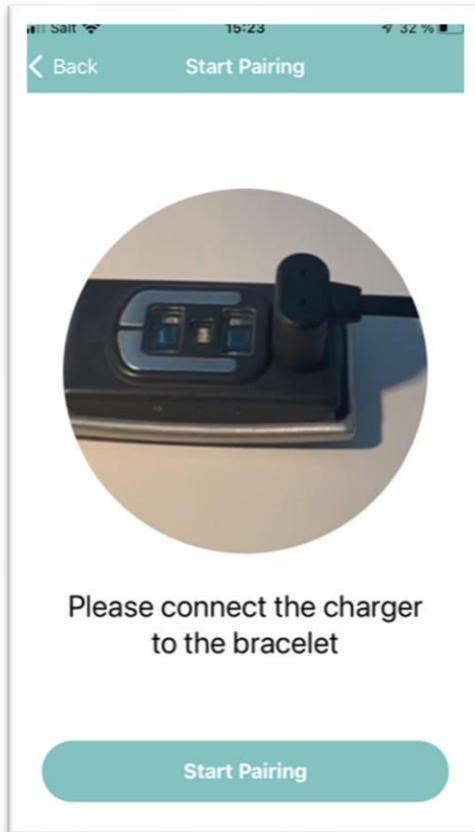
Connect the charger and press Start Pairing
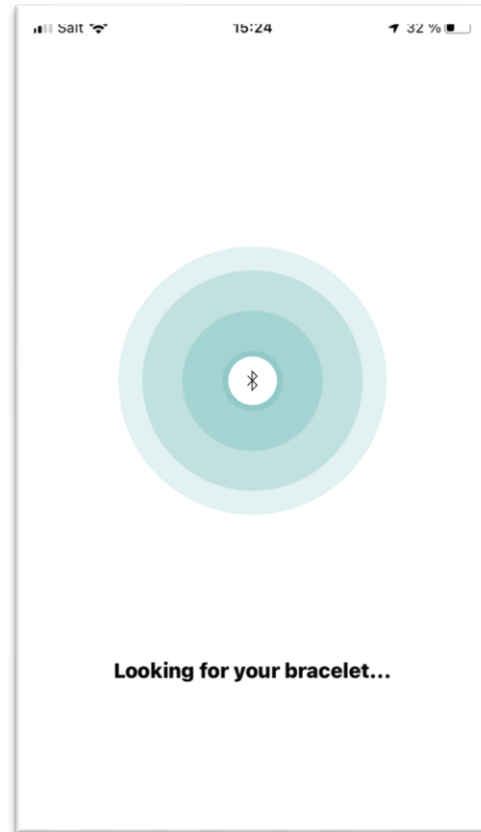
Wait for the app to find the bracelet
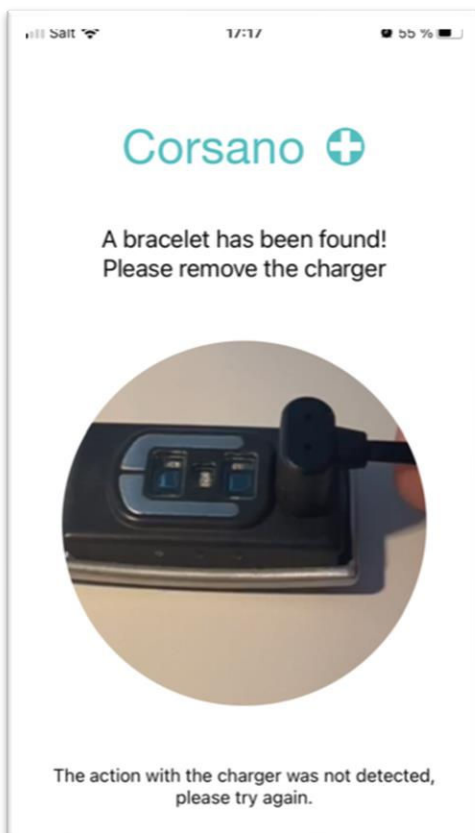
Remove charging cable to complete pairing

7.5 Wearing Optimization

After pairing, the user will be asked to complete the "Wearing Optimization" feature.

The CardioWatch 287-2 Bracelet should be placed on the wrist, about 1 inch above the bone of your wrist (away from your hand).

This ensures that the Bracelet does not move around as much when you are using your hands. The sensing side of the CardioWatch 287-2 Bracelet should be placed in direct contact with the skin, on the top side of the wrist. The CardioWatch 287-2 Strap should be snug, but not too tight – just tight enough to ensure the bracelet makes solid contact with your skin.
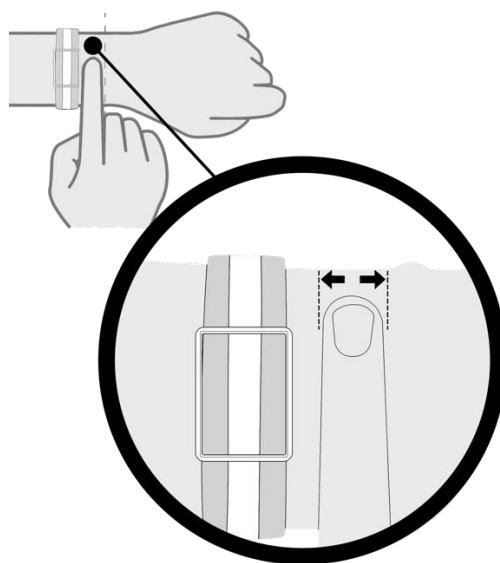
Bracelet Positioning

Tighten the strap so that is secure against the skin, the PPG green LED light should not be visible from the side. Your bracelet should be snug but comfortable.
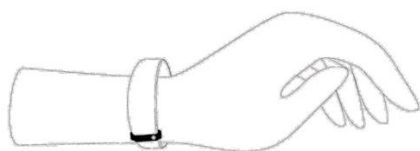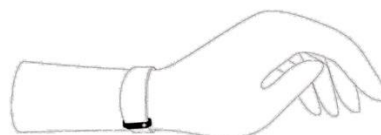
Too loose   Just right

Bracelet Tightness

7.5.1 Bracelet Direction
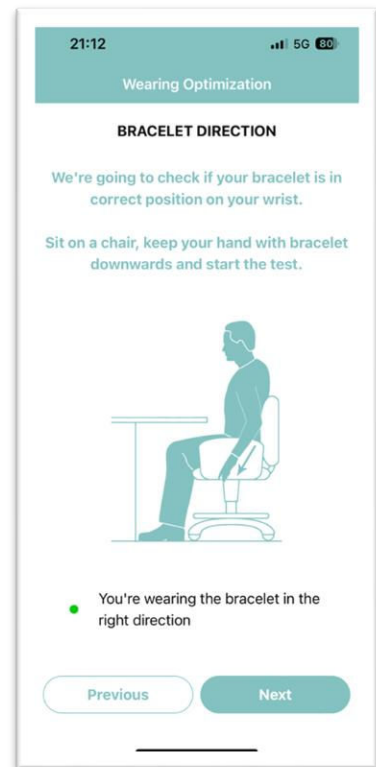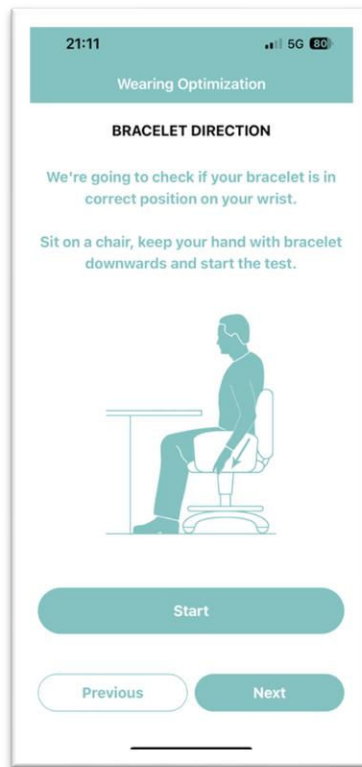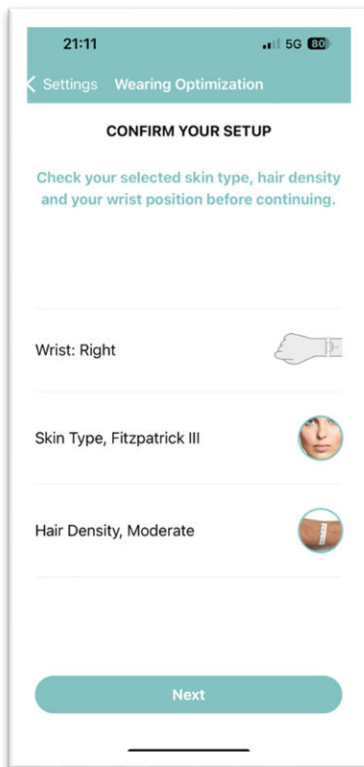
Bracelet Direction

7.5.2 Tightening Check
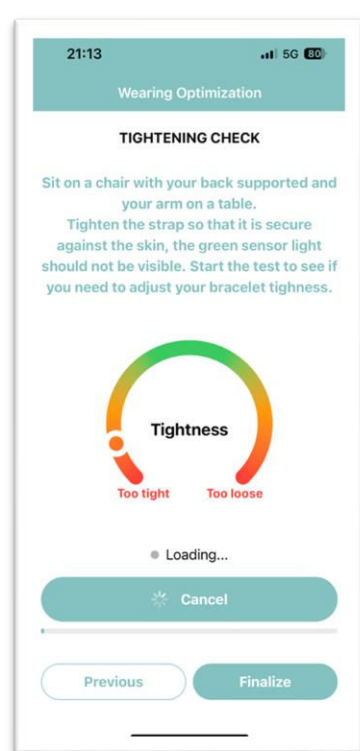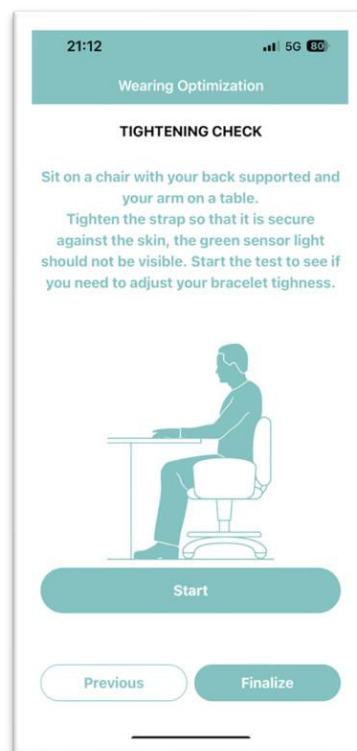
Bracelet Positioning

7.6 Optional Wearing Optimization

To check if the CardioWatch 287-2 Bracelet is well positioned on your wrist and if the bracelet is tight enough, open the Main Setting Menu and select "Wearing Optimization". Then follow instructions on screen.
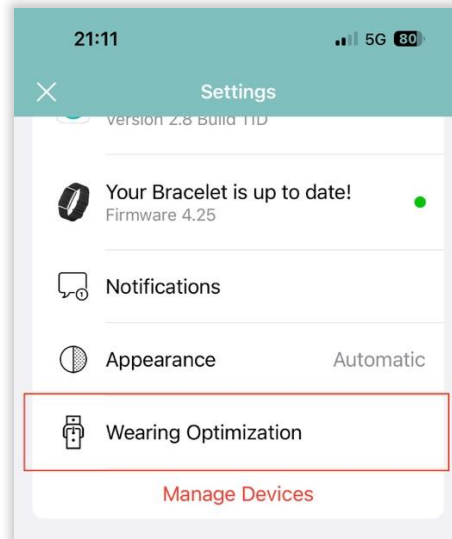
Wearing Optimization

If during use, the wearing detection algorithm identifies a possible issue with tightness or positioning, then User Message will be displayed instructing the patient to complete the "Wearing Optimization" feature.

