

User manual

c-med° alpha*

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Charging box: MC01

Languages available

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English

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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:** 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.

Warnings and precautions

Health status

- The use of the c-med° alpha monitoring system cannot replace the consultation with your doctor.
- c-med° alpha is intended for use in a home healthcare environment only. This product is not suitable for diagnosing diseases, but it is a useful tool for monitoring the temperature, heart rate and the oxygen level. The c-med° alpha is intended only as an aid in the vital signs assessment of you or the monitored person.
- 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, 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 / 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 smartphone App 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 (approx. 20 °C) 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 15 – 40 °C (59 – 104 °F). Do not expose this product to extreme temperatures (below -25 °C / -13 °F or above 70 °C / 158 °F) or excessive humidity (\geq 90% relative humidity, non-condensing).
- At ambient temperatures of 40 °C, self-heating of 1 – 2 °C can increase the in-ear sensor temperature to max. 42 °C.
- 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).
- 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, smartphone 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, pests or children.

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. For

this reason, these devices may experience interference when a Bluetooth connection is established near such products.

- 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

Multiple factors can influence the vitals signs measurement inside the ear:

	NOTE: <ul style="list-style-type: none">• 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.
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External influencing factors

- Direct exposure to 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

- 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.¹ It varies depending on the location of the measurement, age and external factors. It also varies from person to person and varies throughout the day. The c-med° alpha is suitable as a continuous monitoring in-ear sensor for measuring the body temperature.

	NOTE: <ul style="list-style-type: none">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.
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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: <ul style="list-style-type: none">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.
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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 diseases (e.g. lung and cardiovascular diseases).

	NOTE: <ul style="list-style-type: none">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.
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¹ Körpertemperaturmessung, [Pschyrembel Online](#) (Abruf: 27.11.20)

² Herzfrequenz (HF), [Pschyrembel Online](#) (Abruf: 27.11.20)

³ Sauerstoffsättigung (sO₂), [Pschyrembel Online](#) (Abruf: 27.11.20)

Manufacturer information

This product is manufactured by Cosinuss GmbH.

CE 0123

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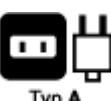
Patents: DE 102 011 081 815 B4, DE102013222131A1, US10478123B2, CA2966232A1,
CA2875901C, DK2717756T3, ES2728673T3

Designed in Germany.

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 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.
	CE 0123: The CE marking and the number of the notified body must attest conformity with the essential requirements Directive 93/42/EEC 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.
 Typ C	Plug type C: European power plug type for small consumers. (without earthing contact).
 Typ A	Plug type A: North American power plug type for small consumers (without earthing contact).
IP 21	Internal 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	Internal Protection 47: The device is protected against temporary submersion and against granular solid foreign bodies (diameter ≥ 1 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° App⁴ (Download)
- c-med° charging box (MC01)
- Power supply (USB charger adapter)

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.

- Charging cable (USB / Micro-USB)
- User manual

Product description

Intended use

The c-med° alpha is intended to be used as a medical measuring device in applications in a home healthcare environment. The c-med° alpha can continuously measure and visualize core body temperature, heart rate and blood oxygen saturation of healthy or sick persons starting at the age of 18.

Intended operator

Intended operator can be every adult person without mental restriction. The medical device is addressed to non-professional persons, who want to monitor their own or someone else's (e.g. partner, family member) health status. The design and the description in the user manual shall ensure a correct and safe handling.

Essential performance

- Measurement of body temperature in the ear
- Measurement of heart rate in the ear
- Measurement of SpO₂ in the ear
- Biocompatible materials
- Reliable, accurate and stable output data
- No harm due to radiation

Use and indication

The wearable in-ear sensor enables the continuous measuring of body temperature, heart rate and SpO₂. 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.

Furthermore, the medical indication of the in-ear sensor is to measure and monitor the vital signs continuously in cases of fever, respiratory diseases or cardiovascular diseases, combinations of these diseases or to check the health status of the user or the monitored person. In contrast to the common medical devices, the user only needs one device (i.e. in-ear sensor) to get three key parameters. Measurements of all body temperature, heart rate and SpO₂ are taken continuously, which makes it easier to classify the user's health state and the medical condition.

