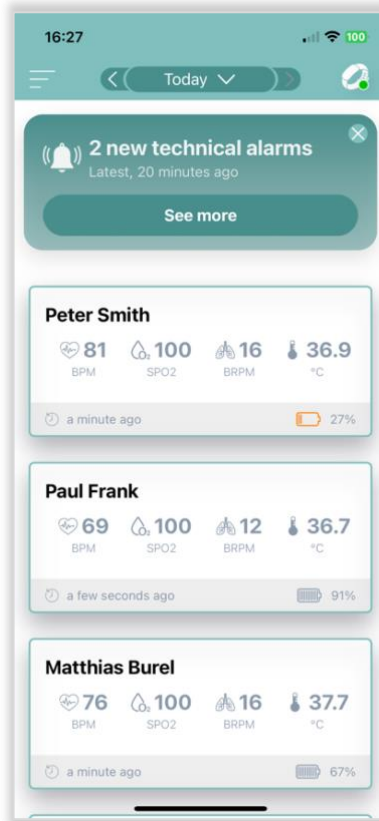




EN



CardioWatch 287-2 System

HCP Mobile 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.


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List of Abbreviations

<u>Abbreviation</u>	<u>Abbreviation Meaning</u>
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.

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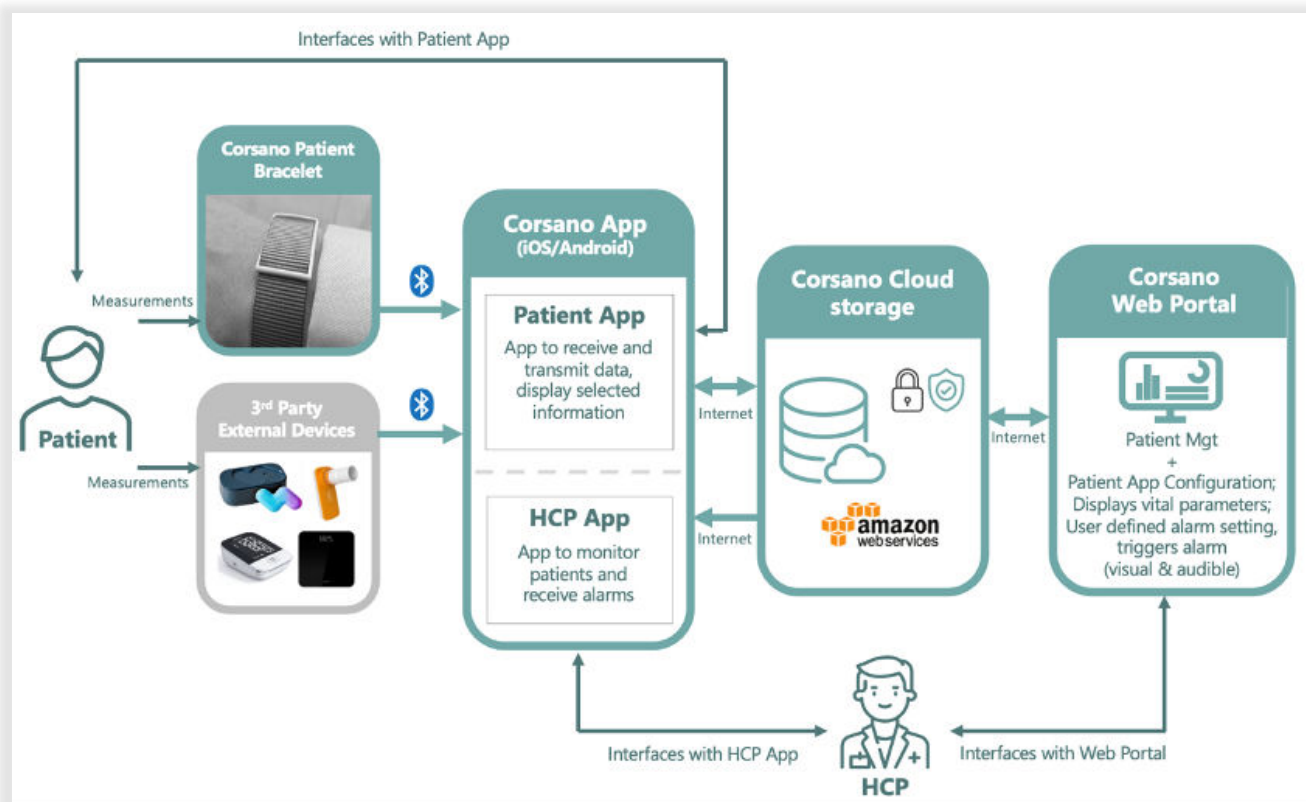
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1 INTRODUCTION

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 Professional (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 User 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 professional 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.

