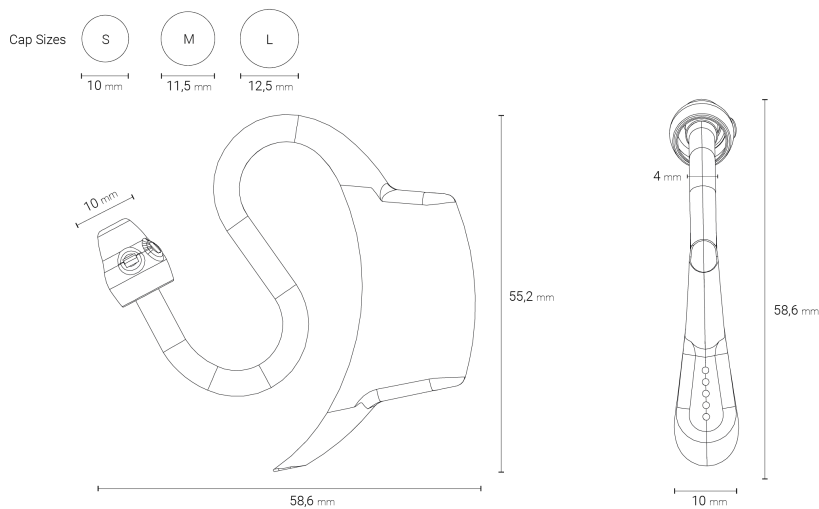


# c-med° alpha - data sheet

Document version: 08  
Status: 20. Nov. 2024  
Document ID: 1603891941  
Basic UDI-DI: 426046302CMED4F

## c-med° alpha

Medical wearable for continuous vital signs measurements



## Features

- Continuous measurement of key vital signs:
  - heart 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
- Operating temperature range:  
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                                 |
| Medical product classification                         | Ila                                                                                                  |
| Certification                                          | Medical CE & 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. 7 g                                                                                          |
| Material                                               | Silicone rubber, medical grade<br>- ISO 10993-5 /-6 /-11 - USP class VI                              |
| Color                                                  | White                                                                                                |
| Battery life                                           | Continuous: approx. 12 h<br>Periodical (3 min every 15 min): approx. 48 h<br>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  | Smaller than 50 hPa                                                                                  |

|                                               |                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Condition                                     |                                                                                                                                                                                                                                                                                                                     |
| Storage temperature and relative air humidity | Temperature   <i>Relative Humidity</i> <ul style="list-style-type: none"> <li>• -25 °C – 5 °C (-13 °F – 41 °F)   0% - 95% (non-condensing)</li> <li>• 5 °C – 35 °C (41 °F – 95 °F)   0% - 95% (non-condensing)</li> <li>• 35 °C – 70 °C (95 °F – 158 °F)   <i>at a water vapor pressure up to 50 hPa</i></li> </ul> |
| 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 (backwards compatible to 4.2)                                                                                                   |
| Frequency          | ISM band 2.4 GHz – 2.485 GHz                                                                                                        |
| Transmitting power | 0 dBm                                                                                                                               |
| Services           | Battery Service, Device Information Service, Health Thermometer Service, Heart Rate Service, Pulse Oximeter Service, Custom Profile |
| Encryption         | AES                                                                                                                                 |
| Transmitting range | approx. 10 m                                                                                                                        |

## Power supply

### Rechargeable battery

|               |                               |
|---------------|-------------------------------|
| Type          | Lithium battery, rechargeable |
| 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            | Heart rate quality, perfusion index                                                        |
| Vital signs                | Heart 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    | Measuring range: 10 °C – 43 °C<br>Measuring limits: -25 °C – 50 °C                                                                                                                                                                                                                                                  |
| Resolution         | 0.1 °C                                                                                                                                                                                                                                                                                                              |
| Technical accuracy | <p> <b>± 0.5 °C (± 0.9 °F) 10.0 – 20 °C (50 – 95 °F)</b><br/> <b>± 0.3 °C (± 0.5 °F) 20.0 – 35.0 °C (68 – 95 °F)</b><br/> <b>± 0.2 °C (± 0.4 °F) 35.0 – 42.0 °C (95 – 107.6 °F)</b><br/> <b>± 0.3 °C (± 0.5 °F) 42.0 – 43.0 °C (107.6 – 109.4 °F)</b> </p> <p>Outside of specified measuring range<br/>± 0.5 °C</p> |
| Sampling rate      | Variable, standard 0.1 Hz                                                                                                                                                                                                                                                                                           |

