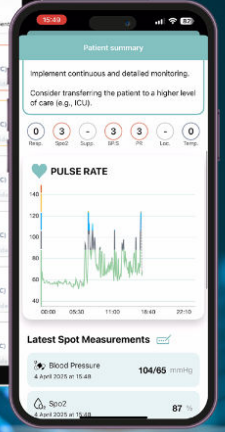
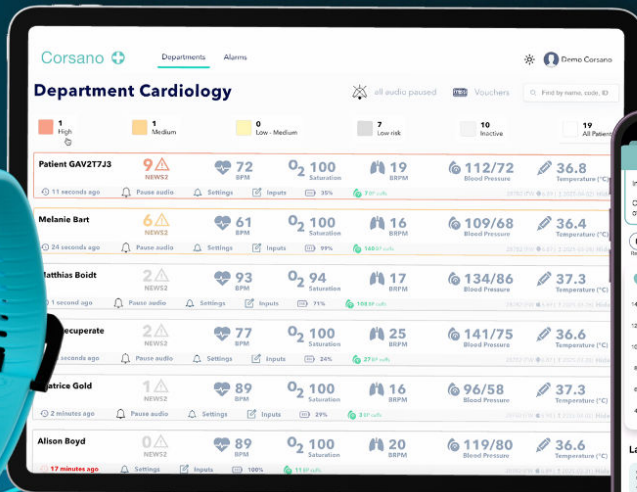


Corsano

Continuous Patient Monitoring
Anytime, Anywhere



CardioWatch 287-2

2nd GENERATION WEARABLE TECHNOLOGY WITH MULTI CHANNEL PPG, ECG AND HEATHFLUX



Best in class ergonomics, ultra light for max patient comfort, one size fits all



State of the art PPG sensor with two diodes and Green/Red/Ir LEDs
One lead ECG, GSR-EDA, Heatflux sensor
Multi sensor algorithms for precise monitoring



Vital Parameters



Continuous Pulse Rate monitoring (PPG & ECG based)

Monitor patient's heart rhythm, assess tachycardia, bradycardia and other rhythm conditions



RR intervals (PPG & ECG based)

Monitor RR intervals and assess HRV (Heart Rate Variability), a crucial parameter for physical stress



BRPM (Breaths/Min)

Monitor Breathing rate (Respiratory rate or frequency) to assess pulmonary and cardiopulmonary status



Third Party Proprietary A-Fib algorithm

Screen and monitor Atrial Fibrillation in chronic Cardiac patients and development of antiarrhythmics / anticoagulants



Activity (data set)

Monitor: Steps / Type of exercise / Cadence / Speed / Energy expenditure/ Caloric data



Sleep

Monitor sleep and classify types of sleep.



Core Body Temperature

Based on Heatflux sensor in combination with PPG



Oxygen Saturation

Monitor percentage of blood that is saturated, known as the SpO2 level



Cuffless Non-Invasive Blood Pressure (NIBP)

Monitor continuous Systolic and Diastolic Blood Pressure



Electrodermal activity (EDA/GSR)

Measure skin conductivity to indicate emotional arousal and stress

Corsano CardioWatch 287-2 should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment. CE-MDR certified and FDA approved (FDA in PR, HRV, SpO2, RR, Skin Temp, NIBP, Activity).



Specifications

Dimensions Bracelet

Size (L x W x H)	42 mm x 25 mm x 10 mm
Weight	19 g
Battery	Rechargeable Lithium-ion Polymer 3.6V 140mAh
Durability	Survives free fall, impact deformation and vibration as per IEC 60601-1:20
Water ingress protection	IP 66 (IEC 60529:2013/COR:2019), Shower proof
Not manufactured with natural rubber latex	

Use Conditions

MRI Safe	No
Single use	No, multiple use
Battery autonomy	11 days (in Intermittent measurement mode)
Required patient actions	Pairing the bracelet to a smartphone. Recharge when battery is empty.
Disposable	Yes, as small electronic waste (WEEE)
Serviceable	No

Performance Vital Parameters

Respiration rate measurement range	4 – 60 breaths per minute (brpm)
Respiration rate accuracy	1 brpm Arms
Respiration rate resolution	1 brpm
Respiration rate calculation	28s average
Pulse rate measurement range	25 – 250 beats per minute (bpm)
Pulse rate accuracy	1 bpm Arms (no motion) 3 bpm Arms (under motion)
Pulse rate resolution	1 bpm
Pulse rate calculation	28s average
SpO2 measurement range	70% – 100%
SpO2 accuracy	1.5% Arms (at rest) 4% Arms (under motion)
SpO2 resolution	1 %
SpO2 calculation	28s average
NIBP measurement range	60 - 200 mm/Hg
NIBP accuracy	5 mm/Hg (SD: 8 mm/Hg)
NIBP resolution	1 mm/Hg
NIBP calculation	Every 30 min
Core Body Temperature measurement range	34 - 42 Degree Celsius



Core Body Temperature accuracy	±0.3 Degree Celsius
Core Body Temperature resolution	0.1 Degree Celsius
Core Body Temperature	Every 28s
calculation Activity	Number of steps per day
Sleep	Bedtime, rise time, sleep cycles (Deep, REM, Light, Awake)
Data transmission interval	Flexible settings starting from once per 30 seconds

