User Manual

cosinuss° Health

Mobile Application

For access to electronic instruction for use
please access the following URL: **health.cosinuss.com/eIFU**

DOC-ID: 1701095121

Manufacturer information

Cosinuss GmbH
Kistlerhofstraße 60
81379 Munich
GERMANY

Other certificates

CE **0123**

Components

(sold individually or combined)

cosinuss° Health	
cosinuss° Health	Mobile application, data entry & local display point

Compatible sensor devices*			
Device name	Description	Firmware	Basic UDI-DI
cosinuss° c-med° alpha	Continuous vital signs sensor	At least 2.3.0	426046302CMED4F

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

Intended Use

The cosinuss° Health app is intended to visualize and store continuously vital signs data measured by any medical sensor device which proves the interoperability with cosinuss° Health app and is in alignment with this intended use, including:

- Photoplethysmogram (PPG)
- Pulse Rate
- Blood oxygen saturation (SpO2)
- Body Temperature

The measured data is received wirelessly, stored, and displayed in the mobile application. Due to the wireless data transfer, the user is not restricted by cables during the measurement. The mobile application can be installed on every state-of-the-art Android or iOS operating mobile device. The corresponding patient information can be entered and managed via the application.

The intended user is any health professional and any adult person without neurodevelopmental or neurocognitive disorders, who wants to monitor their own or their patients' vital parameters. The user can follow the patient's vital parameters and has access to real-time values and vital signs data history via a graphical trend plot. The continuous PPG signal visualization aims for the user to interpret the data and draw conclusions about the data quality. The implemented Application Programmable Interface (API) allows the simultaneous monitoring of the same patient with several mobile devices, which contributes

to seamless, continuous monitoring. Furthermore, this allows multidisciplinary care by offering a comprehensive overview of the patient's health to different healthcare professionals involved in the patient's care.

All data can be exported and transmitted for further analysis. The system has customizable visual and audible notifications and allows the user to set personalized thresholds for these notifications. While the app doesn't provide direct diagnoses or treatment suggestions, it serves as a supportive tool by presenting comprehensive clinical information. This can include vital signs, historical data, trends, and other relevant metrics that contribute to a holistic understanding of the patient's health.

Safety Information

It is vital that the user reads, understands, notes, and, where applicable, observes all warnings, cautions, notes and safety markings within this document and on the devices. It is vital that the user strictly follows all safety directions throughout this manual to help ensure safety of both its users and patients. For specific safety information regarding the cosinuss° in-ear sensors and other optional devices please refer to specific instructions for use at the end of this user manual.

Notice to User or Patient

Any serious incident with the software should be reported to the manufacturer (support@cosinuss.com) or to Competent Authorities.

Indications

A concrete medical indication in terms of specific diseases is not intended. Based on the connected compatible device, the system is able to display different vital signs parameters to allow and simplify the monitoring of different physical reactions:

- hypothermia
- hyperthermia (fever)
- changes in the circulatory system
- tachycardia
- bradycardia

Based on this medical indication, the medical use of continuous measurement is to make it easier to classify and monitor the health state of the user or patient and the respective medical condition. In this context, it should be noted that the software shall not recommend any concrete treatments.

Contraindications

Warnings and Cautions exist and are clearly labeled within the accompanying documentation.

The cosinuss° Health app is NOT intended to:

- Detect heart attacks from PPG display
- Detect arrhythmia from PPG display

The mobile application cosinuss° Health has not been tested, and should not be used:

- in combination with any device that does not comply with the API specification by cosinuss° (see section 'Components'),
- to alarm the user for an acute change in the patients health condition,
- for monitoring during MRI scan.

For safety warnings related to cosinuss° in-ear sensors or optional compatible devices please refer to the User manual of the relevant device.

Warnings and Cautions

These warnings and caution statements are included for information purposes and identify conditions or practices which, if not corrected or discontinued immediately, could lead to equipment failure, equipment damage or data loss.

Do not use the cosinuss° Health app on patients until these warnings and cautions have been fully understood.

Warning statements*

Warnings indicate potentially hazardous situations which, if not avoided, could result in injury or death.

⚠	The cosinuss° Health app is not intended to: ● Be used on critical care patients. ● Replace standard monitoring in ICU (Intensive Care Units). ● Display concrete treatment recommendation.
⚠	You should use medical devices as described by the manufacturer in the instructions. If you use the device in any other way, it is considered 'off-label' use. Specific examples of off-label use include, but are not limited to:

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	• Using the application to detect specific physiological states not intended by the manufacturer. • Allowing non-intended operators to download and use the application. • Relying on the application to provide alarms for critical health conditions of the patient. • Operating the application with non-approved devices.
⚠	Off-label use can lead to unpredictable risks, legal issues, lack of protection, device ineffectiveness, no manufacturer support, and ethical concerns.

* For safety warnings related to compatible sensor devices please refer to the User manual of the relevant device.

Caution Statements*

❗	**Regular monitoring required:** The app must be checked regularly to monitor values accurately.
❗	**Foreground operation:** The app is designed to stay in the foreground unless you actively move it to the background.
❗	**Primary screen check:** The primary method of obtaining accurate information is by checking the screen directly.
❗	**Secondary outputs:** Outputs such as audio signals or notifications are intended to serve as secondary signals. These should not be relied upon without also checking the screen for accurate and up-to-date values.
❗	Incorrect sensor attachment or serial number mismatches can lead to inaccurate data and potential safety risks. Always verify the serial numbers and sensor placement before starting the recording.
❗	**Serial number mismatch:** If the serial numbers do not match, stop recording immediately and make sure the correct sensor is attached to the patient.
❗	**Multiple patients:** Double-check to ensure the data is being recorded for the correct patient. This is especially important when there are multiple patients nearby.
❗	**Data integrity:** To protect your data and ensure the integrity of the displayed information, always use secure methods such as PINs, Face ID, or other biometric authentication.

	Jailbreaking: Do not use jailbroken devices as they may compromise data security and app functionality.
	Output range: The display range of the app can be larger than the rated output range of the device. For range of output values related to compatible sensor devices please refer to the user manual of the relevant device.
	Before use: Please consider the requirements of the respective use environment and inform yourself if the use of your mobile device is permitted.

* For safety warnings related to compatible sensor devices please refer to the User manual of the relevant device.

Clinical Claims

Using the cosinuss° Health app, users can see the course of the vital signs, recognize trends, and (if the used sensor device allows it) see the measured PPG signal continuously. The raw data can be looked up and exported at any time.

The cosinuss° Health app can be installed on every state-of-the-art Android and iOS mobile device and be used as a portable vital data visualization instrument. Due to the wireless data transfer, the patient and user are not restricted by cables during the measurement and the live data can be observed on a mobile device via the cosinuss° Health app.

The cosinuss° Health app enables structured processing of data and provides a basis for patient treatment decision-making in clinical routine. The clinical performance can be summarized as follows:

- Continuous and real-time monitoring of vital signs and wave curves which includes data reception, visualization, storage and export.
- Data security and privacy measures.
- Easy and non-limited access to and export of the measured data for further processing.
- Secure data storage and transmission.
- User-friendly and intuitive interface.
- Good readability and representation of the measured data.
- Stable, seamless data transfer.
- Compatibility with state-of-the-art Android and iOS mobile devices
  (see section: 'Requirements and Recommendations').

Using the System

Installation

The cosinuss° Health app is available on the Google Play Store for Android devices and the Apple App Store for iOS devices. Please follow the steps below to download and install the app.

1. Open the App Store:

- *Android:* Open the Google Play Store on your Android device.
- *iOS:* Open the Apple App Store on your iPhone or iPad.

2. Search for the app:

- Enter 'cosinuss° Health' in the search field.
- Press the search button.

3. Select the app:

- Select the cosinuss° Health app from the search results.

4. Download and Install:

- *Android:* Tap 'Install' to begin downloading and installing the app.
- *iOS*: Tap the download icon to begin downloading and installing the app.

5. Alternatively, Use the QR Code:

- Scan the QR code provided in the manual. This will take you directly to the cosinuss° Health app in the respective app store.
- Use your device's camera or a QR code scanner app to scan the code.

Apple App Store (for iOS devices)	Google Play Store (for Android devices)

6. Open the app:

- Once the installation is complete, locate the cosinuss° Health app on your home screen or in your app list.
- Tap the app icon to open it.

ⓘ	**Internet connection:** An active internet connection is required to complete the download and installation.
ⓘ	**Storage space:** Ensure that there is sufficient storage space available on your device.
ⓘ	**Updates**: Regularly install available updates to keep the cosinuss° Health app and your operating system up to date.

Getting Started

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,
- data privacy policy agreement,
- recognition of preset vital signs thresholds, and
- recognition of safety notes for sensor devices.

Language Selection

Upon launching the app for the first time, you'll be prompted to select your preferred language (see Fig. 1). Choose from the available language options to personalize your app experience.

Access Rights

The app requires certain access rights to function properly. Follow these instructions on the screen to grant the necessary permissions (see Fig. 2). 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.
- Background permission: Required to run the app in the background.
- Nearby devices: Required to receive data from devices.

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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.

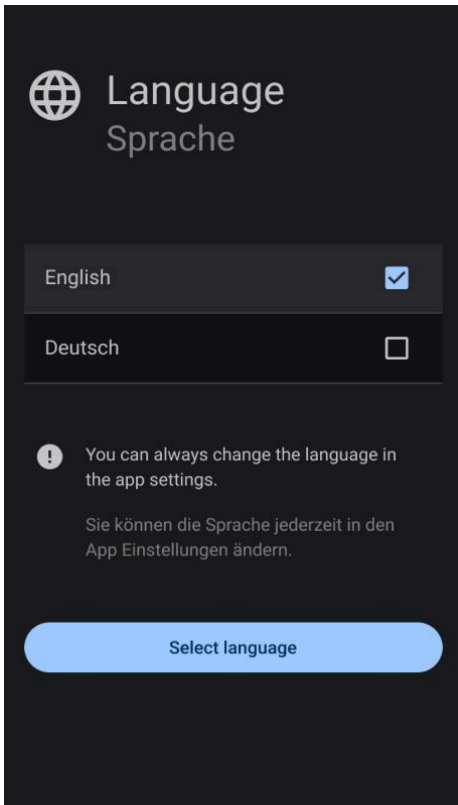| (i)	If some access rights cannot be granted within the app, please navigate to your device settings and locate the app in the list of installed applications. Then assign the rights here manually.

Fig. 1: Onboarding Screen - Select Language: Choose the preferred language for the application from the available options.
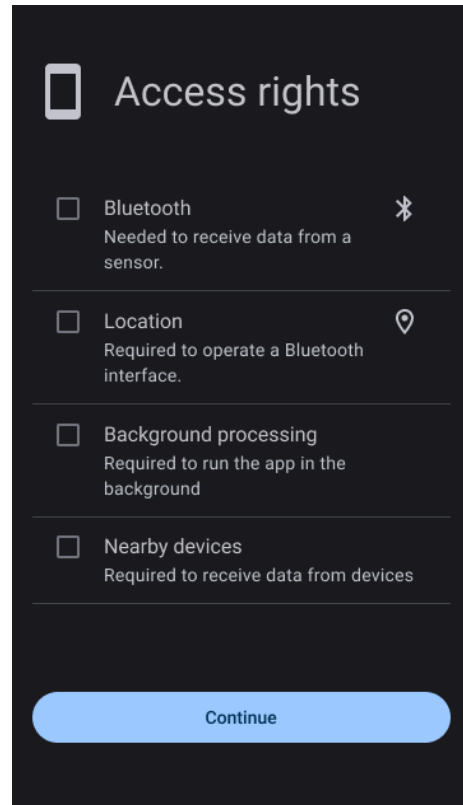
Fig. 2: Onboarding Screen - Access Rights: Grant necessary permissions for the application to function correctly.

Data Privacy Policy Agreement

To proceed, you need to agree to the app's data privacy policy (see Fig. 3).

1. Read through the linked data privacy policy carefully.:
https://support.cosinuss.com/health-app/privacy/.
2. After reading the privacy policy go back to the cosinuss° Health app.
3. Check the box to confirm that you have reviewed the data privacy policy.
4. If you agree to the terms, tap the 'Agree with policy' button.

Thresholds

During the set-up process, we inform you about the preset limits for the vital signs (see Fig. 4). This screen is essential in order to understand when you will be informed about the health status of the monitored persons by meansof a notification.

Preset threshold values

Pulse rate (green)	SpO2 (blue)	Body temperature (orange)
• Upper limit: 110 bpm • Lower limit: 50 bpm	• Upper limit: 100 % • Lower limit: 90 %	• 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.
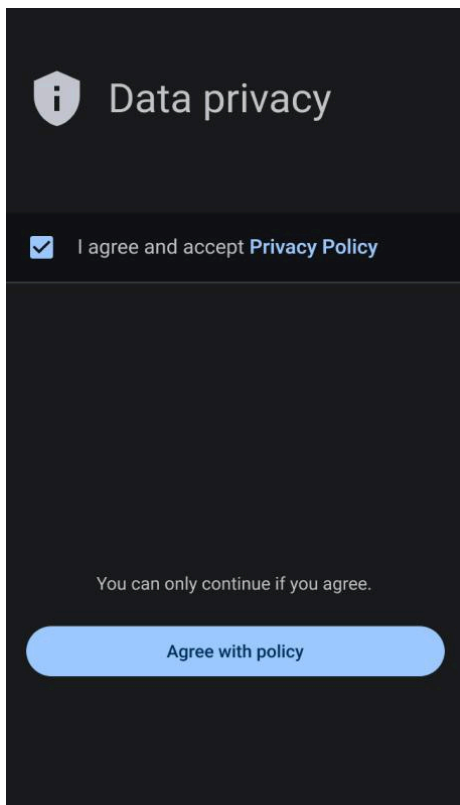

Fig. 3: Onboarding Screen - Data Privacy Policy:
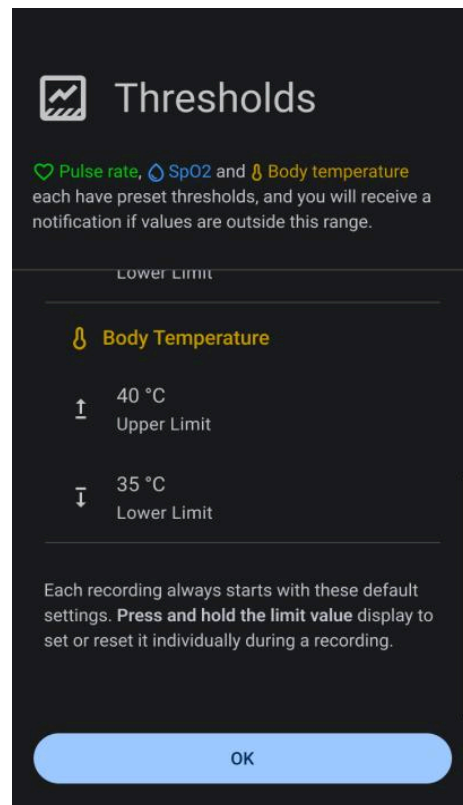Accept the data privacy policy before proceeding with the application onboarding.

Fig 4: Onboarding Screen - Preset Thresholds:
Acknowledge the preset thresholds for vital signs, which must be recognized by users before proceeding.

Safety Notes

Finally, in the onboarding process, we provide important information on the correct handling of the sensor used (see Fig. 5). This step is crucial to ensure that the sensors work accurately and reliably.