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

Contraindication

Do not use the in-ear sensor:

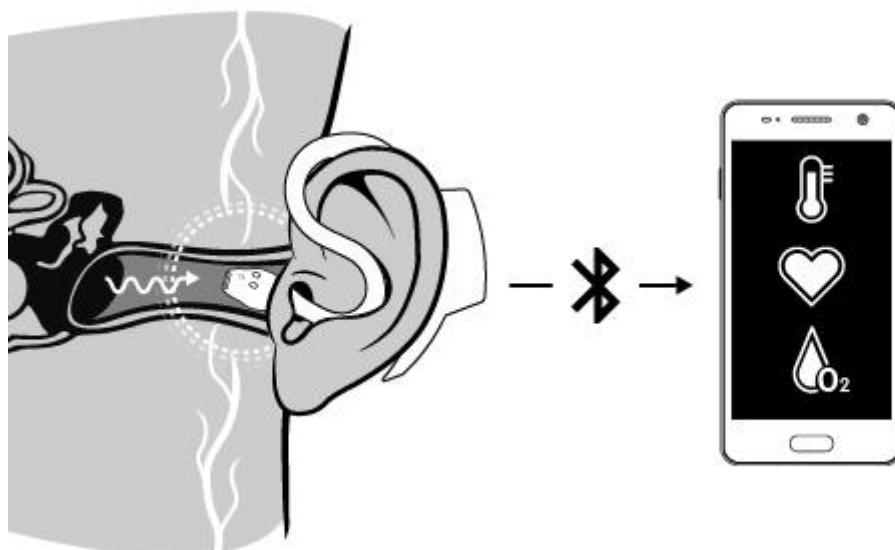
- In cases of any ear diseases.
- Outside or under windy conditions.
- In cases of CO intoxication.
- On children younger than 18 years.
- On any other measure site (only in the ear canal).
- In a magnetic resonance tomography room.
- In potentially explosive areas.

Application principle

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

The measured values of the vital signs are sent via Bluetooth Low Energy to the smartphone, where the c-med° App displays the values as long as the smartphone 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 smartphone and the corresponding c-med° App. Once the App is installed and opened on the smartphone the in-ear sensor must be taken from the charging box and the Bluetooth service on the smartphone 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

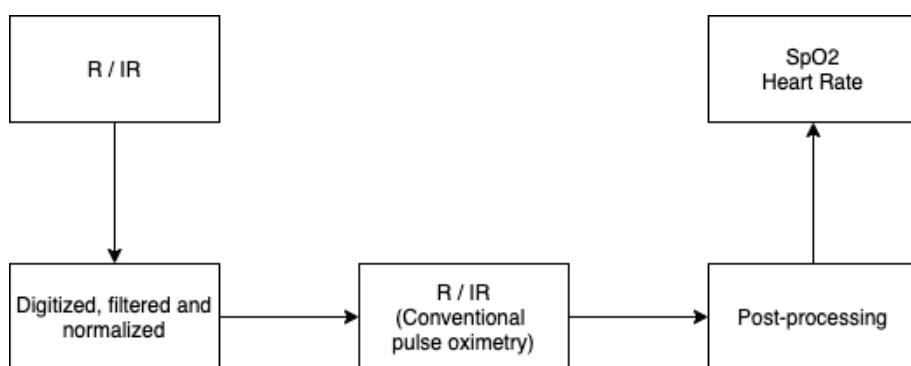
A thermal infrared sensor is used to make raw temperature measurements. This sensor passively measures the heat radiation of the eardrum plus the radiated heat of the surrounding auditory canal. Due to the so-called thermopile sensor the incident thermal radiation can be converted into a voltage signal (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 an accuracy of +/- 0.3 °C within the range of 34.0 °C – 43.0 °C.

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.



Signal processing principle of SpO₂ and heart rate.

Accuracy of heart rate

The heart rate shall be measured with an accuracy of +/- 2bpm (beats per minute) within the range of 50bpm – 180bpm.

Accuracy of SpO₂

The SpO₂ shall be measured with an accuracy of rms +/- 4% 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.

	<p>NOTE:</p> <ul style="list-style-type: none">• 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: <u>Warnings and precautions</u>).• 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 accuracy of A_{RMS} = 1.85 %. Adding the accuracy of the reference pulse oximeter (A_{RMS} = 2 %) this sums up to a final A_{RMS final} of 3.85 % which lies within the 4 % required in the standard DIN EN ISO 80601-2-61:2019.• Based on statistical distribution, two-thirds of the measurements with the c-med° alpha can be expected to fall within the overall root mean square of A_{RMS}=3.85% given above.• The use of functional test equipment cannot be used to verify the measurement accuracy.
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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.

	<p>NOTE:</p> <ul style="list-style-type: none"> • 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.
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Application environment

The c-med° alpha is designed for the use in an indoor, wind protected, home healthcare environment. Operating conditions:

- Temperature: 15 °C – 40 °C
- Humidity: max. 90 % rH
- Barometric pressure: 700-1060 hPa (700-1060 mbar)

