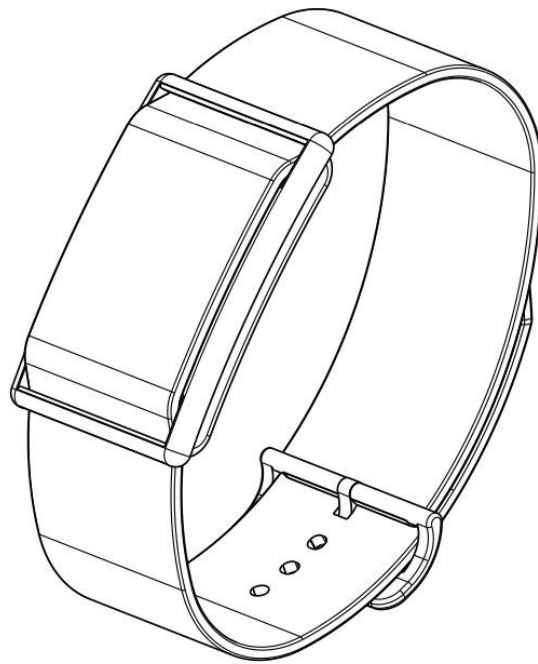


**EN**

# **CardioWatch 287-1B**

## **Bracelet Instruction Manual**

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## 1 INTRODUCTION

Thank you for purchasing the Corsano CardioWatch 287-1B. The CardioWatch bracelet records raw PPG and ACC data, which is transferred to the application and cloud. Subsequently, the raw data is transferred cloud-to-cloud to Preventicus where it is analyzed by CE Medical Certified Preventicus Heartbeats and results are shown in the WebView in the application. Preventicus Heartbeats has been validated in clinical studies and detects irregular heartbeats (e.g. extrasystoles) as well as the presence of absolute arrhythmia with suspected atrial fibrillation (AF). However, irregular heartbeats (e.g. extrasystoles) and atrial fibrillation can only be diagnosed in accordance with the guidelines with an ECG of the thoracic wall, generally carried out by cardiologists.

**If you are feeling unwell or experience other troubling symptoms, please seek medical advice immediately.**

## 2 SAFETY INSTRUCTIONS

This instruction manual provides you with important information about the Corsano CardioWatch 287-1B Bracelet. To ensure the safe and proper use of this bracelet, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact [support@corsano.com](mailto:support@corsano.com) before attempting to use this bracelet. For specific information about your own heartbeats, consult with your physician.

### 2.1 Intended Use

This device is a digital bracelet intended for use in measuring pulse rate and activity in adult patient population. The device provides the data for further cardiovascular analysis by the CE Medical Certified Preventicus Heartbeats algorithm in order to provide a warning signal in case of appearance of irregular heartbeats during measurement. For clarity, a warning signal is provided by Preventicus based on analysis by the CE Medical Certified Preventicus Heartbeats algorithm.

Environments of Use: Hospital and Home Patient Population: Adult

### 2.2 Receiving and Inspection

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

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

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

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

## 2.3 Data Transmission

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

## 2.4 Handling and Usage

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

## 2.5 Charger Handling and Usage

- USE the charger cable with a CE marked adapter with the following characteristics:
  - Input voltage: 100/240 V - 50hz 60hz
  - Output voltage: DC 5V (+/-5%)
  - Maximum current: 500 mA
- DO NOT use the charger if this bracelet or the charger cable is damaged. If this bracelet or the cable is damaged, unplug the charger immediately.
- Plug the charger into the appropriate USB outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the charger from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the charger.

- Fully insert the USB plug at the end of the charger into the USB outlet.
- When unplugging the charger from the outlet, be sure to safely pull from the USB outlet. DO NOT pull from the charger cable.
- When handling the charger cable:
 

DO NOT damage it. DO NOT break it.  
 DO NOT tamper with it.  
 DO NOT forcibly bend or pull it. DO NOT twist it.  
 DO NOT use it if it is gathered in a bundle. DO NOT pinch it.  
 DO NOT place it under heavy objects.
- Wipe any dust off of the charger.
- Unplug the charger when not in use.
- Unplug the charger before cleaning this bracelet.

## 2.6 Warnings

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

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

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

## 2.7 Residual risks

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

## 2.8 Clinical benefit

The CardioWatch 287-1B provides a non-invasive and comfortable solution to continuously and accurately monitor vital signs and enables off-line analysis and screening of cardiac arrhythmia (AFib for instance) by third-party medical applications.

## 2.9 Cleaning and service life

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

Use warm water and hypoallergenic soap to clean the strap.











Dry the wrist band with a soft cloth.  
It is not necessary to sterilize the device.

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

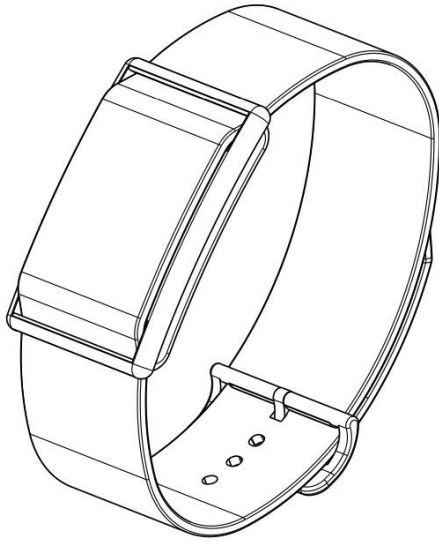


### 3 SYMBOLS

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

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

## 4 CONTENTS / PRODUCT INCLUDES



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



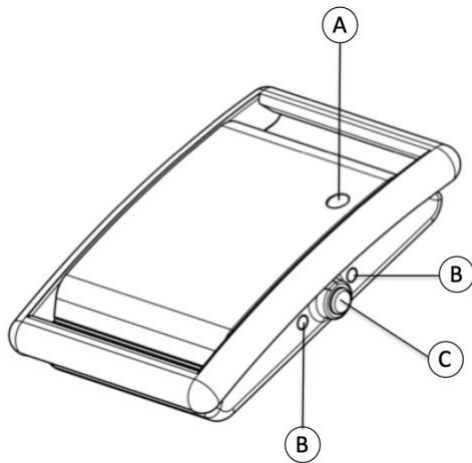
*Figure 2 - Charger (CS-287CH-1)*



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

## 5 KNOW YOUR BRACELET

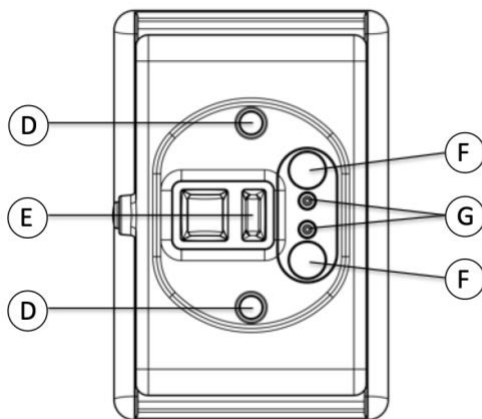
### 5.1 Front of the bracelet



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

*Figure 4 – Front view of Bracelet*

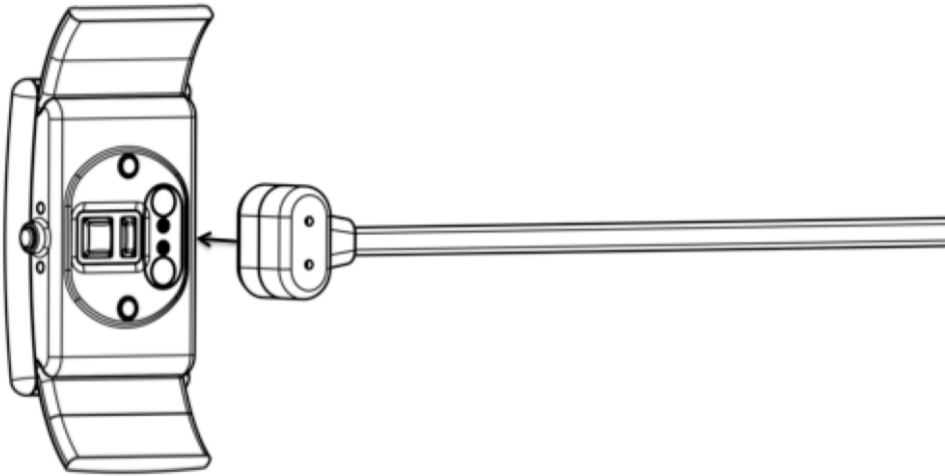
### 5.2 Back and bottom of the bracelet



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

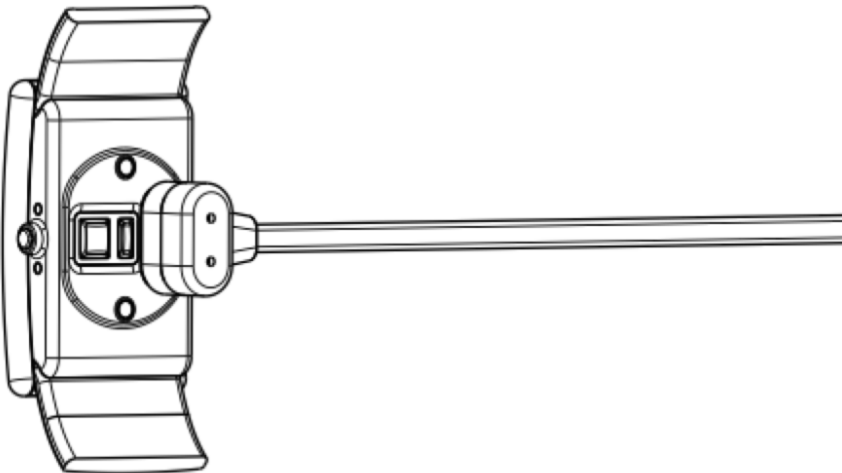
*Figure 5 – Back view of Bracelet*

### 5.3 Charging the bracelet



*Figure 6 – Charging view*

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



*Figure 7 – Charging view – charger attached*

The Magnets will click the charger into position. The LEDS will light up to indicate that charging has started.