7.7 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.
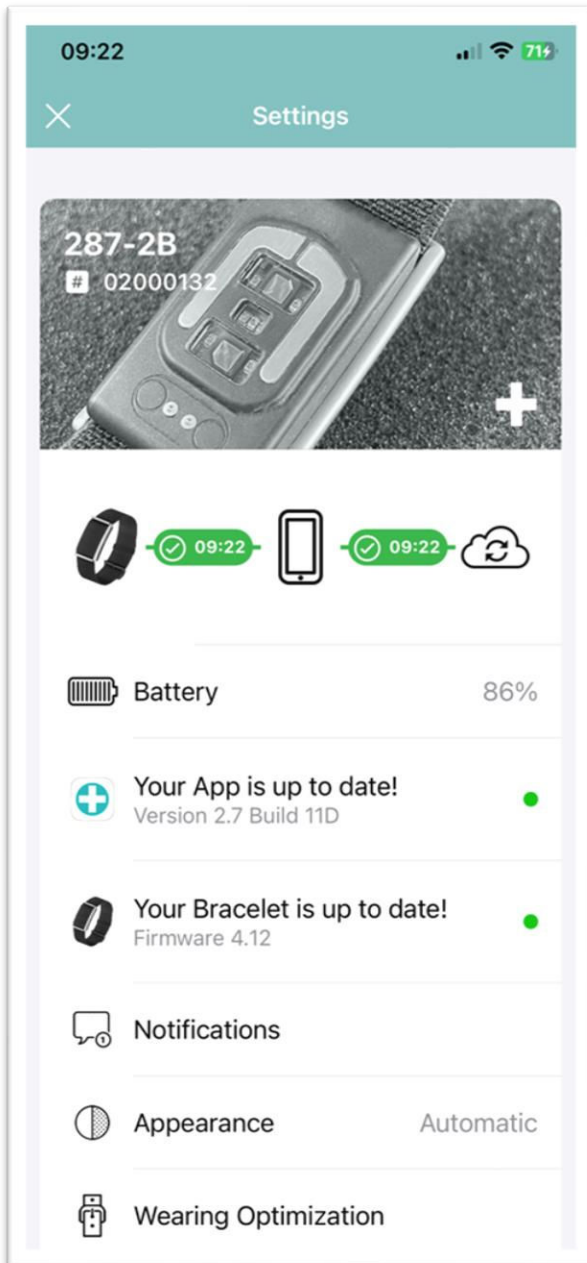
App and Bracelet Status
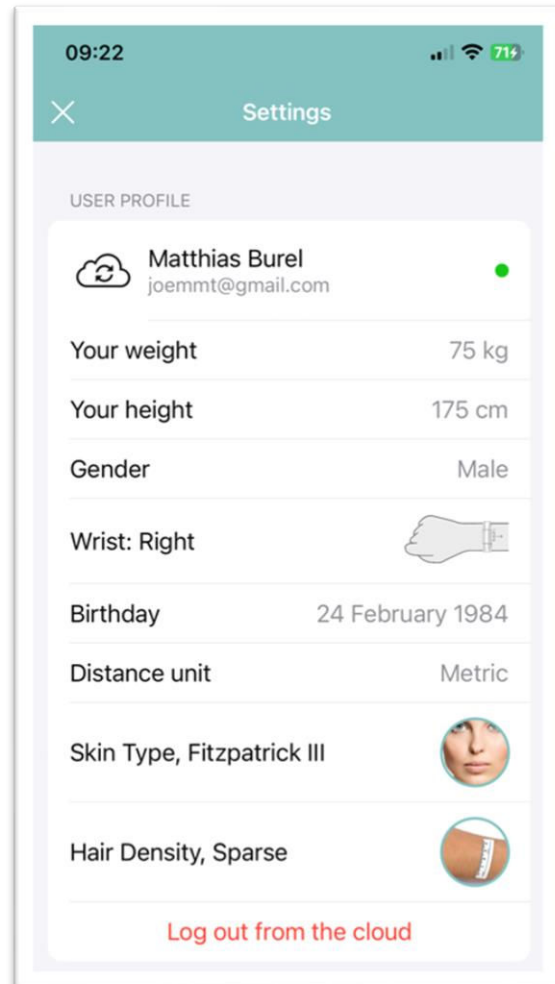
Profile Settings

7.8 Troubleshooting the Bluetooth Connection

If the connection between the bracelet and app is lost, a red "X" will appear:
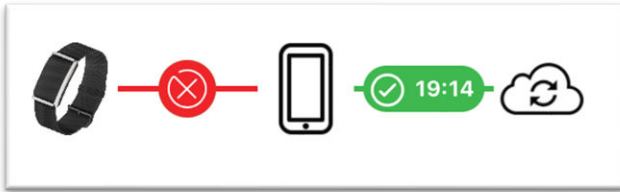
Please follow instructions:

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, 287-2 > 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

7.9 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

8 EXTERNAL DEVICES

In order to provide complementary patient parameters to the Corsano System, the following third party external devices have been selected & validated be interfaced with the Corsano Patient App.

Product	Company / Product Name
Thermometer	Vivalink Fever Scout continuous monitoring thermometer
Non-invasive blood pressure monitor	Transtek TMB-2084-A
Weight scale	Transtek GBS-2012-B
Spirometer	MIR Spirobank G

External Devices

The external devices provide both continuous axillary temperature measurements and spot (intermittent) measurements of non-invasive blood pressure, weight and lung function & spirometry.

Refer to the User Instructions provided with each external device. The following provides only summary information, associating the external device and the Corsano System. It is not intended to replace the external device instructions for use.

Verify systematically that the measurements made by the external devices are correct and that no alarms or technical errors have occurred; if there is an error message on the third party device the measurement should be repeated.

8.1 Axillary Temperature Sensor

Continuous monitoring of **axillary temperature** can be performed with the external, clinical grade Vivalink Axillary Temperature Sensor, a soft, wearable thermometer that continuously measures temperature, manufactured by Vivalink (FDA K162137), which connects to the Corsano App using Bluetooth technology through an API provided by Vivalink. If the Vivalink Temperature Sensor is connected, it will transmit medically accurate readings of Axillary Temperature to the Corsano App, Cloud and Patient Portal.

Vivalink, Fever Scout Continuous monitoring thermometer

Specification of Axillary Temperature Sensor:

Sensing Method	Vivalink Fever Scout Axillary Temperature Sensor
Measurement Range	34°C to 43°C (93.2°F to 109.4°F)
Resolution	0.1°C
Accuracy	+/- 0.1°C (+/- 0.18°F)
Performance	Conform to ASTM E1112
Data Update Period	28 seconds

Specification of Axillary Temperature Sensor

8.2 Cuff blood pressure

Spot-check monitoring of blood pressure can be performed with the external cuff blood pressure monitor TMB-2084-A manufactured by Transtek (FDA K220676), which connects to the Corsano App using Bluetooth technology through an API provided by Transtek. If the non-invasive blood pressure monitor is connected, it will transmit medically accurate readings of bloodpressure to the Corsano App, Cloud and Patient Portal.

Transtek TMB-2084-A Non-invasive blood pressure cuff

Specification non-invasive blood pressure:

Sensing Method	External cuff blood pressure monitor Transtek TMB-2084-A with oscillographic measurement
Measurement Range	SYS: 60 ~ 230 mmHg(8.0-30.7kPa) DIA: 40 ~ 130 mmHg(5.3-17.3kPa)
Accuracy	Pressure: ±3 mmHg (5°C-40°C)

Specification non-invasive blood pressure

8.3 Spirometer

Spot measurement of spirometry & lung function can be performed by using the compatible MIR Spirobank G spirometer (K072979), It can be paired to the Corsano App using Bluetooth technology through an API provided by MIR. The device is intended to be used by a physician or by a patient under the instruction of a HCP. It is intended to test lung function and spirometry for patient of all ages, excluding infants and neonates. If the Spirobank Smart spirometer is connected, it will transmit medically accurate readings of spirometry to the Corsano App, Cloud and Patient Portal.

MIR Spirobank G

Specification spirometry:

Sensing Method	External MIR Spirobank with bi-directional digital turbine
Parameters	FVC FEV1 FEV6 PEF FEV1/FVC ratio (derived from previous meausrements)
Flow Range	0 to 10 L +/- 16 L/s
Volume Accuracy	+/- 2.5% or 0,05 L
Flow Accuracy	+/- 5.0% or 0,20 L/s

Specification spirometry

Parameter	Accuracy	Range
FVC	+/- 2.5% or 0,05 L	0 to 10 L
FEV1	+/- 2.5% or 0,05 L	0 to 10 L
FEV6	+/- 2.5% or 0,05 L	0 to 10 L
PEF	+/- 5.0% or 0,20 L/s	+/- 16 L/s

Specification spirometry parameters performance

Forced vital capacity (FVC)
Forced vital capacity (FVC) is the volume of air that can forcibly be blown out after full inspiration, measured in liters. FVC is the most basic measurement in spirometry tests.

Forced expiratory volume in 1 second (FEV1)
FEV1 is the volume of air that can forcibly be blown out in first 1-second, after full inspiration. Average values for FEV1 in healthy people depend mainly on sex and age. Values of between 80% and 120% of the average value are considered normal. Predicted normal values for FEV1 can be calculated and depend on age, sex, height, mass and ethnicity.

FEV1/FVC ratio
FEV1/FVC is the ratio of FEV1 to FVC. In healthy adults this should be approximately 70–80% (declining with age). In obstructive diseases (asthma, COPD, chronic bronchitis, emphysema) FEV1 is diminished because of increased airway resistance to expiratory flow; the FVC may be decreased as well, due to the premature closure of airway in expiration, just not in the same proportion as FEV1 (for instance, both FEV1 and FVC are reduced, but the former is more affected because of the increased airway resistance). This generates a reduced value (<70%, often ~45%). In restrictive diseases (such as pulmonary fibrosis) the FEV1 and FVC are both reduced proportionally, and the value may be normal or even increased as a result of decreased lung compliance.

Forced expiratory volume in 6 seconds (FEV6)
FEV6 is the volume of air that can forcibly be blown out in first 6-seconds, after full inspiration. From these two values (FEV1 and FEV6) we get a ratio, which depicts how much of the air you exhaled during six seconds was exhaled during the first second. FEV1/FEV6 is given as a percentage, and the higher the result is, the better.

Peak expiratory flow (PEF)
Peak expiratory flow (PEF) is the maximal flow (or speed) achieved during the maximally

forced expiration initiated at full inspiration, measured in liters per minute or in liters per second.

8.4 Weight scale

Spot-check monitoring of weight can be performed with the external weight scale GBS-2012-B manufactured by Transtek (FDA D1545656), which connects to the Corsano App using Bluetooth technology through an API provided by Transtek. If the weight scale is connected, it will transmit accurate readings of weight to the Corsano App, Cloud and Patient Portal.

Transtek GBS-2012-B weight scale

Specification weight scale:

Sensing Method	External Weight Scale Transtek GBS-2012-B
Measurement Range	5 kg to 200 kg/11 lb to 440 lb
Resolution	0.1 kg / 0.1 lb
Accuracy	Up to 50 kg +/- 0.2 kg 51-100 kg +/- 0.3 kg 101-150 kg +/- 0.4 kg 151-200 kg +/- 0.5 kg

Specification weight scale

9   APP SCREENS

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

In particular cases, your Healthcare Practitioner may decide based on therapy, that your app should display trending information, for instance Activity (Motion Levels & Steps) Information can be displayed to encourage you to be more active.