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

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

If you have read and understood the instructions, you have successfully completed the setup process and can start using the cosinuss° Health app (see Fig. 6).
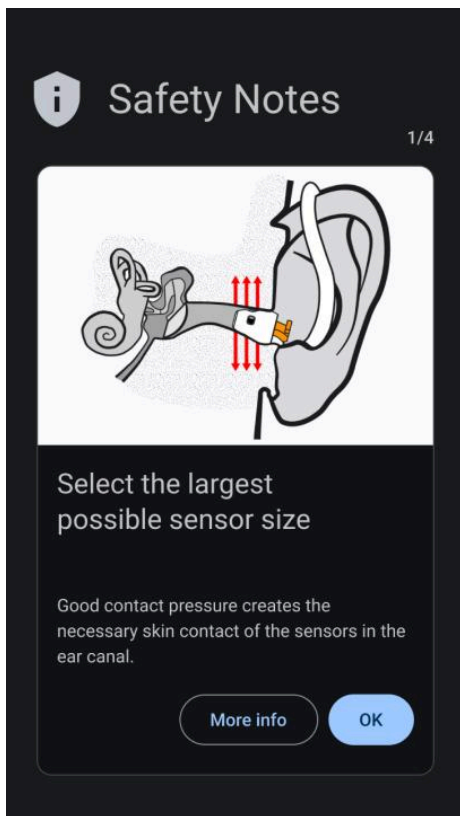

Fig. 5: Onboarding Screen - Safety Notes: Acknowledge safety instructions relevant to your device for proper usage.
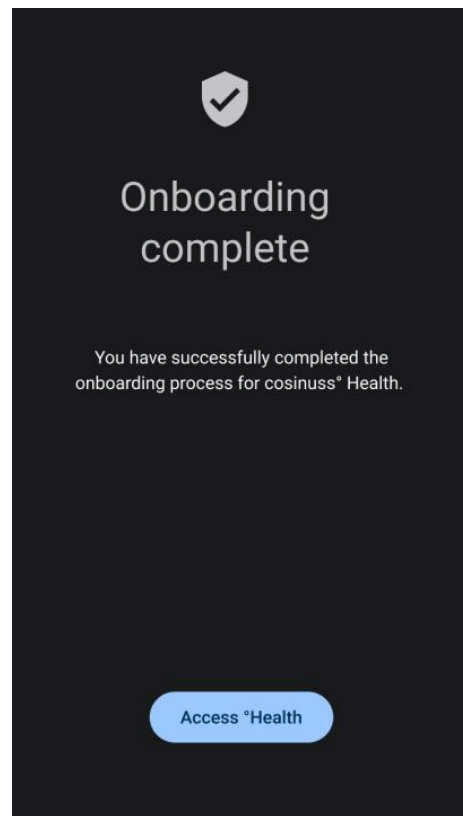
Fig 6: Onboarding Screen - Completion: Marking the completion of the onboarding process, allowing users to begin using the app.

User Interface Overview

Navigation Drawer

The navigation drawer in the cosinuss° Health app (see Fig. 7) allows users to easily access different sections of the app. Here's a detailed description of each item in the navigation:
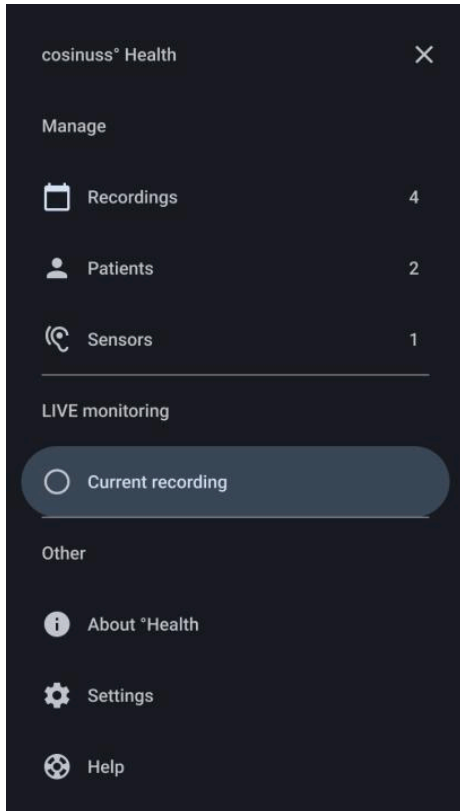

Fig. 7: Navigation Drawer:
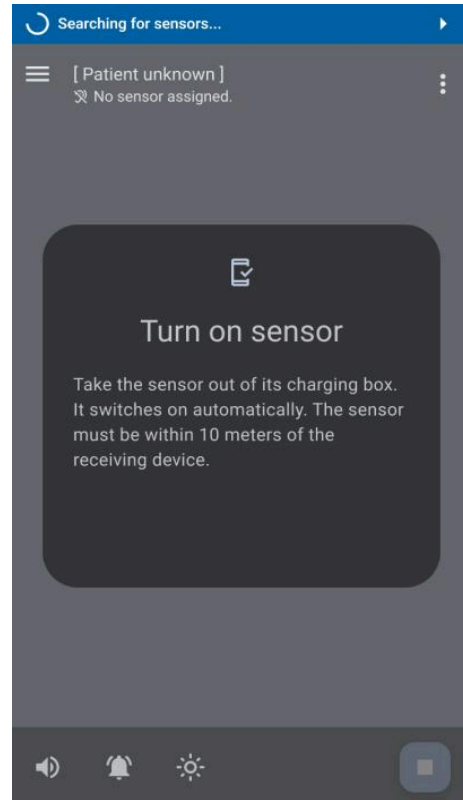Access various sections of the app through the main navigation drawer.

Fig. 8: Recording Screen - Searching for sensors:
The 'Current Recording' screen of the app when actively searching for available sensors.

1. Recordings (Data management)

- **Function:** This section displays all previously recorded data sets.
- **Usage:** Users can review and analyze their health data collected over time.

2. Patients (Data management)

- **Function:** View and manage patient data within the app.
- **Usage:** Create view and edit patients and their associated information and recordings.

3. Sensors (Data management)

- **Function:** View details and additional information about each sensor.
- **Usage:** Access details about each sensor, including additional information and specifications.

4. Current recording (LIVE Monitoring)

The 'Current recording' section of the cosinuss° Health app displays the live monitor of the ongoing recording (see Fig. 9).

- **Function:** Monitor real-time data during active recording sessions.
- **Usage:** This main screen includes core functionalities of the app and facilitates mobile patient monitoring.

5. About (Other)

- **Function:** Access detailed information regarding the app's manufacturer and labeling.
- **Usage:** Obtain relevant details about the app's origins, certifications, and compatibility with associated devices.

6. Settings (Other)

- **Function:** Review and customize app settings.
- **Usage:** Personalize the app according to individual preferences and requirements.

7. Help (Other)

- **Function:** Access the user manual (IFU) and safety notes for comprehensive guidance.
- **Usage:** Review detailed instructions and safety information, and provide feedback directly to the manufacturer for support or suggestions.
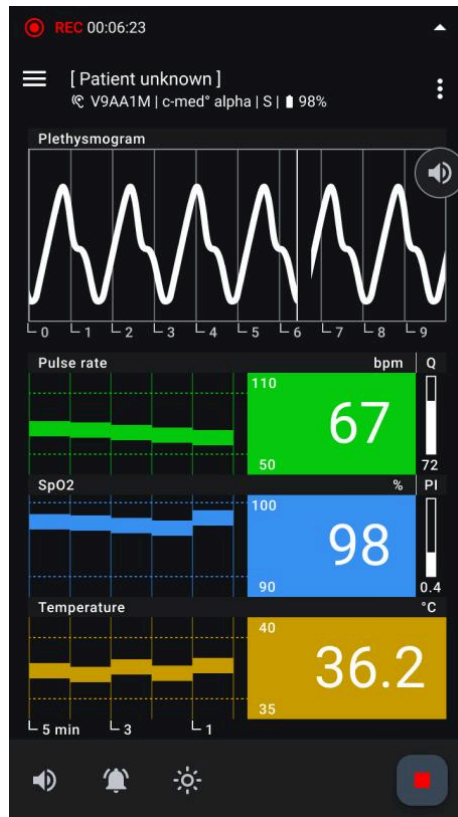
Main Recording Screen

Fig. 9: Recording Screen - Active Measurement:
Layout of the main recording screen during an active measurement, detailing all regions including the Status Bar, Top App Bar (with navigation, patient information, sensor details, and more menu), Main Region (displaying the photoplethysmogram, vital sign items, current values, and quality index), and the Bottom App Bar (with audio options, notification settings, display modes, and stop recording button).

1. **Status Bar:**
   ○ Located at the top of the screen.
   ○ Displays notifications related to system status, sensor connectivity, and recording status.
2. **Top App Bar:**
   ○ Directly below the Status Bar.
   ○ Contains navigation icons to open the navigation drawer.
   ○ Displays patient information, sensor device details, and a more menu for additional options.
3. **Main Region:**
   ○ Located below the Top App Bar.
   ○ Divided into several areas:
      ■ **Photoplethysmogram (PPG):** Provides a graphical representation of blood volume changes over time.
      ■ **Vital Sign Items:** Each vital sign item includes:

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- **Title Area:** Identifies the vital sign being monitored (e.g. Pulse Rate, SpO2).
- **Trend Plot:** Graphical representation of the vital sign's historical values over time.
- **Current Value:** Real-time numerical value of the vital sign (e.g. bpm for Pulse Rate, % for SpO2, °C for Body Temperature).
- **Thresholds:** Appearing as small numbers besides the current value and as dotted lines in the trend plot.
- **Quality Index:** If available, shows the quality of the measurement: Q for Pulse Rate and P for SpO2.

4. **Bottom App Bar:**
    ○ Located at the bottom of the screen.
    ○ Contains functional buttons for:
        - **Audio Options:** Toggle for audio signals related to vital signs.
        - **Notification Options:** Settings for notification preferences.
        - **Display Modes:** Toggle between light and dark modes for screen visibility.
        - **Stop Recording Button:** Allows the user to stop and save the current recording session.

This layout provides a clear understanding of how information and controls are organized on the main recording screen of the app.

Status Bar Notifications

The status bar in the cosinuss° Health app is visible throughout all sections and provides relevant status information on ongoing recording or sensor information. Tapping on the status bar will always navigate you to the current recording screen. There are two groups of notifications that can appear within this status bar:

- Technical notifications
- Physiological notifications

(i)	There is no alarm system.
(i)	Tapping on the status bar will always navigate you to the current recording screen.

Technical notifications

Scanning Status:

Sensor search disabled

Icon: Forbidden.
Text: Sensor search disabled!
Color: Yellow, constant.
Acoustic signal: None.
Meaning: The BLE scan is currently stopped.
Support: Enable sensor search again in the current recording screen.

Searching for sensors…

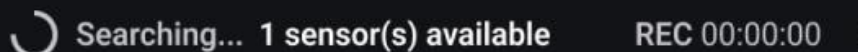**Icon:** Progress indicator.
Text: Searching for sensors…
Color: Blue.
Acoustic signal: 3 pulses every 10 seconds, medium pitch.
Meaning: The app is currently scanning for sensors nearby, but did not find any.
Support: Ensure sensor availability.

Searching… X sensor(s) available

Icon: Progress indicator.
Text: Searching… X sensor(s) available, Recording duration.
Color: Background.
Acoustic signal: None.
Meaning: The app is currently scanning for sensors nearby, and has found at least one.
Support: Choose the sensor available to start recording.

Active Recording Status:

Outside of recording screen

Icon: Recording active.
Text: Patient name, Sensor serial number, Recording duration.
Color: Background.
Acoustic signal: None.
Meaning: The app is currently recording without any detected issues.
Support: None.

Inside recording screen

Icon: Recording active.
Text: Recording duration.
Color: Background.
Acoustic signal: None.
Meaning: The app is currently recording without any detected issues.
Support: None.

Battery status:

Battery warning

Icon: Battery caution.
Text: Battery low.
Color: Blue.
Acoustic signal: 4 pulses every 7 seconds, low pitch.
Meaning: The battery of the sensor device is low.
Support: Charge battery of the sensor device.

Device errors:

Device Error

Icon: Warning.
Text: Device error, Error code.
Color: Light Red.
Acoustic signal: 3 pulses every 10 seconds, medium pitch.
Meaning: The sensor is fully or partially defective. (Affected parameters are also marked)
Support: Contact manufacturer support of the sensor device.

Physiological notifications

Vital sign thresholds:

SpO2 low

Icon: Drop.
Text: SpO2 low.
Color: Red
Visual signal: Parameter blinks alternating between Red and its original color.
Acoustic signal: 7 very fast pulses every 3 seconds, very high pitch.
Meaning: The measured parameter has exceeded the threshold.

Pulse rate high

Icon: Heart.
Text: Pulse rate high.
Color: Red.
Visual signal: Parameter blinks alternating between Red and its original color.
Acoustic signal: 5 fast pulses every 5 seconds, high pitch.
Meaning: The measured parameter has exceeded the threshold.

Pulse rate low

Icon: Heart.
Text: Pulse rate low.
Color: Red.
Visual signal: Parameter blinks alternating between Red and its original color.

Acoustic signal: 5 fast pulses every 5 seconds, high pitch.
Meaning: The measured parameter has fallen below the threshold.

Temperature high

Icon: Thermometer.
Text: Temperature high.
Color: Red.
Visual signal: Parameter blinks alternating between Red and its original color.
Acoustic signal: 5 fast pulses every 5 seconds, half-high pitch.
Meaning: The measured parameter has exceeded the threshold.

Temperature low

Icon: Thermometer.
Text: Temperature low.
Color: Red.
Visual signal: Parameter blinks alternating between Red and its original color.
Acoustic signal: 5 fast pulses every 5 seconds, half-high pitch.
Meaning: The measured parameter has fallen below the threshold.

Quality thresholds:

Quality low, Perfusion low, Perfusion high
Icon: Thumbs down.
Text: Poor measurement quality.
Color: Yellow.
Visual signal: Question mark appears. Parameter blinks alternating between Yellow and its original color.
Acoustic signal: 3 pulses every 10 seconds, medium pitch.
Meaning: The measurement quality of the parameters has fallen below or risen above the threshold value. Aside from that if for more than 30 seconds there were no displayable values for pulse rate or SpO2 within the received data.

Top App Bar

In the recording screen, the top app bar displays all relevant information for the ongoing recording session:
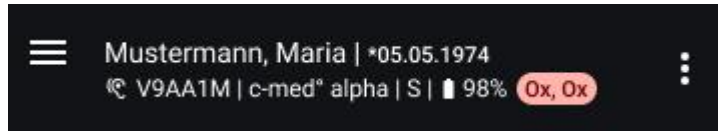
1. **Navigation Button:**
   - Located at the far left.
   - Opens the navigation drawer for switching between different sections of the app.
2. **Patient Information:**
   - Displayed to the right of the navigation button in the upper line.
   - If no patient is assigned, it shows 'Patient unknown'.
   - If a patient is assigned, it shows the patient's last name, first name, and birthdate.
3. **Sensor Information:**
   - Displayed in the second line below the patient information.
   - Includes:
     - **Serial Number:** The unique identifier for the sensor.
     - **Device Name:** The model name or type of the sensor.
     - **Size:** The size of the sensor.
     - **Battery Status:** The current battery level of the sensor.
   - If there is an error with the device, a red marker with the error code will appear here.

4. **More Menu:**
   - Located at the far right end of the top app bar.
   - Clicking the three dots icon opens a menu with additional editing functions available during the recording session.

Bottom App Bar

The bottom app bar is located at the bottom of the main recording screen and contains the following actions, from left to right:

1. **Audio Output Control:**

- ○ **Turn On Audio Output**: Activates the audio output for notifications, represented by a speaker icon without any additional markings.
- ○ **Turn Off Audio Output**: Deactivates the audio output for notifications, represented by a speaker icon with a slash through it.
- ○ **Pause Audio Output for 2 Minutes**: Temporarily pauses the audio output for notifications for 2 minutes, represented by a speaker icon with a pause symbol.

2. **Measurement Notification Control (Audio SIgnal only)**:
   - ○ **Turn On Notifications**: Activates all measurement notifications for vital signs exceeding thresholds, represented by a bell icon without any additional markings.
   - ○ **Turn Off Notifications**: Deactivates all measurement notifications for vital signs exceeding thresholds, represented by a bell icon with a slash through it. System notifications like loss of reception will still be active.
   - ○ **Pause Notifications for 2 Minutes**: Temporarily pauses all measurement notifications for 2 minutes, represented by a bell icon with a pause symbol.
   - ○ This control only affects the audio signal of notifications.

3. **Display Mode Toggle**:
   - ○ **Toggle to Dark Mode**: Switches the display to dark mode for better readability in low-light environments, represented by a moon icon.
   - ○ **Toggle to Light Mode**: Switches the display to light mode for better readability in bright environments, represented by a sun icon.

4. **Stop Recording**:
   - ○ **Stop Button**: Stops and saves the current recording, represented by a red square.