While charging, the Bracelet will not perform any measurement.

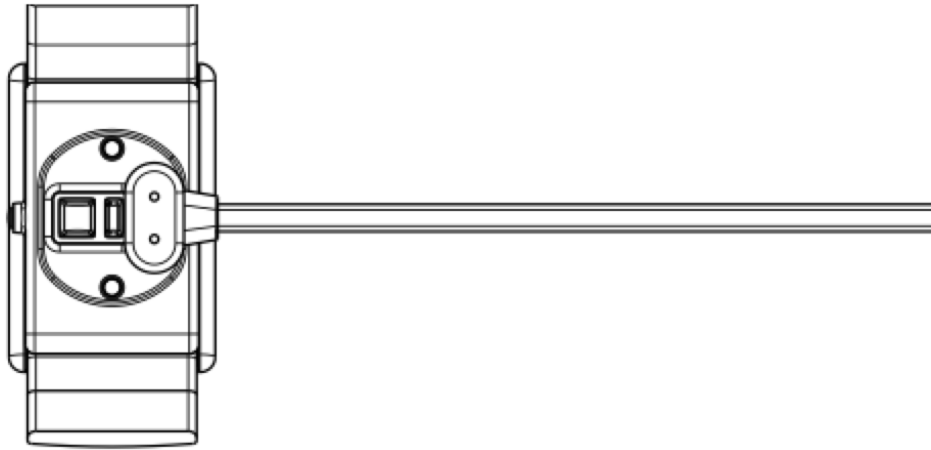


Figure 8 – Charging view – charger attached #2

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

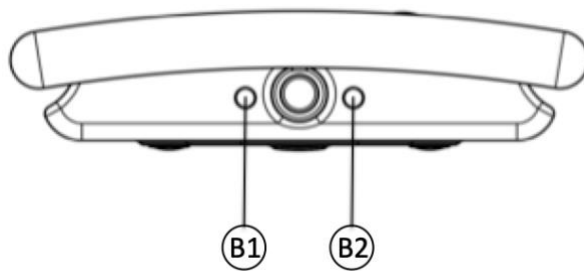


Figure 9 – Bracelet side view

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

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

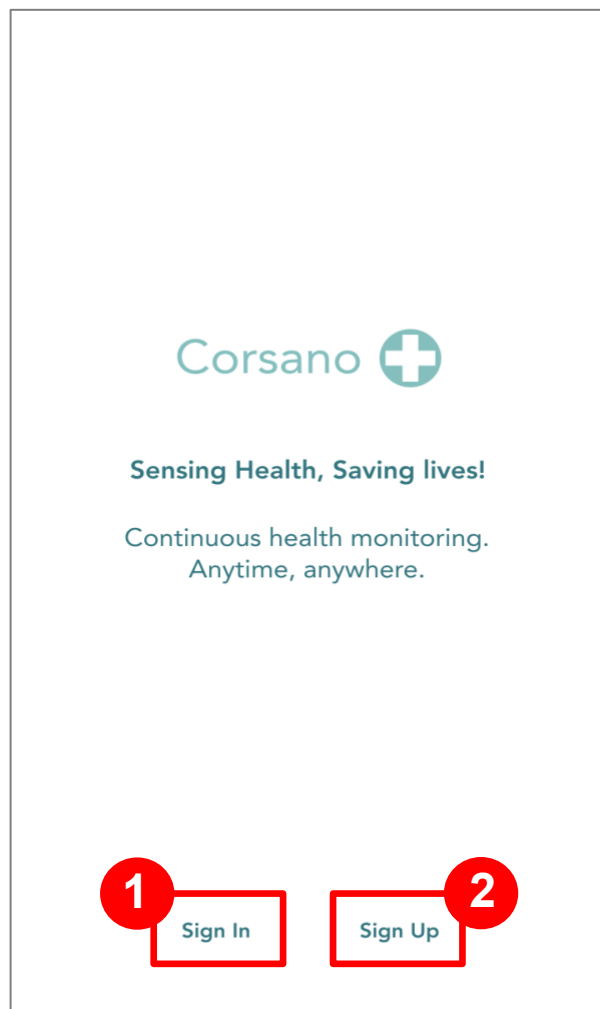
## 6 USING YOUR BRACELET WITH A SMART DEVICE

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

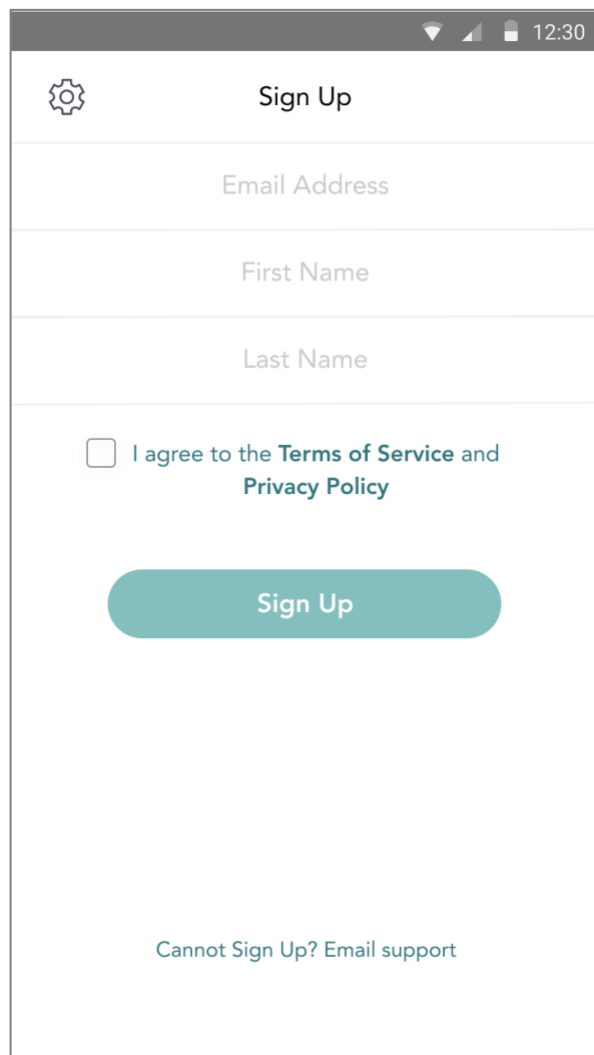


### 6.2 First time use

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

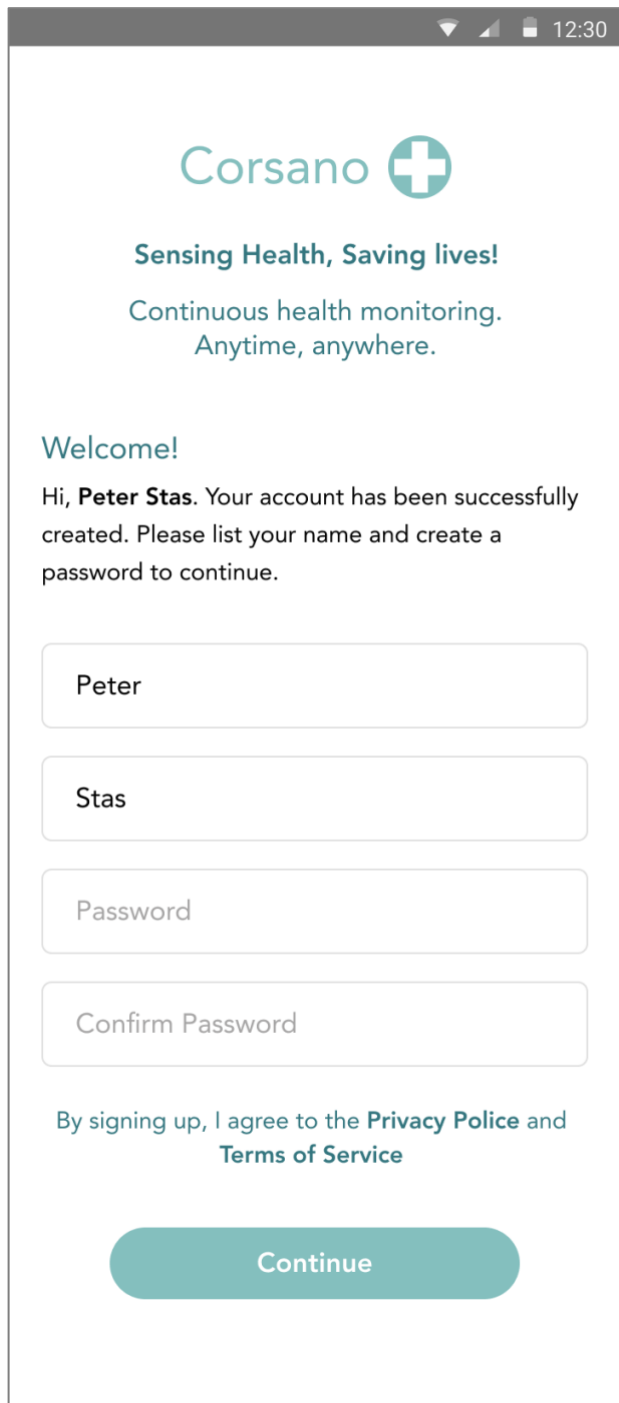



## Sign Up



The image shows a mobile application interface for signing up. At the top, there is a status bar with a Wi-Fi icon, a cellular signal icon, a battery icon, and the time 12:30. Below the status bar is a header bar with a gear icon on the left and the text "Sign Up" in the center. The main form area contains three input fields: "Email Address", "First Name", and "Last Name". Below these fields is a checkbox with the text "I agree to the **Terms of Service** and **Privacy Policy**". Underneath the checkbox is a large, rounded teal button with the text "Sign Up". At the bottom of the form, there is a link that says "Cannot Sign Up? Email support".