⚠   All information displayed in the Patient App is not for diagnostics use.

Your Healthcare Practitioner can select:

- Pulse rate (PR)
- Oxygen saturation (Sp02)
- Temperature (TEMP / aTemp)
- Electrocardiography (ECG)
- Activity (MOTION / STEPS)
- Respiration Rate (RR)
- Non-Invasive Blood Pressure (NIBP)
- Spirometry (SPIRO)
- Weight (Weight)

⚠ The information provided to you is intended to provide trending data to assist your Healthcare Practitioner in providing you motivation. Your Healthcare Practitioner decides which information is shown to you based on therapy.

Such examples may include:

- Activity (Steps) to motivate you 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 you:
    - o   have properly done spot-measurements
    - o   have taken medicine based on instructions of HCP
- Spirometry trending to motivate you to exercise to increase in pulmonary capacity
- Pulse rate to motivate you to exercise to an increased pulse rate (fat burn)

The following figure gives a summary view of the available Patient Mode Screens:
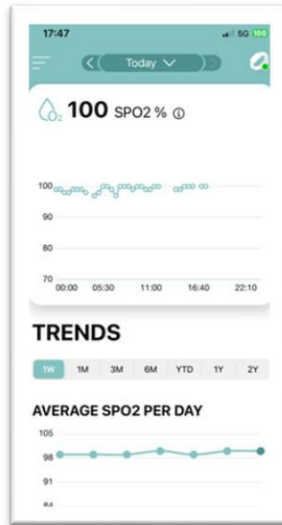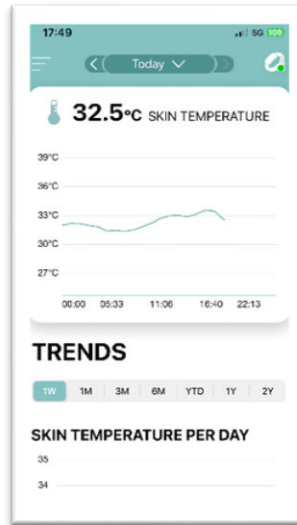
| Pulse rate | SpO2 | Body temperature | Activity |

| Respiration rate | NIBP | Spirometry | Weight |
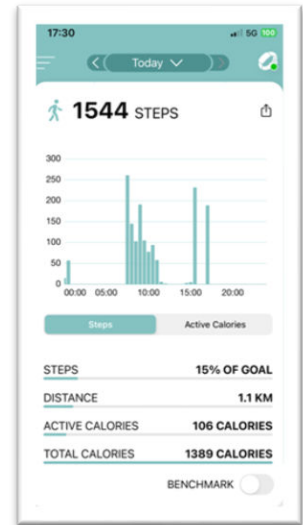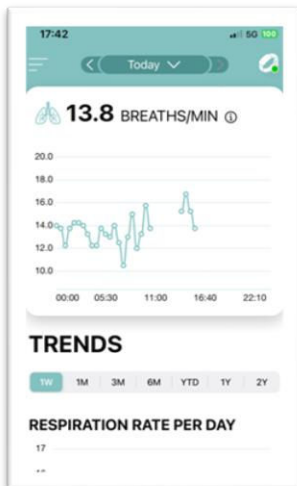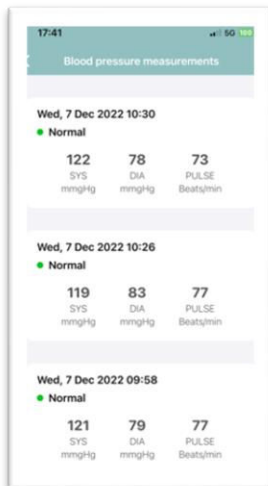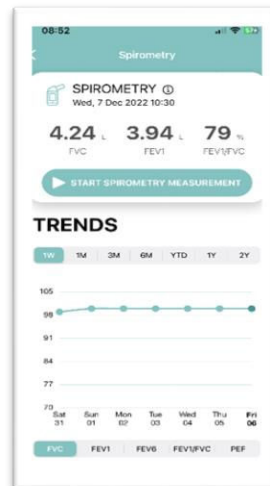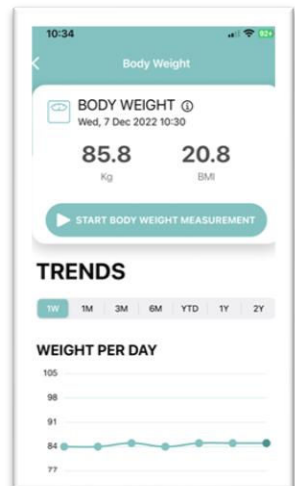
📖 **NOTE:** Your Healthcare Practitioner determines which screens will be seen in the Patient App via the Configuration Panel in the Web Portal (for HCP only).

10 PERFORM AN ECG

10.1 ECG measurement

To record an ECG, launch the measurement from the Dashboard screen and follow the steps.

You can watch the tutorial video on www.corsano.com, Support/Getting Started/Tutorial videos:

https://corsano.com/knowledge-base/movies/
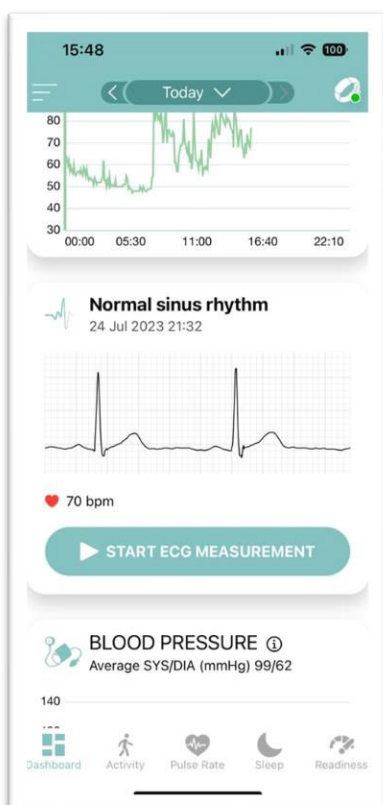
In the Dashboard menu, press "START ECG MEASUREMENT".
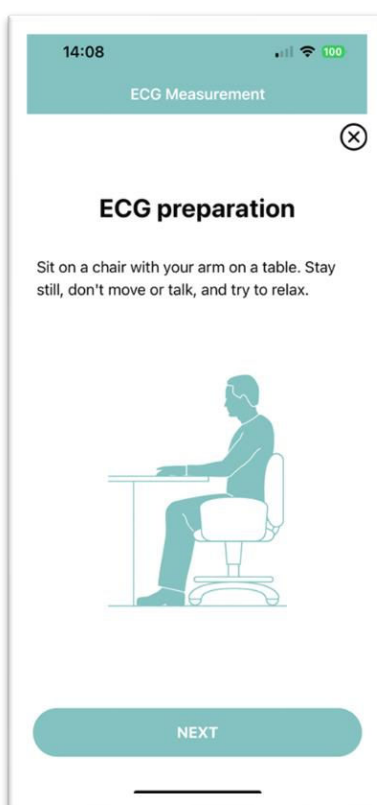
Sit on a chair with your arms on a table.
Check the Bracelet position is the same as the one your entered in the APP settings. (See ECG Troubleshooting section).
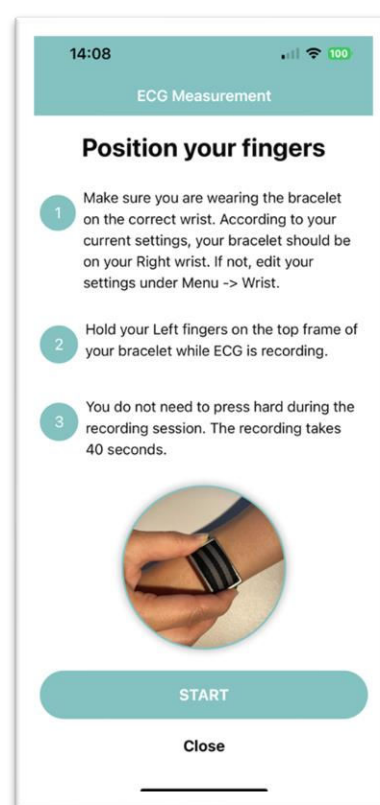
Press "Start".
Hold the Bracelet metal frame with the fingers of your other hand. You need to touch the frame, but don't press hard.
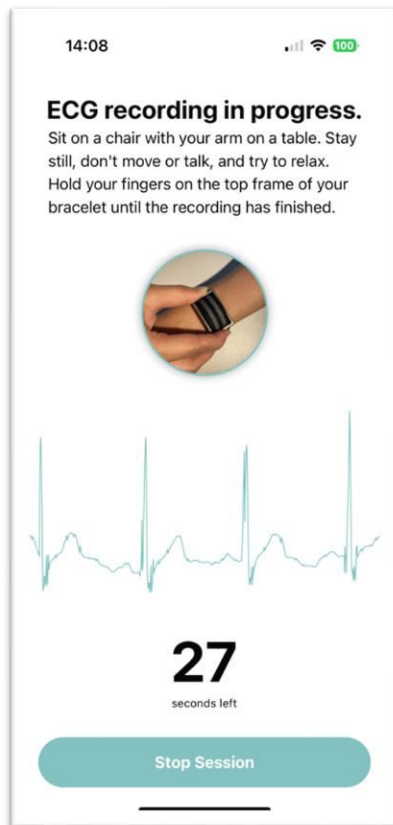
Sit still, don't move, don't talk, try to relax. Muscular tension may generate a noisy signal. The recording lasts about 40s.

At the end of the recording, the APP processes the measurement. It may take several seconds.

10.2 ECG Troubleshooting

If you encounter difficulties in operating your ECG, please consider the following recommendations.
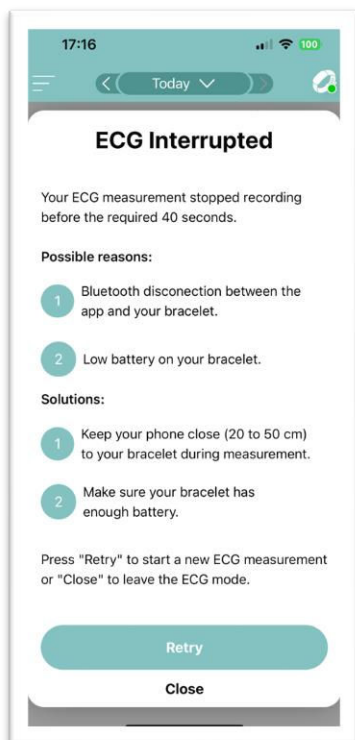
Problem: ECG Interrupted

Solution:

- Make sure the device is charged
- Keep the Bracelet close to the phone running the Corsano APP
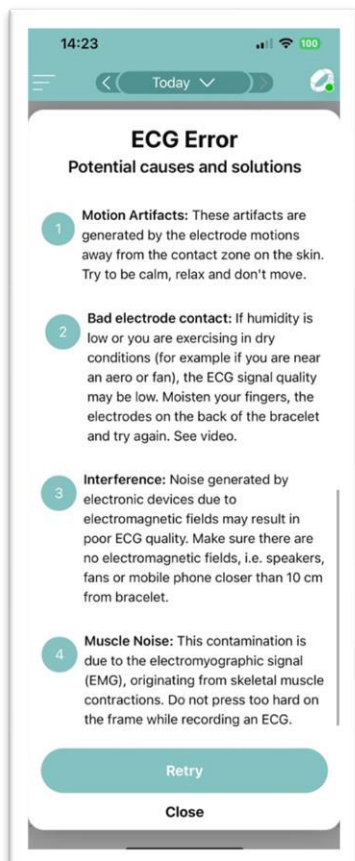
Problem: ECG Error

Solution:

- Keep still, don't move, don't talk. This can generate artefacts on the ECG signal.
- Keep away from electromagnetic disturbances (speakers, phones, metal detectors, NFC devices, wireless chargers, etc.)
- Avoid muscular tensions in arms and hands. This can make the ECG signal noisy.
- Keep away from fan or wind. Wet your fingers. Dry air can prevent proper electrode contacts.
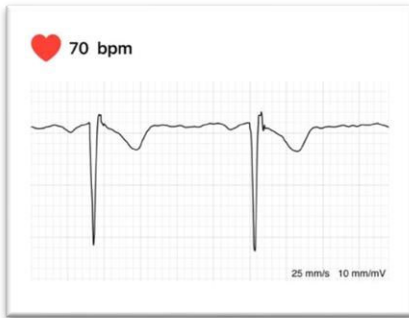
Problem: My ECG signal is inverted

Solution:

- You wear the Bracelet on the wrong wrist. Change wearing wrist. Do the measurement again.

