EN

# CardioWatch 287-2B

## 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 287-2B 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 |
| HCP | Healthcare Practitioner |
| 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 |

**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.

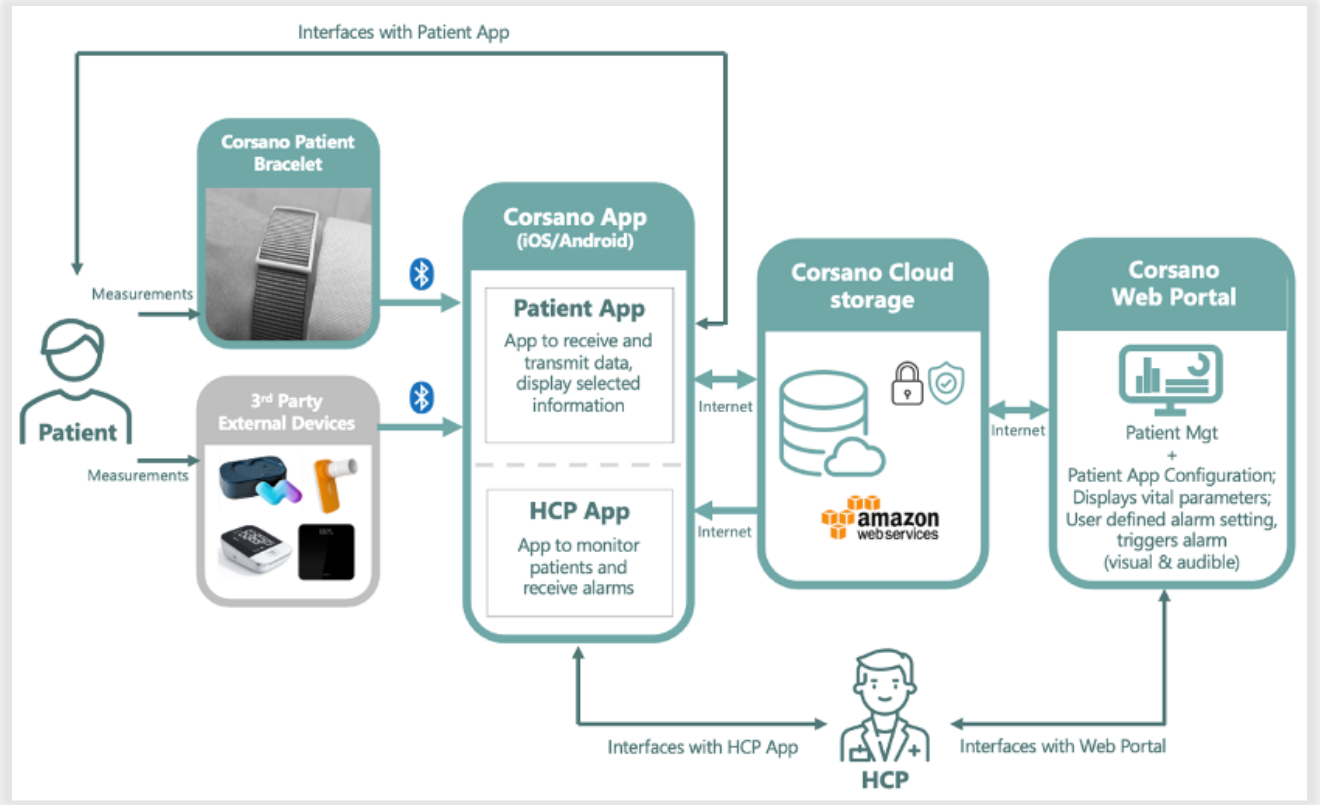
# 1 TABLE OF CONTENTS

# 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 22 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), skin temperature (sTEMP) and activity levels (STEP), and for intermittent monitoring of respiratory rate (RR) from the person being monitored and securely transmit the encrypted data via the Patient App to the secure server.

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

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 (NIBP), 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 287-2B 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 287-2B 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 patients having a Physical Status classification of ASA IV & V (American Society of Anethesiologists).
- 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.
- 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.

## 3.3 NOTES

The CardioWatch 287-2 Bracelet is provided non-sterile.

## 3.4 Indications for Use

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

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

The CardioWatch 287-2 System is intended for monitoring of skin temperature at wrist of the patient or axillary temperature with connected thermometer device.

The CardioWatch 287-2 System is intended for continuous monitoring of the following physiological indices in adults (over 22years old):

- Pulse rate
- Oxygen saturation
- Temperature
- Movement

The CardioWatch 287-2 System is intended for intermittent monitoring with the CardioWatch Bracelet of the following physiological indices in adults (over 22years old):

- Respiration rate.

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

- Non-invasive blood pressure
- Lung function & spirometry
- Weight

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

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

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

## 3.5 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.

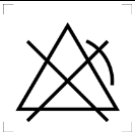
## 3.6 Essential Performance

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, Skin Temperature, Respiration Rate as well as data & alarm 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)<br>TYPE BF Applied Part (IEC 60417-5333) |
|  | Indicates the manufacturer's catalogue number so the medical device can be identified |
|  | Indicates the manufacturer's serial number so that a specific medical device can be identified |
|  | CE marking indicates that a product complies with applicable European Union regulations |
|  | FCC marking indicates the electronic device, which sold in the United States, is certified and the electromagnetic interference from the device is under the limits that are approved by Federal Communications Commission |
|  | Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005 |
|  | Refer to instruction manual/booklet. |
|  | Wearable device (Bracelet) does not generate alarms. |
|  | For prescription use only (USA) |

| Symbol | Meaning |
| --- | --- |
|  | 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

The following hardware is provided as part of the Corsano CardioWatch 287-2 System :

**One bracelet CardioWatch 287-2:**

*Bracelet - CW287-2B*

**One USB charging cable:**


*Charger (CS-287CH-1)*

**One AC / DC Power Supply (USB) Adapter:**

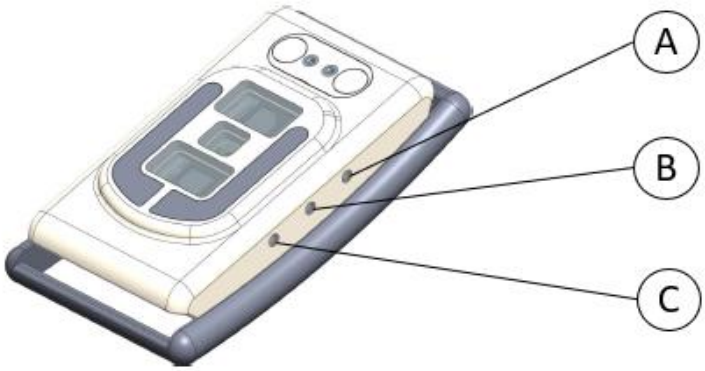

*AC/DC USB Adapter (CS-287AC)*

**One package Box with instructions:**

*Instruction Manual (IFU Corsano CardioWatch 287-2 Bracelet)*

# 6 KNOW YOUR BRACELET

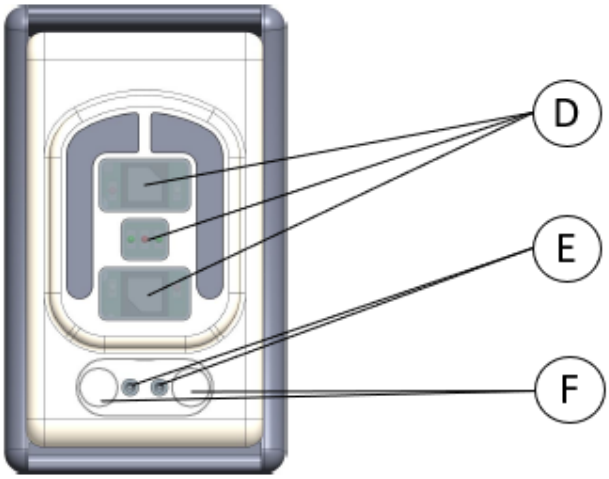
## 6.1 Back and Side of the bracelet




*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 should remove the Bracelet when used in wet environments, such as a shower or swimming, as this may reduce the performance and accuracy of the measurements provided.