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



Corsano 

**Sensing Health, Saving lives!**

Continuous health monitoring.  
Anytime, anywhere.

**Welcome!**

Hi, **Peter Stas**. Your account has been successfully created. Please list your name and create a password to continue.

Peter

Stas

Password

Confirm Password

By signing up, I agree to the [Privacy Policy](#) and [Terms of Service](#)

**Continue**

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





**Sensing Health, Saving lives!**

Continuous health monitoring.  
Anytime, anywhere.

## Welcome!

Hi, **Peter Stas**. Your account has been successfully created. Please list your name and create a password to continue.




Password must:

- Have at least 8 characters
- Have at least 1 letter (a, b, c...)
- Have at least 1 number (1, 2, 3...)
- Include both Upper case and Lower case characters

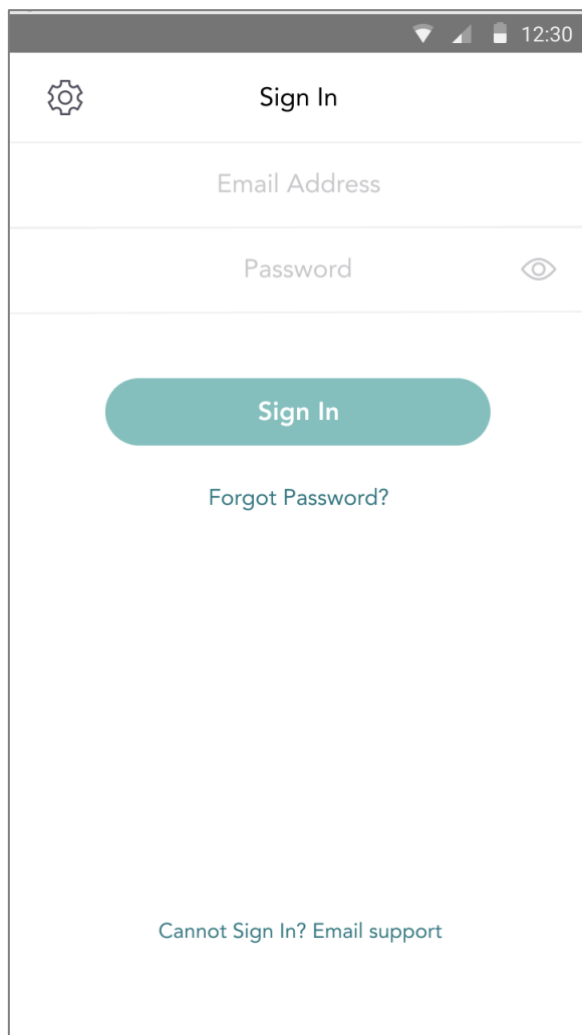
Password must NOT:

- Contain only one character (111111 or aaaaaa)
- Contain only consecutive character (12345678 or abcdefgh)

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

Password must NOT contain only numbers or consecutive characters

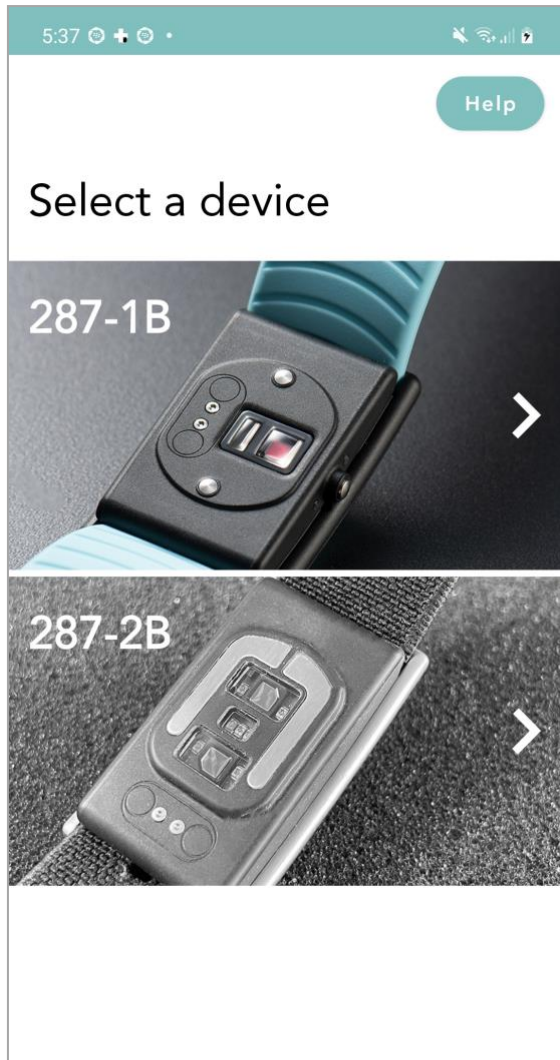
After you have signed up, you can Sign-In:



The image shows a mobile application interface for signing in. At the top, there is a status bar with a dark background showing signal strength, battery level, and the time 12:30. Below this is a header bar with a gear icon on the left and the text "Sign In" in the center. The main content area has a light gray background and contains two input fields: "Email Address" and "Password". The "Password" field has a small eye icon to its right. Below the input fields is a large teal button with the text "Sign In". Underneath the button is a link that says "Forgot Password?". At the bottom of the screen, there is a link that says "Cannot Sign In? Email support".

### 6.3 Pairing Your Bracelet with a Smart Device

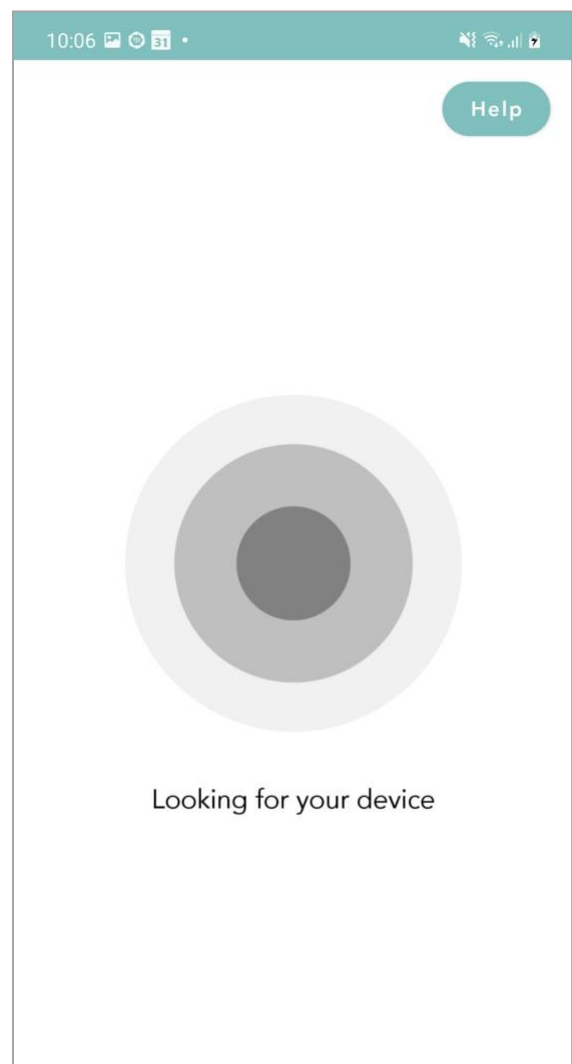
Upon first sign-in, user will be asked to pair a bracelet, follow the instructions.  
First, select “287-1B” in the list:



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



Press on button in the app to start pairing.



