

c-med^o alpha

User Manual



ENGLISH

In-ear sensor: MS01

Charging box: MC01

Basic UDI (Sensor): 426046302CMED4F

Basic UDI (App): 426046302CMEDAPP4R

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Important

Please read the instructions for use carefully before using the c-med® alpha monitoring system for the first time. This makes it easier for you to use the product correctly. Please keep these instructions for use in a safe place.



WARNING: User Manual

A warning is issued if certain health hazards (i.e. injury, serious undesirable side effects) or possible damage to the in-ear sensor or accessories are possible.



NOTE: A note is displayed if additional general information is available.



WARNING: User Manual

Please read the User Manual before using the device.



WARNING: Regulations on the installation, operation and use of medical devices

The manufacturer recommends to conduct training in accordance with §4 MPBetreibV (see section Training and Supporting Instruction)

Manufacturer information

This product is manufactured by Cosinuss GmbH.

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CA2966232A1, CA2875901C, DK2717756T3, ES2728673T3

Designed in Germany.

ENGLISH



WARNING: Manufacturer information

The manufacturer information can be found:

- In the User Manual
- In the c-med° app
- On the c-med° alpha charging box

Warnings and precautions



WARNING: Measurement location

Do not use the in-ear sensor on other body parts than the ear!



WARNING: Prohibited usage

Do not use the in-ear sensor:

- If it has any visible damages.
- In cases of any ear diseases or injuries.
- For more than 12 hours without interruption.
- For self-diagnosis of diseases.



WARNING: Ingress protection (IP class 47)

The device is protected against dust, but only for solid foreign bodies with a diameter of more than 1 mm (class 4).

The sensor is protected against water, but only for temporary submersion (class 7).



WARNING: Allergic reactions

The casing of the in-ear sensor consists of tested, biocompatible silicon. No allergic reactions are known. Stop using the device in case of feeling discomfort and allergic reaction while wearing the device.

**WARNING: Arrhythmia and Circulatory Arrest**

Since pulse rate measurements are based on an optical detection of a peripheral pulsatile flow, the measurement is limited in specific situations:

- Certain arrhythmias may not be detected. Therefore, the pulse oximeter measurement should not be used as a substitute for ECG-based arrhythmia analysis.
- During circulatory arrest, a correct measurement of body temperature, pulse rate and SpO₂ may not be possible due to a sudden stop in effective and normal blood circulation.

Health status

- The use of the c-med[®] alpha monitoring system cannot replace the consultation with your doctor.
- The System is intended to be used in hospitals, clinics, long-term care, and home care environments where the variations of the measured values could not result in immediate danger to the patient.
- This product is not suitable for self-diagnosis of diseases by a lay user.
- Please contact your doctor if you notice symptoms such as unexplained irritability, vomiting, diarrhea, dehydration, changes in appetite or activity levels, seizures, muscle aches, chills, stiffness of the neck, pain when urinating etc., regardless of the displayed measured vital signs and regardless of whether or not fever is present.
- Please contact your doctor if the monitored temperature is elevated for more than two days already.
- Unusually elevated or reduced vital signs may indicate a severe disease, especially in adults who are older or frail or have a weakened immune system. Please seek professional advice immediately from the following groups at elevated temperatures:

- Persons over 60 years of age.
 - Persons with diabetes mellitus or a weakened immune system (e.g. HIV positive, cancer chemotherapy, chronic steroid treatment, splenectomy).
 - Bedridden patients (e.g. Nursing home patients, stroke, chronic illness and/or after surgery).
 - Transplanted patients (e.g. liver, heart, lung, kidney).
- Do not use the c-med° alpha when there are injuries to or in the ear or an increased sensation of pain in the ear.
 - Inspect the in-ear sensor's mounting point at least every 6 to 8 hours to ensure that the in-ear sensor is properly positioned and the skin is intact.
 - The infrared rays of the LED on the sensor head can pose a risk, even if they are not visible to the human eye. Do not look directly into the LEDs on the sensor head for long periods of time.
 - Under certain circumstances, it is possible that the in-ear sensor may erroneously consider a movement as good pulse quality interpreted. Therefore keep movement during the measurement to a minimum.

Usage and application

- Only use the c-med° alpha in the ear.
- The measurement at rest provides the best results. Avoid unnecessary movements, chewing and talking during the measurement as they can influence the quality of the ppg signal and lead to inaccurate readings of SpO2 and heart rate.
- Neither the in-ear sensor nor the mobile device stores data. All displayed vital signs data expire automatically after 30 seconds maximum.
- A continuous wearing time of the c-med° alpha of maximum 12 hours and at least 5 minutes per application is recommended.
- If you do not store the sensor at room temperature, allow the sensor to warm up or cool down for one hour at room temperature of approx. 20 °C (68 °F) before using the sensor again.
- Do not use a damaged in-ear sensor. If the c-med° alpha is damaged in any way, discontinue use immediately and contact the customer service. See chapter: [Customer service](#)
- The c-med° alpha is an electronic precision instrument.

Do not try to repair the in-ear sensor yourself. Do not try to open the housing or repair electronic components. Opening the housing may damage the in-ear sensor whereby the liability for material defects becomes void. Repairs may only be carried out by trained cosinuss® personnel.

- Don't make any modifications to the in-ear sensor or any other parts of the scope of delivery, as these will affect the performance of the c-med® alpha. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This product can be operated at an ambient temperature range of 0 – 40 °C (32 – 104 °F) for continuous operation and 0 -50 °C (32 – 122 °F) for transient operation. As the housing is in contact with the user's or patient's skin during use and the sensor head is in the user's or patient's ear canal, the temperature of the c-med® alpha can be significantly higher than the prevailing ambient temperature.
- Do not store or transport this product under extreme temperatures (below -25 °C / -13 °F or above 70 °C / 158 °F) or excessive humidity (relative humidity must be below 95%, non-condensing). This may influence the

accuracy of the IR-thermometer.

- At ambient temperatures of 40 °C (104 °F), self-heating of 1 – 2 °C (1.8 – 3.6 °F) can increase the in-ear sensor temperature to max. 42 °C (107.6 °F).
- When this instrument is operated under the minimum amplitude of 0.2 or above the maximum amplitude of 1.0 for the Perfusion-index the SpO2 results are possibly inaccurate.
- When this instrument is operated under the minimum amplitude of 30 for the Quality-index the Heart rate results are possibly inaccurate.
- The c-med° alpha is swallow-proof and contains NO small parts that can be swallowed or pose a suffocation risk to children.
- Do not operate the in-ear sensor while charging or cleaning.
- Avoid excessive pressure on the in-ear sensor, as the skin under it could be damaged.
- Applying the in-ear sensor to the left or right ear can affect the signal quality.
- Do not use the in-ear sensor directly after showering,

bathing or swimming as long as there is still water inside the ear canal.

- Do not use the in-ear sensor under water (bath, shower, swimming).
- Do not use the in-ear sensor during a magnetic resonance imaging.
- Do not use the in-ear sensor in places where electrical equipment is prohibited, e.g. in potentially explosive atmospheres.
- To avoid inaccurate monitoring, always clean the c-med[®] alpha after usage according to the cleaning instructions in this document. See chapter: Care and cleaning
- Pay attention to disturbed fitting due to jewelry, glasses or other objects.
- Make sure that your or the monitored person's ear canal is free of any disturbing objects.
- If you use accessories other than those specified in the parts and accessories list, there is a risk of increased electromagnetic emissions and/or reduced immunity of this equipment.
- To avoid improper performance of the instrument and/or

injury to you or the monitored person, ensure the compatibility between in-ear sensor, Bluetooth and mobile device including operating system as stated in the specifications before use.

- Do not operate or charge the in-ear sensor directly next to or on top of other devices. If such a configuration is unavoidable, you need to ensure that normal operation is not affected.
- For medical electronic devices, special precautions must be taken with regard to electromagnetic compatibility (EMC). For detailed information on EMC requirements, please contact your authorized service center.
- Portable and mobile HF communication devices can interfere with medical electrogenes.
- Do not charge the c-med° alpha with a power near water or other liquids when a power supply is used.
- As with all medical devices, lay cables and connections carefully, so that you or the monitored person cannot become entangled in it and possibly be strangled or injured.
- Use only power supplies approved by cosinuss° for in-ear sensor and c-med° alpha charging box.

