

Corsano CardioWatch 287-2

Spec Sheet





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	Author: P. Fraboulet	Date: 30-Aug-23

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1 Description

1.1 Basic UDI-DI

Product generation	Model reference	GMN - Basic UDI-DI	UDI-DI (GTIN)
First	CW287-2	8720256776CW287-2CA	8720256776529

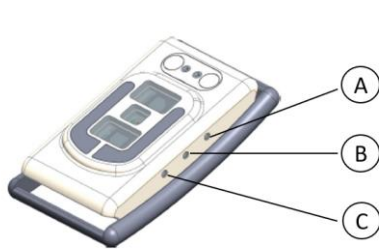
1.2 Dimensions

The outer dimensions of the CardioWatch 287-2 device are:

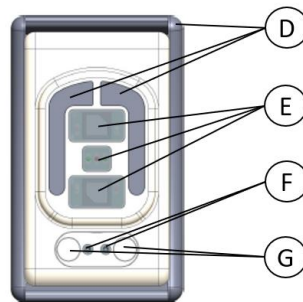
- Length 41.5mm
- Width 24.4mm
- Height 1.0mm



1.3 Device




- (A) Green LED
- (B) Orange LED
- (C) Blue LED



- (D) Electrodes for ECG
- (E) PPG Sensor
- (F) Charge contacts
- (G) Magnets for charge cable holding

1.4 Side LEDs

LED	Pattern	State
Green (A)	Flashing	Bracelet charging
Green (A)	ON	Bracelet fully charged (when on charger)
Green (A)	OFF	Bracelet not on charger
Orange (B)	Flashing for 5 sec	Bracelet is initiating a Bluetooth Low Energy connection
Orange (B)	ON for 5 seconds	Bracelet connected to a

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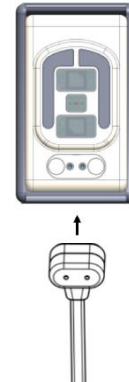
		Smartphone
Blue (C)	ON	Bracelet is performing an ECG measurement

1.5 Charger Adapter

The CardioWatch 287-2 is recharged by its USB magnetic cable.

Use the charger cable with a CE marked adapter with the following characteristics:

- Input voltage: 100/240 V - 50hz 60hz
- Output voltage: DC 5V (+-5%)
- Maximum current: 500 mA



2 Technical specification

2.1 Software requirements

Minimum requirements for mobile device Operating Systems:

- iOS 12.2 or higher
- Android 8.0 or higher

2.2 Hardware specification

PPG Sensor Characteristics

PPG	Red, IR, Green
PPG LED/Photodiode number	7/2
PPG LEDs Peak wavelength	500-900 nm
PPG LEDs max current	128 mA
PPG sampling resolution.....	20 bits
Radiant Intensity 525nm.....	47mW/sr
Radiant Intensity 660nm.....	44mW/sr
Radiant Intensity 880nm.....	35mW/sr

Motion Sensor Characteristics

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

Data Acquisition

PPG sampling rate.....	32 Hz
Motion sampling rate.....	32 Hz
Flash Memory Size	256 Mbit
Recording	Continuous

ECG



Sampling rate..... 256 Hz
 Bandwidth0.05 - 55 Hz

Power Requirements

Average current1.2 mA
 Max current consumption100 mA
 Battery typeRechargeable
 TechnologyLithium Polymer
 Battery capacity140 mAh
 Autonomyup to 1 week

Dimensions

Length x Width x Height24.4 x 40.4 x 9.8 mm

Environmental Specifications


Ingress Protection*IP66
 Operational Temperature+10 to +40 degrees C
 Ambient Temperature when charging+10 to +35 degrees C
 Transport and storage Temperature.....-20 to +60 degrees C
 Operational Humidity20% to 80%
 Transport and storage Humidity.....20% to 90%

