Training

Use of the application “cosinuss° Health” for mobile monitoring of vital parameters in combination with the “c-med° alpha”

Version: 03
2025-06-02

DOC-ID: 1706272983

Software:
cosinuss° Health: from v0.8.1124

Devices compatible with software:
In-ear Sensor: MS01

Replacement part compatible with device:
Charging box: MC01, RC01

The training documents include:

Instructions for use:
CMED_User Manual_EN_1604046957 (PDF)
IFU Cosinuss Health EU EN 1701095121 (PDF)
eIFU °Health Website: https://health.cosinuss.com/eIFU

Additional training material:
COS_Health_TRAINING_EN_1706272983 (PDF)
- Module 1: c-med° alpha
- Module 2: cosinuss° Health - Mobile application

Maintenance:

Firmware Update
COS_Health_FirmwareUpdate (PDF)

You can find all the documents for the briefing under:
training.cosinuss.com/en

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NOTE:
The instructions for use of the c-med° alpha are intended for use with the application supplied with the product. These training documents refer to the use in combination with the cosinuss° Health application.

For this reason, the following chapters of the instructions for use contain deviating information on the purpose of the clinical investigation:

Attention: Deviating information:
Components, Vital sign screen, Components of the system, Accessories, Application, Serial number, Labeling, Product identification number

The manufacturer recommends instruction in accordance with §4 MPBetreibV.

ENGLISH

cosinuss° Health

Mobile patient monitoring system

The mobile patient monitoring system consists of two components that communicate with each other via Bluetooth Low Energy (BLE):

c-med° alpha

Portable wireless in-ear sensor for measuring pulse rate, SpO2 and body temperature.

Placed into the patient's outer ear canal.

cosinuss° Health App

App for recording and visualizing vital signs on mobile devices.

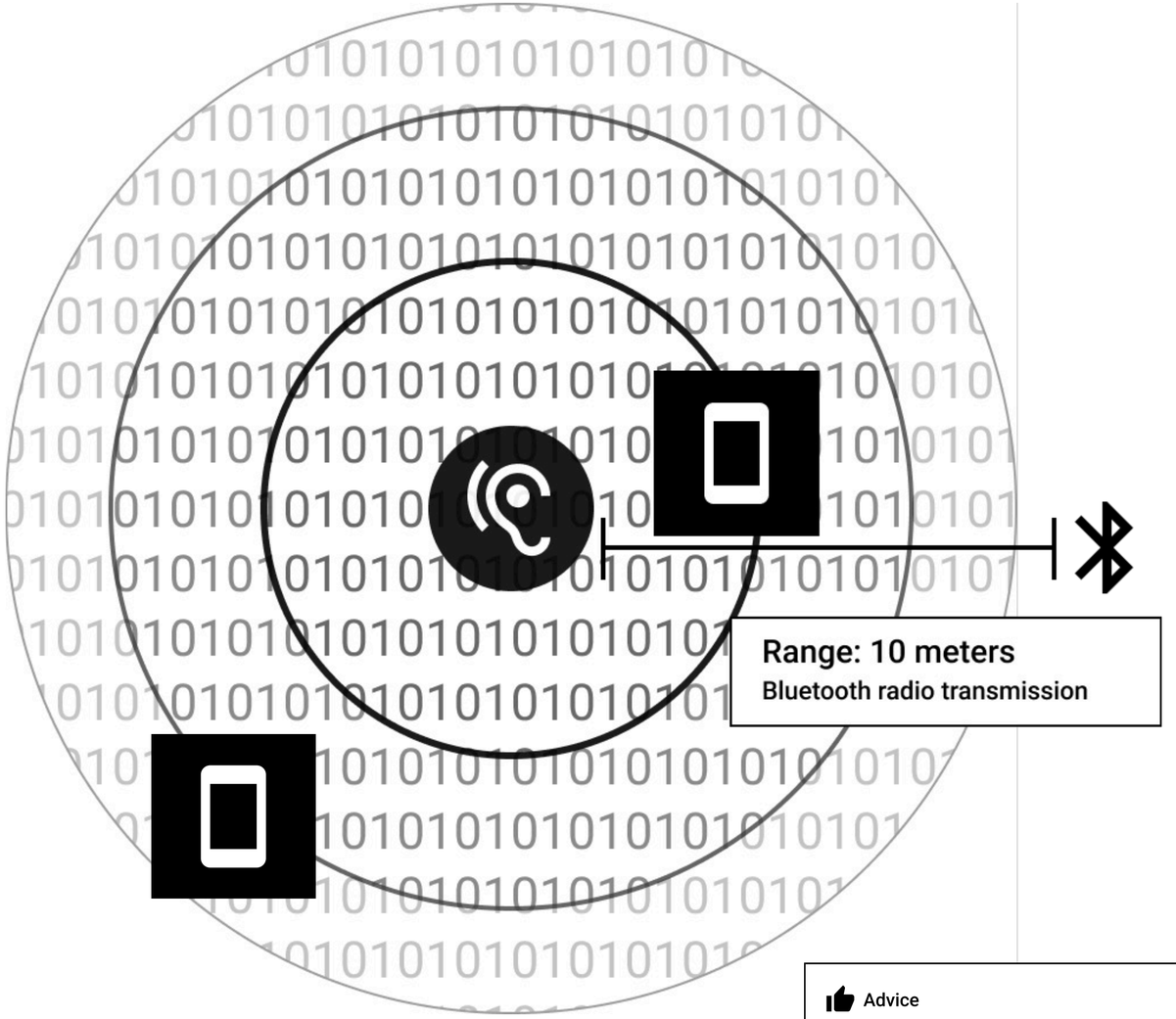
Carried by the user for mobile use.

cosinuss° Health

How does the system work?

The sensor in a patient's ear sends the measured vital data via Bluetooth within a radius of 10 meters.

The data can be solely received and displayed using the cosinuss° Health App. If the app is installed on multiple devices, the data can be displayed on all of these devices at the same time.



Advice

Bluetooth range
While recording, please keep your receiving device within the Bluetooth range of 10 meters from the ear sensor.

Training Module 1

ENGLISH

c-med° alpha

In-ear vital signs sensor

Three important notes to begin with

1. Sensor fit is very important!

The c-med° alpha is a measuring device that records vital parameters in the external auditory canal. It is very important that the measuring probes of the device, which are placed on the sensor head, are positioned far enough in the ear canal and in contact with the skin in the ear canal.

Please ensure that the sensor head is inserted gently but as deeply as possible into the ear canal.

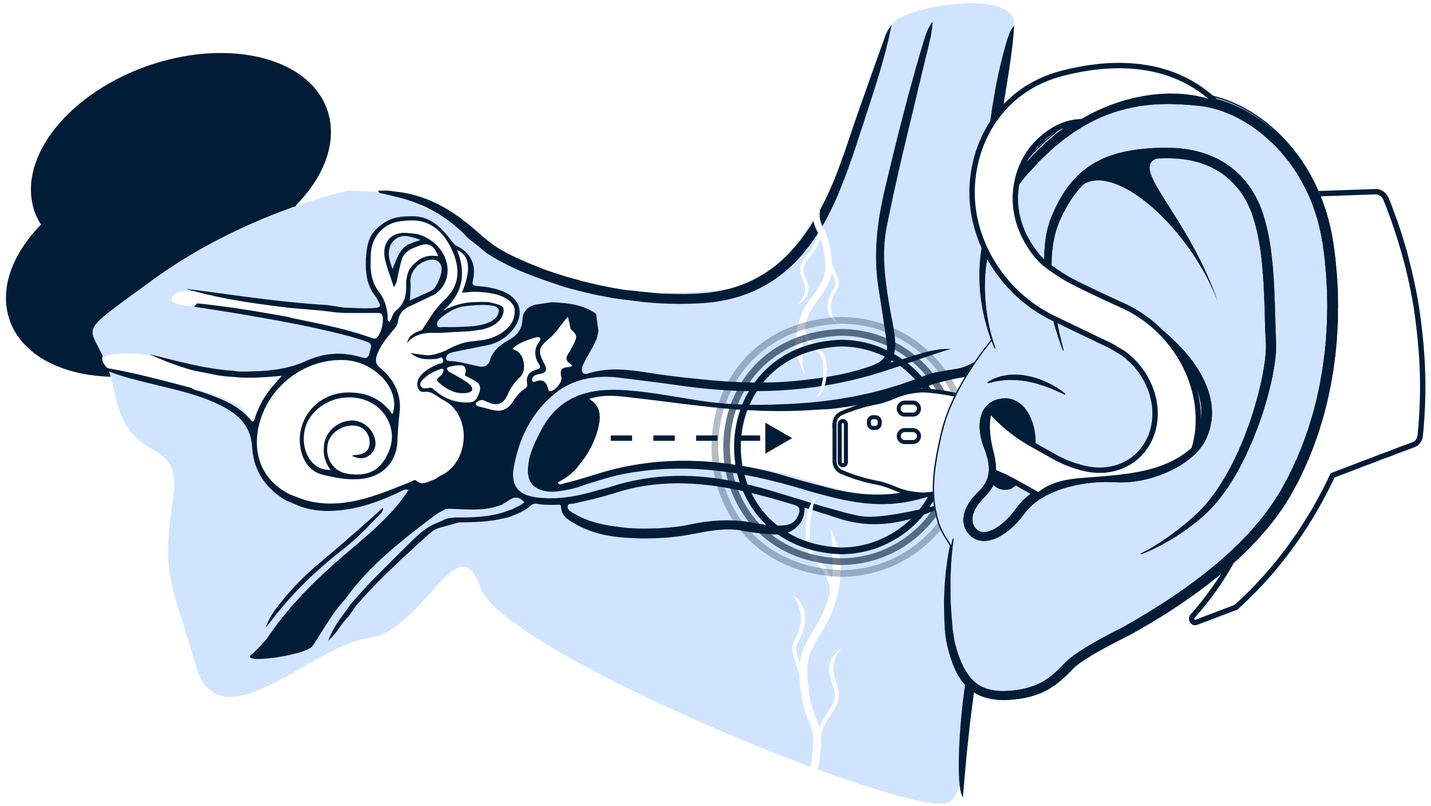
2. No chewing, speaking or moving the jaw!

As the measurements are taken in the external auditory canal, it is essential that there is as little movement as possible.
Please ensure as far as possible that no chewing, talking or similar occurs during the measurements.

3. Direct temperature measurement

The c-med° alpha measures the body temperature with an infrared sensor, which is aimed at the eardrum. However, it is important to note that the c-med° alpha does not extrapolate or add an offset to the measured values. The consequence
of this is:

a. that the temperature output takes a certain amount of time to reach the body temperature.
b. that there is a constant 0.5-0.8°C difference to standard ear IR thermometers.



ENGLISH

c-med° alpha

Portable, wireless in-ear sensor for measurement of vital parameters

The c-med° alpha is for vital signs monitoring in clinics, outside and home environments.

Patients: Individuals 18 years of age or older.

Functionality: The sensor records vital parameters and sends them to terminal devices via Bluetooth. The radio range is up to 10 meters.

The data can be only received and displayed using the cosinuss° Health app. If the app is installed on multiple devices, the data can also be displayed on all devices simultaneously.

General Information: The sensor is protected from temporary submersion, rechargeable, and transported in a single or double charging box. There are two sizes of the sensor head, S and M.

Application: The sensor head must be placed in the external auditory canal. Only one sensor is attached to a patient at a time.

Product description

Parameters

- Pulse wave curve (PPG)
- Puls rate
- Oxygen saturation of the blood (SpO2)
- Body temperature
- Perfusion

Sensor components

1. Sensor head
2. IR-Thermometer
3. Measuring LED
4. Photodiode
5. Applicator
6. Status LED
7. Charging LED
8. Charging pins

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c-med° alpha

Turning the sensor on and off

The sensor switches on automatically as soon as it is removed from the charging box.

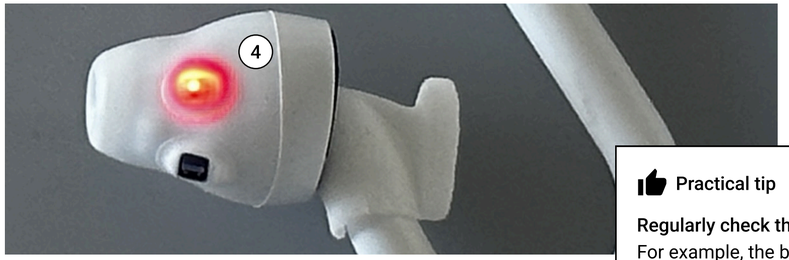
After switching on, the sensor starts measuring and transmitting the values automatically. The LED indicators (status LED and charging LED) on the back of the sensor provide information about the current sensor activity.

If the status LED lights up permanently red, the sensor is defective and should be replaced.

If the status LED flashes red, the battery level of the device is at 5% or below of its capacity. The sensor must be charged.

The sensor switches off automatically as soon as it is returned to the charging box. Switching off is indicated by a blue flash of 2 seconds of the status LED.

During charging of the sensor, the charging LED is permanently red.



Control elements & LEDs

1. Status LED
2. Charging LED
3. Charging pins
4. Measuring LED

Practical tip

Regularly check the status LED:
For example, the blue flash when switching off the sensor also indicates that the sensor is lying correctly in the charging box and can be charged.

Attention: Deviating information:
Components of the system (p. 48)

For more information, refer to the chapters of the Instruction for use:
Components of the system.

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c-med° alpha

Status LED information

Battery charging state at powering on

Battery between 100-51%
Green for 2 seconds

Battery between 50-26%
Orange for 2 seconds

Battery between 25-6%
Red for 2 seconds

Battery < 6%
Red flashing

Practical Advice

Press the button inside the double charging box:
By pressing the button in the right upper corner, you will receive the battery status of both devices without taking them out of the box.

When switched on

Sensor searches
Blue flashing

Sensor measures
Green flashing

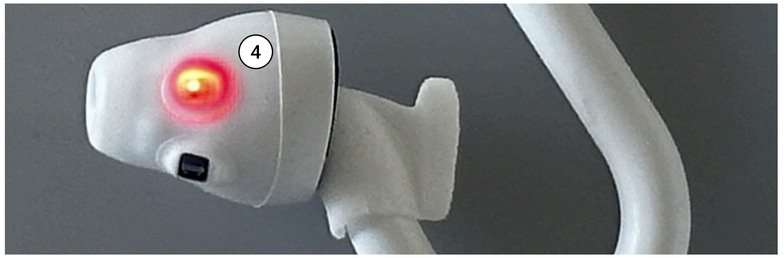
Sensor defective
Red permanently

Battery < 6%
Red flashing

Turning off

Turning off
Blue for 2 seconds

Sensor is off
Off



Control elements & LEDs

1. Status LED
2. Charging LED
3. Charging pins
4. Measuring LED

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c-med° alpha

Application of the sensor

The sensor may only be applied into the ear canal. Only one sensor is intended to be applied per patient.

If possible, the sensor should be applied into the right ear. Experience shows that measurements are more reliable there.

The sensor head is guided using the applicator to gain more control over the flexible material.

1. Hold the applicator between thumb and forefinger and insert the sensor head into the ear canal with light pressure. The sensor head should fill the ear canal in diameter.

2. Position the sensor head in a way that the red measurement LED shines in the direction of the back of the head. Also, the head should be deep enough that the red light is just not directly visible.

3. Now hold the sensor head in place and guide the back of the sensor behind the auricle. The long neck of the sensor now runs over the ear and anchors itself into the auricle in an S-shape.

4. Last, push the applicator against the wall of the auricle.

5. Readjust the sensor head in the ear canal if necessary. You will get the best measurements if the red LED shines in the direction of the back of the patient's head and if it is in good contact with the skin in the ear canal.

Practical Advice

Choosing the right size:
If quality and/or perfusion are not good enough and readjusting does not help, try changing the sensor size.

c-med° alpha

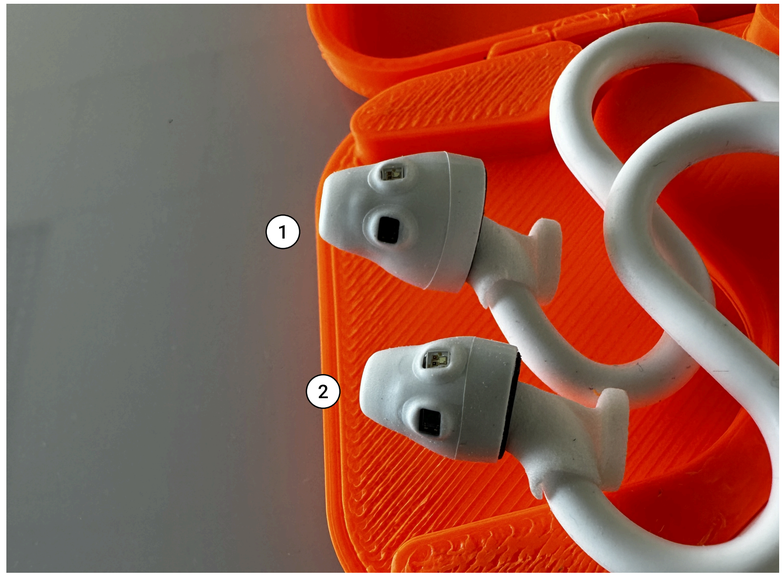
Identifying the right sensor

You have several options for identifying the needed sensor.

Serial number: A unique serial number is engraved on the back of each sensor. You need this to select the sensor in the app, for example.

Signal strength: In the app, you will also find information about the sensor's signal strength (RSSI value). The closer you are to the sensor, the higher this value is (e.g. -50 RSSI is closer than -80 RSSI). This value could also help distinguishing one sensor from another.

Size of the sensor head: An indication of the size of the sensor head is engraved right next to the serial number. You will need this when deciding which sensor to put on a patient. The size must match the diameter of the ear canal.



Control elements & LEDs

1. Sensor head size M
2. Sensor head size S
3. Serial number
4. Size

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c-med° alpha

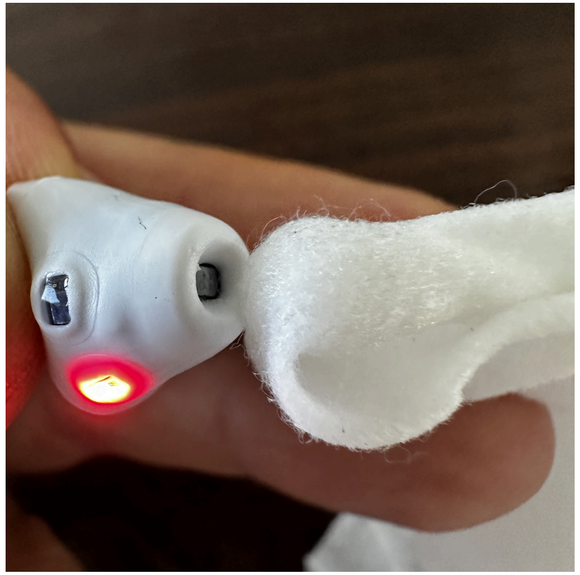
Cleaning the sensor

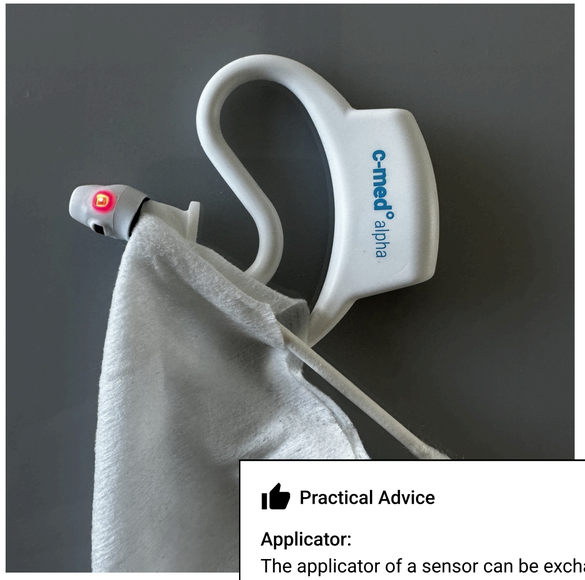
The sensor must be cleaned and disinfected after each use (patient change).

Cleaning: Visible soiling should be removed with a disinfectant wipe. To clean the IR sensor, which is located on the tip of the sensor head, please use a cotton swab soaked in disinfectant (Schülke Mikrozid®).

Disinfection: After cleaning, the sensor should be additionally disinfected.
Spray disinfectant (Schülke Mikrozid®) evenly over the entire surface and leave it a minute to work. Now take a new disinfectant wipe and rub all surfaces well.
To disinfect the area under the sensor head, you should use a cotton swab to guide the disinfectant wipe under the head and carry out the disinfection while turning the swab gently.

The in-ear sensor should be dried well with a lint-free disposable cloth before you place it back into the charging box.





Practical Advice

Applicator:
The applicator of a sensor can be exchanged if it is dirty.

Practical Advice

Desinfectants:
We recommend: Schülke mikrozid® AF liquid.
Other disinfectants should only be used if they are undiluted, on the basis of a total of 60 % (w/w) alcohol and without fragrances.

ENGLISH

c-med° alpha

Charging the sensor

After each day of use, the sensor should be fully recharged overnight.

The double charging box can charge and store both sensors at the same time. Plug the charging cable into the charging box and the power supply into the power socket.

The charging LED lights up red to indicate that the sensor is charging. If the red light goes off, the sensor is fully charged.

The battery life of a sensor, with continuous measurement, is at least 12 hours. The charging time is approx. one hour.

The sensor should be checked for integrity before each use and should not be used again in case of visible damage.

Charging LED (is not the status LED)

○ **Fully charged**
Off

● **Sensor is charging**
Red light

Practical advice

Charging pins
To reliably switch the sensor on and off, as well as to charge it, make sure that the charging contacts of the sensor are in good contact with the charging box charging contacts.

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c-med° alpha

Why measuring inside the outer ear canal?

The measurement location in the ear canal enables the simultaneous measurement of several vital signs with one device.

The head as a whole is usually the first place that is accessible by rescuers. In addition, the head is usually held still by the patient themselves.

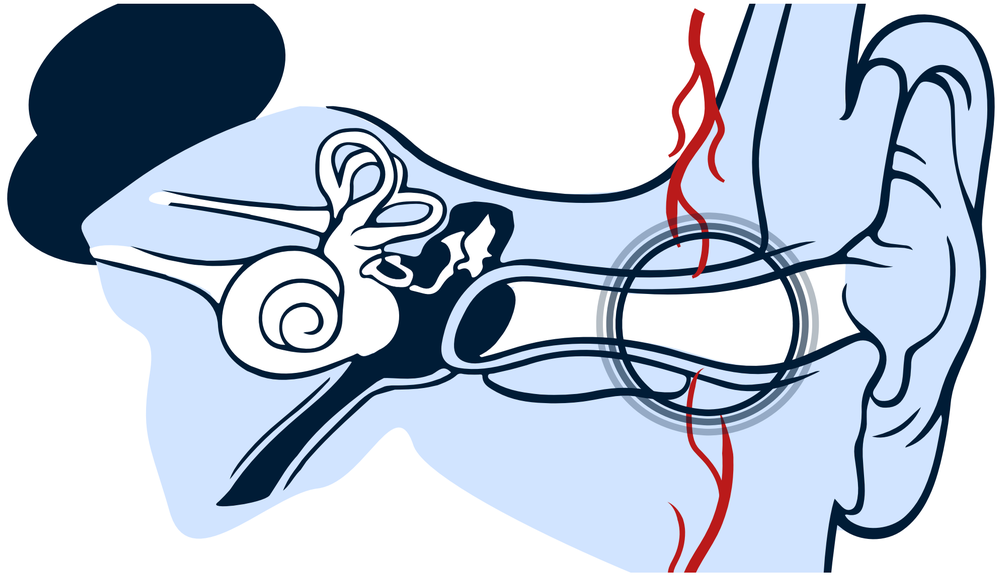
In contrast to other alternatives, it is not necessary to undress the patient to access the measurement location.

The in-ear sensor is accepted by patients since it is very similar to wearing headphones. Thus it allows the sensor to be worn permanently.

Body temperature measurements at the tympanum are taken close to the brain and the body's own temperature regulator.

The blood supply to the tissue around the external auditory canal is located in the central flow area of the facial and cerebral arteries, which is why blood flow is always present here; even in a centralized state.

Measuring the pulse and oxygen saturation in the external auditory canal can also possibly provide information about the blood supply to the brain.



c-med° alpha

NEW

Sensing elements	Infrared thermometer, Pulsoximeter (LED and Photodiode)
Weight	7 gramms
Dimensions	55 x 58 x 10 mm
Rating	IP47 Protected against solid foreign parts with a diameter ≥ 1.0 mm. Protected against immersion of water up to 1 m depth.
Battery	Runtime: Over 12 hours continuous use. Fully charged in 1 hour.
Transmission	Bluetooth Low Energy 5.0, ISM band 2.4 – 2.485 GHz Range approx. 10 meters

Environmental condition for operation

0° – 40 °C	15–95 % rH	Continuous operating state
0° – 50 °C	15–90 % rH	Transient operating state

Environmental condition for transport and storage

-25° – 70 °C	0–95 % rH

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

Pulse rate

Resolution	1 bpm
Range	40 – 220 bpm
Accuracy	± 4 bpm

SpO2

Resolutioin	1 %
Range	0 – 100 %
Accuracy	± 3 % ARMS

Core body temperature

Resolution	0.1 °C
Range	22 – 43 °C
Accuracy	± 0,2 °C (35–42 °C) ± 0,3 °C (other ranges)

⚠ **Attention:** Specified with laboratory measurement accuracy.

c-med° alpha

Indication

- Oxygen deficiency (Hypoxemia)
- Hypothermia
- Fever (hyperthermia)
- Changes in the circulatory system
- Accelerated heartbeat (tachycardia)
- Slowed heartbeat (bradycardia)

Contraindication

The c-med° alpha is not intended to recommend specific treatments and must not be used:

- In case of diseases or injuries of the ear
- For monitoring oxygen saturation in carbon monoxide (CO) poisoning.

Unique Device Identification (UDI)

All sensors are uniquely identifiable by their serial number.
To determine the complete UDI of your system, please contact:

zulassung@cosinuss.com

and report the serial number on the device (Ex: SN 123456).

Important Warnings

- Please do not use the c-med° alpha in cases of ear injuries or increased sensitivity in the ear.
- For accurate SpO2 and pulse rate measurements, especially at rest, please avoid any unnecessary movements like chewing and talking by the patient as these may affect the PPG signal and lead to inaccurate measurements, usually low values.
- Proper fit of the sensor in the ear canal is essential for accurate measurements. Please pay attention to the live PPG signal and check the sensor and its position if unusual signal patterns occur.
- The presence of liquids in the ear canal can affect measurement accuracy, especially core temperature, and usually results in falsely low values. Please do not use the sensor if the patient has blood or water in the ear canal.
- The presence of dirt on the sensor head can affect measurement accuracy, for example, earwax on the IR sensor will result in falsely low-temperature readings. Please clean the device if you notice dirt on the sensor and especially on the sensor head.
- Bluetooth low energy communication between the sensor and the receiver device (smartphone) is limited to a maximum range of 10 meters. If the distance between sensor and receiving device is too big, the connection may be lost, and in this case, no readings will be displayed. Measured values during a connection loss go lost and cannot be recovered. Please ensure that the sensor remains in the immediate vicinity of the smartphone during the measurements.
- Do not use the c-med° alpha during magnetic resonance imaging.
- Since pulse rate measurements are based on an optical detection of a peripheral pulsatile flow, the measurement is limited in specific situations:
  - Certain arrhythmias may not be detected. Therefore, the pulse oximeter measurement should not be used as a substitute for ECG-based arrhythmia analysis.
  - During circulatory arrest, a correct measurement of body temperature, pulse rate and SpO2 may not be possible due to a sudden stop in effective and normal blood circulation.
- If you use the c-med° alpha to measure the body temperature outdoors, please ensure that the ear (measurement site) is covered according to the temperature conditions.
- Please shield the ear (measurement site) against direct sunlight and wind during outdoor use.