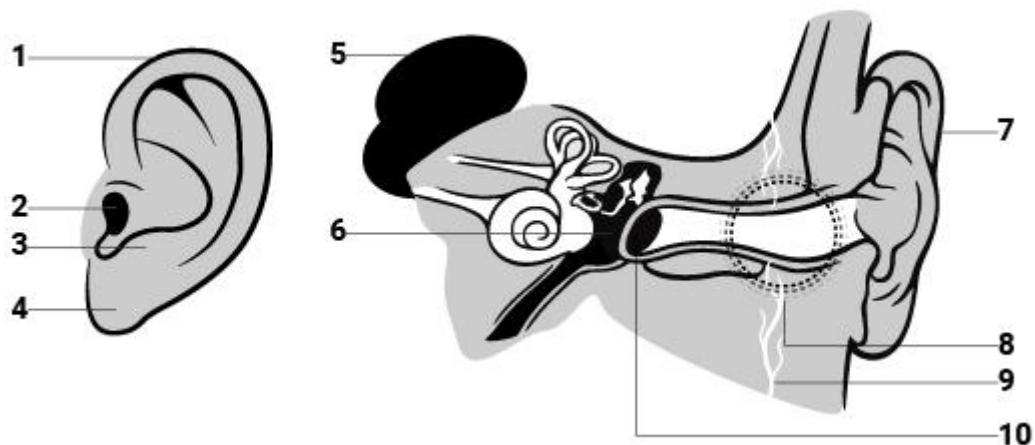
Transport and storage environment

For domestic use, please store the device at room temperature (approx. 20 °C). If this is not applicable, the in-ear sensor and the charging box shall be stored and transported under the following general condition thresholds.

- Temperature: -25 °C – 70 °C
- Humidity: max. 90 % rH

Components

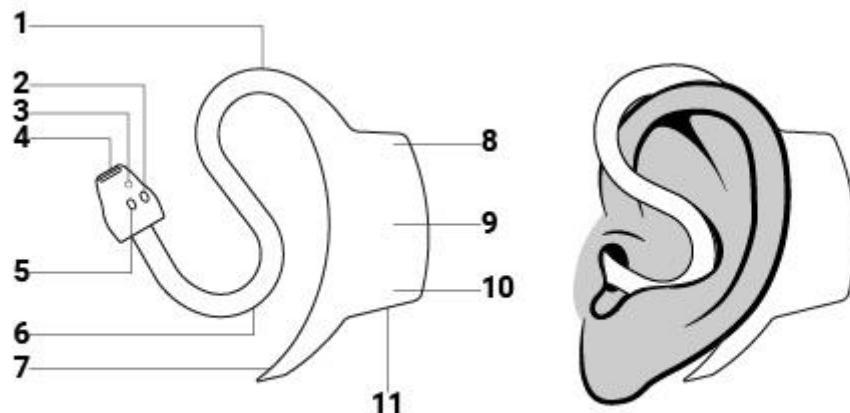
The c-med° alpha can only be used in combination with its charging box, a smartphone of the respective user and the installed App. The medical product is intended for the continuous and non-invasive body temperature, heart rate and SpO₂ measurement in the human auditory ear canal.



Place of measurement in the external auditory canal.

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

In-ear sensor



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

In-ear sensor & LED states

The LEDs of the c-med° alpha has the following possible states:

Status LED

LED behaviour	Description
Blinking blue (a short blink every 2.5 seconds)	Advertising. The in-ear sensor is broadcasting data to available receiving devices and is ready to establish a connection.

Blinking green (a short blink every 2.5 seconds)	Connected. The in-ear sensor is working properly.
Blinking red (a short blink every 2.5 seconds)	Connected. The in-ear sensor is working properly, but the battery is low.
Solid red (only applicable if sensor is placed in the ear)	Connected. But the in-ear sensor is probably damaged, due to improperly working sensors and circuits.
LED is OFF	In-ear sensor is turned OFF. In-ear sensor is positioned correctly in the charging box.

Charging LED

LED behaviour	Description
Solid red	In-ear sensor is charging.
LED is OFF	In-ear sensor is fully charged.

Smartphone application

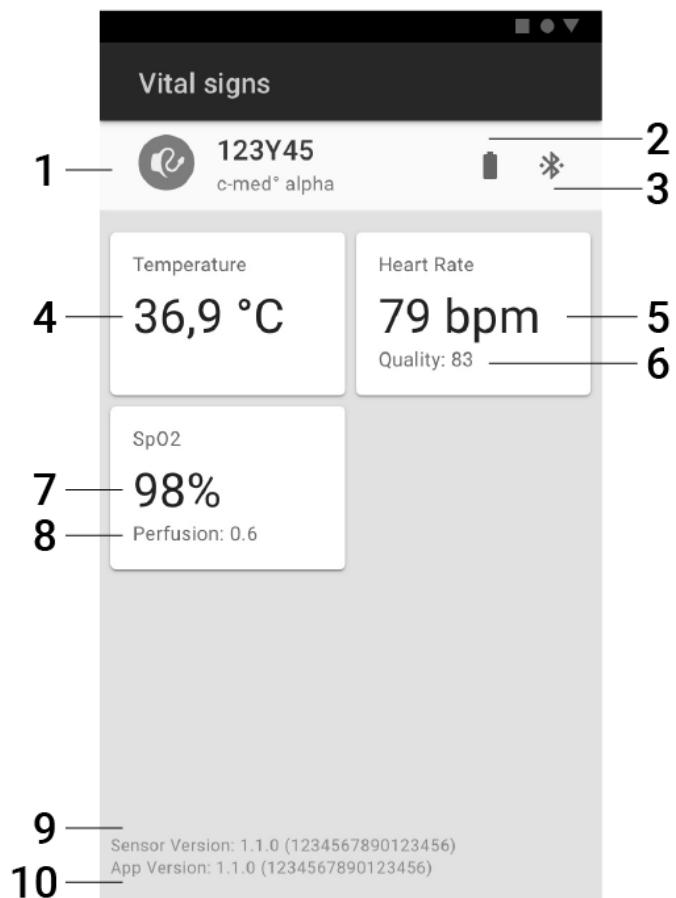
The c-med° smartphone application (App) serves as the display of the c-med° alpha.
The App is displaying:

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

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



Vital signs monitoring screen of the c-med° App.

1	Serial number and in-ear sensor type
2	In-ear sensor battery status
3	Bluetooth connection status
4	Current body temperature value (°C)
5	Current heart rate value (bpm)
6	Quality index
7	Current SpO ₂ value (%)
8	Perfusion index
9	Sensor Firmware Version
10	App Version

Accessories

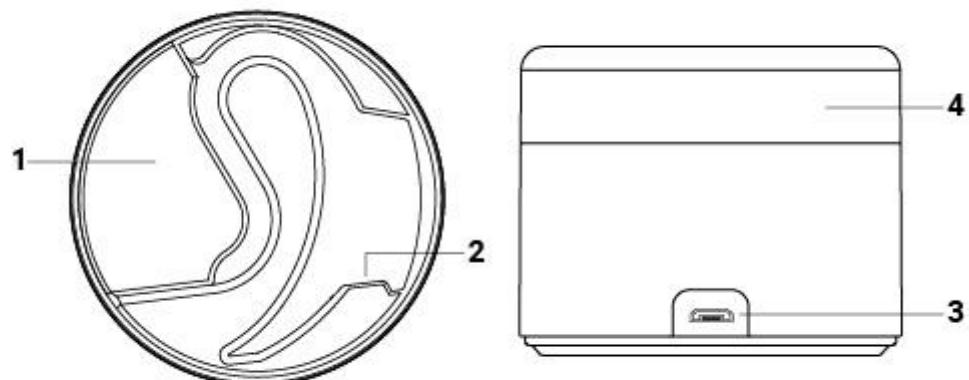
Charging and safe keeping

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: <ul style="list-style-type: none">• 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.
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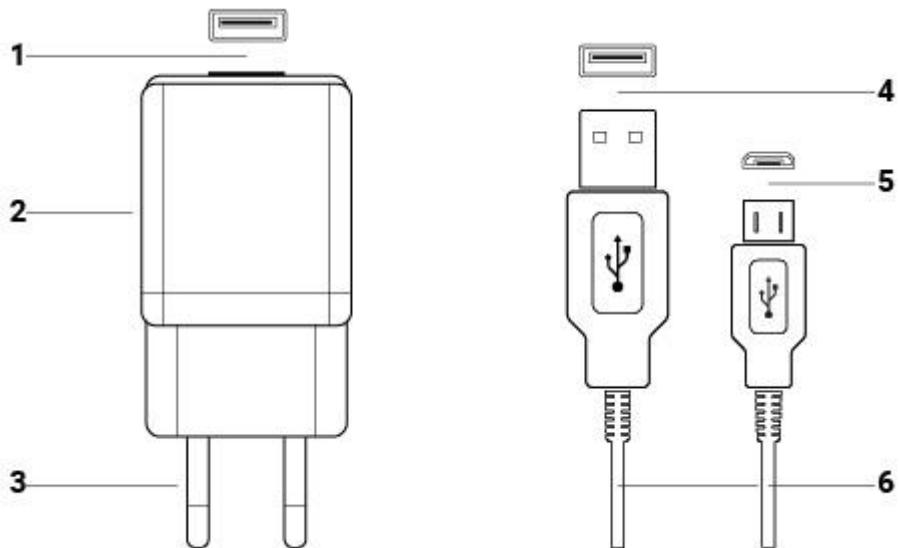
The charging box



The c-med° alpha charging box.

1	Recess
2	Charging contacts
3	Micro USB socket
4	Lid

The power supply and charging cable



The power supply and the charging cable.