- Do not leave the charging cable unattended with small children, there is a danger of strangulation.
- Keep the c-med® alpha out of reach from pets and pests.
- Keep the c-med® alpha out of reach from children.

Usage on the go

- The optimal conditions for the device use are an indoor, wind-protected environment without direct sunlight, such as in hospitals, clinics, long-term care, and home care environments where the variations of the measured values could not result in immediate danger to the patient. However, the device can also be used outdoors given that the ambient temperature specifications are not exceeded, and the ear is covered and protected from wind and direct sun radiation.
- Please be aware of the following when assessing your health status:
- Special environments can have a fundamental effect on your vital signs.
- For example, being in an airplane and/or at high altitude can increase heart rate and decrease blood oxygen levels.

- When using the device on the go, be aware of any impairment of your sense of balance or hearing. Especially when driving or operating machinery.
- Please note that in an environment where network communication is not possible, initial connection of the device may not be possible.
- The use of Bluetooth wireless connections may be restricted or even prohibited in places such as cars, trains or airplanes. Please pay attention to the instructions of the respective providers.
- When traveling to countries with different electronic requirements (e.g. plug shape, mains voltage), please use an appropriate adapter to charge the device.

Bluetooth

- The c-med° alpha transmits its data via radio transmission using Bluetooth Low Energy (BLE). Please be aware that data transmission via Bluetooth may involve security risks. A complete protection of the data against access by third parties is not possible.
- Communication between in-ear sensor and receiver via Bluetooth Low Energy can only be guaranteed within a maximum radius of 10 meters.

- If there are obstacles between the devices, like people, buildings, walls or other, the range may be reduced.
- Please use only trustworthy and properly secured devices to be protected against unauthorized access.
- The use of the Bluetooth function for non-legal purposes is prohibited: pirate copying, wiretapping etc. cosinuss° does not accept any responsibility for the consequences of illegal use of the Bluetooth function.
- Bluetooth Low Energy uses the 2.4 GHz frequency. The same or similar frequencies are also used by some industrial or medical equipment or low power machines. Such devices may experience interference when a Bluetooth connection is established nearby.
- cosinuss° is not responsible for any loss of data sent or received using the Bluetooth function. For example, through improper interception of the data.

Influencing factors



WARNING: Influencing factors

Important influencing factors that can lead to incorrect vitals signs measurements:

- A dirty sensor head
- A damaged sensor
- Unnecessary movements
- Chewing
- Talking

Important environmental conditions that can lead to incorrect vitals signs measurements:

- Cold wind
- Direct sunlight
- Heavy rain

**WARNING: Transient operating conditions**

Body temperature measurements within the specified laboratory accuracy can only be expected within the ambient temperature for operating conditions: 0 °C - 50 °C (32 °F - 122 °F).

As the housing is in contact with the user's or patient's skin during use and the sensor head is in the user's or patient's ear canal, the temperature of the c-med° alpha can be significantly higher than the prevailing ambient temperature.

If the temperature of the operating environment drops below 0 °C (32 °F):

- for example, if you move your location from a warm indoor area to a cold outdoor area - be aware that this may result in less accurate body temperature measurements.

If the device is used outside the specified operating conditions, cosinuss° can not guarantee the accuracy of the measured vital signs.

External influencing factors

- Direct exposure to cold, heat, wind, sun and water
- Ambient temperature
- Ambient light
- Body Movement in general
- Strong movements of the jaw due to speaking and chewing
- Lying on your ear
- Dirty sensor head
- Damaged sensor head
- Incorrectly attached sensor
- Badly fitting sensor
- Wrong sensor size
- Humidity in the sensor

Internal influencing factors

- Anatomical differences of the auditory canal
- Cerumen

- Poor blood circulation
- Poor pulse quality
- Poor Perfusion
- Venous pulsations
- Dark skin color
- Anemia or low hemoglobin concentrations
- Sickle cell anaemia
- Cardiogreen and other intravascular dyes
- Carboxyhemoglobin
- Methemoglobin
- Dysfunctional hemoglobin

Normal body temperature

The “normal” body temperature is not a fixed number but a temperature range. In a healthy adult the normal temperature ranges from 36.5 °C – 37.4 °C (97.7 - 99.32 °F).¹ It varies depending on the location of the measurement, age and external factors. It also varies from person to person

1

Körpertemperaturmessung, Pschyrembel Online (Abruf: 27.11.20)



NOTE: When you talk to your doctor, tell him that the temperature you have monitored with c-med° alpha is a temperature monitored continuously with an infrared thermometer in the ear.

and varies throughout the day. The c-med° alpha is suitable as a continuous monitoring in-ear sensor for measuring the body temperature.

Normal heart rate

The “normal” heart rate is not a fixed number. In a healthy adult the normal resting heart rate varies from 60 to 80 beats per minute.² The heart rate depends on various factors: Physical exertion (e.g. sports activities), weather/temperature, time of the day, medication or illness, but also mainly on physical condition and age. Gender also plays a role: women often have a slightly faster pulse than men.



NOTE: When you talk to your doctor, tell him that the heart rate you have monitored with c-med° alpha is a heart rate monitored continuously by pulse oximetry using a Photoplethysmography (PPG) sensor in the ear.

Normal oxygen saturation (SpO2)

The oxygen saturation indicates the percentage of oxygen in the blood. In a healthy adult the normal oxygen saturation is 95 – 99%.³ Oxygen saturation can be influenced by various factors, including air pressure (different altitudes) or certain c-med° alpha in-ear sensor (MS01)



NOTE: When you talk to your doctor, tell him that the oxygen saturation you have monitored with c-med° alpha is an arterial oxygen saturation (SpO2) monitored continuously by pulse oximetry using a PPG sensor in the ear.

Signs and symbols

The following symbols are used in the operating instructions and on the in-ear sensor.



WARNING: Warning and safety information on health hazards (i.e. injury, serious undesirable side effects, death) or possible damage to the in-ear sensor or accessories.



NOTE: A note is displayed if additional general information is available.



Not to be disposed of with household waste: This product contains batteries and recyclable electrical waste. To protect the environment, it must not be disposed of with household waste, but must be taken to the appropriate local collection points in accordance with the EC Directive on Electrical Waste. cosinuss® makes an annual contribution to the environmentally friendly disposal of its products.



0123

CE 0123: The CE marking and the number of the notified body must attest conformity with the essential requirements Directive MDR (EU 2017/745) for medical devices.



No SpO₂ Alarm



Question Mark: Vital signs data not valid according to quality index.



Follow the instructions for use.



Product with application parts of type BF (Body Floating).



Product with protection class II.



Manufacturer.



Production batch number.

Typ:

Model identifier.



c-med° alpha in-ear sensor.



c-med° alpha charging box.



Universal Serial Bus (USB).



Bluetooth Low Energy (BLE): Radio data transmission by means of electromagnetic radiation.



FCC: American seal, confirms electromagnetic compatibility..



Direct Current (DC) voltage.



Plug type C: European power plug type for small consumers. (without earthing contact).



Language requirement English: Meets the mandatory language requirements for medical devices in English.



Language requirement German: Meets the mandatory language requirements for medical devices in German.

IP 21

Ingress Protection 21: Device is protected against dripping water falling at an angle (up to 15°) and against large solid foreign bodies (diameter ≥ 50 mm).

IP 47

Ingress Protection 47: Device is protected against temporary submersion and against granular solid foreign bodies (diameter ≥ 1 mm).



Medical device (MD): Indicates the item is a medical device.



Unique device identification (UDI): Indicates a carrier that contains Unique Device Identifier information.



Serial number (SN): Indicates a carrier that contains unique serial number.



Size: Small (S) (Tip size Ø 0.39 in = 10 mm).



Size: Medium (M) (Tip size Ø 0.45 in = 11,5 mm).



Size: Large (L) (Tip size Ø 0.49 in = 12,5 mm).