Vital Sign Item

Each vital sign available is represented by a dedicated item consisting of the following components:
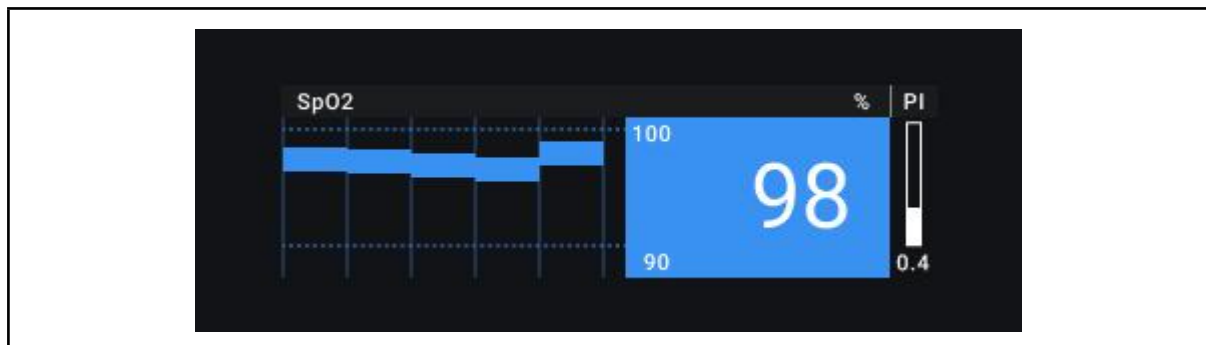
- ● **Title Header:**
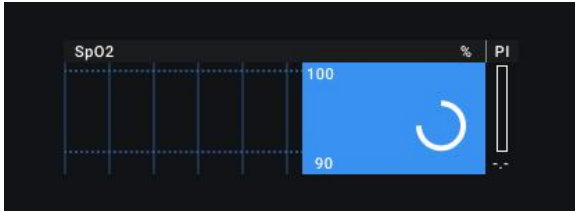
- ○ **Parameter Title:** The name of the parameter being measured.
  - ○ **Unit:** The unit of measurement for the parameter.
  - ○ **Quality Index Title:** The title of the quality index for the parameter.
  - ○ **Notifications:** Any notifications affecting this parameter will be shown here.
- ● **Trend Curve:**
  - ○ **Averaged Value:** Each segment represents the averaged value over one minute.
  - ○ **Parameter Development:** Visual representation of how the parameter changes over time.
  - ○ **Threshold Lines:** Dotted lines indicating the parameter's thresholds.
- ● **Thresholds:**
  - ○ **Current Threshold Values:** Numerical display of the set thresholds.
  - ○ **Adjustment:** Long press to adjust the parameter thresholds.
- ● **Current Value:**
  - ○ **Numerical Display:** The current measurement value transmitted by the sensor.
- ● **Perfusion / Quality Index:**
  - ○ **Visual Representation:** Displayed as a bar with the current value.
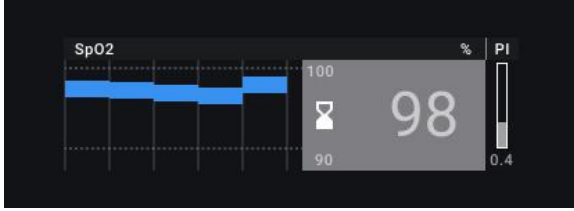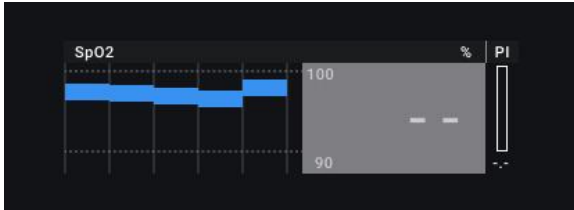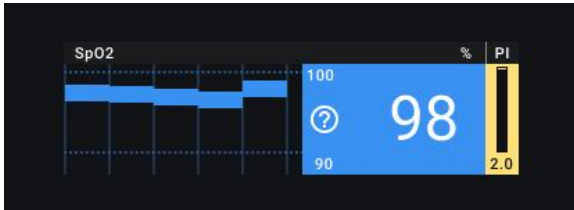
Additional Information:
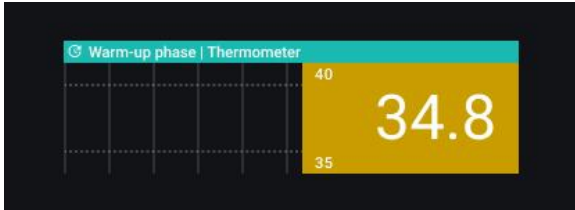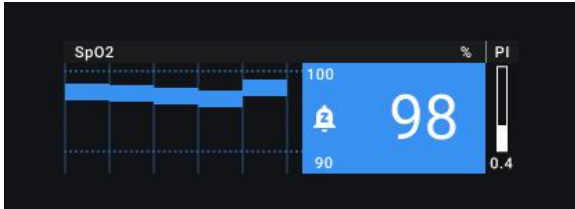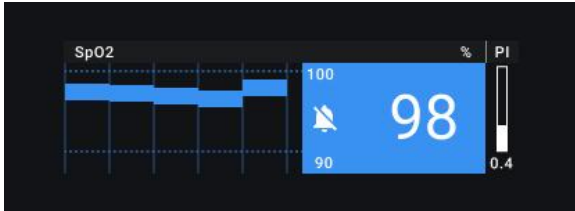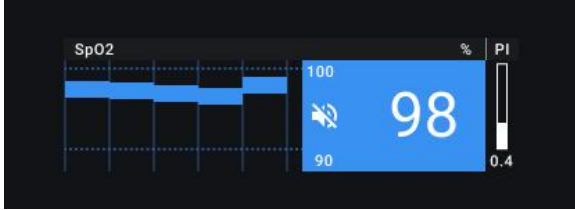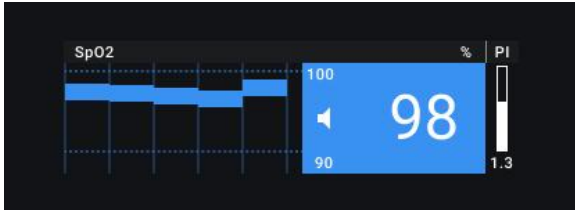
- ● **Status Changes and Notifications:**
  - ○ The item will also display any status changes and notification colors to alert the user of important updates.

States of the Vital Sign Item:

Initializing (Empty): ● **Meaning:** In the current data, there are no displayable values. ● **Display:** Default layout with a processing indicator.	
Enabled: ● **Meaning:** Values are incoming and displayed. ● **Display:** Normal display of all components.	

Timed Out (Waiting): ● **Meaning:** No values are currently incoming. Data is older than 5 seconds but not older than 35 seconds ● **Display:** Last received value is displayed grayed out for 30 seconds, then it disappears.	
Sensor Out of Range: ● **Meaning:** No values incoming from the current sensor. ● **Display:** After 30 seconds, the last values disappear.	
Quality Poor: ● **Meaning:** Quality index has passed its thresholds. ● **Display:** Quality index area blinks yellow, and a 'Poor measurement quality' notification is triggered.	
Vital Signs Threshold: ● **Meaning:** Current value has exceeded its thresholds. ● **Display:** Current value area blinks red, and the corresponding notification is triggered.	
Device Error: ● **Meaning:** Parameter is affected by a device error. ● **Display:** Title area appears red and displays the defect and error code.	

Warm-Up Phase (only applicable for Temperature): • **Meaning:** The thermometer unit in a sensor is using direct measurement, awaiting stable temperature reading. • **Display:** No notifications for temperature during this phase; a warm-up indicator is shown. • **Note:** Users can skip this phase if necessary, e.g. in cases of hypothermia.	
Notifications Paused: • **Meaning:** User has paused notifications for this parameter. • **Display:** A 'Notifications Paused' symbol appears in the current value area.	
Notifications Off: • **Meaning:** User has turned off notifications for this parameter. • **Display:** A 'Notifications Off' symbol appears in the current value area.	
Notification Sound Off: • **Meaning:** User has turned off the acoustic signals for notifications. • **Display:** A 'Notification Sound Off' symbol appears in the current value area.	
Notification Sound Paused: • **Meaning:** User has paused the acoustic signals for notifications. • **Display:** A 'Notification Sound Paused' symbol appears in the current value area.	

Thresholds and Timeouts

Device Related

Connection Timeout
The cosinuss° Health app utilizes a Bluetooth broadcasting interface rather than a standard Bluetooth connection. This means there is no paired connection between the sensor and mobile device; instead, the mobile device continuously scans while the sensor continuously sends data. A sensor device is marked as 'disconnected' if:

- **Foreground:** No Bluetooth package is received for 10 seconds.
- **Background:** No Bluetooth package is received for 30 seconds.

Device Error Timeout
Detected device errors are kept for as long as they are received from the device and for further 15 seconds after the last error was received.

Recording Related

Select Sensor Dialog Popup Conditions
Applicable only if sensor search is enabled and no recording is active.
- **Trigger:** Shown if the app is scanning and at least one device is found.
- **Removal:** Sensors out of range are removed.
- **Closure:** Dialog closes if all sensors are out of range.

Auto Record Start Conditions
- Conditions (for 60 seconds):
    - App is in the 'select sensor' state.
    - Exactly one compatible sensor device in range:
        - Measures temperature > 30 °C.
        - Is in Broadcast Vitals mode.

- **Foreground/Background**: Conditions apply regardless of the app state.

Temperature Warmup Phase Duration
- **Duration:** 2 minutes.

(!)	There are compatible sensor devices that do not extrapolate and do not add an offset to the measured temperature values. For this reason, there is a warm-up phase of a few minutes which is indicated in cosinuss° Health.

Sensor Search Disabled Duration

- **Pause**: Bluetooth scan pauses for 10 minutes when the Select Sensor Dialog is dismissed, then automatically resumes.

Vital Data States

- **State Transition Based on Data Age and Errors:**

State	Conditions
Valid	Data is not older than 30 seconds.
Waiting (greyed out)	Data is older than 5 seconds but not older than 35 seconds
Empty (circular progress)	No data since recording start OR No data since last sensor returned into BLE range OR Data is older than 65 seconds OR
Error	Current device errors.

Errors Affecting Data:

Error Code	Error Description	Affected data
0x0a	PPG-IR error	Pulse Rate, SpO2
0x0b	PPG-Red error	Pulse Rate, SpO2
0x11	TemperatureDefect error	Temperature

Vital Data Display Limits

- **Pulse Rate:** As sent by the sensor.
- **SpO2:** As sent by the sensor.
- **Temperature:** As sent by the sensor.

❗	The display range of the app can be larger than the rated output range of the device. For a range of output values related to compatible sensor devices please refer to the user manual of the relevant device.

Output range of compatible devices

c-med° alpha

Output	Range
Pulse Rate	40–220 bpm
SpO2	0–100%
Temperature	22–43 °C
Quality index	0–100 (a.u.)
Perfusion	0.1–5%

Trend Chart Conditions

- **Segment Length:** 1 minute.
- **Segment States:**

State	Condition	Visual Representation
Empty	No data in segment time range or during Warmup phase.	Segment is invisible.
Reliable	SpO2: median perfusion ≥ 0.1; Heart Rate: max quality > 40; Temperature: always valid.	Segment in full opacity.
Unreliable	If conditions for a reliable state are not met.	Segment in transparent opacity.

Vital Notification Thresholds

Default presets:

Value	Low Threshold	High Threshold
Pulse rate	< 50 bpm	> 110 bpm
SpO2	< 90%	> 100% (fixed)
Temperature	< 35°C	> 40°C
Battery	< 15%	-

Range of Customization:

Value	Lowest setting	Highest setting	Step size

Pulse Rate	10 bpm	200 bpm	5
SpO2	70%	100% (fixed)	1
Temperature	24 °C	41 °C	1.0
Battery	n/a	n/a	n/a

Reset: Custom thresholds reset automatically with each new recording.

Quality Notification Thresholds:

Criteria	Triggering values
Quality index (Q) (a.u.)	< 45 for at least 15 seconds
Perfusion (P) (%)	< 0.15 or > 2.0
Initialising	Data incoming but can not be processed. Or, if quality indicators remain too bad for 30 seconds.

Start Recording Pop-Up Dialog

The start recording pop-up dialog (see Fig. 10) is designed to facilitate the selection and initialization of sensors for recording. It comprises several elements:
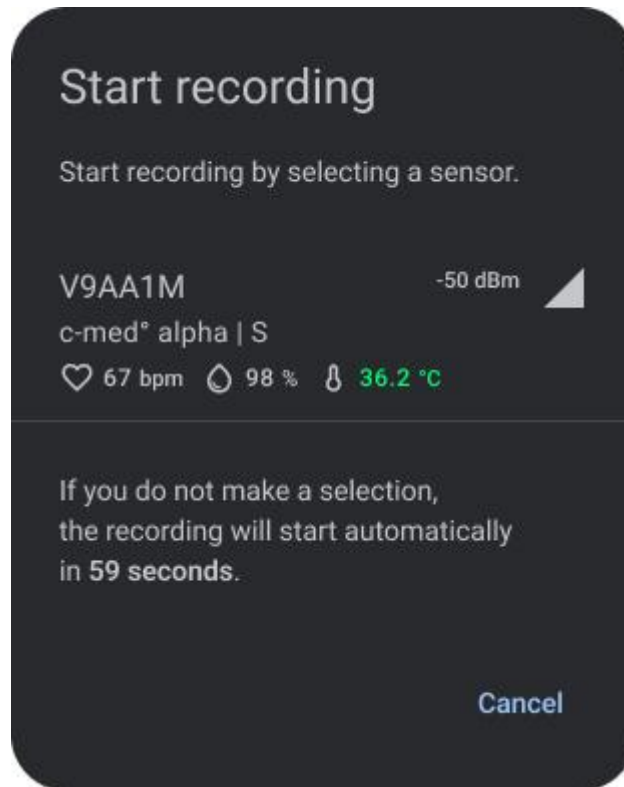
Fig. 10: Start Recording Pop-up Dialog:
Initiates the recording process, displaying available sensors and relevant options.

Elements of the Dialog

1. **Title:**
   ○ The title indicates the purpose of the dialog, such as 'Select Sensor.'
2. **Description Text:**
   ○ A brief explanation of the dialog's function, instructing the user to select a sensor to begin recording.
3. **List of Available Sensors:**
   ○ A list displaying all sensors available for selection. Each list item can have different states based on sensor conditions:
      ■ **Broadcast Mode:** Indicates if the sensor is in broadcast mode (True/False).
      ■ **State:** Indicates if the sensor is enabled or disabled.

- **Temperature:** Indicates if the temperature is above or below 30°C, representing whether the sensor is applied or unapplied.
        - **Error Code:** Indicates if there is an error with the sensor (True/False).
4. **Supporting Text:**
    ○ Additional information or instructions to assist the user in making an informed selection.
5. **Action Buttons:**
    ○ Buttons for user actions, such as 'Cancel' to exit the dialog or 'Start' to begin the recording process with the selected sensor.
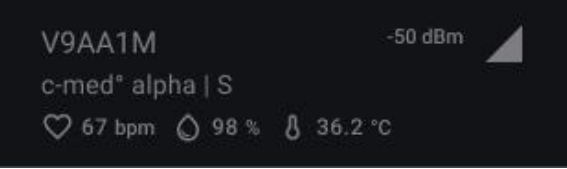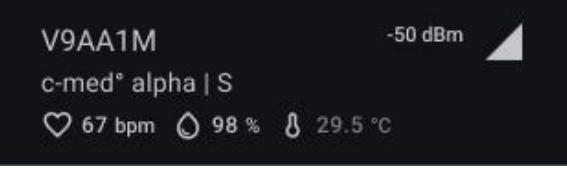
Sensor List Item States

Each sensor in the list can have multiple states, which provide the user with relevant information about the sensor's status:

Broadcast Mode: The sensor is actively broadcasting data. Vital data preview available.	**Other Mode:** The sensor is not broadcasting data.

Enabled: The sensor is available for selection and use.	**Disabled:** The sensor is not available for selection and use.

Temperature above 30 °C: Indicates that the sensor may be applied.	**Temperature below 30 °C:** Indicates that the sensor may be unapplied and should be checked before use.