1	USB socket
2	Power supply
3	Euro plug
4	USB plug
5	Micro USB plug
6	Charging cable

Operation

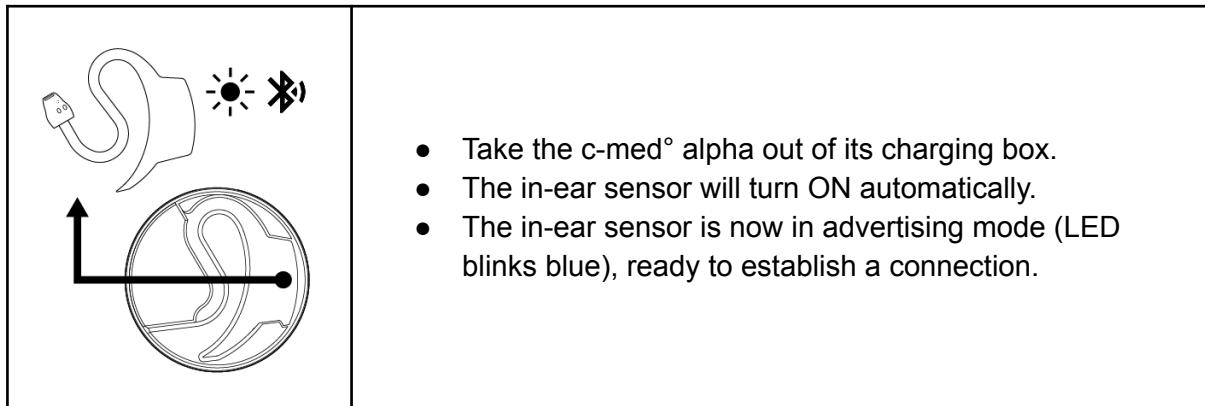
Preconditions

These preconditions are best practice to ensure before operation.

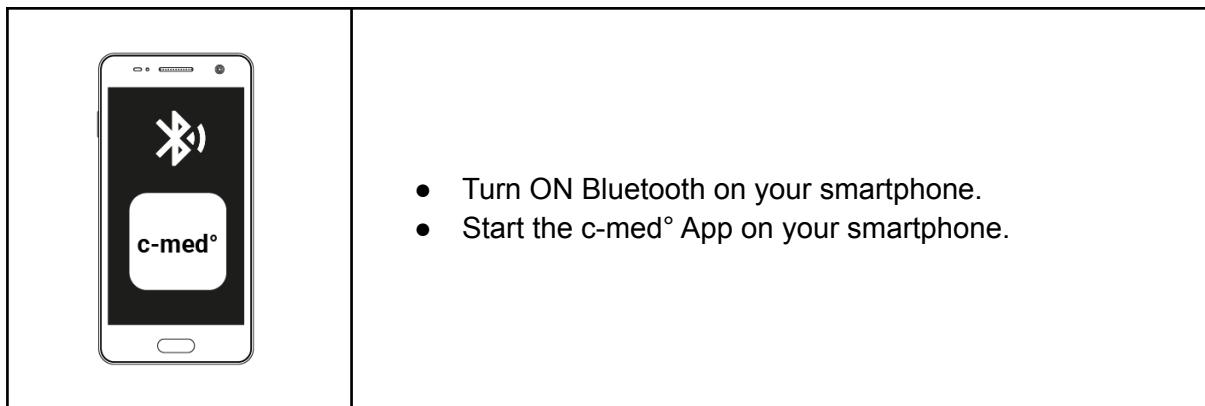
- Charge the c-med° alpha in-ear sensor to full capacity.
- Charge your smartphone to full capacity.
- Install the c-med° App on your smartphone.
- Establish network connection.
- Turn ON Bluetooth on your smartphone
- Read and understand the user manual.
- Read and understand warnings and precautions.

Initial operation

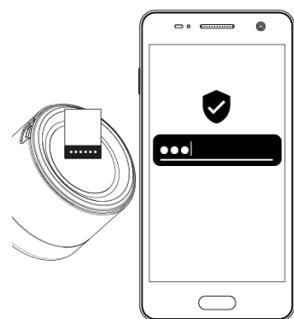
Turn in-ear sensor on



Open the App

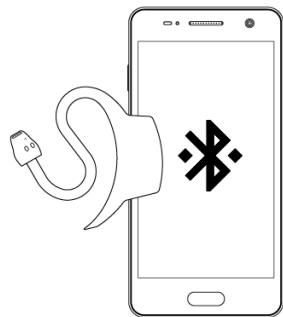


Identify the in-ear sensor



- Find the serial number of your in-ear sensor on the bottom of the charging box.
- 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.
- The App receives the incoming data from the in-ear sensor.

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

	<ul style="list-style-type: none">Guide the rear part of the c-med° alpha behind the auricle.
	<ul style="list-style-type: none">Leave the in-ear sensor gently hanging on top of your ear.
	<ul style="list-style-type: none">Carefully guide the in-ear sensor head into the entrance of the outer ear canal.
	<ul style="list-style-type: none">Adapt the neck of the in-ear sensor to the shape of the ear.



WARNING: Avoid excessive and deep pressure.