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.

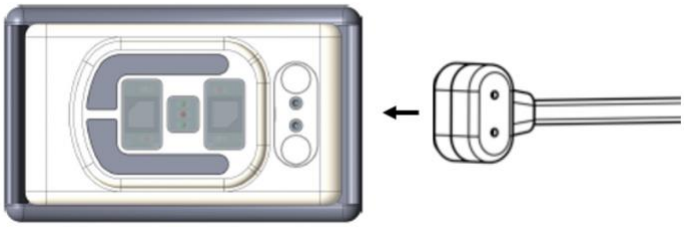
If the device is removed from Bluetooth range, it will store signal data for a maximum of 24 hours. After 24 hours, the oldest data will be erased.

## 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.

⚠ If the Bracelet or USB Adapter gets hot, immediately unplug the USB Adapter from the mains.

⚠ Make sure to position the USB Adapter where it is easy do disconnect.

### 6.5.2 CAUTIONS:

⚠ Use only AC USB Adapter provided with the bracelet to charge the bracelet to avoid potential electrical shock.

⚠ 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.

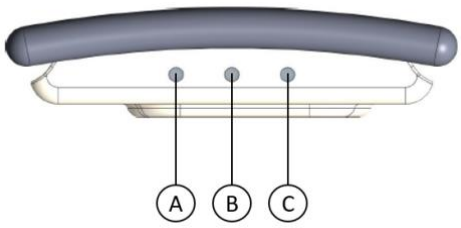
When handling the charger cable:

⚠ 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 287-2B Bracelet, USB Charger Cable & USB Adapter 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 287-2B 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 Charger Cable & USB Adapter 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:

- Wip'Anios Excel
- 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, cable or adapter for damage and do not use in case of damage.

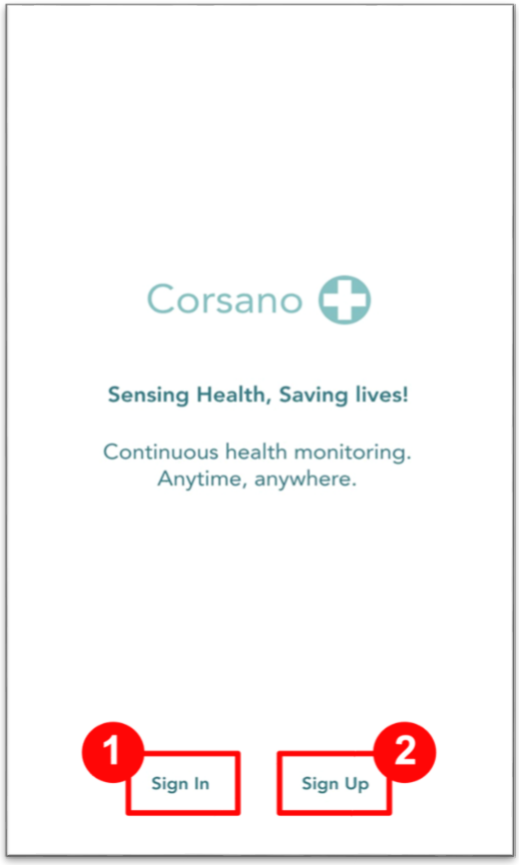
# 7 USING YOUR BRACELET WITH THE CORSANO APP

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

Download on the App Store  GET IT ON Google Play

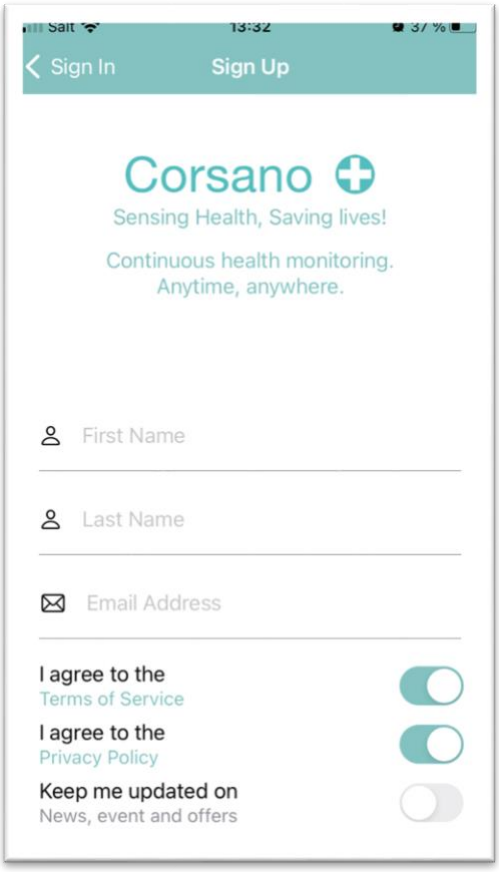
## 7.2 First time use – Sign Up

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




*Choose Sign-Up*

Enter First Name, Last name, Email




*Sign-Up*

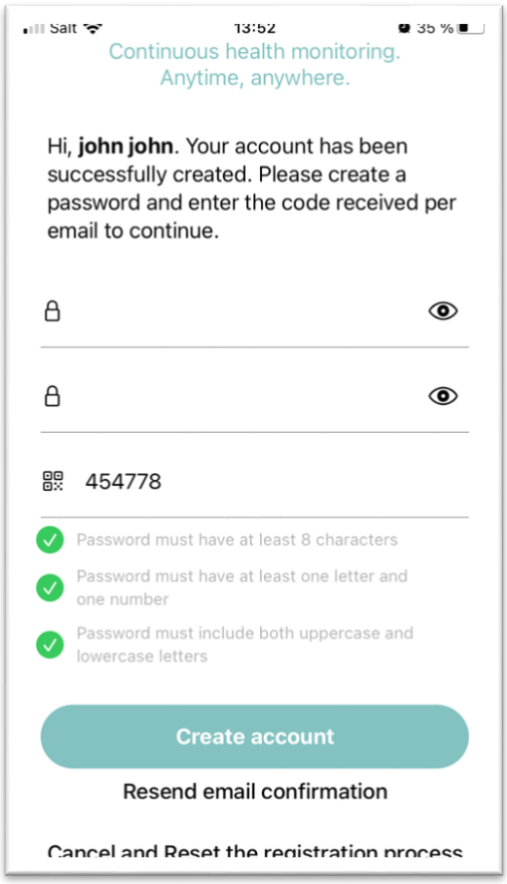
Agree on Terms of Service and Privacy Policy

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

Enter:

- Your password
- Your password again
- The received code

Press “Create account”