These Instructions Manuals assume a working knowledge of vital signs monitoring. To support proper, safe, and accurate operation of the CardioWatch 287-2 System, read all operating instructions carefully before you use the system.

The CardioWatch 287-2 System should only be used by trained healthcare professionals.














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

2 SAFETY INSTRUCTIONS





To ensure the safe and proper use of the CardioWatch 287-2 System, READ and UNDERSTAND all of the safety and operating instructions.

If you do not understand these instructions or have any questions, contact support@corsano.com before attempting to use the system.

2.1 WARNINGS

-  To maintain patient safety, adhere to all WARNINGS and CAUTIONS listed in these Instructions Manuals.
-  The CardioWatch 287-2 System is intended for use by qualified medical personnel only;
-  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 Anesthesiologists).
-  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.
-  The physiological parameters and alarms displayed on the Web Portal & HCP App are for HealthCare Practitioners reference only and cannot be directly used as the basis for clinical treatment.
-  The CardioWatch 287-2 System is not an apnea monitor. DO NOT rely on the respiration monitoring for detection of cessation of breathing.
-  Do not ignore physiological or technical alarms displayed, these alarms are configured to facilitate patient monitoring.
-  If any value displayed is abnormal or questionable, first determine the patient's vital signs by alternative means and then verify that Web Portal / HCP App is working correctly.
-  The Bracelet is intended for use on a single patient, DO NOT use the Bracelet on anyone else during patient monitoring.
-  NEVER allow the Bracelet nor the mobile phone to become discharged.
-  The mobile phone running the software must have audio. DO NOT turn off audio or adjust the volume to zero.
-  A rapid recognition of alarms and an appropriate response are only possible if the

user is in hearing range of the audible alarm signals. The user must stay within the hearing range of the audible alarm signal and adjust the volume according to the distance from acoustic alarm signal.

-  Do not rely exclusively on audible alarm system. Setting alarm volume to a low level may result in a hazard to the patient.
-  When operating in a noisy environment, the volume of the alarm signals must be adjusted to suit. Always set the volume of the alarm signal sufficiently high.
-  Low priority alarms have no auditory signals.
-  Should a loss of monitoring capacity of one or more patients occur with the CardioWatch 287-2 System, the HCP must evaluate the likelihood of health deterioration and take appropriate clinical decisions to ensure patient safety.

2.2 CAUTIONS



Patients at risk for respiratory crises 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.



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

2.3 RECOMMENDATIONS



Multiple factors can affect the accuracy of a SpO2 measurements, such as poor circulation, skin pigmentation, skin thickness, and skin temperature.



Clinical decisions based on SpO2 measurements should be made on trends in pulse oximeter readings over time rather than absolute thresholds.

2.4 NOTES

During normal use of the HCP App, the operator is expected to maintain their smartphone within proximity to ensure patient monitoring.

2.5 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.

2.6 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 (Steps) to encourage the patient to be more active or to better adhere to Healthcare Practitioner instructions.

3 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.
	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)
	Auditory signals can be disabled (sound is muted) and enabled (sound is ON)
	Indicates alarm limits (limits)
	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

Symbol	Meaning
	Refer to instruction manual/booklet.
	The wearable device (Bracelet) does not generate alarms.
	For prescription use only (USA).

4 CORSANO APP

The Corsano App is single application that is user configured for either a Patient or HCP. This Instruction Manual is exclusively destined for the HCP user configuration ; all patient configuration is managed via the Web Browser.