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Training Module 2

ENGLISH

cosinuss° Health

Mobile application

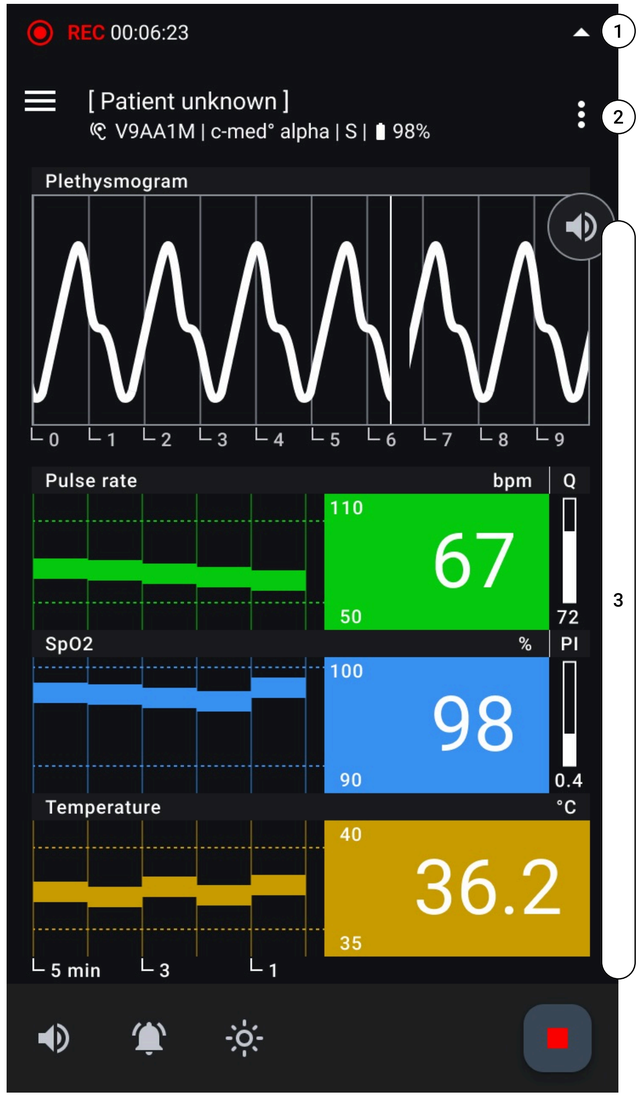
cosinuss° Health _App

Main functions of the app

cosinuss° Health is a stand-alone software solution that can receive data via the Bluetooth broadcasting interface and display it on a mobile device.

The main functions of the mobile application are

- Identification and data reception of the c-med° alpha
- Display of the received values, current measured values and trend curves
- Notifications about the system and measurement status



1. Notification of system status
2. Recording information
3. Current values and trend curves

ENGLISH

Onboarding

The Onboarding process is a crucial step to ensure your seamless experience with the app.

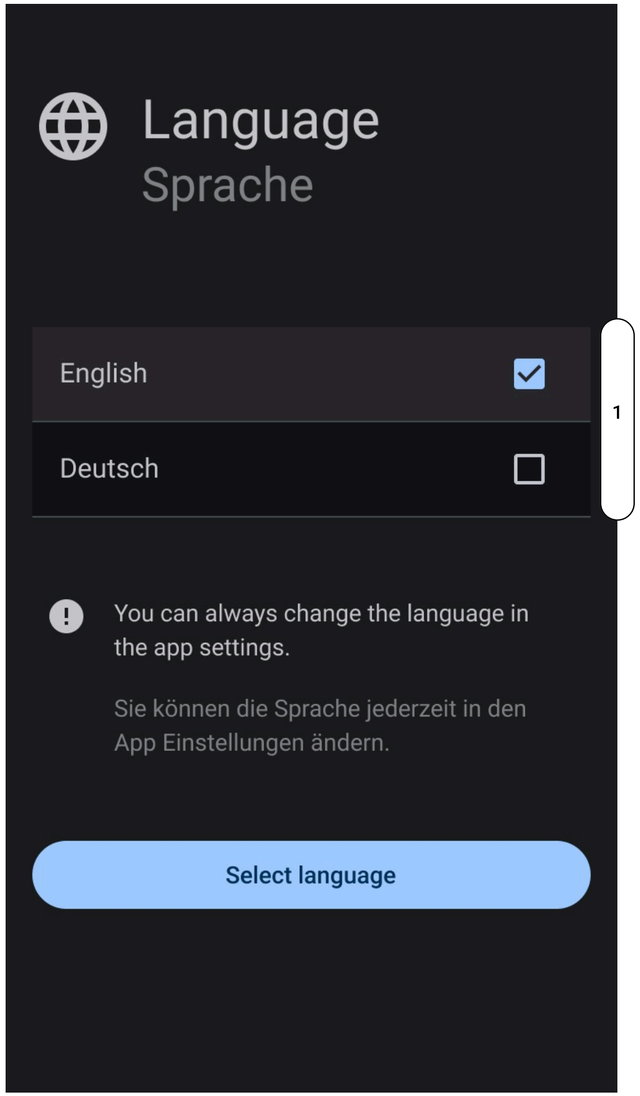
It has to be done only once. Your selections will be saved until you reinstall or change them during other use cases. If needed you can change your preferences in the ‘Settings’ of the app at any time.

Your app should be configured with your:

- preferred language,
- necessary access rights,
- and data privacy policy agreement.

Language Selection

- Upon launching the app for the first time, you'll be prompted to select your preferred language.
- Choose from the available language options to personalize your app experience.



1. **Available languages.**

Note

Due to the individual display settings of your smartphone problems in the display and in the proper functioning of the Health° App may arise.

If, for example, you are unable to tap the "Select language" button, please check the display settings of your smartphone to see whether a higher zoom factor or a different text size is set. Resetting to the default settings should solve the problem.

ENGLISH

Onboarding

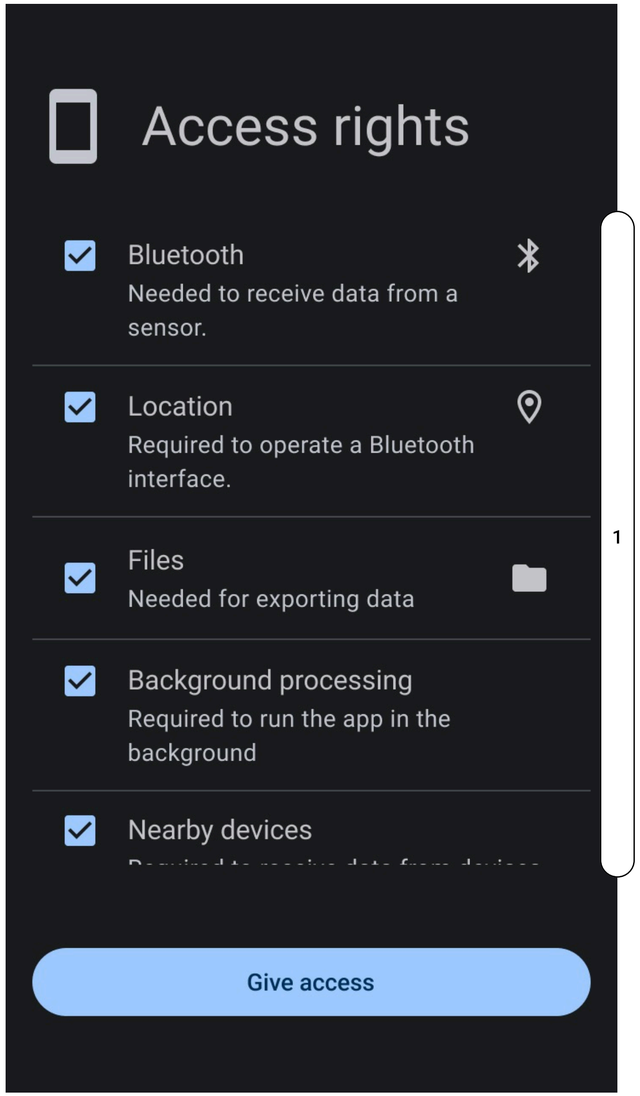
Access rights

The app requires certain access rights to function properly. Follow these instructions on screen to grant the necessary permissions. Depending on your operating system, different rights may be required.

- Bluetooth: Required to receive data from a sensor
- Location: Required to operate a Bluetooth interface
- Files: Needed for exporting data
- Background permission: Required to run the app in the background
- Nearby devices: Required to receive data from devices

Initiate the requests for access rights by tapping on the ‘Give access’ button. The system will prompt a request for all necessary rights. Afterwards the app checks and marks the granted access rights on the list.

If some access rights cannot be granted within the app, please navigate to your device settings and locate the app in the list of installed applications. Then assign the rights here manually.



1. List of required access rights. (These may differ depending on your device and operating system)

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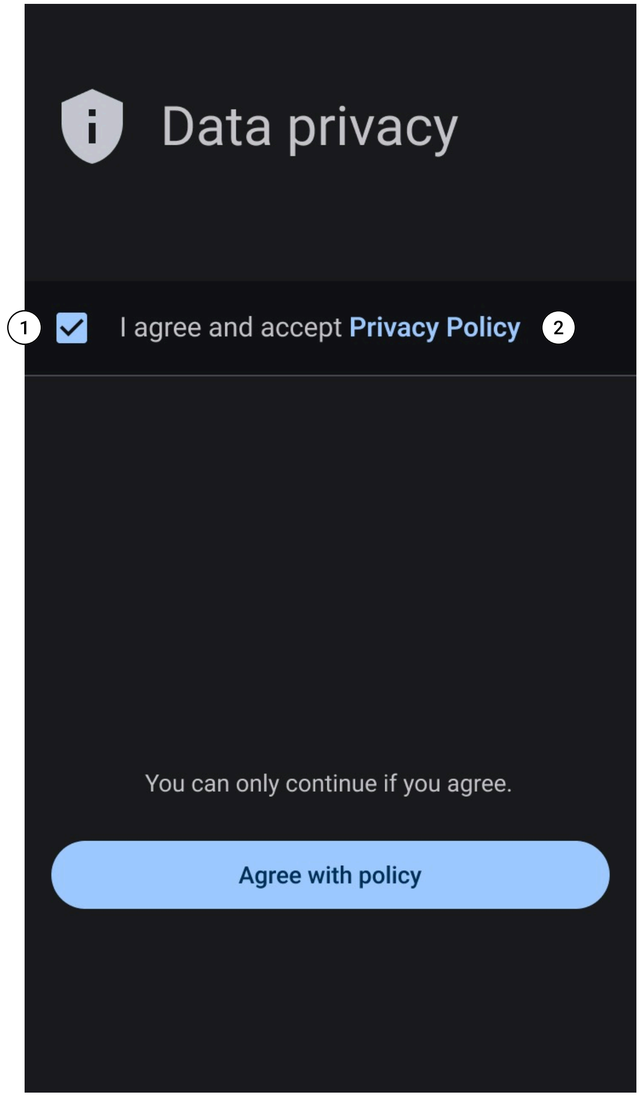
Onboarding

Data privacy Policy Agreement

To proceed, you need to agree to the app's data privacy policy.

- Read through the linked data privacy policy carefully. (https://support.cosinuss.com/health-app/privacy/)
- After reading the privacy policy go back to the health app
- Check the box to confirm that you have reviewed the data privacy policy.
- If you agree to the terms, tap the ‘Agree with policy’ button.



1. Checkbox to be confirmed
2. Link to review the complete Data Privacy Policy Agreement

ENGLISH

Onboarding

Thresholds

During the set-up process, we inform you about the preset limits for the vital signs. This screen is essential in order to understand when you will be informed about the health status of the monitored persons by means of a notification.

Preset threshold values

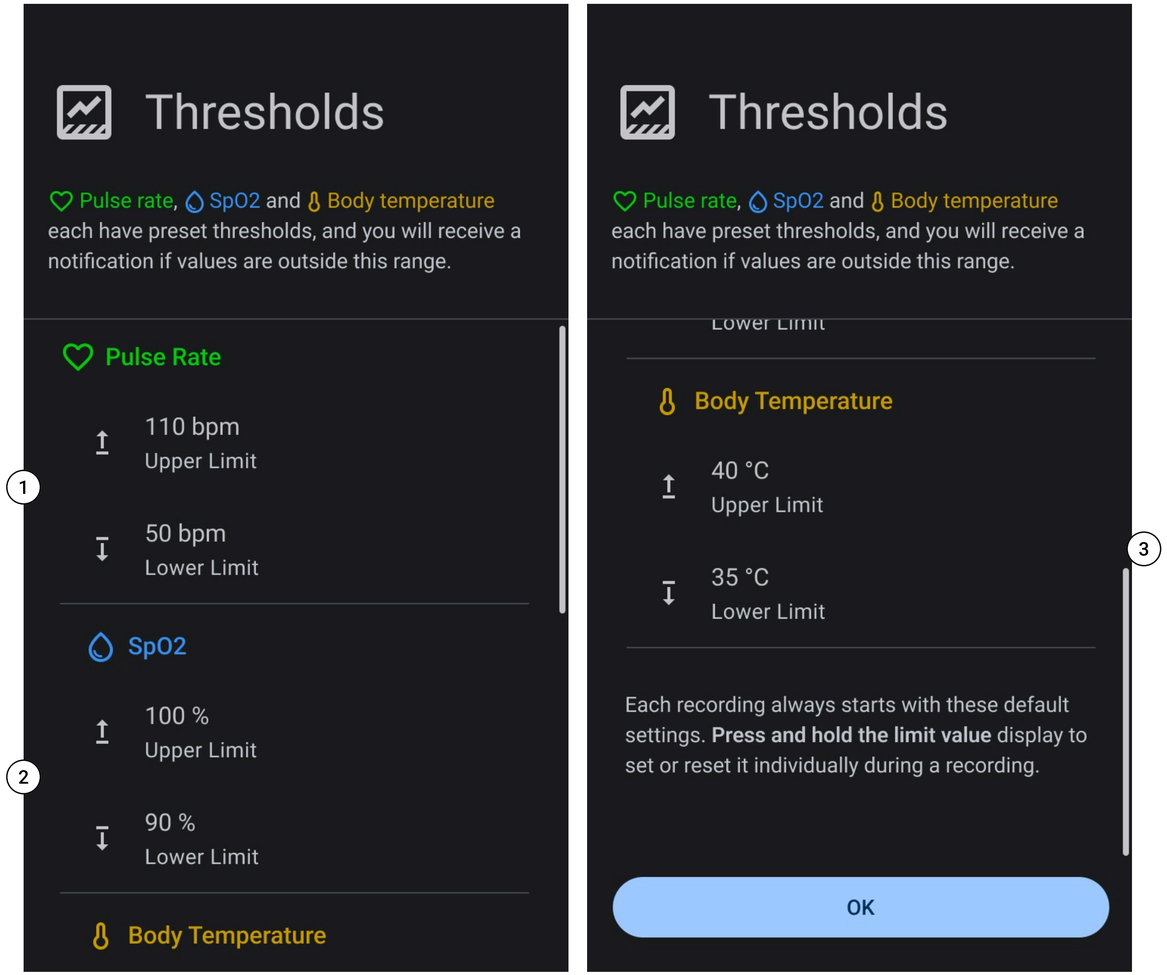
Pulse rate (green)
Upper limit: 110 bpm
Lower limit: 50 bpm

SpO2 (blue)
Upper limit: 100 %
Lower limit: 90 %

Body temperature (orange)
Upper limit: 40 °C
Lower limit: 35 °C

You can set user-defined limits during a measurement by pressing and holding the limit value display.

Confirm that you have read and understood the limits, to continue with the onboarding process.



1. Pulse rate thresholds
2. SpO2 thresholds
3. Body temperature thresholds

ENGLISH

Onboarding

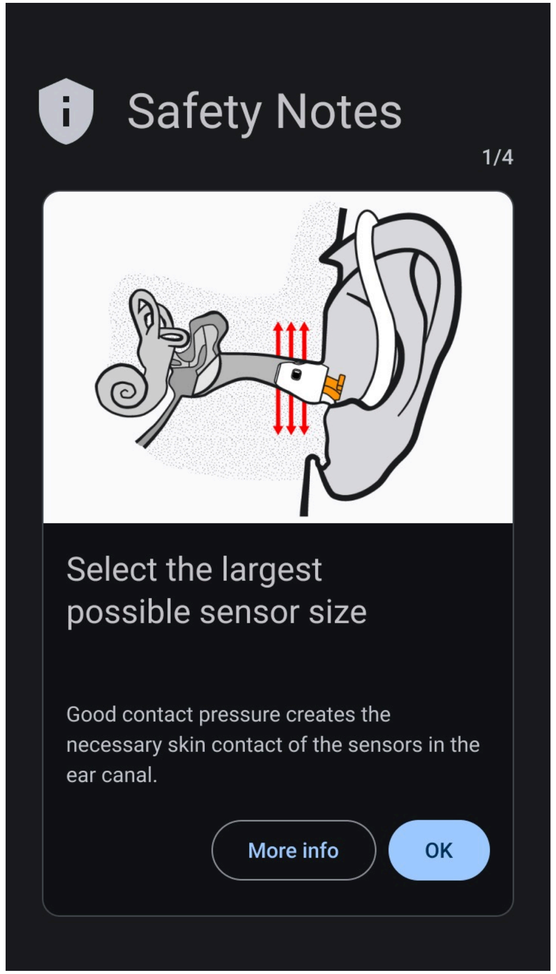
Safety Notes

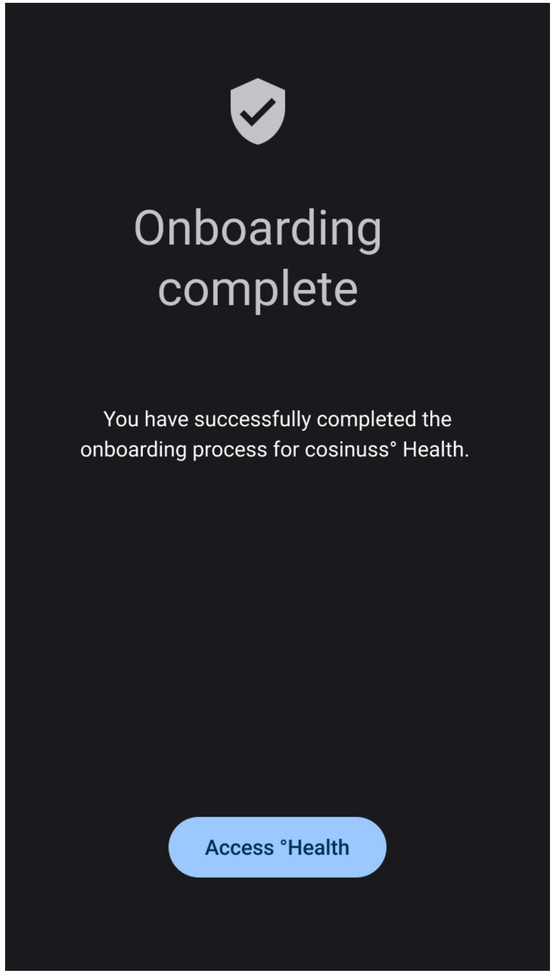
Finally, in the onboarding process, we provide important information on the correct handling of the sensor used. This step is crucial to ensure that the sensors work accurately and reliably.

If you use the c-med° alpha, please note the following instructions:

1. Select the largest possible sensor size.
2. Push the sensor head deep into the ear canal.
3. The patient should not speak or chew during the measurement.
4. The displayed temperature value is the directly in the ear canal measured value.

If you have read and understood the instructions, you have successfully completed the setup process and can start using the °Health app.





ENGLISH

LIVE

RECORDING

Start recording

Intro

The seamless connection between the in-ear sensor, c-med° alpha, and the app doesn't require manual pairing. Instead, the app continuously scans for signals from the sensor, allowing you to effortlessly record data.

This chapter explains the process of starting a recording by selecting a sensor, either manually or through ‘auto-record’.

Prerequisites:

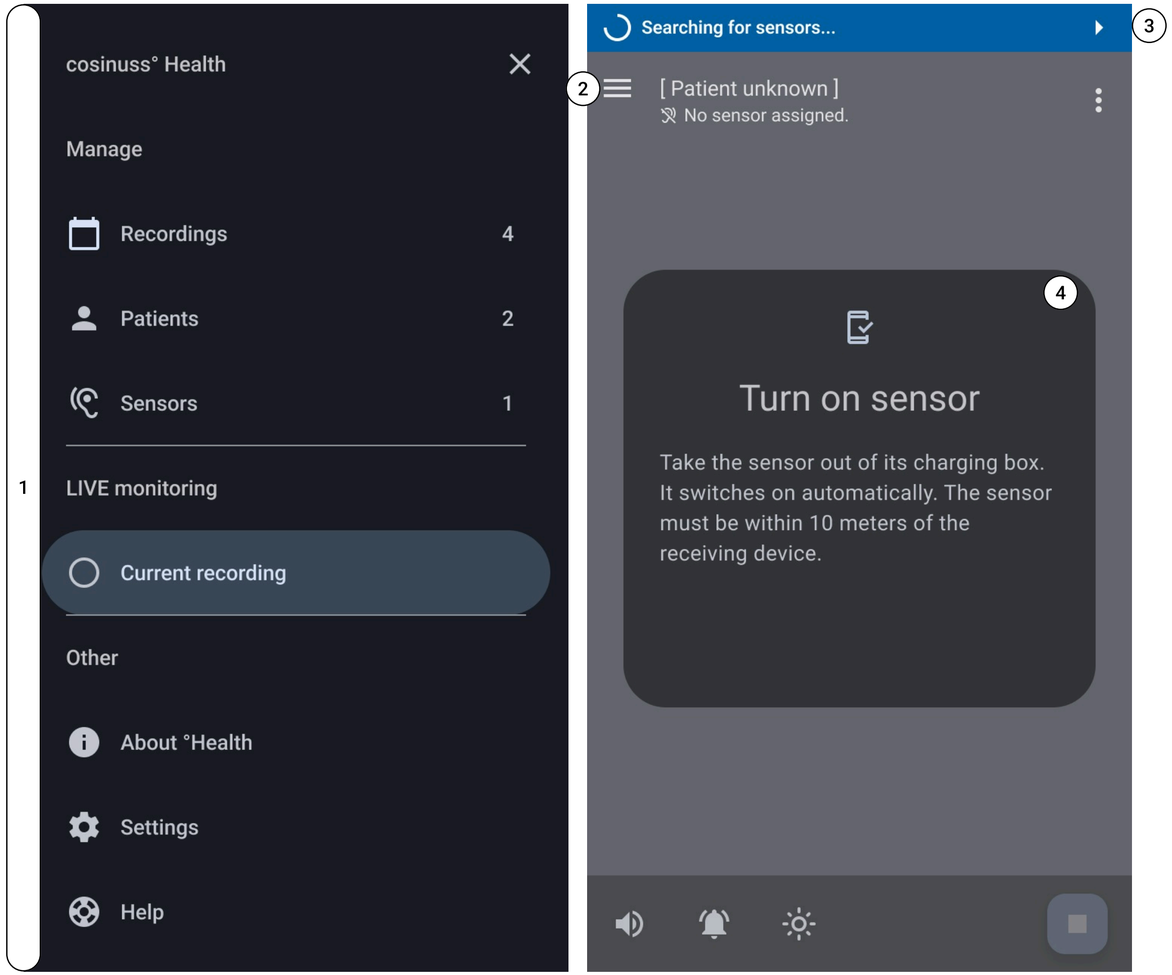
- Activate Bluetooth on your mobile device
- All permissions that were asked for by the app have been given (Bluetooth, Location, Data)
- Sensor is powered on and within BLE range (10m)

Continuous Scanning

The app is designed to detect your in-ear sensor whenever it is within BLE reach distance. The ongoing search is indicated in the notification bar.

Go to the 'LIVE-Recording' page.

You can access the LIVE Recording page either through the Navigation bar by tapping on ‘Recording’ in the Menu icon in the upper left, or by tapping on the Notification bar, which directly leads you to the ongoing LIVE-Recording.



1. Navigation drawer
2. Menu icon
3. Notifications bar
4. ‘Turn on sensor’ note

ENGLISH

Start recording

‘Start recording’ dialog

The "Select sensor" dialog appears as soon as the app has detected a sensor within range.

The sensor is selected manually. If you do not select a sensor, recording can be started automatically under certain conditions if a suitable sensor within range meets the correct conditions.

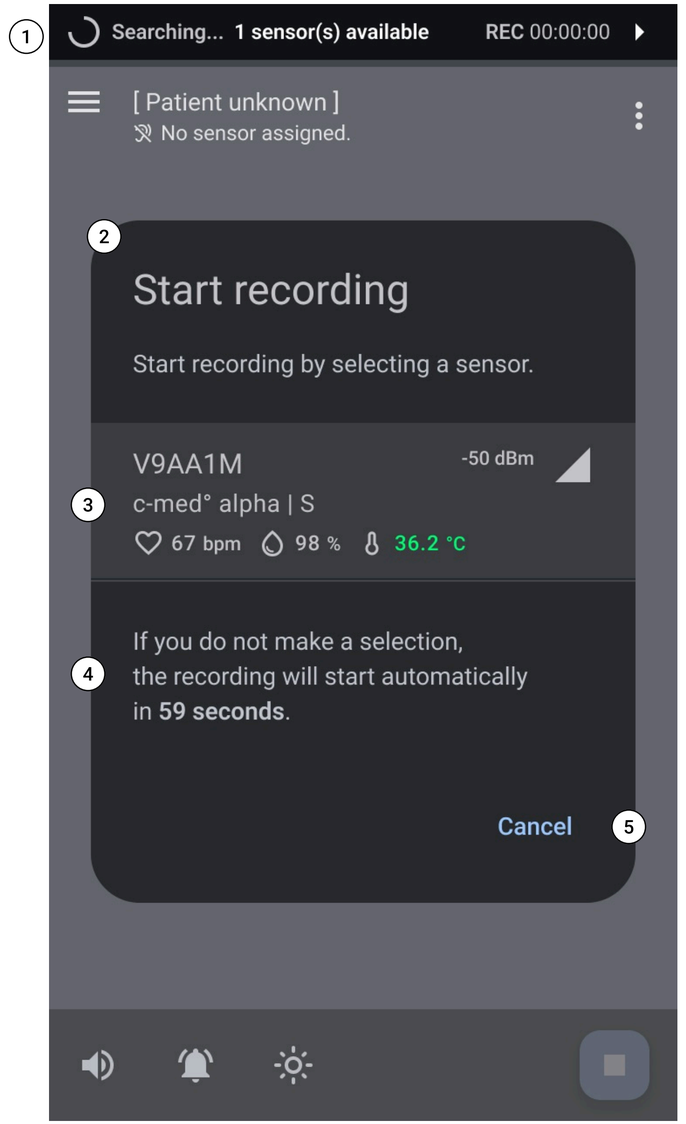
Identify the right sensor

The correct sensor can be identified by its serial number.
This is located, in case of the c-med° alpha for example on the back of the sensor.
The additional information can help with the selection.

