c-med° alpha

Instruction for Use (IFU)

⚠ ***Please read and understand the Instruction for Use before using the device.***

1. Device Identification

Device name and model:
Hardware: c-med° alpha, in-ear vital signs sensor; Software: c-med°, mobile device application.

Hardware variants:
In-ear sensor: c-med° alpha, Type: MS01, Tip size variations (diameter): Small (S, 10 mm), Medium (M, 11.5 mm), Large (L, 12.5 mm); Charging boxes: 1) Single Sensor, Type: MC01; 2) Double Sensor, Type: RC01, color variations: Orange, Black.

Power supplies:
Sockets: Micro-USB (MC01), USB C (RC01); Compatible models: FJ-SW2660501000E (266 CE), FJ-SW2660501000U (266 UL), Output: 5 V, 1000 mA M050120-S86EUU (CE), M050120-S86USU (UL), M050120-S86BSU (UKCA), Output: 5 V, 1200 mA; Cables: USB A to Micro-USB, 2464 OD3.0 1500 ± 50 mm (MC01), USB A to USB C, 2464 OD3.0 1500 ± 50 mm (RC01).

Software versions:
Firmware version: min. 2.3.0; Mobile application: Application name: c-med°, Basic UDI: 426046302 CMEDAPP4R, App version: min. 0.7.XXX; Operating system: min. iOS 12, min. Android 8.1.

UDI-DI:
See labeling information on the labeling and packaging of the product or in the "About" section of the app.

Serial number:
Directly marked on sensor device.

Additional compatible software:
cosinuss° Health (Mobile application)[1]

[1] *For safety warnings related to cosinuss° vital signs sensors or optional compatible devices please refer to the User manual of the relevant device.*

2. Intended Purpose

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 a home care environment 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, 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.

Indications:
Monitoring vital signs; Monitoring of: hypothermia, hyperthermia (fever), circulatory system changes, tachycardia and bradycardia; health state classification and monitoring.

Contraindications:
Ear diseases or injuries, CO intoxication monitoring.

3. Safety Information

General Warnings:
In-ear use only. Do not apply to other body sites. Do not use on children under 18 years. Do not use the device with active ear infections or injured ear canals.

Discontinue use if discomfort, pain, or allergic reactions occur. Maximum continuous wear time: 12 hours. Minimum application time: 5 minutes. Do not use under windy conditions or direct sunlight.

Use only with systems compliant with the cosinuss° API. The device does not recommend any concrete treatments

Physiological Risks:
Ear canal irritation. Potential allergic reactions to device materials. Risk of incorrect measurements. Avoid looking directly into the sensor head's LEDs to prevent eye damage from invisible infrared or other radiation.

Measurement Influencing Factors:

External:
1. Environmental conditions: Direct exposure to cold, heat, wind, sun, water; ambient temperature variations; strong ambient light;
2. User-related factors: Body movement; jaw movements (speaking, chewing); pressure on the device (lying on the ear);
3. Device condition: Dirty sensor head; damaged sensor head; incorrect sensor attachment; poor sensor fit; incorrect sensor size; moisture in the sensor.

Internal/Physiological Factors:
1. Anatomical considerations: Ear canal variations; presence of cerumen (ear wax); dark skin pigmentation;
2. Circulatory factors: Poor blood circulation; low pulse quality; poor perfusion; venous pulsations (e.g., head-below-heart position);
3. Blood composition factors: Anemia; low hemoglobin concentrations; sickle cell anemia; carboxyhemoglobin; methemoglobin; dysfunctional hemoglobin;
4. Medical interventions: Presence of cardiogreen or other intravascular dyes.

Measurement Limitations:
1. Arrhythmia detection: Pulse oximeter measurements may not detect certain arrhythmias; not a substitute for ECG-based arrhythmia analysis;
2. Circulatory arrest: Temperature, pulse rate, and SpO2 measurements may be incorrect during sudden circulatory arrest due to ineffective blood circulation.

Technical Safety Precautions:
Maintain the device within the specified temperature range. Protect from excessive moisture. Avoid mechanical stress during insertion/removal. Clean and disinfect as per instructions. Use only approved equipment for charging, storage, and operation. Disconnect the charging box from the mains after charging. Do not modify the equipment.