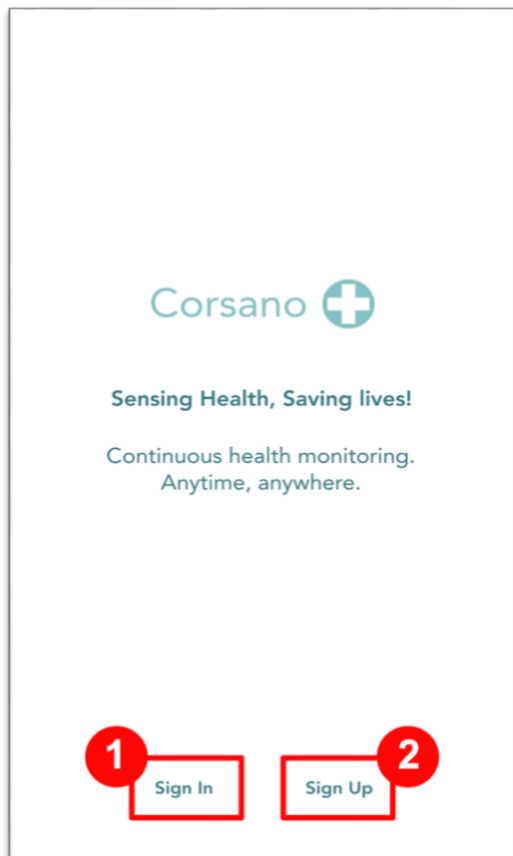
4.1 Download and install the Corsano App onto your smart phone.



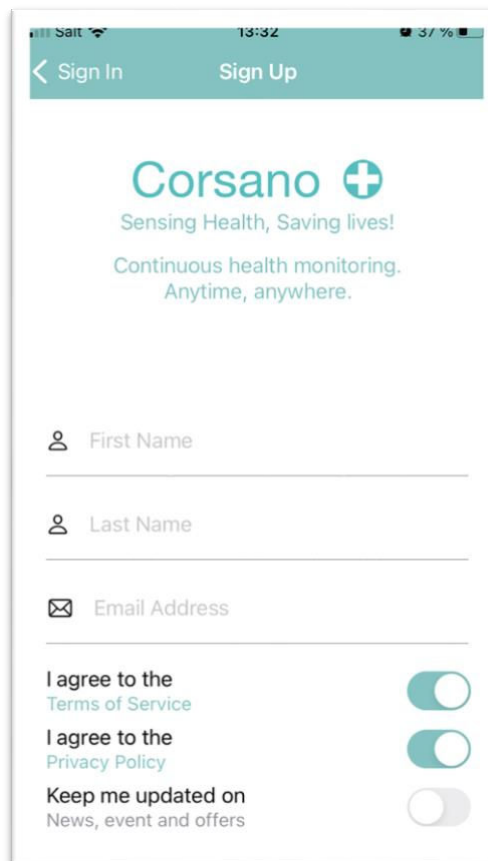
4.2 First time use – Sign Up

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

Enter First Name, Last name, Email



Choose Sign-Up



Sign-Up

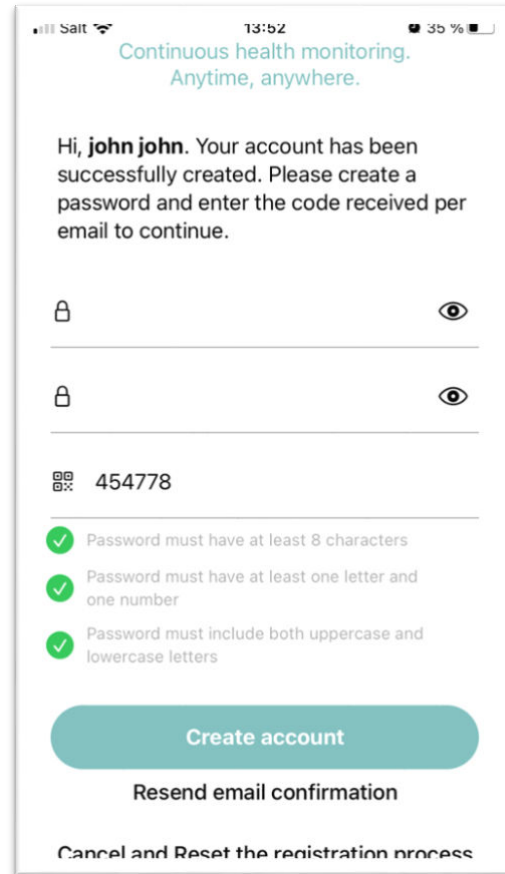
Agree on Terms of Service and Privacy Policy

