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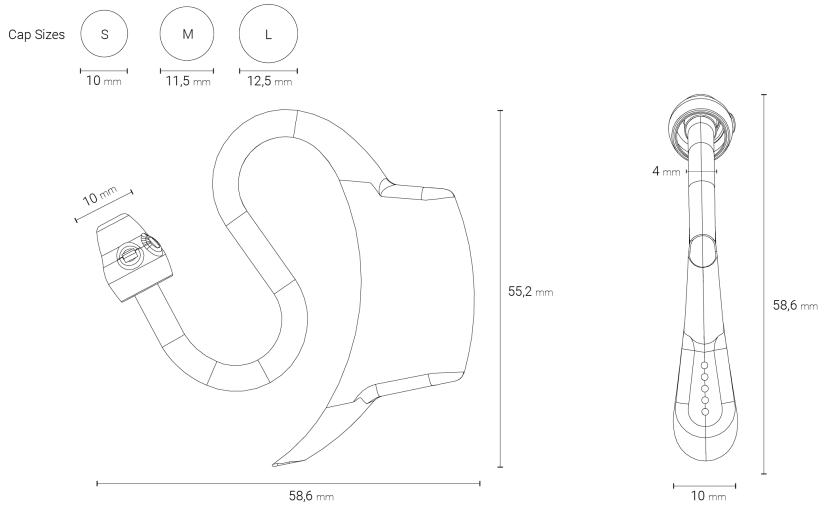
c-med° alpha

Medical wearable for continuous vital signs measurements



Features

- Continuous measurement of key vital signs:
  - pulse rate
  - body temperature
  - blood oxygen saturation (SpO2)
  - more raw data available
- Medically certified
- Approx. 12 hours of battery life when measuring continuously, longer battery life when measuring periodically.
- IP47 protected

- Ambient temperature for Continuous Operating Conditions:
  0 °C and 40 °C (32 °F – 104 °F)
- Ambient temperature for Transient Operating Conditions:
  0 °C – 50 °C (32 °F – 122 °F)

General

Product specification

Type number	MS01
Generation	1
Device type	Continuous vital sign monitor
Usage	Measuring key vital signs continuously in the outer ear canal
Measuring position	Outer ear canal
Measured values	Pulse Rate, oxygen saturation (SpO2), body temperature, RR-intervals
Certification	Medical CE (EU MDR) & FCC, Bluetooth
Status indicators	RGB-LEDs
Size, H x W x D	55.2 mm x 58.6 mm x 10.0 mm
Weight	Approx. 8 g +/-2g
Material	Silicone rubber, medical grade - ISO 10993-5 /-6 /-11 - USP class VI
Color	White
Battery life	Continuous: approx. 12 h Periodical (3 min every 15 min): approx. 48 h Standby: approx. 1 year
Ambient temperature for continuous usage	0 °C and 40 °C (32 °F – 104 °F)
Barometric pressure for continuous usage	620 – 1060 hPa (620 – 1060 mbar)
Ambient temperature for Transient Operating Conditions	0 °C – 50 °C (32 °F – 122 °F)
Water vapour partial pressure for Transient Operating Condition	Smaller than 50 hPa

Storage temperature and relative air humidity	Temperature | *Relative Humidity* • -25 °C – 5 °C (-13 °F – 41 °F) | / • 5 °C – 35 °C (41 °F – 95 °F) | *0% - 95%* (non-condensing) • 35 °C – 70 °C (95 °F – 158 °F) | *at a water vapor pressure up to 50 hPa*
Protection type	IP47
Power supply requirements	BF
Service life	2 years
Scope of delivery	c-med° alpha device, charging box, charging cable, power supply, manual

Radio transmission

Radio data transmission

Type	Bluetooth Low Energy (BLE)
Version	5.0 qualified
Frequency	ISM band 2.402 GHz – 2.480 GHz
Transmitting power	4 dBm
Services	Battery Service, Device Information Service, Health Thermometer Service, heart rate Service, Pulse Oximeter Service, Custom Service
Encryption	AES
Transmitting range	approx. 10 m

Power supply

Rechargeable battery

Type	Rechargeable lithium-ion battery
Capacity	60 mAh
Charging time	approx. 1 h

Sensor technology

Sensor types	Infrared and contact thermometer, optical measurement (LEDs and photodiode), accelerometer
Raw data	PPG green, PPG red, PPG infrared, PPG ambient, ACC x-axis, ACC y-axis, ACC z-axis
Quality indexes	pulse rate quality, perfusion index
Vital signs	pulse rate, body temperature, blood oxygen saturation (SpO2),
Further derived parameters	N/A