V9AA1M -50 dBm c-med° alpha | S ♡ 67 bpm ◊ 98 % 🌡 36.2 °C	V9AA1M Ox, Ox -50 dBm c-med° alpha | S ♡ 67 bpm ◊ 98 % 🌡 --.- °C
No Device Error: The sensor is functioning correctly without errors.	**Device Error:** There is an error with the sensor that may affect its functionality.

How to Use Cosinuss° Health

Start Monitoring (Manually)

To start a measurement with the cosinuss° Health app, follow these steps:

1. Open the app:
Launch the app from the home screen of your device. The app should always start at the 'Current Recording' section (see Fig. 11).

2. Ensure Sensor Availability:
If no sensor is within range, you will be prompted to power on a compatible sensor and bring it within range (see Fig. 12).

3. Select a Sensor:
Once a sensor is detected, a dialog for sensor selection will appear. If multiple sensors are found, they will be displayed in a list. Manually select the sensor you wish to use for the recording (see Fig. 13).

4. Verify Sensor Serial Number:
It is the user's responsibility to verify that the displayed serial number matches the serial number on the sensor being used. This ensures the accuracy of data assignment (see Fig. 14).

5. Start the Recording:

Press the 'Start' button to begin the measurement. The monitoring screen will appear and start populating with real-time data.

❗	Incorrect sensor attachment or serial number mismatches can lead to inaccurate data and potential safety risks. Always verify the serial numbers and sensor placement before starting the recording.
❗	**Serial Number Mismatch:** If the serial numbers do not match, stop recording immediately and make sure the correct sensor is attached to the patient.
❗	**Multiple Patients:** Double-check to ensure the data is being recorded for the correct patient. This is especially important when there are multiple patients nearby.

Fig. 11: Navigation Drawer - Select Current Recording:
Allows users to start a monitoring session by selecting the current recording option.
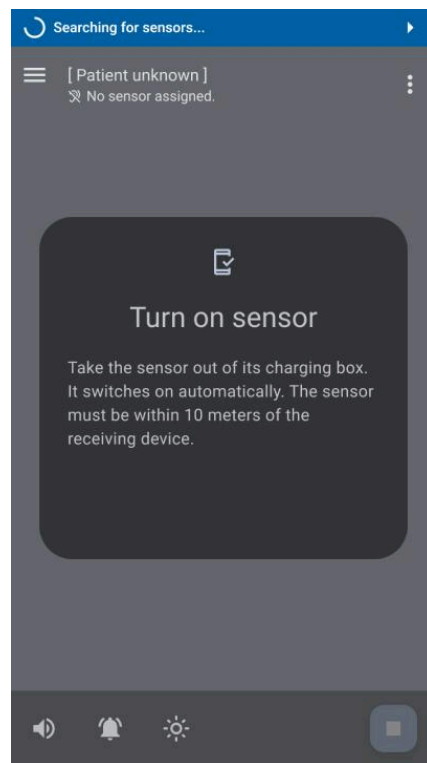
Fig. 12: Current Recording Screen - No Sensor Available:
Displays the default screen prompting the user to turn on a compatible sensor device for the current recording.

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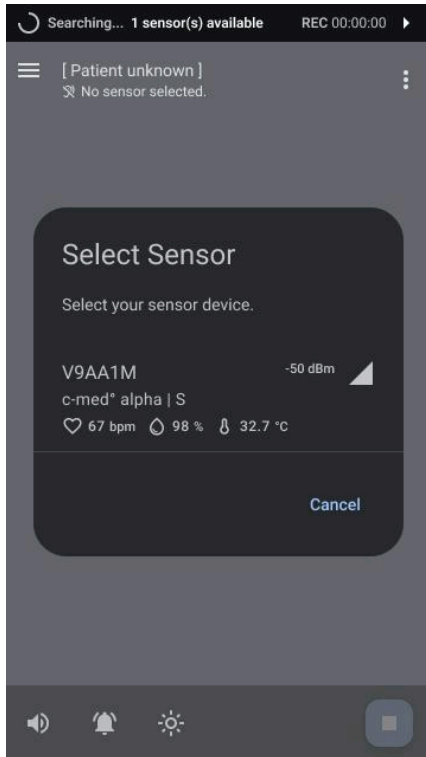
Fig. 13: Current Recording Screen - Select Sensor Dialog:
Displays the select sensor dialog, allowing users to choose an available sensor device to begin monitoring.
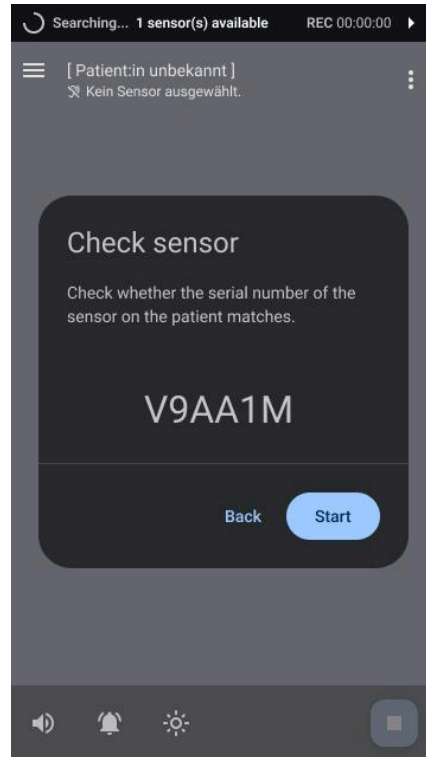
Fig. 14: Current Recording Screen - Check Sensor Dialog:
Prompts the user to verify that the serial number on the device matches the chosen sensor from the list before proceeding.

Start monitoring (by Auto-Recording)

When a single sensor is detected and meets the temperature criteria, the app automatically starts the recording process, reducing the need for manual interaction.

1. Open the app:
Launch the app from the home screen of your device. The app should always start at the 'Current Recording' section.

2. Ensure Sensor Availability:
If exactly one sensor is found that is measuring temperature values above 30°C (indicating it might be in a patient's ear), an auto-select countdown of 60 seconds will start (see Fig. 15).

3. Automatic Sensor Selection:
During the countdown, the manual sensor selection is not needed, and the sensor is automatically selected based on the temperature condition.

Interrupt Auto-Recording:

Users can interrupt this process by manually selecting a sensor from the list if needed.

5. Start the Recording:

After the 60-second countdown, the recording starts automatically. The monitoring screen will appear and start populating with real-time data.

ⓘ	In order to have the automatic recording function available, the sensor must have been connected manually at least once beforehand.
ⓘ	The auto-recording feature only triggers if there is exactly one active and functioning compatible device in range (see Fig. 15).
ⓘ	If the app is running in the background auto-recording still performs with the same conditions as above.
ⓘ	If the measured temperature is below 30 °C, no auto-recording 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 your desired sensor manually (see Fig. 16).
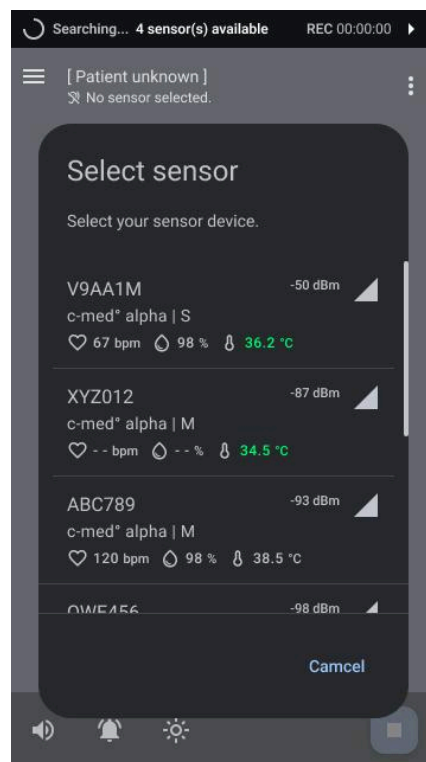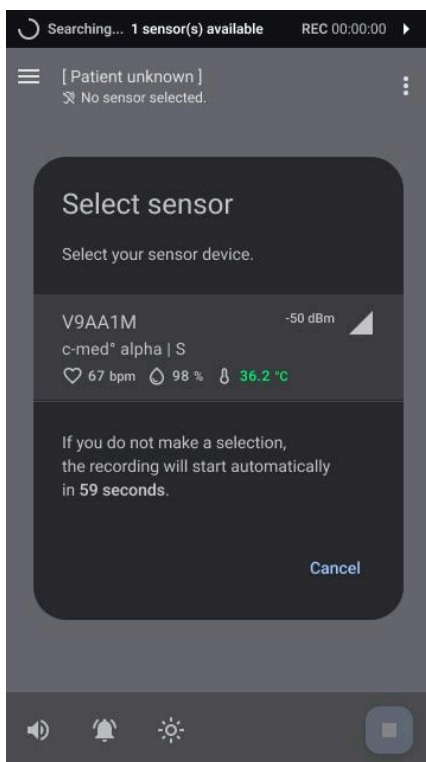
Fig. 15: Current Recording Screen - Auto-Recording Countdown:
Displays the Select Sensor Dialog with a countdown until automatic recording starts, indicating that one sensor meets the auto-recording conditions. Manual selection remains optional.

Fig. 16: Current Recording Screen - Select Sensor Dialog:
Shows the Select Sensor Dialog with multiple sensors meeting the conditions. Since more than one sensor is detected, auto-recording does not initiate, and manual sensor selection is required.

Exceptions

Sensors in Different Bluetooth Low Energy (BLE) Modes

cosinuss° sensors may operate in various Bluetooth modes. Sensors in different Bluetooth modes will still appear in the selection dialog (see Fig.18). When selected, the cosinuss° Health will automatically switch these sensors to BLE Broadcasting mode to ensure all data is displayed on the monitoring screen.

Partly Defective Sensors

It may occur that a sensor suffers from different hardware defects, which can impair its functionality either partially or completely. In such cases, the sensor sends an error code that is displayed in the app alongside the sensor serial number (see Fig.18). If possible, the sensor can still be used, but it will only display data from functional components. Any other parameters from defective parts will be marked as erroneous and will not show any data.

Cancel Start Monitoring

It is important to know that the app continuously scans for sensors in the vicinity, except during an active measurement or when the recording dialog has been closed. In this case, scanning is paused for 10 minutes (see Fig.17). Additionally, the dialog will automatically close if no sensors are available nearby.
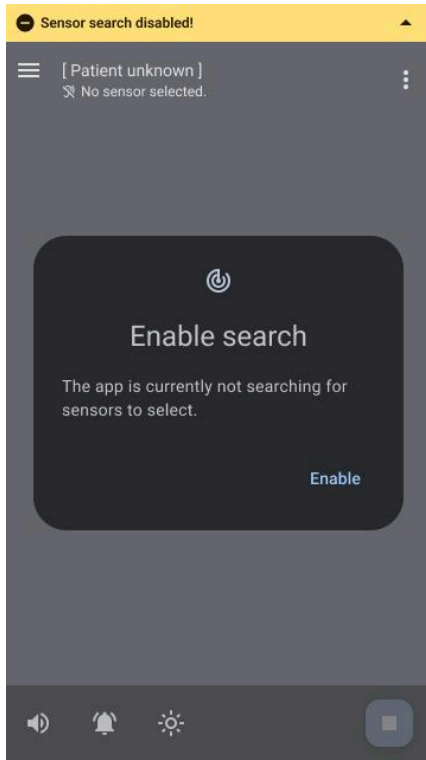
Fig.17: Current Recording Screen - Monitoring Start Canceled:
Displays the screen after canceling the start of monitoring. A 10-minute timeout for scanning new sensors is activated, and scanning can be manually reenabled if needed.
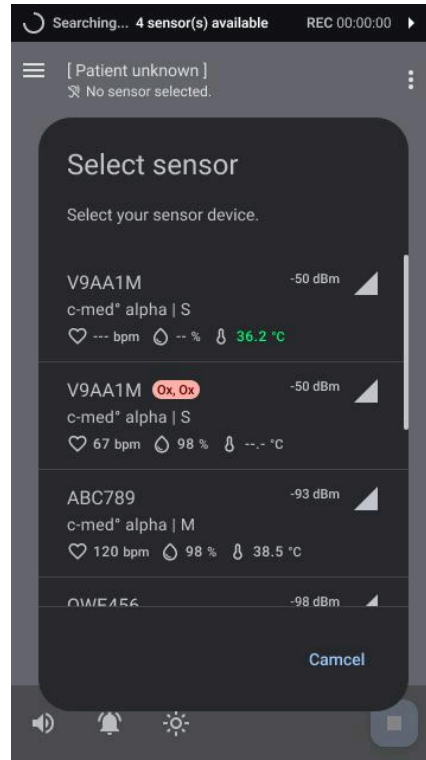
Fig. 18: Current Recording Screen - Select Sensor Dialog:
Displays the dialog during exceptional sensor states, including device errors and varying BLE modes of available sensors.

Perform Monitoring

1. Verify System Status:

To initiate monitoring in the cosinuss° Health app (see Fig.20), the user must first identify the system status:

- Check for error-free sensor display in the top app bar.
- Ensure the recorded sensor is within range and actively receiving data.
- Continuous data reception should be observed without any 'Out of Range' notifications.

2. Check Current Vital Signs:

Review and understand the visual representations of current vital signs. There are two ways of visualizing the data:

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

- **Photoplethysmogram (PPG)**

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.

The photoplethysmogram (PPG) signal is supplemented with an additional acoustic signal to indicate pulse rate and oxygen saturation. Here's how it works and how to use it:

- **Acoustic Pulse wave signal:**
  - **Pulse Rate:** The interval between the sounds reflects the pulse rate.
  - **Oxygen Saturation:** The frequency or pitch of the tone represents the oxygen saturation level.

The Photoplethysmogram (PPG) can help to monitor and analyze the pulse rate and possible irregularities.

- **Vital sign item**

To review the current vital signs in the cosinuss° Health app, follow these steps for each vital sign tile:

Pulse Rate: Title: Pulse Rate | Numeric Value: Displayed in beats per minute (bpm) | Unit: bpm | Color: Green | Preset Thresholds: 110 bpm (upper threshold), 50 bpm (lower threshold) | Quality Index (a.u.): Quality | Abbreviation: 'Q', Thresholds for Q: Should be over 20.

Arterial Blood Oxygen Saturation (SpO2): Title: SpO2 | Numeric Value: Displayed in percent (%) | Unit: % | Color: Blue | Preset Thresholds: 100% (upper threshold), 90% (lower threshold) | Quality Index: Perfusion (%) | Abbreviation: 'P' | Thresholds for P: Should be over 0.15%.

Body Temperature: Title: Temperature | Numeric Value: Displayed in degree Celsius | Unit: °C | Color: Yellow | Preset Thresholds: 40°C (104°F) (upper threshold), 35°C (95°F) (lower threshold) | Quality Index: N/A.

3. Reviewing the Trend of Vital Signs Over Time

When reviewing the trend of vital signs over time in the cosinuss° Health app:

- Historical values for each vital sign are shown as a trend curve on the left next to the current values.
- Each segment represents the averaged value of the parameter over 1 minute.
- Thresholds are marked with dotted lines on the curve.
- Segment Status:
    - Segments can be within or above thresholds.
    - Some segments may be disabled due to data loss or incomplete data capture.