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

Enter:

- Your password
- Your password again
- The received code

Press “Create account”



Create account

4.3 Sign In

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

Select “Sign In” (1)

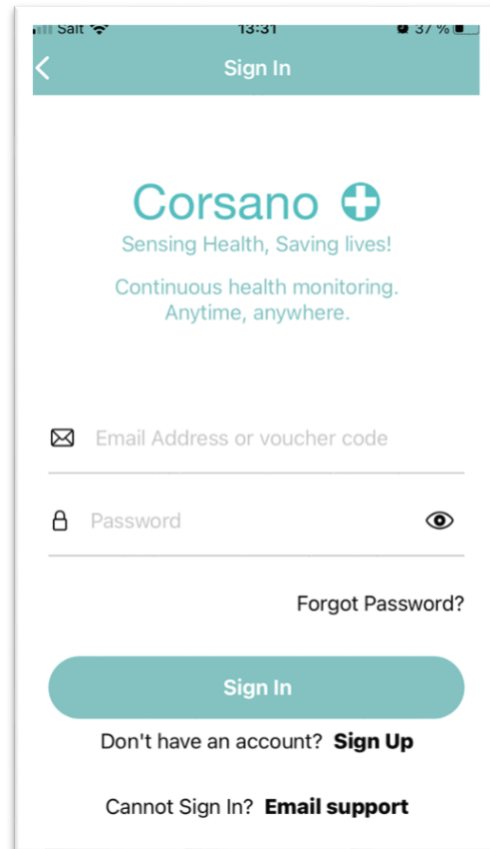


Choose Sign-In

Enter:

- Email
- Password

Press **“Sign In”**



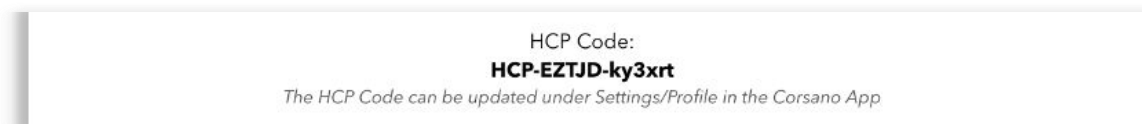
Sign-In

5 HCP APP (HCP Mode)

5.1 HCP App Configuration

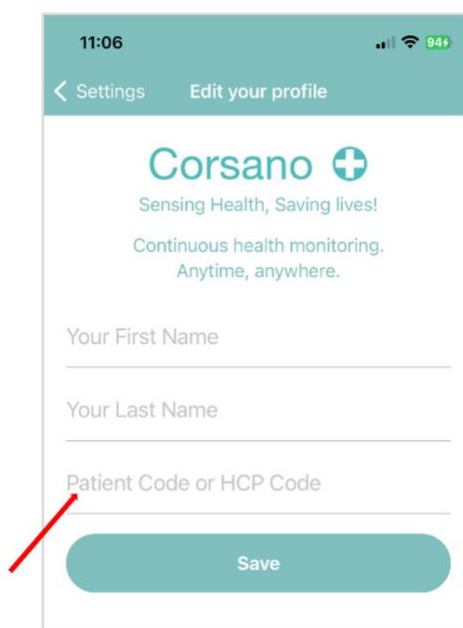
The Corsano App can be configured for the Healthcare Practitioner by entering the HCP Code.

The HCP Code is available on the Web Portal, please click on settings for a department to access the Configuration Panel for the Department:



Configuration Panel

To configure the Corsano App in HCP Mode, the HCP must enter the HCP Code under Settings/Profile in the Corsano App, which configures the Corsano App in the HCP App mode.