Scope of delivery

Check the scope of delivery for external intactness of the carton packaging and completeness of the contents. Before use, make sure that the in-ear sensor and accessories are free of visible damage and that all packaging material is removed. In case of doubt, do not use the in-ear sensor and contact your salesperson or our customer service. See chapter: [Customer service](#)

- c-med° alpha in-ear sensor (MS01)
- c-med° App (Download)⁴
- c-med° charging box (MC01)
- Power supply (USB charger adapter)
- Charging cable (USB / Micro-USB)
- User manual

Product description

Intended Use

The c-med° alpha is intended to be used as a medical measuring in-ear device for body temperature, pulse rate and blood oxygen saturation. The optimal conditions for the device use are an indoor, wind-protected environment without direct sunlight, such as in hospitals, clinics, long-term care, and home care environments where the variations of the measured values could not result in immediate danger to the patient. However, the device can also be used outdoors given that the ambient temperature specifications are not exceeded, and the ear is covered and protected from wind and direct sun radiation. The device continuously measures,

⁴ The c-med° App (smartphone application) is a digital product. It can be downloaded anytime for free and is available for Android from the Google Play Store and for iOS from the Apple App Store.

transfers and /or visualizes the stated parameters of healthy or sick persons starting at the age of 18. As a reusable and wearable device, the intended operator is any adult person without neurodevelopmental or neurocognitive disorders.

Intended operator

The intended user can be any adult person without neurodevelopmental or neurocognitive disorders. The medical device is intended for both lay persons and healthcare professionals who wish to monitor their own health or that of another person. The design and the description in the user manual shall ensure a correct and safe handling.

Intended patient population

The medical device is especially designed to measure the vital parameters of adults. Thus, the patient population includes independent of gender, all humans from an age of 18 year under the condition that the sensing earbud fits into the auditory ear canal and the patient does not have any injuries regarding the auditory ear canal.



WARNING: Vital signs

Only the following vital signs can be measured using the c-med° alpha:

- Body temperature
- Heart rate
- Blood oxygen saturation (SpO₂)

Performance

- Measurement of body temperature in the ear canal
- Measurement of heart rate in the ear canal
- Measurement of arterial blood oxygen saturation in the ear canal
- Continuous measurement
- Reliable, accurate and stable measurement
- Good readability of the measured data
- Long-term use (Biocompatibility)
- Radiation: no harm regarding EMC and human exposure.

Use and indication

The wearable in-ear sensor enables the continuous measuring and monitoring of body temperature, pulse rate and blood oxygen saturation (SpO₂) in hospitals, clinics, long-term care,

and home care environments where the variations of the measured values could not result in immediate danger to the patient. The device can also be used outdoors given that the ambient temperature specifications are not exceeded, and the ear is covered and protected from wind and direct sun radiation.

More specifically, its medical use is to determine these vital signs by a continuous and non-invasive method in the auditory ear canal. Thereby the captured values shall be monitored through mobile and wireless methods to provide the user or the monitored person a more mobile measurement device.

In contrast to the common medical devices, the user only needs one device (i.e. in-ear sensor) to get all relevant parameters and sees continuously the current values. A concrete medical indication in terms of specific diseases is not intended. Based on the vital parameter measurement, it is intended to allow and simplify the monitoring of different physical reactions: hypothermia, hyperthermia (fever), changes in circulatory system, tachycardia and bradycardia.

Based on this medical indication, the medical use of the continuous measurement is to make it easier to classify and

monitor the health state of the user or patient and the respective medical condition.

In this context it should be noted that the c-med° alpha monitoring system shall not recommend any concrete treatments.

The c-med° alpha is intended to be used with the c-med° App. A connection via other applications or systems is only intended if the respective second system adheres to the cosinuss° Application Programming Interface (API) specifications. For more information or if you want to integrate the c-med° alpha in your own system, contact cosinuss°.

Contraindication

The product c-med° alpha shall not recommend any concrete treatments and shall not be used :

- **In cases of any ear diseases or injuries.**
- **For monitoring oxygen saturation in case of CO intoxication.**

Alternative measurement methods

Depending on the design, these other methods or devices can be applied to different parts of the body and may result in different readings. Please follow the instructions for use of the respective device. For a continuous monitoring of these vital signs each spot measurement procedure needs to be done repeatedly.

Body temperature

Body temperature can be measured with mercury thermometers, electronic contact thermometers or infrared thermometers.



NOTE: Different methods of measuring body temperature can give different results.

ASTM laboratory accuracy requirements in the display range of 37 to 39 °C (98 to 102 °F) for IR thermometers is ± 0.2 °C (± 0.4 °F), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E1112-86 is ± 0.1 °C (± 0.2 °F).

Pulse rate

Pulse rate can be measured manually or by means of special devices. The pulse rate can be measured manually by “palpation” with the fingers at all points on the body where arteries run superficially. The best-known palpation site is in the area of the wrist (radial pulse).

Electronic measurement of heart rate takes place by means of electrocardiogram (ECG). For optical measurements of the pulse rate, various devices and sensors can be used at different locations on the body, such as finger clips, smart-watches, fitness trackers or in-ear sensors.

Oxygen saturation (SpO₂)

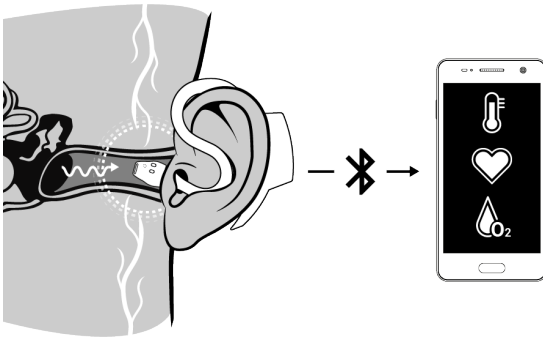
Oxygen saturation (SpO₂) can be measured with other special pulse oximetry devices, which often involve attaching a clip with a sensor to the fingertip or earlobe.

Application principle

The in-ear sensor can only be used in combination with its charging box, a mobile device of the respective user and the installed App. The medical device is intended for the continuous and non-invasive body temperature, pulse rate and SpO2 measurement in the human auditory canal.

The measured values of the vital signs are sent via Bluetooth Low Energy to the mobile device, where the c-med° App displays the values as long as the mobile device is within the Bluetooth range. The user can see the values as soon as the in-ear sensor is processing values within the measurement ranges. The Light Emitting Diode (LED) on the back of the sensor shows the status of the battery and the connection.

The measured vital signs can be seen by the user through the mobile device and the corresponding c-med° App. Once the App is installed and opened on the mobile device the in-ear sensor must be taken from the charging box and the Bluetooth service on the mobile device must be enabled. The in-ear sensor automatically connects to the App.



Application principle of the c-med° alpha.

Technical principle

Two different sensor types within the c-med° alpha will be used to get the relevant raw data: An infrared temperature sensor and an optical Photoplethysmography (PPG) sensor, consisting of two LEDs and one photodiode.

Infrared temperature sensor

A thermal infrared sensor is used to make raw temperature measurements. This sensor passively measures the heat radiation of the eardrum plus the radiated heat of the

surrounding auditory canal. Due to the so-called thermopile sensor the incident thermal radiation can be converted into a voltage signal (principle of the thermoelectric effect).

Through calibration and with the help of a proportional to absolute temperature sensor (PTAT1) element which measures the ambient sensor-temperature it is then possible to determine the absolute temperature of the measured object or, more specifically, the eardrum plus the surrounding auditory canal.

Accuracy of body temperature

The body temperature shall be measured with a laboratory measurement accuracy of:



NOTE: Even though the design of the c-med® alpha supports optimal positioning, the measurement result may vary because an exactly identical positioning and alignment of the thermometers is not always reproducible.

Temperature range

34.0 – 35.0 °C (93.2 – 95 °F)

35.0 – 42.0 °C (95 – 107.6 °F)

42.0 – 43.0 °C (107.6 – 109.4 °F)

Laboratory measurement accuracy

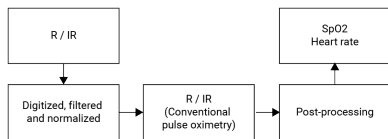
± 0.3 °C (± 0.5 °F)

± 0.2 °C (± 0.4 °F)

± 0.3 °C (± 0.5 °F)

Photoplethysmography (PPG) sensor

The c-med[®] alpha measures the oxygen saturation inside the ear by pulse oximetry using a PPG sensor. Two LEDs, one with red light, one with infrared light, will be used to send light into the tissue of the ear canal. A photodiode will capture the light coming out of the skin, convert the light into electrical current. The current will be converted by a trans impedance amplifier (TIA) into an electrical voltage, which can be easily digitized. The light is modulated by the blood flow inside the ear canal's tissue. Based on this modulation and the well known method of pulse oximetry the heart rate and the SpO₂ can be calculated.