ⓘ	The duration of time you can look back depends on the screen size of the mobile device being used, with a minimum viewing capability of 5 minutes.
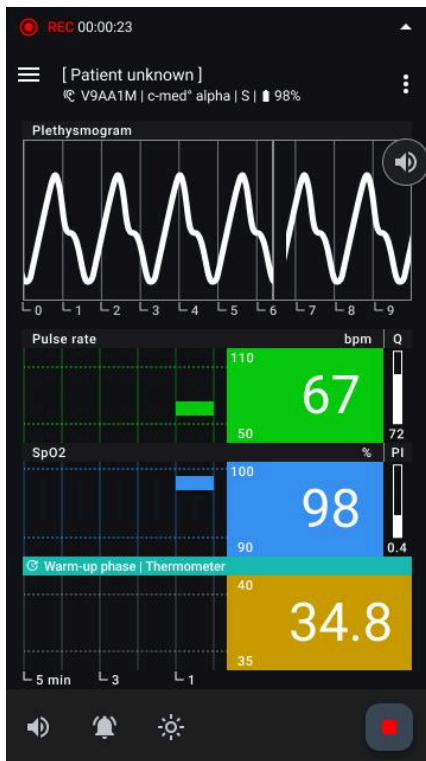
Fig. 19: Performing Monitoring - Warm-Up Phase:
Shows the initial minutes of data population with the thermometer in warm-up phase; no data is displayed until stabilization, but this phase can be skipped if necessary.
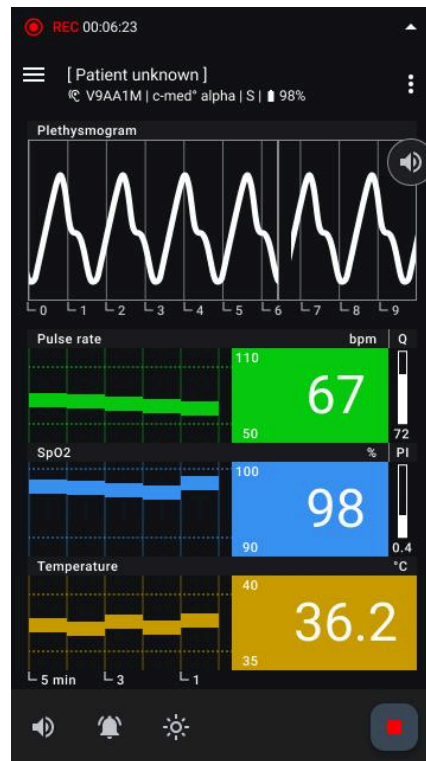
Fig. 20: Performing Monitoring - Active Recording Screen:
Displays the current recording with all vital signs and metadata actively being monitored.

Act and Adapt During Monitoring

Check Sensor Functionality:

To ensure effective monitoring in the cosinuss° Health app, follow these steps:

- Ensure data is continuously received and provides meaningful values.
- No error codes should be displayed next to the sensor serial number.
- Verify the sensor's battery level is adequate.
- Ensure the absence of the following notifications:
    - Device Defect (see Fig.22)
    - Low Battery Warning
    - Connection Loss (see Fig.21)

Check Data Validity:

Monitoring these aspects helps ensure the reliability and accuracy of the health data captured by the app. To ensure the validity of incoming data in the cosinuss° Health app, follow these guidelines:

- **Verify Quality Index:**

    - **Pulse Rate:** Check the Quality index (Q); it should be above 45 for sufficient measurement quality.
    - **SpO2:** Check the Perfusion index (P); it should be above 0.15% and under 2.0% for sufficient measurement quality.

If these values are not met, a question mark will be displayed alongside the current value to indicate questionable data quality. Additionally the notification 'Poor Measurement Quality' will appear (see Fig.23).

- **Review PPG Curve Characteristics:**

    An ideal PPG curve typically exhibits the following characteristics:

    - **Clear Peaks:** Distinct peaks representing each heartbeat.
    - **Regular Pattern:** Consistent intervals between peaks indicating regular heartbeat.
    - **Smooth Baseline:** A smooth baseline between peaks without irregular fluctuations.
    - **Amplitude Consistency:** Consistent amplitude of the waveform reflecting consistent blood flow.
    - **Absence of Artifacts:** Minimal interference or noise, ensuring accurate measurement of blood flow dynamics.

	The displayed ppg signal is normalized. The amplitude cannot be used to draw conclusions about the perfusion. The perfusion index must be considered.

Check for Vital Signs Outside Thresholds:

Monitoring these indicators helps to promptly identify and respond to any remarkable changes in the patient's vital signs. To ensure the monitored vital signs are within acceptable ranges, follow these steps:

- **Verify Threshold Compliance:**
  - **Threshold Indicators:** The thresholds are displayed in small text to the left of the current value.
  - **Status Change:** If the current value exceeds or falls below these thresholds, the status of the display changes.
  - **Notifications:** Corresponding notifications will appear to indicate if the parameter is too high or too low. (see Fig.24)
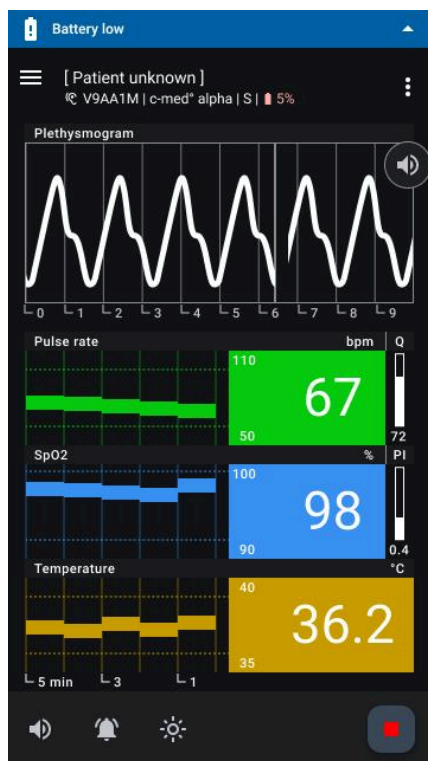
Fig. 21: Sensor functionality - Sensor Low Battery:
Displays the screen during monitoring indicating that the sensor device has a low battery state.
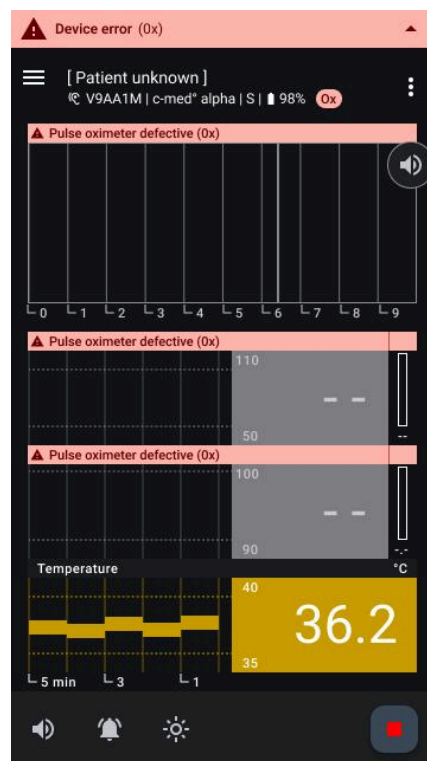
Fig. 22: Sensor functionality- Device Error:
Displays the screen during monitoring where a device error, such as a defective pulse oximeter, is impacting specific vital signs.
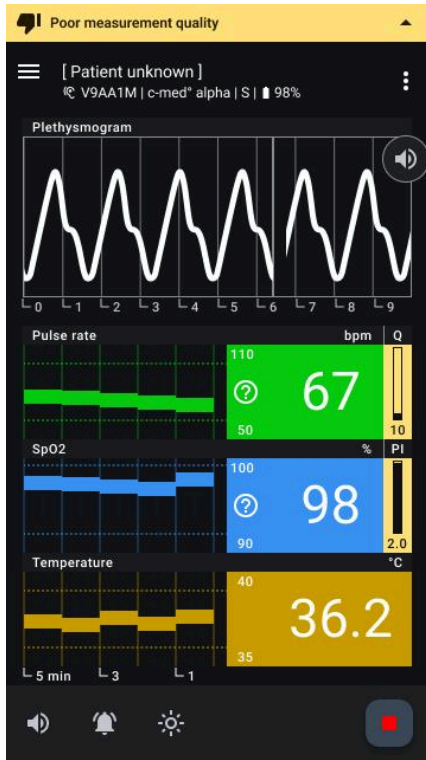
Fig. 23: Data validity - Invalid Data:
Shows the screen where data is marked as invalid due to poor measurement quality, indicating unreliable vital sign readings.
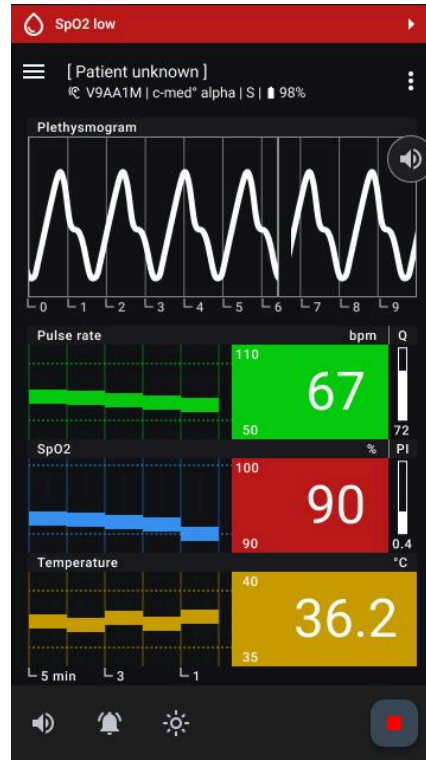
Fig 24: Vital Sign Threshold Exceeded:
Displays the screen where a vital sign has gone beyond or below its set threshold, indicating the exceeded value and triggering relevant notifications.

Switching Display Modes

To accommodate changing environmental conditions and ensure readability, the cosinuss° Health app offers a light and dark display mode (see Fig.25). Follow these steps to switch modes:

- **Toggle Display Mode:**
    - **Light Mode:** Click on the sun icon to activate the light mode.
    - **Dark Mode:** Click on the moon icon to activate the dark mode.

Acoustic Pulse Wave Signal

The Acoustic Pulse Wave Signal is an additional acoustic signal that indicates pulse rate and oxygen saturation. By listening to changes in the acoustic signal, one can discern if these parameters are rising or falling.

- **Toggle Audio:**
    - The signal can be turned on or off by clicking the 'Audio' button next to the PPG curve (see Fig.26).
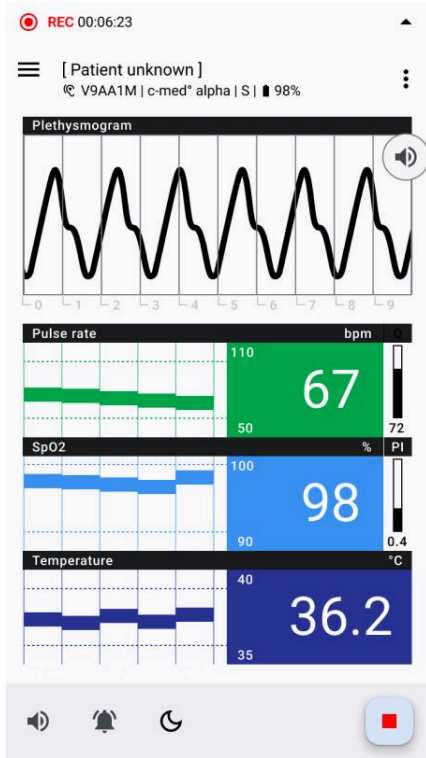
Fig. 25: Display Mode Switch - Dark to Light:
Shows the transition of the display mode from dark to light, enhancing readability for different lighting conditions.
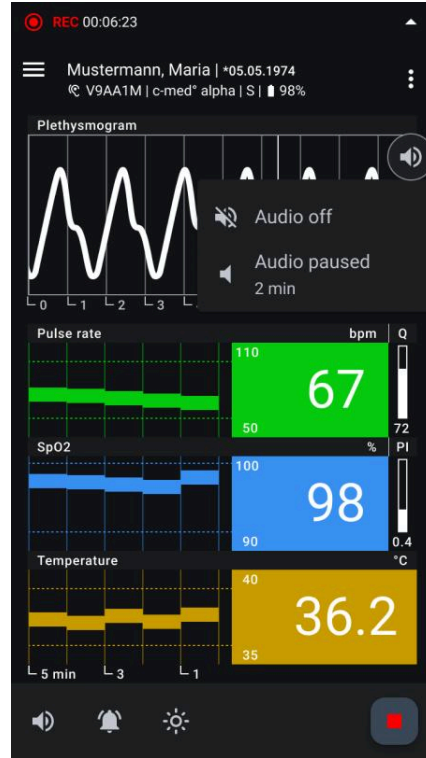
Fig. 26: Acoustic Pulse Wave Signal Controls:
Displays the options to turn on, off, or pause the acoustic pulse wave signal for notifications during monitoring.

Customizing Vital Sign Thresholds

Users can adapt individual vital sign thresholds to meet their specific needs, context and use case, helping to prevent alarm fatigue and provide individualized care. Here's how to customize these thresholds:

- **Functionality:**
  - **Adapt Thresholds:** Long-press on the area where the thresholds are displayed (to the left of the current values) (see Fig.27).
  - **Open Bottom Sheet:** A bottom sheet will appear, allowing the user to enter new values from a drop-down menu. Only reasonable values can be selected (see Fig.28).
  - **Confirm or Reset:** The user can either confirm their new custom thresholds or reset the values to default settings (see Fig.29).
  - **Custom Threshold Indicator:** Custom thresholds will be marked with a small indicator to show they have been customized (see Fig.30).
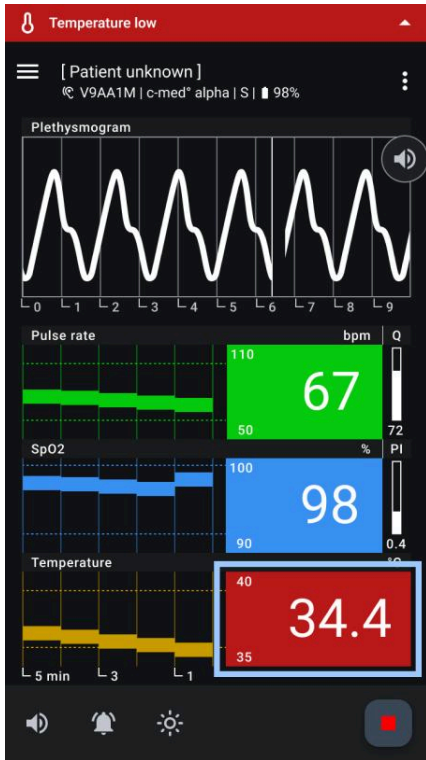
Fig. 27: Customizing Vital Sign Thresholds:
Shows the options for adjusting vital sign thresholds, which can be accessed by a long press on the threshold area.
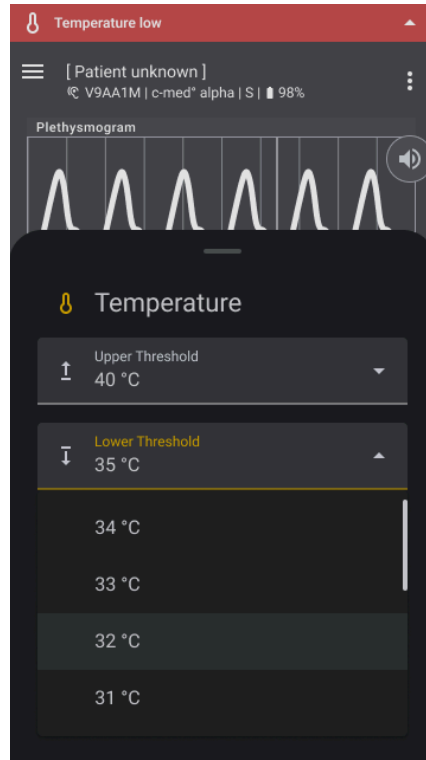
Fig. 28: Selecting New Vital Sign Threshold Values
Displays the dropdown menu for choosing a new value for vital sign thresholds.
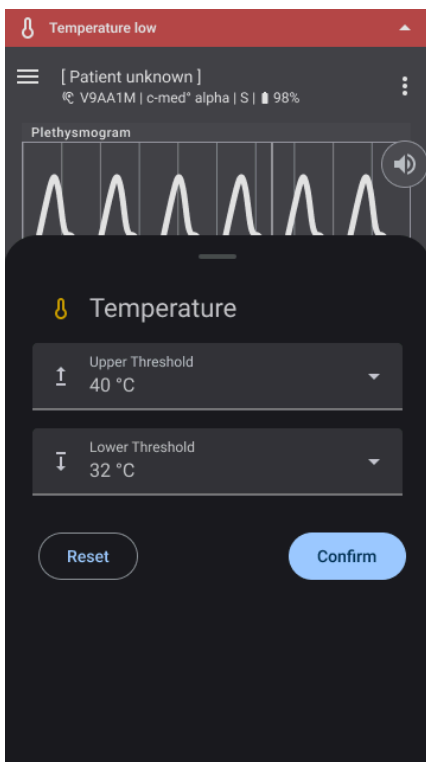
Fig. 29: Confirming Vital Sign Threshold Selection:
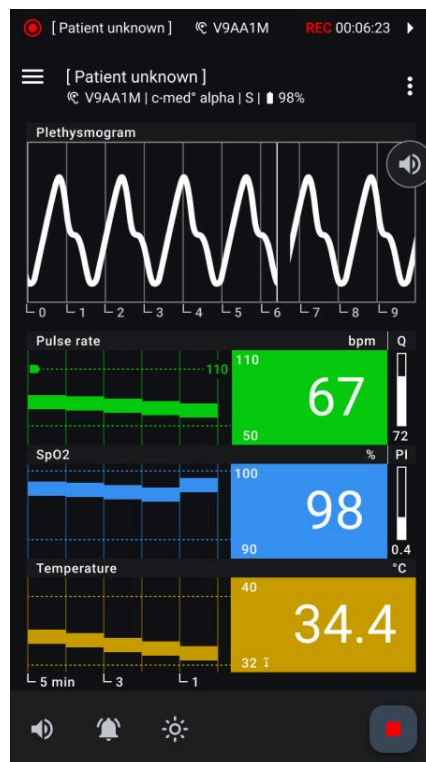
Fig. 30: Customized Vital Sign Display:

Shows the confirmation step for finalizing the chosen value for vital sign thresholds.