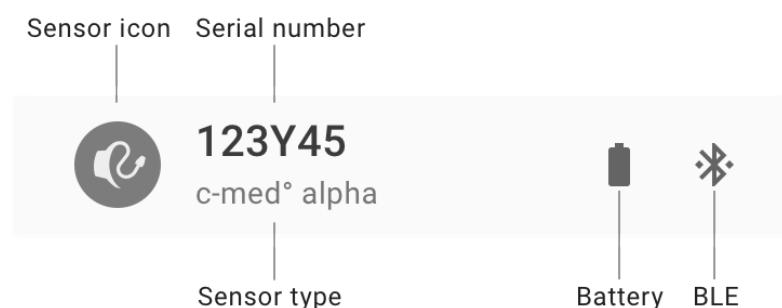
NOTE:

- 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.
- Eventually you want to pre-bend the sensor neck for easier application.

Monitoring

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.



Concept of the status bar.

Status bar behaviour

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.

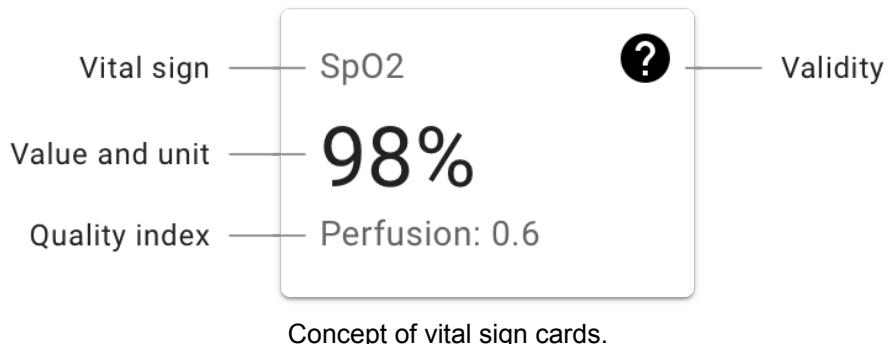
	Battery 20 – 100 %
	Battery 0 – 20 %

	Battery level unknown
	Bluetooth connected
	Searching for Bluetooth connection
	Bluetooth disabled

	NOTE: <ul style="list-style-type: none"> • In-ear sensor and smartphone must be within the Bluetooth maximum range of 10 meters. <p>See chapter: Warnings and precautions > Bluetooth.</p>
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Vital sign cards specification

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



Vital sign cards behaviour

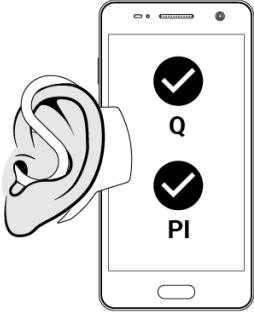
The vital signs values will be updated every second. If no new data arrives within 30 seconds, the current values expire. Then no values are displayed.

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

<p>SpO₂</p> <p>98%</p> <p>Perfusion: 0.6</p>	<p>Value is valid.</p> <p><i>Value: High emphasis.</i> <i>Quality index: Low emphasis.</i></p>
<p>SpO₂</p> <p>98%</p> <p>Perfusion: 0.0</p>	<p>Value is not valid.</p> <p><i>Notification: Question mark.</i> <i>Value: Low emphasis.</i> <i>Quality index: High emphasis.</i></p>
<p>SpO₂</p> <p>---</p> <p>Perfusion: -.-</p>	<p>No value.</p>

	<p>NOTE:</p> <ul style="list-style-type: none"> 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. The reliability of the signal is also affected by different influencing factors (See chapter: Warnings and precautions).
---	--

Check signal quality

	<ul style="list-style-type: none"> Check quality index and perfusion index Assess if the vital signs calculation is reliable. Improve the signal quality by avoiding influential factors. <p>See chapter: Warnings and precautions.</p>
---	--

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 SpO ₂
0.2 – 1.0	Reliable SpO ₂
more than 1.0	Unreliable SpO ₂

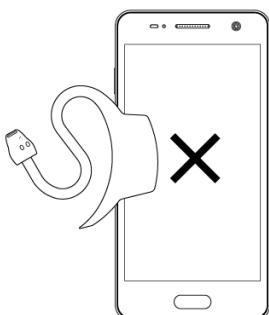


NOTE:

- 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](#)).

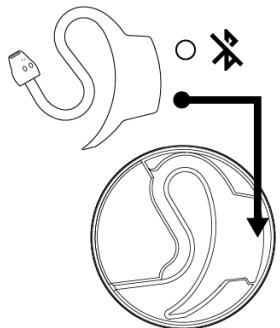
Shutdown

Close the App



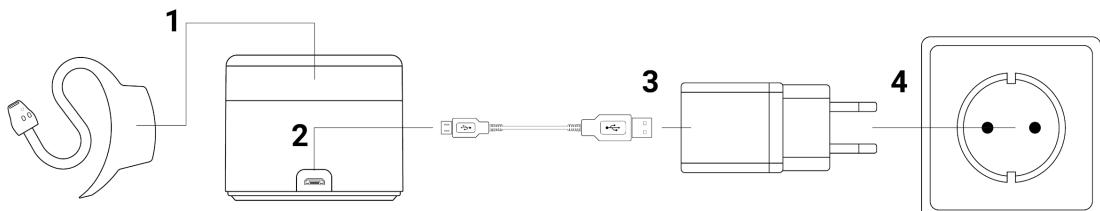
- Close the c-med° App on your smartphone.
- The in-ear sensor will lose connection.
- The measurement will stop.
- The in-ear sensor goes back to advertising mode (LED blinks blue).
- The in-ear sensor will not send any data anymore.