After button is pressed app will look for the bracelet



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



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

*Figure 10 – APP Pairing, complete*

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



## 6.4 Troubleshooting the Bluetooth Connection

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



Click on the button Please Reconnect and follow instructions:

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

If these steps did not reconnect, please proceed:

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

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

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

## 6.5 Troubleshooting the Cloud Connection

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



Click on the button Please Reconnect and follow instructions:

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

If these steps did not reconnect, please proceed:

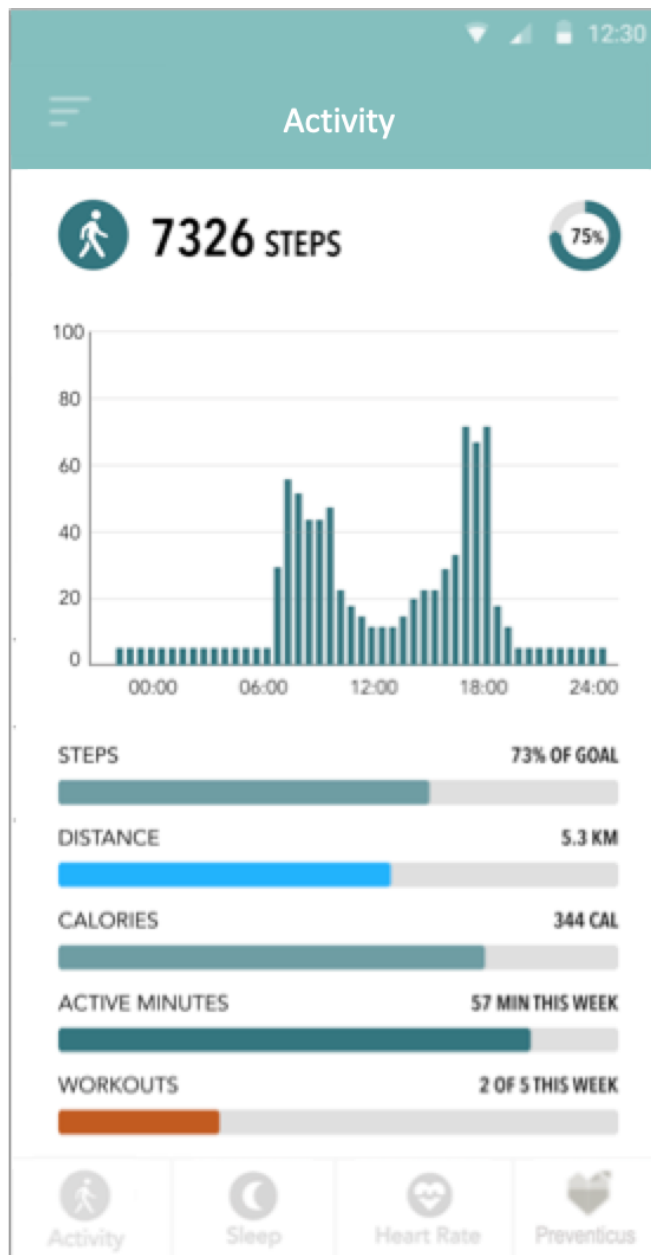
1. Shut down your phone (do not do restart; completely shut the phone off and turn it back on). This will fully reset your phone
2. Turn your phone on again
3. Re-open the app

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

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

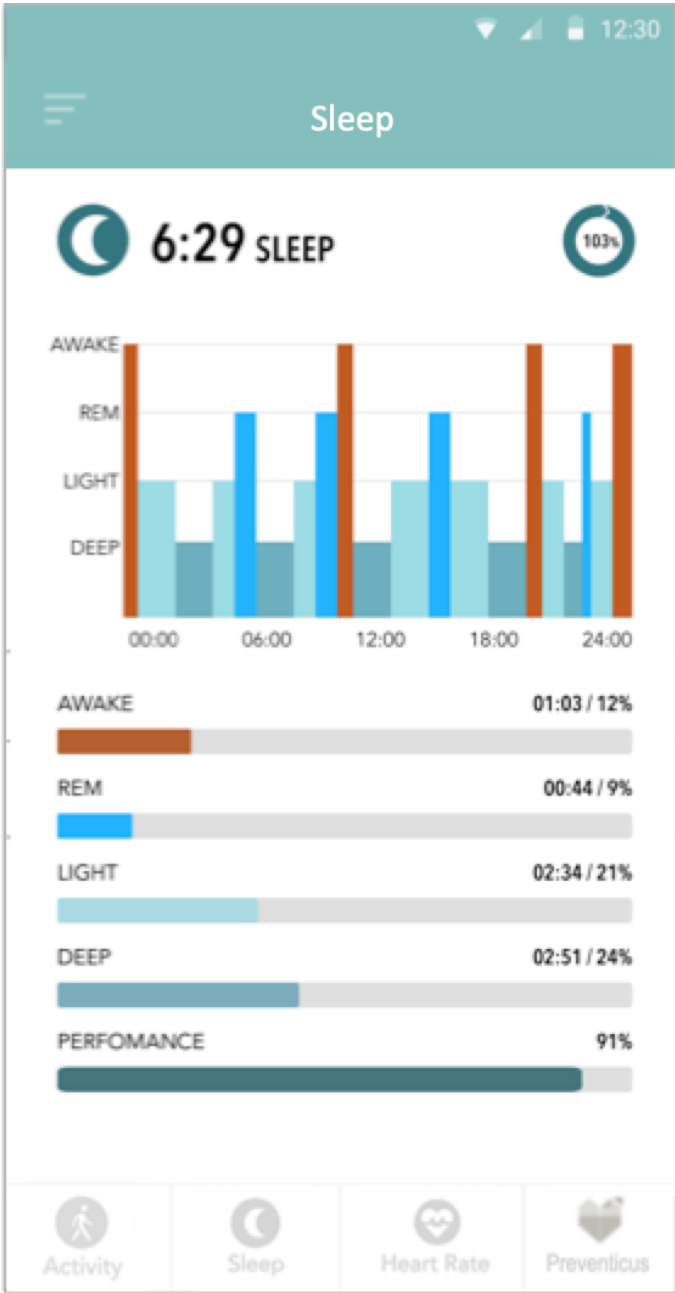
## 7 NON-MEDICAL INFORMATION

The CORSANO AF app provides non-medical information like Activity:

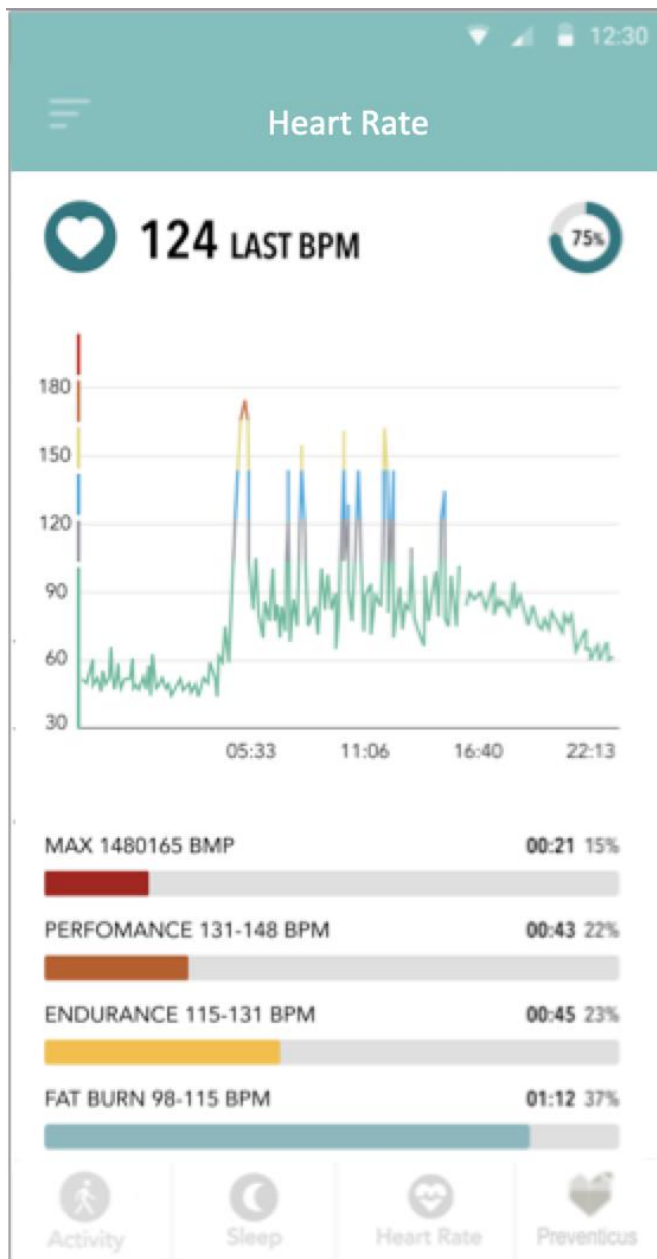




Sleep:

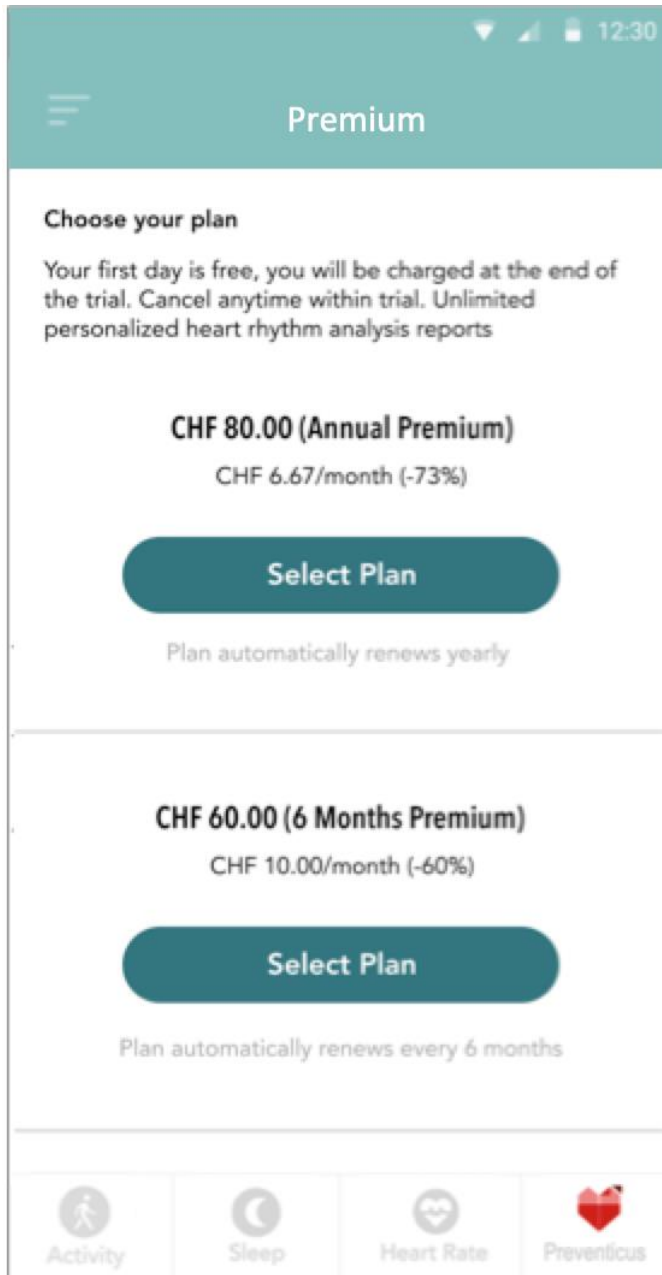


## Heart Rate:



## 8 PREMIUM SERVICE

The CORSANO AF app offers Preventicus Heartbeats as a Premium Service. User needs to select a plan:



## 9 PREVENTICUS HEARTBEATS

The CORSANO AF app provides seamless integration with Preventicus Heartbeats, a CE Class IIa certified medical device to analyse your heartbeat, but also and especially your heart rhythm.

### 9.1 Purpose

The purpose of Preventicus Heartbeats is to detect signs of the presence of cardiac arrhythmias in a non-clinical environment. This includes the following cardiac arrhythmias: **detection of signs of absolute arrhythmia with suspected atrial fibrillation, detection of signs of extrasystoles as well as measuring the heart rate with signs of bradycardia and tachycardia without further diagnostic differentiation.**

**Under no circumstances may this app be used for diagnosis in situations considered to be life- threatening.**

Using the PPG sensor in the bracelet, a pulse curve is captured continuously and the heart rate data derived. If any evidence of arrhythmia is found, the user can store the underlying information in a measurement report. The user is also recommended to undergo further medical assessment by professionals. Preventicus has verified the detection of atrial fibrillation and extrasystoles and the accuracy of the heart rate detected with in-house clinical studies (see also: [www.preventicus.com/Studien](http://www.preventicus.com/Studien)). These have shown that the underlying algorithm of the app can distinguish between atrial fibrillation and a regular heart rhythm with an accuracy of more than 96%.

Heart rate is displayed as normal (grey traffic light) or abnormal (orange traffic light) based on a 1-minute measurement. Three categories are distinguished: no abnormalities (green traffic light), slight arrhythmia (>5% of all beats are irregular -> yellow traffic light) or the presence of severe arrhythmia (red traffic light) detected. In addition, the user is informed of any suspected relevant bradycardia or tachycardia (without differentiating between possible causes) and is advised that prompt cardiac assessment is necessary if this occurs regularly and is not already under medical observation. Any interferences occurring during the measurement (wobbling, coughing, shaking, etc.) are automatically detected and eliminated.

The app also links to a measurement report of the results and allows you to print it off. The report shows the original pulse curve over the course of maximum 5 minutes and integrates symbolic R peaks in each cardiac cycle. This allows the treating physician to visually assess the heart rhythm, understand the automatic interpretation and take any further diagnostic measures.

The result obtained is purely a suspicion and not a diagnosis in the medical sense of the word. The results obtained are for information purposes only and should under no circumstances replace a personal diagnosis or personal advice, care or treatment by medical or medically trained personnel.

**Preventicus Heartbeats should not be used for decision-making in life-threatening situations or for real-time monitoring of vital functions nor should it intervene with existing diagnostic pathways or therapeutic measures according to the guidelines.**

A basic distinction should be made between AF detection (screening or progress monitoring) and subsequent AF diagnosis. **AF should be exclusively diagnosed with an ECG of the thoracic wall, generally performed by cardiologists, in accordance with the guidelines.** Preventicus apps are not intended for the final diagnosis of AF with therapeutic implications, but exclusively for AF screening or AF progress monitoring without therapeutic implications. Any therapeutic implications should only arise based on a real ECG, not on plethysmographic technology, as accurate as this may be.

## 9.2 Intended use

Preventicus Heartbeats can be used independently by anyone of either gender aged 18 or older.

## 9.3 Additional notes and comments

ECGs are the gold standard for rhythmological diagnostics. An analysis of the heart rhythm based on the pulse curve is an appropriate screening method as a preliminary step to further diagnosis.

According to the studies conducted, Preventicus Heartbeats detects atrial fibrillation with an overall accuracy of 96.5%. Its sensitivity (correct positive rate) is approximately 91.6%. The sensitivity is the probability with which atrial fibrillation is recognised as such. At the same time, the specificity (correct negative rate) provides the percentage of users not suffering from atrial fibrillation, whose results were correctly displayed with a green traffic light. The specificity of Preventicus Heartbeats is 99.6%.

This means that there is a very low residual risk that Preventicus Heartbeats will not detect atrial fibrillation despite it being present in a measurement. If you feel unwell or experience other worrying symptoms, please contact your treating physician directly. It cannot be ruled out that existing conditions such as diabetes, vascular diseases or the patient's condition after cardiovascular surgery may affect the accuracy of Preventicus Heartbeats.

## 9.4 Service life of the product

The service life of the product is the timeframe until a new version of the app is released. This is indicated by an increase of at least the second digit of the version number. Details of the version number can be found in the relevant app store.

Update information is provided by the operating system. Depending on the smartphone's user settings, the update will either be carried out automatically or will have to be actively approved and started by you.

## 9.5 Data backup

Data can be backed up in the following way:

The reports can be exported and sent as PDF files, e.g. by email. This allows them to be stored in other databases (e.g. PDMS, Praxis software) or on other storage media (e.g.

hard drive, memory card).

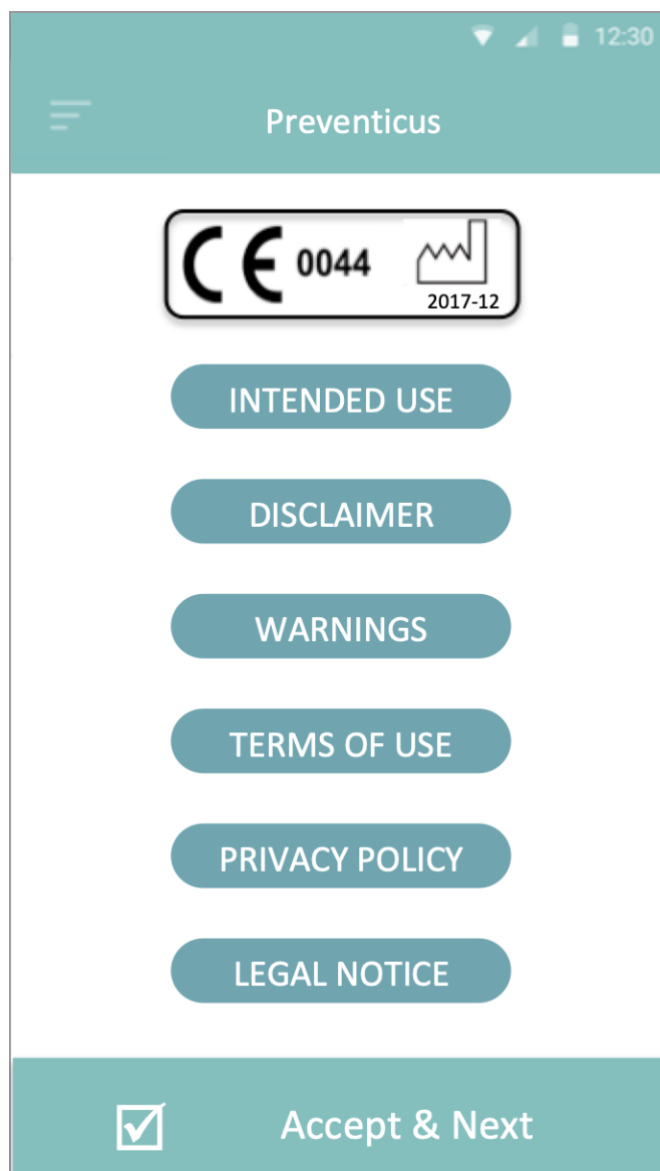
## 9.6 Measuring principle: basics of the pulse curve analysis

Preventicus Heartbeats is used to capture the so-called pulse curve. Signal analytical methods are then used to derive the pulse curve from the PPG signal, in a similar way to the medical procedure photoplethysmography. The pulse curve corresponds to the blood pulsation resulting from the activity of the heart.