Shows the monitoring screen with a small indicator highlighting that the vital sign threshold has been customized.

(i)	Customized thresholds will be reset to default settings with every new start of a recording or restart of the app.

Swapping a sensor during recording

You may need to swap the sensor if you want to change the sensor size or if the sensor's battery is low. To swap a sensor during a recording, follow these steps:

1. **Accessing the Swap Sensor Function:**
   ○ To swap a sensor, click on the three dots at the right in the top app bar. A bottom sheet will open with the 'Swap sensor' option at the bottom. Click on it to open the dialog for sensor selection (see Fig.31).
2. **Tap on 'Swap sensor':**
   ○ Tap on the 'Swap sensor' option to initiate the sensor replacement process. This feature allows you to seamlessly assign a new sensor to the ongoing recording.
3. **Selecting a New Sensor:**
   ○ The 'Swap Sensor' dialog will appear, displaying a list of available sensors. Choose another sensor from the list by identifying it through its serial number and signal strength (see Fig.32).
4. **Continued Recording:**
   ○ The current recording will continue uninterrupted during the sensor selection process.

This functionality ensures flexibility and continuity in monitoring by enabling swift sensor replacements without interrupting ongoing recordings.
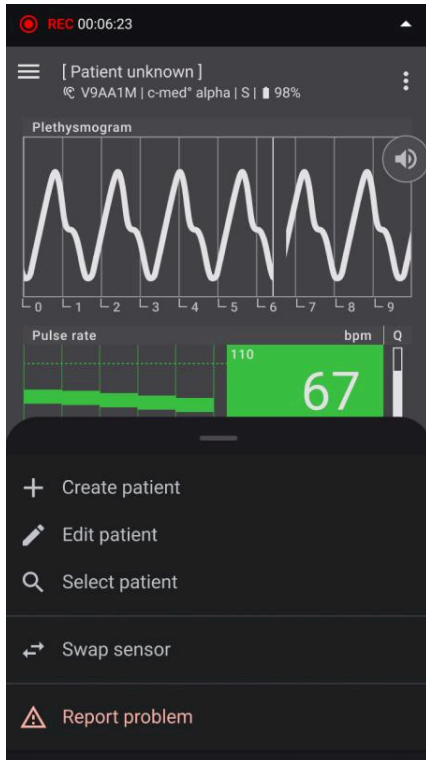
Fig. 31: Bottom Sheet with Swap Sensor Option:
Displays the bottom sheet containing the option to swap the current sensor, allowing users to select a different sensor for continued monitoring.
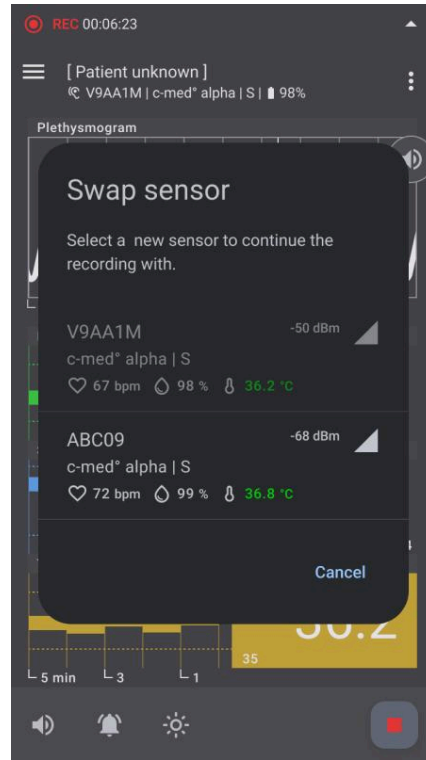
Fig. 32: Swap Sensor Dialog:
Shows the dialog for selecting an alternative sensor when swapping, similar to the Select Sensor Dialog, allowing users to choose a different sensor from the available options.

8. Report a problem during recording

The 'Report problem' function in the cosinuss° Health app allows you to provide feedback on current or saved recordings if irregularities or incidents occur. This feature is essential for continuous app improvement and addressing your concerns effectively.

How to Report a Problem

To report a problem, click on the three dots at the right in the top app bar. A bottom sheet will open with the 'Report problem' option at the bottom (see Fig.33). Click on it to open the input mask for reporting problems (see Fig.35).

Report Problem (Input Mask)

- **Problem Description (Required):** Provide a detailed description of the problem that occurred in the text field. This is mandatory.
- **Anonymized CSV File (Opt-out):** The affected measurement is automatically attached as an anonymized CSV file. You can choose not to include this file, but it aids us in investigating the problem thoroughly.

- **Add Photos (Optional):** Optionally, attach photos to visually illustrate the problem.
- **Contact Information (Optional):** For personalized feedback, provide your name and email address.

Additional Information

- **CSV File:** Click on the 'Additional information on CSV file' link to learn about the data contained in the attached CSV file and its use.
- **Photos:** Use the link to get instructions on correctly uploading photos to assist in problem analysis.

This reporting feature ensures that we can promptly address any issues and enhance your experience with our app.
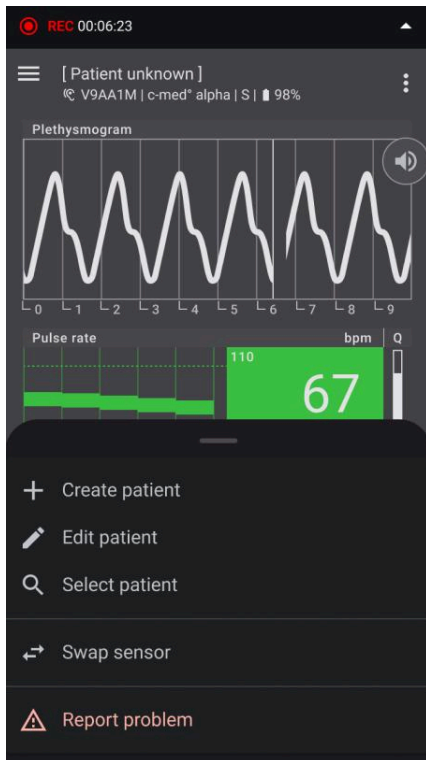
Fig. 33: Bottom Sheet - Report Problem:
Displays the bottom sheet with the option to report a problem, enabling users to report issues directly from the app.
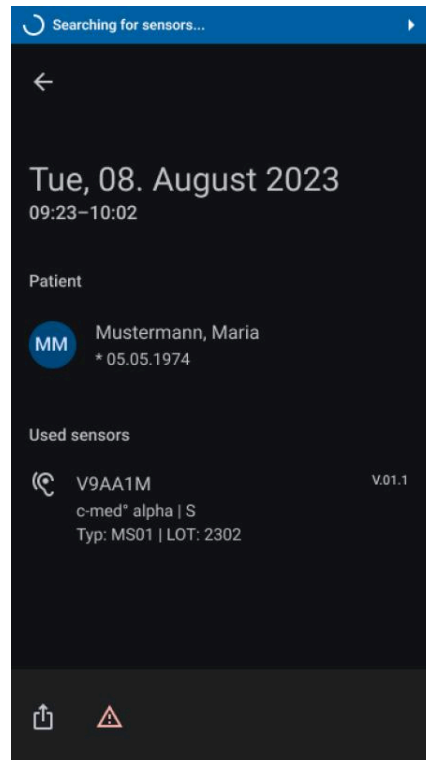
Fig. 34: Problem Report Function in Past Records:
Shows the location of the problem report option in the bottom app bar while viewing historical records, enabling users to report issues with past data directly from this view.

Fig. 35: Problem Report Input Mask:
Shows the input mask for reporting a problem, where users can enter details about the issue they are experiencing.

Add Information to Recording

Adding Patient Information

In the top app bar, all information relevant to the patient and sensor associated with the recording is displayed. If no patient is assigned, it will show 'Patient Unknown.' If a patient is assigned, their last name, first name, and date of birth are displayed. To add or edit this information, follow these steps:

- **Access Patient Information:**
    - Click the menu icon (three dots) on the far right of the top app bar.
    - A bottom sheet will appear with editing options (see Fig.36).
- **Options in Bottom Sheet:**
    - **Create New Patient:** Add a new patient's information.
    - **Edit Existing Patient:** Modify details of an existing patient.
    - **Search and Add Patient:** Find and assign an existing patient to the recording.

- **Edit Patient Information:**
  - When editing, a screen with patient details will open (see Fig.37).
  - Fill in or modify the necessary fields.
  - Press 'Save' to confirm and save your changes.

This feature allows for accurate association of patient data with recordings, ensuring that all relevant information is correctly documented and easily accessible.
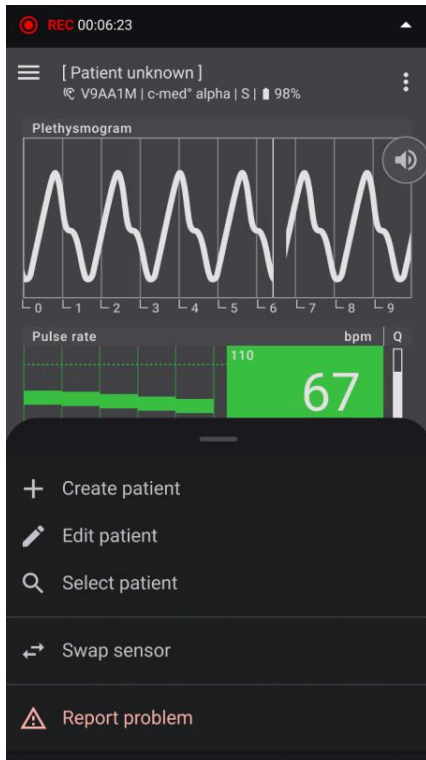
Fig. 36: Patient Information Management:
Shows the options available in the bottom sheet for managing patient information, including creating new patient records, editing existing ones, or searching for specific patients.
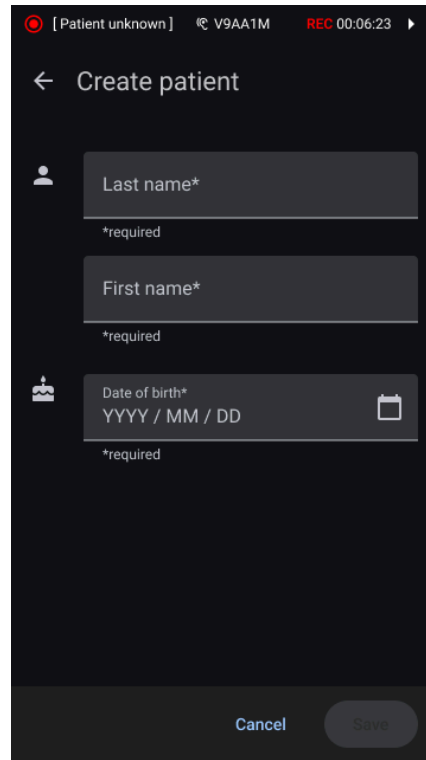
Fig. 37: Input Mask - Patient Information:
Displays the form for entering or updating patient details, including fields for name, date of birth, and other relevant information.

Stopping a Recording

To stop a recording in the cosinuss° Health app, follow these steps:

- **Stop Recording:**
  - Click the 'Stop' button in the bottom app bar.
  - Click on 'Save and Quit' (see Fig.38).
  - A dialog box will appear to confirm if you want to stop and save the recording.

○ Click 'Save' to confirm (see Fig.39).

● **Post-Recording Actions:**
  ○ All recordings are automatically saved when ended.
  ○ You can find all saved recordings navigating to the 'Recordings' section.
  ○ In the 'Recordings' section, you can view or export the recordings.

This ensures that all data is securely saved and easily accessible for future reference or further analysis.
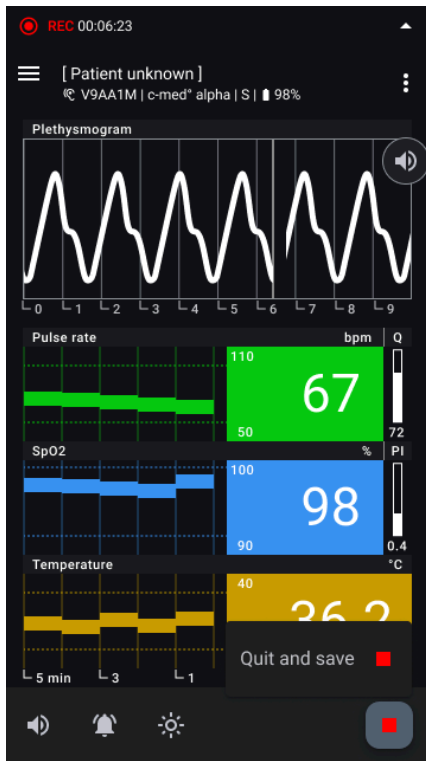
Fig. 38: Stop Recording:
Press the red square icon on the far right of the bottom app bar to stop and save the current recording.
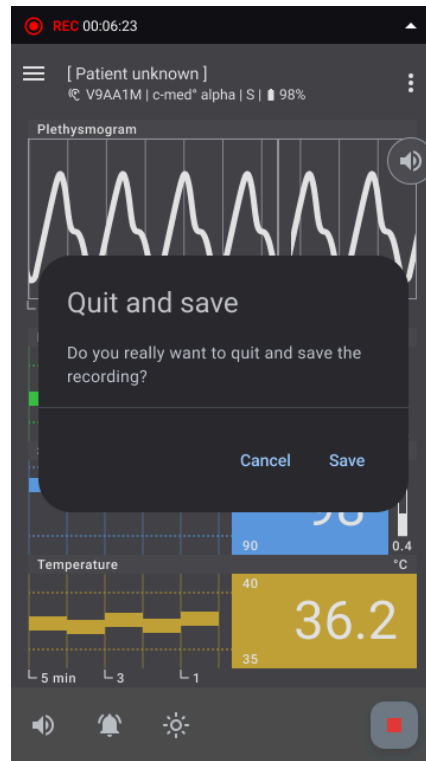
Fig. 39: Stop Recording Confirmation:
Confirm and save the recording by following the on-screen prompts after pressing the Stop button.

ⓘ	If the app is closed during an active recording, the recording will be stopped and saved automatically.