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



WARNING:

- 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.

	<ul style="list-style-type: none"> • 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 and the harmonized standard ISO 13485. The c-med° alpha and the associated software is a class IIa medical device and conforms to the MDD medical device directive 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.

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 smartphone is turned OFF.	Turn ON Bluetooth on the smartphone and retry.
The Bluetooth connection is interrupted repeatedly.	The status bar in the monitoring screen shows varying Bluetooth states.	See chapter: <u>Warnings and precautions > Bluetooth</u>	See chapter: <u>Warnings and precautions > Bluetooth</u>
The serial number is wrong.	Error message.	Typing error.	Correct typing error and try again.
The serial number is not recognized.	Error message.	The smartphone 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: <u>Customer support</u>

Vital signs display

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

Wearing comfort

Problem	Indicator	Reason	Solution
The in-ear sensor hurts.	Individual perception.	Wrong fitting.	<p>Check the correct fitting of the in-ear sensor.</p> <p>See chapter: <u>Apply the in-ear sensor to the ear</u></p>
		Wrong in-ear sensor size.	Check the long term behaviour of the quality indices.
		Exceeded wearing time. More than 12 hours without interruption.	Cancel the measurement.

			See chapter: <u>Warnings and precautions</u>
		Sensor mechanically broken.	Cancel the measurement. See chapter: <u>Warnings and precautions</u>
		The monitored person's ear is injured.	Cancel the measurement. See chapter: <u>Warnings and precautions</u>

Care and cleaning

Care

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

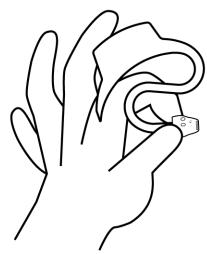
The sensor head and the sensor lens are the most sensitive parts of the c-med° alpha. They should always be clean and faultless to ensure accurate monitoring. Store and charge your in-ear sensor only within the c-med° alpha charging box.

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

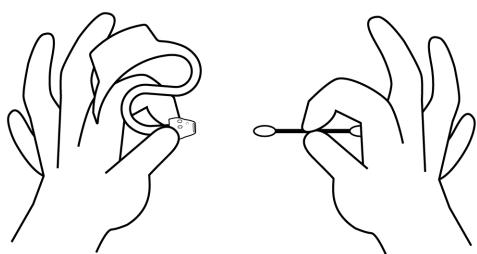
Cleaning

In-ear sensor

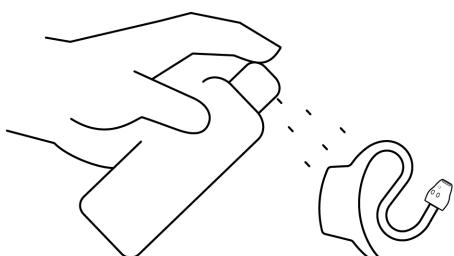
Before and after each use clean the in-ear sensor as shown in the following instructions. For disinfection and cleaning Cosinuss GmbH recommends the use of 'Schülke mikrozid® AF liquid' as an alcohol-based cleaning agent. Alternatively, any other disinfectant with the following composition can be used: 35% (w/w) 1-propanol, 25% (w/w) ethanol, no fragrances, undiluted application.



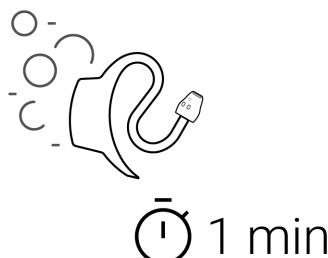
1. Fixate the sensor head between your fingers.



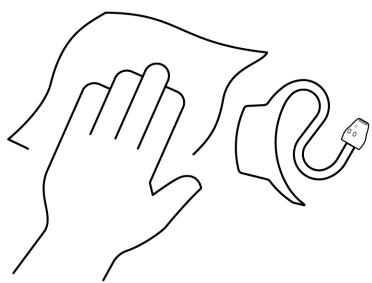
2. Clean the sensor head with a cotton swab soaked in disinfectant.



