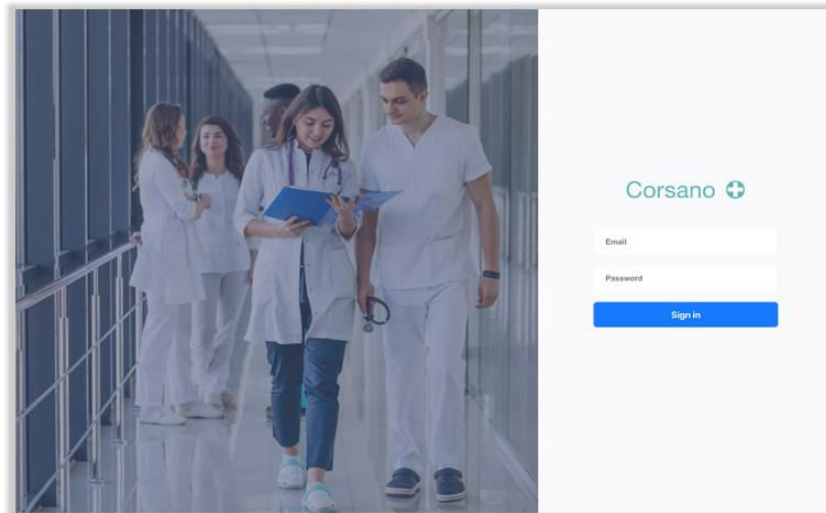




EN



CardioWatch 287-2 System

Web Portal Instruction Manual



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

www.corsano.com
info@corsano.com

 1912

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.

All rights are reserved. Corsano Health B.V. reserves the right to alter the products described in this manual at any time without notice. No part of this manual may be reproduced, copied, translated, or transmitted in any form or by any means without the prior written permission of Corsano Health B.V. Information provided in this manual is intended to be accurate and reliable. However, Corsano Health B.V. assumes no responsibility for use of this manual, for any infringements upon the rights of third parties which may result from such use. All brand and product names mentioned herein are trademarks or registered trademarks of their respective holders.

Copyright Notice: Corsano is a trademark of Corsano Health B.V. This document is copyrighted by Corsano Health B.V.

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.

0. TABLE OF CONTENTS

| | | |
|------------|--|-----------|
| 0. | TABLE OF CONTENTS | 4 |
| 1. | INTRODUCTION | 6 |
| 2. | SAFETY INSTRUCTIONS | 8 |
| 2.1. | WARNINGS..... | 8 |
| 2.2. | CAUTIONS | 9 |
| 2.3. | RECOMMENDATIONS | 9 |
| 2.4. | NOTES..... | 9 |
| 2.5. | Indications for Use..... | 10 |
| 2.6. | Clinical Benefit..... | 10 |
| 3. | SYMBOLS | 11 |
| 4. | WEB PORTAL..... | 12 |
| 4.1. | Sign-Up | 12 |
| 4.2. | Sign-In..... | 13 |
| 4.3. | Department Dashboard | 14 |
| 4.4. | Add Department..... | 14 |
| 4.5. | Delete Department..... | 14 |
| 4.6. | Assign Patients | 15 |
| 4.7. | Patients Overview | 16 |
| 4.8. | Un-assign Patient..... | 19 |
| 4.9. | Patient Portfolio | 19 |
| 5. | ALARMS IN WEB PORTAL..... | 21 |
| 5.1. | Alarm overview | 21 |
| 5.2. | Position of the Operator | 22 |
| 5.3. | Alarm Defaults..... | 22 |
| 5.4. | How to Verify the Alarm functions | 23 |
| 5.5. | Audible Alarms | 24 |
| 5.6. | Alarm Limits | 24 |
| 5.7. | Alarm Delays | 25 |
| 5.8. | Alarm Notifications..... | 26 |
| 5.9. | Alarm Emails | 26 |
| 5.10. | Alarm History..... | 27 |
| 6. | TECHNICAL ALARMS | 28 |
| 7. | PATIENT APP SETTINGS | 29 |
| 8. | HCP & Patient Training | 31 |
| 8.1. | HCP Training..... | 31 |
| 8.2. | Evaluating Patients medical condition | 31 |
| 8.3. | Evaluating Patients familiaristion with modern technology..... | 31 |
| 8.4. | Patient Training & Assistance | 32 |
| 9. | CYBERSECURITY..... | 33 |
| 9.1. | Information Security Management System..... | 33 |
| 9.2. | About password policies, password expiration and auto-logout..... | 33 |
| 9.3. | About periodical software updates and patches | 34 |
| 9.4. | Dealing with a lost or stolen Corsano Bracelet | 34 |
| 9.5. | General Guidelines for Security | 34 |
| 10. | WARRANTY..... | 35 |
| 11. | SPECIFICATIONS | 36 |

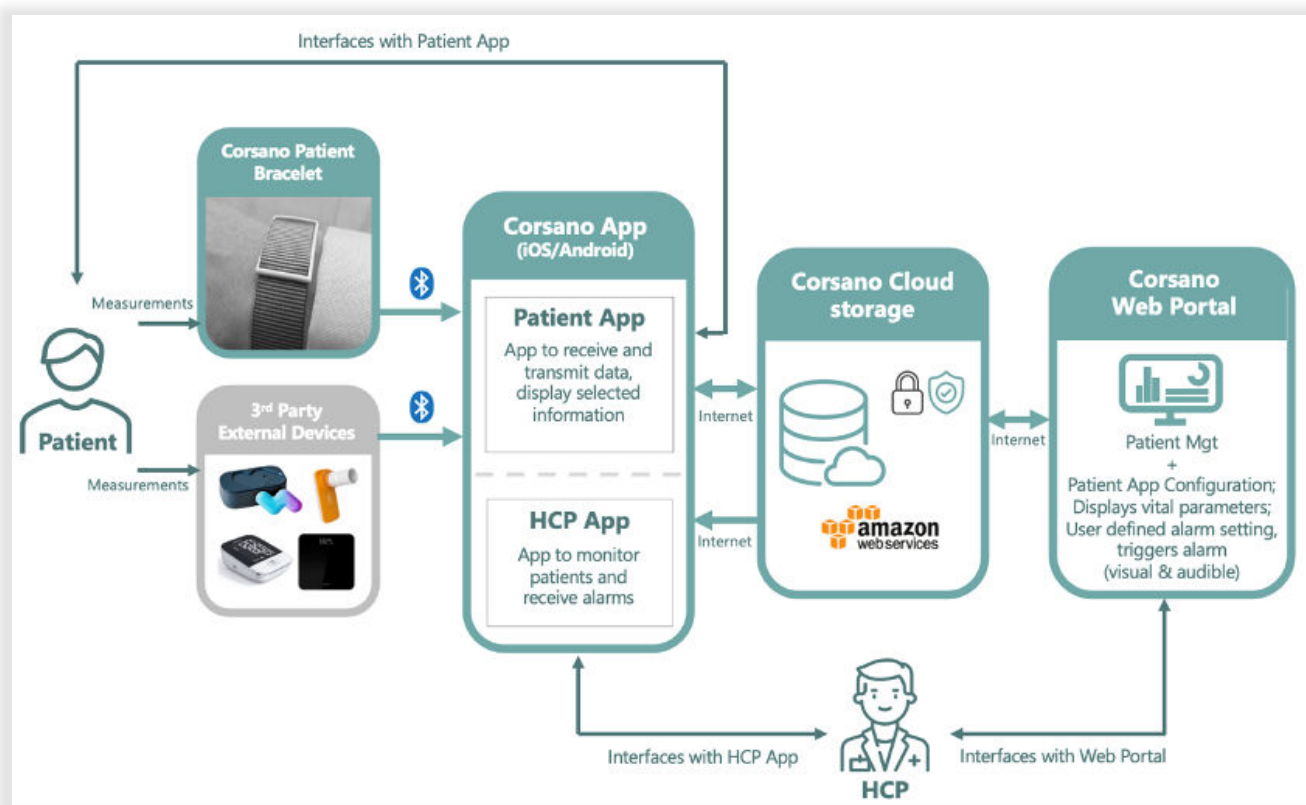
- 11.1. Corsano Web Portal App36**
- 11.2. Alarms Sound Levels36**
- 11.3. Corsano Bracelet.....36**
- 11.4. Regulatory Conformity36**
- 11.5. Applied Standards.....36**
- 12. DISPOSAL / END OF LIFE36**
- 13. CORSANO CONTACT INFORMATION37**

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 287-2B System, READ and UNDERSTAND all of the safety and operating instructions.