- Or, select the right wearing wrist in the APP settings. (From Dashboard, press Menu icon in top left corner, scroll down to User Profile, edit Wrist position).
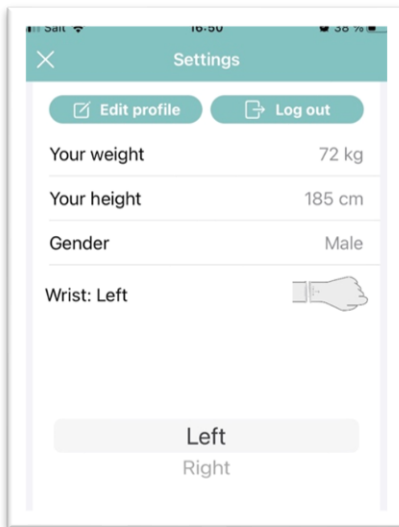
10.3 ECG Results

To see the results of the ECG recordings:
- Press on the ECG window, in the APP Dashboard, to access the history of recordings
- Press to select your recording.
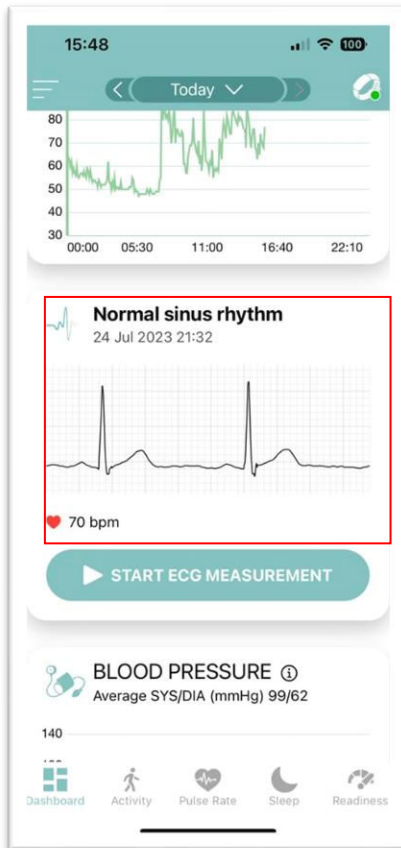
Tap on the ECG window, in the APP Dashboard, to access the history of recordings.
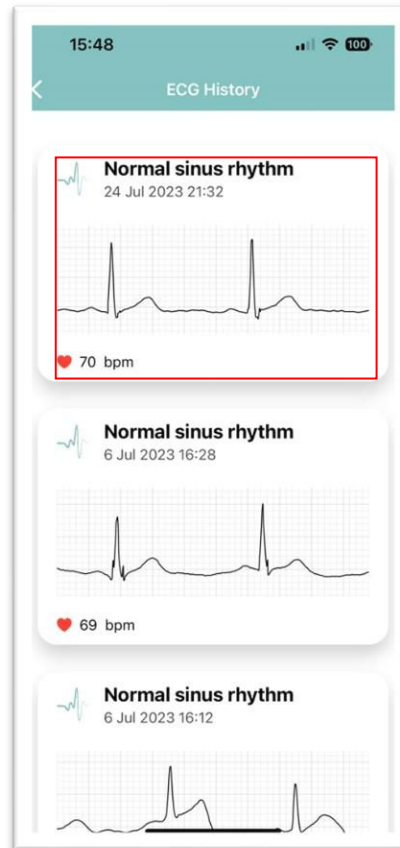
Select you recording by tapping on it.
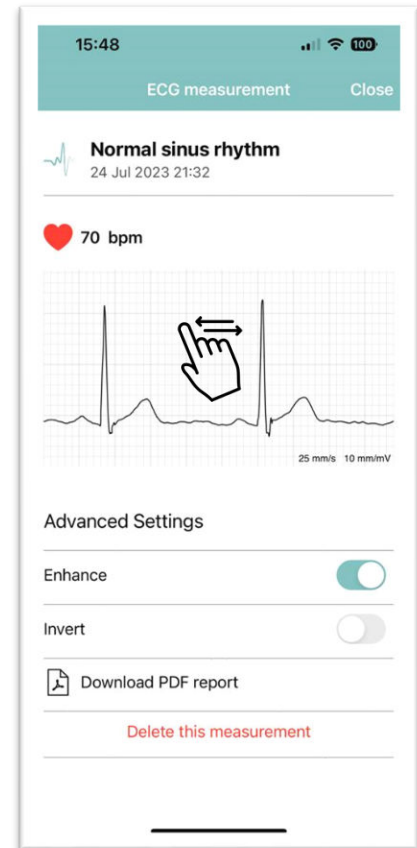
You can go through the recording by swiping left and write.
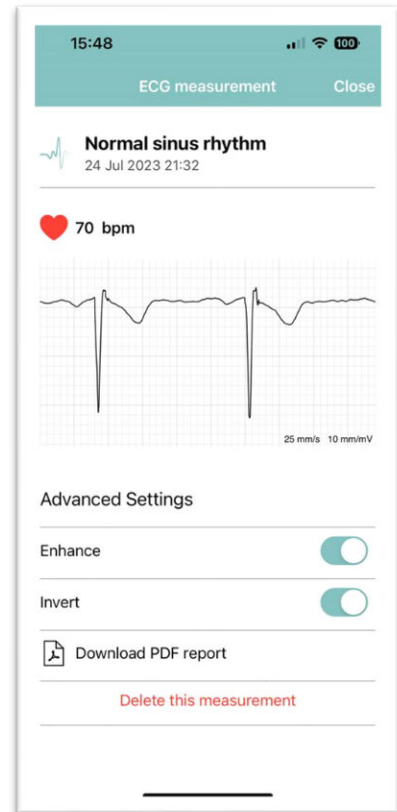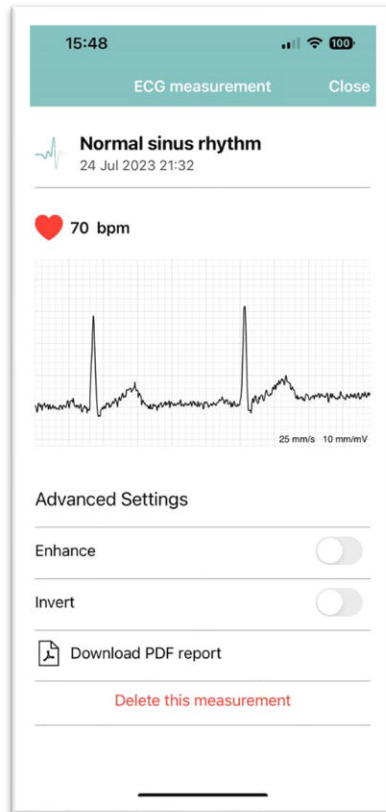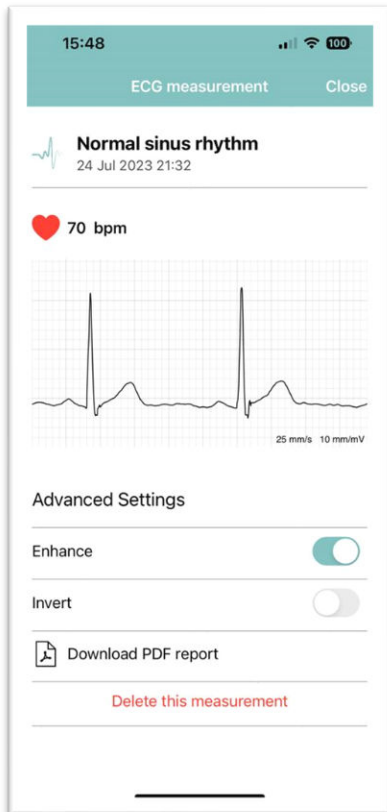
The "Enhance" button enables to show the filtered or unfiltered signal.
The "Invert" button enables to show the inverted signal.

Unfiltered signal

Inverted signal
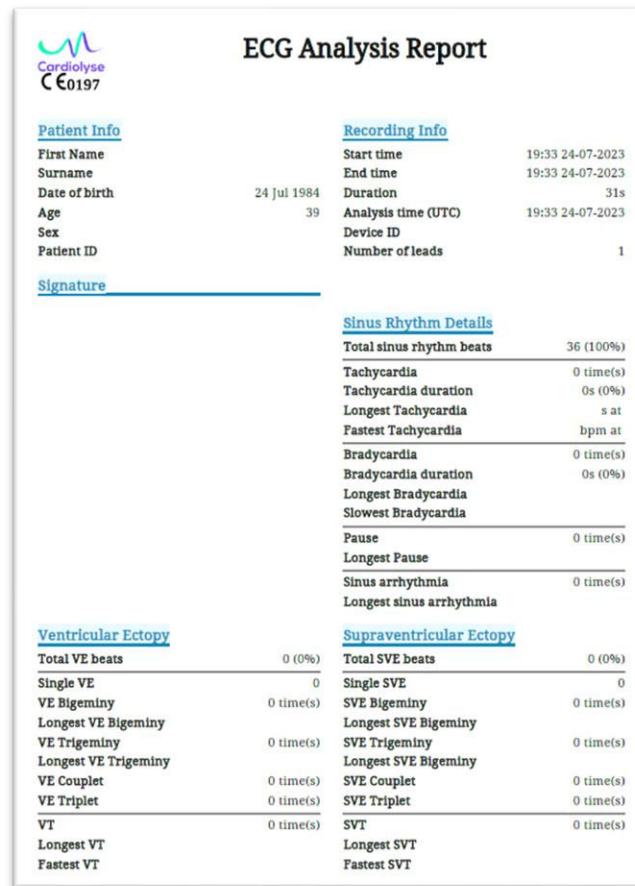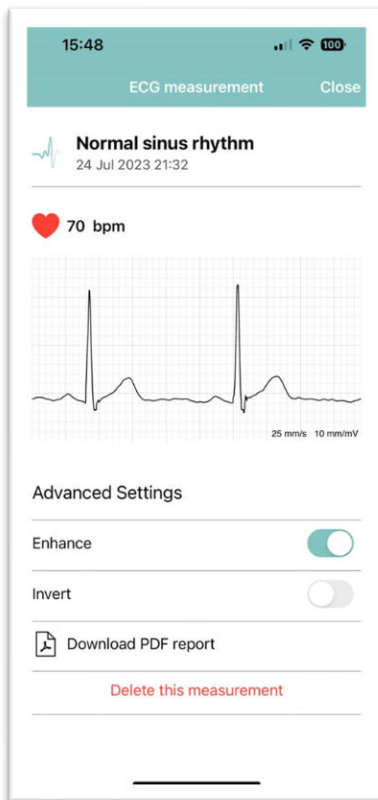
You can delete the measurement by pressing "Delete this measurement". You can export a PDF report by pressing "Download PDF report".