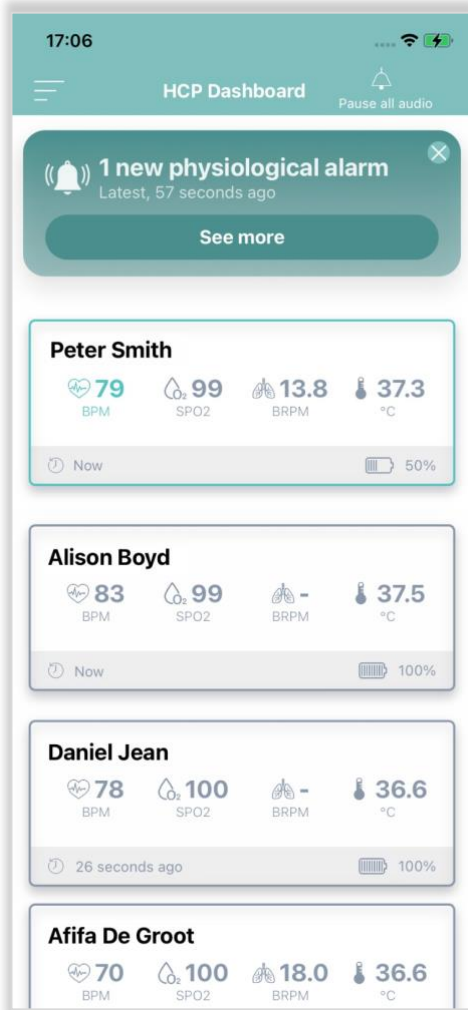
Corsano App Profile

The HCP can then see the list of patients linked to the Department, monitor their vital parameters and receive the alarms (patient & technical).

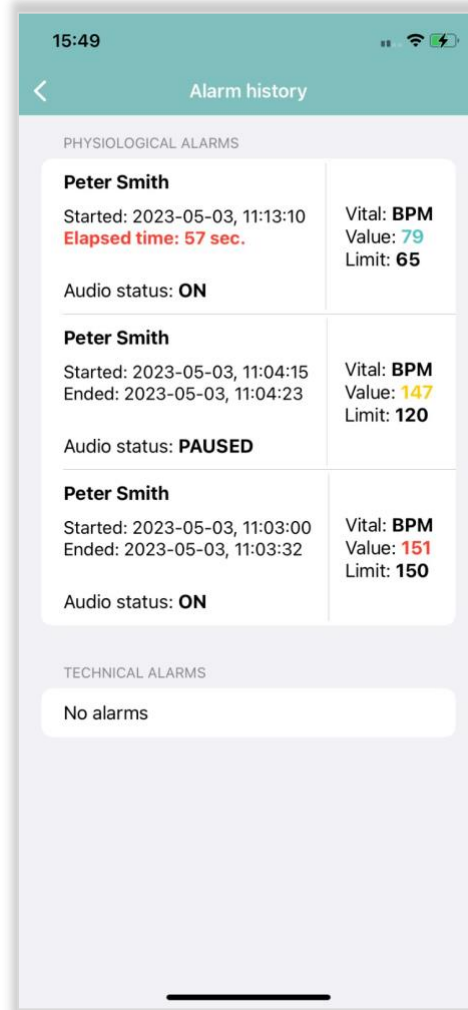
5.2 HCP App Patient Listing

The HCP Mode provides the following functionality:

- a. Secure logging
- b. Displaying the vital parameters (PR, SpO2, RR, Temp) of the Patients
- c. Displaying the Battery Levels of the Corsano Bracelet of the Patients
- d. Transmitting the Patient Alarms from the Web Portal
- e. Transmitting Technical Alarms when connection problems are detected



Patient Listing on HCP App



Alarm History on HCP App

6 Alarms in Corsano App (HCP Mode)

For full details on Alarm Management, refer to the Instruction Manual for the Web Portal (Section 6).

Alarms must have been configured in the Web Portal prior to using the alarm information in the Corsano App (HCP Mode).

The Corsano App (HCP Mode) will only :

- displays the alarms previously configured in the Web Portal
- replicate the alarms limits previously configured in the Web Portal



The alarms are information to help the Healthcare Practitioners to see if the metrics are in a pre-defined range. The system is not intended to be used in high-acuity environments where the condition of the patient may require immediate action.



Third-party external devices do not generate alarms on the Corsano System unless otherwise stated in these instructions for use.