If you do not understand these instructions or have any questions, contact Corsano Health via 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 computer running the Web Portal software must have audio. DO NOT turn off audio or adjust the volume to zero. Do not block the speaker.
-  Do not rely exclusively on audible alarm system. Setting alarm volume to a low level may result in a hazard to the patient.
-  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



The computer running the Web Portal software must utilize the hospital emergency power system. Failure to do so will result in loss of monitoring during extended periods of power failure. Hospitals without an emergency power system should use an Uninterruptible Power Supply (UPS) to power the computer running the Web Portal software. When there is a power failure, the system should be shut down by following the specified shutdown procedure before the UPS is turned off. If the system has a sudden power failure, system failure may occur and consequently, the system will not work correctly next time.



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 the patient is experiencing shock, hypothermia, anaemia 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, the operator is expected to face the front of the equipment.

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) |
|  | 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. |
|  | For prescription use only (USA). |

4. WEB PORTAL

The Corsano Web Portal enables the HCP to manage the data monitoring of their patients.

Via a Web Browser, the HCP configures the data to be monitored, the physiological alarms and visualize the list of patients and vital parameters (Pulse rate, SpO2, skin temperature, respiration rate, movement) obtained from data originating from the Corsano Bracelet.

Parameters measured by compatible Third Party medical devices (Non-invasive blood pressure, lung function & spirometry, weight, axillary temperature) are displayed on the Corsano Web Portal.

When alarm conditions are met, the Corsano Web Portal generates visible and audible alarms.

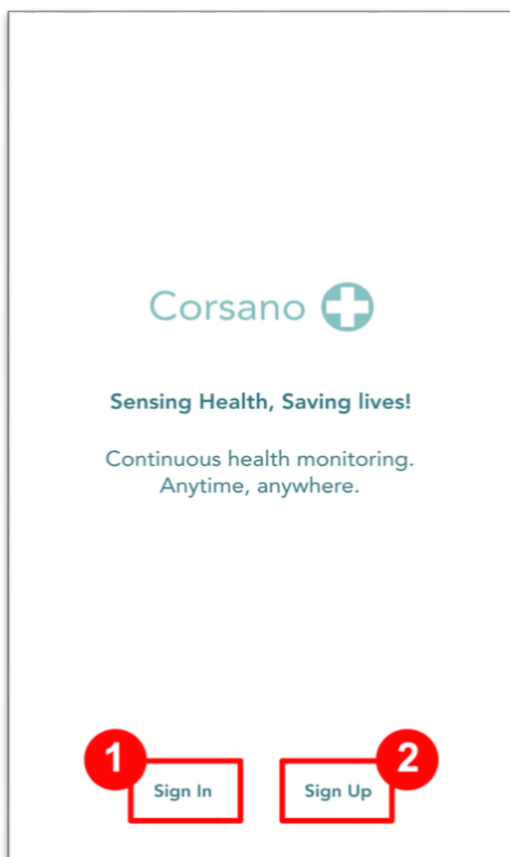
4.1. Sign-Up

You will first need to sign-up via the Corsano App. Please download and install the Corsano App app onto your smart device.

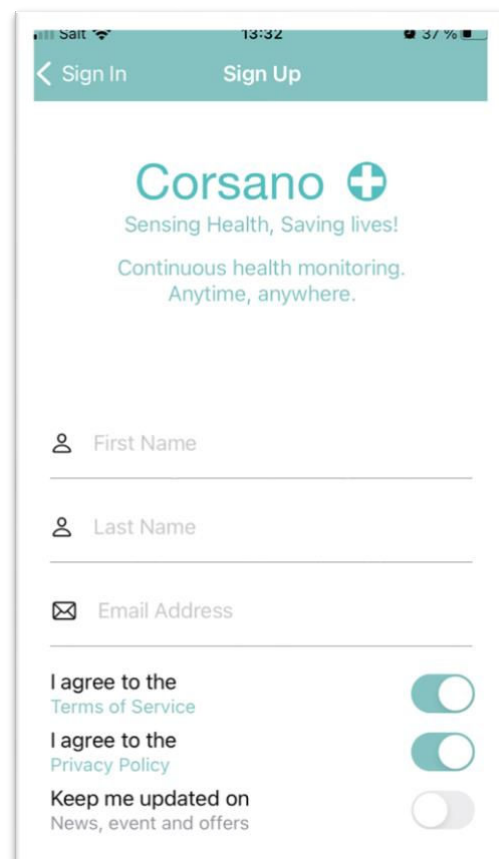


Select "Sign Up" to create a user account (2)

Enter First Name, Last name, Email



Choose Sign-Up



Sign-Up

Agree on Terms of Service and Privacy Policy

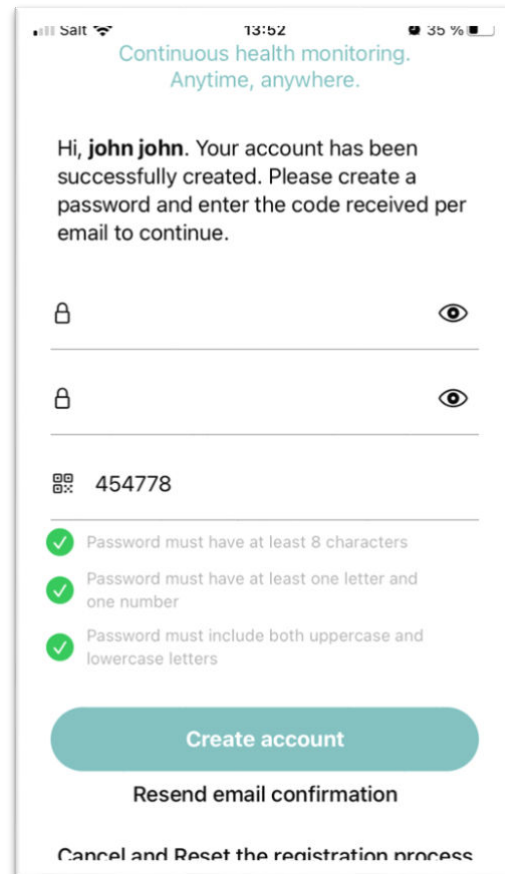
An email is sent to you with a 6-digit code.