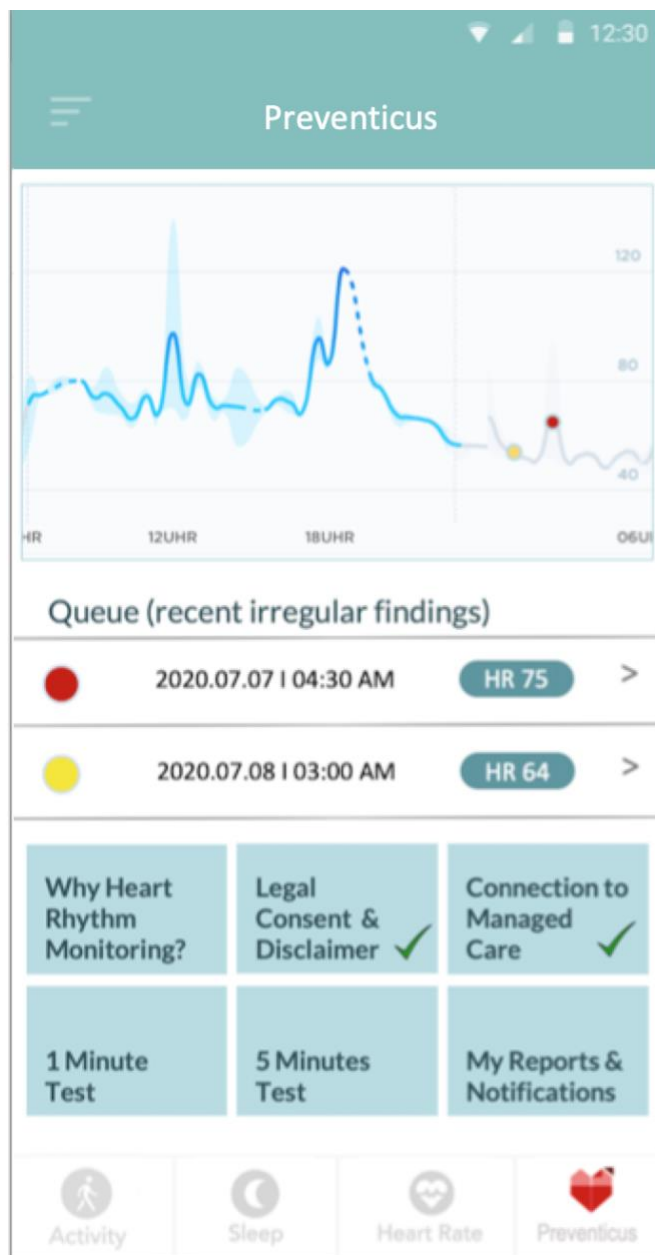
Based on the variability of the heartbeat in combination with biosignal analytical methods, the app can detect any signs of arrhythmia.

## 9.7 Reading and accepting the purpose, incl. warnings, Terms and Conditions and Privacy Policy

Please read the Terms and Conditions carefully and accept them to continue:






Upon acceptance of the purpose, including warnings, Terms and Conditions and Privacy Policy, the following screen will appear:



- Sequences with irregular results are marked in the heart rate graph with a yellow or red dot. Dots can be tapped to display the json result, plus a PDF can subsequently be pulled. PDFs will go into an be collected in the section <<My Reports & Notifications>>.
- In addition, a queue displays the recent five active measurements or irregular sequences recorded passively. Tap for details and PDF.

## 9.8 Interpretation of the results

Traffic light color	Meaning
Green 	Regular heart rhythm <b>and</b> normal heart rate
Yellow 	Slight arrhythmia (>5% of all beats are irregular) <b>and/or</b> a slightly increased or decreased heart rate
Red 	Absolute arrhythmia with suspected atrial fibrillation <b>and/or</b> a significantly increased or decreased heart rate (tachycardia/bradycardia). <b>If you are not under medical observation and if this occurs repeatedly, it is imperative you see the cardiologist immediately.</b>

*Table 8.8.1 Preventicus Heartbeats color coded results*



## 9.9 Overview of the measurement report

After you select a measurement you will receive your result as a summary measurement report. This includes the recorded pulse curve, the heart rate (bpm) over time and detailed information about the heart rhythm. The measurement report is made up of three sections (see Fig. 8.9.1):

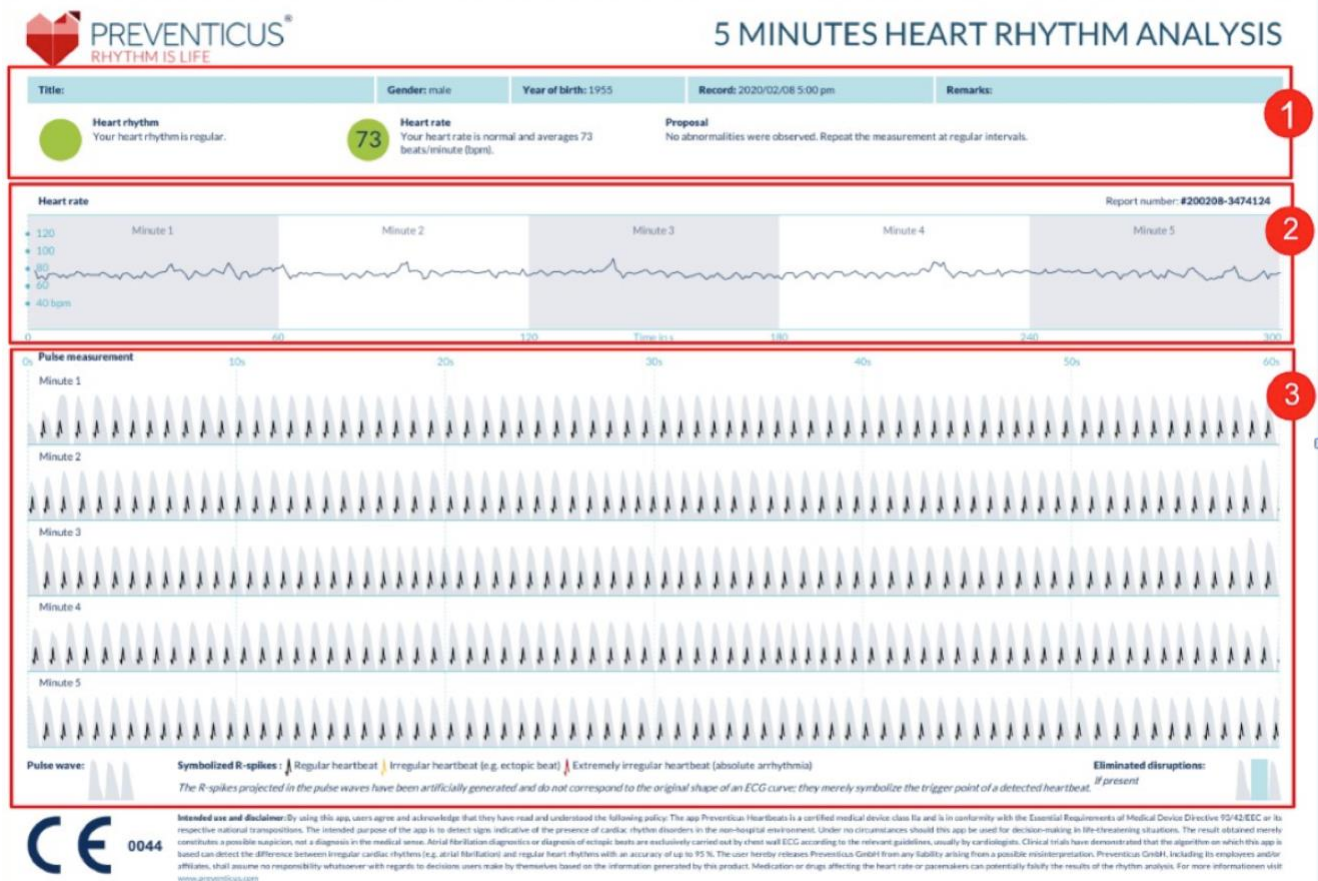


Fig. 8.9.1 Preventicus Heartbeats measurement report consisting of three sections: 1 - Summarised results of the heart rhythm analysis, 2 – Heart rate in beats per minute (bpm) over the entire measurement, 3 – Original pulse curve over the entire measurement

The summarised results of the heart rhythm analysis (see Fig. 8.9.1/section 1) contain both baseline data and optional information, such as name and comments on the measurement. In addition, the heart rate and heart rhythm results are made available to you in text form, including colour label. The coloured labels correspond to the traffic light colours in the results screen of the app (see Table 8.8.1). Depending on the result, you are offered an additional medical assessment by a medical professional.

In the second part of the report (see Fig. 8.9.1/section 2), the heart rate is displayed in beats per minute (bpm) over the entire measurement. Slight and regular fluctuations in heart rate, as shown in Fig. 8.9.1/section 2, are normal and are usually caused by the interaction between breathing and heartbeat.