Select Sensor

Sensors can be selected manually or by auto-record:

- To start record manually: Tap on the list item to select a sensor.
- To auto-record: Wait for the countdown to run off for an automatic start.



1. Notifications bar
2. ‘Start recording’ dialog
3. Sensor item
4. ‘Auto-record’ description
5. ‘Cancel’ dialog
6. Serial number on sensor
7. Size

ENGLISH

Start recording

"Check sensor" dialog

Before starting a recording manually, you will be prompted with a "Check sensor" dialog to check the serial number of the sensor on the patient.

Checking the serial number

Compare the serial number displayed in the dialog with the serial number of the sensor attached to the patient (see illustration on the right).

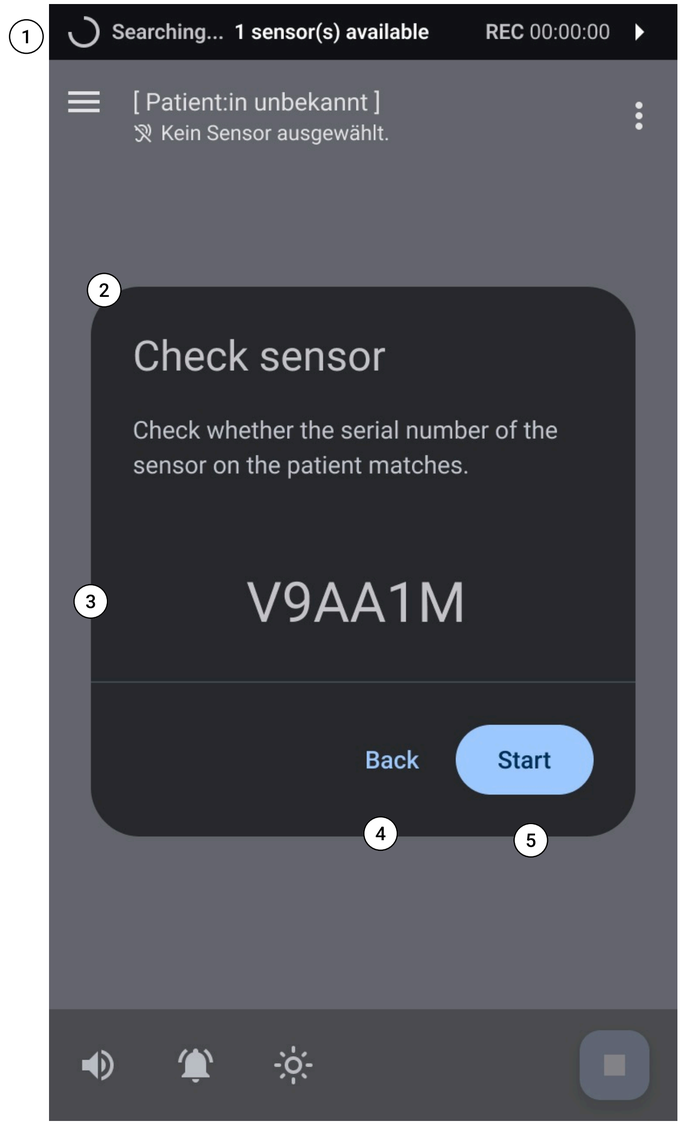
Start recording

Once the serial number has been checked and confirmed, you can start recording the data by selecting the "Start" button.

Important notes

Pay attention!
Make sure that the serial numbers match exactly to avoid confusion.

No match?
If the serial numbers do not match, cancel the recording and check that the correct sensor is attached to the patient.



1. Notification bar
2. "Check sensor" dialog
3. Serial number of the desired sensor
4. "Cancel" button
5. "'Start" button
6. Serial number on the sensor: c-med° alpha

ENGLISH

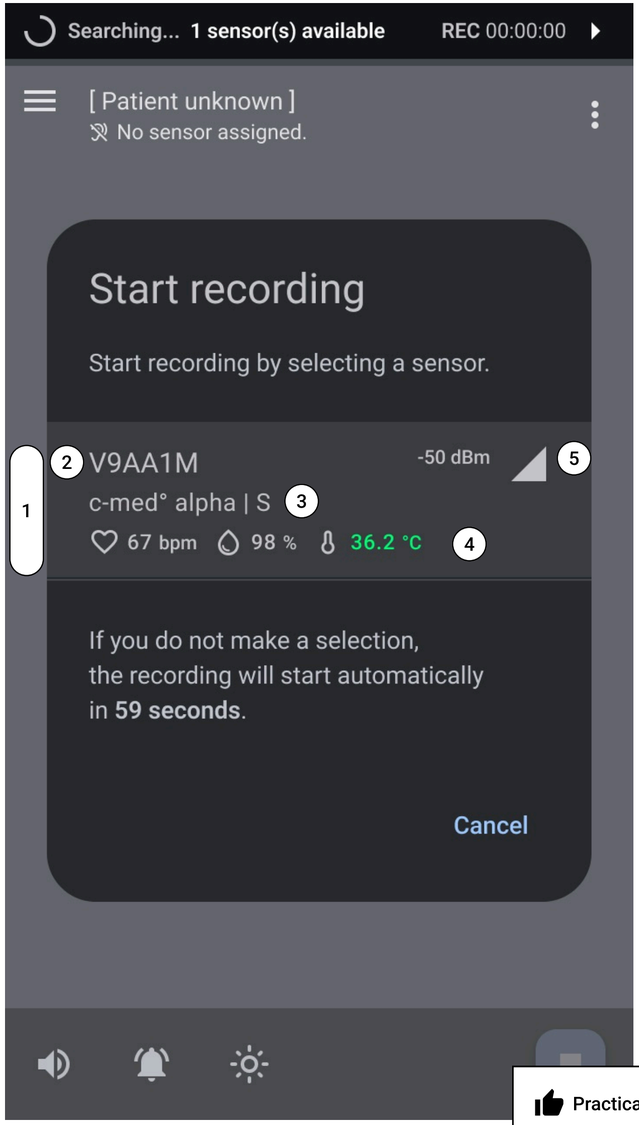
Start recording

Conditions for automatic recording

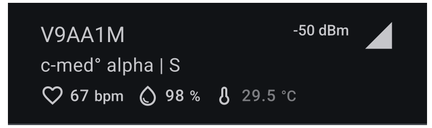
An automatic recording is only started if **there is exactly one sensor found that is measuring temperature values above 30°C** (indicated by green temperature values).
In this case an auto-select countdown of 60 seconds starts.

If one of the conditions is not met:

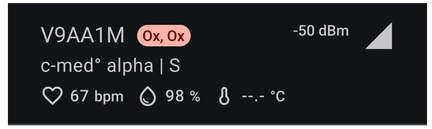
- If the measured temperature is below 30 °C, no automatic measurement is started. You can still select the sensor manually (indicated by a grayed-out temperature value).
- If multiple sensors meet the temperature threshold, they are listed on top in the order of their distance, and you must select manually.
- Sensors that are not in the needed mode only display the temperature. You have the option to manually select them, thus they will automatically switch to the right mode.
- Sensors with defects are indicated and can be selected manually.



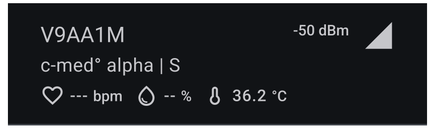
1. Sensor list-item
2. Sensor serial number
3. Sensor size
4. Temperature value
5. Signal strength (RSSI value)



Not considered for auto-record:
Temperature value below 30 °C.



Sensor defective: I.e.: Thermometer defective.



Sensor not in BLE Broadcasting mode:
No vital signs are advertised.

Practical tip

Auto-record
In order to have the automatic recording function available, the sensor must have been connected manually at least once beforehand.

ENGLISH

Start recording

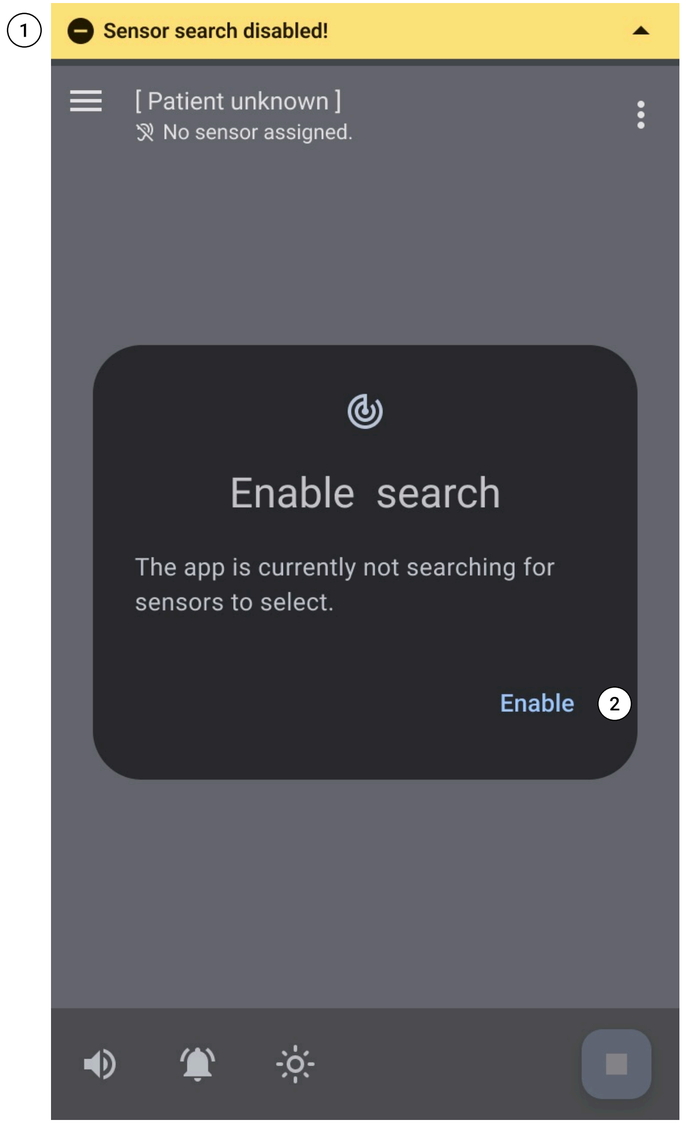
Close recording dialog

Disable scanning
Tap ‘Cancel’ to close the dialog (see previous page). This action will temporarily halt the continuous scanning for sensors, as indicated in the notification bar. The pause lasts either for 10 minutes or until you manually re-enable it.

Turn off sensor(s)
The dialog closes automatically if:

- sensors in reach are turned off
- there are no sensors in BLE reach anymore.

Please note:
If the app is running in the background auto-connect still performs with the same conditions as above.



1. **Notification: ‘Sensor search disabled!’**
2. **Enable scanning again**

LIVE

RECORDING

Representation and Visualization Options for Measurement Data

There are two ways of visualizing the data:

1. Photoplethysmogram (PPG)
2. Vital signs item with current value, trend curves and according quality index

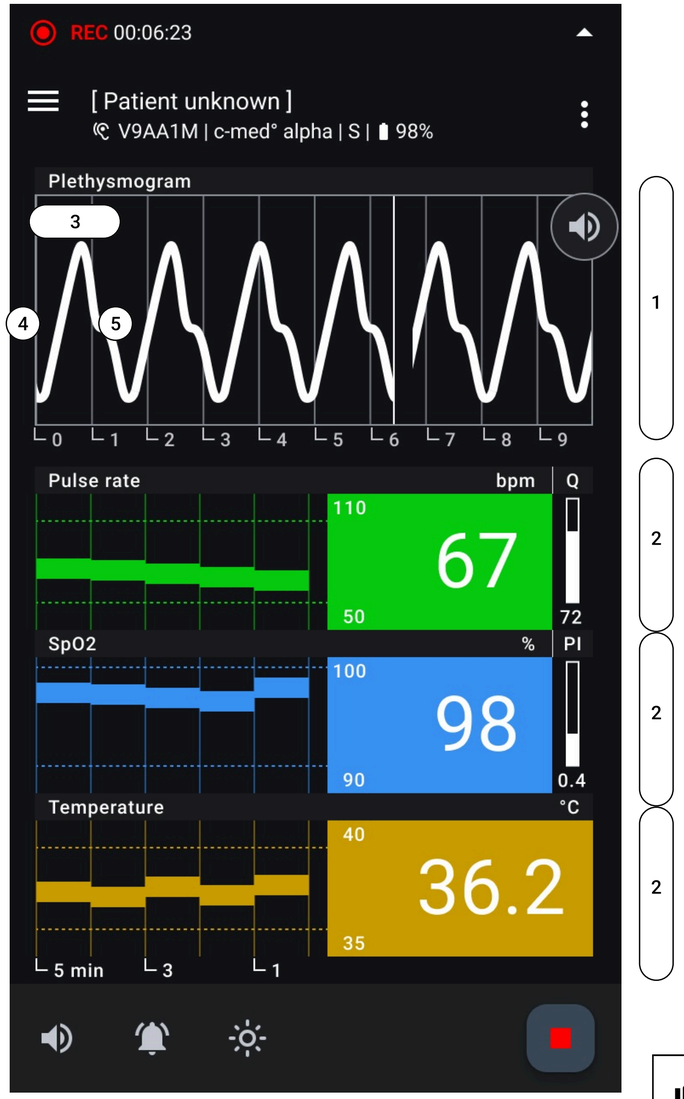
Photoplethysmogram

The photoplethysmogram is a signal curve drawn in real time over 10 seconds, which is always overwritten. It represents changes in blood volume that occur in connection with the heartbeat at the measurement location.

This signal can be viewed as a series of waves. Each wave corresponds to a heartbeat. The systole (= "rising phase" of the wave) shows how the blood vessels dilate as the blood is pumped, while the diastole (= "falling phase") reflects the contraction of the blood vessels.

This curve can help to monitor and analyze the heart rate, heart rhythm and possible irregularities.

Visualization Photoplethysmogramm



1. Photoplethysmogram
2. Vital signs item
3. Pulse wave
4. Rising phase
5. Falling phase

Practical advice

Information carried by the photplethysmogram
The pulse waves displayed in the photoplethysmogram can be helpful to assess if the displayed systoles are clean or disturbed by external factors which could be an indicator for the validity of the measured values.

ENGLISH

Representation and Visualization Options for Measurement Data

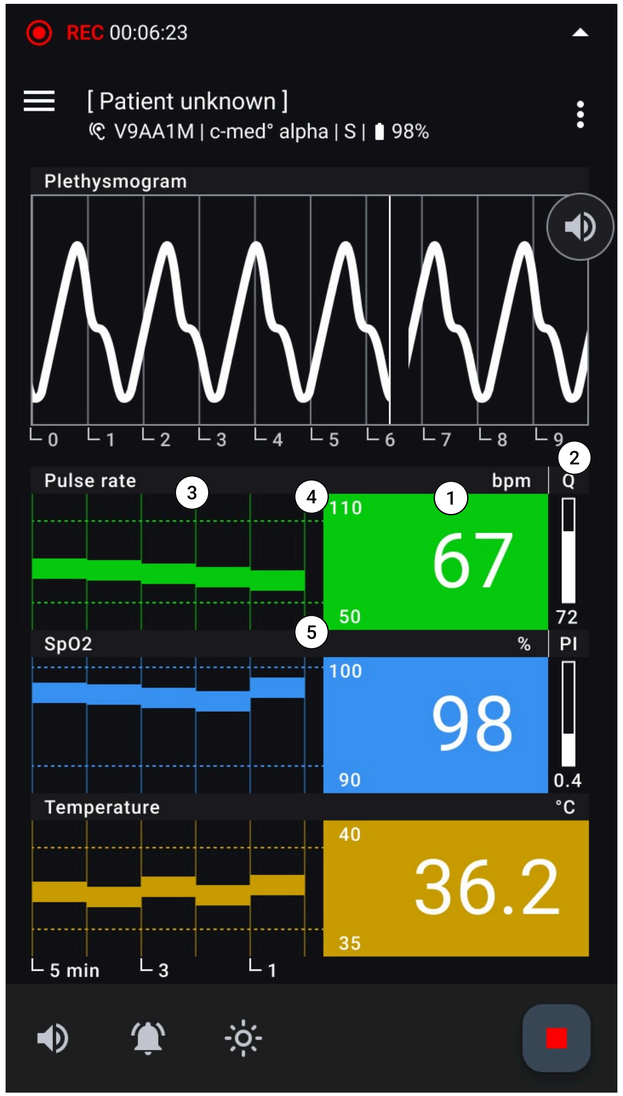
Vital sign item

The different vital parameters are differentiated by color.

The historical values for each vital sign are displayed as a curve, the current measured values in numbers with the corresponding unit. One segment of the trend curve corresponds to the averaged value of the parameter over 1 minute.

The associated index (perfusion and quality) is shown to the right of the numerical value, which provides information on the measurement quality of the parameter.

The upper and lower threshold values that trigger a notification are also described numerically and as a line in the trend curve.



Representation and Visualization Options for Measurement Data

1. Current value
2. Quality index
3. Trend curve
4. Upper threshold
5. Lower threshold

ENGLISH

LIVE

RECORDING

Status bar notifications

The status bar plays a crucial role in keeping you informed about the current state of the monitoring system. The status bar is visible in every view within the app. Outside of the recording screen a tap on the notification will bring you to the current recording.

This chapter outlines the various notifications, states, and thresholds displayed in the status bar. In general there are two types of notifications

1. System notifications

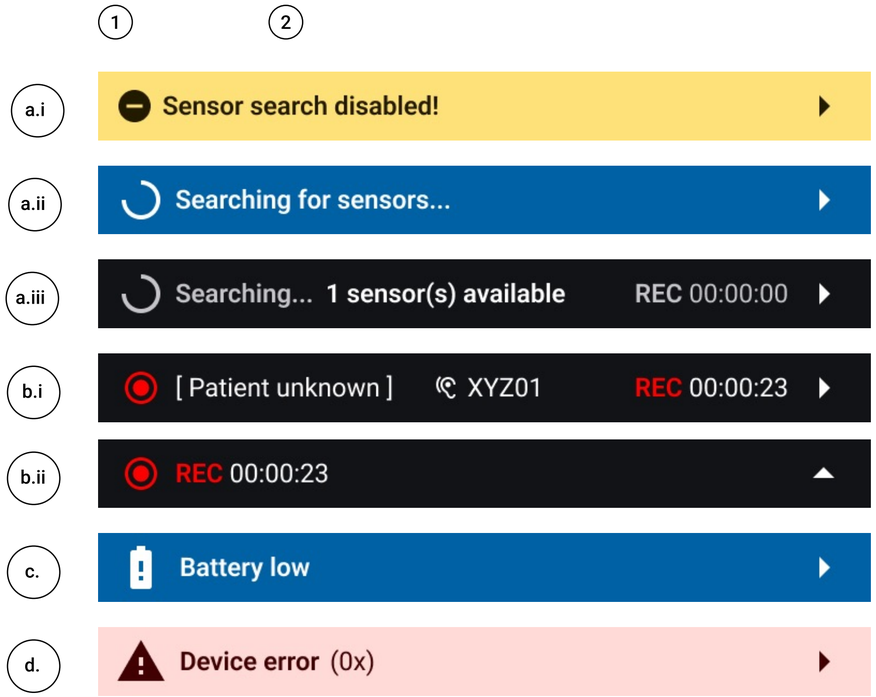
a. Scanning status
   i. Scanning disabled
   ii. Scanning for sensors
   iii. Scanning... X sensor(s) available

b. Active recording state
   i. Outside of Recording
   ii. Inside Recording

c. Battery warning

d. Other device errors

1. Leading icon
2. Information text



Status bar notifications

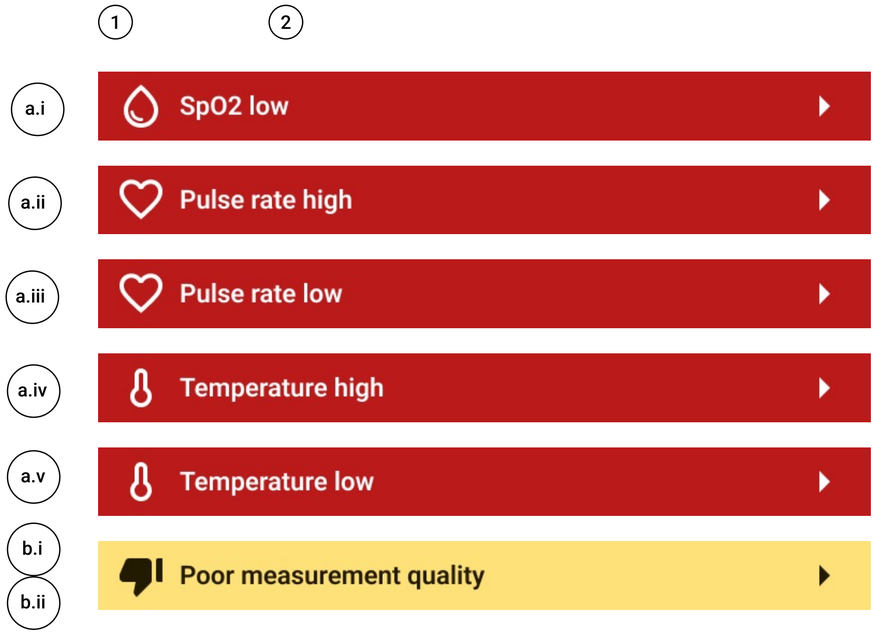
Status bar notifications

2. Measurement notifications

a. Vital sign thresholds
   i. SpO2 low
   ii. Pulse rate high
   iii. Pulse rate low
   iv. Temperature high
   v. Temperature low

b. Quality thresholds
   i. Quality low
   ii. Perfusion low/high

The order of these notifications as they are written here is the order of their prioritization.



1. Leading icon
2. Information text

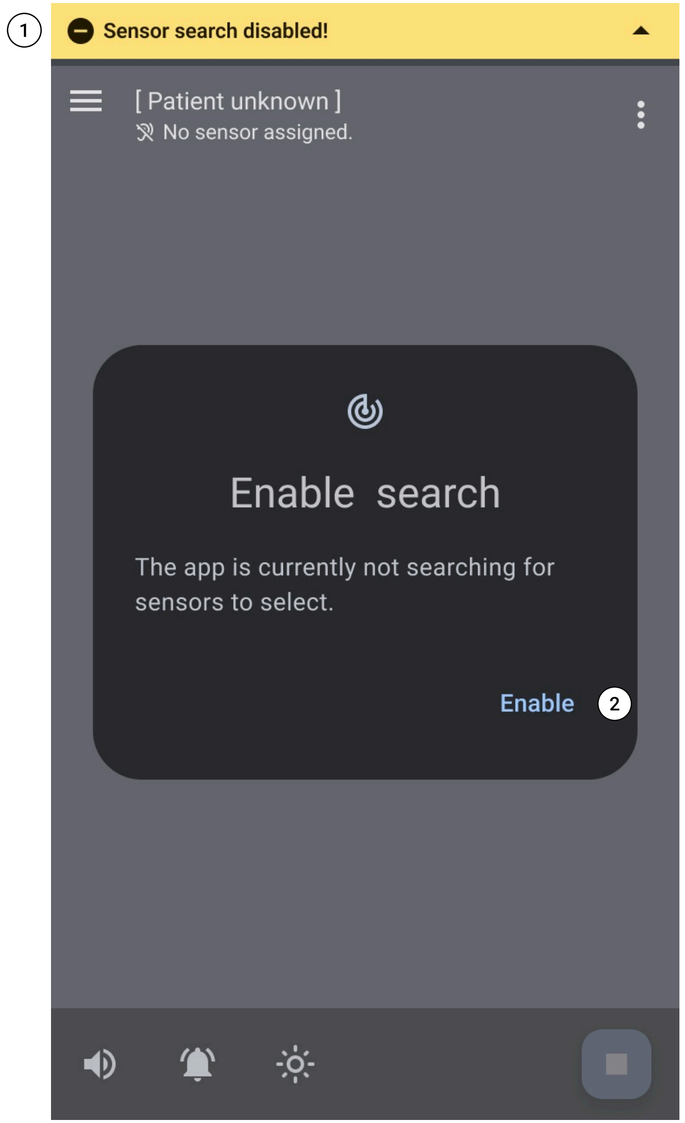
ENGLISH

Status bar notifications

System notifications
Scanning disabled

If the search for sensors is not possible because you have deactivated scanning, the message 'Sensor search disabled' appears.

Tap on the error message to return to the recording. Here you can resume the search by activating scanning.
To do this, tap on 'Enable' in the dialog box



1. Notification: 'Sensor search disabled!'
2. Enable search again.

Status bar notifications

Status bar notifications

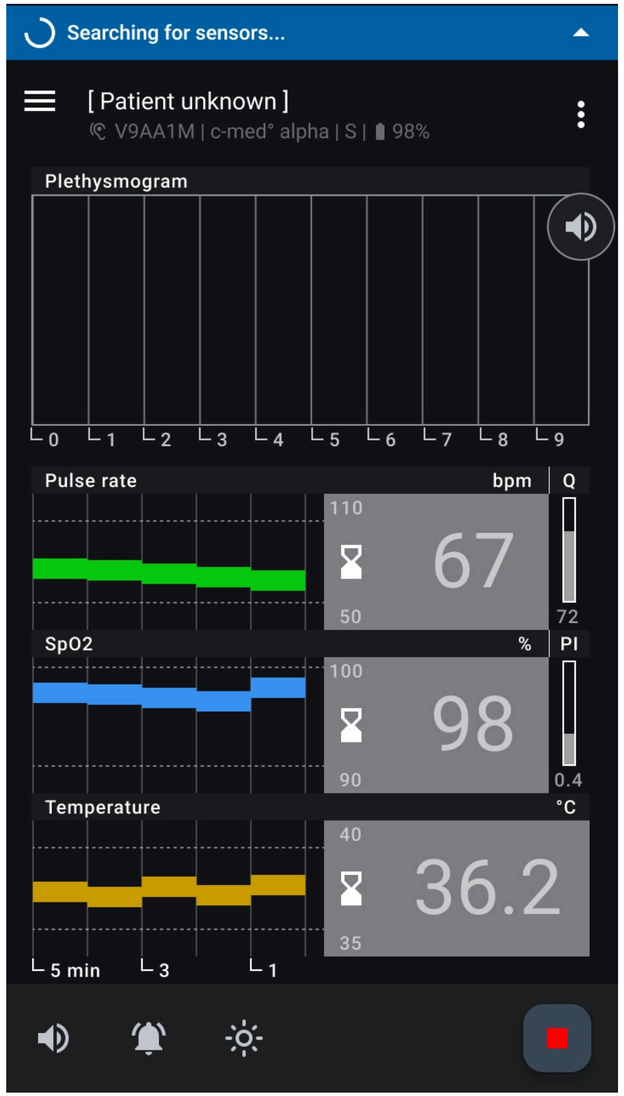
System notifications
Scanning for sensors

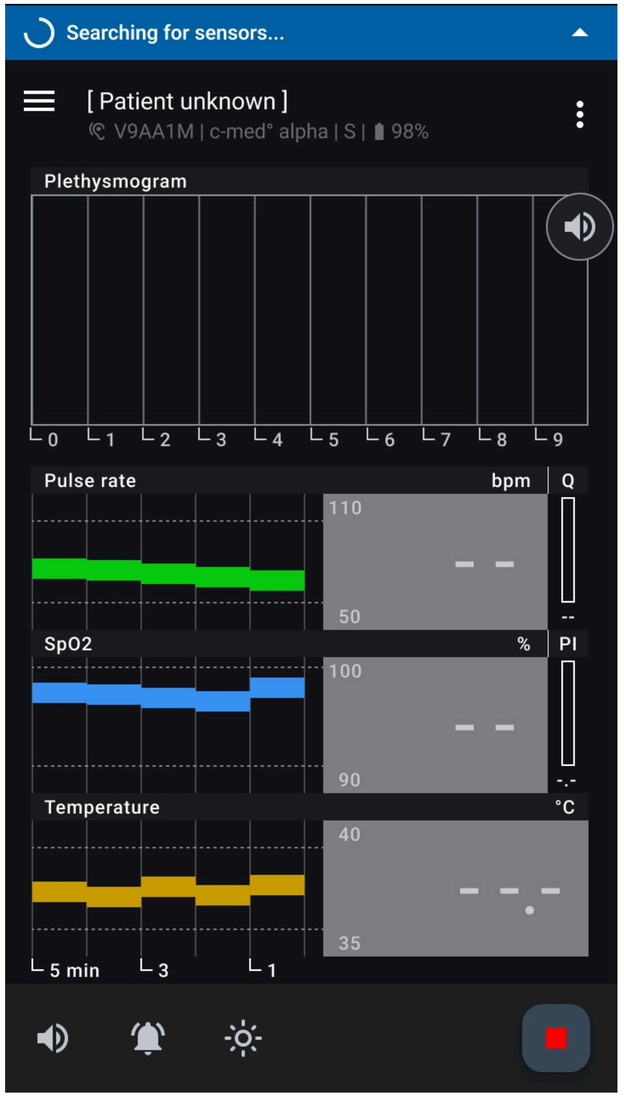
If you move outside the BLE range of the sensor (10 meters), the app loses reception. The app starts scanning for sensors again. The notification appears: ‘Searching for sensors...’