Enter:

- Your password
- Your password again
- The received code

Press “Create account”

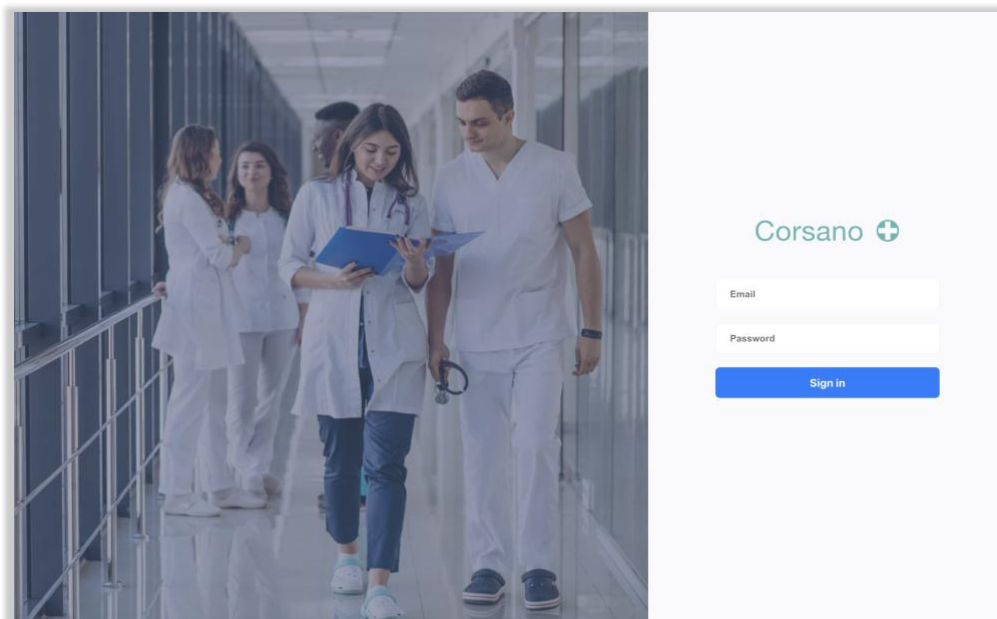
The password you use during registration is encrypted and will be known to you only (Corsano will not have it).



Create account

4.2. Sign-In

After registration via the Corsano App, you can sign-in with your email address and password to the Corsano Web Portal at <http://portal.corsano.com>.



Sign-in Web Portal

4.3. Department Dashboard

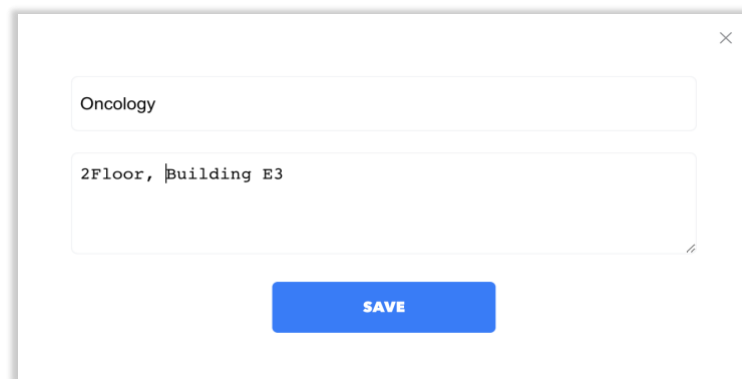
The Department Dashboard is the homepage of the Corsano Web Portal. You can select the relevant department.



Department Dashboard


4.4. Add Department

If no department has been setup on the Department Dashboard, or you want to add a new department, please click on the [Add] button top right. You can type the name of the department and a description, then click [Save].



Add Department

4.5. Delete Department

A department can be deleted by clicking on the  icon. To avoid that a department is accidentally deleted, you will need to confirm deletion.



Delete Department

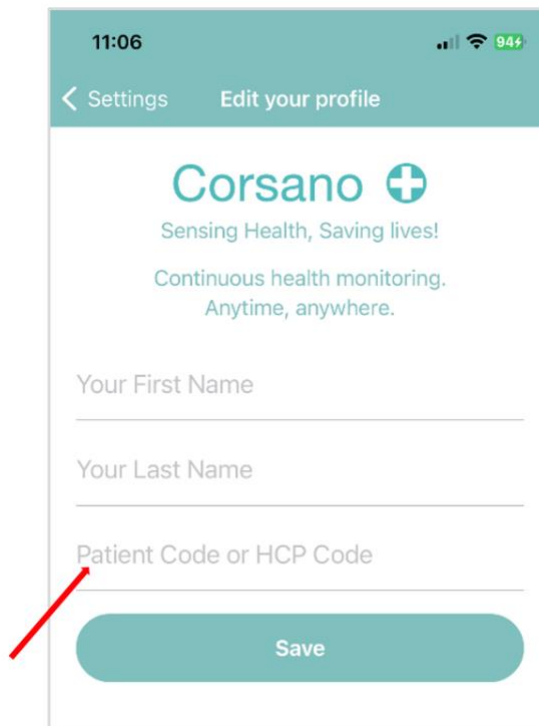
4.6. Assign Patients

See the Department Code on right side, i.e. **EZTJD** in the above example. To assign patients to a department, please ask the patient to add the Department Code in their Corsano App under Settings/Profile.



Department Dashboard

On the Profile page in Corsano App, the User is requested to enter either the Patient Code in the Code Field:



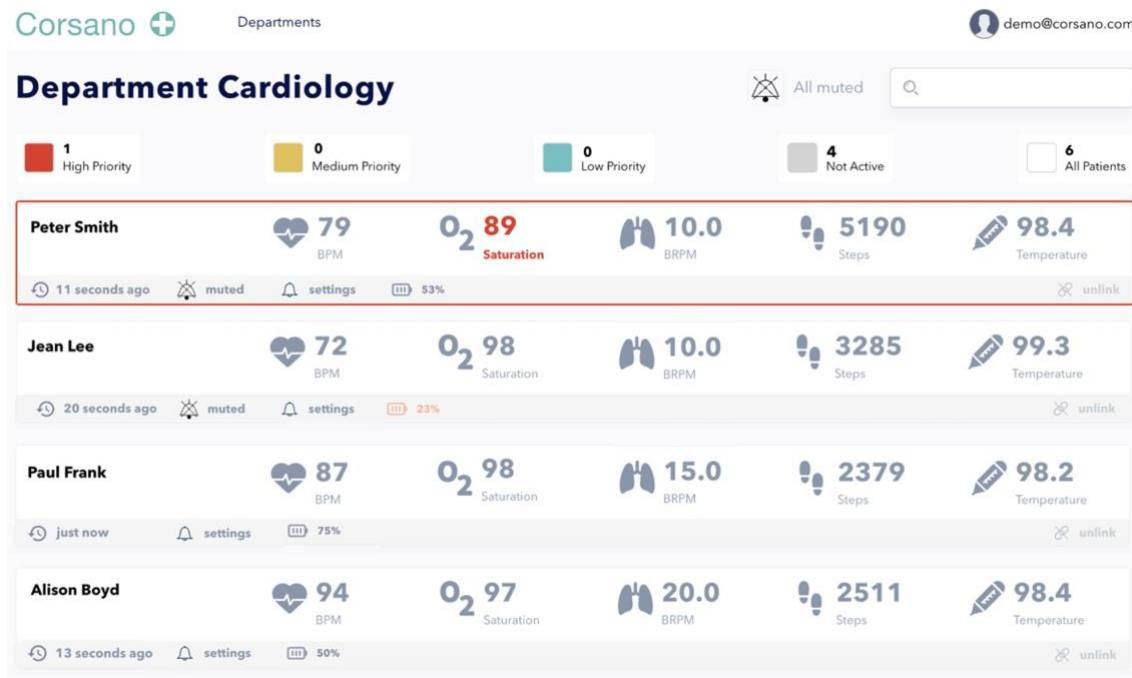
Corsano App Configuration depending on the Patient or HCP Code



NOTE: To add a Department Code in the Corsano App, please see section on App Settings in the Bracelet Instruction Manual. Once the Department Code is added in the patient App, data for the patient will automatically appear in the Department Dashboard.