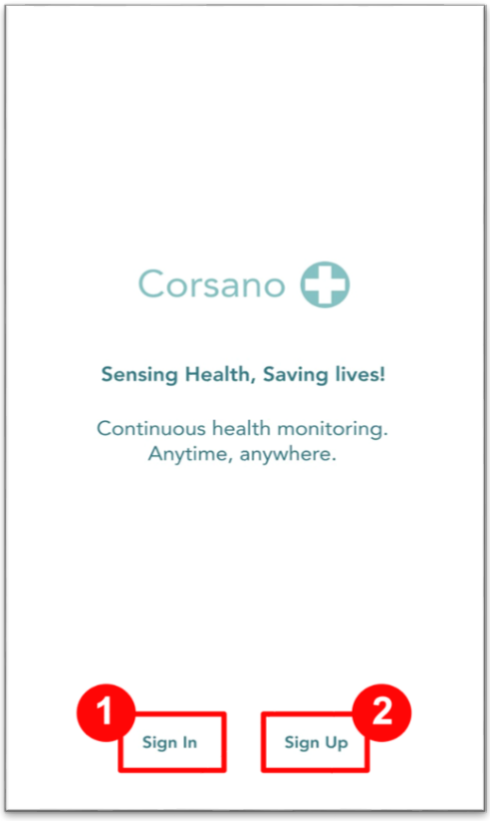



*Create account*

## 7.3 Sign In

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

Select “Sign In” (1)

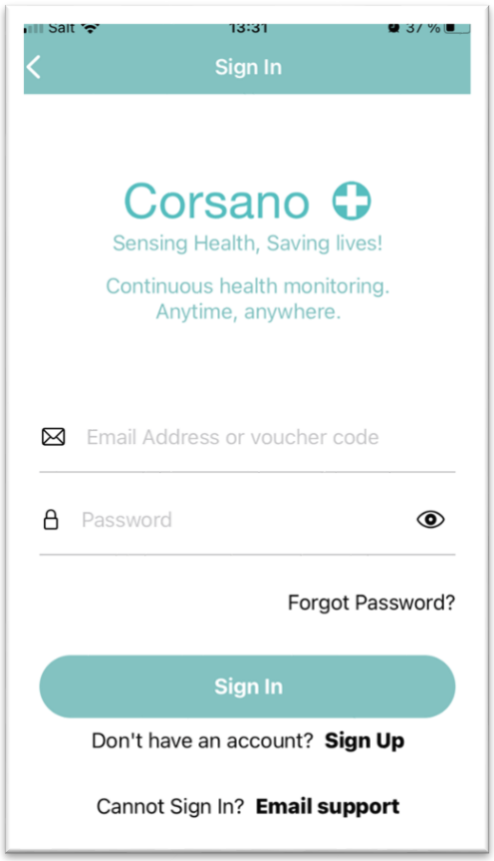



*Choose Sign-In*

Enter:

- Email
- Password

Press **“Sign In”**



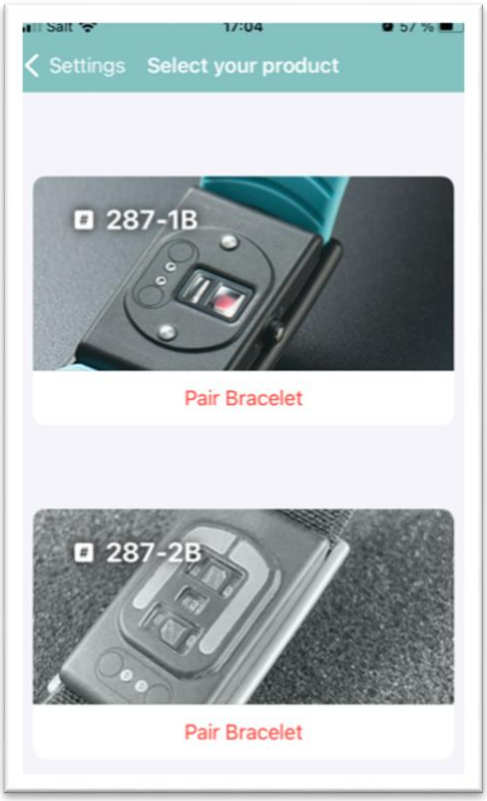

*Sign-In*

## 7.4 Pairing Your Bracelet

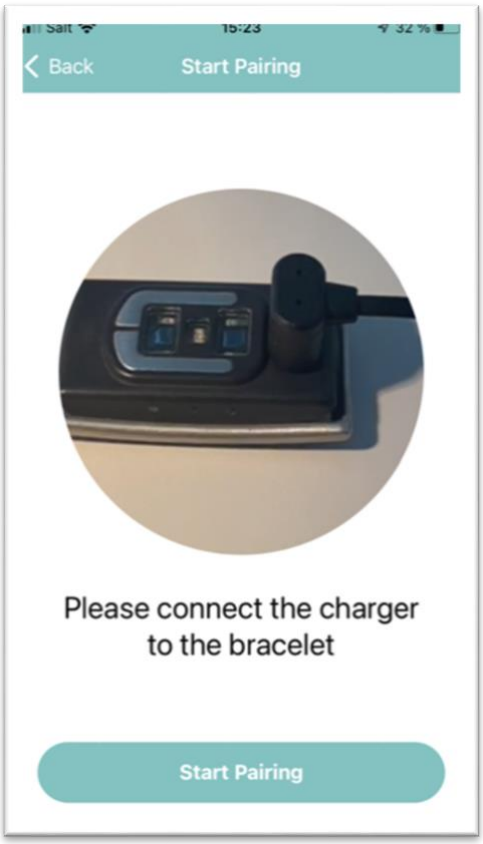
Upon first sign-in, user will be asked to pair a bracelet, follow the instructions:

First, select your bracelet in the list:

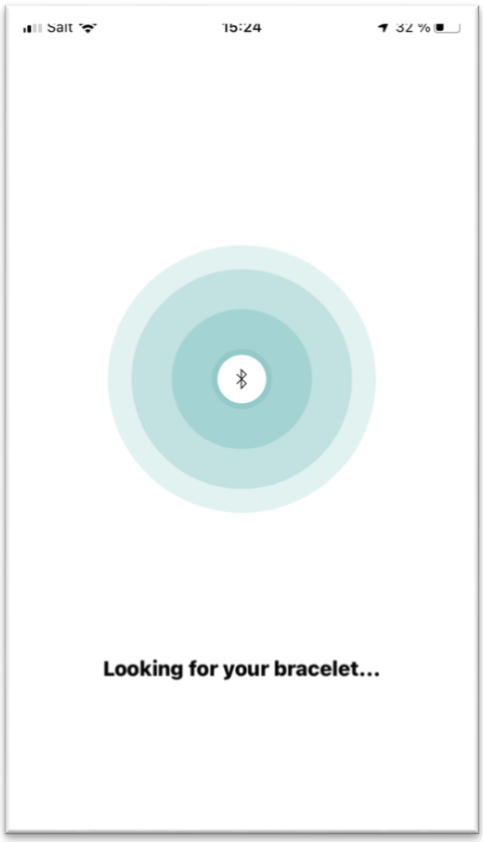
- 287-2B



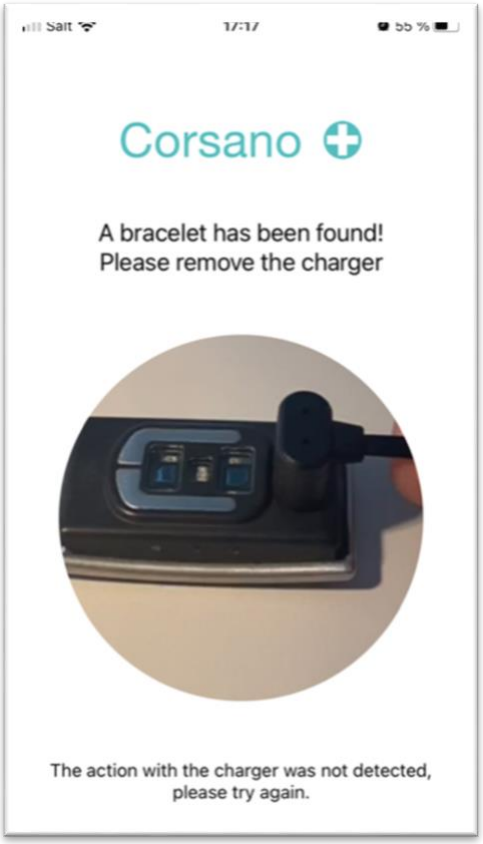

*Pair Bracelet*




*Connect the charger and press Start Pairing*




*Wait for the app to find the bracelet*



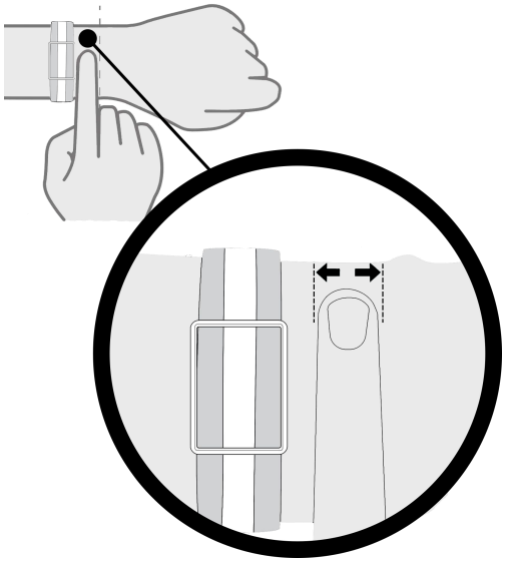

*Remove charging cable to complete pairing*

## 7.5 Wearing Optimization

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

The 287-2B 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 287-2B Bracelet should be placed in direct contact with the skin, on the top side of the wrist. The 287-2B Strap should be snug, but not too tight – just tight enough to ensure the bracelet makes solid contact with your skin.