As soon as the app stops receiving new data, it displays the last current values as expired and grays them out. After 30 seconds, the values disappear completely.

The app continues to search for a sensor signal and displays the sensor data again as soon as it is available again.

Solution: Return to the BLE range of the sensor.





Status bar notifications

Condition:
Sensor and mobile device are more than 10 meters apart.

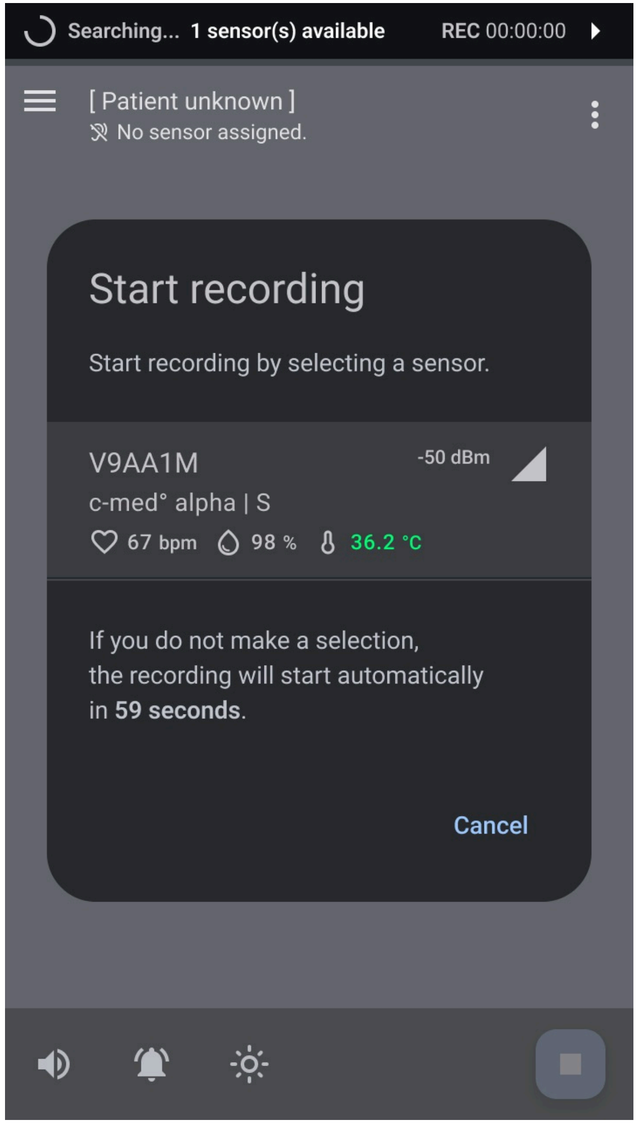
Signal tone:
3 pulses with longer intervals and medium pitch

ENGLISH

Status bar notifications

System notifications
Sensors available

The sensor search runs continuously. As soon as sensors are available, it is displayed in the status bar. At the same time, the dialog for selecting the sensors opens automatically. You can start a recording immediately by making a selection.



Status bar notifications

Condition:
Sensor and mobile device are less than 10 meters apart.
Sensor is on.
App is searching.

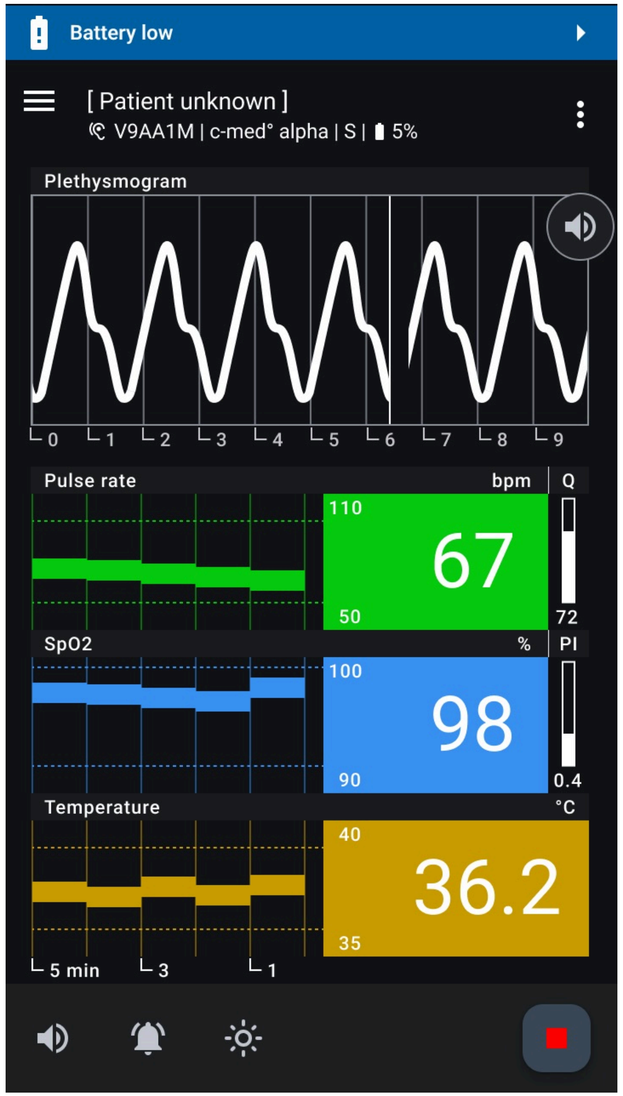
ENGLISH

Status bar notifications

System notifications
Battery low

If the battery level of the sensor drops to 5 % or below, you will receive the message: ‘Battery low’.

Solution: Charge the sensor as soon as possible or replace the sensor if possible. The continuous running time of the sensor is 12 hours, a complete charging process takes one hour.



Status bar notifications

Condition:
Battery Sensor ≤ 5 %

Signal tone:
4 pulses with medium interval and medium pitch

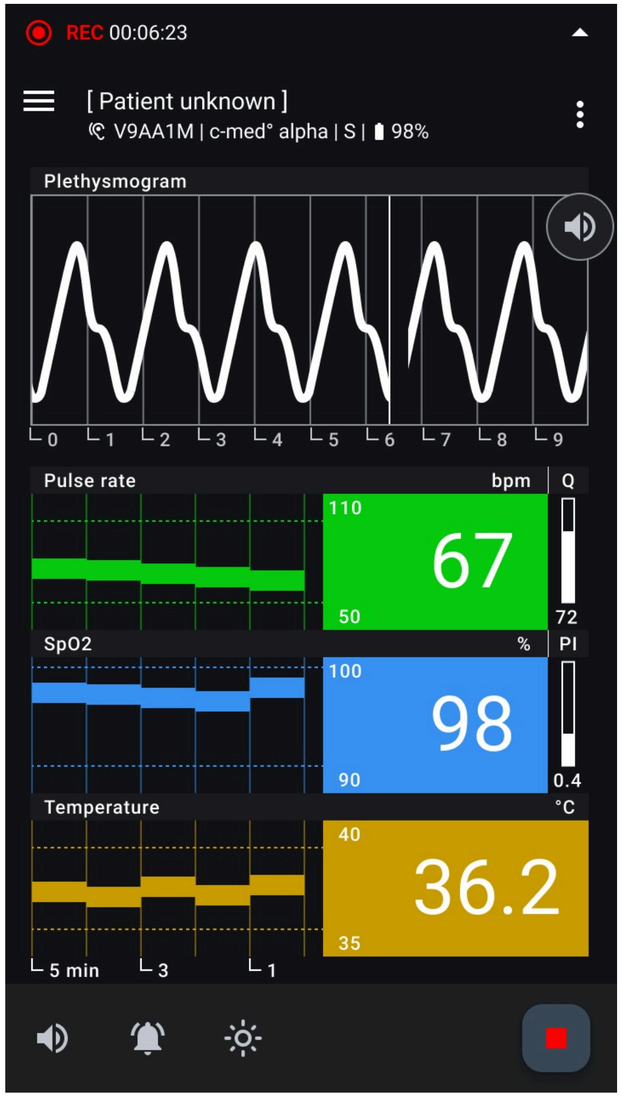
Status bar notifications

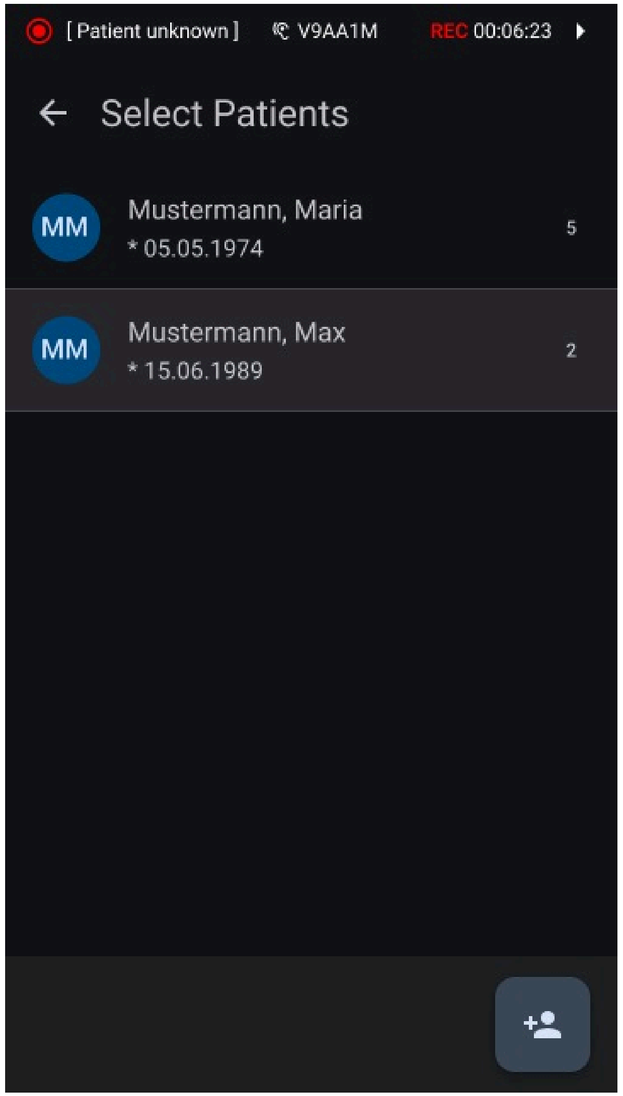
System notifications
Active recording

If a recording is active and there are no notifications, there are two views of the status bar - one within the recording and one in every other navigation point of the app.

Within:
Here you will see an active red recording icon and next to it the recording time.

Outside:
Here you will see the name of the patient, the serial number of the sensor and the recording time.





Status bar notifications

Condition:
Recordings active

Signal tone:
None

ENGLISH

System notifications
Device error

If the sensor suffers from a technical or hardware error, it recognizes this and sends an error code.

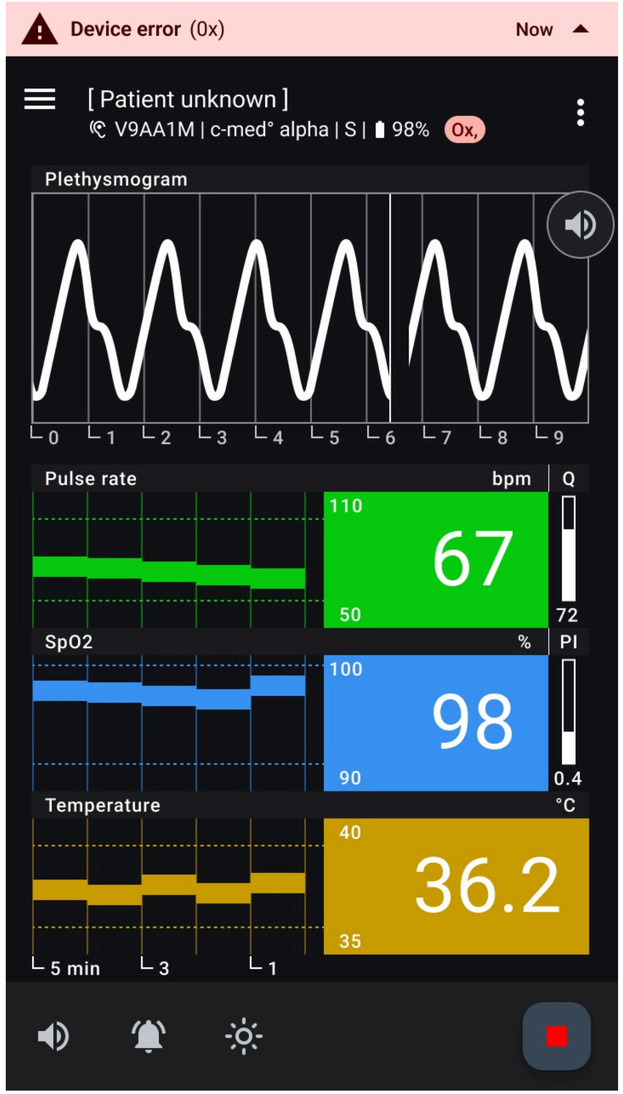
The message appears: Sensor defective.

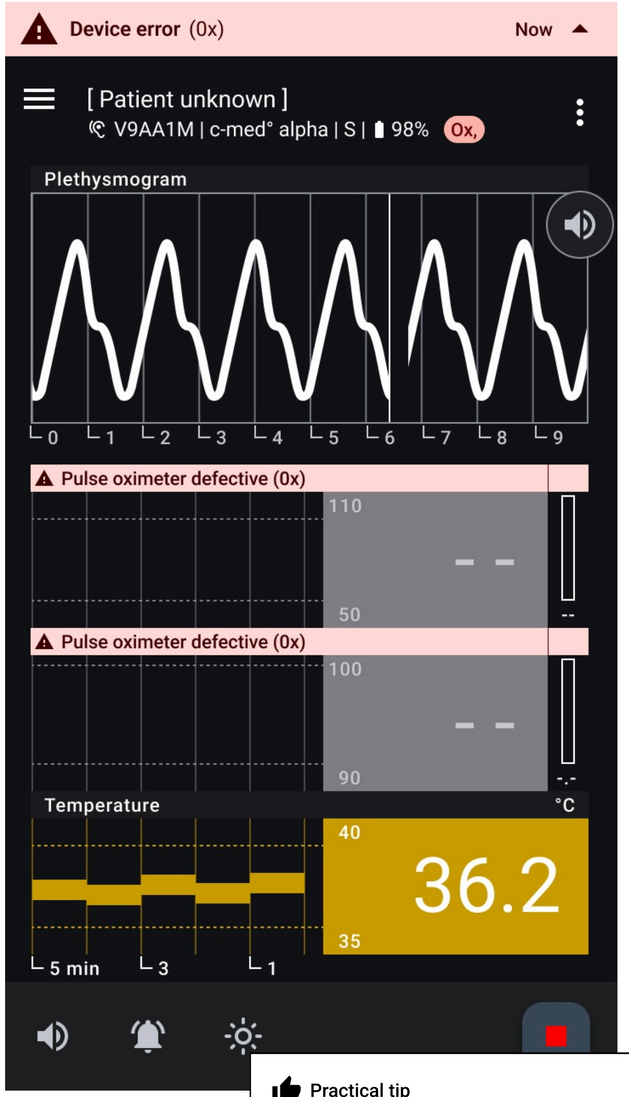
- If no vital parameter is affected, it appears in the notification bar.
- If a vital parameter is affected, the error additionally appears in the corresponding vital item.

In addition, an error badge always appears next to the sensor information.

In this case, the sensor should not be used.

Solution: Replace the sensor as soon as possible.





Status bar notifications

Condition:
Sensor sends an error code

Signal tone:
1 long, low tone

Practical tip

Visible damage
The sensor should be checked for integrity before each use and should no longer be used in the event of visible damage.

ENGLISH

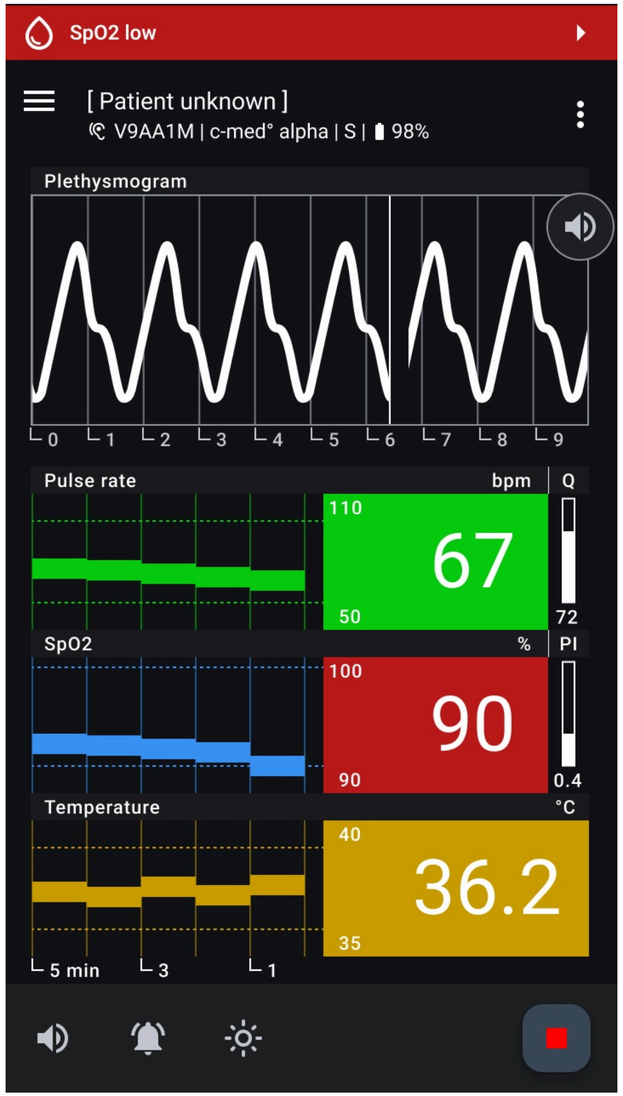
Status bar notifications

Measurement notifications
Vital signs thresholds

If the current value of a vital parameter reaches its upper or lower limit, you will receive a corresponding message, e.g. SpO2 low.

The SpO2 value has the highest priority, followed by the pulse rate and finally the body temperature.

The app only displays the values if they are valid. The app does NOT give a diagnostic or therapeutic interpretation.



Status bar notifications

Default limits settings:

SpO2 < 90 %

Pulse rate > 110 bpm
Pulse rate < 50 bpm

Temperature > 40 °C
Temperature < 35 °C

Signal tone:

SpO2: 7 pulses with very short intervals and very high pitch

Pulse rate: 5 pulses with short intervals and high pitch

Temperature: 5 pulses with short intervals and medium pitch

Practical tip

Keep the sensor thoroughly clean!
It is very important that all sensing elements (IR window, LED and photo diode) on the sensor head are always thoroughly clean. A soiled sensor head could e.g. lead to lower measured temperatures.

Status bar notifications

Measurement notifications
Quality thresholds

If the sensor detects an insufficient quality index when measuring the pulse rate or an insufficient perfusion index when measuring the oxygen saturation, it will show the notification: ‘Poor measurement quality’.

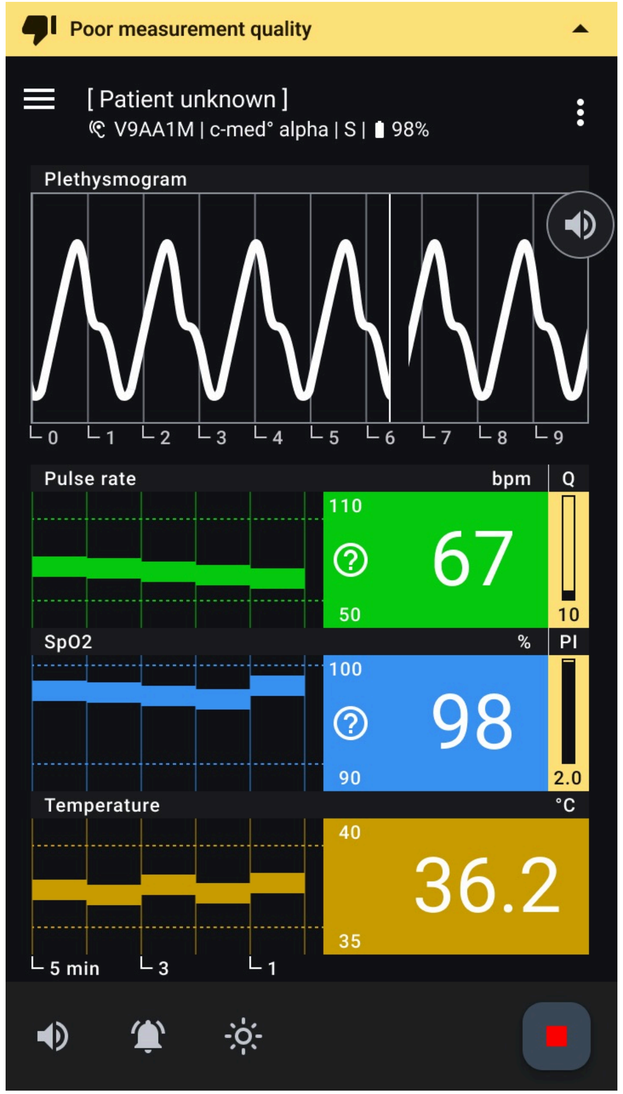
The vital parameter values displayed may not be valid under these circumstances and are also marked with a question mark. They appear as a transparent bar during the course of the measurement.

This can have different reasons, but the most common are:

- Strong vibration or movement of the head or jaw
- Soiling in the ear canal or on the sensor
- Poor sensor fit
- Incorrect sensor size

Solution: Make sure that the sensor is positioned correctly and that the patient is not talking or chewing a lot. If the quality does not improve, check the correct positioning of the sensor in the ear canal and readjust it. If this does not lead to any improvement, you should select a different sensor size.

A precondition is always that you use clean sensors.



Status bar notifications

Condition:
Quality index (Q) < 45
Perfusion index (P) < 0.2
Perfusion index (P) > 2.0

Signal tone:
3 pulses with medium interval and medium pitch

Practical tip

Swap sensor
If it becomes necessary to swap the sensor, this can be easily done by tapping on "Swap sensor" under the menu icon while the recording is ongoing.

Practical tip

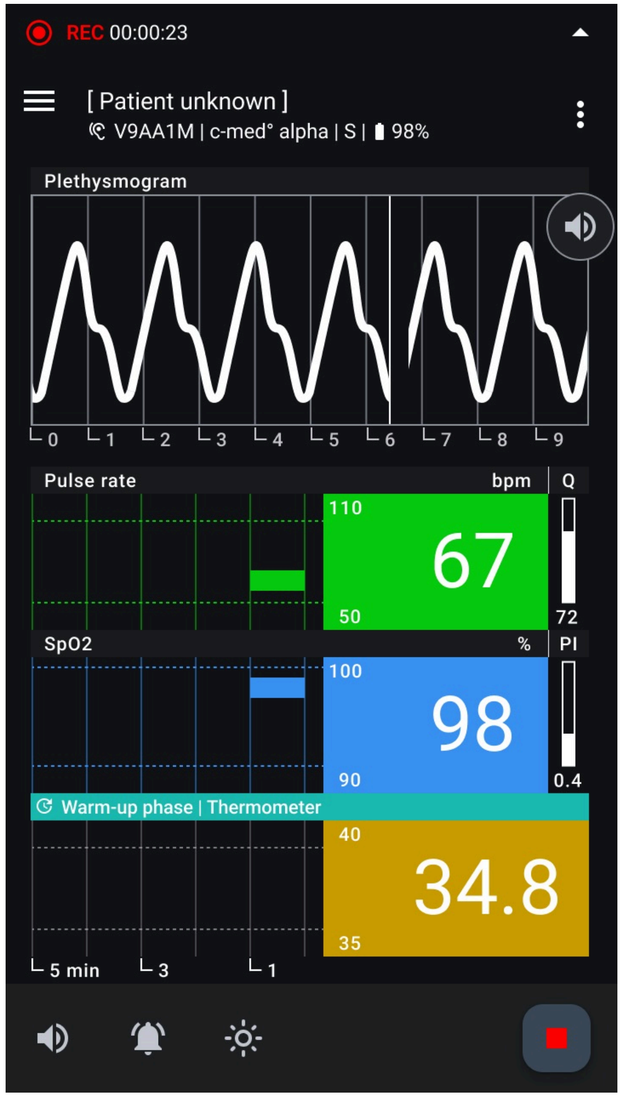
Cerumen in the ear canal
The measurements could be disturbed by excessive cerumen in the ear canal. Remove the sensor once, clean the sensor head and the ear canal briefly and reinsert it.

Status bar notifications

Measurement notifications
Warm-up phase | Thermometer

At the start of a new measurement with a new sensor, the sensor's thermometer is in a warm-up phase. Considering the vital sign 'Temperature' no notifications are issued during this time. The warm-up phase ends automatically after 2 minutes.

Tap on the vital sign header to skip the warm-up phase. This can be useful if you want to work with direct measurement of the current temperature right from the start.



Status bar notifications

Condition:
New recording, sensor needs to warm up

Signal tone:
No signal tone

ENGLISH

LIVE

RECORDING

User interactions

Select sensor and start recording

Select the desired sensor from the list in the ‘Start recording’ dialog.
Identify your desired sensor using the serial number. The signal strength can be of additional help.
You start the recording by selecting a sensor.