4.7. Patients Overview

Click on a department to see an overview of patients that are assigned to the department.



Department Cardiology

Summary: 1 High Priority, 0 Medium Priority, 0 Low Priority, 4 Not Active, 6 All Patients

| Patient Name | BPM | O ₂ Saturation | BRPM | Steps | Temperature |
|--------------|-----|---------------------------|------|-------|-------------|
| Peter Smith | 79 | 89 | 10.0 | 5190 | 98.4 |
| Jean Lee | 72 | 98 | 10.0 | 3285 | 99.3 |
| Paul Frank | 87 | 98 | 15.0 | 2379 | 98.2 |
| Alison Boyd | 94 | 97 | 20.0 | 2511 | 98.4 |

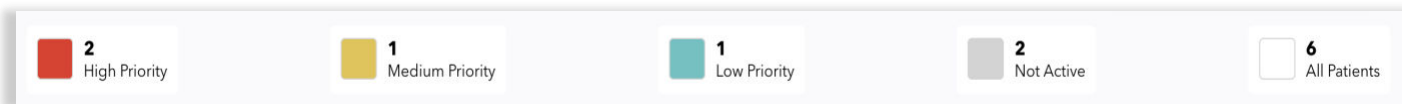
Patients Overview

The screen gives the HCP user a general overview of the department status. Patients, alarms and system settings can be accessed from this screen.

Patients Status – displays high, medium and low alarms on top of the patient listing for the department. Alarms are explained in the next chapter.



NOTE: Each patient alarm limit may be changed through patient portfolio, see next chapter.



Summary: 2 High Priority, 1 Medium Priority, 1 Low Priority, 2 Not Active, 6 All Patients

Patients that need attention with priority

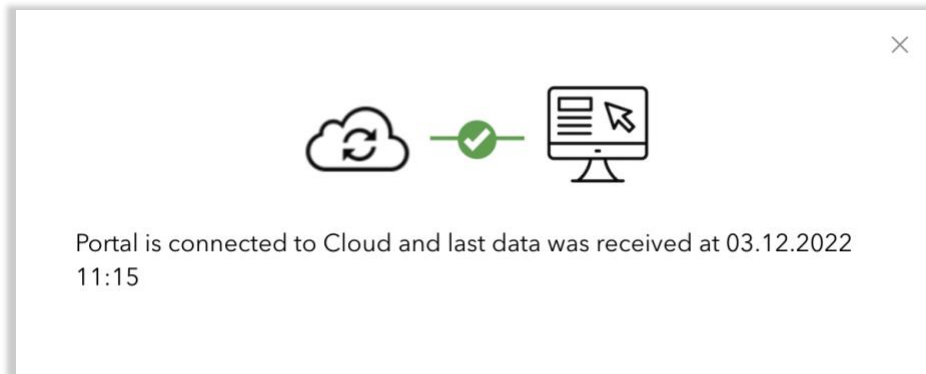
Last Update – displays how long-ago patient data was received on the portal. If last data was received more than 5 min ago, number of minutes will be displayed in red.

 22 seconds ago

 26 minutes ago

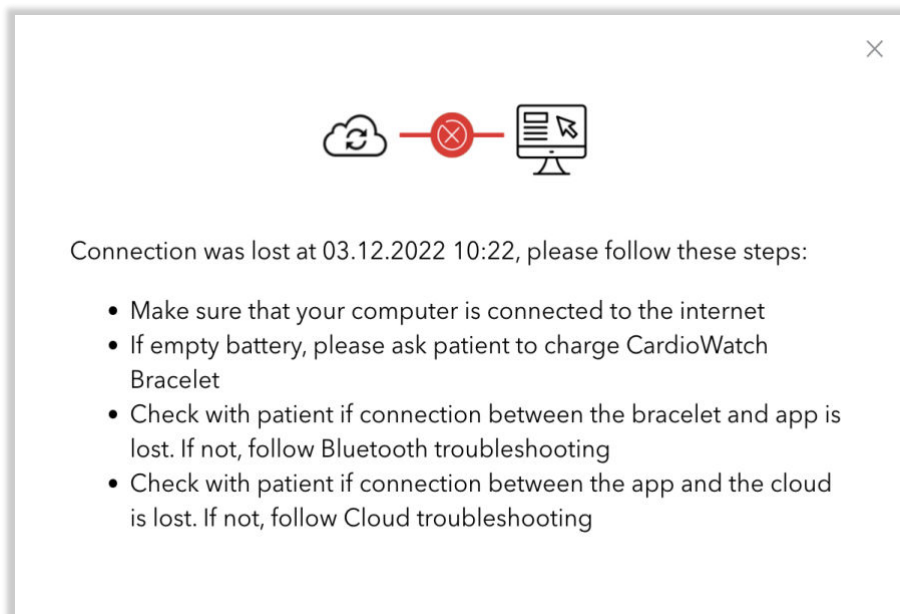
This could be due to several reasons, such as an issue with the device, the connection to the App, connection between the App and the Cloud or connection between the Web Portal and the Cloud.

Click on the Last Update icon to see connection status. If connection is good, you will see:



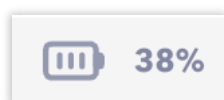
Portal is connected and receiving data

If connection is lost you will see:



Connection Troubleshooting

Batteries – displays the remaining battery for Corsano Bracelets. Low battery levels (under 20% left) will have a yellow battery icon. Under 10% the battery icon will turn red and under 5% it will start blinking.



If battery is empty the system will display an alarm on the Dashboard:

Low battery. Charge device

Patient Listing – displays the vital parameters of patients in numbers. An unstable patient is a patient that has appeared on the exceeding vitals tile, having passed the limit for one of the following vitals: pulse rate, SPO2, respiration rate or temperature.

Vital Parameters

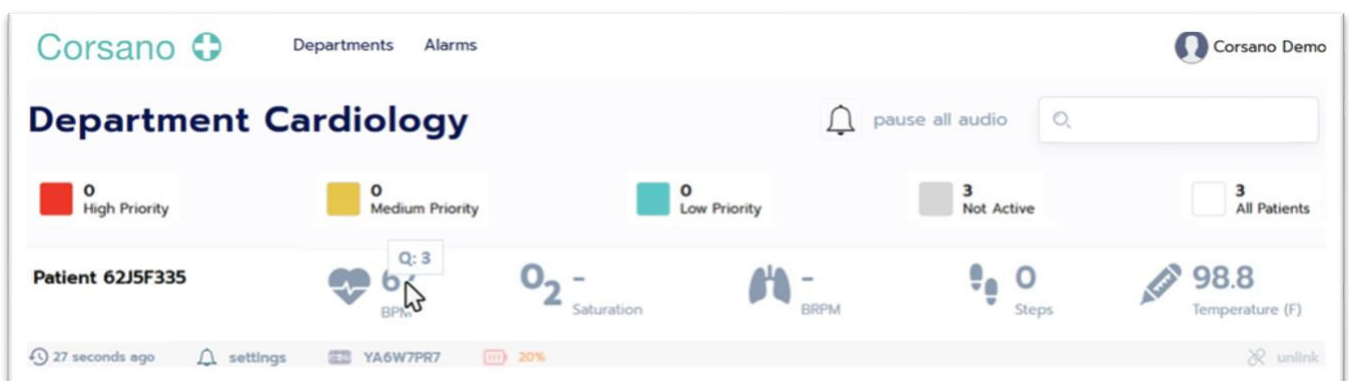
The dashboard shows five vital parameters for each patient. The parameters presented are:

- Pulse Rate (PR, bpm)
- Blood oxygen saturation (SPO2, %)
- Respiratory Rate (RR, brpm)
- Activity (Steps for day)
- Temperature (°C/°F)

Patient Lookup – on the top right of the dashboard. Enables the search of a specific patient. Once selected, a list of all patients in the department will appear. You can look up a patient by name or voucher code.