A full report is provided, generated by a CE MDR certified Cloud based ECG algorithm, by Cardiolyse.

10.4 ECG Warning

⚠️ The ECG recording cannot detect heart attacks. If you experience acute symptoms, call emergency services.

⚠️ DO NOT take ECG recording in vicinity of strong electromagnetic fields (metal detector, NFC systems, wireless chargers)

⚠️ DO NOT take ECG recording during medical procedure (MRI, diathermy, cautery)

⚠️ DO NOT use to diagnose heart problems, heart disease or heart-related conditions.

⚠️ DO NOT change your medication without talking with your general practitioner.

⚠️ Consult your general practitioner if your heart rate at rest is lower than 50 or over 150 bpm.

10.5 ECG Cautions

⚠ Presence of Atrial Fibrillation (AF) in your ECG results may represent only potential findings. If you have symptoms or concerns, please contact your general practitioner. If you believe you are experiencing a medical emergency, contact emergency services.

⚠ Error in ECG recording can be due to too much artefact or noise in the signal, because of too much movement during recording, bad wearing of the device or bad electrode contact. In rare cases, users may have certain physiological conditions preventing good ECG signal to be generated.

⚠ The CardioWatch 287-2 system is not intended for infants weighting less than 10 kg.

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

⚠ The Heart Rate from ECG is calculated as the rounded average over 30 seconds.

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

⚠ The CardioWatch 287-2 system 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

⚠ A low heart rate can be due to medications. Athlete training can also lead to a low heart rate.

⚠ A high heart rate can be due to exercise, stress, nervousness, alcohol dehydration, infection, AF or another arrhythmia.

⚠ Interpretations made by the CardioWatch 287-2 system are potential findings, not full diagnosis of cardiac conditions. The user shall not interpret or take clinical action based on the results. The user shall first consult a qualified healthcare professional.

⚠ The CardioWatch 287-2 system is meant to help in rhythm classification and abnormalities monitoring, and shall not replace traditional methods for diagnosis and treatment.

11 NON-INVASIVE BLOOD PRESSURE MEASUREMENT

To perform measurements of Cuffless Non-Invasive Blood Pressure from the pulse signal, the Corsano CariodWatch 287-2 system must first be calibrated with a Blood Pressure Cuff monitor. Corsano provides an external monitor (FDA K220676) that connects with the Corsano App to transmit the calibration data.

11.1 Pair the Blood Pressure Cuff to the Corsano APP

Please follow the steps to pair the external Blood Pressure Cuff to the Corsano App.
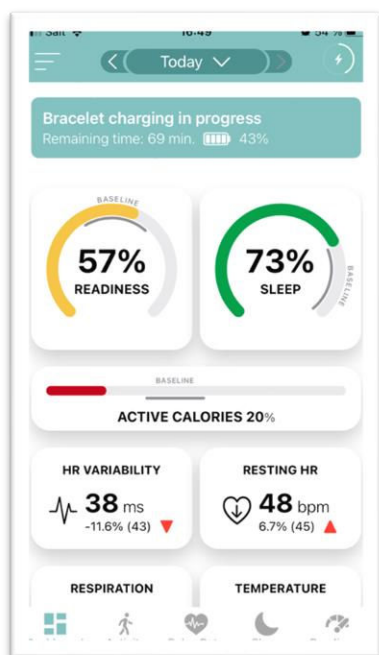
In the Dashboard, select the Menu icon, in the top left corner.
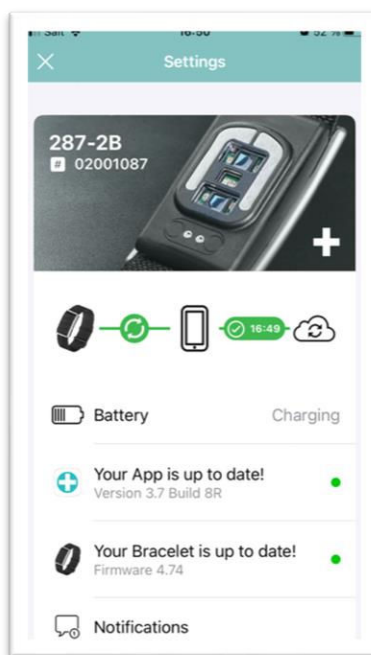
Scroll down to reach "Manage Devices"

Press "Blood Pressure Cuff".
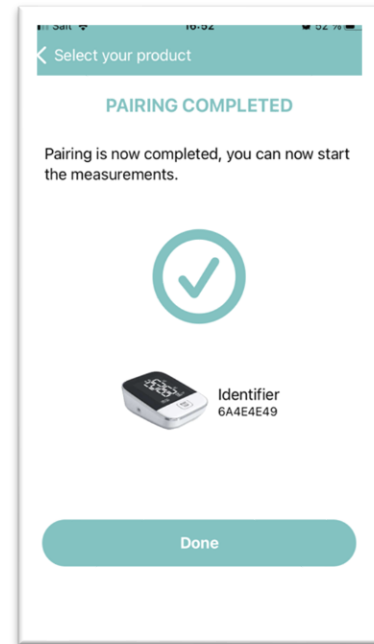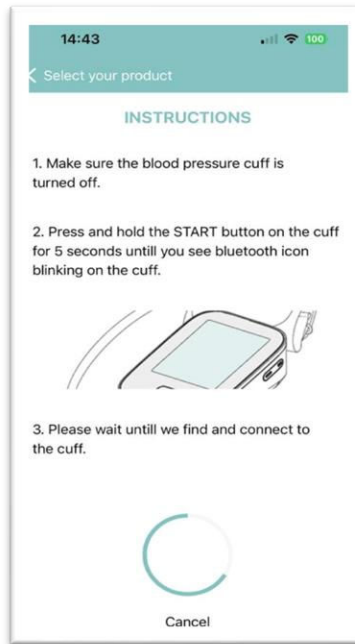
Make sure the Cuff monitor is powered (on batteries or with USB cable plugged to a power source).

In the APP, press "Start Paring".

Don't press the "START" button of the Cuff monitor.

If the APP does not connect, press "Cancel" to abort the pairing process and try again.

When the Corsano APP detects the Cuff monitor, it will show the identifier of the BP Cuff.

Make sure this is your device by visually checking the identifier number on the Cuff monitor.

Press the "Done" button to complete the pairing.

11.2 Perform a calibration measurement with the Blood Pressure Cuff

Please follow the steps to perform a calibration measurement with an external Blood Pressure Cuff.

You can watch the tutorial video on www.corsano.com, Support/Getting Started/Tutorial videos:

https://corsano.com/knowledge-base/movies/
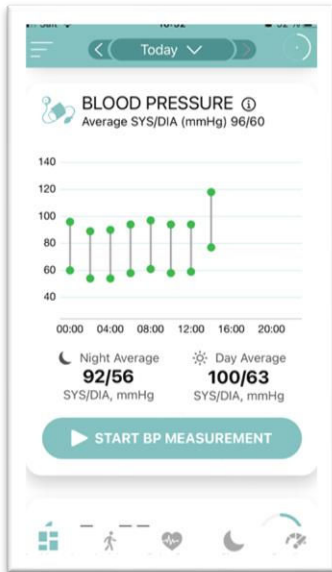
From the Dashboard view, press "START BP MEASUREMENT".
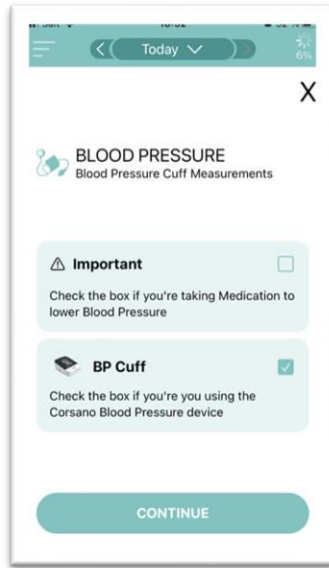
Tick the box if you take medication to lower Blood Pressure.

Make sure a Blood Pressure Cuff is paired to your Corsano APP.

Follow the instructions to properly adjust the tightness of the bracelet.

Follow the instructions to properly position the bracelet on the wrist.

Before the next steps, make sure the Blood Pressure Cuff is powered with internal batteries or external USB cable plugged to a power source. Sit on a chair, relax. Put the Cuff on your arm.

⚠ The Blood Pressure Cuff and the Corsano Bracelet on opposite arms. The BP Cuff and Bracelet **shall not be worn on the same arm!**
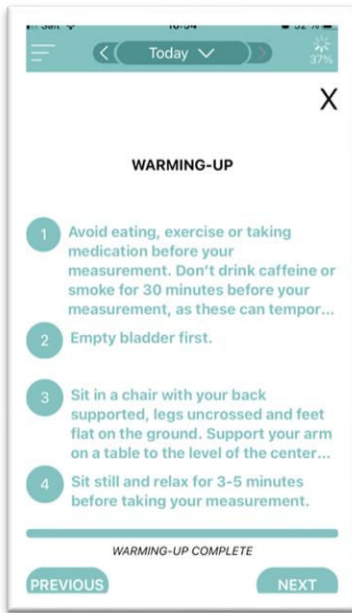
Prepare for the Blood Pressure Cuff measurement. Sit and follow the instructions.
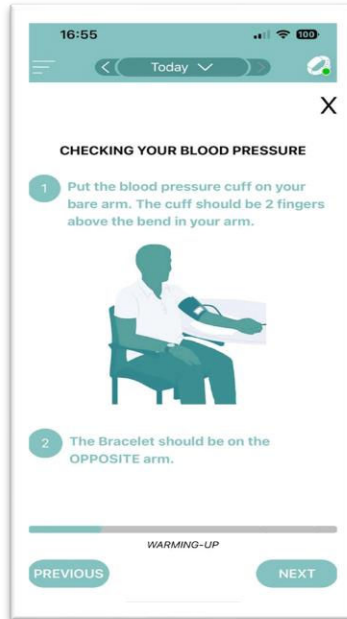
Rest your arm on a table at the same level as your heart.
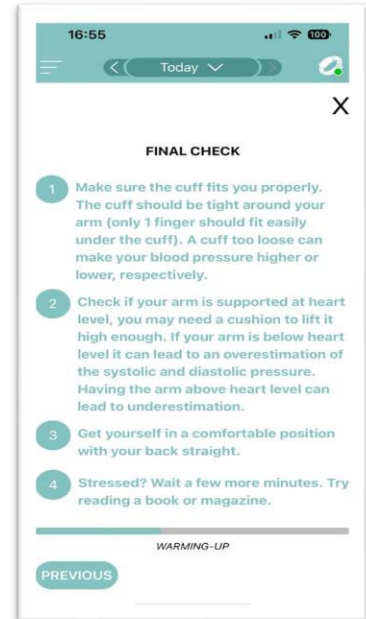
Check the tightness of the Cuff.
Your arm shall be at heart level. Sit and relax.
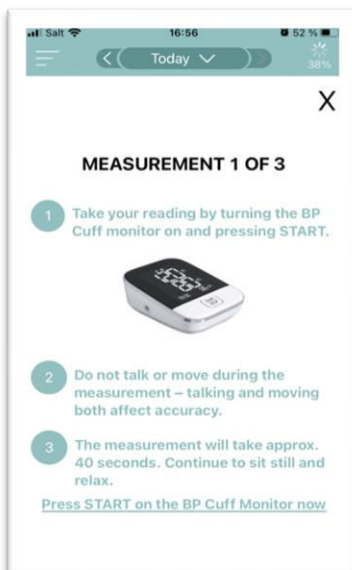
Press the "START" button on the Cuff monitor.
The Cuff will inflate and measure your Blood Pressure.
Wait for the measurement to finish. This takes about 30s.
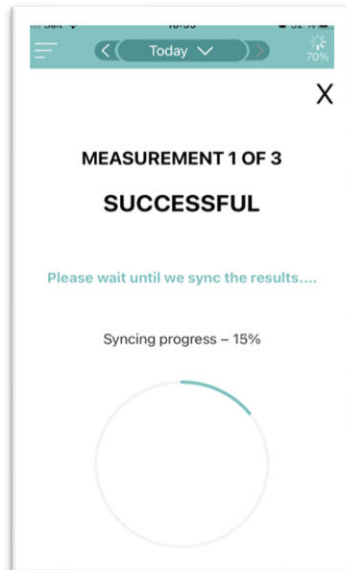
Wait for the data to synchronize to the APP. This takes about 30s.