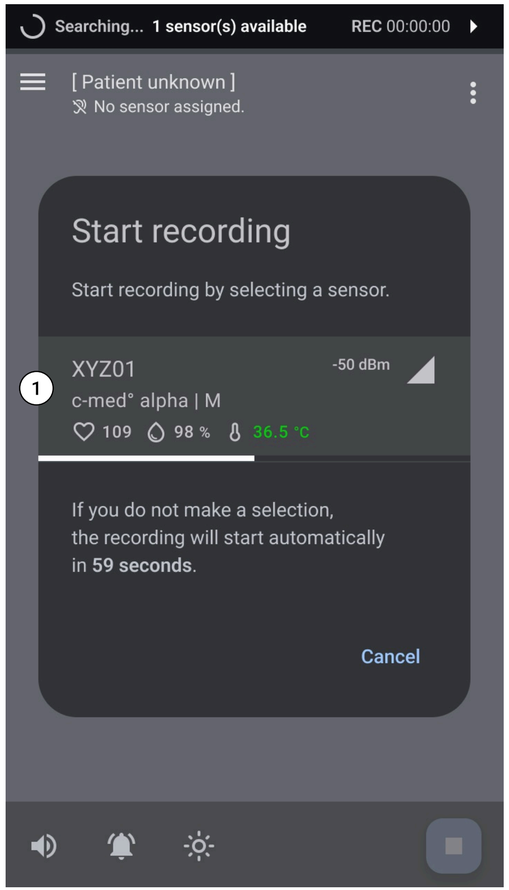
NEW

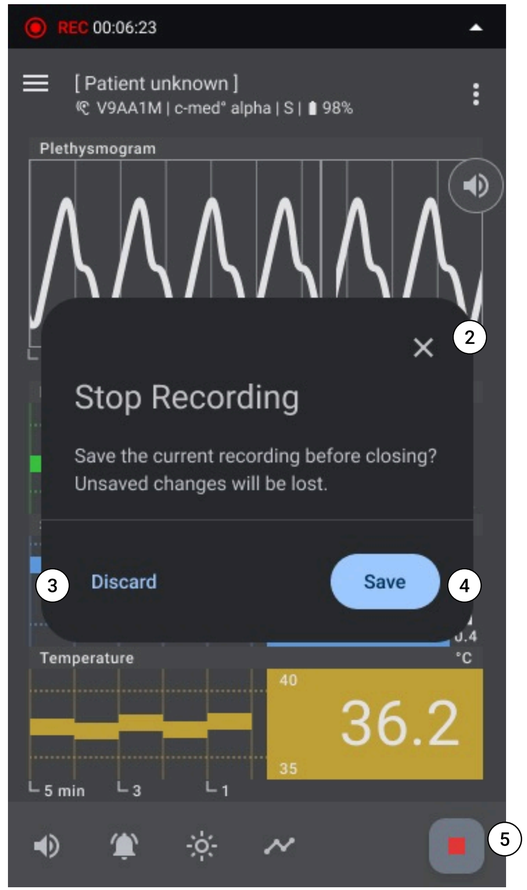
End recording

By tapping the "Stop icon" in the bottom app bar, you can end the recording.
A dialog window will appear.

Tap "Save" to stop and save the recording.
Tap "Discard" to stop the recording without saving it.
Tap the "X" in the top right corner to close the dialog and return to monitoring.

You can find the saved recording in the Navigation point: ‘Recordings’.





1. List of available sensors.
2. Cancel Dialog
3. Discard Recording
4. Save Recording
5. Stop Recording

Practical tip

Add patient
Anytime during an ongoing recording, you are able to add or choose a patient from the list to add him/her to the recording.

ENGLISH

User interactions

Plethysmogram
Audio on, off, pause

The PPG signal provides continuous acoustic feedback.

From the intervals between the tones the pulse rate can be derived. The pitch provides information about the arterial oxygen saturation of the blood (SpO2). A lower pitch indicates a lower oxygen saturation.

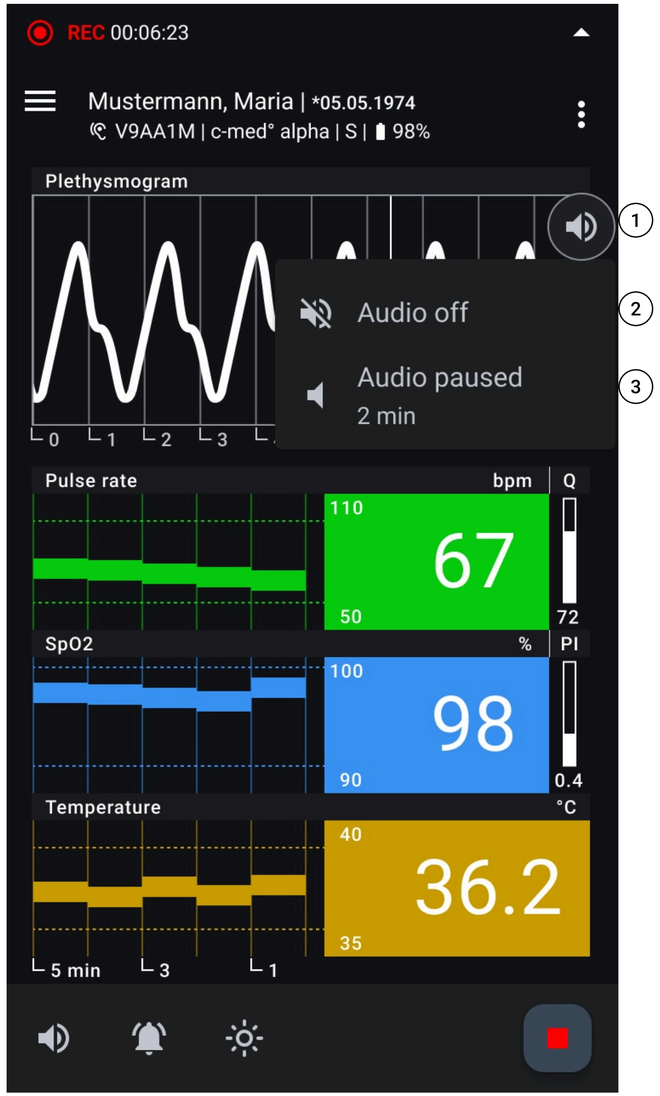
The sound output of the Plethysmogram can be changed by tapping on the speaker icon into:

- Audio ON
- Audio OFF
- Audio paused (2 min)

NEW

SpO2 Dropout Pulse Tone

A special acoustic signal is emitted when a valid pulse is detected but no valid SpO2 signal is available—typically due to motion artifacts or poor peripheral perfusion. This tone differs clearly from the normal pulse tone and indicates a technical or physiological issue affecting SpO2 measurement.



1. Pleth. audio ON
2. Pleth. audio OFF
3. Pleth. audio paused (2 min)

ENGLISH

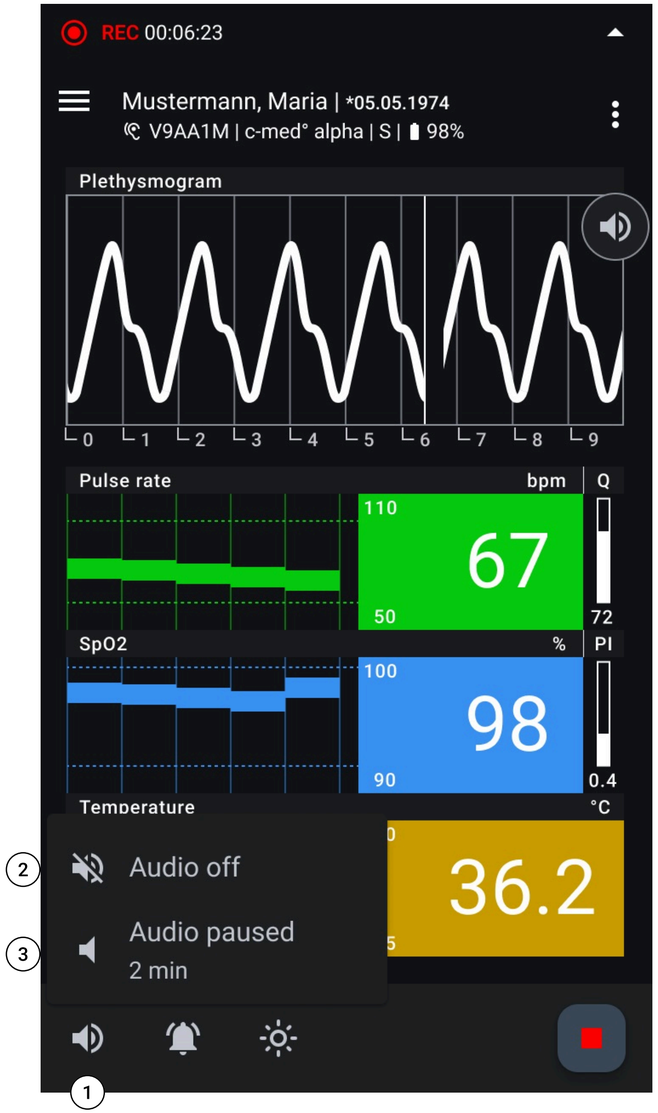
User interactions

Audio on, off, pause

The global sound output setting applies to all acoustic signals. This therefore includes the sounds of the photoplethysmogram and the notification sounds. The following selection is available:

- Audio ON
- Audio OFF
- Audio paused (2 min)

Switching off the sound output only deactivates the audio output, but not the visual notifications.



1. Audio ON
2. Audio OFF
3. Audio paused (2 min)

ENGLISH

User interactions

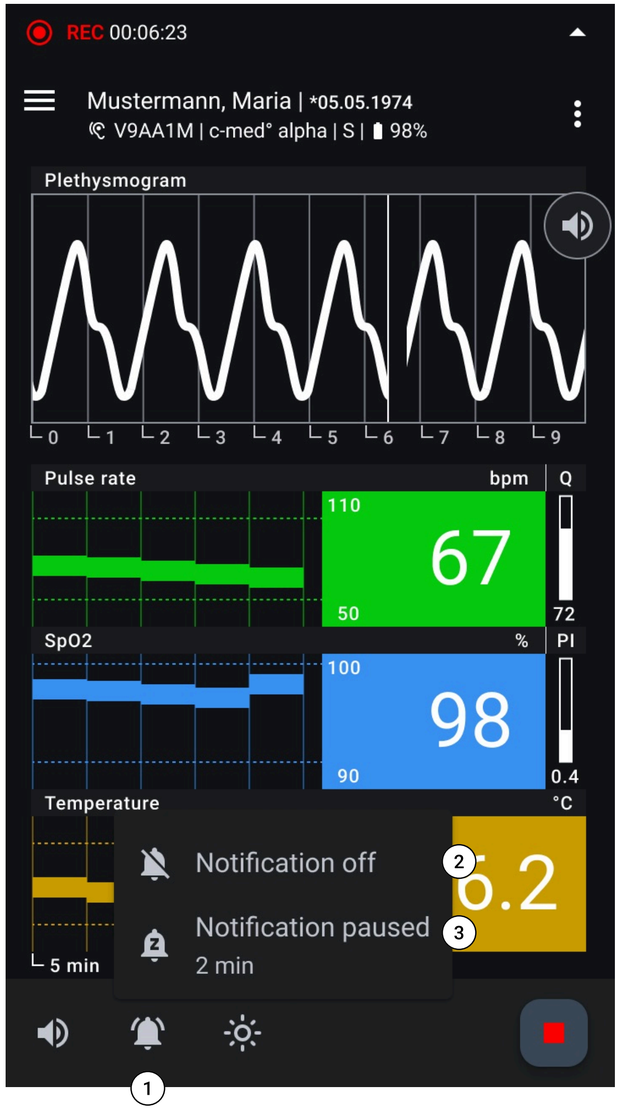
Notification sounds on, off, pause

Three user interactions are available tapping on the notification icon in the bottom app bar. These selections will apply for all notifications in the current recording:

- Notification sounds ON
- Notification sounds OFF
- Notification sounds paused (2min)

By default notification sounds are turned on. You can pause all notification sounds for two minutes. Or you can switch them off permanently until you switch them on again - or restart the app.

The visual display of the notifications always remains the same.



1. Notification sound
2. Turn off notification sounds
3. Pause notification sounds

ENGLISH

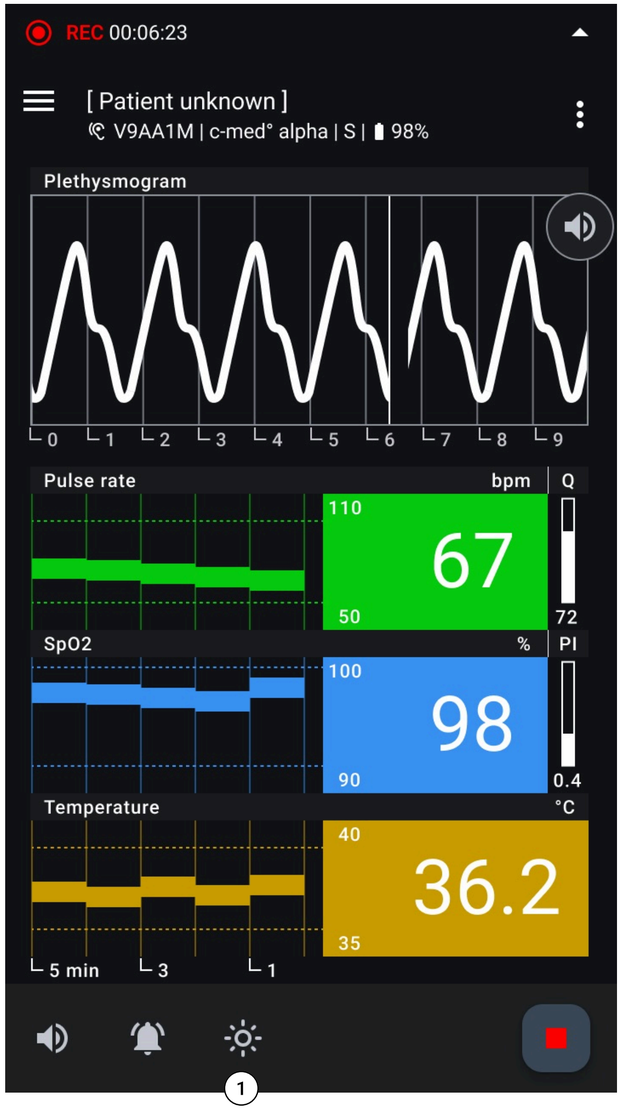
User interactions

Switch between light and dark mode

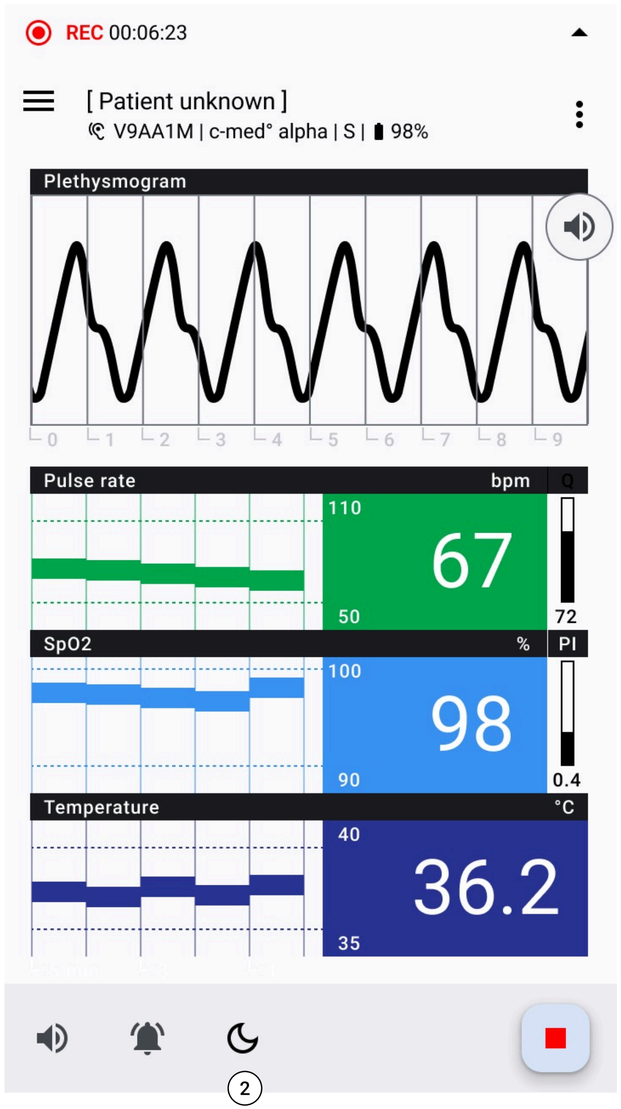
In the footer of the app there is a switch third from the left to switch between a so-called day mode and night mode.

As the app is likely to be used in different ambient conditions and lighting conditions, you can adjust the view:

- To avoid reflections on the screen
- To improve the contrast of the display
- To achieve the desired brightness



1



2

1. Enable light mode
2. Enable dark mode

ENGLISH

User interactions

Adaptable vital signs thresholds

Notifications (visual and audio feedback) with high priority are triggered if a predefined threshold of the measured vital signs is reached.

Adjusting Thresholds

1. Choose the vital sign:
   Long-press on the area of the wanted vital signs, which is displaying the current live value to open the bottom sheet.

2. Threshold Adjustment:
   In the bottom sheet, use the dropdown menu to adjust upper and lower thresholds individually for each vital sign.

3. Confirmation:
   Confirm your threshold adjustments to apply custom values.

1. Long-press vital sign element to open bottom sheet
2. Upper and lower threshold fields
3. Dropdown menu

ENGLISH

User interactions

Adaptable vital signs thresholds

Custom Threshold Indication

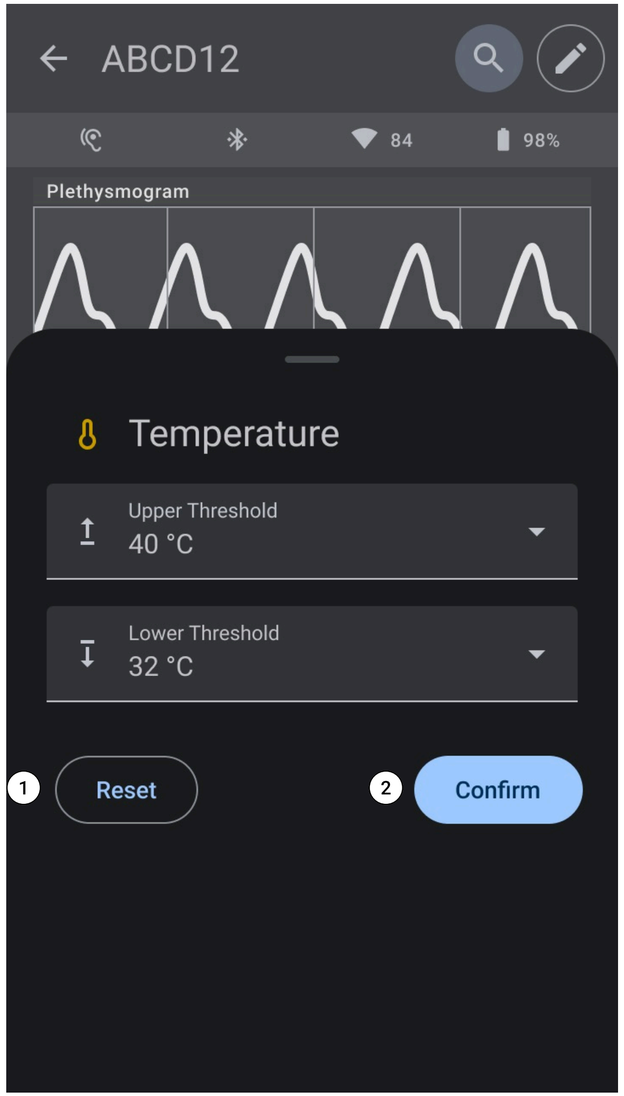
A small threshold icon next to the value indicates that custom thresholds have been set.

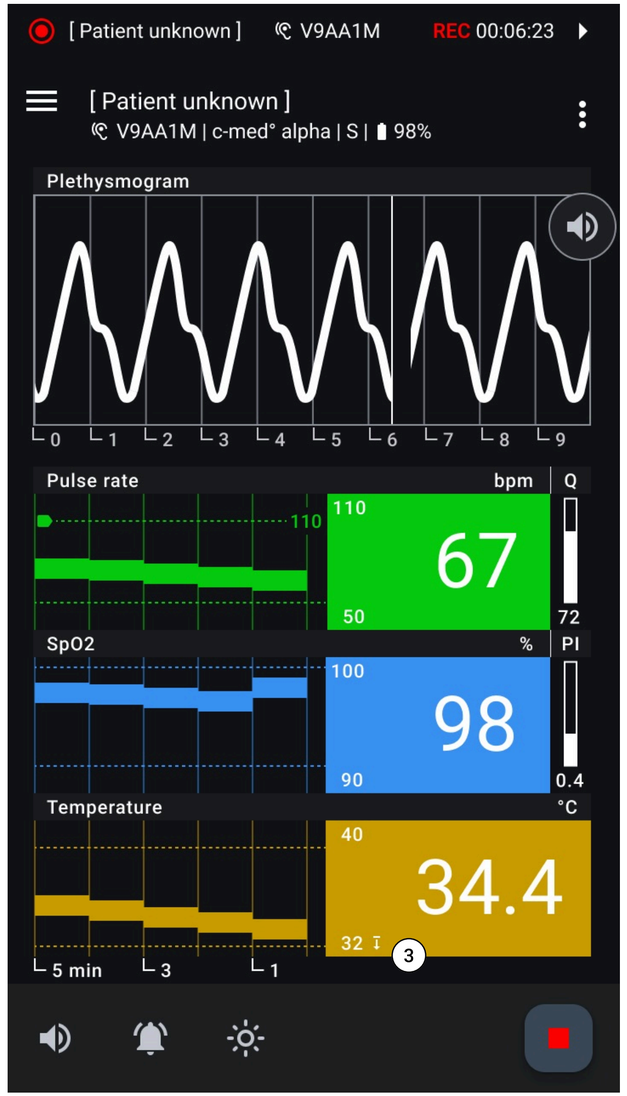
Resetting Thresholds

In the bottom sheet, tap ‘Reset’ to revert thresholds to default values.

Individual Threshold Adaption

Adjust upper and lower thresholds separately for each vital sign to tailor the monitoring experience.





1. ‘Reset’ buttton
2. ‘Confirm’ button
3. Custom threshold indicator

ENGLISH

User interactions

Edit, Add, Select patient

Tap on the the ‘More menu’ Icon button at the upper right of the top app. This opens the bottom sheet with more options for patient and sensor management.

Patient management

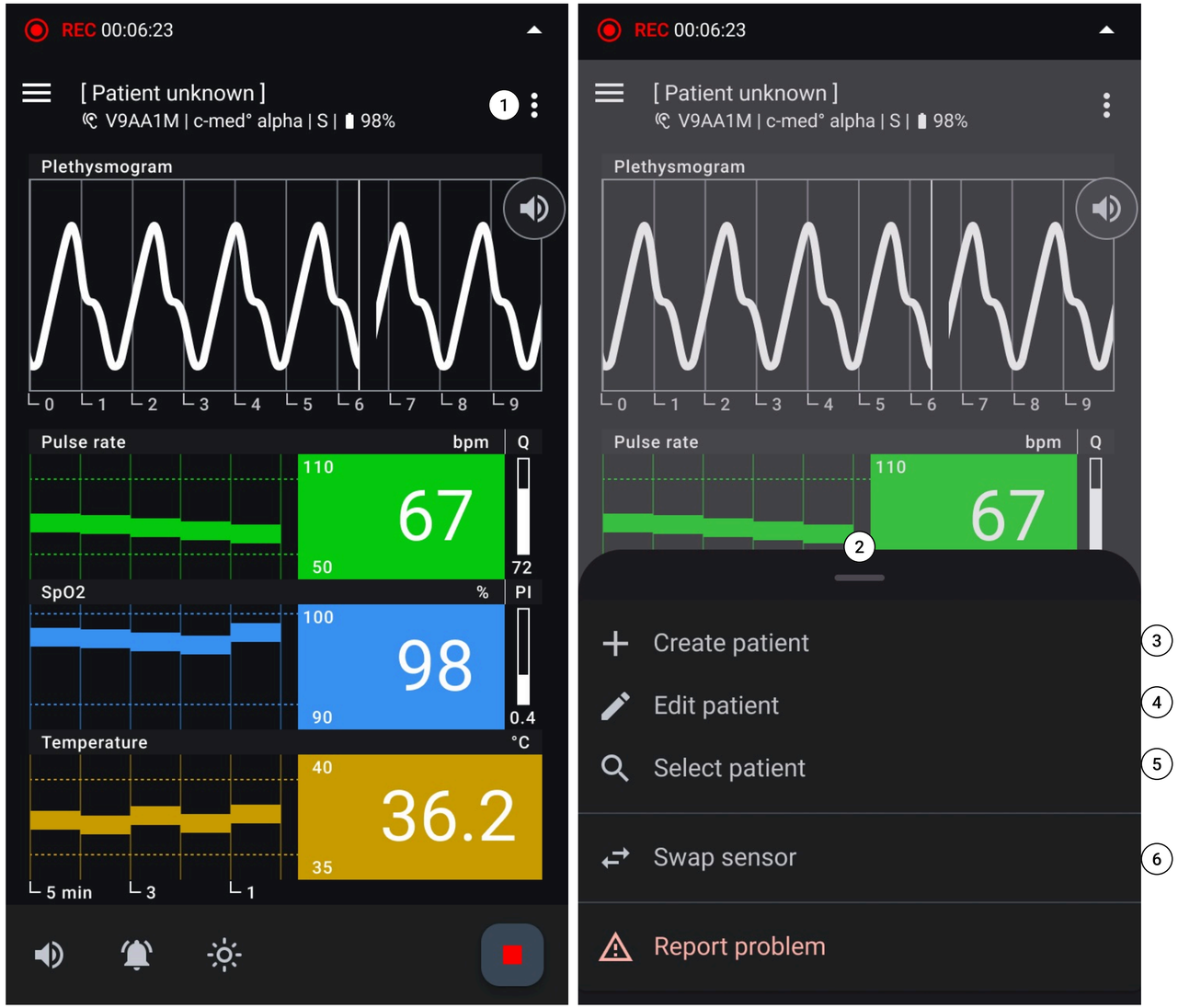
Add patient:
Create a new patient and add required information.

Edit patient:
Edit the existing patient information.

Select patient:
Select a patient you have already created by simply selecting it from a list.

Sensor management

Swap sensor:
If the currently connected sensor needs to be replaced during active recording, e.g. if the sensor size is changed, this can be done simply by tapping on ‘Swap sensor’ without having to stop the recording.



1. More Menu icon button
2. Bottom sheet
3. Edit exisiting patient
4. Add new patient
5. Select patient from list
6. Swap sensor

Practical tip

When you add a patient during an active recording, this patient will be automatically assigned.

ENGLISH

User interactions

Add patient

Tap on ‘Add patient’.
Fill out the text fields within the patient form and either:

- Tap ‘Save’ to create a new patient.
  The patient will be added to the current recording.
  The patient can be found later in the patient list.