Application principle of the c-med[®] alpha.

Accuracy of heart rate

The heart rate shall be measured with an accuracy of ± 4 bpm (beats per minute) within the range of 50bpm – 180bpm.

Accuracy of SpO2

The SpO2 shall be measured with an accuracy of ARMS \pm 3% within the range of 70% – 100%.

Functional oxygen saturation

Functional oxygen saturation is the percentage of saturation given by the concentration of oxyhemoglobin (cO2Hb) divided by the sum of the concentrations of oxyhemoglobin and deoxyhemoglobin (cHHb).

$$\frac{100 \times cO2Hb}{cO2Hb + cHHb}$$

According to the Clinical Laboratory Standards Institute (CLSI), the term for this ratio is hemoglobin-oxygen saturation, and its designation is SO2. For SpO2 this percentage saturation refers to arterial blood.



NOTE: The pulse oximeter equipment is calibrated to display functional oxygen saturation (SpO2).

The accuracy of the measurements are influenced by internal and external factors. See chapter: [Warnings and precautions](#)

SpO2 measurement accuracy of the c-med® alpha has been validated using a controlled desaturation study without



movement in healthy volunteers (Men and women, adult age, non-smoking, normal weight, skin tone according to Fitzpatrick scale) within a range of 70%-100% SpO₂ and in reference to a secondary standard pulse oximeter.

In this desaturation study the c-med® alpha achieves an overall accuracy of ARMS = 3 % when compared to blood gas analysis. Since the pulse oximeter measurements are statistically distributed, it can be expected that about two-thirds of the measurements will be within \pm ARMS compared to CO-oximeter measurements.

The use of functional test equipment cannot be used to verify the measurement accuracy.

A report on the clinical properties and accuracy, as well as their documentation of the studies are available on request from the manufacturer.

Why inside the ear?

The ear canal is an ideal place of measurement for vital sign monitoring:

Blood supply:

The ear canal is part of the body core and therefore optimally supplied with blood. This is essential for all optical measurements on the body and ensures the possibility for a data collection of high accuracy.

Temperature:

The body temperature can be measured at various places in and outside of the body. The core temperature refers to the temperature of the vital organs. The temperature in the ear correlates with the body core temperature, because the eardrum (the place where c-med° alpha monitors) and the hypothalamus (the temperature control center in the brain) have the same blood supply. Changes in this core temperature therefore affect the ear more quickly than other parts of the body.

Skin contact:

With the c-med° alpha it is possible to ensure a steady contact of optical sensing elements and the ear canal tissue

which is critical for accurate measurements with this method anywhere on the body.

Dark surrounding:

The place of measurement is already minimizing the ambient light that falls into the receiving photodiode. This is essential for reducing noise artefacts in the received signal and improves the overall signal quality.

Static movement:

The head, and with that also the ear, is by nature protected from abrupt and fast movements in order to protect the brain. Motion artifacts are thus minimized due to the placement of the sensor in the outer ear canal.



NOTE: The measurement at rest provides the best results. Avoid unnecessary movements, chewing and talking during the measurement as they can influence the quality of the ppg signal and lead to inaccurate readings of SpO2 and heart rate.

Only use the c-med® alpha in the ear.

Application environment

The optimal condition for the device use is an indoor, wind-protected environment without direct sunlight, such as in hospitals, clinics, long-term care, and home care environments where the variations of the measured values could not result in immediate danger to the patient.

However, the device can also be used outdoors given that the ambient temperature specifications are not exceeded, and the ear is covered and protected from wind and direct sun radiation.

The System is intended to be used within the following limits:

Continuous Operating Condition:

Temperature	Humidity	Barometric pressure
0 °C – 40 °C (32 °F – 104 °F)	15%- 95% rH (non-condensing)	620-1060 hPa (620-1060 mbar)

Transient Operating Condition:

Temperature	Humidity	Barometric pressure
0 °C – 50 °C (32 °F – 122 °F)	15%- 90% rH (non-condensing)	Smaller than 50 hPa

**WARNUNG: Transient operating conditions**

Body temperature measurements within the specified laboratory accuracy can only be expected within the ambient temperature for operating conditions: 0 °C - 50 °C (32 °F - 122 °F).

As the housing is in contact with the user's or patient's skin during use and the sensor head is in the user's or patient's ear canal, the temperature of the c-med° alpha can be significantly higher than the prevailing ambient temperature.

If the temperature of the operating environment drops below 0 °C (32 °F)

- for example, if you move your location from a warm indoor area to a cold outdoor area - be aware that this may result in less accurate body temperature measurements.

If the device is used outside the specified operating conditions, cosinuss° can not guarantee the accuracy of the measured vital signs.



HINWEIS: If you use the c-med° alpha to measure the body temperature outdoors, please ensure that the ear (measurement site) is covered according to the temperature conditions.

Transport and storage environment

For domestic use the in-ear sensor and the charging box shall be stored and transported under the following conditions - other environments may influence the accuracy of the IR-thermometer and PPG-sensor.

Temperature

-25 °C – 5 °C (-13 °F – 41 °F)

5 °C – 35 °C (41 °F – 95 °F)

35 °C – 70 °C (95 °F – 158 °F)

Relative Humidity

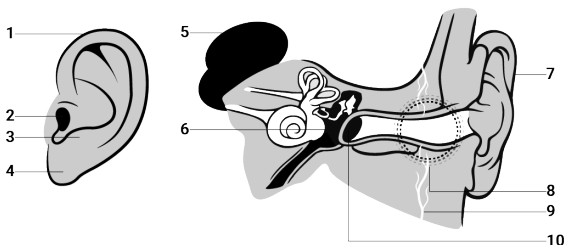
/

0% - 95% (non-condensing)

at a water vapor pressure up to 50 hPa

Components

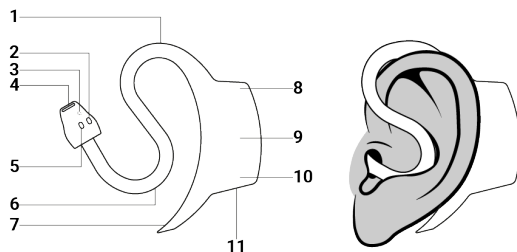
The c-med° alpha can only be used in combination with its charging box, a mobile device of the respective user and the installed App. The medical product is intended for the continuous and non-invasive body temperature, pulse rate and SpO2 measurement in the human auditory ear canal.



Ort der Messung im äußeren Gehörgang.

- | | |
|----------------------------------|------------------------|
| 1 Auricle rim | 6 Middle ear |
| 2 Entrance to the auditory canal | 7 Auricle |
| 3 Antitragus | 8 Outer auditory canal |
| 4 Earlobe | 9 Blood vessels |
| 5 Hypothalamus | 10 Eardrum |

In-ear sensor



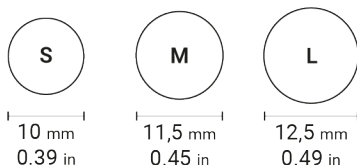
ENGLISH

The c-med® alpha in-ear sensor for vital signs monitoring.

- 1 Sensor neck
- 2 Red/Infrared LED
- 3 Contact thermometer
- 4 Infrared thermometer
- 5 Photodiode
- 6 Antitragus curve
- 7 Pickaxe
- 8 Status LED
- 9 Circuit board and battery
- 10 Charging LED
- 11 Charging contacts

Available Tip sizes

The c-med® alpha in-ear sensor is available in three sizes: Small, Medium and Large. These differ only in the diameter of the sensor tip. The sensor tip is flexible and can adapt to the ear canal. The quality of the measurement depends largely on choosing the right size for your ear canal. Continuous contact of the measurement sensors with the ear canal achieves optimal results.



Size: Small (S) (Tip size Ø 0.39 in = 10 mm).