Repeat the measurement 2 more times.
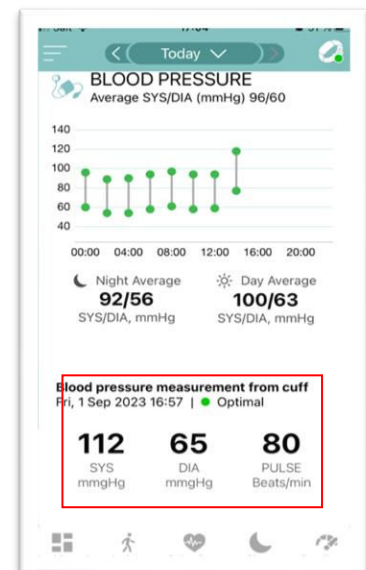
After completion of the third measurement, the Non-Invasive Blood Pressure is calibrated.
The result of the calibration is available in the APP.

⚠ The calibration of the Non-Invasive Blood Pressure with the external Blood Pressure Cuff monitor shall be performed **once per month**. Please follow the instructions of your Corsano APP.

12 PRINCIPLE OF OPERATION

The software in the CardioWatch 287-2 System generates Vital Parameters with Corsano proprietary algorithms within the Corsano Bracelet as well managing unadjusted measurements with external devices.

The following vital parameters are managed as part of the Corsano Algorithm:

Corsano Vital Parameter	Algorithm
Pulse Rate (PR)	Corsano Proprietary in Firmware
Saturation (Sp02)	Corsano Proprietary in Firmware
Respiration Rate (RR)	Corsano Proprietary in Firmware
Body temperature (TEMP)	Surface probe in direct mode
Motion Levels (MOTION)	Corsano Proprietary in Firmware
Steps (STEPS)	Corsano Proprietary in Firmware

Algorithms on Corsano Bracelet

The following external vital parameters are managed by each external device. Measurement data from the external device is transmitted via BLE APIs provided by the manufacturers of the external devices. The Corsano App (Patient Mode) receives the data and transmits data to the Corsano Cloud without adjustments:

External Vital Parameter	External Device	Status
Axillary Temperature (aTemp)	External Vivalink Axillary Temperature Sensor	FDA Cleared (K162137)
Non-Invasive Blood Pressure (CuffBP)	External Non-Invasive Blood Pressure Monitor Transtek TMB-2084-A	FDA Cleared (K220676)
Spirometry (SPIRO)	External MIR Spirobank	FDA Cleared (K072979)
Weight (WEIGHT)	External Weight Scale Transtek GBS-2012-B	FDA Listed (D1545656)

Measurements with External Devices

12.1 Pulse Rate principle of operation

The Corsano Bracelet utilizes a Photoplethysmography (PPG) sensor that consists of Light Emitting Diodes (LEDs) and photodiodes to capture reflected light. PPG is a commonly used in determining Pulse Rate (BPM), Oxygen Saturation (SpO2) and Respiration Rate (BRPM).

The working principle of the PPG sensor is based on the emission of LED light which penetrates the skin and blood vessels. This light is then reflected and captured by the photodiodes in Corsano Bracelet to measure the blood stream. The results of the PPG signal depend primarily on the flow of blood to the capillary vessels in each heartbeat. The waveform of the PPG signal indicates the changes in pulsatile blood flow from which the detection of signal peaks allows the calculation of peak-to-peak intervals. By determining the peak-to-peak distances between two subsequent PPG pulses, the algorithm derives the Pulse Rate of the patient.

The accelerometer (ACC) is utilized to compensate for movement artifacts. PPG and ACC are measured at 32Hz and data is processed by the algorithm to give a new reading of

Pulse Rate every 28 seconds utilizing averaging to smooth pulse rate data and prevent inappropriate and transient artifacts from affecting stability of results.

Specification claims of Pulse Rate:

Sensing Method	PPG, ACC
Measurement Range	25 bpm to 250 bpm
Resolution	1 bpm
Accuracy (Arms)	<3 bpm
Bias (+95%CI)	±0,5 bpm
Data Update Period	28 seconds

Pulse Rate Specification

12.2 SpO2 principle of operation

Corsano Bracelet utilizes the Photoplethysmography (PPG) sensor photodiodes to capture reflected light calculates your functional oxygen saturation (SpO2) using pulse oximetry on the wrist, a non-invasive technique to monitor oxygenation. It monitors the percentage of hemoglobin that is oxygen-saturated. The working principle is spectrophotometry: the relative absorption of red (absorbed by deoxygenated blood) and infrared (absorbed by oxygenated blood) light of the systolic component of the absorption waveform correlates to arterial blood oxygen saturations. Two light-emitting diodes, red with wavelength of 660 nm and infrared with a wavelength of 880 nm, are positioned so that they are opposite their respective photodiodes through 5-10 mm of tissue. Absorption of light at these wavelengths differs significantly between blood loaded with oxygen and blood lacking oxygen. Oxygenated hemoglobin absorbs more infrared light and allows more red light to pass through. Deoxygenated hemoglobin allows more infrared light to pass through and absorbs more red light. The accelerometer (ACC) is utilized to compensate for movement artifacts. Measurements of relative light absorption and ACC are measured at 32Hz and data is processed by the algorithm to give a new reading of SpO2 every 28 seconds utilizing averaging to smooth SpO2 data and prevent inappropriate and transient artifacts from affecting stability of results.

Specification claims of SpO2:

Sensing Method	Pulse Oximetry
Measurement Range	0% to 100%
Resolution	1%
Accuracy (Arms)	70-100%: <2 % 90-100%: <2 % 80-90%: <2 % 70-80%: <2 %
Bias (+95%CI)	70-100%: ±0,5 % 90-100%: ±0,5 % 80-90%%: ±0,5 % 70-80%: ±0,5 %
Data Update Period	28 seconds

Sp02 Specification

12.3 Respiration Rate principle of operation

The Respiration Rate is the number of breaths a person takes per minute (BRPM). Corsano Bracelet utilizes a proprietary time-frequency algorithm to extract the respiratory-induced intensity, amplitude and frequency variation signals from the photoplethysmography (PPG) signal.

The accelerometer (ACC) is utilized to compensate for movement artifacts. PPG and ACC are measured at 32Hz and data is processed by the algorithm to give a new reading of Respiration Rate every 28 seconds utilizing averaging to smooth pulse rate data and prevent inappropriate and transient artifacts from affecting stability of results.

Specification claims of Respiration Rate:

Sensing Method	PPG, ACC	
Measurement Range	4 brpm – 60 brpm	
Resolution	1 brpm	
Accuracy	Pooled	<2 brpm
	Supine	<1 brpm
	Prone	<2 brpm
	Lateral	<1 brpm
	Sitting 90°	<2 brpm
	Sitting 45°	<1 brpm
	Hyperventilation	<2 brpm
	Hypoventilation	<1 brpm
	Coughing	<1 brpm
	Treadmill	<2 brpm
Bias	Pooled	±0,5 brpm
	Supine	±0,5 brpm
	Prone	±1 brpm
	Lateral	±1 brpm
	Sitting 90°	±1 brpm
	Sitting 45°	±0,5 brpm
	Hyperventilation	±0,5 brpm
	Hypoventilation	±0,5 brpm
	Coughing	±0,5 brpm
	Treadmill	±1 brpm
Data Update Period	28 seconds	
Apnea Detection	No	

Respiration Rate Specification

12.4 Steps Activity principle of operation

Steps are calculated by the proprietary algorithm based on the intensity and frequency of your acceleration data.

Accuracy of Steps with Corsano Bracelet will be studied in February-March by RadboudMC versus Reference Device FDA Cleared Actigraph CenterPoint Watch.

📖 **NOTE :** the Activity (Motion Levels & Steps) parameter is considered a software function solely intended to *monitors and records daily energy expenditure and cardiovascular workout activities to allow awareness of one's exercise activities*

to improve or maintain good cardiovascular health.

As per the FDA guidance on General Wellness: Policy for Low Risk Devices, Sept 2019; such a software function is not a device function, as such Activity Levels are provided for information purposes only.

⚠️ Motion levels are provided for information purposes only. They should not be relied upon to inform patient care.

12.5 Temperature principle of operation

Corsano Bracelet monitors **skin temperature** in direct mode from a sensor in the wearable device. Skin temperature is presented in °C, or in °F as configured in Settings/Profile.

Specification claims of skin temperature:

Sensing Method	Surface probe in direct mode
Measurement Range	34.0 °C to 42.0° C (93.2°F to 107.6°F)
Resolution	0.1°C
Accuracy	± 0.3°C (0.54°F)
Performance	Conform to ISO 80601-2-56
Data Update Period	28 seconds

Skin Temperature Specification

12.6 Cuffless Non-Invasive Blood Pressure

Advanced photoplethysmography (PPG) signal analysis extracts the characteristics of the reflection waveforms. They are then fed to an artificial intelligence (AI) model. Thus, the model can predict systolic and diastolic blood pressure values.

The Corsano Bracelet makes use of the PPG sensor, which includes the emission of light by LEDs to the skin and the measurement of reflected light by photodiodes. The PPG signal is strongly dependent on the amount of light that is absorbed by the arterial blood in the tissue and reflectance on arterial/arteriole blood flow. As such, the PPG signal contains a pulsatile component that fluctuates with the blood volume changes in the peripheral tissue introduced during each cardiac cycle. This waveform contains information that is either directly or indirectly related to blood pressure. By extracting this information from the waveform and comparing it to previously acquired data from patients' datasets, a prediction is made of blood pressure. The Corsano Bracelet extracts information from 6 simultaneously acquired waveforms, combining 3 wavelengths, 6 LEDs and 2 photodiodes.

From the PPG segments, features are extracted, which are used in the Machine learning model. To get a valid prediction, a combination of statistical features, time and frequency domain features, demographic features, first/second derivative features, width related PPG features and features from the PPG signal are used.