Vouchers – on the top middle of the dashboard. You can create voucher codes to de-identify patients. Health data for each patient is saved under the voucher assigned to that patient.

Quality Index – suspending the mouse over Pulse Rate, SpO2 and Respiration Rate vital parameters, will display the current Quality Index of the measurement signal.



Q-Index conditions :

| Q-Index | Description | Conditions | Impact |
|---------|---|---|--|
| Q:0 | Very bad quality or no measurement possible | Good PPG pulses in the measurement period < 20% OR Standard deviation in the measurement period is > 20% | Not transmitted by the Bracelet Firmware |
| Q:1 | Bad quality | Good PPG pulses in the measurement period are > 20% AND Standard deviation in the measurement period is > 20% | Not transmitted by the Bracelet Firmware |
| Q:2 | Fair quality | Good PPG pulses in the measurement period are > 20% AND Standard deviation in the measurement period is 10 to 20% | Transmitted |
| Q:3 | Good quality | Good PPG pulses in the measurement period are > 20% AND Standard deviation in the measurement period is 5 to 10% | Transmitted |
| Q:4 | Very good quality | Good PPG pulses in the measurement period are > 20% AND Standard deviation in the measurement period is < 5% | Transmitted |

If a physiological parameter is not updated because the Q-Index is too low (ie Q:0 or Q:1),

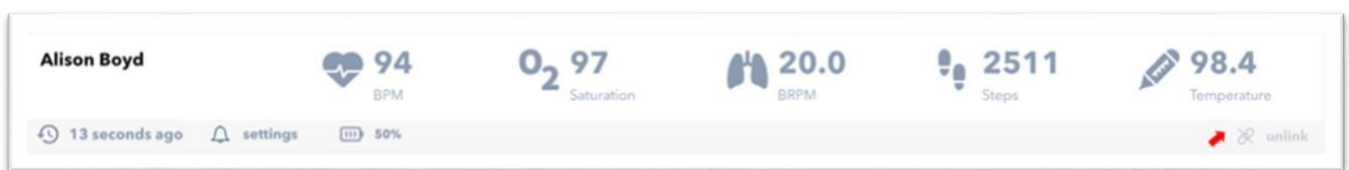
a Technical Alarm indicating “Communication lost, no data was updated for device” is raised in the Web Portal (refer to §6 below).

If the Q-Index of a physiological parameter is low (ie 0 or 1) for more than 10 consecutive minutes, the Corsano Patient APP will guide the user through the “Wearing Optimization” feature to adjust and verify the wearing tightness and position of the Bracelet.

Note : No Q-Index indication is provided in HCP App.

4.8. Un-assign Patient

This function is used to un-assign a patient from the overview, for example, when a patient is discharged. Click on the Unlink icon and select confirm on the pop-up message.



Remove patient from Patients Overview



NOTE: Once a patient is removed, their medical history and measurements will no longer be available on the dashboard. All data will still be saved in the Corsano Cloud.

4.9. Patient Portfolio

A click on a patient on the dashboard opens the detail page for that patient. The Patient Portfolio presents the patient’s medical and personal information and allows access to the patient graphs per vital parameter.



Patient Portfolio

Compliance – displays percentage of day for which data was received for the Patient.

Edit Profile – The Personal Information is where patient demographics are listed. To edit a patient’s personal information, click the Edit Profile button on the top right of the section in the Patient Portfolio and edit Patient Name, Gender, Year of Birth, Weight, Height.

Edit profile | Peter Stas

Profile | Alarms | Reset password

First name: Peter | Last name: Stas

Weight (kg): 78 | Height (cm): 187 | Gender: Male | Wrist: Left

Birth year: 1963

SAVE

Edit Patient Profile

5. ALARMS IN WEB PORTAL

5.1. Alarm overview

Alarms are essential for knowing when to intervene. If the HCP notices something is going wrong, then they can do something about it. Corsano implemented Alarms with the following specifications:

Color Coded Alarms

Alarms are colored RED/YELLOW/CYAN to indicate priority.

Audible Alarms

Alarms are audible on the Web Portal and the Corsano App (HCP Mode)

Default Alarms

These are configured by default in the Portal

Individual Alarms

Alarm limits can be easily updated at the individual or patient level

Alarms Emails & Notifications

Healthcare Practitioners can opt to receive alert emails and push notifications for alarms for their patients on their mobile device



Similar equipment may be in the same area as the Corsano System that may use different Alarm Presets.



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



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.



Ensure that the computer where the Web Portal is running has audio switched on and is at an appropriate volume.



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.

5.2. Position of the Operator

The Web Portal is intended to be displayed on a computer screen in a room or office of a healthcare center. The HCP in charge of monitoring the Patient must sit in the vicinity of the display. The display is intended to be visible and clearly visible at a distance of 1 meter.

5.3. Alarm Defaults

There are many published physiological alarm systems, which can be separated into single-parameter “track and trigger” systems, and multiple-parameter systems. These systems use a scoring table, which assigns a pre-defined risk score to each vital sign measurement.

- *Churpek MM, Yuen TC, Edelson DP. Risk stratification of hospitalized patients on the wards. Chest. 2013;143(6):1758-1765.*

Corsano System implemented alarms based on single parameter track and trigger **Between the flags (BTF)**. A single parameter will be the trigger (PR, or SpO2, or Temperature, or RR).

- *Green M, Lander H, Snyder A, Hudson P, Churpek M, Edelson D. Comparison of the Between the Flags calling criteria to the MEWS, NEWS and the electronic Cardiac Arrest Risk Triage (eCART) score for the identification of deteriorating ward patients. Resuscitation. 2018; 123:86-91.*

Defaults Alarm Limits used in the Corsano System are derived from the NEWS score, which is one of the most-validated scores.

- *Bein B, Seewald S, Gräsner JT. How to avoid catastrophic events on the ward. Best practice & research. Clinical Anaesthesiology. 2016; 30(2), 237-245.*

| | | | | | | | |
|---------------------|-----|-------|-----------|-----------|-----------|---------|------|
| Pulse Rate (BPM) | ≤40 | | 41-50 | 51-90 | 91-110 | 111-130 | ≥131 |
| Saturation (SpO2 %) | ≤91 | 92-93 | 94-95 | ≥96 | | | |
| Temperature (°C) | ≤35 | | 35.1-36.0 | 36.1-38.0 | 38.1-39.0 | ≥39.1 | |

