corpuls auryx **EN-English**

Instruction for Use (IFU)

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

1. Device Identification

Device name and model:
corpuls auryx, in-ear vital signs sensor

Hardware variants:
In-ear sensor: corpuls auryx, 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-S86, 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)

Firmware version:
Firmware version: min. 2.4.1 (In-ear vital signs sensor).

Compatible software and systems:
corpuls auryx App (Mobile application)[1]
– please see https://eifu.cosinuss.com

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.

[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 sensor device is a non-invasive in-ear sensor designed for continuous vital sign measurement. The measured data is transferred wirelessly to compatible third-party medical devices and/or healthcare IT systems.

Intended conditions of use:
Transportable Wearable - not fixed or permanently installed in an ambulance or aircraft.

Display of data:
Compatible software is required to display the data. (see section Compatible software and systems)

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. The device is reuseable. The intended operator is any adult person without neurodevelopmental or neurocognitive disorders.

Discontinue use if discomfort, pain, or allergic reactions occur. Maximum continuous wear time: 12 hours. Minimum application time at 20°C ambient temperature : 2 minutes.

Do not use outdoors under windy conditions or direct sunlight without covering the ear. Do not use outside the specified ambient temperature range (see section Operational Environments).

Use only with systems compliant with the cosinuss° API (see section Compatible software and systems). The device does not recommend any concrete treatments.

First-time use:
Before using the product for the first time, you should practice using it. You can find a video tutorial here:

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. Do not use a device with visible damage.

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); moisture / water in the ear;
3. Device condition: Dirty sensor head; damaged sensor head or hardware error; 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:
The corpuls auryx enables continuous measurement of body temperature, pulse rate, and SpO2 in the ear canal with wireless, interoperable data transfer to compatible systems. Continuous measurement supports timely review of vital sign trends and can support patient management by alerting the user to clinically relevant changes based on predefined criteria.

Intended User:
The intended user is any health professional and any adult person without neurodevelopmental or neurocognitive disorders. The design and the description in the user manual shall ensure a correct and safe handling.

Patient Target Group:
The medical device is especially designed to measure the vital parameters of adults. Thus, the patient population includes independent of gender, all adults from the age of 18 years under the condition that the sensing earbud fits into the auditory ear canal.

Performance characteristics:
Clinical Label claim

Body Temperature (Direct reading):
Measurement range[2]: 22.0–43.0°C, Laboratory Accuracy: ±0.2°C (35–42°C) ±0.3°C (other ranges), Resolution: 0.1°C; Clinical measurement accuracy (Reference body site: esophagus) Clinical bias: -0.1 °C, ARMS 0.3 °C.

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

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

NOTE: Measurement performance may be affected by factors such as sensor placement, patient movement, perfusion conditions, and environmental influence

[2] *Display ranges refer to compatible software*

[3] *The corpuls auryx 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.*

Lay User Guidance When to Consult a Healthcare Professional

Users should consult a healthcare professional in the following situations:

- if measured values are outside normal ranges,
- if symptoms persist despite normal readings,
- if the device indicates abnormal or unclear results,
- if there is uncertainty regarding the interpretation of the results.

Device characteristics:
Charging time: approx. 1 hour; Size: 55 x 59 mm; Weight: 8.6 g; IP: 47 (see Symbols glossary); Material: Medical-grade, hypo- allergenic; 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.

The internal electrical power source provides a typical operation time of 10 hours per full charge, with a typical service life of 500 charging cycles (maintaining at least 80% of initial capacity).

Network characteristics:
Wireless Transmission: Bluetooth Low Energy (BLE), Frequency: 2.4 GHz, ≤ 0 dBm, Transmission range: Max. 10 meters

IT Security Measures:
Data Protection: Bluetooth transport encryption, no data storage on sensor device, GDPR compliance, Vulnerability Management: Regular security updates, secure API interfaces, third-party security certification.