Interface

Wireless CommunicationBLE 5.0
 Display LEDs.....green, orange, blue


3 Performance

	Definition	Unit	Range	Acquisition Time	Update interval	Accuracy
Pulse Rate	Number of beats of the heart per minute	beats/minute (bpm)	30-240	5-10 sec	1 sec	±3 bpm Arms
RR Interval	Elapsed time between two consecutive heart beats	msec	300-2000 ms	5-10 sec	1 sec	±50 ms MAD, ±5% MARD (at rest)
Heart Rate Variability	Beat to beat (RR interval) variations	msec	0-200 ms	5-10 sec	1 sec	HRV ±10 ms MAD, ±5% MARD (at rest)
Respiration Rate	Number of breaths (inhalation - exhalation cycles) per minute	breaths/minute (brpm)	5-45 brpm	20-30 sec	1 sec	±1 brpm Arms


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	Definition	Unit	Range	Acquisition Time	Update interval	Accuracy
Sleep Stages	Detection of specific sleep stages & sleep HR	awake, light sleep, deep sleep, REM	sleep stage	upon end of the entire sleep event	1 min	Sleep Stage $\pm 10\%$ MAD
Sleep Score	Sleep performance and sleep consistency with equal weight	%	0-100%	upon end of the entire sleep event	1 sec	Sleep Score $\pm 5\%$ MAD
SpO2	Functional oxygen saturation	% Saturation	70-100%	1 min	1 sec	$\pm 4\%$ Arms (excl. high motion and low perfusion)
Body Temperature	Temperature of the body at the measurement site	Degree Celsius	34-42°C	30 min	1 sec	+/- 0.3°C
NIBP	Non-invasive blood pressure measurement	mm/Hg	60-200 mm/Hg	30s	1s	Diastolic BP Error: 5mm/Hg (SD 8mm/Hg) Systolic BP Error: 5mm/Hg (SD 8mm/Hg)

4 Electromagnetic Compatibility


	IEC 60417-5333	TYPE BF APPLIED PART
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Guidance and manufacturer's declaration - electromagnetic emissions		
<p>The Corsano Bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano Bracelet should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment - guidance


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RF emissions CISPR 11	Group 1	<p>The Corsano Bracelet uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p> <p>The Corsano Bracelet is suitable for use in home environment and Professional Health Care facilities environment.</p>
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration—electromagnetic immunity			
<p>Corsano Bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Corsano Bracelet is a battery powered device	Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1.2 kV Line-to-ground ±0.5 kV, ±1 kV Line-to-line	Corsano Bracelet is a battery powered device	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50-60 Hz	30 A/m 50-60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.

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Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	±0.5 kV, ±1 kV Line-to-line	Corsano Bracelet is a battery powered device	Not applicable
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Guidance and manufacturer's declaration—electromagnetic immunity			
Corsano bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	NA	Portable and mobile RF communications equipment should be used no closer to any part of Corsano bracelet, including cables and accessories, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance (m) $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			

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^a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Corsano bracelet is used exceeds the applicable RF compliance level above, Corsano bracelet should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Corsano Bracelet.

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


Recommended separation distances between portable and mobile RF communications equipment and Corsano Bracelet			
Corsano Bracelet is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Corsano bracelet can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Corsano bracelet as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz <i>d = 1.2 √P</i>	80 MHz to 800 MHz <i>d = 1.2 √P</i>	800 MHz to 2.5 GHz <i>d = 2.3 √P</i>
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

5 Product validation

Test Name	Description	Standard	Status
Electrical Safety	Testing to the standard IEC 60601-1 to ensure electrical safety of the device	IEC 60601-1	PASSED