Photoplethysmography (PPG) sensor

Type	Red LED, Infrared LED, Green LED and photodiode
Method	Photoplethysmography (PPG)
Resolution	19 bit
Sampling rate	Variable, standard 200 Hz

Thermometer

Type	Infrared sensor
Measuring range	Depending on App: c-med° App Measuring range: 34 °C – 43 °C Health° App Measuring range: 22 °C – 43 °C
Resolution	0.1 °C
Technical accuracy	**± 0.3 °C** (± 0.5 °F) **20.0 – 35.0 °C** (68 – 95 °F) **± 0.2 °C** (± 0.4 °F) **35.0 – 42.0 °C** (95 – 107.6 °F) **± 0.3 °C** (± 0.5 °F) **42.0 – 43.0 °C** (107.6 – 109.4 °F) Outside of specified measuring range ± 0.5 °C
Sampling rate	Variable, standard 0.1 Hz

Accelerometer

Type	3-axis, linear
Measuring range	Up to ± 16 ***g*** (± 156.96 m/s^2)
Resolution	16 bit
Technical accuracy	± 0.002 m/s^2
Sampling rate	Variable, standard 100 Hz

Vital Signs

Body temperature

Type	Infrared thermometer
Measuring range	Depending on App: C-med° App Measuring range: 34 °C – 43 °C Health° App Measuring range: 22 °C – 43 °C
Resolution	0.1 °C
Technical accuracy	**± 0.3 °C** (± 0.5 °F) **22.0 – 35.0 °C** (68 – 95 °F) **± 0.2 °C** (± 0.4 °F) **35.0 – 42.0 °C** (95 – 107.6 °F) **± 0.3 °C** (± 0.5 °F) **42.0 – 43.0 °C** (107.6 – 109.4 °F)
Interval	Variable, standard 0.1 Hz

Pulse rate

Type	PPG
Measuring range	40 bpm – 220 bpm
Resolution	1 bpm
Accuracy	± 4 bpm
Interval	Variable, standard 1 Hz

Oxygen saturation (SpO2)

Type	PPG
Measuring range	70 % – 100 %
Resolution	1 %
Accuracy	± 3 %
Interval	Variable, standard 1 Hz

Accessories

Charging box

Model	MC01 (single charging box) / RC01 (double charging box)
Usage	Storage, transport and charging of the c-med° alpha. Also switches it on and off.
Material	PC and ABS blend, flame retardant UL 94 V-0
Protection type	IP21
Socket	Micro-USB B / USB-C

Power supply

Model	1. FJ-SW2660501000E (266 CE; Plug type C), 2. FJ-SW2660501000U (266 UL), 3. M050120-S86EUU (CE; Plug-type C), 4. M050120-S86USU (UL; Plug-type A), 5. M050120-S86BSU (UKCA; Plug-type G) 6. M050120-S86AUU (AUS/NZ; Plug-type I)
Input	100 – 240 V ~ 50/60 Hz, 0.35 A Max.
Output	5 V, 1000 mA (1,2) 5 V, 1200 mA (3,4,5,6)
Plug	Europlug CEE 7/16 (Type C) , Plug-type G (BS 1363), Plug-type A (NEMA 1), Plug-type I (AUS/NZ)
Socket	USB A

Charger cable

Model	2464 OD3.0 1500±50mm
Socket	USB A to Micro-USB B / USB A to USB C

Compatibility

cosinuss° components	*c-med° App* and *cosinuss° Health App*, LabGateway (for study purposes)
cosinuss° Lab System	Yes (for study purposes)
Third party apps	Yes, if application adheres to the cosinuss° API specifications. Currently, the sensor is only compatible with the specified cosiuss apps.
Smartwatches	Yes, if application adheres to the cosinuss° API specifications. Currently, the sensor is only compatible with the specified cosiuss apps.
Bike computers	No

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Glossary

Symbol	**Quantity**
bpm	Beats per minute
°C	Degree Celsius
m, cm, mm	Meter, centimeter, millimeter
dBm	Decibel milliwatt
g	Grams
g	Gravity of earth (approx. 9.81 m/s²)
H x W x D	Height x width x depth

Symbol	Quantity
hPa, Pa	Hectopascal, Pascal
Hz, kHz, MHz, GHz	Hertz, Kilohertz, Megahertz Gigahertz
mbar	Millibar
mAh	Milliampere hour
s, h	Second, hour
m/s²	Acceleration in meter per second squared
Mbit	Megabit
Mbps	Megabit per second

Abbreviations

approx.	Approximately
PPG	Photoplethysmography

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