The Corsano CardioWatch 287-2 System was validated against the harmonized standard ISO 81060-2:2019 and AAMI/ESH/ISO collaboration statement "A Universal Standard for the Validation of Blood Pressure Measuring Devices" 2018. for Non-Invasive Blood Pressure measurement devices, in a clinical investigation on 97 subjects.
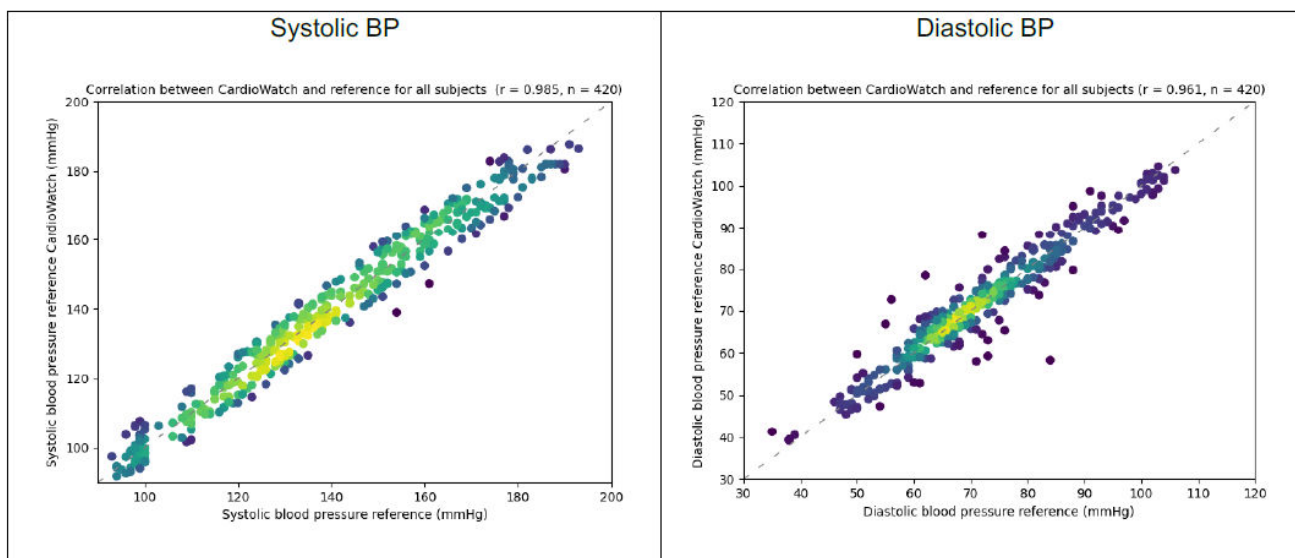
Correlation between Corsano Non-Invasive Blood Pressure measurement and the reference (Invasive measurement, Fysicon)
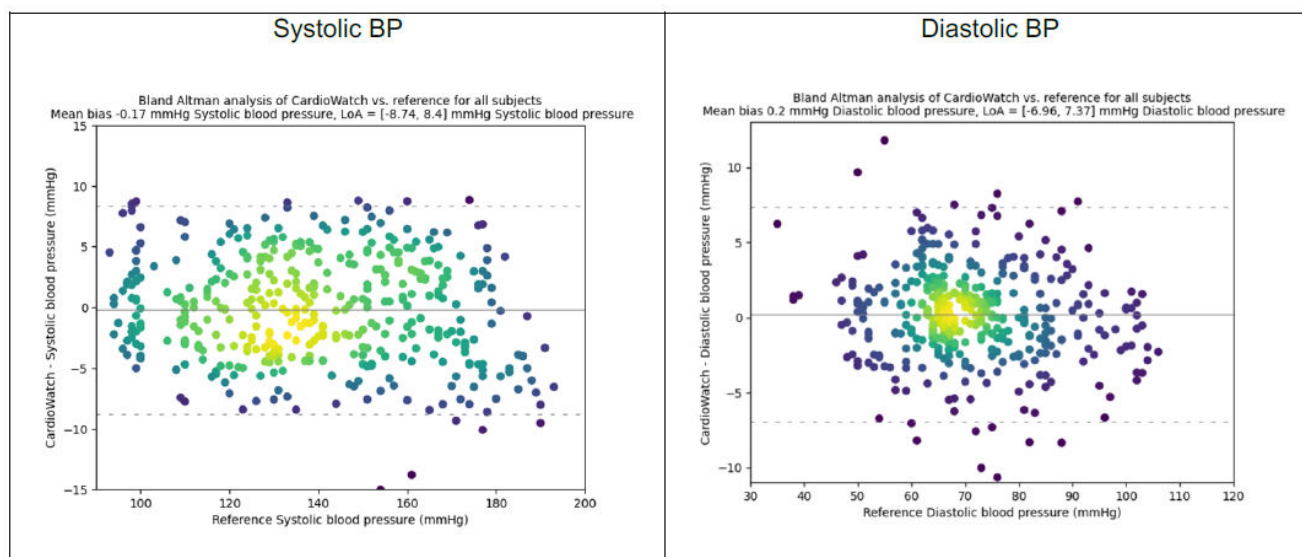
Bland-Altman plot comparing the Corsano Non-Invasive Blood Pressure measurement and the reference (Invasive measurement, Fysicon)

Specification claims of Non-Invasive Blood Pressure:

Sensing Method	Derived from PPG signal
Measurement Range	60-230 mmHg (Systolic) 40-130 mmHg (Diastolic)
Resolution	1 mmHg
Accuracy	± 5 mmHg
Data Update Period	28 seconds

Non-Invasive Blood Pressure Specification

12.7 ECG

A 1-lead ECG system records the electrical activity of the heart using one electrode pair. The electrode pair consists of an electrode at the underside of the Corsano Bracelet and the frame on the top. The 1-lead ECG measures the voltage difference between the two electrodes which reflects the direction and magnitude of the cardiac electrical currents. A third electrode is used to reject noise and artefacts.

The Corano Bracelet can perform 1-lead ECG measurement thanks to the three electrodes of the enclosure. Two electrodes are located on the bottom of the enclosure and are in contact with the wrist skin. One is the positive electrode. The second bottom electrode is used to reject DC signal and electrical noise and enables an increase of the accuracy of the measurement. The third electrode is located in the stainless-steel frame of the Bracelet enclosure. This is the negative electrode of the 1-lead ECG system.

The Corsano Bracelet 1-lead ECG is CE MDR certified and was tested against the harmonized standard IEC 60601-2-47:2015 for ambulatory electrocardiographic systems.

The Corsano Bracelet 1-Lead ECG is composed of a front-end analogue pass-band filter (0.05-55 Hz). The electrical signal is sampled at 256 Hz on 15 bits, on an AC dynamic range of 200mVp-p. The raw signal is sampled by the Bracelet and sent to the Corsano APP and Cloud.

The Cloud algorithm performs the filtering of the signal. The DC component of the ECG is removed. A "Pan and Tompkins" QRS detection identifies the QRS complexes and enables to reject the high frequency noise on the other sections of the signal.
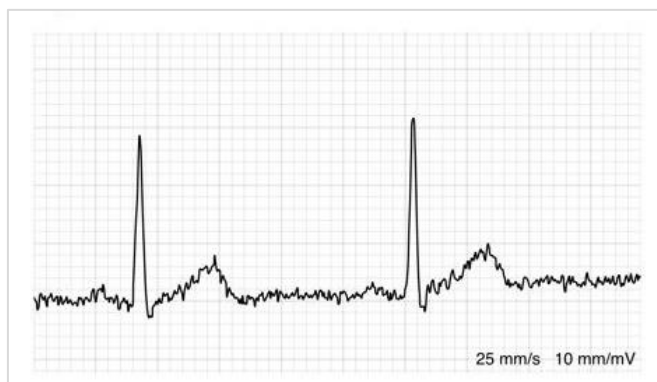
Raw ECG signal without DC component
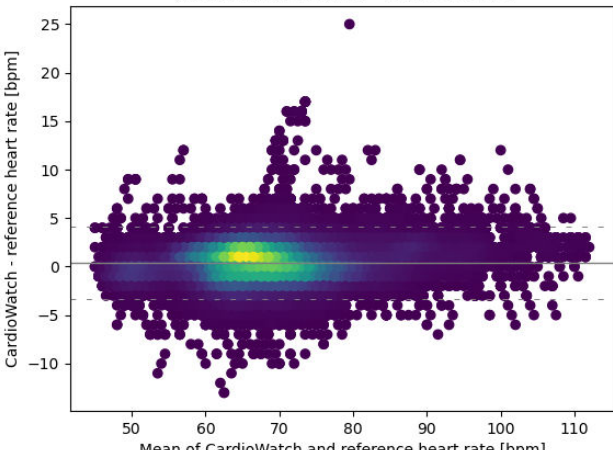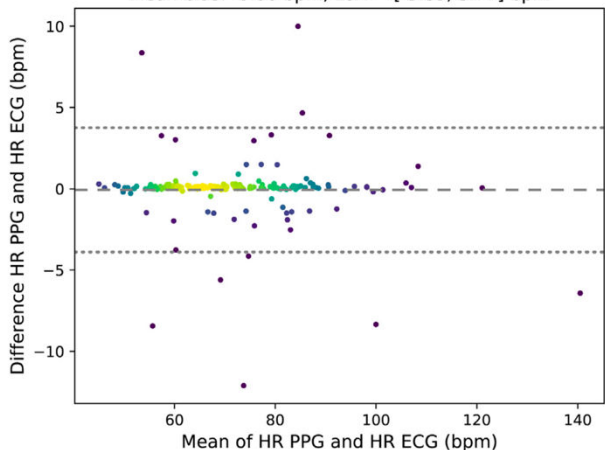
ECG signal after Pan-Tompkins QRS detection and filtering

13 CLINICAL PERFORMANCE

Measurements of Vital Parameters with multi-sensor, convenient Cardiowatch 287-2 system were validated in multiple clinical trials and test laboratories.
Please find a summary, full reports and publications are available on request.

13.1 Pulse Rate

Accuracy has been measured in multiple studies, below are results of two those studies:

Accuracy of CardioWatch 287-2 during profound hypoxia (ISO 80601-2-61)	The accuracy of heartbeat detection using photoplethysmography technology in cardiac patients
Complementair Medisch Centrum (CMC) Europe, Genk, Belgium	Cardiologie Centra Nederland, Amsterdam UMC, Location AMC, The Netherlands
12 healthy volunteers in hypoxia lab	180 cardiovascular patients in a real-life outpatient setting
PPG derived pulse rate versus reference pulse oximeter (Nellcor PM10)	PPG derived pulse rate versus reference 12-lead ECG (Welch Allyn Pro)
Arms = 1,95 Bias = 0.44 (0.42 - 0.46) bpm	PPG-accuracy pulse rate 94.6%

Pulse Rate validation

13.2 Pulse Oximetry (SpO2)

Accuracy was measured in a controlled, induced hypoxia study in 24 healthy adult volunteers in accordance with ISO 80601-2-61 at rest and under motion. Study title: Accuracy of CardioWatch 287-2 during motion and different positions of the body, with or without hypoxia. Location: Complementair Medisch Centrum (CMC) Europe, Belgium. The Corsano CardioWatch 2872 system was calibrated with reference oximeter Nellcor PM10.