Size: Medium (M) (Tip size Ø 0.45 in = 11,5 mm).



Size: Large (L) (Tip size Ø 0.49 in = 12,5 mm).

In-ear sensor & LED states

The LEDs of the c-med® alpha have the following possible states:

Status-LED

LED-behavior		Description
When switching on		
Green		100-51% Battery charge level
Orange		50-26% Battery charge level
Red		25-6% Battery charge level
Red	(blinking)	< 6% Battery charge level
In activated state		
Blau	(blinking)	Sensor is searching.
Grün	(blinking)	Sensor is measuring.
Rot	(blinking)	< 6% Battery charge level
Rot		Sensor is defective
When switching off		
Blau		Sensor confirms switching off.
Aus		Sensor is switched off.

**WARNING: Defective sensor / Hardware error**

Do not use the in-ear sensor, if it is defective.

Hardware errors are occurring, if:

- The Status-LED lights up permanently red.
- The device has visible damages.

Charging LED

LED behaviour

Solid red

LED is OFF

Description

In-ear sensor is charging.

In-ear sensor is fully charged.

Mobile application

The c-med° mobile application (App) runs on mobile devices and serves as the display of the c-med° alpha. The App is displaying:

- Current body temperature value (°C / °F)
- Current heart rate value (bpm)
- Current SpO2 value (%)
- Perfusion index
- Quality index
- In-ear sensor battery status
- Bluetooth connection status



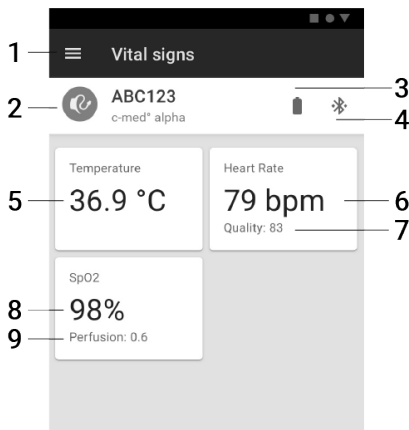
NOTE: The c-med° alpha is intended to be used with the c-med° App. A connection via other applications or systems is only intended if the respective second system adheres to the cosinuss° API specifications. For more information or if you want to integrate the c-med° alpha in your own system, contact cosinuss°.

Installation of the App

The c-med° App is a digital product. You can download it anytime for free. It is available for Android from the Google Play Store and for iOS from the Apple App Store.



Vital signs screen



The c-med® alpha in-ear sensor for vital signs monitoring.

- | | |
|---|--------------------------|
| 1 Menu opening navigation drawer to access all app destinations | 6 Heart rate value (bpm) |
| 2 Serial number and in-ear sensor type | 7 Quality index |
| 3 In-ear sensor battery status | 8 SpO2 value (%) |
| 4 Bluetooth connection status | 9 Perfusion index |
| 5 Body temperature value (°C / °F) | |

Accessories

Charging and safe keeping

A charging box is used for charging and safe keeping of the in-ear sensor. A docking station within the charging box allows the charging of the in-ear sensor's battery through its charging connections. In that way it is impossible to charge the c-med° alpha while wearing it. The in-ear sensor can only be connected to a power supply through the charging box, which connects to power via an USB cable.

For charging put the in-ear sensor into the charging box. Connect the charging box itself to the main power supply. The charging status is indicated through the shining LED of the c-med° alpha.



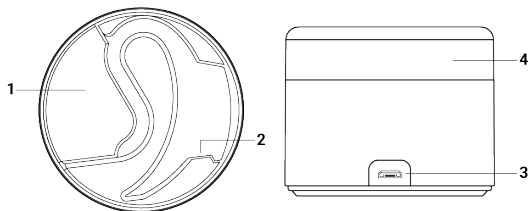
WARNING: Charging

- The use of power supplies and charging cables, other than those in the delivery scope is not permitted and is unsafe.
- The supplied power supply unit is used for safe disconnection from the electrical mains.
- The use of any other power supply unit may endanger the user/patient.
- The use of a different power supply unit cannot guarantee

electromagnetic compatibility.

- Do not touch the charging contacts or the USB interface simultaneously with the monitored person.
- The charging box must not be placed in such a way that it is difficult to disconnect it from the mains by unplugging the power supply from the socket.

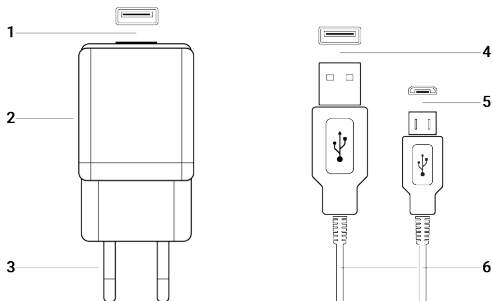
The charging box



The c-med° alpha in-ear sensor for vital signs monitoring.

- 1 Recess
- 2 Charging contacts
- 3 Micro USB socket
- 4 Lid

The power supply and charging cable



The c-med° alpha charging box.

1 USB socket

2 Power supply

3 Euro plug

4 USB plug

5 Micro USB plug

6 Charging cable

Operation

Before initial operation

These preconditions are best practice to ensure before operation.

- Check for physical damage of device and accessories.
- Charge the c-med® alpha in-ear sensor to full capacity.
- Charge your mobile device to full capacity.
- Install the c-med® App on your mobile device.
- Establish network connection.
- Turn ON Bluetooth on your mobile device.
- Read and understand the user manual.
- Read and understand warnings and precautions.

Initial operation

Turn in-ear sensor on



- Take the c-med® alpha out of its charging box.
- The in-ear sensor will turn ON automatically.
- The in-ear sensor is now in advertising mode (LED blinks blue), ready to establish a connection.

Open the App



- Turn ON Bluetooth on your mobile device.
- Start the c-med® App on your mobile device.

Identify the in-ear sensor



- Find the serial number labeled on your in-ear sensor.
- Enter the serial number in the App.
- The App automatically verifies your in-ear sensor.

Connect the in-ear sensor



- The App establishes a Bluetooth connection automatically.



NOTE: In-ear sensor and mobile device must be within the Bluetooth maximum range of 10 meters.

See chapter: [Warnings and precautions > Bluetooth](#)

Follow instructions on screen.



- Follow the instructions on screen.
- The app will guide you through all steps needed to receive and monitor your data.

Clean the in-ear sensor



- Clean the in-ear sensor before and after each use.
- Follow the instructions on screen.

See complete cleaning instructions in chapter:
Care and cleaning

Apply the in-ear sensor to the ear



- Guide the rear part of the c-med° alpha behind the auricle.



- Leave the in-ear sensor gently hanging on top of your ear.



- Carefully guide the in-ear sensor head into the entrance of the outer ear canal.



- Adapt the neck of the in-ear sensor to the shape of the ear.

**WARNING: Sensor Size**

- A wrong sensor size can lead to incorrect measurements.
- Avoid excessive and deep pressure during application.

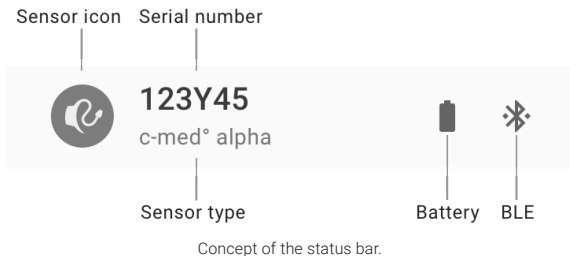
**NOTE:**

- The sensor head may just disappear into the auditory canal.
- The sensor head must point towards the eardrum.
- A reinforced shaped wire in the sensor neck helps to maintain the individual positioning.
- The sensor head should fill the entire ear canal
- Eventually you want to pre-bend the sensor neck for easier application.

Monitoring vital signs

Status bar specification

The c-med° App shows the in-ear sensor information of current battery level and the current Bluetooth connection status in the status bar on top of the vital signs monitoring screen.



Status bar behavior

After verifying your in-ear sensor the status bar shows the serial number and sensor type in the status bar in order to identify the sensor during monitoring the vital signs.

During an active Bluetooth connection the in-ear sensor information of battery level and connection status are dynamically updated.