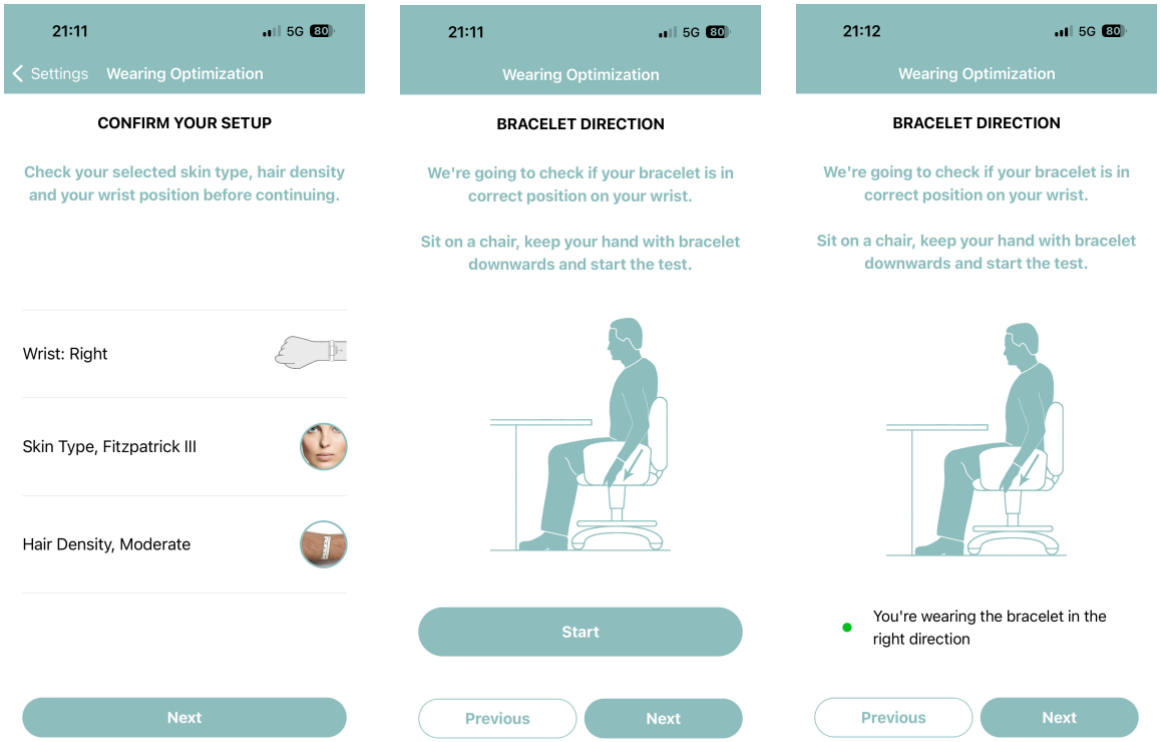
*Bracelet Positioning*

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

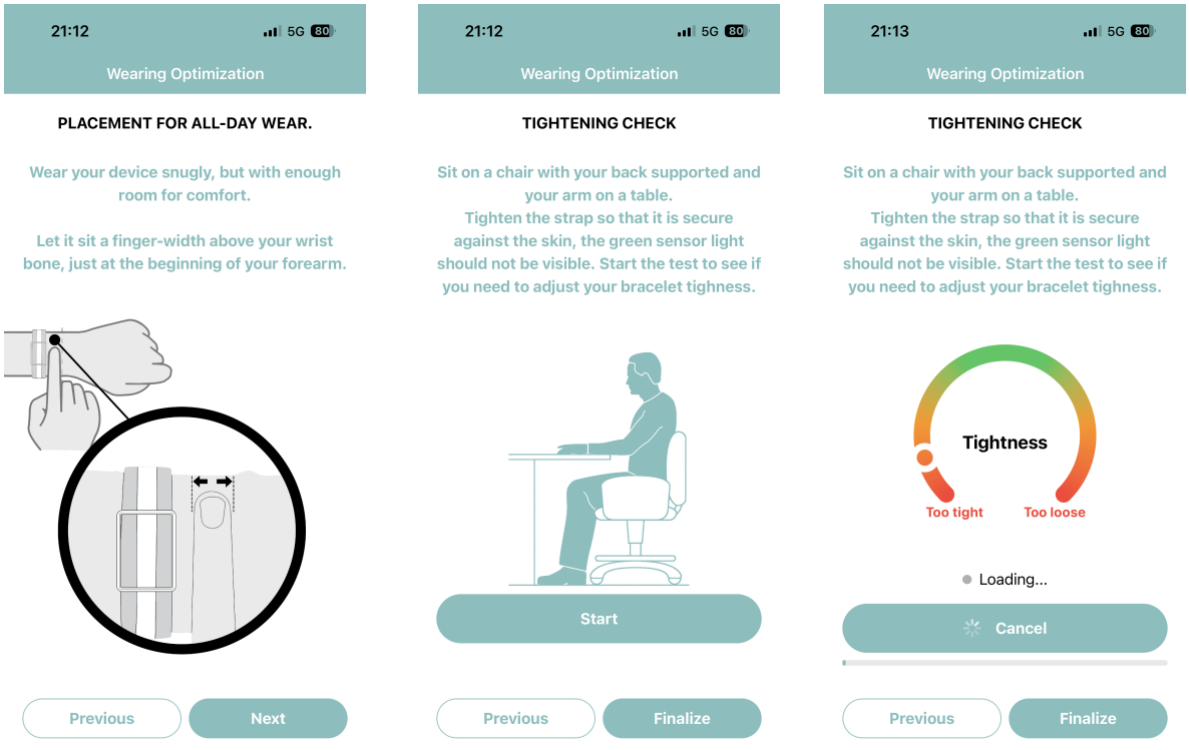
*Bracelet Tightness*

### 7.5.1 Bracelet Direction




*Bracelet Direction*

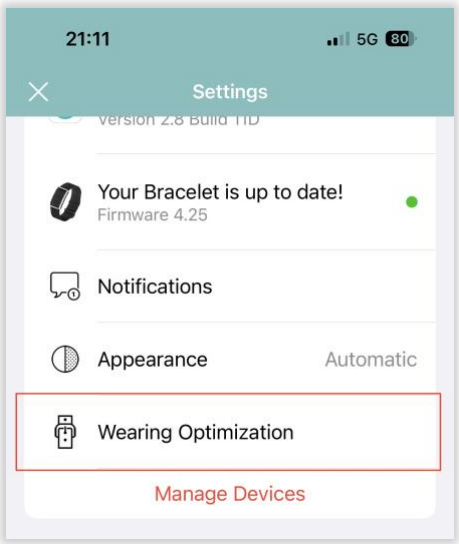
### 7.5.2 Tightening Check




*Bracelet Positioning*

## 7.6 Optional Wearing Optimization

To check if the 287-2B 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.



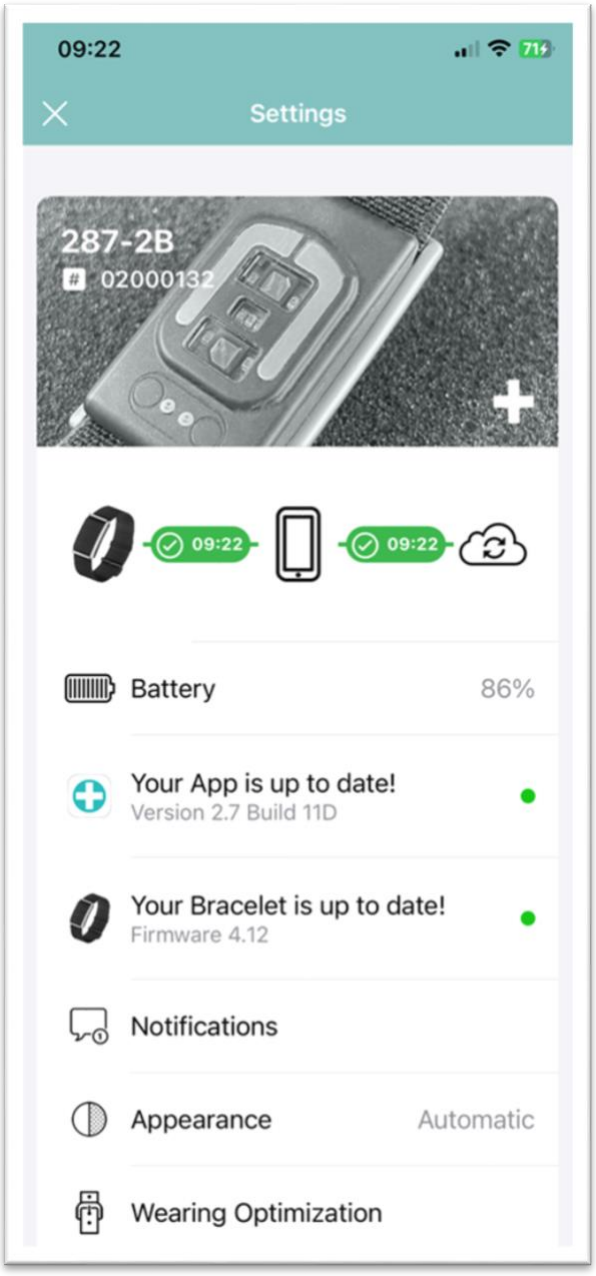

*Wearing Optimization*

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.

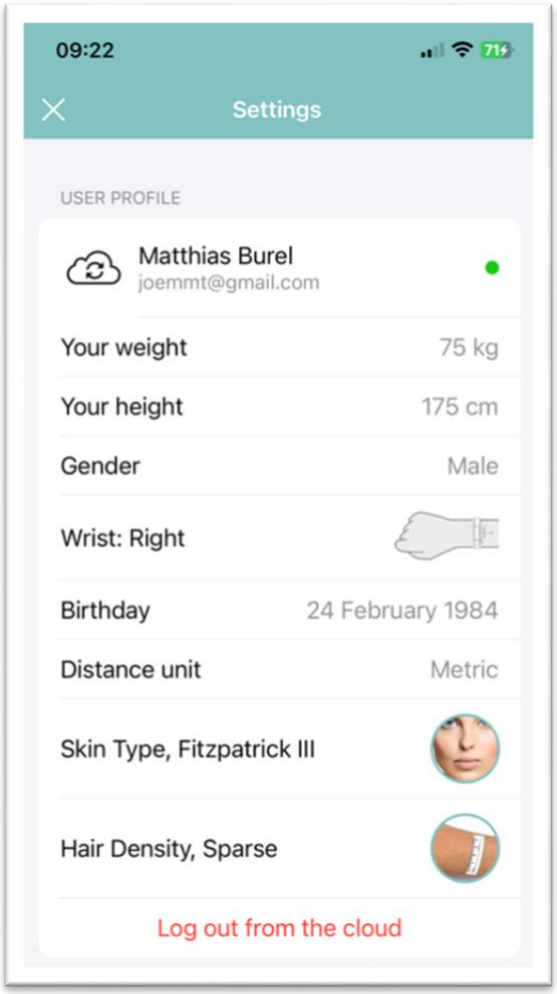
You can see the information about the app and device.




*App and Bracelet Status*

You can see your profile data and modify if needed.

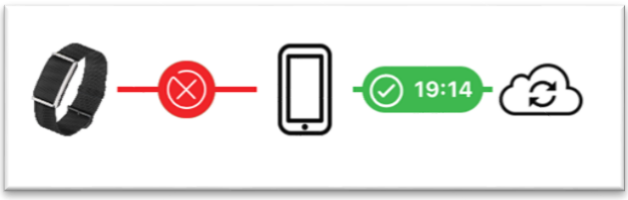
These parameters are important for the measurement accuracy.




*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 287-2B > Click Forget Device/Unpair
3. Force quit the app on your phone
4. Re-open the app
5. Press the (+) inside the watch icon in upper right corner
6. Follow pairing instructions

## 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.

In the Corsano App, select “Settings” and “Manage Devices” to pair an external device. Follow the step-by-step instructions in the App.