Manage Recordings

List View of all Recordings

All recordings are accessible under the 'Recordings' menu in the navigation bar (see Fig.40). Recordings are displayed in chronological order, with the newest recordings appearing at the top (see Fig.41). Each recording can be uniquely identified by its date, start and end times, and the patient's name (if available). To view detailed information for a recording, simply click on its entry in the list (see Fig.42).
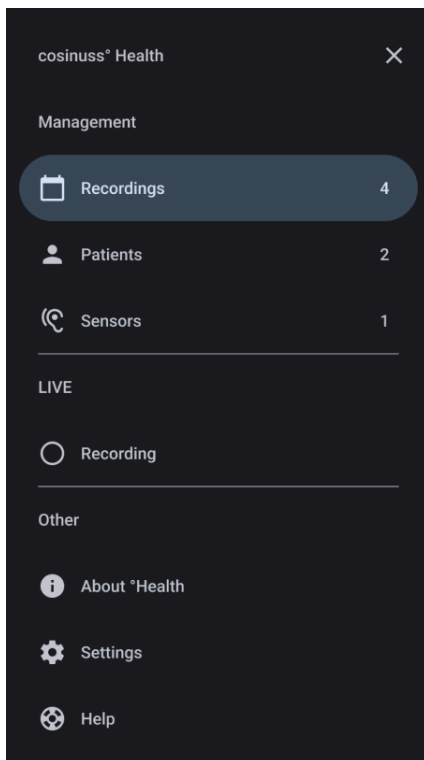
Fig. 40: Manage Recordings - Navigation Drawer:
Navigate to the 'Recordings' section in the navigation drawer to manage your recordings.
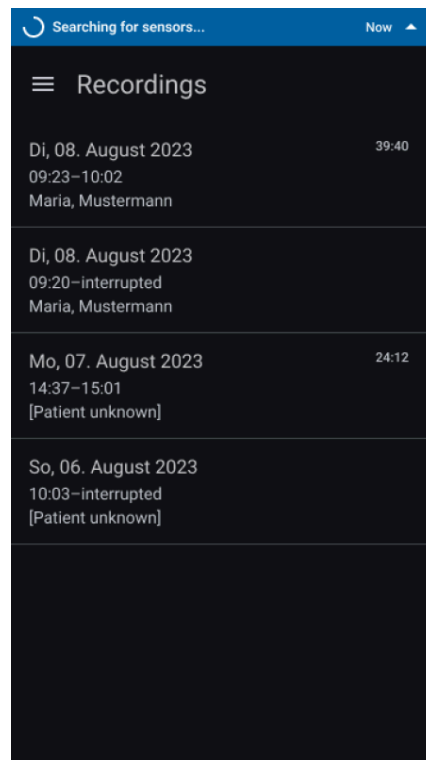
Fig. 41: 'Recordings' Screen:
Displays a list of all recorded sessions, allowing you to review and manage past recordings.

Detail View of a Recording

In the detail view of a recording, you can access all pertinent information, including patient details and the sensors utilized for the recording (see Fig.43). You can perform the following actions:

- **Assign Patient:** Click on the three dot menu in the top app bar to access the patient options.

Language:	English (US)	Document Version:	04	
Release date:	2025-02-03	Software Version:	1.xx.xxx	Page **51** of **67**

- **Export Recording:** Click the export icon in the bottom app bar to access export options. You can choose to export the data in CSV format via email, messenger or other.

(i)	**Sharing Anonymized Patient Data** When sharing patient records, personal data such as names or birthdates are excluded from the export to ensure anonymization.
(i)	**Handling Health Data Responsibly** Please handle health data with responsibility and ensure compliance with applicable privacy and security guidelines.

- **Report Problem:** Click the report problem button in the bottom app bar to report any issues encountered during the recording. This opens an input form where you can describe the problem in detail. You can also attach the CSV file of the affected measurement, as well as relevant screenshots or photos to aid in troubleshooting.
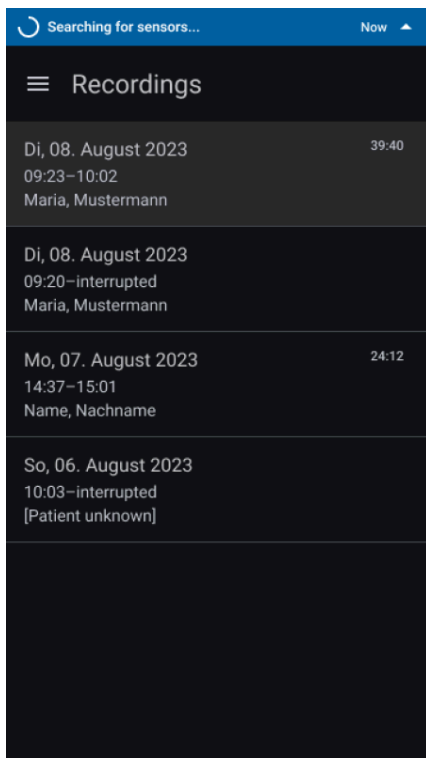
Fig. 42:Select a Past Recording:
Selecting an item from the recordings list brings you to the detailed view, where more options and information about the selected recording are available.
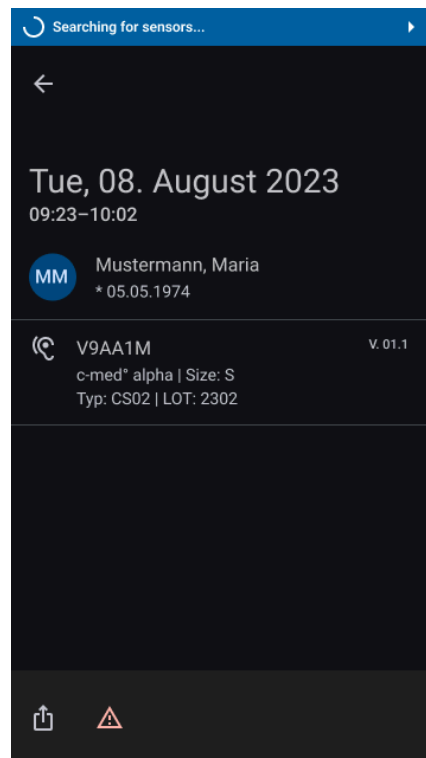
Fig. 43: Detailed Recording Screen:
Provides an in-depth view of a selected recording, including timestamps, metadata and more options in the bottom sheet.

Manage Patients

List of all Patients

In the monitoring app, users can manage all previously created patient profiles by selecting the 'Patients' option from the navigation menu in the sidebar (see Fig.44). This opens a list view displaying all existing patients, sorted alphabetically (see Fig.45). Each patient is uniquely identifiable by their last name, first name, and date of birth. You can perform the following actions:

- **Add New Patient:** Click on the 'Add Patient' icon in the bottom app bar to create a new patient profile.
- **View Patient Details:** Click on a patient entry in the list to access the detailed view of that patient (see Fig.46).
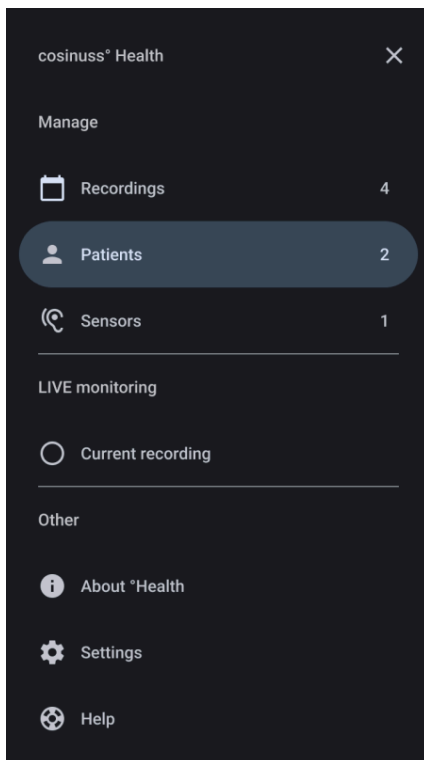
Fig. 44: Manage Patients - Navigation Drawer:
Navigate to the 'Patients' section in the navigation drawer to manage your patients.
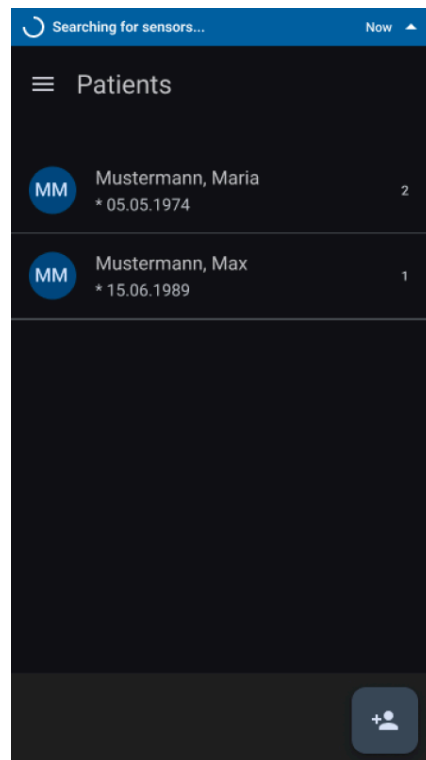
Fig. 45: Patients Screen:
Displays a list of all patients, allowing you to identify and select patients.

Patient Detail View

In the detailed view of the selected patient, you can access patient information including their last name, first name, and date of birth (see Fig.47). Additionally, you'll find an overview of all monitoring sessions associated with the patient, allowing for easy tracking and management of recorded data. You can perform the following actions:

- **Edit Patient Details:** In the patient's detailed view, click on the edit symbol (pencil icon) located next to the patient's name in the top app bar to edit patient information.
- **Review Recording History:** In the detailed view of a patient, all recordings associated with that patient are listed. This provides an overview of all monitoring sessions linked to the patient.
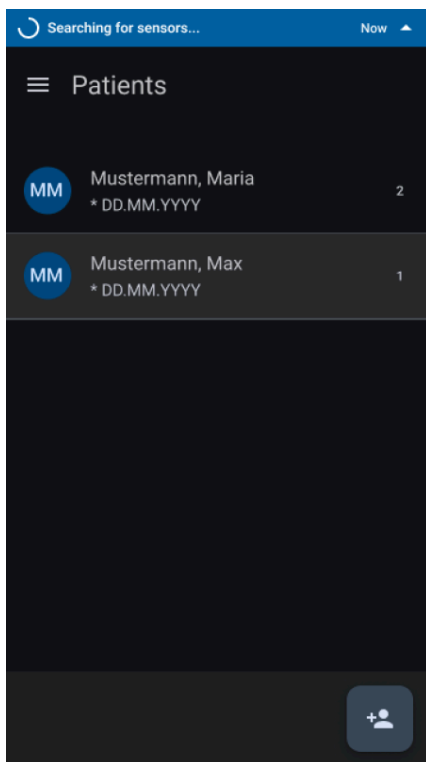
Fig. 46:Select a Patient:
Selecting an item from the patient list brings you to the detailed view, where more options and information about the selected patient are available.
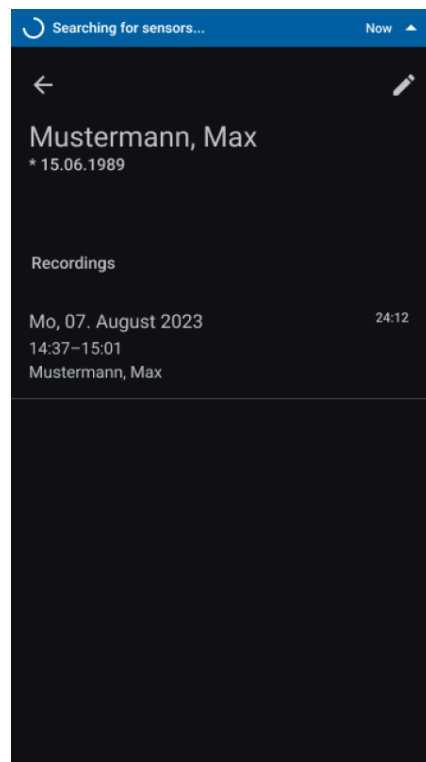
Fig. 47: Detailed Patient Screen:
Provides an in-depth view of a selected patient, including recordings that have already been performed.

Manage Sensor Devices

In the monitoring app, users can manage all previously used sensor devices by selecting the Sensors option from the navigation menu in the sidebar (see Fig.48). In this section, all sensor devices that have been utilized are listed in alphabetical order. Each entry in the list includes the following details(see Fig.49):

- **Serial Number:** Unique identifier for each sensor device.
- **Model Description:** Description of the sensor model.
- **Size:** Physical dimensions or size specification of the sensor.
- **Type:** Type of sensor device.
- **Lot Number:** Lot number associated with the sensor.
- **Firmware Version:** Current firmware version installed on the sensor device.

This information allows you to easily identify and manage sensor devices used within the app.
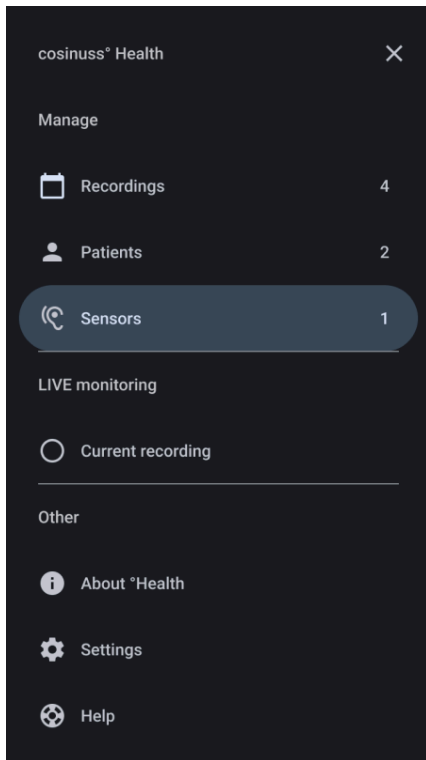
Fig. 48: Manage Sensors - Navigation Drawer:
Navigate to the 'Sensors' section in the navigation drawer to manage your sensors.
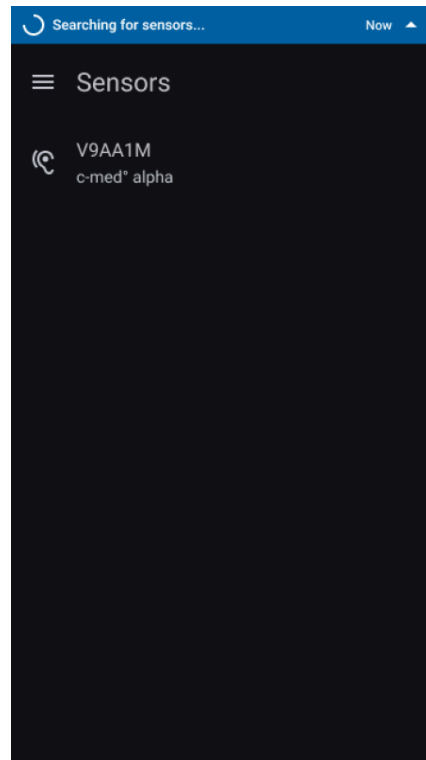
Fig. 49: Sensors Screen:
Displays a list of all sensors that have been recorded allowing you to identify certain sensors.

Other App Sections

About °Health

Explore the 'About °Health' section for comprehensive information about the software, regulatory markings, and contact details for the manufacturer (see Fig.50, 51).
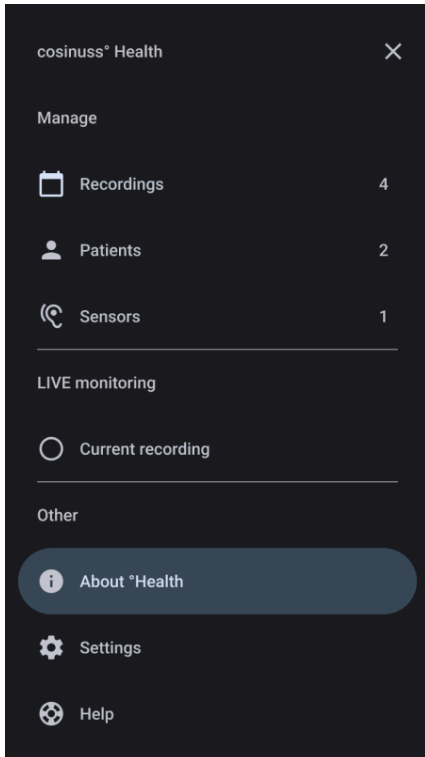
Fig. 50: About °Health:
Navigate to the 'About' section in the navigation drawer to access detailed information about the °Health app.
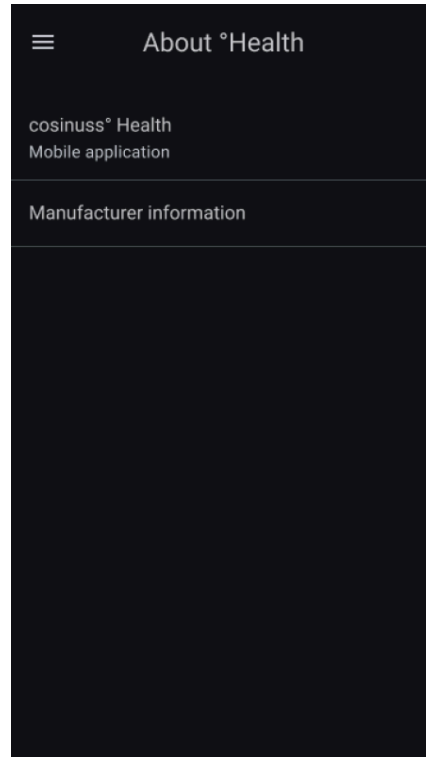
Fig. 51: About Screen - °Health App:
Displays information about the app and manufacturer.