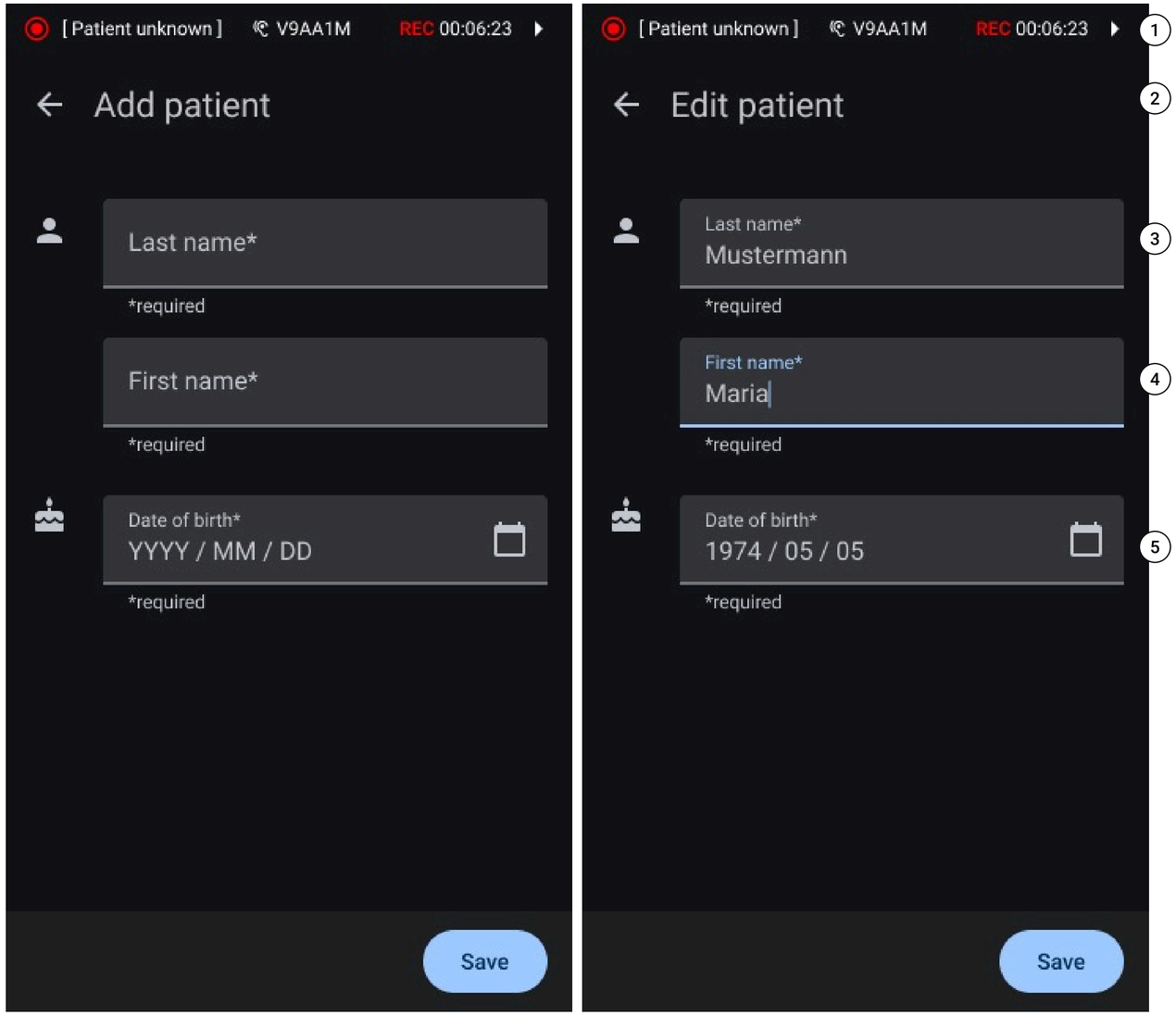
- Or tap ‘Cancel’ to end the action, all changes will be discarded .

Edit patient

Tap on ‘Edit patient’.
You can edit the existing information and:

- Tap ‘Save’ to confirm the changes.

- Or tap ‘Cancel’ to end the action, all changes will be discarded.



1. Notification bar
2. Top app bar
3. Last name
4. First name
5. Date of birth

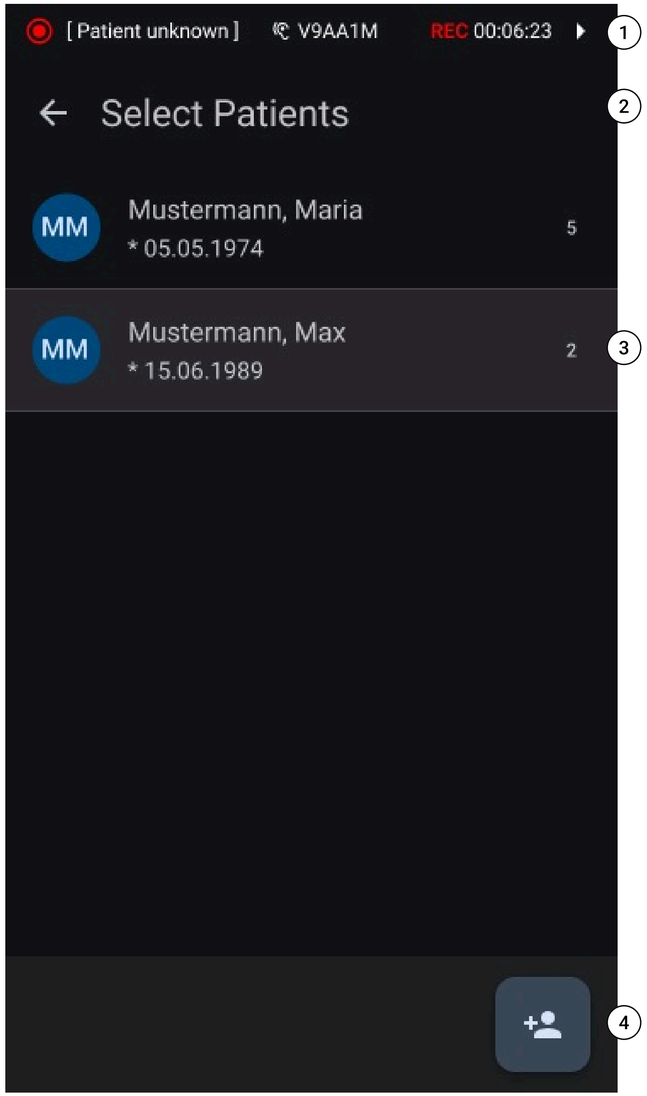
ENGLISH

User interactions

Select patient

Tap on the ‘Select patient`

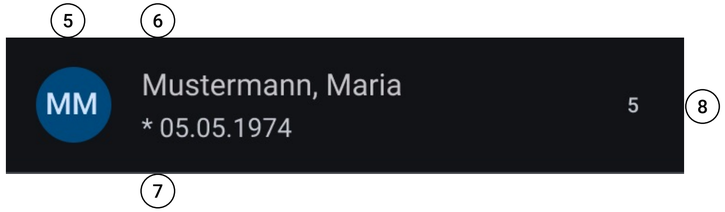
- Tap on one patient to assign him/her to the current recording
- Tap on the ‘Add patient’ button on the bottom to create a new patient and assign that one to the record.



1. Notification bar
2. Top app bar
3. Patient item
4. Create new patient

Patient item

5. Monogram
6. Name
7. Date of birth
8. Recordings



ENGLISH

User interactions

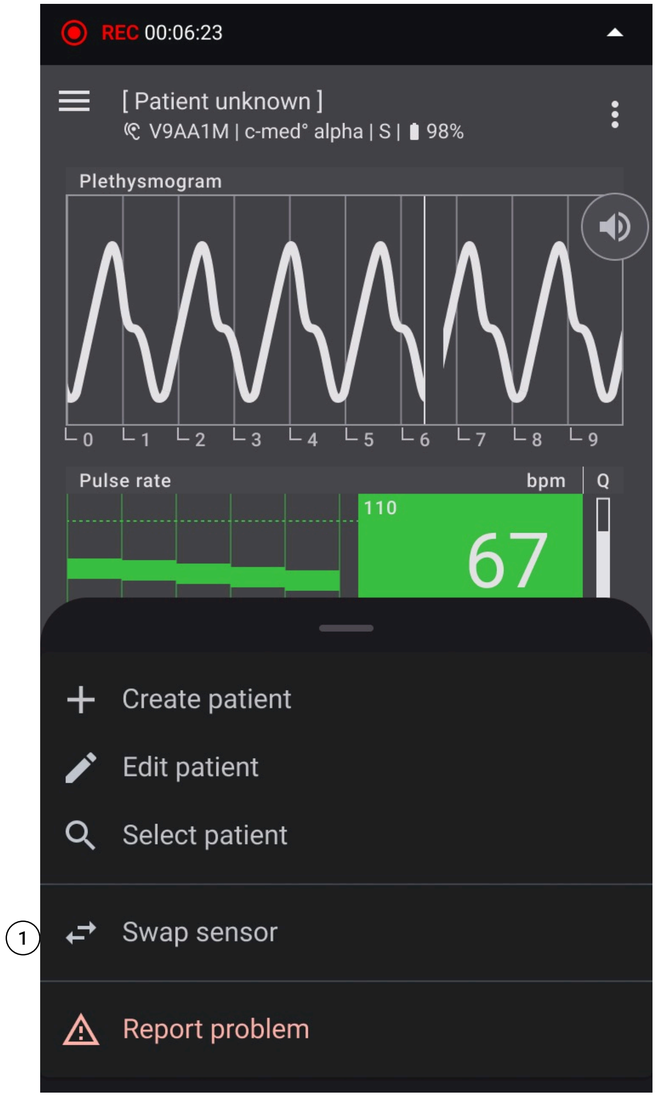
Swap sensor

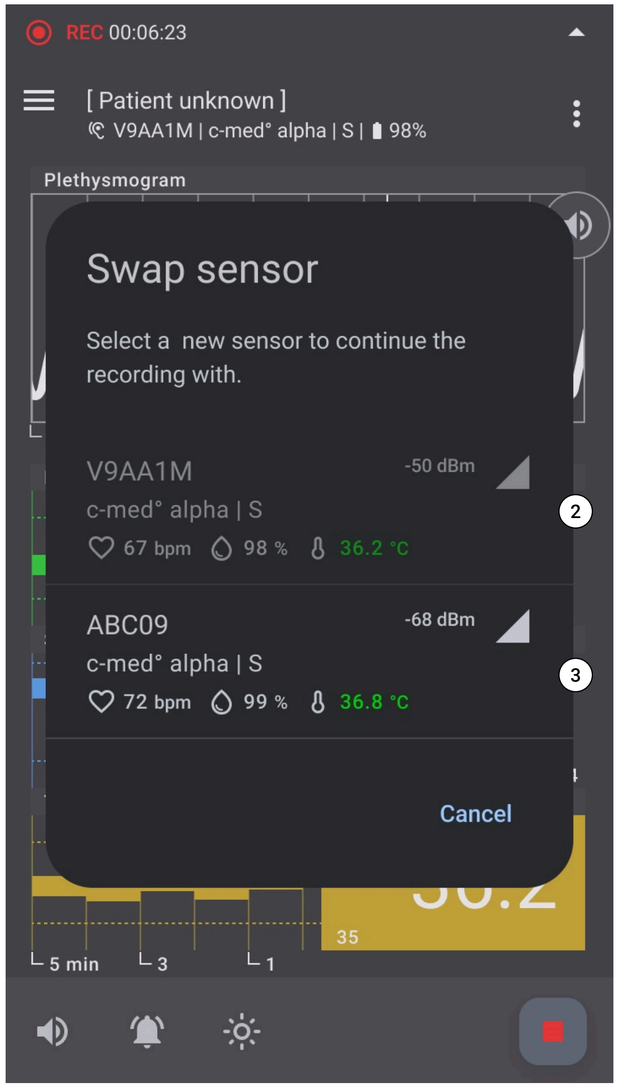
Tap on ‘Swap sensor’.
This will allow you to seamlessly assign a new sensor to the ongoing recording.

This could be the case, if
- you want to change the sensor size
- or the sensor battery is low.

The ‘Swap Sensor’ dialog appears and you can simply select another available sensor from the list displayed. The serial number and signal strength can again be used to identify the desired sensor.

During the selection process, the current recording continues to run continuously.





1. Swap sensor
2. Currently selected sensor
3. Other available sensors

ENGLISH

User interactions

Report problem

The "Report problem" function in our monitoring app allows you to provide feedback on current or saved recordings if irregularities or incidents occur. This function helps us to continuously improve the app and respond to your concerns.

Entry points

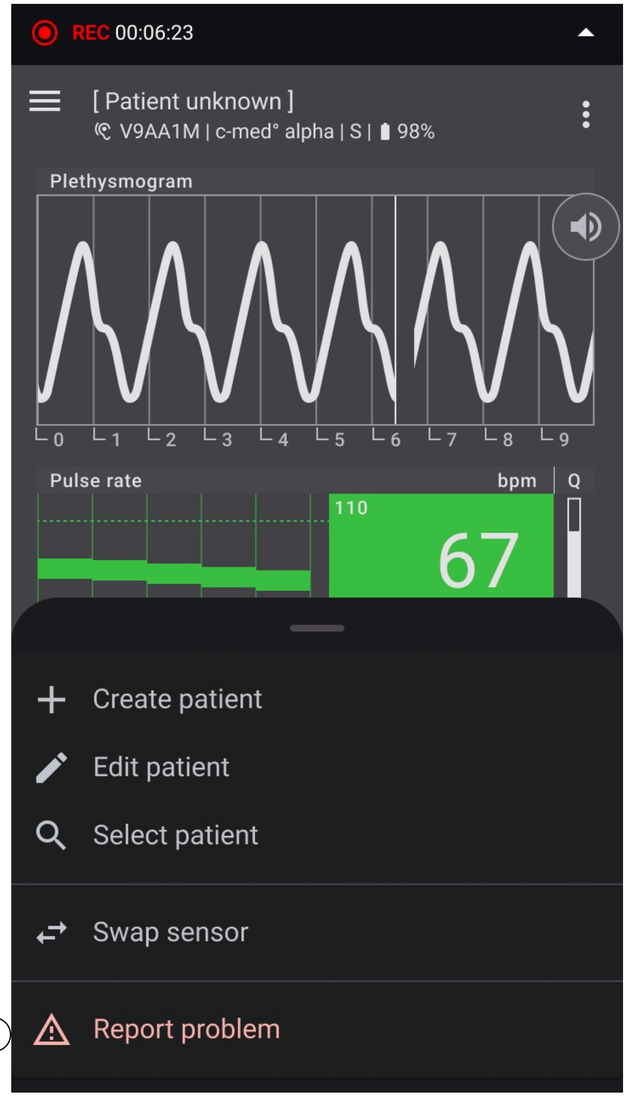
Create patient:in:
Create a new patient and enter patient information.

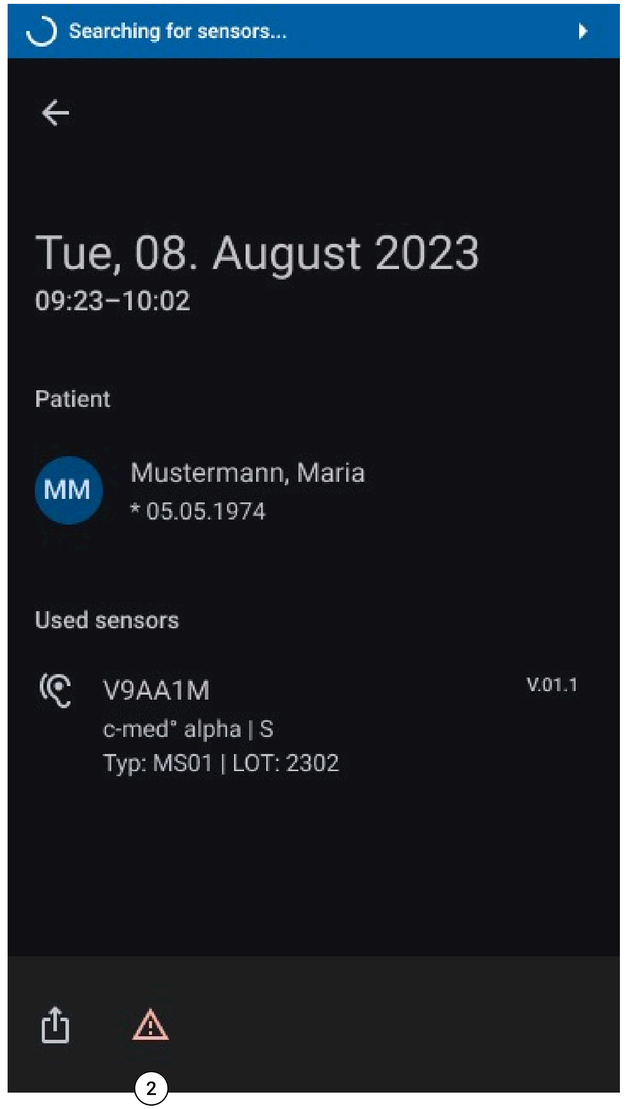
Edit patient:
Allows you to edit all the information of an existing patient.

Select patient:
Select an existing patient from a list.

Sensor management

Swap sensor:
If the currently connected sensor in the active recording needs to be replaced, e.g. if the sensor size is changed, this can be done simply by tapping on "Swap sensor" without having to stop the recording.





1. More Menu icon button
2. Bottom sheet
3. Edit exisiting patient
4. Add new patient
5. Select patient from list
6. Swap sensor

ENGLISH

User interactions

Report problem (input mask)

Problem description (required):
Fill in the text field with a detailed description of the problem that has occurred. This field is mandatory.

Anonymous CSV file (opt-out):
The measurement in question is automatically attached as an anonymized CSV file. You can deselect this file, but it helps us to better investigate the problem.

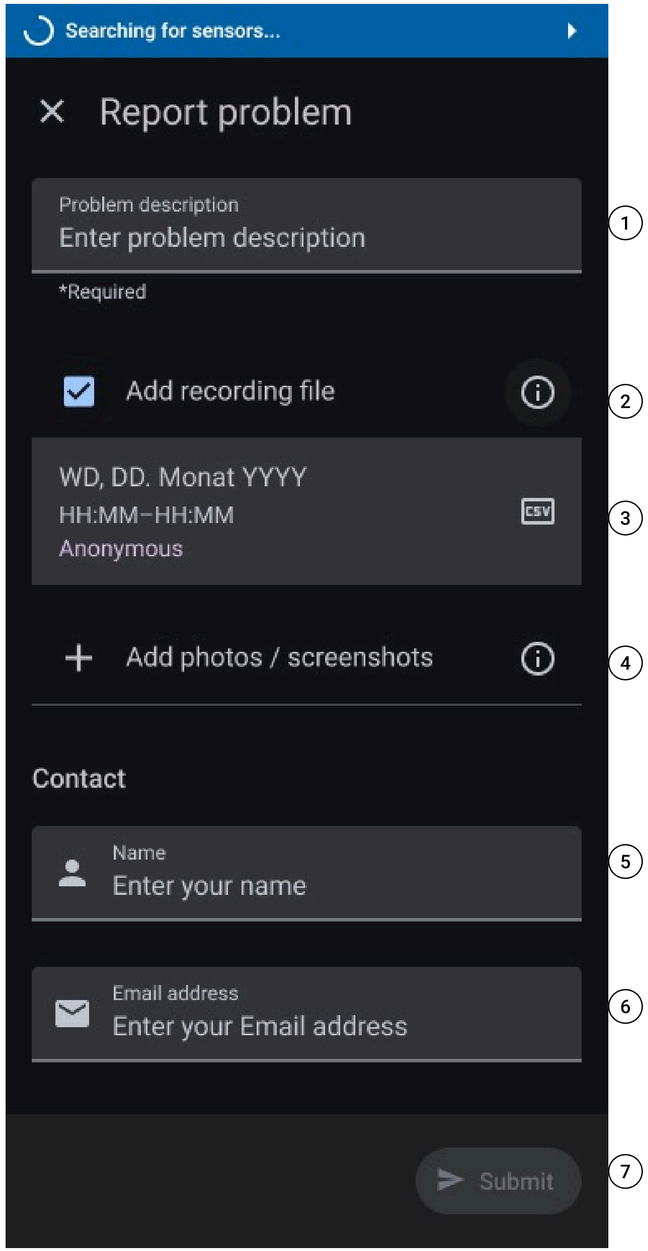
Add photos (optional):
Optionally, you can add photos to illustrate the problem.

Contact information (optional):
If you would like personalized feedback, enter your name and email address in the appropriate fields.

Additional information

CSV file:
Click on the "Additional information on CSV file" link to find out what data is contained in the attached CSV file and how it is used.

Photos:
Another link provides you with instructions on the correct handling when uploading photos to facilitate problem analysis.



1. Problem description (text field)
2. Add recording (button)
3. Added recording (display element)
4. Add photos (button)
5. Name (text field)
6. E-mail address field (text field)
7. Send problem report (button)

ENGLISH

Manage

RECORDINGS

NEW

Visualization and Interactions

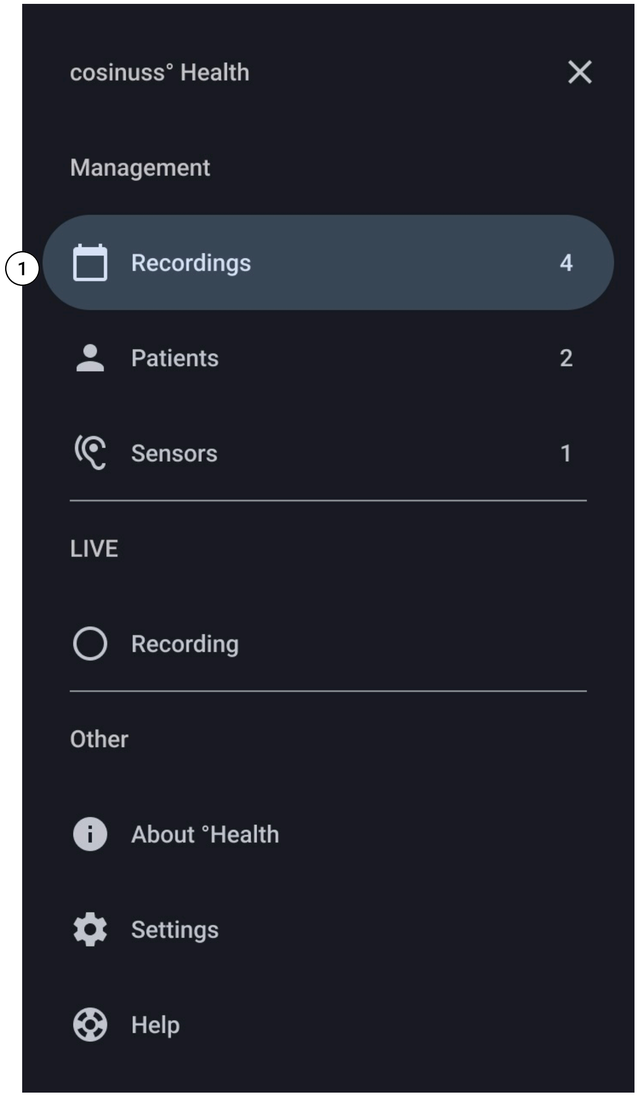
List view

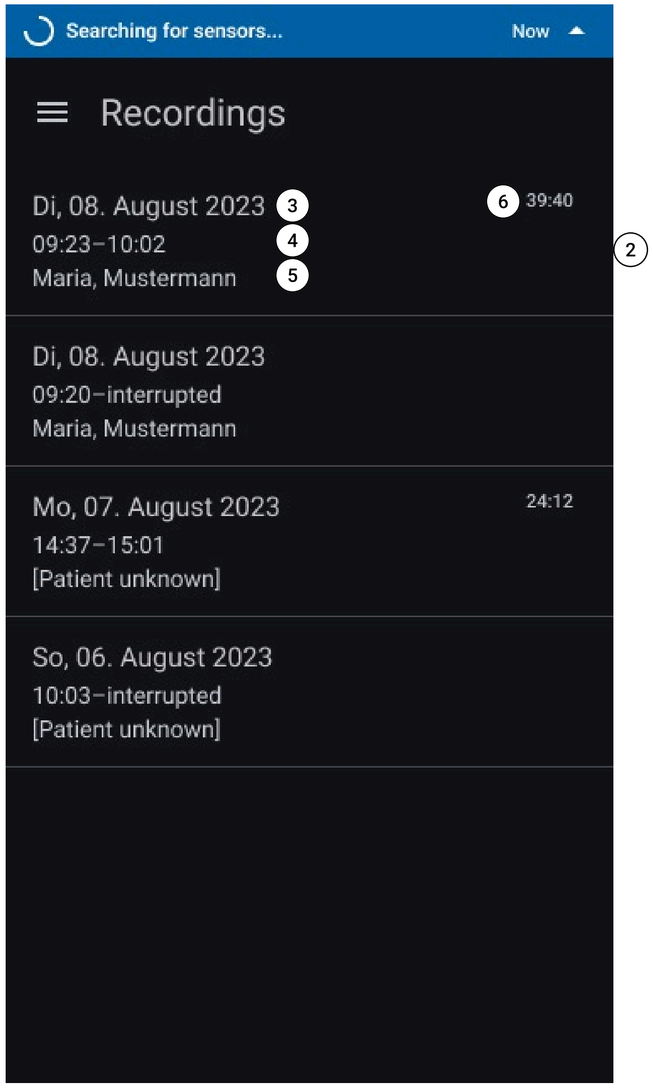
AAll recordings are accessible via the "Recordings" menu in the navigation bar.

The list is sorted in reverse chronological order, meaning the most recent recordings appear at the top.

Each entry can be clearly identified by:
– Date
– Start and end time
– Patient name (if available)

Tap on an entry to open the detailed view of that recording.