Electromagnetic Compatibility (EMC):
Complies with IEC 60601-1-2 standards. No harm regarding EMC and human exposure. May be affected by portable RF communications equipment. Avoid use near strong electromagnetic fields.

Data and Privacy Risks:
Potential for wireless data transmission vulnerabilities. Ensure secure network connections. Protect personal health information.

Biological Safety:
Biocompatible materials. Hypoallergenic design. Regular cleaning to prevent microbial growth.

4. Performance Characteristics

Clinical benefits:
Continuous measurement of body temperature, pulse rate and arterial blood oxygen saturation in the ear canal. Reliable, accurate and stable measurement. Good readability of measured data. Long-term use and low radiation.

Measurement specifications:

Body Temperature (Direct reading):
Measurement range: 22.0–43.0°C, Laboratory Accuracy: ±0.2°C (35–42°C) ±0.3°C (other ranges), Display range[2]: 34–43°C, Resolution: 0.1°C.

Pulse Rate:
Measurement range: 40–220 bpm, Accuracy: ±4 bpm, Display range[2]: 40–220 bpm, Resolution: 1 bpm.

Functional Oxygen Saturation (SpO2):
Measurement range: 0–100%, Accuracy: ARMS ±3% (70–100%, for 2/3 of the measurements)[3], Display range[2]: 70–100%, Resolution: 1%.

[2] *Display ranges refer to c–med° app; other compatible software may vary.*

[3] *The c-med° alpha measures functional oxygen saturation (SpO2) with Accuracy Root Mean Square (ARMS) = 3% accuracy (70-100% SpO2), validated through controlled desaturation studies against blood gas analysis in healthy adult volunteers. Since the pulse oximeter measurements are statistically distributed, it can be expected that about two-thirds of the measurements will be within ± ARMS compared to CO-oximeter measurements. Functional test equipment is not suitable for accuracy verification. Detailed clinical validation reports are available upon request.*

Device characteristics:
Battery life: Min. 12 hours; Charging time: approx. 1 hour; Size: 55 x 59 mm; Weight: 7g; IP: 47 (see Symbols glossary); Material: Medical-grade, hypoallergenic; Wavelength and max. optical output: Red LED: 655 nm, 14 mW; Infrared LED: 940 nm, 11 mW; Green LED: 530 nm, 14 mW; Accelerometer: 3-axis, linear; Infrared thermometer: Direct mode (no adjusted mode available); Default sampling rates: PPG 200 Hz, IR-Thermometer 0.1 Hz, Accelerometer 100 Hz, Pulse Rate 1 Hz, SpO2 1 Hz, and Body Temperature 0.1 Hz.

Mobile Device Requirements:
iOS: min. 12.0; Android: min. 8.1; Bluetooth: min. 4.2; Recommended screen resolution: 1280x720; Required storage:150MB; Internet connectivity initially required (sensor verification, external links).

Network characteristics:
Wireless Transmission: Bluetooth Low Energy (BLE), Frequency: 2.4 GHz, ≤ 0 dBm, Transmission range: Max. 10 meters; Network Connectivity: Wi-Fi: 2.4 GHz / 5 GHz, Protocols: HTTPS.

IT Security Measures:
Data Protection: Bluetooth transport encryption, no data storage (c-med° app), GDPR compliance, user consent management; Access Control: Serial number verification; Vulnerability Management: Regular security updates, secure API interfaces, third-party security certification.

5. Installation and Setup

Hardware Setup:
Physical setup: Clean, dry hands before handling, Inspect device for damage before use, Ensure ear canal is clean and free from obstructions, Verify proper ear canal fit due to sensor size.

Device preparation: Charge using provided charging adapter/cable, Clean and disinfect device.

Software installation:
Download c-med° App: iOS: App Store, Android: Google Play Store.

First-Time Setup:
1. Select preferred language, 2. Check required app permissions (Bluetooth, Location), 3. Agree with privacy policy. Note: No user account is required.