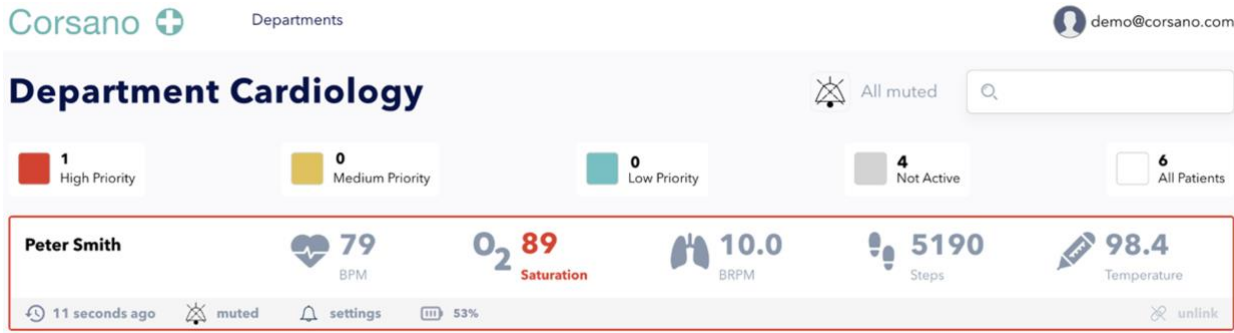
With temperature in Fahrenheit

| | | | | | | | |
|------------------|-----|--|-----------|------------|-------------|--------|--|
| Temperature (°F) | ≤95 | | 95.1-96.8 | 96.9-100.4 | 100.5-102.2 | ≥102.3 | |
|------------------|-----|--|-----------|------------|-------------|--------|--|

Default Alarm Limits

High priority alarms are colored RED
 Medium priority alarms are colored YELLOW
 Low priority alarms are colored CYAN

The alarm indication is available for the Healthcare Practitioner on the main Dashboard of the Web Portal. Vital Parameters outside limits are displayed with priority color RED/YELLOW/CYAN. The rectangular box around the vital parameters for the patients is colored with the color of the highest priority active alarm. High-priority alarms are moved to top of the Patient Overview.



Alarms are color coded and audible

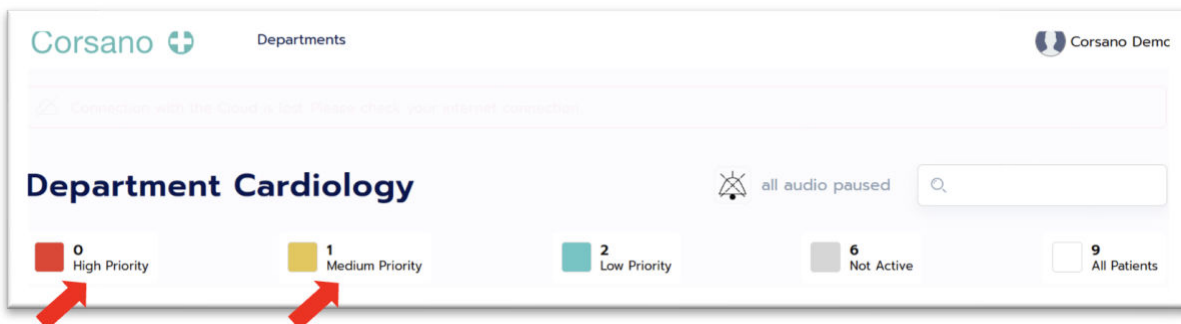


The alarms are information to help the Healthcare Practitioners to see if the metrics are in a pre-defined range. The system is not intended to be used in high-acuity environments where the condition of the patient may require immediate action.

5.4. How to Verify the Alarm functions

The Alarm function must be regularly checked by the Healthcare Practitioner responsible for patient monitoring.

A temporary Alarm can be generated by clicking on the Priority Alarm squares shown in the figure below. This will generate an alarm sound for 5s confirming that the Alarm functions correctly. The Operator can also adjust the sound level to the environment.



5.5. Audible Alarms

Alarms are audible with following characteristics.

| | HIGH PRIORITY | MEDIUM PRIORITY |
|---------------------|-----------------------------------|-----------------------------------|
| Pulse Rate (BPM) | Cardiovascular HP | Cardiovascular MP |
| Saturation (SpO2 %) | Saturation HP | Saturation MP |
| Temperature (°C/°F) | Temperature HP | Temperature MP |

Alarm Sounds



Alarms can be disabled and enabled by clicking on the Alarm Icon for each patient or on Mute All on the top of the main Dashboard of the Corsano Web Portal.

5.6. Alarm Limits

Via Settings on the main Dashboard of the Corsano Web Portal, the Healthcare Practitioner can review and adjust the Alarm Limits for each patient.



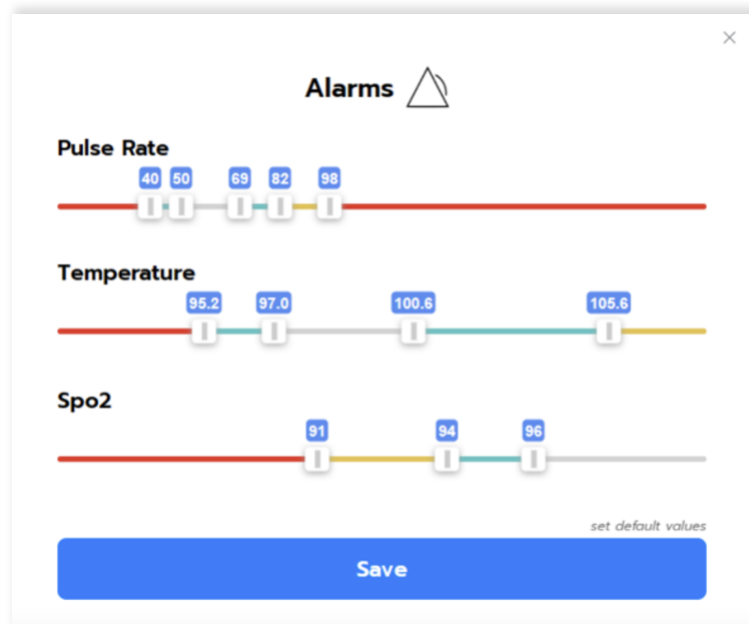
Alarms Limits for each patient

Alarm Limits can be adjusted for the following metrics upto the maximum validated clinically claimed ranges :

- Pulse Rate (BPM)
- Saturation (SpO2)
- Respiratory rate (BRPM)
- Temperature (°C/°F)

When a Physiological alarm condition is met, the Corsano Web Portal generates an alarm.

HCP can adapt from the system Physiological Default Settings and save alarm limits specific for each Patient:



Example of Alarm Limits Settings



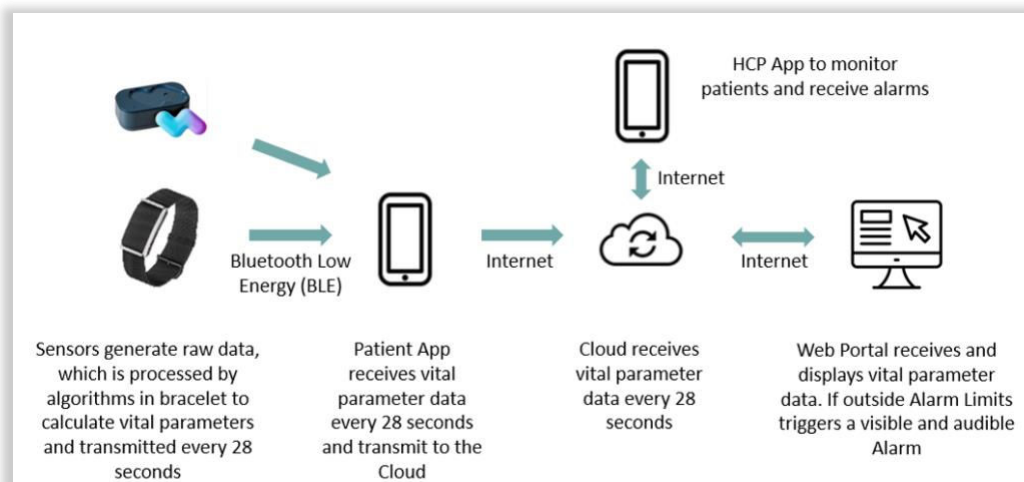
The alarm limits should only be changed by a medical professional after considering the outcomes. Setting the limits to inappropriate levels may hide alarm conditions.