7 Technical Alarms

The Corsano System may generate the following Technical Alarms:

Technical Alarms	Level	Cause or solution
Network Disconnected	High	Please check the local network. Contact your local Network Administrator.
Communication lost, no data was updated for device <ul style="list-style-type: none"> • >30s Low (Cyan) • >1 Min High (Red) 	High / Low	Corsano Bracelet is disconnected from the Web Portal. Please check Connectivity Troubleshooting.
Low Battery CardioWatch <ul style="list-style-type: none"> • <20% Medium (Yellow) • <10% High (Red) 	High / Medium	Please contact the patient to recharge their device.

8 PATIENT APP (Patient Mode)

8.1 Patient App Configuration

Please ask the patient to download and register the Corsano App on their mobile phone. (you may do for the patient).

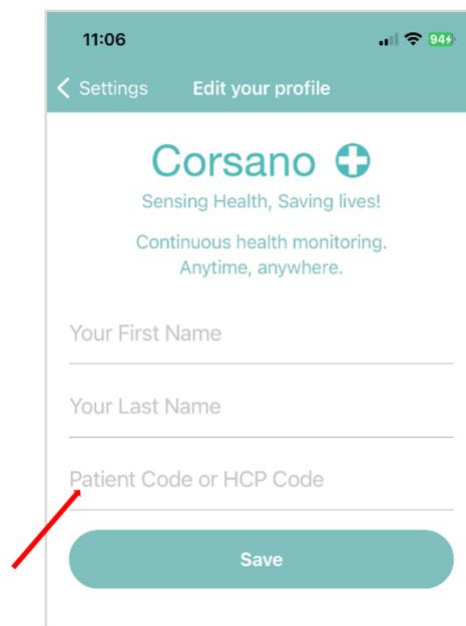
The Corsano App can be configured for the Patient by entering the Patient Code.

The Patient Code is available on the Web Portal, please click on settings for a department to access the Configuration Panel for the Department:



Configuration Panel

To configure the Corsano App in Patient Mode, please ask the patient to enter (or enter for patient) the Patient Code under Settings/Profile in the Corsano App, which configures the Corsano App in the Patient App mode.



Corsano App Profile

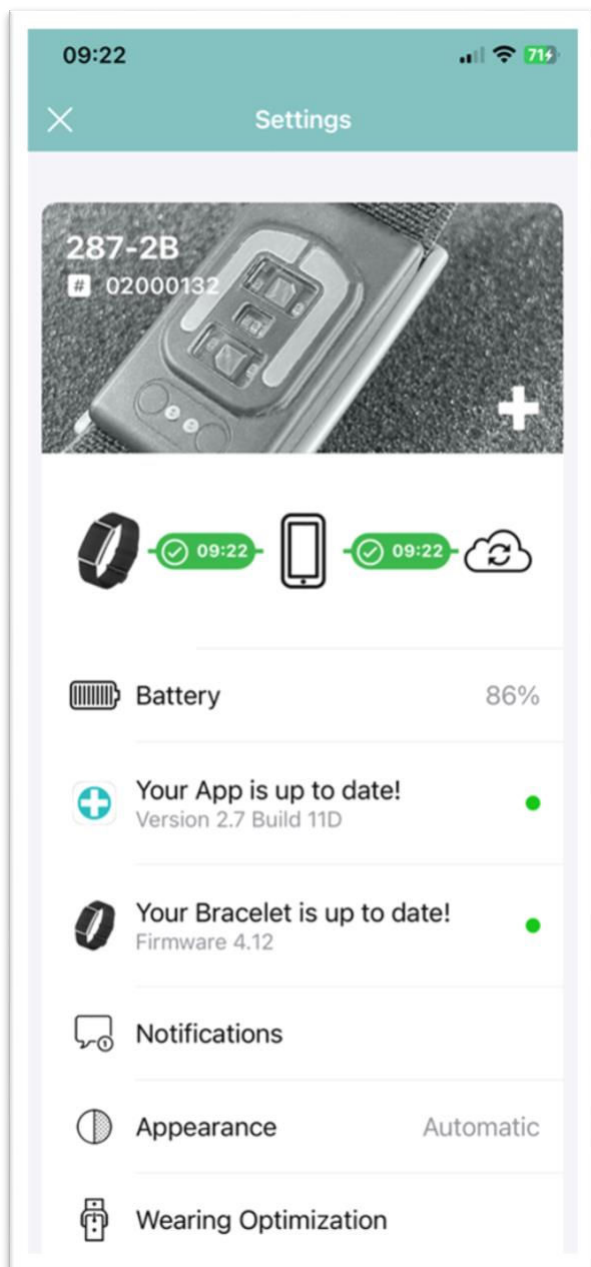
8.2 Patient App Settings

In the Corsano App on the mobile phone of the patient, the you can open the Settings Menu by clicking on the icon on the top left corner.