5. Installation and Setup

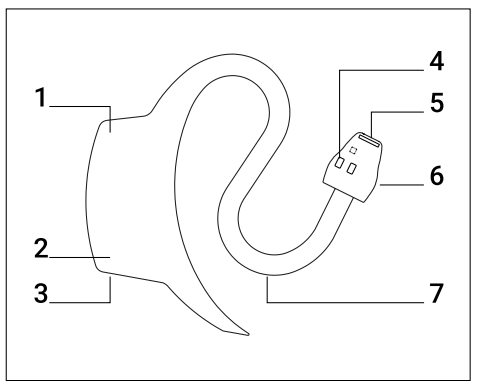
Hardware Setup:
Physical setup: Clean, dry hands before handling, Inspect device for damage before use, Ensure ear canal is clean and free from obstructions, Verify proper ear canal fit due to sensor size.
Device preparation: Charge using provided charging adapter/cable, Clean and disinfect device.

Software installation:
Download corpuls auryx 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. Please see https://eifu.cosinuss.com for more information.

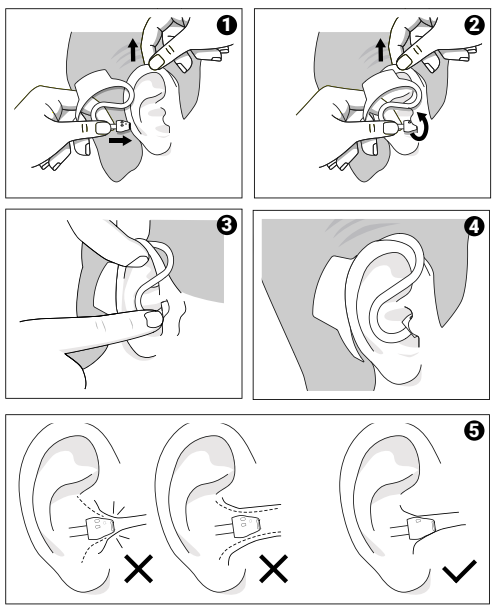
System Integration:
Supported Integration Methods: cosinuss° Bluetooth API specification; Third-Party System Requirements: Must adhere to cosinuss° API specifications, Compliance with medical data protection standards, Secure authentication mechanisms, Limited read-only access by default.

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:
Choose the largest possible sensor size. 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 – see section Measurement quality indicators).

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.** Sensor starts broadcasting data after being turned on and stops after being turned off.

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

Battery Status – After Power on / pressing button on RC01 charging box (Status LED):
Green: Battery 100–51%, Orange: Battery 50–26%, Red: Battery 25–6%, Blinking Red: Battery below 6%;

During Use (Status LED):
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.

Display of Data and exact battery status:
The data can only be displayed on compatible devices. For displaying the data and exact battery status via the corpuls auryx App please see https://eifu.cosinuss.com for more information.

Possible Measurement quality indicators by compatible App:
A question mark appears when the data may be invalid – for example, in SpO_2 measurement if the perfusion is below 0.15 %, or in pulse rate measurement if the signal quality falls below the threshold of 45 a.u.

Offline operation:
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***

The sensor does not switch ON.
Status LED does not turn ON. Battery is empty. Charge the in-ear sensor.

The sensor does not turn OFF.
Status LED does not turn OFF. The sensor is not correctly positioned in the charging box. Re-position the sensor and ensure good contact with the charging pins.

The sensor is not charging.
Charging LED does not turn ON. The sensor is not correctly positioned in the charging box. Re-position the sensor and ensure good contact with the charging pins. Use original charger. Avoid extreme temperatures.

Device not connecting (no broadcasting)
Compatible App[4]: no connection/no data
Broken device, no battery, out of bluetooth range
Check Bluetooth range (10m). Check battery level.

No data, but connected (broadcasting)
Red Status LED, Compatible App[4]: no connection/no data; Hardware Error, Broken Sensor element;
Use different sensor device.

[4] *Please see also the Instruction for Use of the compatible devices and Apps - see section Compatible software and systems*

Measurement Inaccuracy:
Compatible App[4]:
- question mark
- perfusion < 0.15 %
- quality indicator < 40
- bad ppg signal

Wrong sensor size / or external influence
– see section Measurement Influencing Factors
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.