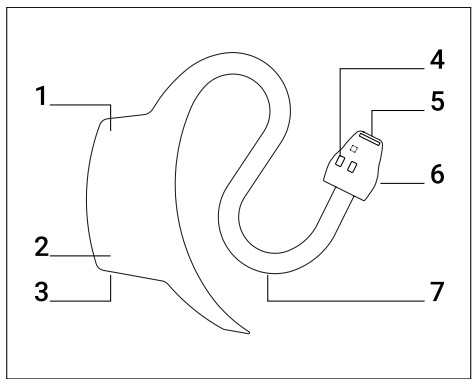
System configuration:
Turn on Bluetooth. Establish network connection.

User Access Levels/Permissions:
Using the device with the provided c-med° application there is only one personal user with viewing permission on own health data on display.[4]

[4] *With compatible software the device is capable of broadcasting Bluetooth, allowing multiple devices to simultaneously receive and display the sensor data.*

System Integration:
Supported Integration Methods: cosinuss° Bluetooth API specification; Third-Party System Requirements: Must adhere to cosinuss° API specifications, Compliance with medical data protection standards, Secure authentication mechanisms, Limited read-only access by default.

6. Usage Instructions

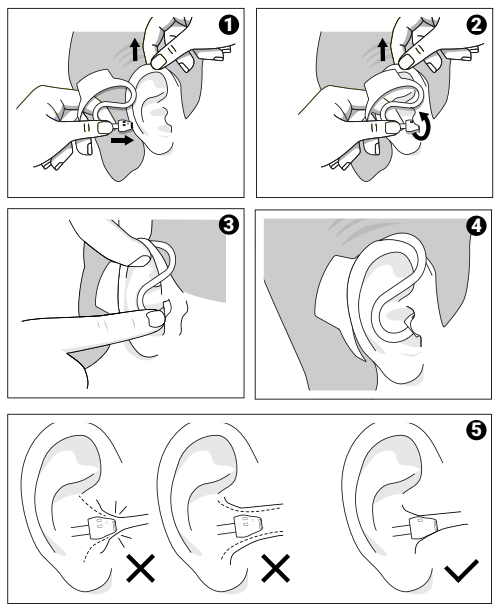


Product description:
1. Status LED, **2.** Charging LED, **3.** Charging contacts, **4.** Measurement LED and Photodiode,**5.** Infrared thermometer, **6.** Sensor head, **7.** Sensor neck.

Device Preparation:
1. Charge device fully before first use. **2.** Inspect device for damage and contamination. **3.** Clean device, hands and ear canal. **4.** Choose appropriate ear tip size.

Insertion and Positioning:
1. Insert sensor gently into ear canal (preferably right ear). **2.** Ensure snug, comfortable fit. **3.** Device should sit securely without pressure. **4.** Measurement LED should face toward back of head. **5.** Fixate sensor neck into auricle.

Sensor Size Validation:
The sensor tip has the right size if: Sensor fills ear canal diameter; Tip has minimal protrusion from ear canal; Measurement LED light is not directly visible; Stable measurement readings (i.e., Measurement quality indicators do not exceed thresholds).



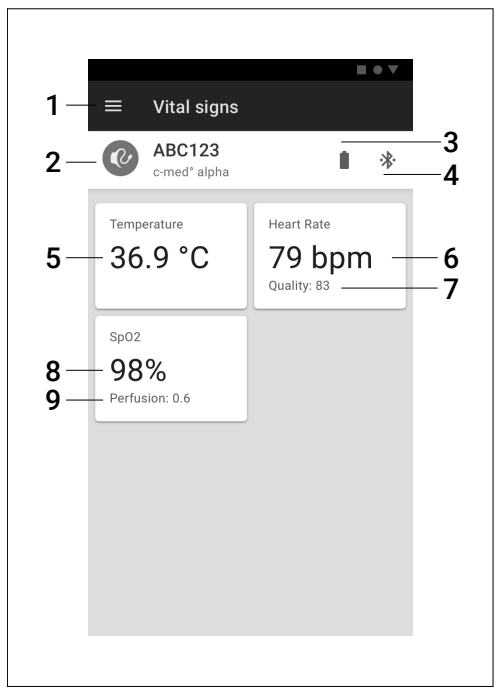
Power and Connectivity:
1. Power on the device by taking it out of the charging box and turn it off by placing it back in. **2.** Receive data via Bluetooth: Automatically when sensor serial number is entered.

