

Corsano

Continuous Cardiac Monitoring
Anytime, Anywhere

CardioWatch 287-2

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



Similar ergonomics
as CardioWatch 287-1

One size fits all
types of patients



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

In the United States, CardioWatch 287 Bracelets are for Investigational Use Only. The performance characteristics of the CardioWatch 287-2 System have not been established and CardioWatch 287 Bracelets have not been FDA cleared or approved. FDA 510(k) clearance pending.



Vital Parameters



Continuous heart 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.

*Proprietary algorithm for OSAHS (Obstructive Sleep Apnea Hypopnea Syndrome) in development



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



Specifications

Dimensions Bracelet

Size (L X W X H)	42 mm x 25 mm x 10 mm
Weight	19 g
Battery	Rechargeable Lithium-ion Polymère 3.6V 140mAh
Durability	Survives free fall, impact deformation and vibration as per IEC 60601-1:2014
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 calculation	Every 28s
Activity	Number of steps per day
Sleep	Bedtime, rise time, sleep cycles (Deep, REM, Light, Awake)
Data transmission interval	Typically, every 1 minute

Compliance

Certification	CE-marked – EU MDR 2017/745
Class	Class IIa medical device,
In compliance with	IEC 60601-1-11:2015; Regulation EU MDR 2017/745 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)
Applied part	BF
Patient information	See IFUs
Release countries	The Netherlands, Belgium, Germany, France, Italy, Spain, Denmark

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 range	20 – 90% relative humidity (non-condensing)
Transport and storage atmospheric pressure 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
	Access to camera and geolocation required for bracelet pairing

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.

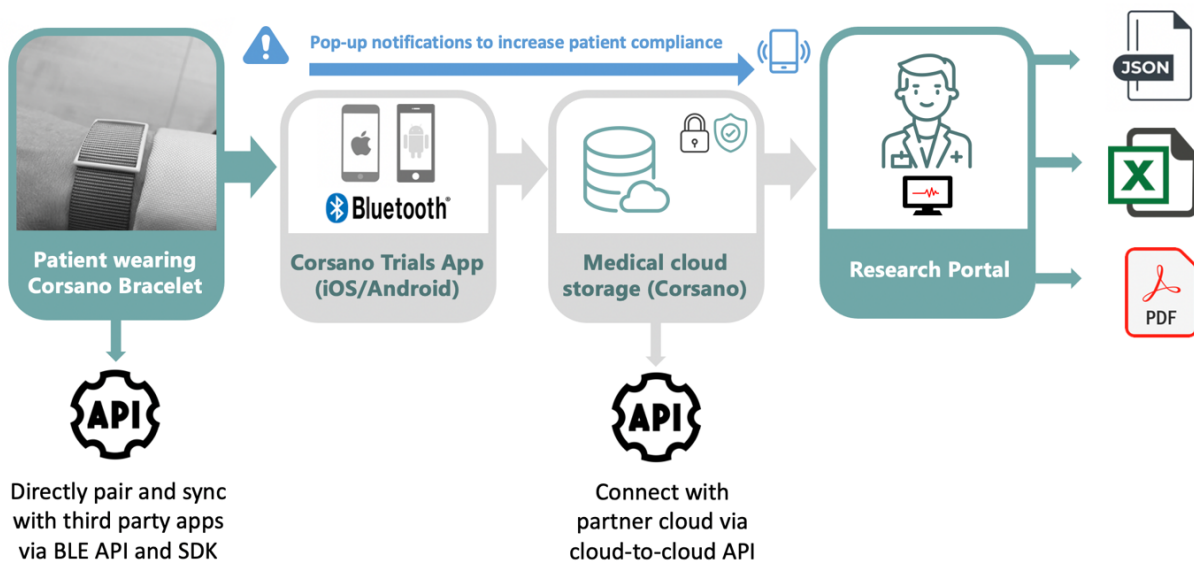
Web Interface

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)
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System & Access Data

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



Cloud

Infrastructure	AWS, MongoDB
Location	Within the EU (Frankfurt, Germany)
Security	Encryption in transit and at rest (TLS1.2+, AES-256) ISO 27001, SOC 1, SOC 2, SOC 3

Product number (GTIN)

08720256776529	Corsano CardioWatch 287-2
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