Battery 20 – 100 %



Battery 0 – 20 %



Battery level unknown



Bluetooth connected



Searching for Bluetooth connection



Bluetooth disabled/disconnected



WARNING: Bluetooth

- The Bluetooth icon indicates the status of the connection between sensor and mobile device.
- You cannot monitor your vital signs if the Bluetooth connection to your mobile device is interrupted..

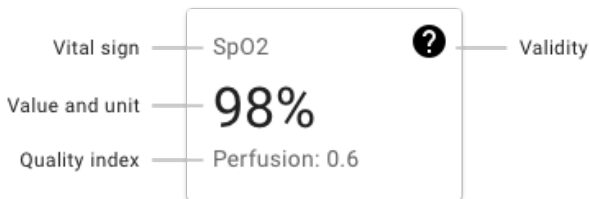


NOTE: In-ear sensor and smartphone must be within the Bluetooth maximum range of 10 meters.

See chapter: [Warnings and precautions > Bluetooth](#)

Vital sign cards specification

The c-med° App shows the current vital signs values. Each vital sign is displayed in its own card.



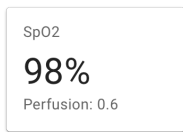
Concept of vital sign cards.

Vital sign cards behaviour

The vital signs values will be updated every second. If no new data arrives within 30 seconds, the current values expire. Then no values are displayed.

If the displayed value is not reliably determined due to a signal insufficiency, a question mark is displayed.

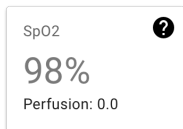
Value is valid.



Value: High emphasis.

Perfusion index: Low emphasis.

Value is not valid.

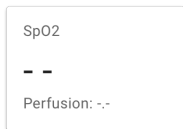


Notification: Question mark.

Value: Low emphasis.

Perfusion index: High emphasis.

No value



In case of:

- Expired values,
- Disconnects
- Broken hardware or other issues.

**WARNING: Thresholds and indicators**

Update of vital signs	Every 1 second
Expiration of vital signs	Every 1 second
Poor Quality of Heart Rate (Question mark)	Quality lower than 30
Poor Quality of SpO2 (Question mark)	Perfusion lower than 0.2 Perfusion higher than 1.0

NOTE:

The measurement at rest provides the best results. Avoid unnecessary movements, chewing and talking during the measurement as they can influence the quality of the ppg signal and lead to inaccurate readings of SpO2 and heart rate.

Only use the c-med® alpha in the ear.

The reliability of the signal is also affected by different influencing factors. See chapter: [Warnings and precautions](#)

Check signal quality



- Check quality index and perfusion index
- Assess if the vital signs calculation is reliable.
- Improve the signal quality by avoiding
- influential factors.

See chapter: [Warnings and precautions](#)

Quality index

Quality index for the Photoplethysmography (PPG) signal is an indicator for the reliability of the currently calculated heart rate values.

Less than 30

Unreliable heart rate

30 – 100

Reliable heart rate

Perfusion index

The Perfusion index for the Photoplethysmography (PPG) signal is an indicator for the reliability of the currently calculated SpO2 values.

0 – 0.2

Unreliable SpO2

0.2 – 1.0

Reliable SpO2

More than 1.0

Unreliable SpO2

NOTE:

- The reliability of the signal can also be an indicator for a good fitting sensor size.
- The reliability of the signal is also affected by different influencing factors.

See chapter: [Warnings and precautions](#)

Shutdown

Close the App



- Close the c-med® App on your mobile device.
- The in-ear sensor will lose connection.
- The measurement will stop.
- The in-ear sensor goes back to advertising mode (LED blinks blue).
- The in-ear sensor stops sending data.

Turn in-ear sensor off and storage



- Put the in-ear sensor back into its charging box.
- The in-ear sensor turns OFF.
- Store the in-ear sensor safely within the charging box.

Charging



1. Put the in-ear sensor into its charging box.
2. The in-ear sensor turns OFF.
3. Connect the charging cable to the charging box.
4. Connect the power supply to the charging cable.
5. Plug the power supply into a power socket.
6. The in-ear sensor is now charging (LED solid red).
Charging from zero to full capacity takes approx. 1 hour.
7. In-ear sensor is fully charged (LED turns OFF).
8. Unplug the charging box from the socket.

**WARNING: Charging**

- The use of power supplies and charging cables, other than those in the delivery scope is not permitted and is unsafe.
- The supplied power supply unit is used for safe disconnection from the electrical mains.
- The use of any other power supply unit may endanger the user/patient.
- The use of a different power supply unit cannot guarantee electromagnetic compatibility.
- Do not touch the charging contacts or the USB interface simultaneously with the monitored person.
- The charging box must not be placed in such a way that it is difficult to disconnect it from the mains by unplugging the power supply from the socket.

Health data

Cosinuss GmbH

Cosinuss GmbH is a certified medical device manufacturer and meets all requirements for quality management of the harmonized standard ISO 13485. The c-med[®] alpha and the associated software is a class IIa medical device and conforms to the MDR 2017/745/EU - Medical Device Regulations and IEC 62304. The effectiveness of quality

management is regularly checked by the notified body within the framework of external audits. Cosinuss GmbH assures that it will always strive to improve its products in terms of quality, usability and safety.

Data privacy and data security

We take the protection of your personal data very seriously. We treat your personal data confidentially and accordingly to the legal data protection regulations (GDPR) as well as our data protection declaration. This privacy statement applies to our mobile iPhone or Android c-med° App. It explains the type, purpose and scope of data collection in the context of usage of the c-med° App.

Please take note of the current status of the complete privacy policy under: support.cosinuss.com/c-med/privacy

The c-med° alpha in-ear sensor generates and sends data via Bluetooth Low Energy to the c-med° App, but does not store any data itself. If there is no Bluetooth connection for a short period of time, the vital signs data recorded and calculated by the in-ear sensor will be lost at that point in time. The App displays the received data and does not require you to enter personal data. A measurement can be stopped at any time

by closing the App or switching off the in-ear sensor by putting it into the charging box.

The c-med° App serves as an extended display of the c-med° alpha in-ear sensor technology and therefore does not provide any storage of the calculated and received vital parameter data of the user. The data is displayed for 30 seconds, after which it is irreversibly deleted.

As a user, please protect the display of your data on your local receiver device against unauthorized access by unauthorized persons on your own responsibility. Please use only trustworthy and secure devices and services.

Cosinuss GmbH has no access to your data via the c-med° App and will not transfer any data to third parties without your prior consent.

**WARNING: Data storage**

- The c-med° app does not store your health data.

Troubleshooting

If a problem occurs with your c-med° alpha, please follow these troubleshooting information first. If this does not solve the problem, please contact Cosinuss GmbH customer service. See chapter: [Customer service](#)

Switching on and off, charging

PROBLEM	INDICATOR	REASON	SOLUTION
The c-med° alpha does not switch ON.	Status LED does not turn ON.	Battery is empty.	Charge in-ear sensor.
The c-med° alpha does not turn OFF.	Status LED does not turn OFF.	The sensor is not correctly positioned in the charging box.	Position sensor with good contact of the charging pins.
The c-med° alpha is not charging.	Charging LED does not turn ON.	The sensor is not correctly positioned in the charging box	Position sensor with good contact of the charging pins.