Indicator lights:
During charging (Charging LED):
Red: Charging, Off: Fully charged;

After Power on (Status LED):
Green: Battery 100–51%, Orange: Battery 50–26%, Red: Battery 25–6%, Blinking Red: Battery below 6%;

During Use (Status LED):
Blinking Blue: Sensor is searching, Blinking Green: Sensor is measuring, Blinking Red: Battery below 6%, Red: Sensor defective;

After Power off (Status LED):
Blue: Sensor is turning off, Off: Sensor is off.



Software Interface, Main Screen:
1. Menu (Navigation drawer to access all app destinations); **2.** Device identification (Serial number, In-ear sensor type); **3.** Battery status; **4.** Bluetooth connection status; **5.** Current body temperature value (Degree Celsius) ; **6.** Current pulse rate value (beats per minute); **7.** Quality index (a.u.); **8.** Current SpO2 value (percentage); **9.**Perfusion index (percentage).

Display of Data:
The display continuously updates to show real-time vital sign data. If no new data is received, the display will expire after 30 seconds.

Measurement quality indicators:
A question mark appears when the data may be invalid – for example, in SpO_2 measurement if the perfusion is outside the valid range of 0.2 % to 2.0 %, or in heart rate measurement if the signal quality falls below the threshold of 30 a.u.

Offline support:
The system supports offline operation after initial verification, allowing the sensor to function without an active network connection.

Error Messages and Troubleshooting

⚠ *Contact support if persistent: support@cosinuss.com*

Device not connecting:
Check Bluetooth range (10m). Restart Bluetooth. Reboot device. Restart/Reinstall App. Check battery level.

Measurement Inaccuracy:
Reposition device (Preferably right ear with sensing elements oriented towards the back of the head). Clean ear canal. Clean device. Check for defects. Check environmental conditions. Avoid head-below-heart position.

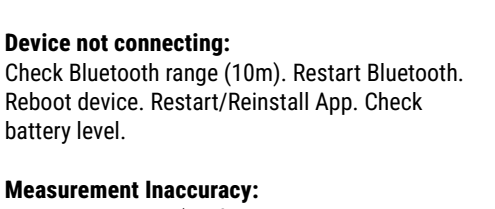
Battery Issues:
Check that device is correctly seated in the charging box. Use original charger. Avoid extreme temperatures.

Cleaning and Disinfection

⚠ *Cleaning before and after each use. Disinfection between patients.*

⚠ *Safety During Cleaning: Disconnect from power, No use possible during charging, No usage during cleaning. Do not use abrasive materials/ sharp objects. Do not use UV-light/Ultrasound/Hot water/ harsh chemicals. Avoid excessive pressure.*

Recommended Cleaning Agents:
Primary recommendation: Schülke mikrozid® AF liquid and wipes; Alternative: Alcohol-based disinfectant (60% w/w), No fragrances, Undiluted application.



In-ear sensor cleaning:

1. Cleaning: Fixate sensor head between fingers. Use cotton swab with disinfectant. Remove visible dirt with disinfectant wipe.

2. Disinfection Process: Distribute disinfectant evenly. Cover the entire in-ear sensor. Ensure coverage behind sensor head. Let disinfectant work for 1 minute.

3. Mechanical Cleaning: Use disinfectant wipe. Rub surface thoroughly. Use cotton swab for hard-to-reach areas. Gently turn while cleaning under sensor head.

4. Drying: Use disposable cloth. Ensure complete drying before use.

Charging box cleaning:
Wipe desinfection.