Compliance

Certification	CE-marked – EU MDR 2017/745 / FDA 501K
Class	Class IIa medical device,
In compliance with	ISO 13485 IEC 60601-1-11:2015; EN 60601-1:2006 + A2:2021 (Basic safety and essential performance) EN 60601-1-2:2015 + A1:2021 (Electromagnetic compatibility) DA 60601-1-6:2010 + A2:2021, EN IEC 62366-1:2015 + A1:2020 (Usability) EN 60601-1-11:2015 + A1:2021 (Use in home environment) EN IEC 62304:2006 + AC:2008 + A1:2015 (Software Lifecycle) EN ISO 14971: 2019 + A11: 2021 (Risk Management) EN ISO 10993-1:2020 (Biocompatibility) EN 60601-2-47:2015 (Ambulatory ECG) EN ISO 80601-2-56:2017 + A1:2020 (Electrical clinical thermometer) EN ISO 80601-2-61:2019 (Pulse oximeter equipment) EN ISO 81060-2:2019 + A1:2020 (Non-Invasive Blood Pressure) ISO 27001
Applied part	BF
Patient information	See IFUs

Wireless & Security

Radio	Bluetooth Low Energy
Frequency band	2.4 GHz
RF radiated power output	0 dBm
Coverage	10m (Line of sight)
Security	AES-CCM 128-bit, end- to-end data encryption.

Operating Environment

Operating ambient temperature range	+10°C – +40°C
Operating humidity range	20 – 80% relative humidity (non-condensing)
Operating atmospheric pressure range	700 – 1060 hPa
Transport and storage temperature range	-20°C – +60°C
Transport and storage relative humidity	20 – 90% relative humidity (non-condensing)
Transport and storage range	700 – 1060 hPa
Shelf life	24 months



Mobile Application

Corsano mobile application, accessible with smartphone on Apple Store and Google Play

Minimal system requirements iOS 14.5, or higher
 Android 8.0, or higher

Gateway

Connection Bluetooth Low Energy to Ethernet

Installation requirements Standard power socket. Fixation on walls possible

Connected to hospital LAN Ethernet
 Connection to WIFI possible

Range Actual range will vary depending on the layout of the building the gateway is used in.

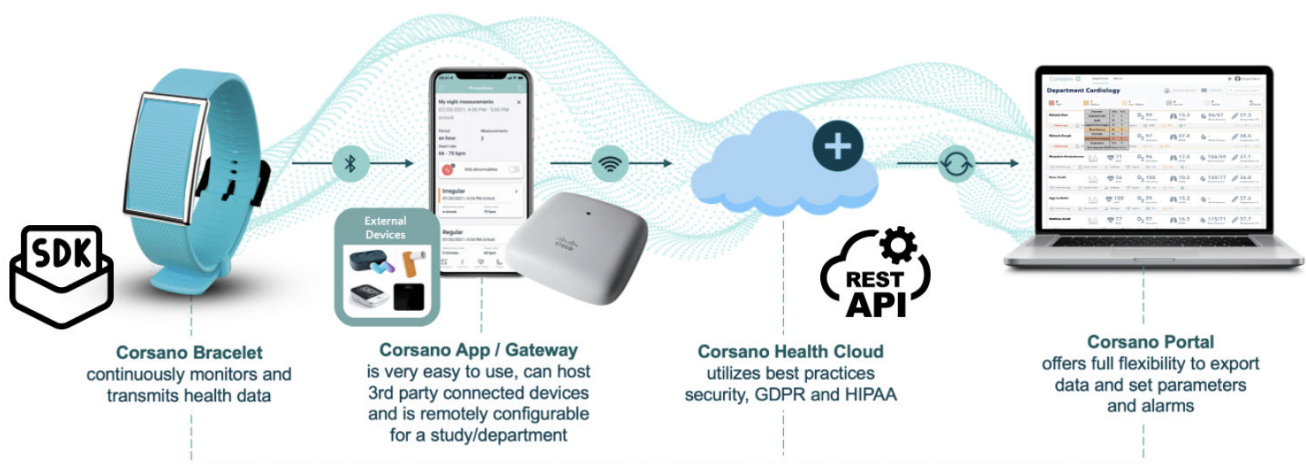
Web Interface

Corsano Research Portal & Corsano Patient Portal, web applications accessible with PC and notebooks.

Minimal system requirements Web browser with current version (Safari, Chrome, Microsoft Internet Explorer, Microsoft Edge, Firefox)

System & Access Data

Corsano offers the possibility to connect to the Corsano System via SDK and API: <https://developer.corsano.com>



Cloud or On-Prem

Infrastructure AWS, MongoDB / Local On-Prem DB

Cloud Location Within the EU (Frankfurt, Germany)

Security Encryption in transit and at rest (TLS1.2+, AES-256)
 ISO 27001, SOC 1, SOC 2, SOC 287-2

Product number (GTIN)

08720256776529 Corsano CardioWatch 287-2