1. ‘Recording’ section
2. Recording item
3. Date
4. Time of beginning and end
5. Name of the patient
6. Duration

ENGLISH

NEW

Visualization and Interactions

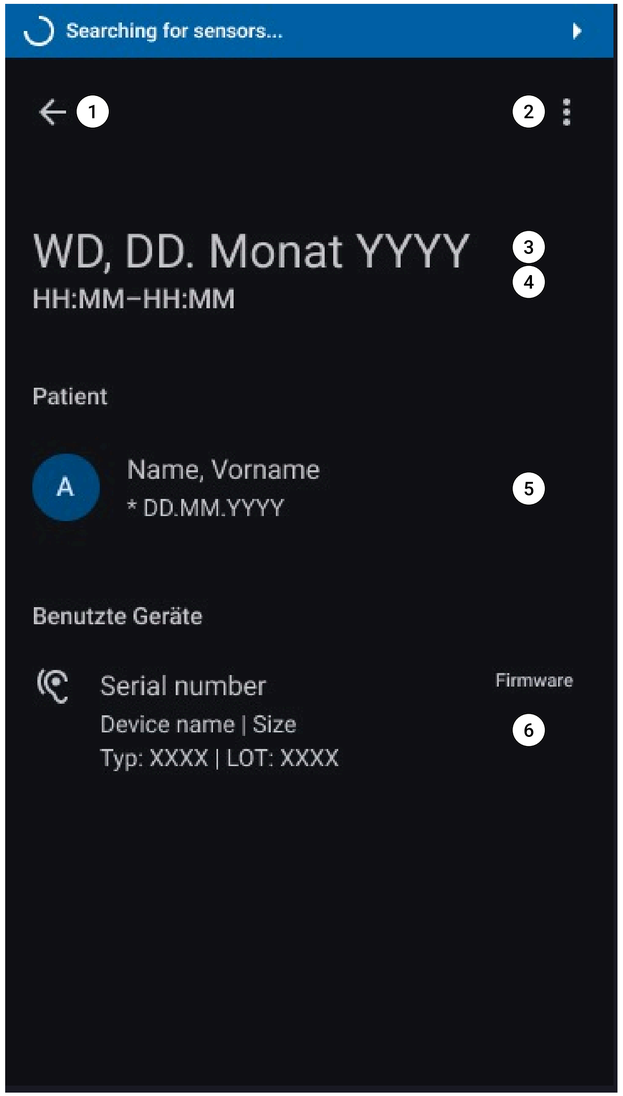
Detail view

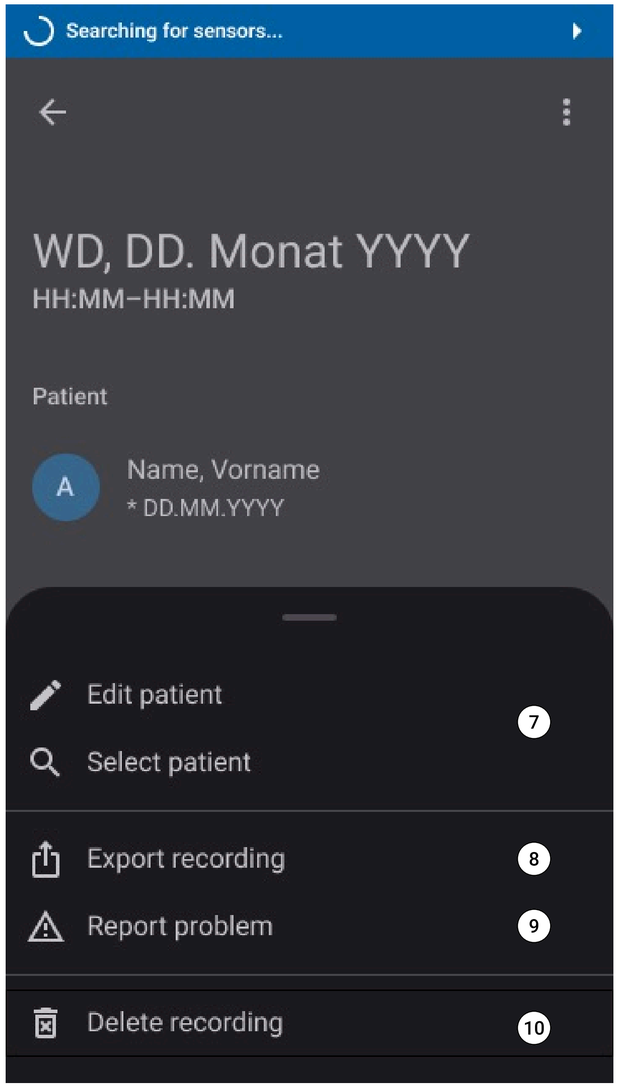
The detailed view of the selected recording shows you:

- Date and time in title
- Patient assigned to the recording
- Sensors used for the recording

In the detail view, patient data and used sensors are visible.
The "More Menu" offers the following actions:

- Patient Management: Create, select, or edit patient data
- Export: Export recording as a CSV file (e.g., via email or messenger)
- Report a Problem: Fill out a form to describe issues; attach CSV files or screenshots if needed
- Delete Recording: Permanently delete the recording (cannot be restored)





1. Back icon
2. Menu button
3. Date
4. Start and end time
5. Assigned patient for the recording
6. Recorded sensor
7. "Edit patient" or "Add patient" button
8. "Share recording" button
9. "Report an issue with the recording" button
10. "Delete recording" button

Practical tip

Sharing patient data
If you share patient records, personal data such as name or birthday are not included in the export.

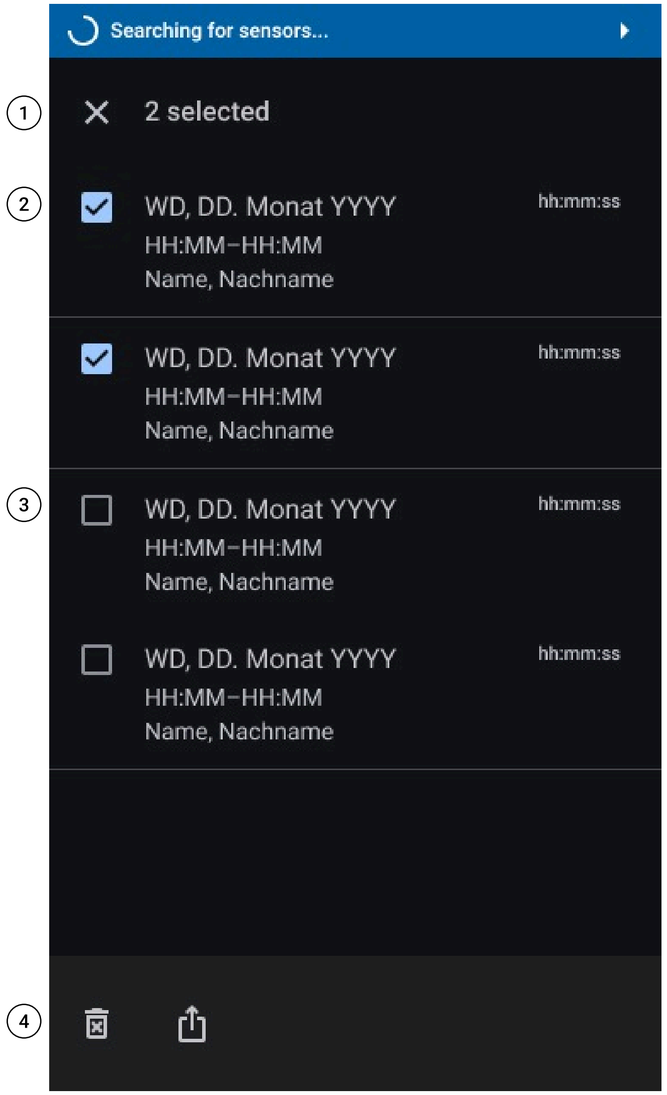
ENGLISH

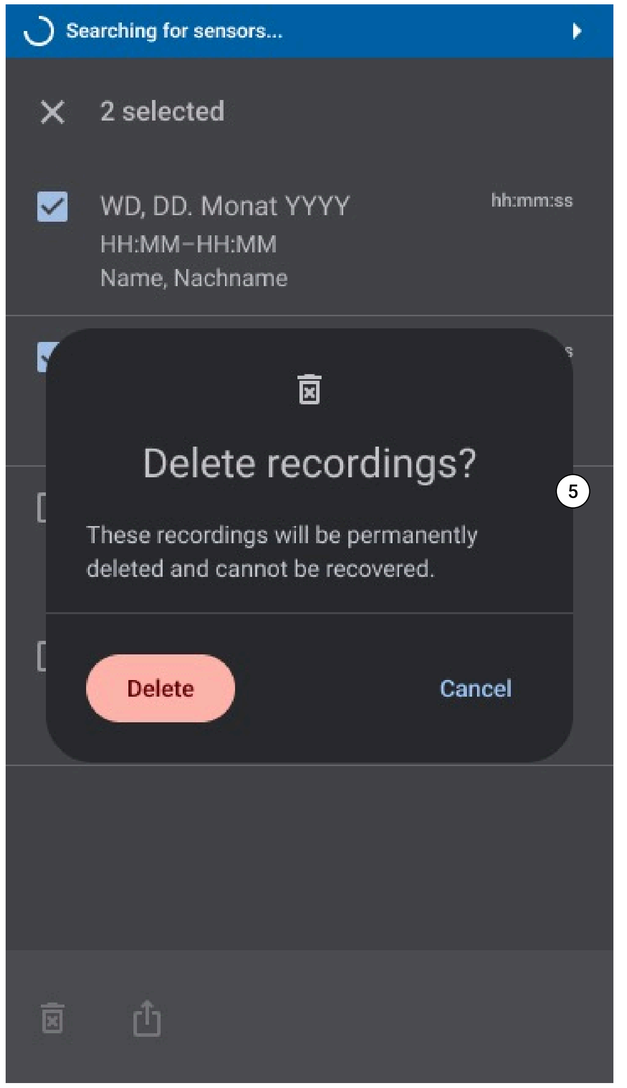
NEW

Visualization and Interactions

Multi-Selection

To select multiple recordings at once, tap the checklist button in the top app bar. This activates multi-selection mode, allowing you to mark multiple entries and, for example, delete them simultaneously.





1. Info bar for selection
2. Selected list item
3. Unselected list item
4. Editing functions (e.g., delete and export)
5. Dialog window: Delete recording

Practical tip

Sharing patient data
If you share patient records, personal data such as name or birthday are not included in the export.

ENGLISH

Manage

PATIENTS

Visualization and Interactions

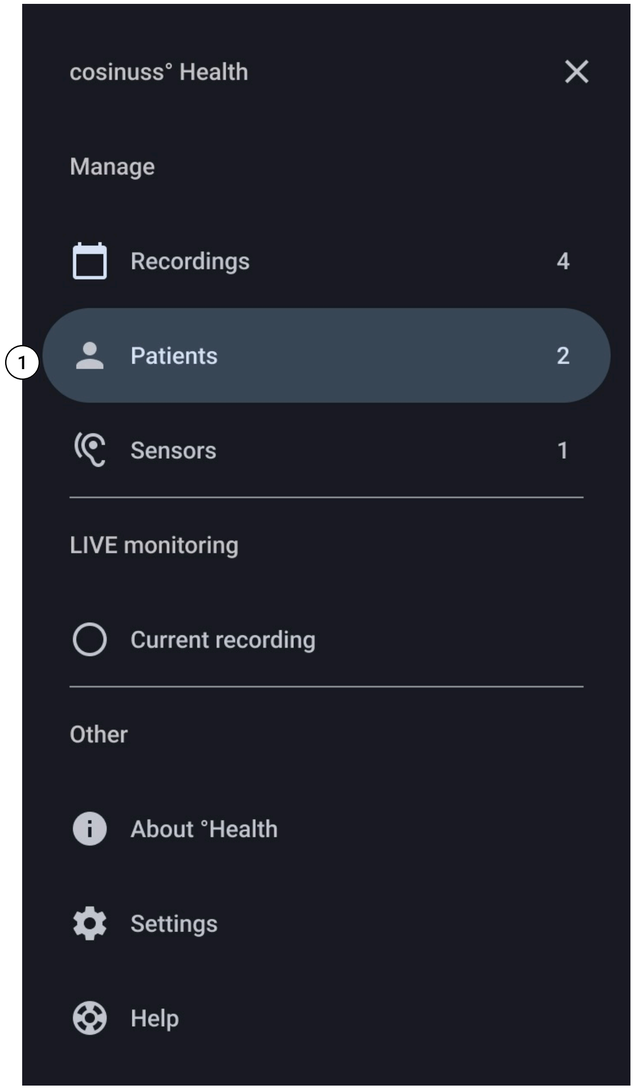
List view

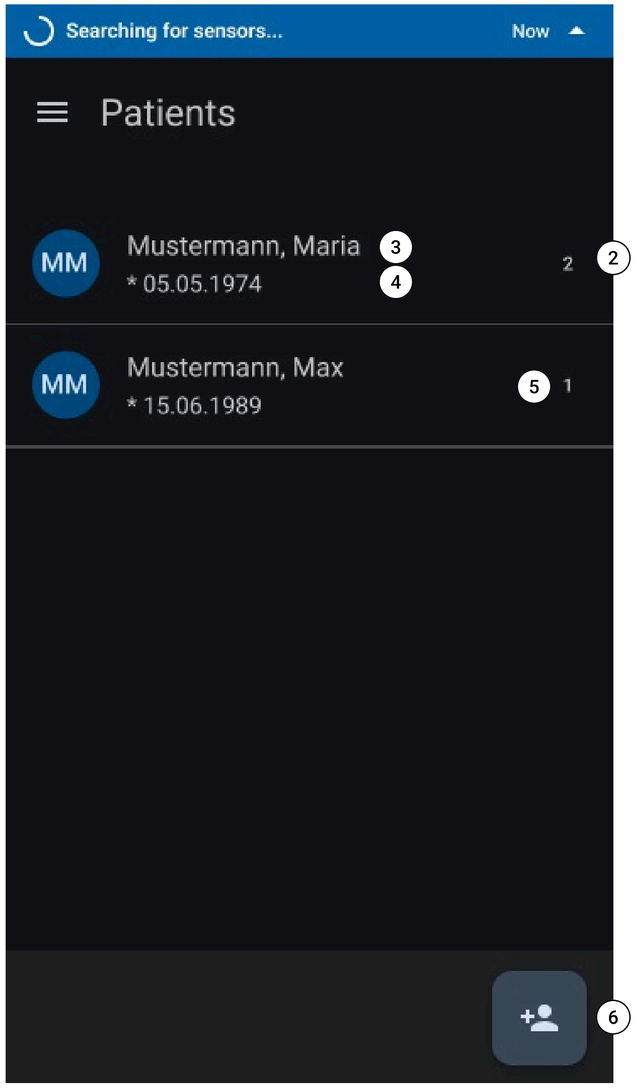
In the °Health app, all previously created patient profiles can be managed via the "Patients" option in the sidebar navigation.

Patients are displayed in an alphabetically sorted list, and each entry is clearly identified by last name, first name, and date of birth.

The following functions are available:

- Add a new patient: Tap the "Add patient" icon in the bottom app bar to create a new patient profile.
- View patient details: Tap a list entry to open the detailed view of that patient.
- Activate multi-selection: Tap the checklist icon in the top app bar to enable multi-selection mode. This allows you to select multiple patients at once and, for example, delete them together (including their recordings).





1. "Patients" section
2. Checkliste" button
3. "Add patient" button
4. Name
5. Date of birth
6. Number of recordings
7. Patient record

ENGLISH

NEW

Visualization and Interactions

Detail view

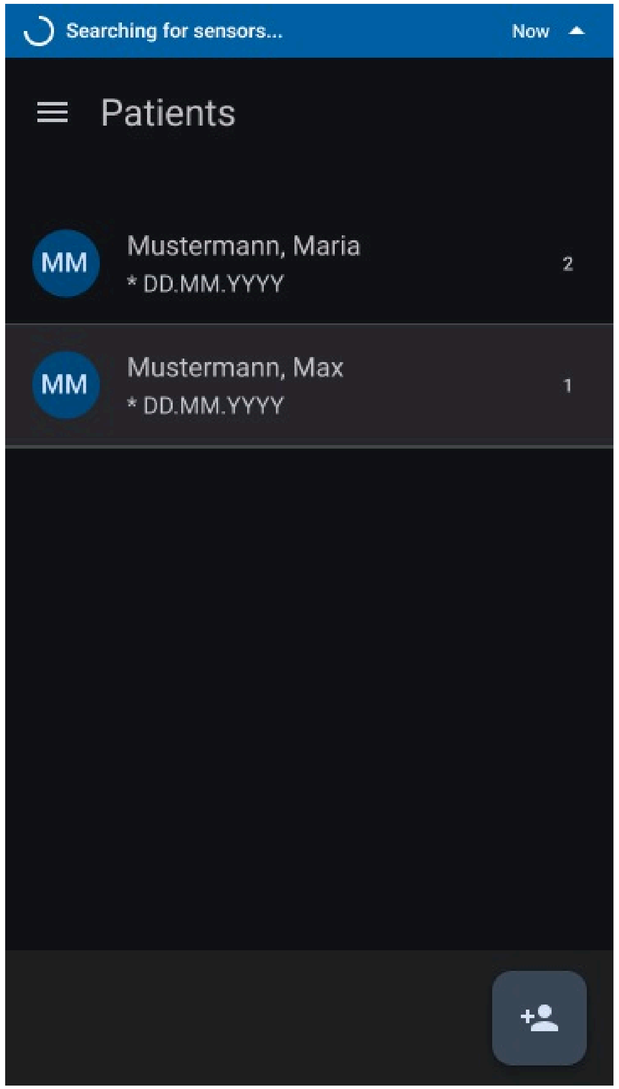
The detail view of the selected patient shows:

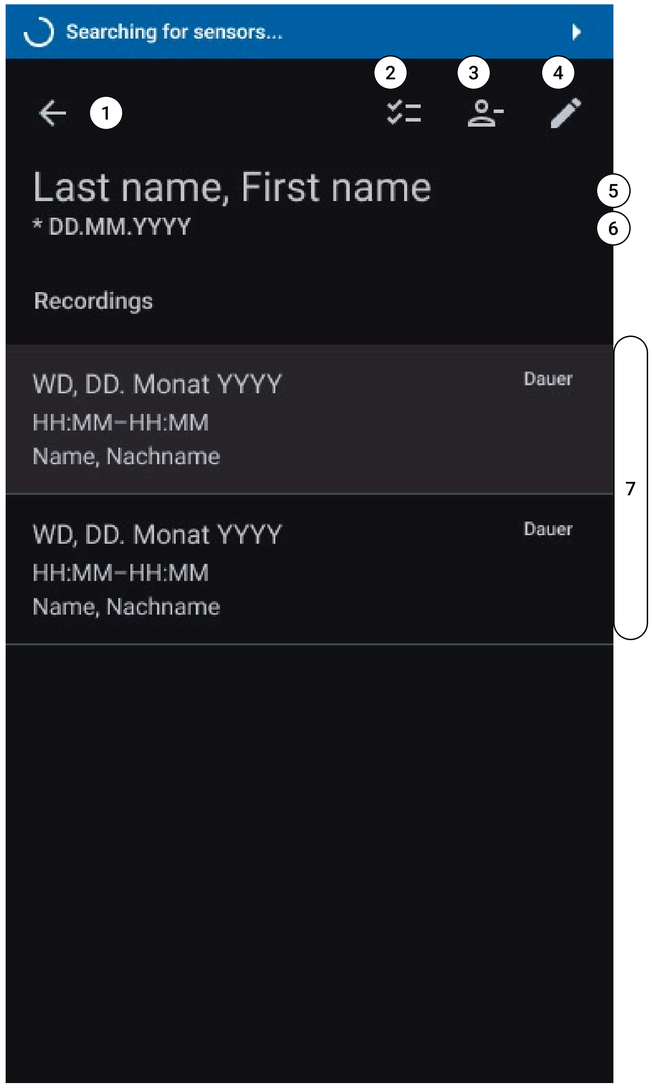
- Name and date of birth in the title
- Recordings associated with this patient

In the patient detail view, the last name, first name, and date of birth are visible. Additionally, an overview of all recordings linked to the patient is provided, enabling easy tracking of the recorded data.

The following actions are available:

- Edit patient data: Use the edit icon (pencil) in the top app bar to modify patient information.
- Review recording history: All recordings associated with the patient are listed for easy reference.
- Delete recordings: Activate selection mode via the checklist icon, select recordings, and delete them using the trash icon.
- Delete patient: Use the “Delete patient” icon to permanently remove the patient along with all associated recordings.





1. ‘Back’ button
2. ‘Checklist’ button
3. ‘Delete’ button
4. ‘Edit patient’ button
5. Name
6. Date of birth
7. Recordings of this patient

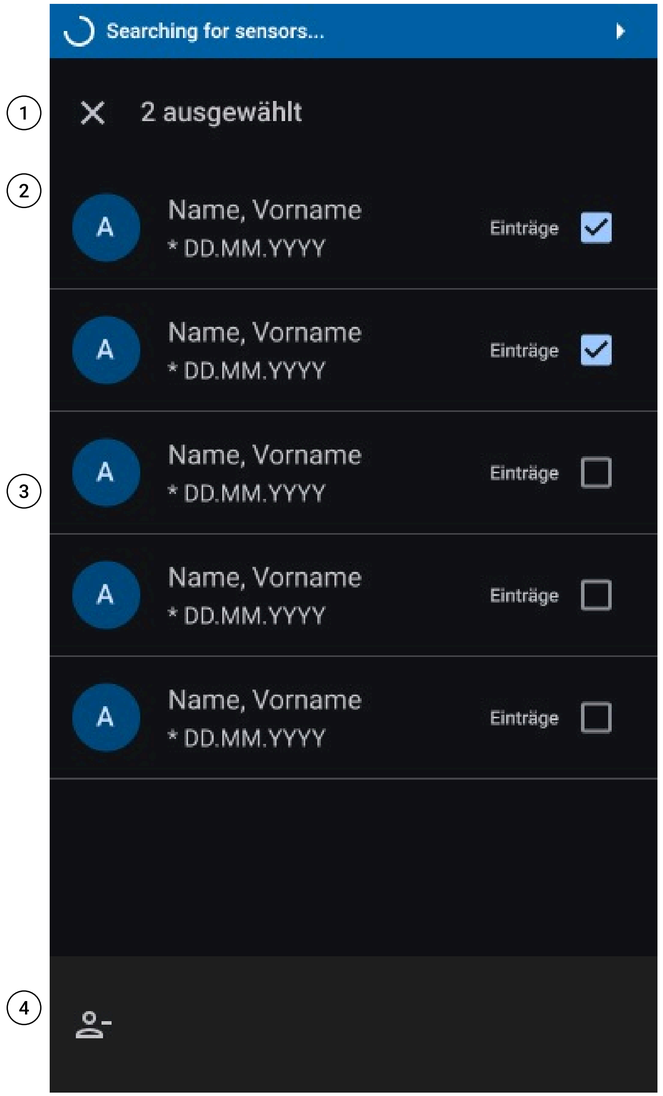
ENGLISH

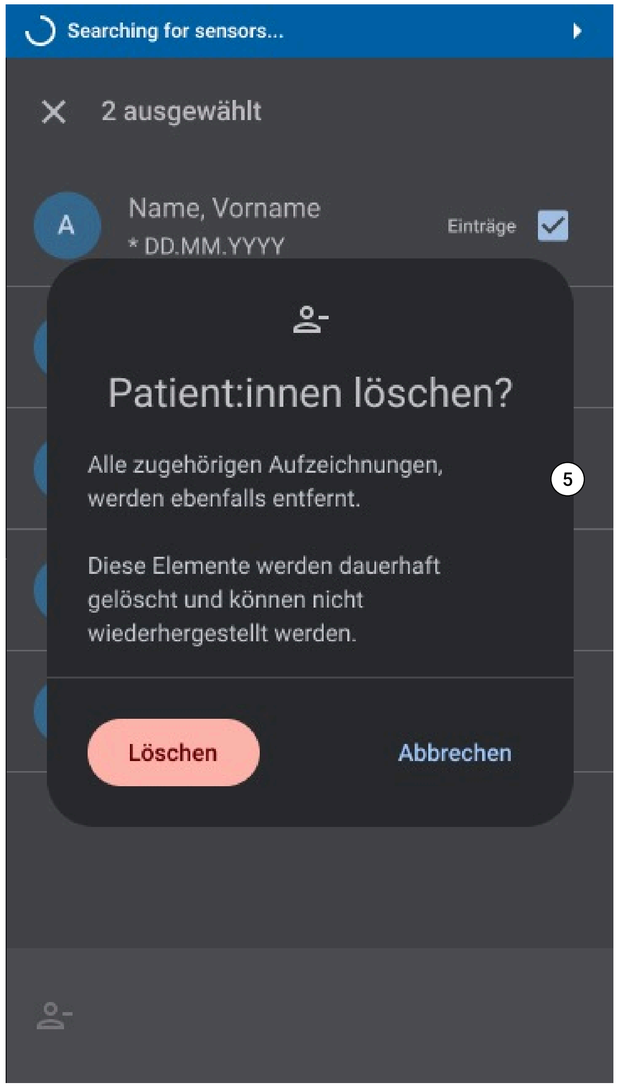
NEW

Visualization and Interactions

Multi-selection

- Activate multi-selection: Tap the checklist icon in the top app bar to enable multi-selection mode. This allows you to select multiple patients at once and, for example, delete them together (including their recordings).





1. ‘Back’ button
2. ‘Edit patient’ button
3. Name
4. Date of birth
5. Recordings of this patient

ENGLISH

SENSORS

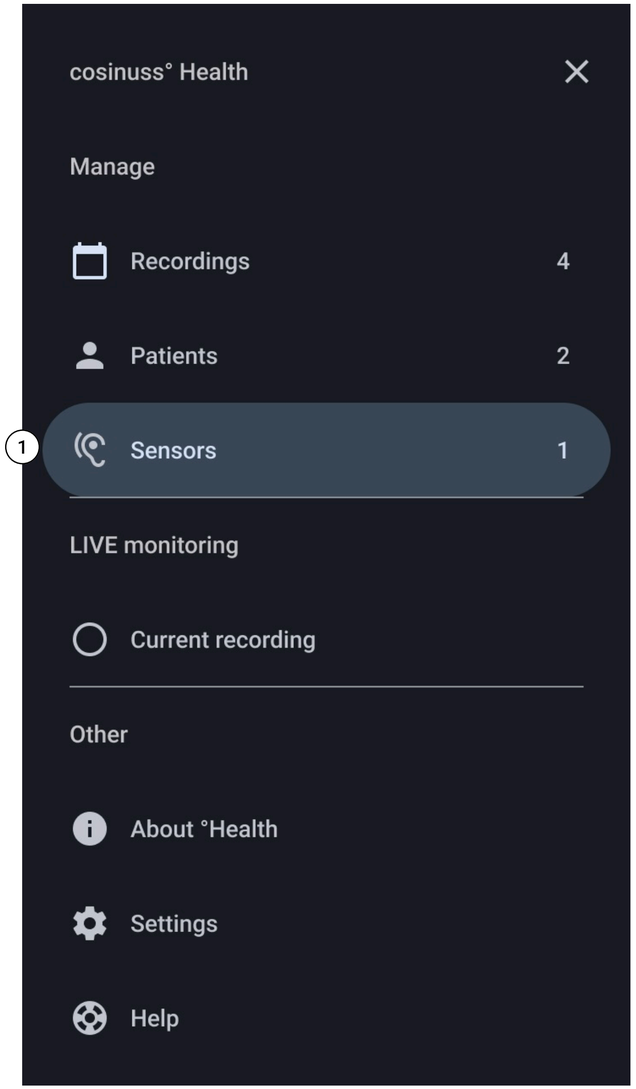
Visualization and Interactions

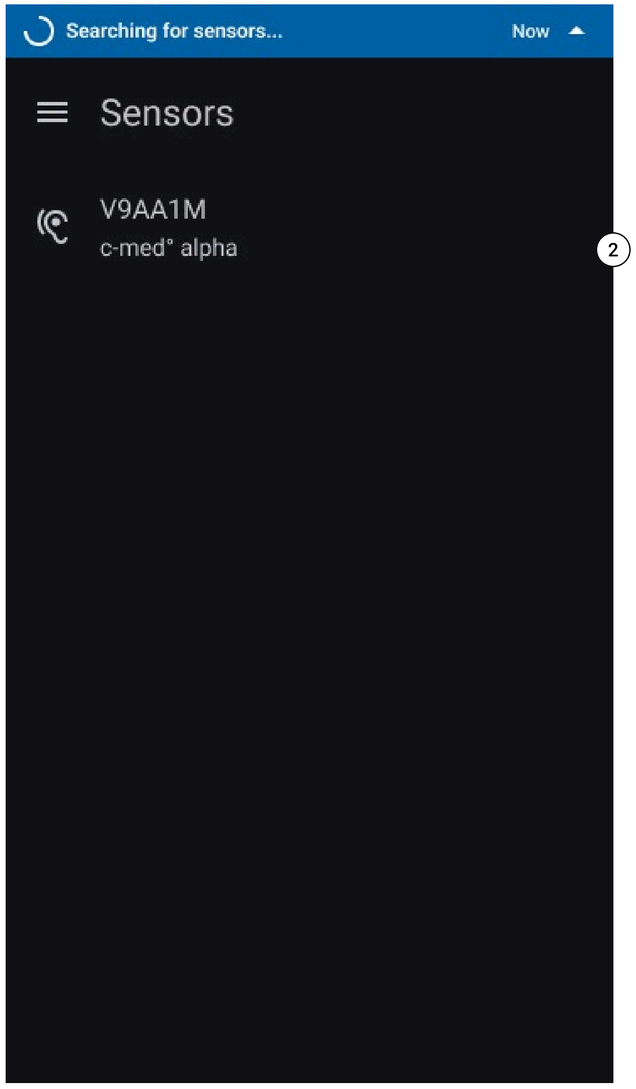
List view

All sensors you have received can be found in the ‘Sensors’ section.