7. Maintenance and Updates

⚠ *Do not maintain or update devices when in use on patients.*

⚠ *Not Safe to Use If: The device has physical damage, the red status LED is on, in-app error messages appear, measurement accuracy is compromised, battery performance is insufficient, the Bluetooth connection is unstable, the sensor is unresponsive, or data transmission is unreliable.*

⚠ *Handling precautions: Avoid extreme temperatures. Keep away from direct sunlight. Protect from moisture. Use only provided charging accessories. Do not touch charging contacts or USB interface of the charging box simultaneously with the monitored person. Store in charging box when not in use. Keep away from pets, pests and children. Cables may pose risk of strangulation to children.*

Hardware maintenance:
Routine inspection: Visual check for physical damage. Inspect sensor head and lens. Verify battery contacts and are intact.

Battery care:
Charge device in charging box with supplied equipment. Avoid complete discharge. Store at room temperature. Full charge recommended monthly if not in use.

Software update procedures

App Updates:
Default setting: Automatic updates. Wi-Fi or mobile data required. Updates downloaded in background. Minimal user intervention.

Sensor Firmware Updates:
Install cosinuss° Lab app. Connect sensor with app. Navigate to Settings > Device Updates. Check for available updates. Ensure device is charged >50%. Confirm update installation. Do not interrupt update process.

Update Types:
Firmware updates; Security patches; Performance improvements; New feature additions; Compatibility enhancements.

Backup and Restore Procedures:
With the c-med° app there is no Data Storage/ Backup.

8. Storage and Handling

⚠ *Measurement accuracy and device performance depends on regular maintenance and specified operational environments. Follow guidelines carefully.*

Storage conditions
(applies to all parts of equipment)

Environmental Requirements:
Temperature ranges: -25°C to 70°C, Humidity conditions: 0% – 95% (non-condensing), Water Vapor Pressure: Up to 50 hPa, Atmospheric Pressure: Recommended: 700 hPa – 1060 hPa.

Recommended Storage Practices:
Use original packaging/charging box for storage and transport. Protect from direct sunlight. Avoid mechanical stress. Keep away from magnetic fields. Store in clean, dry environment.

Long-Term Storage Guidelines:
Charge to 50% before long-term storage, Store in temperature-stable location, Perform periodic (quarterly) system check, Protect from dust and corrosive environments.

Hardware lifespan:
Expected Service life of all supplied parts: 2 years from Manufacturing date; No replaceable parts. Device is calibrated upon delivery. The metrological inspection must be carried out in accordance with the respective operator regulations (e.g., MPBetriebV / MPBV).

Operational Environments:

Continuous Operating Conditions:
Temperature Range: 0°C – 40°C, Humidity: 15% – 95% rH (non-condensing), Barometric Pressure: 620 hPa – 1060 hPa (620 mbar –1060 mbar).

Transient Operating Conditions:
Temperature Range: 0°C – 50°C, Humidity: 15% – 90% rH (non-condensing), Water Vapor Partial Pressure: less than 50 hPa.

Critical Operating Warnings:

Temperature Measurement Accuracy:
Body temperature measurements are accurate at ambient temperatures 0-50°C. Device may reach up to 42°C in-ear due to body contact and self- heating.[5]

[5] *Particularly at ambient temperatures above 40°C. ASTM laboratory accuracy requirements differ by thermometer type: IR thermometers ± 0.2°C (37 – 39°C range), while mercury and electronic thermometers require ±0.1°C per ASTM E667-86 and E1112-86 standards.*

Environmental Transition Risks:
Sudden temperature changes may impact measurement accuracy. Specifically, moving from warm indoor to cold outdoor environments. Potential accuracy reduction when temperature drops below 0°C.

Performance Limitations:
Outside specified operating conditions, cosinuss° cannot guarantee: Vital sign measurement accuracy, Sensor performance, Device reliability.

Recommended Usage Precautions:
Minimize rapid temperature transitions. Allow device to stabilize when moving between environments. Avoid extreme temperature differentials. Protect device from direct environmental exposure.

Software lifecycle support

Update and Support Timeline:
Guaranteed Software Updates: 2 years; Security Patch Support: 3 years; Minimum Compatibility: iOS versions: Last 3 major releases, Android versions: Last 3 major releases.

End of Life Management:
After 2 years, the manufacturer is not responsible for any performance, accuracy, or reliability issues. For safety reasons, maintenance and storage as described is advised during the product's lifespan. For upgrade, replacement or recycling options, please contact our customer service.