Sudden positive or negative peaks, as shown in Fig. 8.9.2, however, are caused by individual irregular heartbeats and may be evidence of extrasystoles

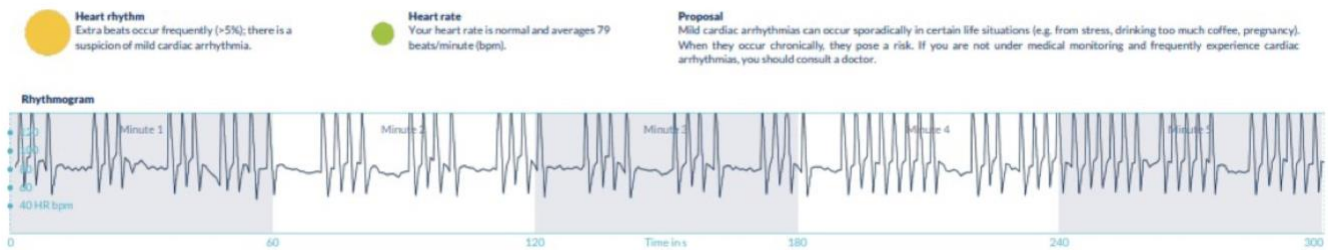


Fig. 8.9.2 Summarised results of the heart rhythm analysis and heart rate in beats per minute (bpm) over the entire measurement of a report with slight arrhythmia

Positive peaks result from irregular heartbeats, which have a significantly reduced time interval from the previous heartbeat compared to the average. Negative peaks in the pulse rate, on the other hand, indicate a significantly greater time interval between the irregular heartbeat and the previous normal heart rate, compared to the average.

Fig. 8.9.3 shows a heart rate with the presence of atrial fibrillation. The heart rate is strongly irregular over the entire measurement. The fluctuations of the heart rate occur chaotically throughout the entire measurement.

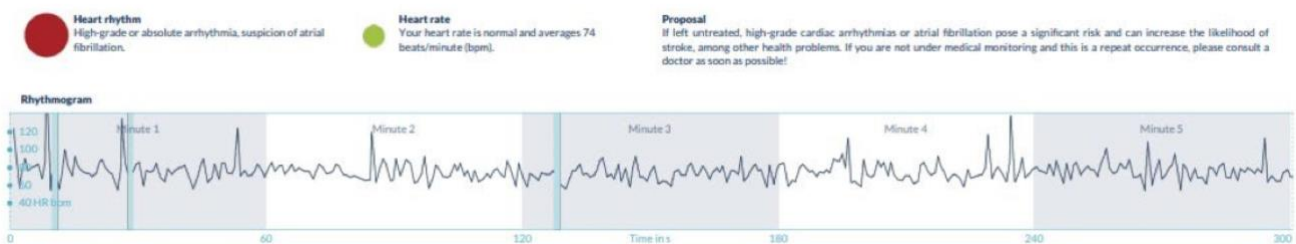


Fig. 8.9.3 Summarised results of the heart rhythm analysis and heart rate in beats per minute (bpm) over the entire measurement of a report with absolute arrhythmia

The third section of the measurement report consists of the original pulse curve. A wave in the pulse curve represents one heartbeat. For the heart rhythm analysis, points are detected in the pulse curve, which behave equivalent to the R peaks in an ECG. These points are shown in the form of R peaks in the original pulse curve to illustrate a detected/recognised heartbeat (see Fig. 8.9.4). Black R peaks symbolise a regular heartbeat, yellow an irregular heartbeat (such as extrasystole) and red R peaks an extremely irregular heartbeat based on absolute arrhythmia (suspected atrial fibrillation).

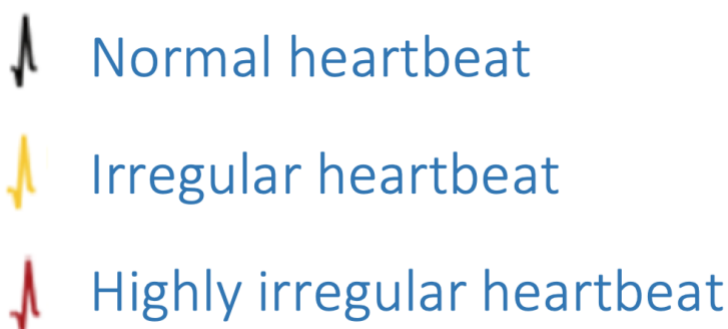


Fig. 8.9.4 Legend of the R peaks in the original pulse curve

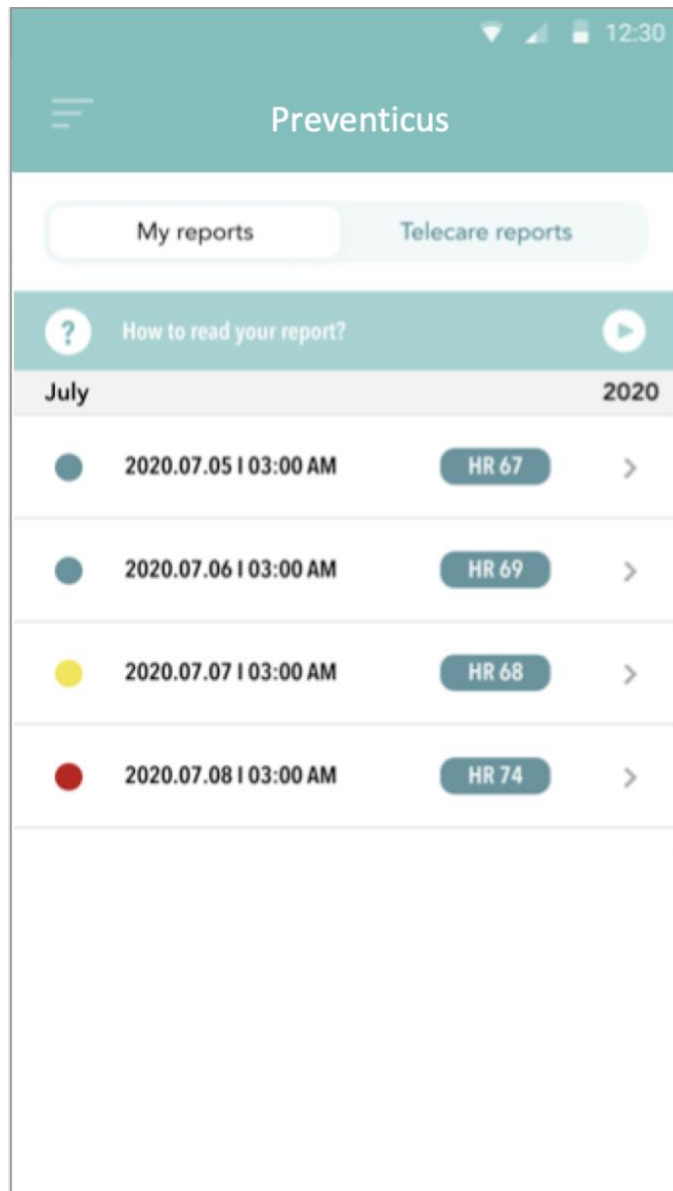
Blue bars in the pulse curve (see Fig. 8.9.5) indicate an automatically detected disruption, which could be caused by movement, environmental light or camera readjustments.



*Fig. 8.9.5 Original pulse curve of the measurement report with detected disruption (blue bar)*

## 9.10 Measurement reportlist

After each measurement, the reports are stored in a list and can be viewed via the menu item "My results".



To better understand how to read such a report, see the video guide in the "My reports" area.

The list shows the reports and their main information in sequence: heart rate measurement, the corresponding traffic light color of the measurement, comments and time of the measurement.

The measurement report is displayed in detail by tapping on the relevant report.

Measurement reports can be deleted from the list at any time. To do this, go to the bin icon. Now you can select individual reports in the list that should be deleted. In this mode, you can cancel your selection at any time by tapping on a new report. To cancel the entire selection, tap the "Cancel" button. Press "Delete" to delete the reports. The reports will be deleted immediately.

In the detailed view, you can share a report with other people. To do this, tap the "Share" button. You can then choose from a selection of services to send the report or store it on your smartphone outside of the app. You receive a message that encryption or password protection of the document is recommended when sending the report.