**Accelerometer**

|                    |                                                         |
|--------------------|---------------------------------------------------------|
| Type               | 3-axis, linear                                          |
| Measuring range    | Up to $\pm 16 \text{ g}$ ( $\pm 156.96 \text{ m/s}^2$ ) |
| Resolution         | 16 bit                                                  |
| Technical accuracy | $\pm 0.002 \text{ m/s}^2$                               |
| Sampling rate      | Variable, standard 100 Hz                               |

**Vital Signs****Body temperature**

|                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Type               | Infrared thermometer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Measuring range    | Depending on App:<br><br>Measuring range: $34 \text{ }^{\circ}\text{C} - 43 \text{ }^{\circ}\text{C}$<br>Measuring limits: $-25 \text{ }^{\circ}\text{C} - 50 \text{ }^{\circ}\text{C}$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Resolution         | $0.1 \text{ }^{\circ}\text{C}$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Technical accuracy | $\pm 0.5 \text{ }^{\circ}\text{C}$ ( $\pm 0.9 \text{ }^{\circ}\text{F}$ ) <b><math>10.0 - 20 \text{ }^{\circ}\text{C}</math></b> ( $50 - 95 \text{ }^{\circ}\text{F}$ )<br>$\pm 0.3 \text{ }^{\circ}\text{C}$ ( $\pm 0.5 \text{ }^{\circ}\text{F}$ ) <b><math>20.0 - 35.0 \text{ }^{\circ}\text{C}</math></b> ( $68 - 95 \text{ }^{\circ}\text{F}$ )<br>$\pm 0.2 \text{ }^{\circ}\text{C}$ ( $\pm 0.4 \text{ }^{\circ}\text{F}$ ) <b><math>35.0 - 42.0 \text{ }^{\circ}\text{C}</math></b> ( $95 - 107.6 \text{ }^{\circ}\text{F}$ )<br>$\pm 0.3 \text{ }^{\circ}\text{C}$ ( $\pm 0.5 \text{ }^{\circ}\text{F}$ ) <b><math>42.0 - 43.0 \text{ }^{\circ}\text{C}</math></b> ( $107.6 - 109.4 \text{ }^{\circ}\text{F}$ ) |
| Interval           | Variable, standard 0.1 Hz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

**Heart rate**

|                 |                         |
|-----------------|-------------------------|
| Type            | PPG                     |
| Measuring range | 35 bpm – 220 bpm        |
| Resolution      | 1 bpm                   |
| Accuracy        | $\pm 4 \text{ bpm}$     |
| 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  | M050120-S86EUU (Plug-type C), M050120-S86BSU (Plug-type G), M050120-S86USU (Plug-type A)<br><br>FJ-SW2660501000E (Plug-type C)<br>FJ-SW2050501000E (Plug-type C) |
| Input  | 100 – 240 V ~<br>50/60 Hz, 0.35 A Max.                                                                                                                           |
| Output | 5 V, 1000 mA                                                                                                                                                     |
| Plug   | Europlug CEE 7/16 (Type C) , Plug-type G (BS 1363), Plug-type A (NEMA 1)                                                                                         |
| 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 | <i>c-med° App</i> and <i>cosinuss° Health App</i> ,<br>LabGateway (for study purposes) |
| cosinuss° Lab System | Yes (for study purposes)                                                               |
| Third party apps     | Yes, if App adheres to the cosinuss° API specifications.                               |
| Smartwatches         | Yes, if application adheres to the cosinuss° API specifications.                       |
| Bike computers       | No                                                                                     |

Illustration: © Cosinuss GmbH

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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                                             |
| <b><i>g</i></b> | Gravity of earth (approx. 9.81 m/s <sup>2</sup> ) |
| H x W x D       | Height x width x depth                            |
| hPa, Pa         | Hectopascal, Pascal                               |

| Symbol            | Quantity                                 |
|-------------------|------------------------------------------|
| Hz, kHz, MHz, GHz | Hertz, Kilohertz, Megahertz Gigahertz    |
| mbar              | Millibar                                 |
| mAh               | Milliampere hour                         |
| s, h              | Second, hour                             |
| m/s <sup>2</sup>  | Acceleration in meter per second squared |
| Mbit              | Megabit                                  |
| Mbps              | Megabit per second                       |

**Abbreviations**

|         |                      |
|---------|----------------------|
| approx. | Approximately        |
| PPG     | Photoplethysmography |

**Signature and approval:** *This document/record is approved and signed digitally.*