Disposal instructions:
This device contains a non-removable lithium-ion battery and must be disposed of as electronic waste (e-waste). Do not dispose of it in regular trash. Follow local electronic recycling regulations and use designated recycling points. Do not incinerate. No personal data is stored on the device or in its software (other compatible software may vary).

9. Additional Information

⚠ *Always refer to the most recent version of the Instructions for Use. Contact manufacturer for the latest documentation.*

⚠ *The manufacturer recommends to conduct training in accordance with §4 MPBetreibV*

⚠ *Always seek professional medical advice for health concerns. This device helps monitor vital signs but does not treat or diagnose any medical condition.*

Technical support contact

Manufacturer information:
Cosinuss GmbH; Kistlerhofstraße 60
81379 Munich, Germany; cosinuss.com

Also available in the About section of the app and on the labeling of the charging box.

Customer Support:
Email: support@cosinuss.com
Phone: +49 (0)89 740 418 32
(Support Hours: Monday-Friday, 9:00-17:00 CET)

Online Support:
Additional Training:
training.cosinuss.com
Firmware Updates:
cosinuss° Lab app

Regulatory Information:
Medical Device Classification: Class IIa
Regulatory Compliance: Medical Device Regulation (MDR) 2017/745

Declaration of Conformity:
A full Declaration of Conformity is available upon request from the manufacturer.

Clinical validation:
Detailed reports available upon request.

Notice to User or Patient: Any serious incident with the device and/or software should be reported to the manufacturer (support@cosinuss.com) or to Competent Authorities.

Standards and Regulatory Compliance:
Medical Device Regulations: EU MDR 2017/745, Radio Equipment Directive 2014/53/EU Safety and **Performance Standards:** EN 60601-1: General safety requirements, EN 80601-2-61: Pulse oximeter requirements, EN 80601-2-56: Medical thermometer requirements, ASTM E1965-98: Infrared thermometers for periodic temperature measurement, EN 60601-1-2: EMC requirements, EN 60601-1-11: Home healthcare environment, EN 60601-1-12 (Partial): Emergency medical services **Quality and Risk Management:** EN ISO 14971: Risk management, EN ISO 10993-1: Biocompatibility, IEC 62304: Software lifecycle, ISO 17664-2:2021: **Device processing Labeling and Symbols:** EN ISO 15223-1: Medical device symbols Radio Compliance: FCC/ISED Compliance Statement: This device complies with FCC Part 15 and ISED RSS-GEN. Operation subject to: 1. Device may not cause interference. 2. Must accept any interference received. Note: Unauthorized modifications void operation authority. RSS-GEN Statement/ Déclaration: [English version as above] [Version française comme ci-dessus]

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

Symbols glossary:

	Do not dispose of with household waste
CE 0123	Compliance with 2017/745 Medical Device Regulation (EU) and NB number
FC	Compliance with FCC part 15 subpart B
SpO_2	No SpO2 Alarm
	Potentially invalid measurements
	Follow the instructions for use
	Type BF applied part (IEC60601-1)
	Product with protection class II
IP21	Protection against foreign objects larger than 12 mm and water droplets from above.
IP47	Protection against foreign objects larger than 1 mm and against water ingress from temporary immersion.
	Manufacturer
	Date of manufacturing
LOT	Production batch number
Typ:	Model identifier
MD	Medical device
UDI	Unique device identification
SN	Serial number
	c-med° alpha in-ear sensor
	Single charging box
	Double charging box
	Universal Serial Bus (USB)
	Bluetooth
⎓	Direct current (DC voltage)
	Plug type (Variants C, A and G)
EN	Language requirement (variable)
Ⓢ	Small (S) Tip size Ø 10 mm
Ⓜ	Medium (M) Tip size Ø 11.5 mm
Ⓛ	Large (L) Tip size Ø 12.5 mm

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c-med° alpha (MS01); Charging box (MC01,RC01)

FCC ID: 2ATBZMS01MC01
IC-ID: 25048C-MS01M01

Basic UDI (Sensor): 426046302CMED4F
Basic UDI (App): 426046302CMEDAPP4R

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