EMC	testing to the standard EMC60601-1-2 to ensure EMC compatibility of the device	IEC 60601-1-2	PASSED
Charger Testing	Testing of the charging system	IEC 60601-1-11 IEC 60335-2-29	PASSED
Environmental Testing	Testing to confirm the storage and operating temperature ranges	ASTM D4169	PASSED
Pulse Rate Testing	Testing to confirm the accuracy of the pulse rate monitoring system	ISO 80601-2-61 FDA Guidance	PASSED
Battery Testing	Testing to determine battery life of the device as well as time to fully charge	Performance testing	PASSED
PDU buffering time	Tested to evaluate the difference between the theoretical maximum PDU buffering time and the observed maximum PDU buffering time.	Performance testing	PASSED
Usability Test	Testing with regarded to usability	IEC 62366 IEC 60601-1-6 FDA Guidance	PASSED
Device ship/transit testing	Testing to ensure the device functions after transportation	ASTM D4169 +functional test	PASSED
Biocompatibility Testing	Testing to ensure the device is biocompatible	ISO 10993-1 ISO 10993-5 ISO 10993-10	PASSED
SpO2 Testing	Ensure the accuracy of the Communication of the SpO2 function within the device	ISO80601-2-61 FDA Guidance	PASSED
Respiratory Rate Testing	Ensure the accuracy of the device to measure the respiratory rate via end-tidal CO2 in a variety of postures	IEC 80601-2-55	PASSED
Temperature Measurement Accuracy	Ensure the device can accurately measure temperature	ISO 80601-2-56	PASSED

<p>Wireless Radio Communication</p>	<p>Ensure the device can communicate via wireless radio in its intended environment</p> <p>- ETSI EN 300 328 V2.2.2, Data transmission equipment operating in the 2.4 GHz ISM band</p> <p>Tests for FCC</p> <p>RF measurements according to FCC Part 15.247/RSS-247: Proprietary Application in 2.4 GHz range - (test mode supported)</p> <p>RF partial radiated Test acc. FCC Part 15.247/RSS-247: Bluetooth (LE 1Msps -Transceiver or Transmitter) 2,4 GHz Basic radio tests</p> <p>Health Assessment of Radio Product</p> <p>EMC</p>	<p>ETSI EN 300 328 V2.2.2</p> <p>FCC Part 15.247</p> <p>FCC Part 15.407/RSS-247</p> <p>Health assessment of radio products (including Specific Absorption Rate SAR)</p> <p>EN 301 489-01 V2.2.3</p> <p>EN 301 489-17 V3.2.4</p>	<p>PASSED</p>
<p>System Verification Testing</p>	<p>System verification and validation testing to verify the software and firmware of the device. This includes interoperability of the any peripherals that will be used (i.e. blood pressure, scale)</p>	<p>Functional testing</p>	<p>PASSED</p>
<p>Water resistance</p>	<p>Ensure enclosure meets the IP66 requirements</p>	<p>IP66</p> <p>IEC 60529</p>	<p>PASSED</p>

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ECG	Ensure ECG meets the medical standards	ISO 60601-2-47:2012	PASSED
NIBP	Ensure system meets the requirements and performance for Non-invasive sphygmomanometers	ISO 81060-2:2018	Estimated date: Dec. 2022

6 Applicable standards and Regulations

Medical device is in conformity with:

- Regulation (EU) 2017/745 on Medical Devices (EU-MDR),
- Directive 2011/65/EU on the Restriction of Hazardous Substances (RoHS)
- Regulation (EU) 2016/679 on General Data Protection Regulation (GDPR)

Applicable Standards

- EN-IEC 60601-1:2006
- EN-IEC 60601-1-6:2010
- EN-IEC 60601-1-11:2015
- IEC 60601-2-47:2012
- IEC 80601-2-55:2018
- ISO 80601-2-56:2017
- ISO80601-2-61:2017
- EN-ISO 62366 :2015
- EN-ISO14971 :2021
- EN-ISO 62304 :2015
- ISO 10993-1:2018
- ISO 10993-5:2009
- ISO 10993-10:2010
- ISO 80601-2-56:2017
- ASTM D4169-22
- EN 60529:2019
- EN-IEC 62366-12015
- EN-ISO 14791 :2019
- EN-IEC 62304 :2006
- EN 301 489-01 V2.2.3
- EN 301 489-17 V3.2.4
- ISO 81060-2:2018
- IEC 60529:2019