Software Information

Version Information:
View details about the current version of the cosinuss° Health app (see Fig.52).

Unique Device Identification:
Find the unique identification number associated with your instance of cosinuss° Health for tracking and support.

CE Marking and Other Regulatory Symbols:
Learn about the CE marking and other significant regulatory symbols related to the cosinuss° Health app.

Manufacturer Information

Manufacturer Details:

Obtain information about the manufacturer of the cosinuss° Health app, ensuring transparency regarding the software's origin (see Fig.53).

Contact Information:
For any issues, questions, or support needs, please submit a support ticket at: https://support.cosinuss.com/submit-a-ticket/.
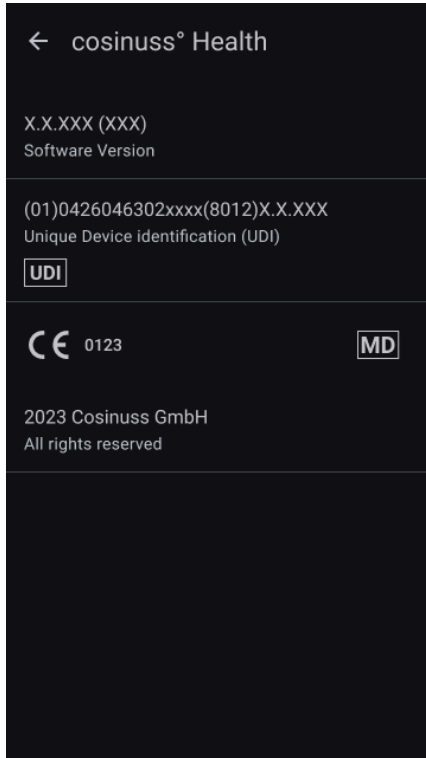
Fig. 52: Software Information - °Health App:
Displays details about the app's version, unique device identification, CE marking, and other important regulatory markings.
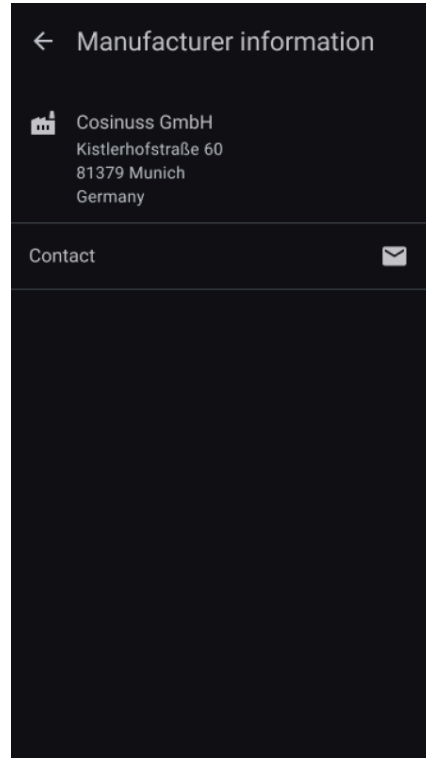
Fig. 53: Manufacturer Information - °Health App:
Provides details about the manufacturer of the °Health app and contact information for support and inquiries.

Settings

Access Rights Overview:
Review and verify the access rights granted to the cosinuss° Health app to ensure optimal functionality and data security.

Language Selection:
Choose your preferred language for a personalized app experience, allowing you to interact with the app in your chosen language.

Measurement Units:

Customize the app to display measurements in units that best suit your preferences, ensuring ease of understanding and use.
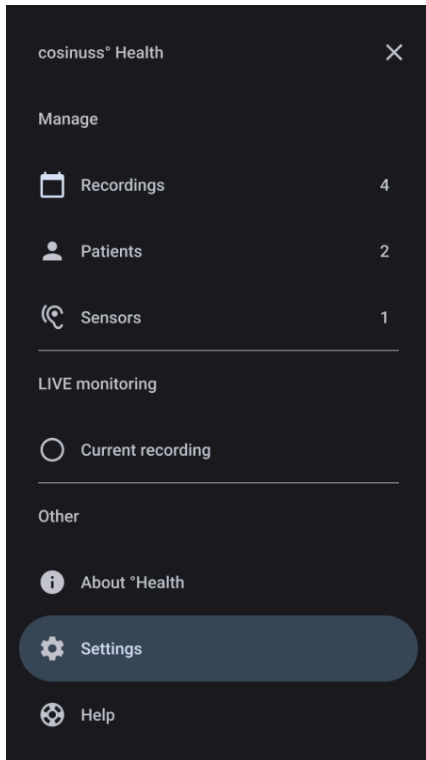
Fig. 54: Settings - Navigation Drawer:
Navigate to the 'Settings' section in the navigation drawer to to review and adjust app settings.
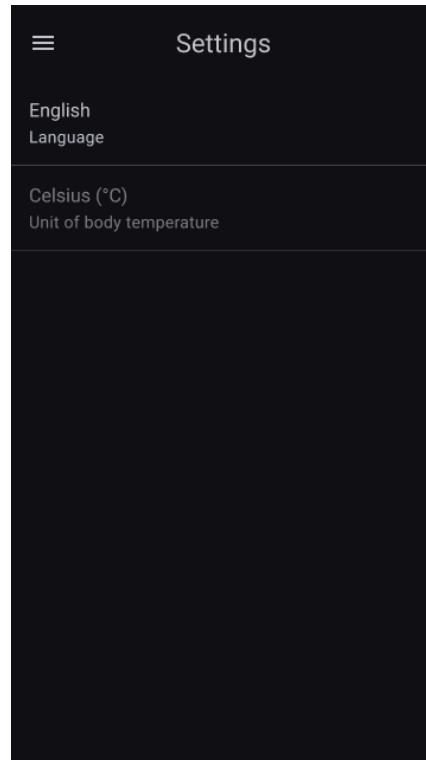
Fig. 55: Settings Screen:
Settings include access rights, language selection, and measurement units.

Help

Electronic Instructions for Use (eIFU):

The button provides access to an electronic version of the IFU available at health.cosinuss.com/eifu. This website contains all information needed to identify and read the right version of the IFU in electronic form and will open in your browser (see Fig.57).

If the digital version of the manual is not sufficient for you and you require a paper version, please contact: eifu@cosinuss.com

Safety Notes:

Review critical information on the correct use of measuring devices and sensors. This section reiterates the essential safety notes provided during the setup process.

Send Feedback:

Submit your suggestions, questions, or criticism by filling out the general feedback form. We welcome your input to help improve our services and address any concerns.
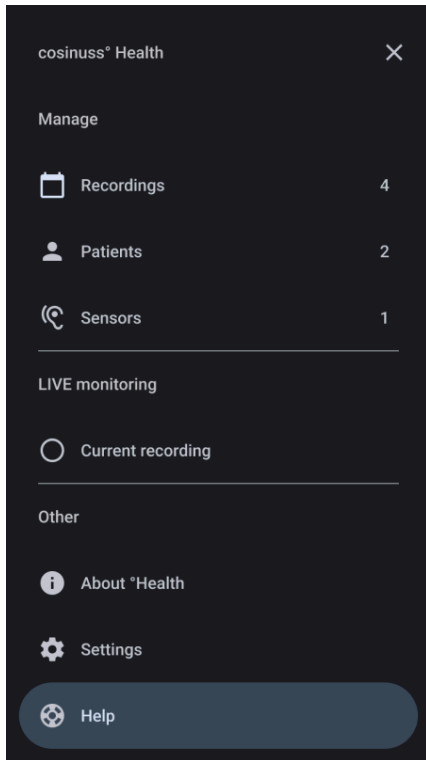
Fig. 56: Help - Navigation Drawer:
Navigate to the 'Help' section in the navigation drawer to access user manuals, training materials, safety notes, and feedback options.
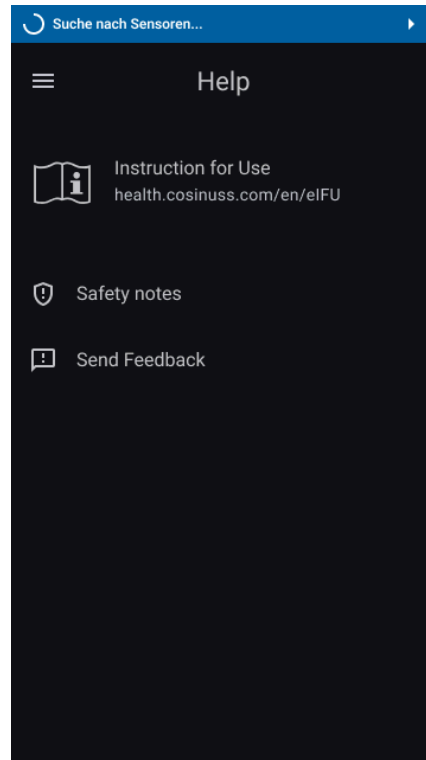
Fig. 57: Help Screen:
Here you can access official user manual and detailed information about the app, as well as provide feedback and review safety notes.

Requirements and Recommendations

Category	Requirements	
	iOS devices	**Android devices**
Operating Systems	- iOS 15.0 or later	- Android 10 or later

Supported Devices	While the software should function on any device running iOS 15 or later, full support and testing are focused on the latest devices. If you encounter any issues, please contact our support team for assistance: support@cosinuss.com	While the software should work on devices running Android 10 or later, full support and testing are focused on the latest devices. If you encounter any issues, please contact our support team for assistance: support@cosinuss.com
Screen Sizes	The software is optimized for a range of screen sizes. For the best experience, we recommend using devices with screen sizes of 5.5 inches or larger.	
Hardware Requirements	The software requires a modern multi-core processor. Performance may vary based on the specific hardware configuration. Minimum of 2 GB of RAM is required for smooth operation. More RAM may be needed for optimal performance.	
Bluetooth Requirements	While the software is compatible with devices meeting Bluetooth 4.2 or later, optimal performance is achieved with devices using newer Bluetooth versions and standards. Ensure that Bluetooth is enabled on your device. For specific Bluetooth compatibility questions, please contact our support team: support@cosinuss.com	
Storage	Ensure at least 150 MB of free storage space for installation and operation. Additional space may be required for updates and data.	

Compliance Declaration

cosinuss° Health is a Class IIa Medical Device.
A declaration of conformity is available on request: support@cosinuss.com

Instructions for Disposal

If Hardware has been supplied as part of the installation, please refer to the User manual of the relevant device or contact Cosinuss GmbH for disposal. The app can be uninstalled according to the settings on your mobile device.

Maintenance

The cosinuss° Health app is designed to operate seamlessly without requiring any specific maintenance activities from users. All necessary updates, including feature enhancements, security patches, and performance improvements, are managed centrally by Cosinuss GmbH. These updates are delivered through regular software releases, ensuring that the app remains current with the latest advancements and standards. Users will receive notifications about available updates, which can be installed directly from the app store.

Troubleshooting

Problem	Possible cause	Action/Solution
No data or device is appearing on cosinuss° Health app interface.	The devices are not compatible.	See chapter 'Components' for compatible devices
	Patient out of range.	Ensure the patient is within 10 m of your receiving device. Sensor device should appear as 'connected' on the °Health display.
	Bluetooth wireless failure.	Check system status of the sensor and the cosinuss° Health app on the °Health display. Check if the sensor is indicating to be functioning correctly, and is within 10 m of BLE range.

		Reset sensor device and app if necessary by following the instruction manuals.
Data not updating	No data from the sensors getting through to cosinuss° Health .	Restart the app and connect the sensors in accordance with the Instructions for Use.
	Poor wireless connection between sensor and receiving device.	Refer to Bluetooth wireless failure. Ensure the sensor is as near as possible to the receiving device.
	Interference blocking or intermittently out of range.	Refer to Bluetooth wireless failure. Ensure the sensor is positioned to obtain as near as possible line-of-sight transmission path from the sensor to the receiving device.
Suspect data appearing on cosinuss° Health app.	Failure of the sensor to collect and analyze signals effectively.	Take care of correct preparation, positioning and sizing of sensor devices. Reposition sensor or replace with new sensor if necessary.
	High levels of noise in signal due to motion artifacts.	Depending on the measurement site, keep still.
	High levels of noise in signal due to dirty sensor devices.	Clean the sensor device accordingly.
	Sensor device out of range.	Move the mobile device closer to the sensor.
Issues with optional devices.	Battery too low.	Swap and/or charge device.
	Device not compatible.	See chapter '<u>Components</u>' for compatible devices.
	Device not registered.	
	Failure of the device.	Depending on the compatible device, functionality may be restricted. Always contact the manufacturer in case of a

	device malfunction.

# Symbols

Symbols in User Manual

⚠	WARNING: Warnings resulting in injury or death.
❗	CAUTION: Caution damaging equipment or other property.
ⓘ	NOTES: Notes to inform or emphasize a point or procedure.

Symbols in User Interface

🌐	LANGUAGE:	⤓	LOWER LIMIT
📱	MOBILE DEVICE	🛡	SAFETY NOTES
🛡	POLICY	✕	CLOSE
📈	THRESHOLDS	☰	NAVIGATION DRAWER
♡	PULSE RATE	📅	RECORDINGS
💧	SPO2	👤	PATIENTS
🌡	BODY TEMPERATURE	👂	SENSORS
❋	BLUETOOTH	ⓘ	ABOUT

⬆	UPPER LIMIT	⚙	SETTINGS
⊕	HELP	■	STOP RECORDING
⋮	MORE MENU	⊖	SENSOR SEARCH DISABLED
◢	SIGNAL STRENGTH	◉	RECORDING ACTIVE
@	SENSOR SEARCH	○	RECORDING INACTIVE
(C	SENSOR (IN-EAR) enabled	🔋	BATTERY LOW
⊠	SENSOR (IN-EAR) disabled	⚠	ERROR
🔊	AUDIO ON	👎	POOR QUALITY
🔇	AUDIO OFF	⧗	TIMED OUT
◀	AUDIO PAUSED	👤	PATIENT
🔔	NOTIFICATIONS ON	🎂	DATE OF BIRTH
🔕	NOTIFICATIONS OFF	+	ADD / CREATE
🔔z	NOTIFICATIONS PAUSED	✏	EDIT
☀	LIGHT THEME	🔍	SEARCH
☾	DARK THEME	⇄	SWAP

	CSV FORMAT		REPORT PROBLEM
	EMAIL		EXPORT
	MORE INFORMATION		SEND / SUBMIT
			FEEDBACK

Symbols in Product Labeling

	MANUFACTURER
	CE CERTIFICATE
SpO$_2$	NO SPO2 ALARM

Training

This user manual is the primary reference document supporting any additional training materials supplied by the Cosinuss GmbH.

Further to these documents there is a training program, which can be requested at support@cosinuss.com.

Electronic training material is available at: training.cosinuss.com.

Training documents	
Training cosinuss° Health and c-med° alpha	COS_Health_Training_EN_1706272983
Training Video	COS_Health_TrainingVideo_1693213789

User Manuals of Compatible Devices

Detailed, sensor specific information can be found within the user manuals accompanying every compatible sensor device.

Compatible sensor device	User manual
c-med° alpha from cosinuss°	CMED_User Manual_EN_1604046957

These documents will be provided as part of your initial setup, additional copies are available on request.

- End of document -