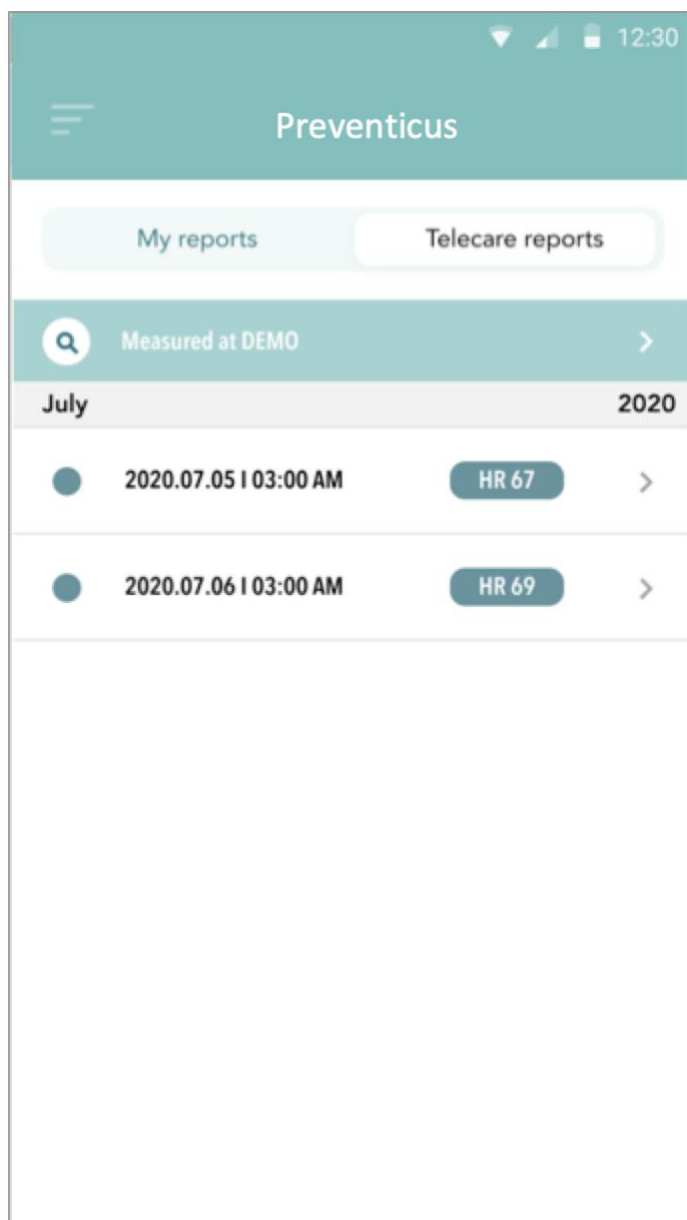
## 9.11 Telecare reportlist

If you have one or more reports with suspected mild arrhythmia (yellow traffic light) or absolute arrhythmia (red traffic light), you have the option to send these reports to the Telecare service for a fee.

The Telecare service offers you a direct medical assessment of your measurements by Telecare employees who specialise in heart rhythm analyses of heart rate data.

The Telecare service will verify your measurement report. You will receive the result directly on your smartphone under Telecare reports.

See the "Telecare reports" section for a sample report.  
Just like the measurement reports, you can also delete the Telecare reports.



In addition, the General Terms and Conditions and Privacy Policy of the Telecare service can be found in this section.

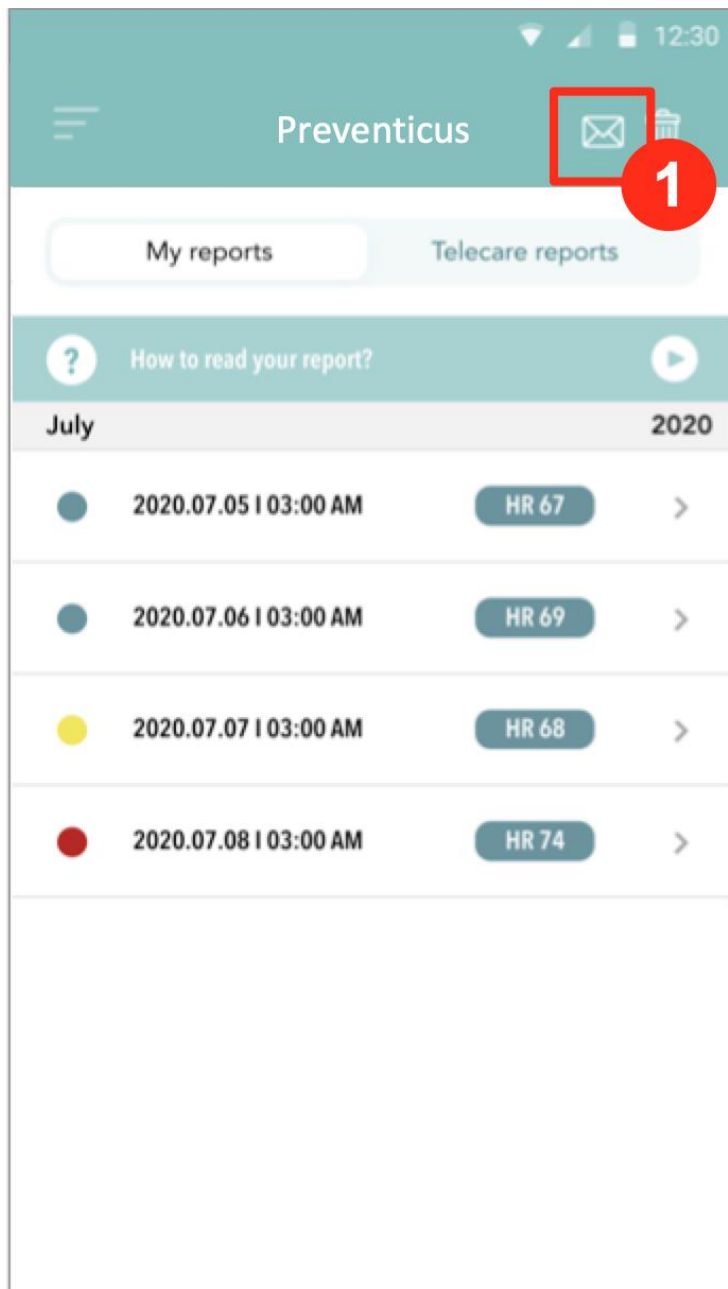
You can also share the detailed view of the Telecare report with others. To do this, select a Telecare report from the list and go to the detailed view. Tap the “Share” button to subsequently receive a selection of services to send the report or store it on your smartphone outside of the app.



## 9.12 Telecare order report

To order a Telecare report you have to be in the "My reports" list. Next, select the "Send" (1) icon.

You can send a single measurement or up to 5 measurement reports.



Single measurement: select "Single measurement" if you only want to send one report. Keep in mind that you can send each report only once.

Several measurements: if you want to send several measurements at the same time, select "Send up to 5 measurements". Please note that you can only select abnormal measurements (red and yellow traffic lights).



## 10 HEALTH APP AND GOOGLE FIT INTEGRATION

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

- Heart Rate
- Blood pressure
- Height
- Weight

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

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

## 11 CLINICAL PERFORMANCE

	Definition	Unit	Range	Acquisition Time	Update interval	Accuracy *
<b>Heart Rate</b>	Number of beats of the heart per minute	beats/minute (bpm)	30-220	5-10 sec	1 sec	HR is $\pm 4$ bpm MAD, $\pm 5\%$ MARD (at rest)
<b>RR Interval</b>	Elapsed time between two consecutive heart beats	msec	300-2000 ms	5-10 sec	1 sec	RR Interval $\pm 50$ ms MAD, $\pm 5\%$ MARD (at rest)
<b>Heart Rate Variability</b>	Beat to beat (RR interval) variations	msec	0-200 ms	5-10 sec	1 sec	HRV $\pm 10$ ms MAD, $\pm 5\%$ MARD (at rest)
<b>Respiration Rate</b>	Number of breaths (inhalation - exhalation cycles) per minute	breaths/minute (brpm)	5-45 brpm	20-30 sec	1 sec	Respiration Rate $\pm 1$ brpm MAD, $\pm 5\%$ MARD (at rest)
<b>Sleep Stages</b>	Detection of specific sleep stages & sleep HR	awake, light sleep, deep sleep, REM	sleep stage	upon end of the entire sleep event	1 min	Sleep Stage $\pm 10\%$ MAD
<b>Sleep Score</b>	Sleep performance and sleep consistency with equal weight	%	0-100%	10 sec	1 sec	Sleep Score $\pm 5\%$ MAD

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

## 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 Pruysenweg 35, 2595 AN The Hague, The Netherlands or its authorized representative. Corsano Health shall not have any responsibility in the event of loss or damage in transit.

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

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

## 14 SPECIFICATION

Minimum requirements for mobile device Operating Systems:

- iOS 12.2 or higher
- Android 8.0 or higher

### PPG Sensor Characteristics

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

### Motion Sensor Characteristics

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

### Data Acquisition

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

### Power Requirements

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

### Dimensions

Length x Width x Height .....	25mm x 37mm x 9mm
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### Environmental Specifications

Ingress Protection.....	IP66
Operational Temperature .....	+10 to +40 degrees C
Transport and storage Temperature .....	-20 to +60 degrees C
Operational Humidity.....	20% to 80%
Transport and storage Humidity .....	20% to 90%


### Interface

Wireless Communication.....	BLE 5.0
Display LEDs .....	1 green, 1 orange
User action.....	pusher button

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


## 15 ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

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

	IEC 60417-5333	TYPE BF APPLIED PART
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Guidance and manufacturer's declaration—electromagnetic immunity			
Corsano racelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-5	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-6	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.



Guidance and manufacturer's declaration—electromagnetic immunity			
Corsano bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted	3 Vrms	NA	Portable and mobile RF communications equipment should be used no closer to any part of Corsano bracelet, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance (m)</b>  $d = 1.2 \sqrt{P}$  $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz  $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> .  Interference may occur in the vicinity of equipment marked with the following symbol:  
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz	NA	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	NA	
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			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Corsano bracelet is used exceeds the applicable RF compliance level above, Corsano bracelet should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Corsano Bracelet.			

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

Corsano Bracelet is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Corsano bracelet can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Corsano bracelet as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

## 16 DISPOSAL OF THE DEVICE

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



## 17 CORSANO CONTACT INFORMATION

**Corsano Health B.V.**

Wilhelmina van Pruisenweg 35  
2595 AN The Hague  
The Netherlands

[www.corsano.com](http://www.corsano.com)