*Pairing of external devices*

## 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 Non-invasive blood pressure

Spot-check monitoring of non-invasive blood pressure can be performed with the external non-invasive 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 non-invasive blood pressure monitor Transtek TMB-2084-A with oscillographic measurement |
| Measurement Range | SYS: 60 ~ 230 mmHg(8.0-30.7kPa)<br>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<br>FEV1<br>FEV6<br>PEF<br>FEV1/FVC ratio (derived from previous meausrements) |
| Flow Range | 0 to 10 L<br>+/- 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<br>51-100 kg +/- 0.3 kg<br>101-150 kg +/- 0.4 kg<br>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:

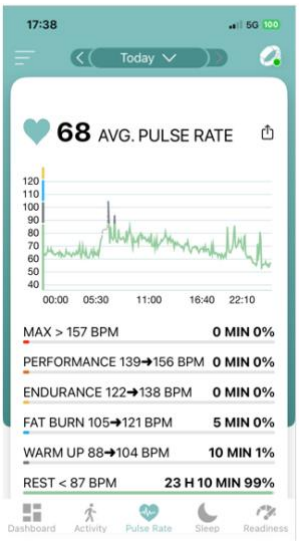
- Pulse rate (PR)
- Oxygen saturation (Sp02)
- Temperature (sTemp / aTemp)
- Activity (MOTION / STEPS)
- Respiration Rate (RR)
- Non-Invasive Blood Pressure (NIBP)
- Spirometry (SPIRO)
- Weight (Weight)

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:

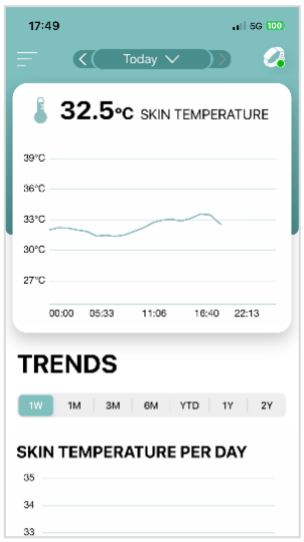
- Activity (Steps) to motivate you to move sufficiently
- Tracking Temperature and take medicine on instruction of HCP in case of fever
- Non-invasive blood pressure spot-measurements data to ensure that you:
  - have properly done spot-measurements
  - have taken medicine based on instructions of HCP
- 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:

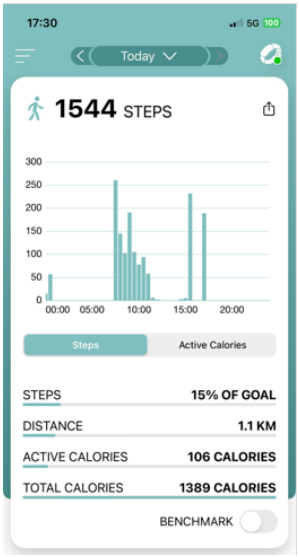



*Pulse rate*

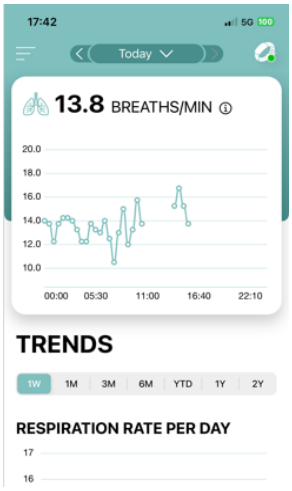

*SpO2*



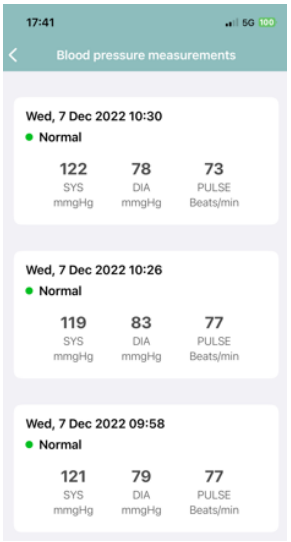

*Skin Temperature*



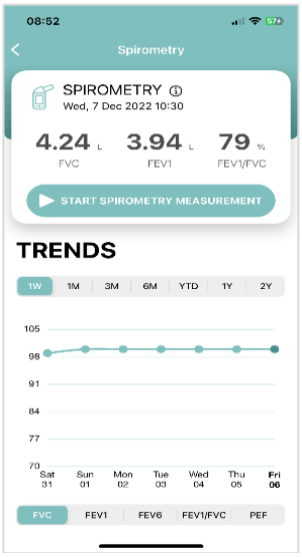

*Activity*



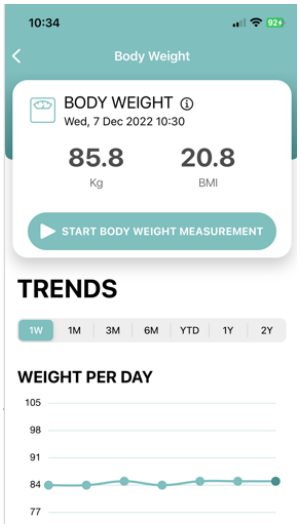

*Respiration rate*




*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 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 and Philips VitalSigns.

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 |
| Skin Temperature (sTemp) | 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 (NIBP) | 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*

## 10.1 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*

## 10.2 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 from 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 | 70% to 100% |
| Resolution | 1% |
| Accuracy (Arms) | 70-100%: <2 %<br><br>90-100%: <2 %<br>80-90%: <2 %<br>70-80%: <2 % |
| Bias (+95%CI) | 70-100%: ±0,5 %<br><br>90-100%: ±0,5 %<br>80-90%%: ±0,5 %<br>70-80%: ±0,5 % |
| Data Update Period | 28 seconds |

*Sp02 Specification*

## 10.3 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<br><br>Under the following conditions: | ±3 brpm<br><br>Supine<br>Prone<br>Lateral<br>Sitting 90°<br>Sitting 45°<br>Hyperventilation<br>Hypoventilation<br>Coughing<br>Walking on Treadmill | |
| Data Update Period | 28 seconds | |
| Apnea Detection | No | |

*Respiration Rate Specification*

## 10.4 Steps Activity principle of operation

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

Accuracy was measured in the study TR1305 Philips VSO test protocol results by Philips Research, Eindhoven, The Netherlands. The study monitored activity using an accelerometer with 17 healthy volunteers. Data was monitored during free living: sitting, walking, typing, drinking and during exercise: warming up, walking, running.

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.

## 10.5 Skin 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 |

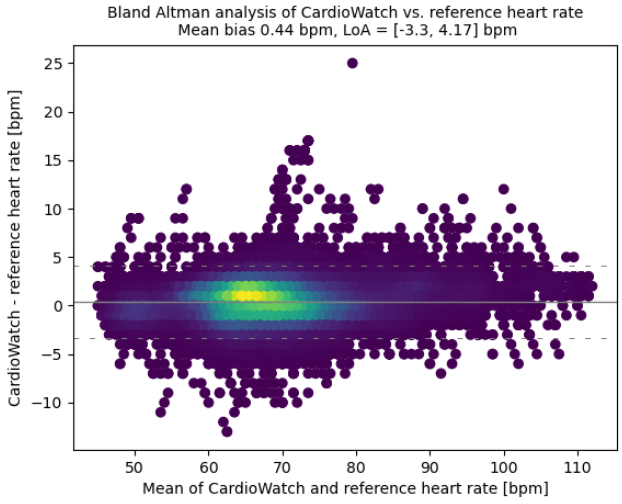
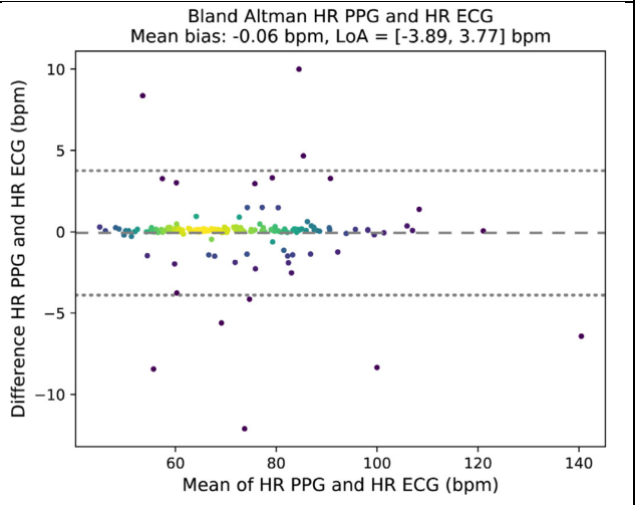
*Skin Temperature Specification*