3. Distribute disinfectant evenly over the entire in-ear sensor.



4. Let the disinfectant work for about 1 minute.



5. Dry the in-ear sensor with a disposable cloth.



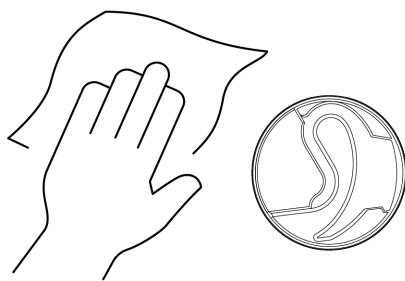
6. The in-ear sensor is now ready for use.



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



1. Clean the charging box with a simple wipe disinfection.



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

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 (SpO_2), core body temperature.
Status indicators	RGB-LEDs
Vital signs display	Smartphone application (App): Current temperature ($^{\circ}C$), heart rate (bpm) and SpO_2 (%) in numbers.
Medical product classification	IIa
Certification	Medical CE & FCC, Bluetooth
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 - ISO 10993-5 /-6 /-11 - USP class VI
Color	White
Battery life	approx. 12 hours
Ambient temperature for usage	15 $^{\circ}C$ – 40 $^{\circ}C$ (59 $^{\circ}F$ – 104 $^{\circ}F$)
Barometric pressure for usage	700 – 1060 hPa (700 – 1060 mbar)
Storage temperature and relative air humidity	Temperature Relative Humidity -25 $^{\circ}C$ – 5 $^{\circ}C$ / 5 $^{\circ}C$ – 35 $^{\circ}C$ \leq 90% (non-condensing) 35 $^{\circ}C$ – 70 $^{\circ}C$ at a water vapor pressure up to 50 hPa
Protection type	IP47 solid foreign bodies with diameter \geq 1.0 mm, submersible to a depth of 1 m
Appliance class	II

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

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	4 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

Rechargeable battery

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	Heart rate, core body temperature, SpO ₂

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 ⁵	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.
Resolution	0.01 °C
Technical accuracy	±0.2 °C
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

⁵ Information about wavelength range can be especially useful to clinicians.

Vital signs

Body temperature

Type	Infrared thermometer, direct reading
Measuring range	34 °C – 43 °C
Resolution	0.1 °C
Accuracy	Inside of the measuring range ± 0.3 °C Outside of the measuring range (--.)
Interval	Variable, standard 0.1 Hz

Heart rate

Type	PPG
Measuring range	35 bpm – 220 bpm
Resolution	1 bpm
Accuracy	± 2 bpm
Interval	Variable, standard 1 Hz

Oxygen saturation (SpO_2)⁶

Type	PPG
Measuring range	70 % – 100 %
Resolution	1 %
Accuracy	± 4 %
Interval	Variable, standard 1 Hz

Accessories

Charging box

Typ	MC01
-----	------

⁶For detailed explanations of the measuring principle and the measuring accuracy, please see chapter: Technical principle

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 Objects bigger than 12,5 mm, waterdrops
Protection class	II
Socket	Micro-USB B

Power supply

Model	FJ-SW2050501000E (Type C), FJ-SW2050501000U (Type A)
Usage	Power supply, voltage transformer
Input	100 – 240 V ~ 50/60 Hz, 0.35 A Max.
Output	5 V, 1000 mA
Plug	Plug-type C (CEE 7/16), Plug-type A
Socket	USB A

Model	FJ-SW2660501000E (Type C), FJ-SW2660501000U (Type A)
Usage	Power supply, voltage transformer
Input	100 – 240 V ~ 50/60 Hz, 0.35 A Max.
Output	5 V, 1000 mA
Plug	Plug-type C (CEE 7/16), Plug-type A
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

Smartphone 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	The software download is free with the purchase of the hardware product. <ul style="list-style-type: none"> • Google Play Store for Android • Apple App Store for iOS
Version	The version of the installed app can be viewed at any time in the app page About c-med°. Updates reserved.

Standards and directives

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.

EN 980: Symbols for use in the labeling of medical devices.

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.

This product complies with the provisions of the EC Directive 93/42/EEC.

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.

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.

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.

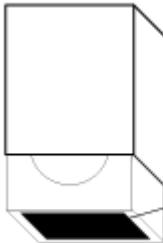
Manufacturer number	Check digit	Typ	LOT
4-260463-02014-4-0-MS02-2001-ABC123			
Country prefix	Article number	Packaging index	Serial number

Serial number

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

Where to find Labeling information?

Where is the Label?	Information on Label
SENSOR:  Labelling	<ul style="list-style-type: none">• CE marking,• LOT number,• TYP/Model number
CHARGING BOX:	<ul style="list-style-type: none">• Serial number

	<ul style="list-style-type: none"> • IP class • CE marking • LOT, TYP/Model • Charging information • Safety information • UDI • Manufacturer information • Date of manufacturing
SALES LABEL: 	<ul style="list-style-type: none"> • Production QR-code • 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

Where to find the UDI and serial number?

Both numbers can be easily found:

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

	NOTE: <ul style="list-style-type: none"> • Please always quote the UDI and serial number of your c-med° alpha when making enquiries.
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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)

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.

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.