Connection and transmission

PROBLEM	INDICATOR	REASON	SOLUTION
The c-med® alpha does not connect to the app.	The sensor stays in advertising mode. Status LED blinks blue.	The Bluetooth function of the mobile device is turned OFF..	Turn ON Bluetooth on the mobile device and retry.
The Bluetooth connection is interrupted repeatedly.	The status bar in the monitoring screen shows varying Bluetooth states.	See chapter: Warnings and precautions > Bluetooth	See chapter: Warnings and precautions > Bluetooth
The serial number is wrong.	Error message.	Typing error.	Correct typing error and try again.
The serial number is not recognized.	Error message.	The mobile device has no network connection.	Establish network connection and retry.
The serial number is not valid.	Error message.	No match on server.	Contact customer support. See chapter: Customer support

Vital signs display

PROBLEM	INDICATOR	REASON	SOLUTION
No vital signs are displayed.	The app shows no value (--.).	No in-ear sensor connected.	Connect your sensor.
		No in-ear sensor in Bluetooth range.	See chapter: Warnings and precautions > Bluetooth
		No new values incoming since 30 seconds.	Check Bluetooth connection.
		Measured values are out of range.	See chapter: Product specifications
Vital signs are marked invalid.	Question mark in vital sign card.	Quality index and/or Perfusion index are low..	Minimize influencing factors. See chapter: Warnings and precautions

Wearing comfort

PROBLEM	INDICATOR	REASON	SOLUTION
The in-ear sensor hurts.	Individual perception.	Wrong fitting.	Check the correct fitting of the in-ear sensor. See chapter: Apply the in-ear sensor to the ear
		Wrong in-ear sensor size.	Check the long term behavior of the quality indices.
		Exceeded wearing time. More than 12 hours without interruption.	Cancel the measurement. See chapter: Warnings and precautions
		The sensor is defective.	Cancel the measurement. See chapter: Warnings and precautions

PROBLEM	INDICATOR	REASON	SOLUTION
The in-ear sensor hurts.	Individual perception.	The monitored person's ear is injured.	Cancel the measurement. See chapter: Warnings and precautions

Care and cleaning

Care

Take good care of your c-med° alpha to ensure a long lasting performance.

The sensor head and the sensor lens are the most sensitive parts of the c-med° alpha. They should always be clean and faultless to ensure accurate monitoring. Store and charge your in-ear sensor only within the c-med° alpha charging box.

If the sensor head or sensor lens is damaged, please contact customer service. See chapter: [Customer service](#)

Cleaning

In-ear sensor

Before and after each use clean the in-ear sensor as shown in the following instructions. For disinfection and cleaning Cosinuss GmbH recommends the use of 'Schülke mikrozid® AF liquid' and wipes as an alcohol-based cleaning agent. Alternatively, any other disinfectant/disinfectant wipes based on a total of 60% (w/w) alcohol with no fragrances can be used in undiluted application.



WARNING: Care and cleaning

Physical damage

- Do not use any sharp objects for cleaning.
- Do not apply with too much pressure while cleaning.

Prohibited cleaning methods

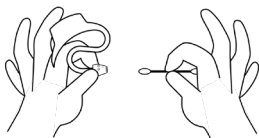
- Do not use UV-light.
- Do not use Ultrasound.
- Do not use hot water.
- Do not use aggressive disinfectant with more than 60% alcohol.

Electrical safety

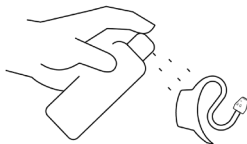
- Never connect the charging box to any power supply during cleaning. Disconnect the charger before cleaning.



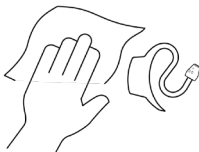
- Fixate the sensor head between your fingers.



- Clean the sensor head with a cotton swab soaked in disinfectant (Schülke Mikrozid® AF liquid).
- Remove other visible dirt with a disinfectant wipe (Schülke Mikrozid®).



- Distribute disinfectant evenly over the entire in-ear sensor. Do not forget to spray behind the sensor head.

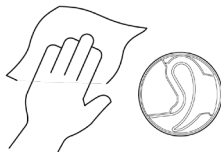


- Let the disinfectant work for about 1 minute
- Take another disinfectant wipe (Schülke Mikrocid®).
- Rub the surface well in all areas to mechanically clean the surface.
- To disinfect the area under the sensor head, you should use a cotton swab to guide the disinfectant wipe under the head and carry out the disinfection while turning it gently.
- Dry the in-ear sensor with a disposable cloth.
- The in-ear sensor is now ready for use.



NOTE: Do not use the in-ear sensor until the alcohol has completely evaporated and the in-ear sensor is in a dry state.

Charging box



- Clean the charging box with
- a disinfectant wipe (Schülke Mikrozyd®).

Product specifications

General

Typ	MS01
Generation	1
Device type	Continuous vital signs monitor
Usage	Measuring key vital signs continuously in the outer ear canal.
Measuring position	Outer ear canal
Measured values (parameters)	Heart rate, oxygen saturation (SpO2), body temperature.
Status indicators	RGB-LEDs
Vital signs display	Mobile application (App): Current temperature (°C / °F), heart rate (bpm) and SpO2 (%) in numbers.
Medical product classification	Ila
Certification	Medical CE & FCC, Bluetooth
Sensor dimensions, H x W x D	55.2 mm x 58.6 mm x 10.0 mm

Tip sizes available	Small (S) (Tip size Ø 0.39 in = 10 mm) Medium (M) (Tip size Ø 0.45 in = 11,5 mm) Large (L) (Tip size Ø 0.49 in = 12,5 mm)
Weight	Approx. 7 g
Material	Silicone rubber, medical grade - ISO 10993-5 /-6 /-11 - USP class VI
Color	White
Battery life	approx. 12 hours
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% rH
(non-condensing); 35 °C – 70 °C (95 °F – 158 °F) | at
a water vapor pressure up to 50 hPa

Protection type

IP47
solid foreign bodies with diameter ≥ 1.0 mm,
submersible to a depth of 1 m

Type of applied part

BF

Service life

2 years (also applies to all supplied parts and
accessories)

Scope of delivery

c-med° alpha in-ear sensor, charging box, charging
cable, power supply, manual

Firmware

The version of the installed firmware can be viewed
any time in the c-med° App under About / c-med°
App. Updates reserved.

Radio data transmission

Type	Bluetooth Low Energy (BLE)
Version	5.0 (backwards compatible to 4.2)
Frequency	ISM band 2.4 – 2.485 GHz
Transmitting power	≤ 0 dBm
Supported services	Battery Service, Device Information Service, Health Thermometer Service, Heart Rate Service, Pulse Oximeter Service, Custom Profile
Encryption	Advanced Encryption Standard (AES)
Transmitting range	approx. 10 meters

Power supply

Type	Lithium battery, rechargeable
Capacity	60 mAh
Charging time	approx. 1 hour
Runtime	approx. 12 hours
Standby time	approx. 1 year

Sensor technology

Sensor types	Infrared and contact thermometer, optical measurement (LEDs and photodiode), accelerometer
Raw data	PPG (red, infrared and ambient light), acceleration
Quality indices	Quality index, Perfusion index
Vital signs	Pulse rate, body temperature, SpO2

Photoplethysmography (PPG) sensor

Type	Red LED, infrared LED and photodiode
Method	Photoplethysmography (PPG)
Resolution	24 bit
Sampling rate	Variable, standard 200 Hz
Wavelength range and max. optical output power	Red LED: 660 nm, 15.1 mW Infrared LED: 950 nm, 11.3mW

Infrared temperature sensor

Type	Infrared temperature sensor, contactless
Measuring range	Calibrated in the ambient temperature range from 15 - 40 °C (59 - 104 °F).
Resolution	0.01 °C (0.05 °F)
Technical accuracy	±0.2 °C (±0.4 °F) within 35.0 – 42.0 °C (95 – 107.6 °F)
Sampling rate	Variable, standard 0.1 Hz

Accelerometer

Type	3-axis, linear
Measuring range	Up to ± 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, Direct mode (no Adjusted mode available)
Measuring range	34 °C – 43 °C (93.2 °F – 109.4 °F)
Resolution	0.1 °C (0.2 °F)
Accuracy (Laboratory)	<p>± 0.3 °C (± 0.5 °F) within 34.0 – 35.0 °C (93.2 – 95 °F)</p> <p>± 0.2 °C (± 0.4 °F) within 35.0 – 42.0 °C (95 – 107.6 °F)</p> <p>± 0.3 °C (± 0.5 °F) within 42.0 – 43.0 °C (107.6 – 109.4 °F)</p> <p>Outside of the measuring range (--.) No display of values</p>
Interval	Variable, standard 0.1 Hz

Heart rate

Type	PPG
Measuring range	35 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

Typ	MC01
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Usage	Storage, transport and charging of the c-med° alpha. Also switches it on and off.
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Material	PC and ABS blend, flame retardant UL 94 V-0
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Protection type	IP21 Objects bigger than 12,5 mm, waterdrops
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Socket	Micro-USB B
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Power supply