# 11 CLINICAL PERFORMANCE

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

## 11.1 Pulse Rate

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

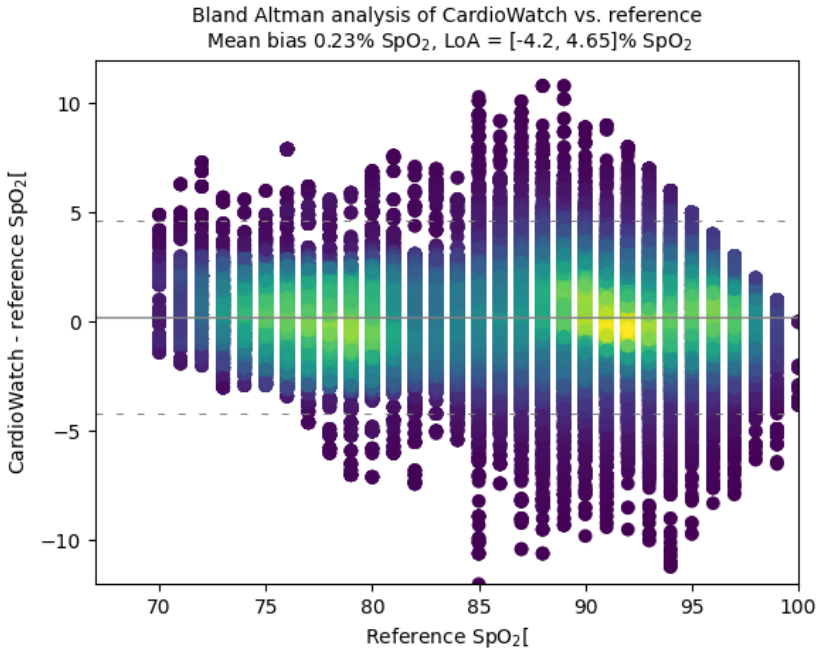
| **Accuracy of CardioWatch 287-2 during profound hypoxia (ISO 80601-2-61)** | **The accuracy of heartbeat detection using photoplethysmography technology in cardiac patients** |
|---|---|
| Complementair Medisch Centrum (CMC) Europe, Genk, Belgium | Cardiologie Centra Nederland, Amsterdam UMC, Location 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<br>Bias = 0.44 (0.42 - 0.46) bpm | PPG-accuracy pulse rate 94.6% |

*Pulse Rate validation*

## 11.2 Pulse Oximetry (SpO2)

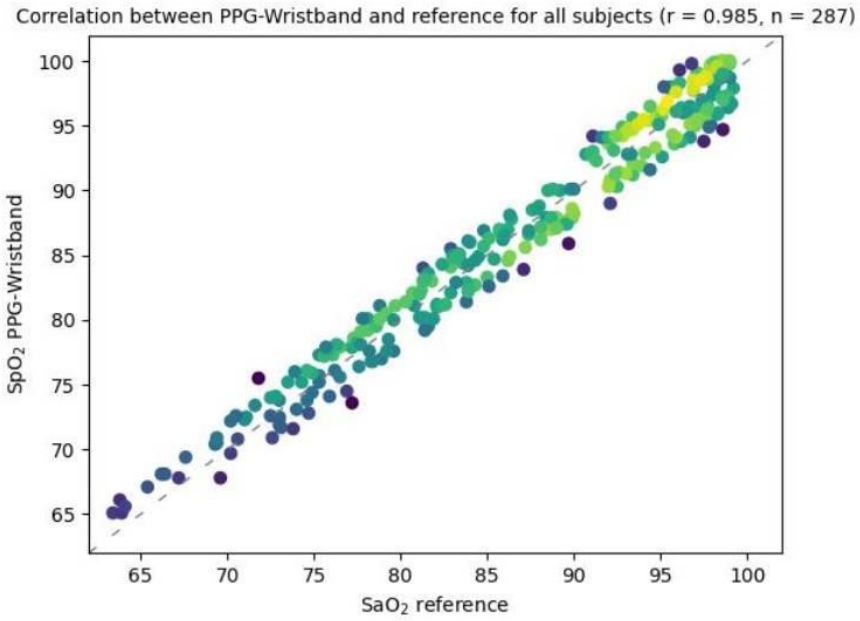
Accuracy was measured in a controlled, induced hypoxia study in 24 healthy adult volunteers in accordance with ISO 80601-2-61 at rest and under motion. Study title: Accuracy of CardioWatch 287-2 during motion and different positions of the body, with or without hypoxia. Location: Complementair Medisch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



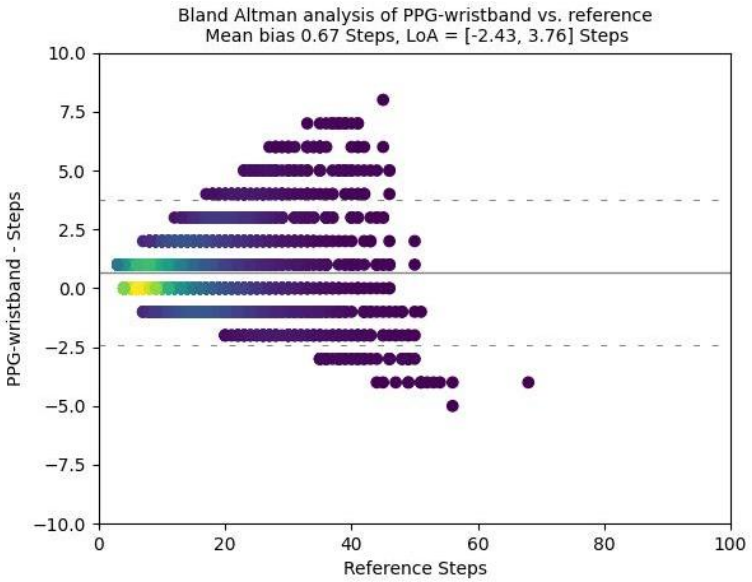

*Bland Altman SpO2 CardioWatch 287 versus SaO2*

## 11.3 Temperature

Accuracy of CardioWatch 287-2B 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.