5.7. Alarm Delays

The Corsano Bracelet calculates vital parameters in the firmware. The measurements from the Corsano Bracelet and Axillary Thermometer are transmitted once per 28 seconds to the Patient App. The Corsano (Patient mode) App transmits data to the Corsano Cloud upon receipt. This leads to a short delay before displaying a visible and audible alarm on the Physician Web Portal and in the Corsano (HCP Mode) App.

The maximum Alarm delay is 32 seconds.

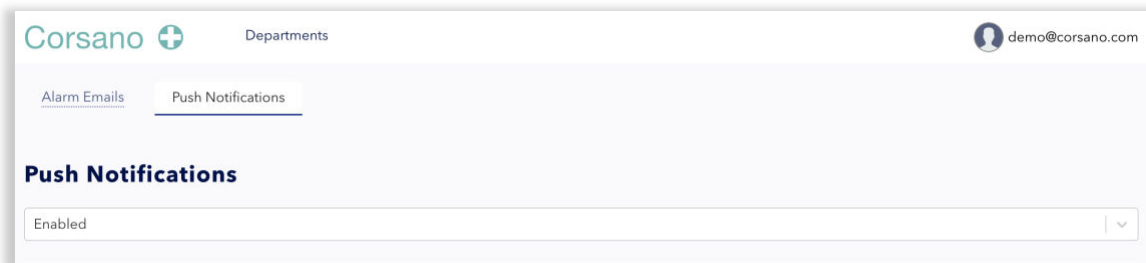
The following figure shows the Corsano System alarm data flow :



Corsano Alarm Delays


5.8. Alarm Notifications


Healthcare Practitioners can enable/disable under Settings to receive a push notification detailing an alarm for their patients on their mobile phone. Click on the account icon top right corner, select Settings and enable/disable Push Notifications should be received.




Enable/Disable Push Notifications

Alarms generated on the Web Portal are transmitted to the Corsano App on the HCP’s mobile phone, so that HCP will receive visible and audible Alarm while not being physically in front of the Web Portal.

 Push Notifications will be shown in the Corsano App installed on the mobile phone of the Healthcare Practitioner.

 Push Notifications will be shown on the Home Screen of the mobile phone even when the Corsano App is not running or running in the background.

 All Alarm Alerts are shown on the top of the Dashboard of the HCP App.

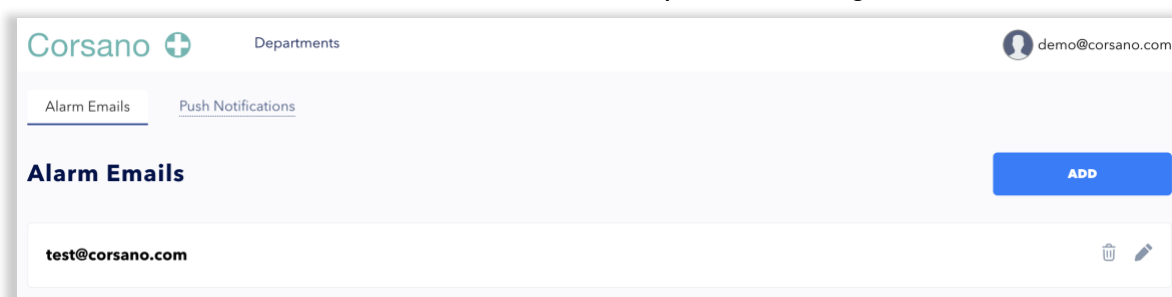
5.9. Alarm Emails

Healthcare Practitioners can enter their email under Settings to receive an email detailing an alarm for one of their patients to their mobile phone. With this optional function Healthcare Practitioners can keep track of the history of prior Alarms.

Click on the account icon top right corner, select Settings and add email address where the Alarm Email should be sent.



Alarm Emails should not be used for patient management.



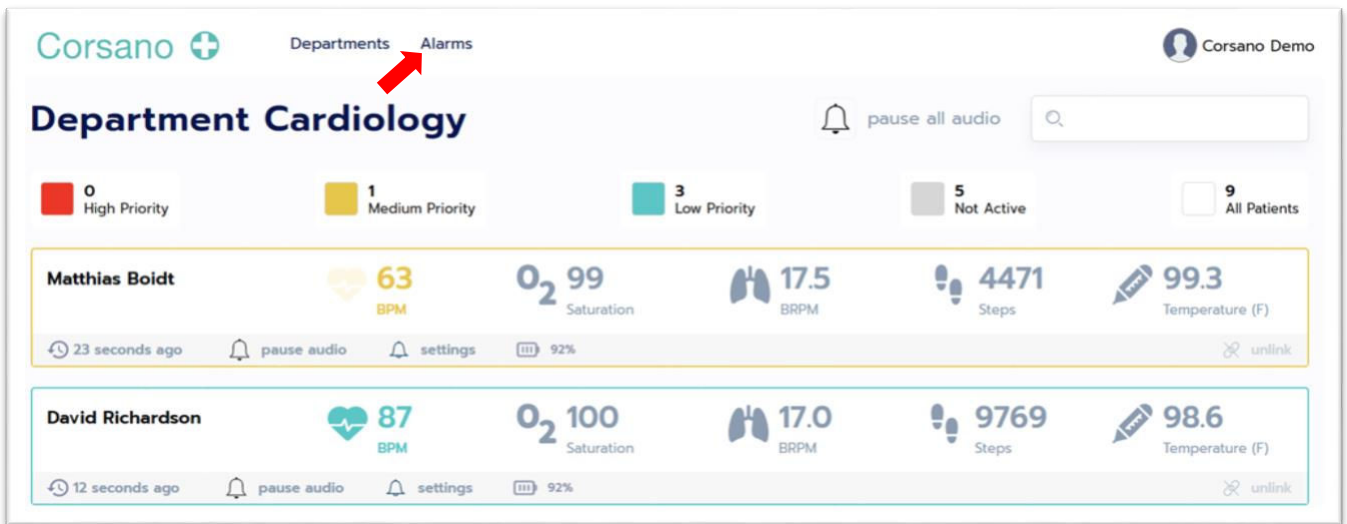
Enter email of HCP to receive Alarm Emails



Alarm Emails will go to the Inbox of the Healthcare Practitioner.

5.10. Alarm History

Alarm events are logged in an Alarm History accessible by clicking “Alarms” at the top of the Dashboard.



The screenshot shows the Corsano dashboard for the Department of Cardiology. At the top, there are navigation tabs for 'Departments' and 'Alarms', with a red arrow pointing to 'Alarms'. Below the navigation, there are summary statistics for patient counts by priority: 0 High Priority, 1 Medium Priority, 3 Low Priority, 5 Not Active, and 9 All Patients. Two patient monitoring cards are visible: Matthias Boidt and David Richardson. Each card displays vital signs such as Heart Rate (BPM), Saturation (O2), BRPM, Steps, and Temperature (F). A '23 seconds ago' timestamp is shown for Matthias Boidt's data.