Model	FJ-SW2050501000E (Type C), FJ-SW2660501000E (Type C)
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Protection class	II
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Usage	Power supply, voltage transformer
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Input	100 – 240 V ~ 50/60 Hz, 0.35 A Max.
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Output	5 V, 1000 mA
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Plug	Plug-type C (CEE 7/16)
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Socket	USB A
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Model	M050120-S86EUU (Plug-type C), M050120-S86BSU (Plug-type G), M050120-S86USU (Plug-type A)
Protection class	II
Usage	Power supply, voltage transformer
Input	100 – 240 V ~ 50/60 Hz, 0.5 A Max..
Output	5 V, 1200 mA
Plug	Plug-type C (CEE 7/16), Plug-type G (BS 1363), Plug-type A (NEMA 1)
Socket	USB A

Charger cable

Model	2464 OD3.0 1500 ± 50mm
Usage	Connecting charging box and power supply.
Socket	USB A to Micro-USB B

Mobile application (App)

Name	c-med®
Usage	Digital display of the c-med® alpha in-ear sensor.
Operating system	Android 5 and higher. iOS 9 and higher.
Download and installation	<p>The software download is free with the purchase of the hardware product.</p> <ul style="list-style-type: none">• Google Play Store for Android• Apple App Store for iOS
Version	<p>The version of the installed app can be viewed at any time in the app page</p> <p>About c-med®. Updates reserved.</p>

Standards and regulations

DIN EN ISO 80601-2-61: Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

EN ISO 80601-2-56: Particular requirements for the safety, including essential performance, of medical thermometers for measuring body temperature.

EN 60601-1: Medical electrical equipment - Part 1: General requirements for safety, including essential performance.

EN ISO 14971: Medical devices - Application of risk management to medical devices.

EN ISO 10993-1: Biological evaluation of medical devices - Part 1: Assessment and verification under a risk management system.

EN 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for safety, including essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

DIN EN ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied.

EN 60601-1-11: Medical electrical equipment - Part 1-11: General requirements for safety, including essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems for household medical use.

Partly compliant with IEC 60601-1-12: Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.

ISO 17664-2:2021 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices.

This product complies with the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (EU MDR).

2014/53 EV Radio equipment directive.

IEC 62304 - Medical device software - Software life cycle processes.

FCC / ISED according information and statements

User Information according to FCC 15.21: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Statement according to FCC 15.19: This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. this device may not cause interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

Statement according to RSS GEN Issue 5: This device

contains license-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS.

Operation is subject to the following two conditions:
L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. this device may not cause interference, and
 - a. l'appareil ne doit pas produire de brouillage, et
2. this device must accept any interference received, including interference that may cause undesired operation.
 - a. l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Training and Supporting Instruction

The manufacturer recommends completing and conducting training in accordance with §4 MPBetreibV (applicable in Germany). In order to make this easier, cosinuss° provides supporting instructions:

<https://training.cosinuss.com/en>

If you have any questions regarding the correct use of the product please contact cosinuss° customer service.

Customer service

If you are experiencing any unexpected operation or event, or if you need help or assistance in applying the c-med° alpha monitoring system, please contact our customer service with a detailed description of your concern:

Cosinuss GmbH
Kistlerhofstraße 60
D-81379 Munich, Germany

Phone: +49 (0)89 740 418 32
Email: support@cosinuss.com
Internet: www.cosinuss.com

Online Support: support.cosinuss.com

We will answer your request within 48 hours and do our best to provide you with a viable solution.

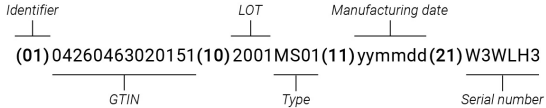
If you have any health questions, please always consult your doctor.

ENGLISH

Unique Device Identification

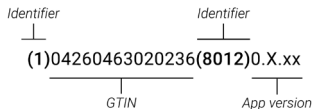
The Unique Device Identification (UDI) is a machine-readable tag that serves as a key to a UDI database. The Cosinuss GmbH as manufacturer identifies the entire product and associated parts with this code. This allows cosinuss° to trace back the origin of the product in case of a malfunction, defect or recall. Furthermore this code combats issues of privacy as well as eliminates the possibility of duplicate reports and counterfeiting. It contains the following information of the c-med° alpha.

Sensor UDI



PART NUMBER	IDENTIFIER	LENGTH	DESCRIPTION
GTIN (country prefix, manufacturer number, article number, check digit)	(01)	13+1	Contains information regarding the product and manufacture (+country) to identify the product worldwide
Manufacturing date	(11)	6	Format: yyymmdd
Typ	(10)	4	Model of sensor device (e.g.: MS01)
LOT	(10)	4	Identification to track production batch
Serial number	(21)	6	Unique serial number

App UDI



PART NUMBER	IDENTIFIER	LENGTH	DESCRIPTION
GTIN (country prefix, manufacturer number, article number, check digit)	(01)	13+1	Contains information regarding the product and manufacture (+country) to identify the product worldwide
Application identifier (Software version) number)	(8012)	4	c-med° App version X.xx will update with every new release

Serial number

The serial number consists of the last 6 digits of the UDI. cosinuss° uses this number to verify the c-med° alpha monitoring system during its usage.

Where to find the serial number?

The serial number can be easily found:

- On the in-ear sensor.
- On the packaging label.
- On the charging box label.
- In the About section of the c-med° App.



NOTE: Please always quote the serial number of your c-med° alpha when making enquiries.

Liability for material defects

If you purchase a new product you have a 24 months warranty of defects in case the product was defective at the time you received it.

To claim the warranty please address your seller. If the purchased item is defective, you are entitled to the following rights, whereby supplementary performance has priority:

- **Supplementary performance**
- **Reduction of price**
- **Withdrawal**
- **Compensation (for futile expenses)**



WARNING: Disposal

This product contains batteries and recyclable electrical waste:

- The c-med® alpha is **not** to be disposed of with household waste.

Statement

Cosinuss GmbH can only offer these services for products sold directly by cosinuss° or by salespersons authorized by cosinuss°. If you have purchased from another seller, please contact them for any claims.

Bluetooth® is a registered trademark of Bluetooth SIG Inc.

Metrological control (infrared thermometer):

A metrological control can be required at intervals of 2 years. The inspection can only be carried out by the manufacturer, an authority responsible for metrology or persons who meet the requirements of MPBetriebV § 6 (applicable in Germany).

Disclaimer

For questions about health and for medical advice, please always consult your doctor.

Cosinuss GmbH does not make any medical recommendations.

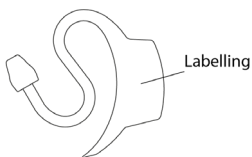
Cosinuss GmbH is not liable for any misuse or unauthorized use of the product.

Cosinuss GmbH is not liable for the loss or misuse of personal data or the product.

There are no replaceable parts in the in-ear sensor. Components supplied must not be exchanged. Replacement of the components or manipulation of the in-ear sensor must never take place without the consent of Cosinuss GmbH.

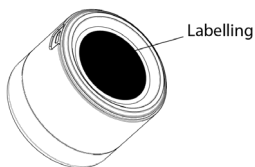
Where to find labeling information?

Sensor:



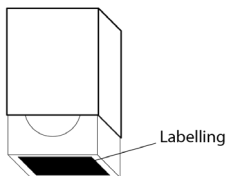
- CE marking,
- LOT number,
- TYP/Model number
- Serial number
- Size indicator
- 2D data matrix

Charging box:



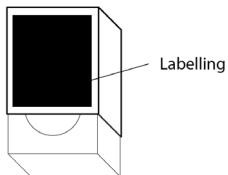
- Serial number
- 2D data matrix
- IP class
- CE marking
- LOT, TYP/Model
- Charging information
- Safety information
- UDI
- Manufacturer information
- Date of manufacturing
- Size indicator

Sales Label:



- 2D data matrix
- Medical class
- Size
- TYP/Model
- CE marking
- GTIN barcode
- UDI
- FCC ID, IC ID
- Operating, transport and storage
 ambiance
- Safety information
- Charging adapter type
- Manufacturer information
- Date of manufacturing

Principal Display:



- Statement of Identity
- Declaration of net quantity of
 contents.
- Product illustration