## 11.4 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.

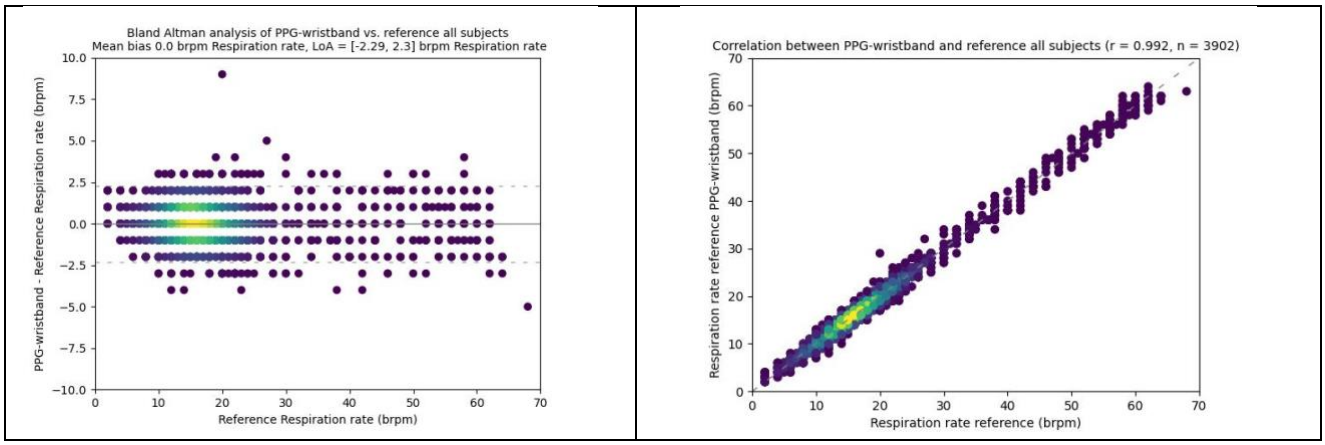



*Accuracy Steps*

## 11.5 Respiration

Accuracy was measured in multiple studies, here are the pooled results ACW2-PAT, ACW2-RR, ACW2-MOT and MULTI-VITAL study:

| | ***Pooled*** | ***Normal weight BMI < 25*** | ***Overweight BMI between 25 and 29*** | ***Obese BMI > 29*** | ***Fitzpatrick I-IV*** | ***Fitzpatrick V-VI*** | ***Female*** | ***Male*** |
|---|---|---|---|---|---|---|---|---|
| # of data points | 3902 | 2221 | 1053 | 628 | 3694 | 208 | 1112 | 2790 |
| Arms | 1.17 | 1.22 | 1.13 | 1.05 | 1.16 | 1.41 | 1.22 | 1.15 |
| Between-subject variance | 0.07 | 0.08 | 0.08 | 0.03 | 0.06 | 0.13 | 0.06 | 0.07 |
| Bias *(+95% CI)* [%] | 0.0 (-0.03, 0.04) | 0.01 (-0.04, 0.06) | -0.06 (-0.13, 0.01) | 0.08 (-0.01, 0.16) | 0.02 (-0.02, 0.06) | -0.26 (-0.45, -0.07) | 0.0 (-0.07, 0.06) | 0.01 (-0.04, 0.05) |
| *95% LoA (+ 95% CI)* [%] *Lower* | -2.29 (-2.33, -2.26) | -2.38 (-2.43, -2.33) | -2.28 (-2.35, -2.21) | -1.97 (-2.05, -1.88) | -2.25 (-2.29, -2.21) | -2.98 (-3.17, -2.79) | -2.39 (-2.46, -2.32) | -2.25 (-2.30, -2.21) |
| *95% LoA (+ 95% CI)* [%] *Upper* | 2.30 (2.26, 2.34) | 2.41 (2.36, 2.46) | 2.15 (2.08, 2.22) | 2.12 (2.04, 2.20) | 2.28 (2.25, 2.32) | 2.45 (2.26, 2.64) | 2.38 (2.31, 2.45) | 2.26 (2.22, 2.31) |




*Respiration Rate validation*

# 12 CYBERSECURITY

## 12.1 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+.

## 12.2 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.

## 12.3 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.

## 12.4 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.

## 12.5 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.

# 13 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.

# 14 TECHNICAL SPECIFICATIONS

## 14.1 Corsano Mobile App

Minimum requirements for mobile device Operating Systems:

- iO 14.5 or higher
- Android 8.0 or higher

## 14.2 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 |

**Direct Mode Thermometer**

| | |
|---|---|
| Heating transient time | 160 s |
| Cooling transient time | 120 s |

**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).

## 14.3 AC-DC Power Supply (USB Adapter)

The USB Adapter provided with the CardioWatch 287-2 is conform to UL/cUL 60601-1 with the following characteristics:

- Input voltage: AC 100-240V, 50/60hz
- Output voltage: DC 5V (+/- 5%)
- Maximum Output current: 1.2A

The following USB Adapter Model has been validated by Corsano :

| Company | CUI Inc | Corsano Reference |
|---|---|---|
| Manufacturer Part Number | SWM6-5-NH-I38 | CS-287AC |

Should you have questions please contact support@corsano.com.

## 14.4 Regulatory Conformity

FCC registration: 2AXRW0003
FCC 47 CFR Part 15B
FCC 47 CFR Part 15C
FCC 47 CFR Part 2.1093

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)

### 14.5 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
ANSI C63.27:2017

## 15 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), 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<br>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<br>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.<br><br>The Corsano Bracelet is suitable for use in home environment and Professional Health Care facilities environment. |
| RF emissions<br>CISPR 11 | Class B | |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable (power < 50W) | |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3 | Not applicable (No power fluctuation) | |

| **Guidance and manufacturer's declaration—electromagnetic immunity** | | | |
|---|---|---|---|
| The Corsano Bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance** | **Electromagnetic environment - guidance** |
| Electrostatic Discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact<br>±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%.<br><br>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.<br><br>Portable and mobile RF communications equipment should be used no closer to any part of the Corsano Bracelet, including cables and |
| Electrical fast transient/burst<br>IEC 61000-4-4 | ±2 kV for power supply lines | Compliant | |

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration—electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Surge<br>IEC 61000-4-5</td><td>±1 kV, ±2 kV<br>Line-to-line</td><td>Compliant</td><td rowspan="5">accessories, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance (m)<br><br>d = 1.2 √P<br><br>d = 1.2 √P 80 MHz to 800 MHz<br><br>d = 2.3 √P 800 MHz to 6 GHz<br><br>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).<br><br>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].<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  </td></tr>
<tr><td>Power frequency (50/60Hz) magnetic field<br>IEC 61000-4-8</td><td>30 A/m<br>50-60 Hz</td><td>Compliant</td></tr>
<tr><td>Voltage dips, short interruptions and voltage variations on power supply<br>IEC 61000-4-11</td><td>60Hz 110Vac<br>60Hz 230Vac<br>50Hz 110Vac<br>50Hz 230Vac</td><td>Compliant</td></tr>
<tr><td>Conducted RF<br>IEC 61000-4-6</td><td>10Vrms<br>150 kHz to 80 MHz</td><td>Compliant</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3 V/m<br>80 MHz to 6 GHz,<br><br>10 V/m<br>80 MHz to 2.7 GHz,<br><br>28 V/m<br>450 MHz to 6 GHz</td><td>Compliant</td></tr>
<tr><td colspan="4">NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people</td></tr>
<tr><td colspan="4">[a] Field 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.<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

**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.

# 16 LEGAL NOTICE FOR FCC AND ISED

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the 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.

# 17 DISPOSAL / END OF LIFE

Equipment : once your Bracelet, USB Charge Cable or USB Adapter 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 & USB Adapter 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.

# 18 CORSANO CONTACT INFORMATION

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

www.corsano.com
support@corsano.com