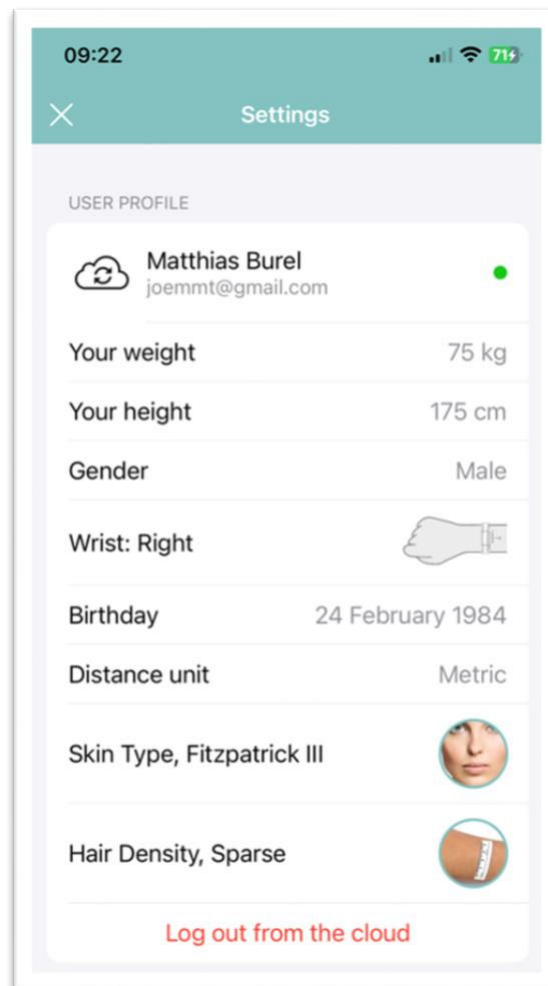
You can see the information about the Patient App and Bracelet.

You can see your profile data for the patient and modify if needed.

These parameters are important for the measurement accuracy.



App and Bracelet Status



Profile Settings

8.3 Patient App Screens

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

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

The HCP can select:

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

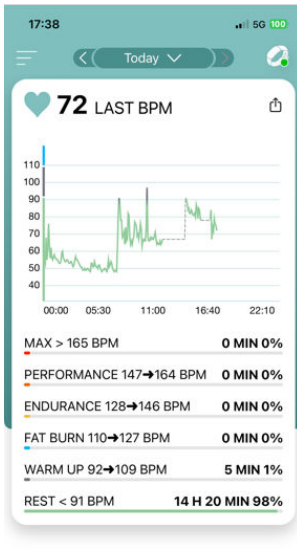


The information provided to the Patient is intended to provide trending data to assist the HCP in providing patient motivation. HCP decides which information is shown to the patient based on therapy.

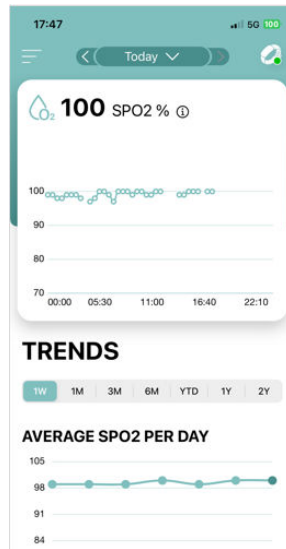
Such examples may include:

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

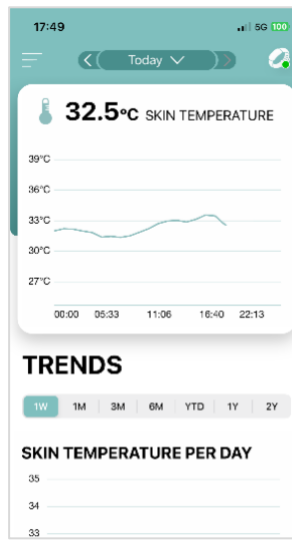
The following figure gives a summary view of the available Patient Mode Screens:



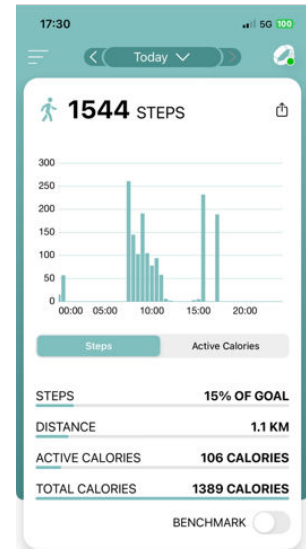
Pulse rate



SpO2



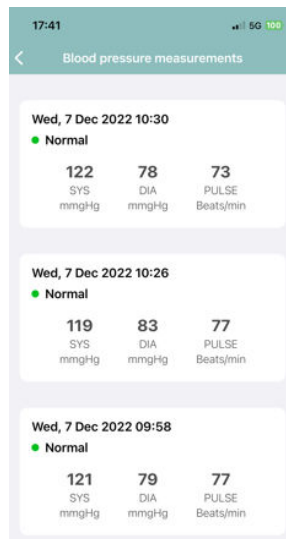
Skin Temperature



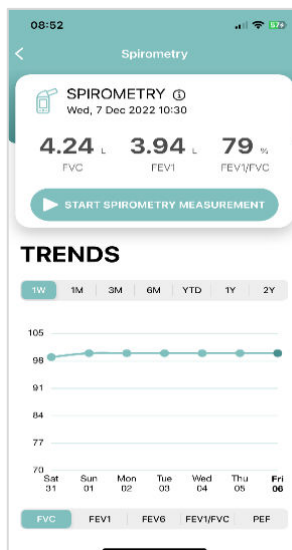
Activity



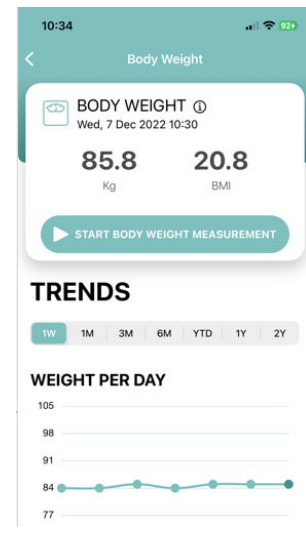
Respiration rate



NIBP



Spirometry



Weight



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

9 CYBERSECURITY

9.1 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, Microsoft Edge or Google Chrome web browser. All communications between the Web Portal and the Corsano Cloud are encrypted to an industry-standard, using TLS1.2+.

9.2 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.

9.3 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 the patient will be notified of its update as an integrated part of an update to the Corsano App.

9.4 Dealing with a lost or stolen Corsano Bracelet

In case a Corsano Bracelet is lost or stolen, please notify Corsano Health via support@corsano.com providing the Serial Number of the lost bracelet. Please ensure that the lost bracelet is immediately disassociated with the Patient Records.

9.5 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 system
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.

10 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.

11 SPECIFICATIONS

11.1 Corsano App

Minimum requirements for mobile device Operating Systems:

- iOS 14.5 or higher
- Android 8.0 or higher

Minimum requirements for Smart Phone

- BLE 4.2+ interface
- Loud speaker
- iPhone, Samsung A5 or more recent

11.2 Alarms Sound Levels

The Corsano App (HCP mode) sound levels have been tested in accordance with the IEC 60601-1-8 standard to :

Alarm sound pressure level (dB)	High Priority Alarms:	34 dB to 72 dB
	Medium Priority Alarms:	34 dB to 70 dB

11.3 Corsano Bracelet

Refer to Instruction Manual for **CardioWatch 287-2B Bracelet & Mobile Patient App.**

11.4 Regulatory Conformity

Refer to Instruction Manual for **CardioWatch 287-2B Bracelet & Mobile Patient App.**

11.5 Applied Standards

Refer to Instruction Manual for **CardioWatch 287-2B Bracelet & Mobile Patient App.**

12 DISPOSAL / END OF LIFE



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

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

13 CORSANO CONTACT INFORMATION



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