The sensors are sorted alphabetically.
Each sensor is clearly identifiable by:

- Serial number





1. ‘Sensors’ section
2. Sensor item

ENGLISH

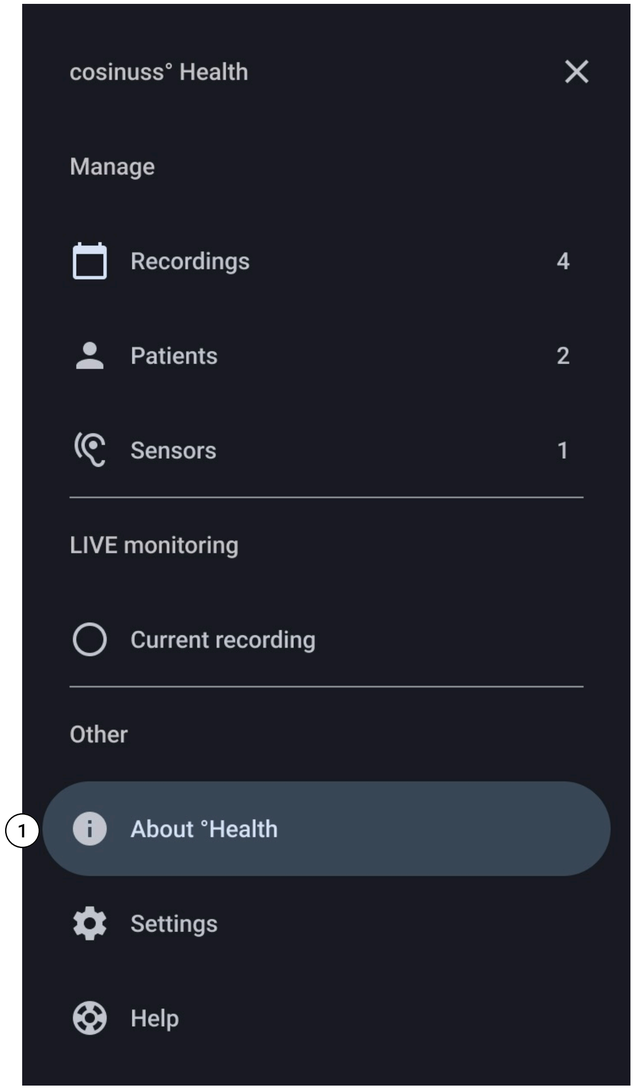
Other

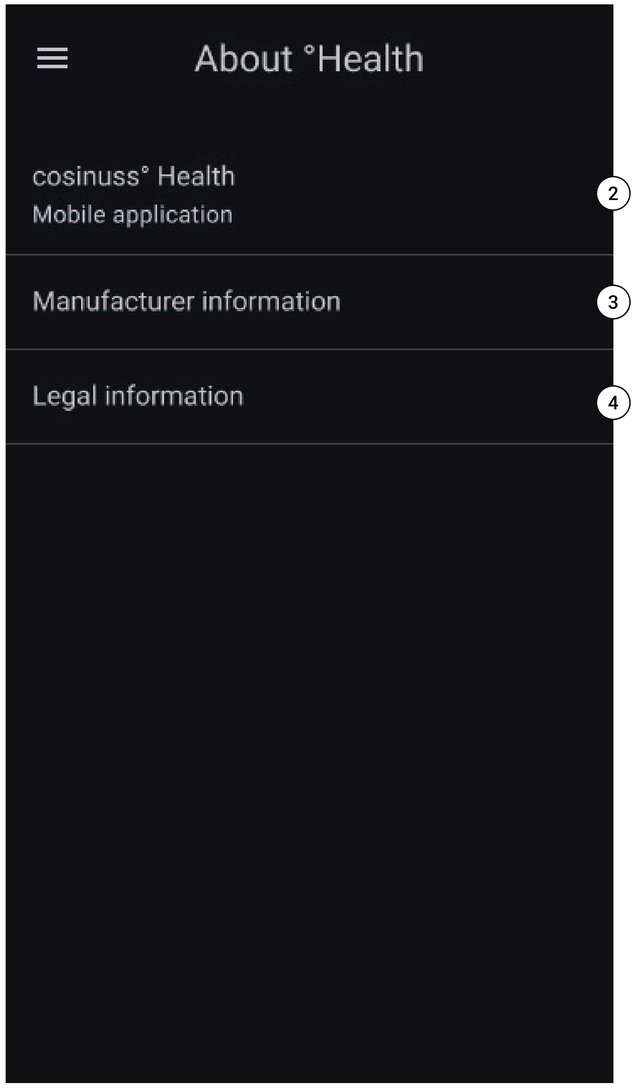
About °Health

NEW

Software Information

Explore the ‘About °Health’ section for comprehensive information about the software, regulatory markings, and contact details for the manufacturer.





1. ‘About °Health’ section
2. Information about the mobile application
3. Manufacturer information
4. Legal information for the usage in certain countries

ENGLISH

Other

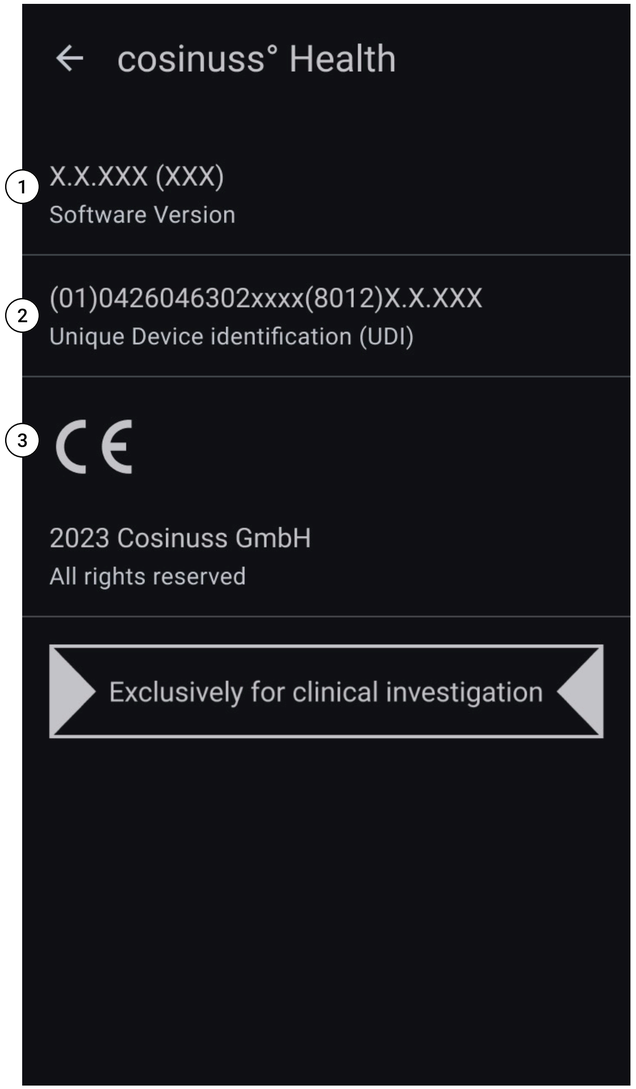
About °Health

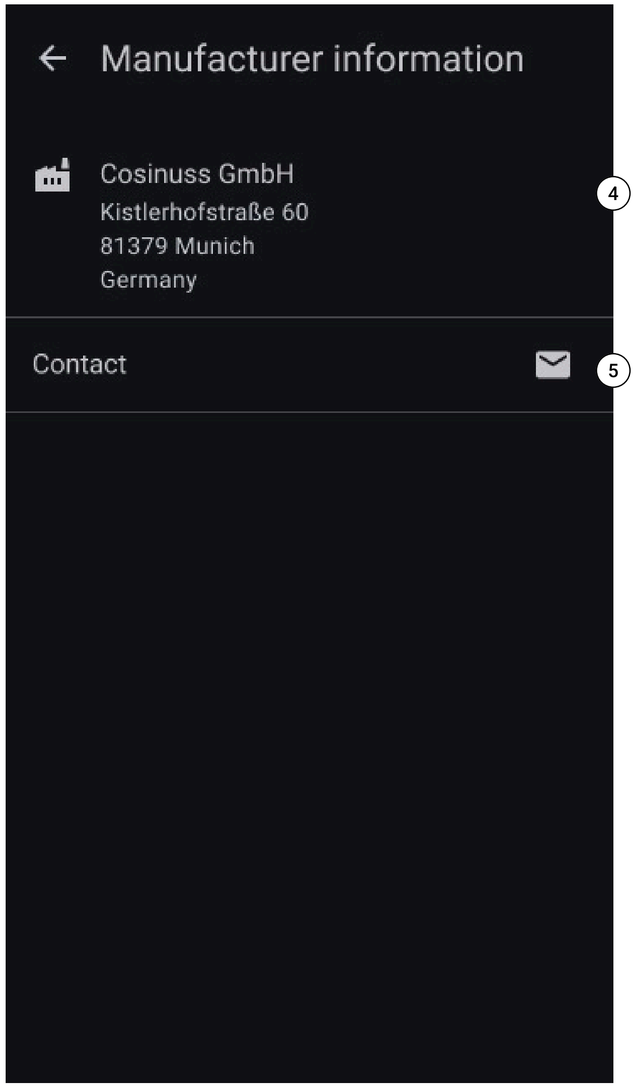
Software Information

- Version: Find information about the current version of the °Health app.
- Unique Device Identification:
  Discover the unique identification associated with your device for tracking and support purposes.
- CE Marking and Other Important Markings
  Learn about regulatory markings, such as CE, and other important symbols relevant to the °Health app

Manufacturer information

- Manufacturer Details:
  Get details about the manufacturer of the °Health app, ensuring transparency about the software's origin.
- Contact Information:
  In case of any issues, questions, or support needs, you can reach out to us by submitting a support ticket.
  https://support.cosinuss.com/submit-a-ticket/





1. Software Version number
2. Unique device information (UDI)
3. CE and other markings
4. Manufacturer information
5. Contact / Submit a ticket

ENGLISH

Other

About °Health

NEW

Rechtliche Hinweise

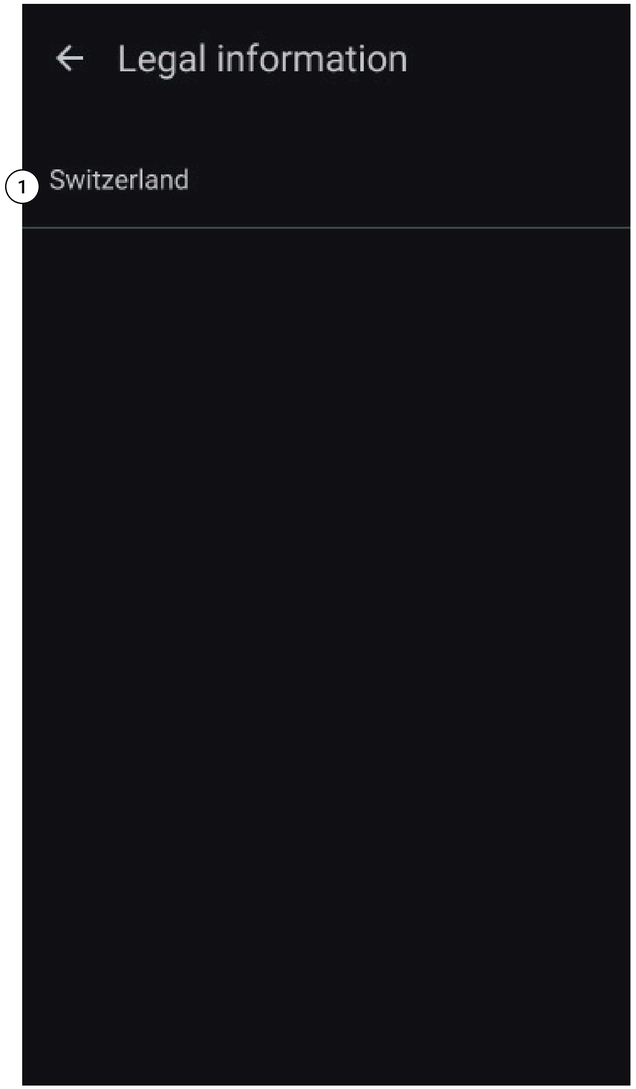
In the app, under the “About °Health” section, you will find the menu item “Legal Information”.

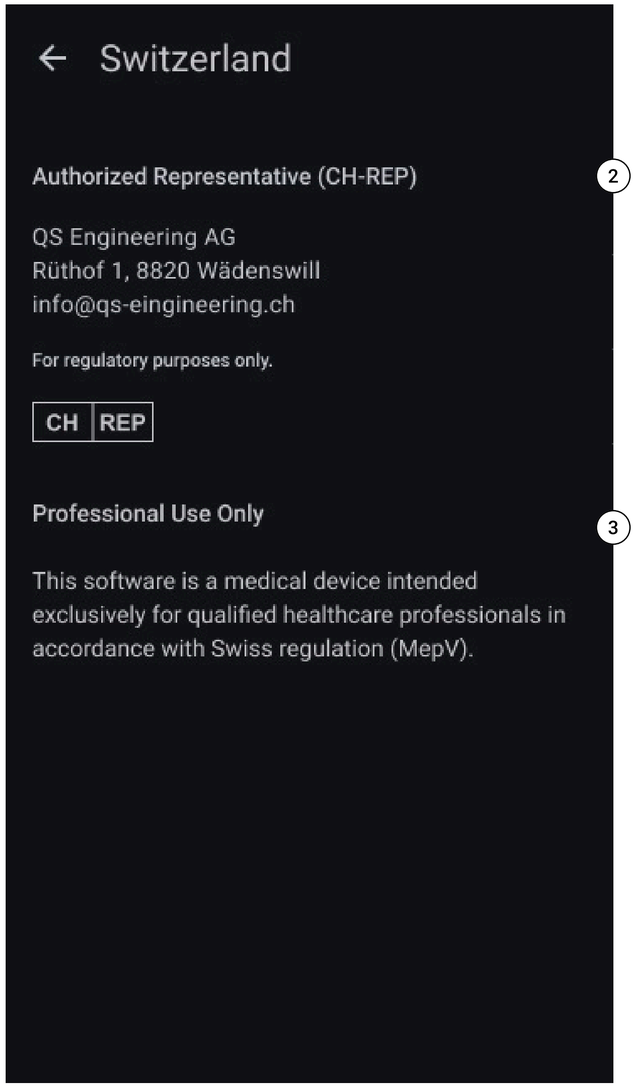
This section contains a list of countries for which legal notices are provided.

Switzerland

- Authorised Representative for regulatory purposes (CH-REP): Name and address of the Swiss Authorised Representative (CH-REP), as required by local regulations.

- Special notice “For Professional Use Only”:
  This software is a medical device intended exclusively for qualified healthcare professionals in accordance with Swiss regulation (MepV).





1. List of countries for which legal notices are available
2. Authorised representative in the respective country
3. Special notices

DEUTSCH

Other

Settings

Explore the ‘Settings’

Access Rights Overview

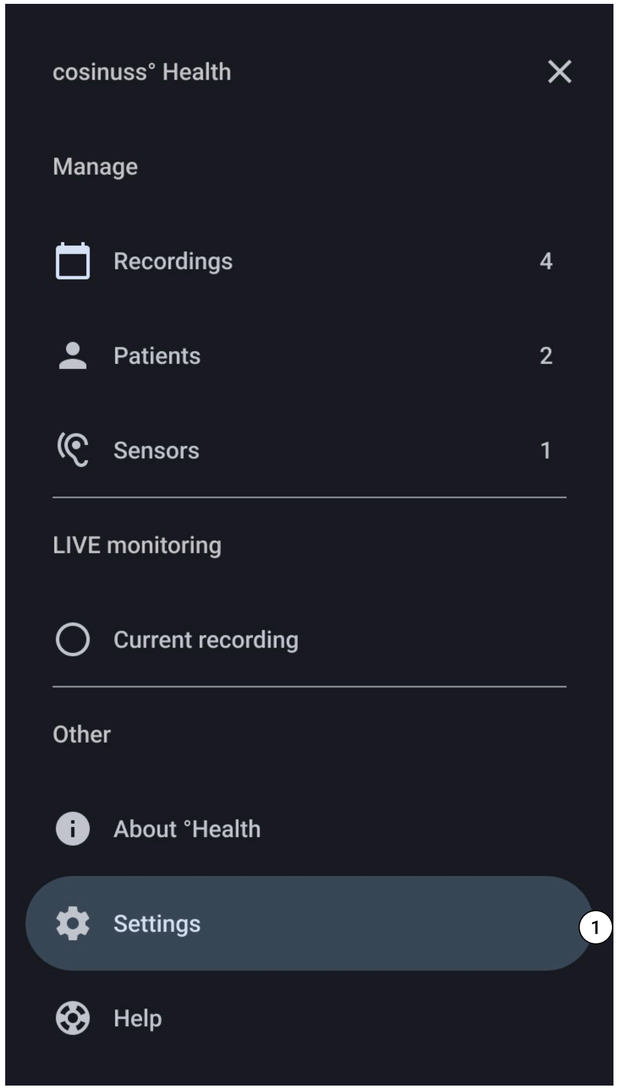
Review and verify the access rights granted to the °Health app for optimal functionality.

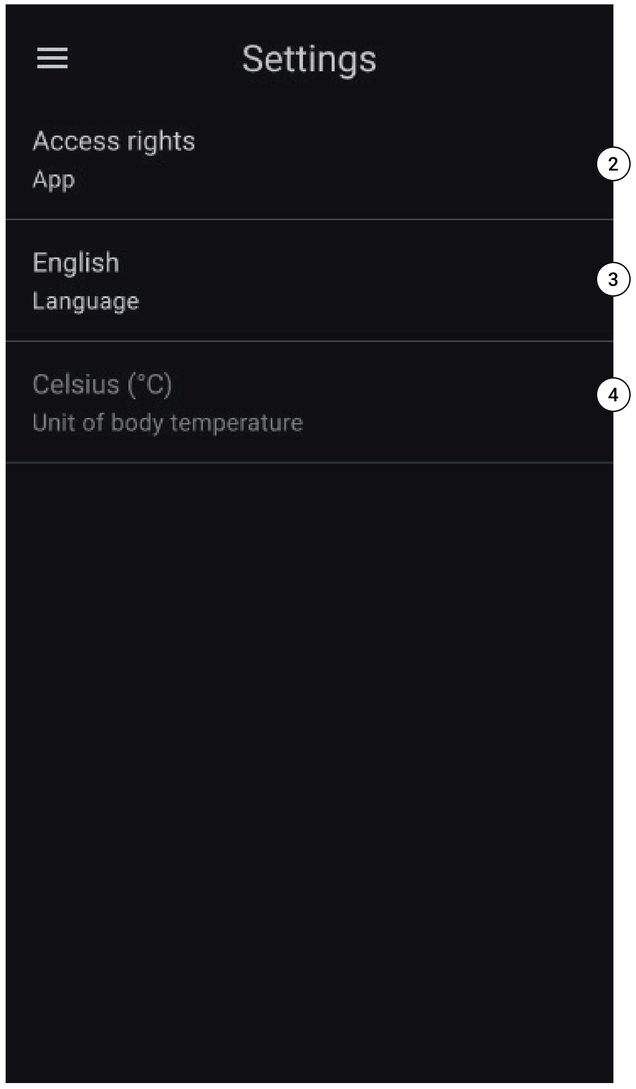
Preferred Language

Choose your preferred language for a personalized app experience.

Measurement Units

Customize the app to display measurements in units most applicable to your preferences.





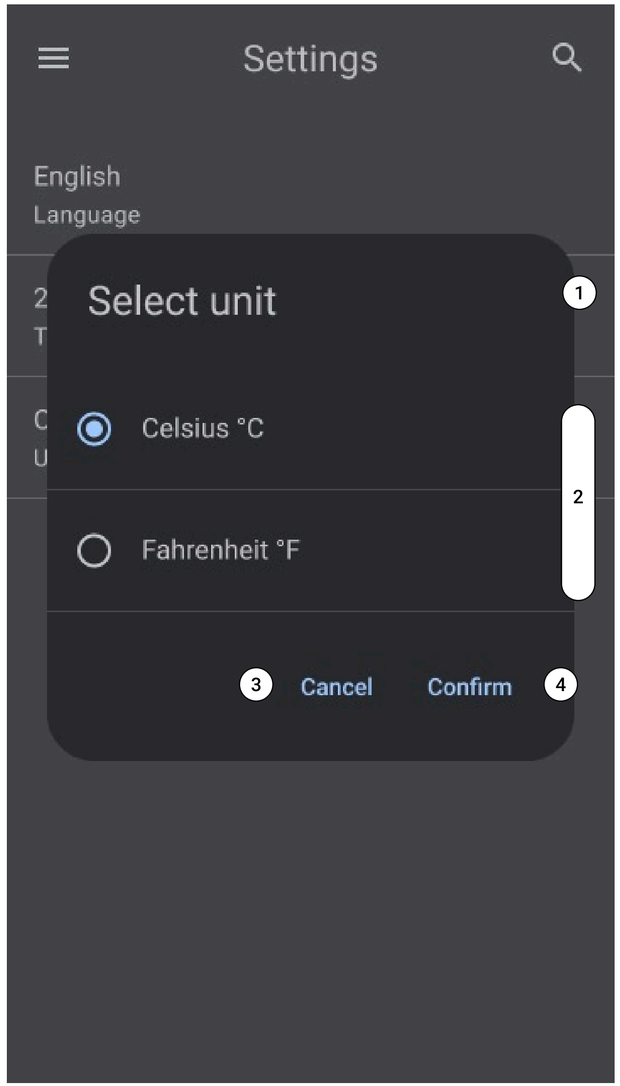
1. ‘Settings’ section
2. Access rights
3. Language selection
4. Measurement units

ENGLISH

Settings

Example: Body temperature units

- Select the units for vital signs such as, e.g. Body temperature
- Customize the app to display measurements in units most applicable to your preferences.
- Body Temperature:
  - Celsius (°C)
  - Fahrenheit (°F)
- Confirm or cancel your selection



1. Dialog setting title
2. Selection options
3. Cancel
4. Confirm

Other

Help

Visit the "Help" section to access official user manuals, training materials and detailed information about the sensor, mobile application and system operation.

Instructions for Use (IFU)

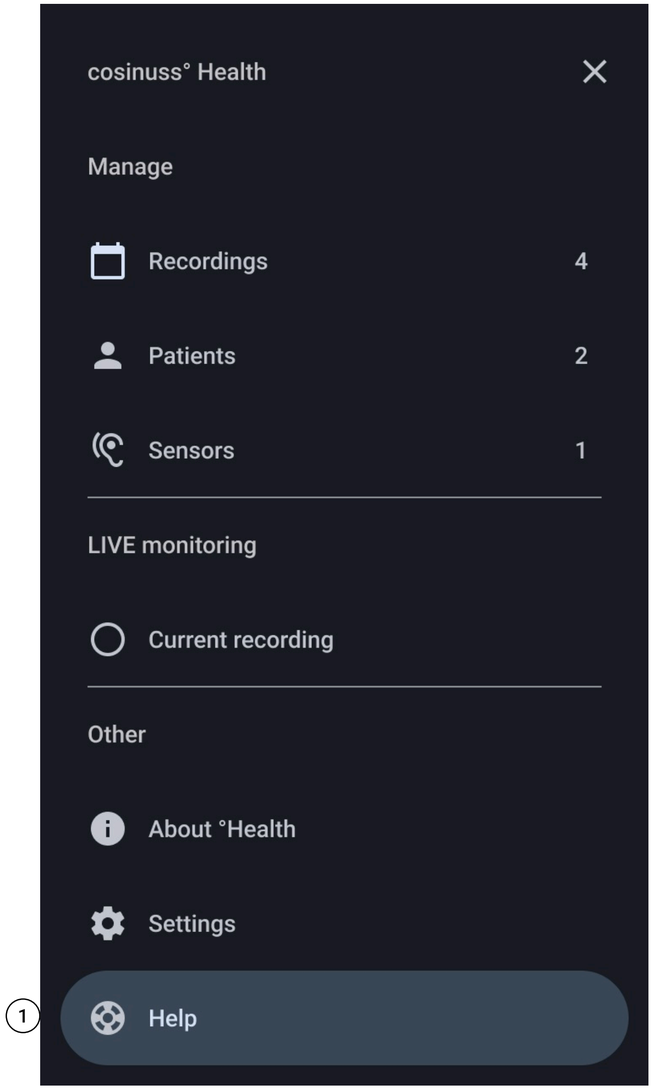
The button takes you to the website with our training materials, where you will find the instructions for use of the °Health app and all compatible devices.

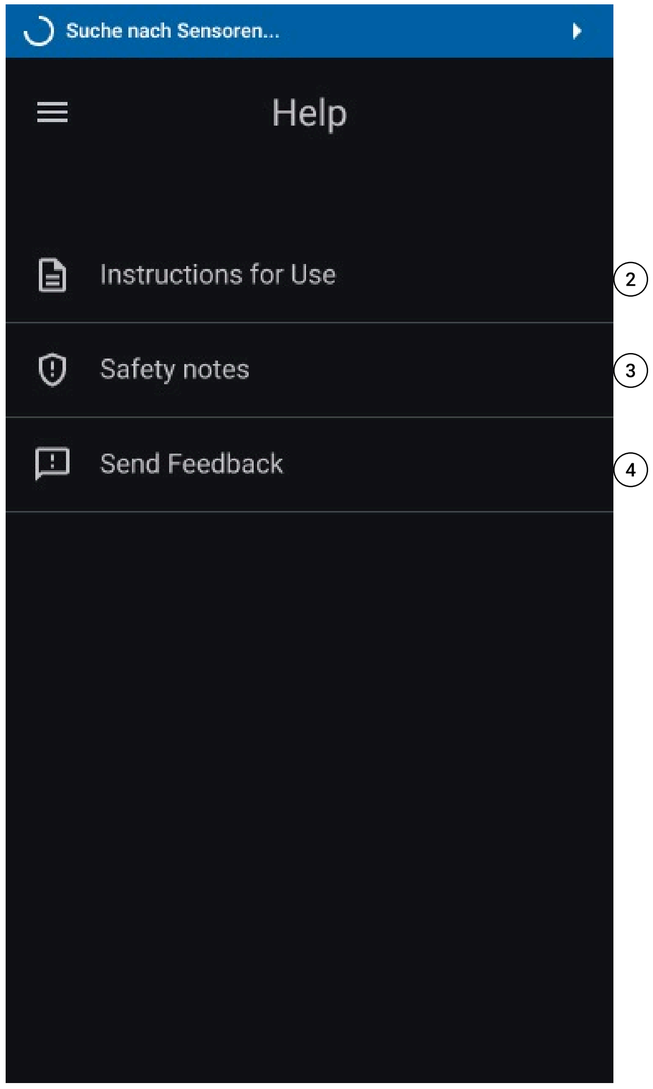
Safety Notes

Here you will once again find the most important information on the correct use of the measuring devices and sensors, as described in the set-up process.

Send Feedback

Here you can fill in a general feedback form and send us your suggestions, questions or criticism.





1. ‘Help’ section
2. Link to: training.cosinuss.com/en
3. Safety notes on the measuring devices
4. °Health app feedback form

ENGLISH

cosinuss° Health

⚠ Important Warnings:

- The cosinuss° Health application is a stand-alone software for displaying data.
- For practical use, please observe the safety instructions of the compatible device used, e.g. those of the c-med° alpha.

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ENGLISH