See Bland-Altman plot next page comparing the CardioWatch 287-2 Software-derived SpO2 and the Nellcor reference SpO2 pooled over all subjects at rest. The solid line represents the bias and the dashed line represents the limits of agreement.
Testing confirmed the accuracy of the SpO2 monitoring of 2,3 Arms with a Bias of 0.23 (0.21 - 0.24) %, N=94'572.
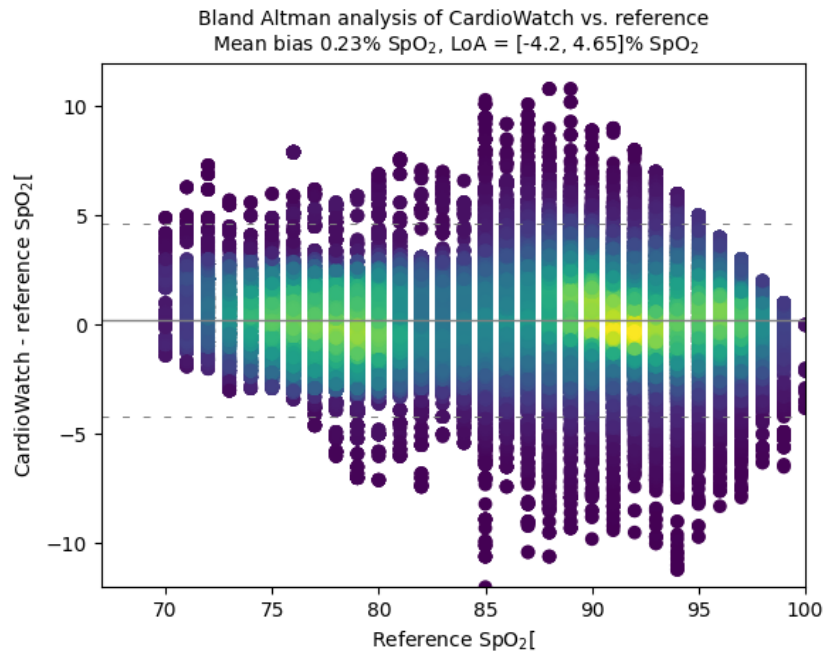
Bland Altman SpO2 CardioWatch 287 versus Nellcor PM10

Bland-Altman plot for CW2 SpO2 and CO-oximetry SaO2 in the invasive study under motion. Accuracy of SpO2 of CW2 compared to CO-SaO2 for all subjects, for pooled conditions, was 1.63 Arms with Bias of 0.05 (-0.14, 0.23) %, N=287.
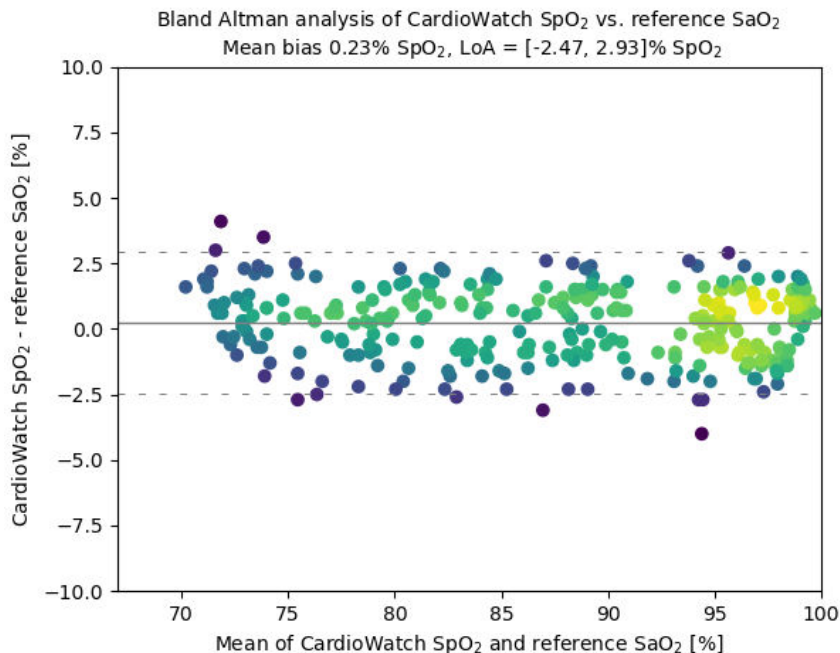
Bland Altman SpO2 CardioWatch 287 versus SaO2

13.3 Temperature

Accuracy of CardioWatch 287-2 Skin Temperature was measured by testing laboratory VDE Prüf- und Zertifizierungsinstitut GmbH, Offenbach, Germany in accordance with ISO 80601-2-56 - Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for temperature measurement.

13.4 Activity (Steps)

RadboudMC, Nijmegen, The Netherlands compared measured steps per minute determined by the Cardiowatch with steps per minute determined with the Actigraph CENTREPOINT Insight Watch. Accuracy of was 1,2 Arms with Bias of 0.7 (0.6, 0,7) Steps, N=3695.

Accuracy Steps
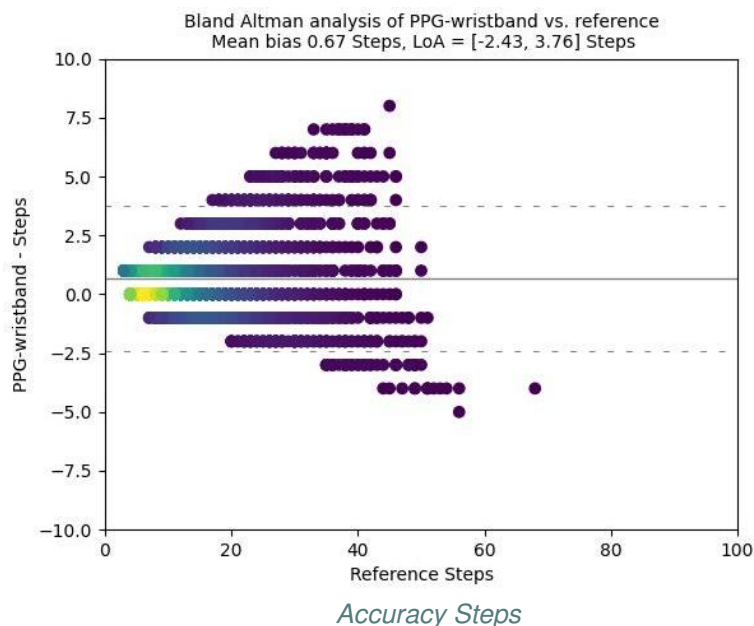
13.5 Respiration

Accuracy was measured in multiple studies, here are results of two studies:

Accuracy of CardioWatch 287-2 during profound hypoxia	Continuous respiration rate monitoring using photoplethysmography technology in patients with Obstructive Sleep Apnea
Complementair Medisch Centrum (CMC) Europe, Genk, Belgium	Haaglanden Clinics, The Hague, The Netherlands
12 healthy volunteers in hypoxia lab	26 subjects with and without diagnosed Obstructive Sleep Apnea (OSA)
PPG derived respiration rate versus reference pulse oximeter (Nellcor PM10)	PPG derived respiration rate versus reference respiratory polygraphy (Noxturnal T3)
Accuracy respiration rate 0.91 Arms, Bias 0.03 brpm, N=31'260	Accuracy respiration rate 0.6 Arms, Bias -0.14 brpm, N=31'083

Respiration Rate validation

14 CYBERSECURITY

14.1 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+.

14.2 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.

14.3 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.

14.4 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.

14.5 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.

15 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.

16 TECHNICAL SPECIFICATIONS

16.1 Corsano Mobile App

Minimum requirements for mobile device Operating Systems:

- iO 14.5 or higher
- Android 8.0 or higher

16.2 Corsano Bracelet

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[1] IP66

Operational Temperature.. +10 to +40 ºC

Ambient Temperature when charging .... +10 to +35 ºC

Transport and storage Temperature .... -20 to +60 ºC

Operational Humidity... 20% to 80%

Transport and storage Humidity.. 20% to 90%

Interface

Wireless Communication .... BLE 5.0

Display LEDs.. green, orange, blue

Expected Service Life[2]

Bracelet .... 2 years

[1] IP66: Totally protected against dust. Protected against strong jets of water.
[2] the time period during which the bracelet is expected to remain safe for use (maintain basic safety & essential performance as per IEC60601-1).

16.3 AC-DC Power Supply (USB Adapter)

USB adapter must conform to UL/cUL 60601-1 with the following characteristics:
- Input voltage: AC 100-240V, 50/60hz
- Output voltage: DC 5V (+/- 5%)
- Output current: 500 mA (minimum)

The following USB Adapter Model has been validated by Corsano :

Company	CUI Inc
Manufacturer Part Number	SWM6-5-NH-I38

For any other models, please confirm the conformity to the above standards.Should you have questions please contact support@corsano.com

16.4 Regulatory Conformity

Regulation (EU) 2017/745 on Medical Devices (EU-MDR)
Directive 2011/65/EU on the Restriction of Hazardous Substances (RoHS)
Regulation (EU) 2016/679 on General Data Protection Regulation (GDPR)
Regulation (EU) 2014/53 on Radio Equipment (RED)

16.5 Applied Standards

IEC 60601-1:2005 + AMD1:2012 + AMD2:2020
IEC 60601-1-2:2014 + AMD1:2020
IEC 60601-1-6:2010 + A2:2021
IEC 60601-1-8:2006 +AMD1:2012 + AMD2:2022
IEC 60601-1-11:2015 + AMD1:2020
IEC 62304:2006 + AC:2008 + AMD1:2015
IEC 62366-1:2015 + A1:2020
IEC 82304-1:2016

ISO 10993-1:2018
ISO 13485:2016
ISO 14971:2019 / EN14971:2019 + A11: 2021
ISO 14155:2020
ISO 15223-1:2021
ISO 20417:2021

ISO 80601-2-55:2018
ISO 80601-2-56:2017
ISO 80601-2-61:2017

17 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) is recommended to 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 Bracelet. The Bracelet shall be removed during treatments.

⚠️ Security systems (e.g., electromagnetic anti-theft systems (EAS), metal detectors), near-filed 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 Bracelet.

⚠️ 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 cannot 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 Corsano Bracelet 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	Corsano Bracelet TYPE BF APPLIED PART

PPG sensor is exposed on the back of the Corsano bracelet. The PPG sensor makes contact with the user's skin (as per IEC 60601-1).

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 home environment and Professional Health Care facilities environment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable (power < 50W)	
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**

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 the 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)** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	60Hz 110Vac 60Hz 230Vac 50Hz 110Vac 50Hz 230Vac	Compliant	$d = 2.3 \sqrt{P}$ 800 MHz to 6 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).
Conducted RF IEC 61000-4-6	10Vrms 150 kHz to 80 MHz	Compliant	
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	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:

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**
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 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 the 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 the 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			
The 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.			

18 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 Corsano Health B.V. or an experienced technician for help.

NOTICE: This device complies with Part 15 of the FCC Rules and with *Innovation, Science and Economic Development Canada's licence-exempt RSS(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 superior.

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: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

19 DISPOSAL / END OF LIFE

Equipment : once your bracelet & USB charge cable has reached its end of life the must be properly recycled so that the material can be reused and will not end up in the environment. Preferably take your device to a recycling service for Waste Electrical and Electronic Equipment.

The Strap is not considered WEEE and should be disposed of separately.

⚠ Once your application is no longer required, it is recommended to delete the application from your telephone : all data (patient & results) will be deleted.

Should you have questions please contact support@corsano.com

⚠ The strap is single patient use and should be disposed of in clinical waste or according to local guidelines and regulations.

⚠ Risk of infection. The Bracelet & USB Charge Cable must be cleaned & disinfected before disposal.

⚠ The Bracelet contains a lithium-ion battery. Do not incinerate the device or place in a trash compactor. Do not puncture the battery.

20 CORSANO CONTACT INFORMATION

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21 HISTORY OF CHANGES

Version	Date	Changes
v. 1	11-11-2021	First internal release.
v. 2	08-12-2021	Preliminary release for regulatory assessment
v. 3	30-12-2021	Preliminary release for regulatory assessment
v. 4	10-02-2022	Preliminary release for regulatory assessment
v. 5	16-02-2022	Preliminary release for regulatory assessment
v. 6	17-03-2022	First release for market
v. 7	28-03-2022	Update disposal information
v. 8	28-03-2022	Add Instructions for ECG recording
v. 9	24-04-2022	Update Safety Information
v. 10	11-05-2022	Update Clinical Performance
v. 11	03-06-2022	Update Safety Information
v. 12	20-09-2022	Remove CardioWatch 287-1
v. 13	02-03-2023	Update Electrical Safety and EMC
v. 14	15-03-2023	Add Cybersecurity considerations
v. 15	17-08-2023	Add instructions for Non-Invasive Blood Pressure Add Principles of Operation Update Safety Instructions Update Cautions and Warnings Add instructions for external devices
v. 16	22-06-2024	Add version history