Alarm conditions and inactivations are logged:

- Event type (Alarm condition or Alarm inactivation)
- Date (YYYY-MM-DD)
- Time of the occurrence (Local time of the Web Portal)
- Patient name
- Vital parameter
- Value
- Alarm Priority
- Alarm Limit
- Status: Audio ON, Audio Paused / Pause Audio, Pause All Audio



| Event Type | Date | Time | Patient | Vital | Value | Limit | Priority | Status |
|--------------------|------------|----------|-------------|-------|-------|-------|----------|-----------------|
| Alarm condition | 2023-05-03 | 11:03:10 | Peter Smith | BPM | 146 | 120 | Medium | Audio on |
| Alarm inactivation | 2023-05-03 | 11:03:50 | Peter Smith | N/A | N/A | N/A | N/A | Paused Audio |
| Alarm condition | 2023-05-03 | 11:04:15 | Peter Smith | BPM | 147 | 120 | Medium | Audio Paused |
| Alarm condition | 2023-05-03 | 11:13:00 | Peter Smith | BPM | 151 | 150 | High | Audio On |
| Alarm inactivation | 2023-05-03 | 12:22:00 | All | N/A | N/A | N/A | N/A | Pause All Audio |
| Alarm condition | 2023-05-03 | 11:13:00 | Peter Smith | BPM | 151 | 150 | High | Audio Paused |

Alarms are logged on the cloud. The Alarms System remains operational even when the Web Portal is shut down.

When log entries are monitored by the Web Portal, they are stored on the Corsano Cloud and saved for 7 days. After 7 days the log entries are deleted.

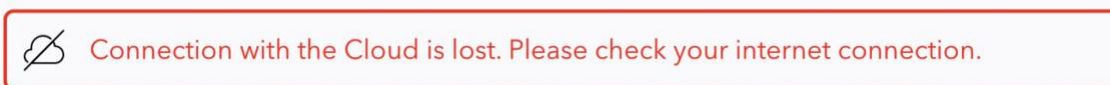
6. TECHNICAL ALARMS

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 |

Technical Alarms

Example Technical Alarm:



7. PATIENT APP SETTINGS

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



Information provided in the Corsano App (Patient Mode) 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 Levels (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)



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

From the Configuration Panel in the Web Portal, the HCP decides what information is to be displayed in the Patient App.



Click Settings

By default, no medical information is displayed,

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)

EZTJD ×

HCP Code:
HCP-EZTJD-ky3xrt

The HCP Code can be updated under Settings/Profile in the Corsano App

Patient Code:
EZTJD

Please ask the patient to enter the Patient Code under Settings/Profile in the Corsano App

Patient App Information

Set which information should be shown in the App of the Patient.

Tab Settings
Select maximum 4

| | | | |
|--------------------------------------|-------------------------------------|--------------------------------------|-----------------------------------|
| <input type="checkbox"/> Pulse rate | <input type="checkbox"/> Saturation | <input type="checkbox"/> Temperature | <input type="checkbox"/> Activity |
| <input type="checkbox"/> Respiration | <input type="checkbox"/> NIBP | <input type="checkbox"/> Spirometer | <input type="checkbox"/> Weight |

SAVE

Configuration Panel



Information viewable by the Patients and notifications should be set by a medical professional after considering the outcomes.

8. HCP & Patient Training

In addition to the familiarization of the Corsano System using the accompanying documentation, you may find additional assistance available in the Corsano Knowledge Base available on the Corsano Website.

If additional support is required, please contact Corsano Health via support@corsano.com.

8.1. HCP Training

No specific further training is required to use the Corsano System and to assist the patients in their familiarization and their use.

In all cases, the HCP must, as part of their medical training have a working knowledge of vital signs monitoring and be familiar with modern technology devices (eg smart phones, use of websites, PC's etc).

In order to assist the patient, it is recommended that the HCP is familiar with the use of the Corsano Bracelet & App ; this familiarization could for example be that the HCP sets up & wears the bracelet for a given period of time (eg 48hrs).

For the HCP (Physician): is considered to be the person responsible for prescribing the system to a patient, ensuring the patient is familiar with the Bracelet & Patient App, monitoring patient data, assuring general patient interaction, adjust alarm limits, device hygiene, etc.

For the HCP (Registered Nurse): is considered to be the person professional responsible for ensuring the patient is familiar with the Bracelet & Patient App, monitoring patient data, assuring general patient interaction, adjust alarm limits, device hygiene, etc.

8.2. Evaluating Patients medical condition

The Corsano 287-2 System is not intended for acutely ill patients and should not be used to monitor patients for conditions such as : sleep apnea, arrhythmia detection, etc. Refer to the intended use (§2.5 above) as well as the Warnings & Cautions (§2.1 & §2.2 above).

8.3. Evaluating Patients familiaristion with modern technology

Evaluation Patients capacity to use the Corsano Bracelet & App

The following information is to assist the HCP in determining if the patient has or does not have the capacity to use the Corsano Bracelet & App.

As required, the following checklist may be used :

- Confirm that the patient has a smart phone (unless one is provided by the hospital)
- Ensure the patient is familiar with smart phone & is familiar in:
 - downloading software applications
 - pairing devices via bluetooth
 - following on-screen instructions
- Ensure the patient is comfortable with :
 - using the third-party devices prescribed
 - using apps.

If YES to all, then the patient should be able to manage themselves the installation & use of the Corsano Bracelet & App (as per the patient specific Information for Use).

If NO to any one of the above, then it is recommended that the Patient is assisted by the HCP to install & familiarized on how to use the bracelet & Patient App ; and 3rd Party external devices.

8.4. Patient Training & Assistance

The HCP must be familiar with the use of the Corsano Bracelet & App (as per the patient specific Information for Use) in order the appropriately familiarize the patient, this may include (as appropriate) :

- Pairing the devices
- Wearing & using the Corsano Bracelet
- Familiarization of the Corsano App
- Using the third-party external devices
- Charging Corsano Bracelet
- Cleaning & disinfecting the Corsano Bracelet

Should the Patient be uncomfortable with the use of this technology, despite the HCP assistance, it is recommended that the Physician evaluate individually the patients benefit of using the system with respect to risks such as failure to use the device, failure to charge the device, etc.

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 Web Poertal and 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. The computer running the Web Portal must have up-to-date anti-malware software installed
2. The computer running the Web Portal must have password protection
3. Any mobile device with the Corsano App installed must also have a device passcode set
4. You should never disclose your Corsano username or password. No Corsano Health staff will ever ask you for these details
5. You should never write your Corsano username or password down
6. You should never provide an unauthorized user access to the Corsano App
7. You should never leave the Corsano App and Web Portal logged in and unattended. Please log out when you have finished using the system
8. 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) malfunction or damage of third party external devices ; e) malfunction or erroneous data provided in through any third party applications.

11. SPECIFICATIONS

11.1. Corsano Web Portal App

Minimum requirements for Operating Systems:

- Apple MacOS 12 or higher
- Windows 10 or higher



Browser / Operating System versions must be maintained upto date.

Minimum requirements for PC

- PC or Laptop with Loud-Speaker 4W or more

11.2. Alarms Sound Levels

The Corsano Web Portal sound levels have been tested in accordance with the IEC 60601-1-8 standard to :

| | | |
|---------------------------------|-------------------------|----------------|
| Alarm sound pressure level (dB) | High Priority Alarms: | 38 dB to 83 dB |
| | Medium Priority Alarms: | 38 dB to 81 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

No patient data is maintained on this computer, there is no deinstallation required once the software application is no longer required.

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

13. CORSANO CONTACT INFORMATION



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

www.corsano.com
support@corsano.com