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.***

⚠ ***Sensor damage is possible: Do not use abrasive materials/ sharp objects. Do not use UV-light/Ultrasound/Hot water/ harsh chemicals. Avoid excessive pressure and stretching.***

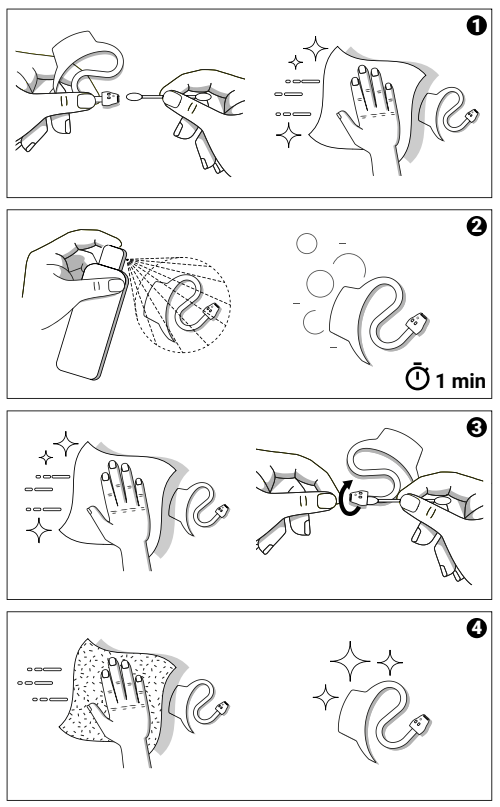
Recommended Cleaning Agents:
Primary recommendation: Schülke mikrozid® AF liquid and wipes; Alternative: Alcohol-based disinfectant (60% w/w), No fragrances, Undiluted application.

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 that battery contacts 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

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:
The sensor device does not store any (patient) data.

8. Storage and Handling

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

Storage and Transport conditions:
(applies to all parts of equipment with original packaging)

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.

- Cooling Down (from max. 70°C) at 20°C: 5 min
- Warming Up (from min. -25°C) at 20°C: 5 min

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 a clean, dry environment.

Long-Term Storage Guidelines:
Charge to 100% before long-term storage, Store in temperature-stable location. Fully charge battery every six months, battery capacity decreases 10% per month. Protect from dust and corrosive environments.

Warranty:
The hardware product corpuls auryx is warranted to the original end-user purchaser to be free from defects in material and workmanship when used in accordance with the applicable user manuals, technical specifications, and other published guidelines. This warranty remains valid for a period of twenty-four (24) months from the date the product was originally obtained by the end-user purchaser.

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.

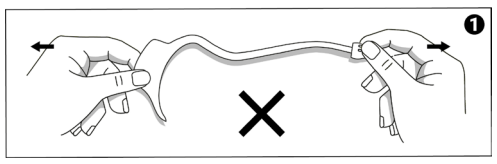
Critical Operating Warnings:

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 Factors:
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.

Handling Limitation:
Excessive bending, stretching, or pressure on the ear device must be avoided. Improper handling may compromise device integrity or function, potentially leading to device malfunction or patient injury.



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.

End of Life Management:
Over time, the product's performance and reliability may change. Proper maintenance and storage are recommended throughout its lifespan. For information on upgrades, replacement, or recycling, 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 IIb
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.

International Representatives

Swiss Authorised Representative (CH-REP)
QS Experts AG
Rütihof 1, 8820 Wädenswil
info@qs-engineering.ch
CH REP

Australia – Sponsor
Corpuls Pacific Pty Ltd
41 Ada Street
Watermans Bay, WA 6020

New Zealand – Sponsor
Universal Specialities Ltd
(trading as USL Medical)
P O Box 15 645
New Lynn, Auckland 0600
New Zealand

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
	Defibrillation proof 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
	corpuls auryx in-ear sensor
	Single charging box
	Double charging box
	Button on the right side of the double charging box. Pressing it while the sensor is in the charging box shows the battery status via the sensor's status LED.
	Universal Serial Bus (USB)
	Bluetooth
⎓	Direct current (DC voltage)
	Plug type (Variants C, A and G)
EN	Language requirement (variable)
S	Small (S) Tip size Ø 10 mm
M	Medium (M) Tip size Ø 11.5 mm
L	Large (L) Tip size Ø 12.5 mm
#	Model number
	Authorized distributor
	Importer
REF	Catalogue number
	Temperature limits
%	Humidity limits
	Atmospheric pressure limits

Document Details:
Document Version: 01
DOC ID: 1782380634
Date of Issue: 2026-06-30

Device Version:
Sensor Device (MS01); Charging box (MC01,RC01)

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

Basic UDI (Sensor): 426046302AURYX6S

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