

User Manual

corpuls auryx App

Mobile Application



!! Please read and understand the Instruction for Use before using the App / device.

For access to electronic instruction for use
please access the following URL: <https://eifu.cosinuss.com>

DOC-ID: 1701095121

Manufacturer information

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GERMANY

Other certificates

CE 0123

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Components

(sold individually or combined)

corpuls auryx App	
corpuls auryx App Former tradename: cosinuss° Health	Mobile application, data entry & local display point

Compatible sensor devices*			
Device name	Description	Firmware	Basic UDI-DI
corpuls auryx	Continuous vital signs sensor	2.4.1 or higher	426046302AURYX6S
c-med° alpha	Continuous vital signs sensor	2.4.1 or higher	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 device is intended to visualize and store vital signs data measured by compatible sensors. The device optionally transfers the data to a third party systems for further processing.

The measured data is transmitted wirelessly, stored, and displayed in the mobile application. Moreover, corresponding patient information can be entered and managed via the application. The device includes notifications and alarm functions, such as alarms based on configurable physiological thresholds for vital signs.

The intended user is any health professional and any adult person without neurodevelopmental or neurocognitive disorders. The user can follow the patient's vital parameters and has access to real-time values, alarms, event logs, and vital signs data history via a graphical trend plot. Depending on the connected compatible device, the system can also display the measured vital signs waveforms, which can be beneficial for the user and assist with data interpretation. All data can be exported and transmitted for further

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analysis, including the transmission of data to server-based systems or telemetry software used for remote monitoring or telemedicine applications

The product is intended for use in a wide range of environments, e.g. home settings, clinical care environments, transport, and emergency settings. It is suitable for use under varying lighting, noise, and stress levels.

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

These are specified exclusively in the intended use of the connected medical device.

A concrete medical indication in terms of specific diseases is not intended. Based on the vital parameter measurement, it is intended to allow and simplify the monitoring of different physical reactions, e.g.: Hypothermia, Hyperthermia (fever), Changes in circulatory system, Tachycardia and Bradycardia. The medical use of the 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 device shall not recommend any concrete treatments.

Contraindications

Contraindications: These are specified exclusively in the intended use of the connected medical device*.

The device shall not recommend any concrete treatments and shall not be used (**Warnings**):

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- in combination with any device that does not comply with the API specification by the manufacturer
- for monitoring during MRI scan
- for a heart attack detection via PPG
- for arrhythmia detection via PPG

**For safety warnings and contraindications related to compatible 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 corpuls auryx App 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 corpuls auryx App is not intended to: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Using the application to detect specific physiological states not intended by the manufacturer. • Allowing non-intended operators to download and use the application. • 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.*

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Caution Statements*

	Attended Monitoring required: The app must be checked to monitor values and alarms accurately. The alarm system is intended for attended monitoring. Unattended monitoring is not in the scope of the intended use of the medical device.
	Foreground operation: The app is designed to stay in the foreground and is not intended for use in 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.
	<p>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.</p> <p>To ensure the security of corpuls auryx App, only install applications from trusted sources and strictly limit the number of apps on your mobile device to avoid malware risks.</p>
	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 a 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.

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Do not set alarm limits to extreme values, as this may render the alarm system ineffective and prevent timely detection of clinically relevant conditions.

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

Performance characteristics

Clinical benefits

The corpuls auryx App supports patient management by wirelessly displaying and storing continuously measured vital signs from compatible sensors with real time and trended views, enabling timely recognition of relevant changes and optional notification based on predefined criteria.

Performance characteristics

Clinical Label claim

Performance outcomes associated with the clinical usage of corpuls auryx and corpuls auryx App:

Body Temperature:

- Measurement range: 22.0–43.0°C
- Resolution: 0.1°C

Pulse Rate:

- Measurement range: 40–220 bpm
- Resolution: 1 bpm

Functional Oxygen Saturation (SpO₂):

- Measurement range: 0–100%
- Resolution: 1 %

The corpuls auryx App provides live notifications for changes in temperature, pulse and SpO₂, and enables a structured approach to alarm management based on established standards. It is designed for use in emergency and acute care environments.

Lay User Guidance When to Consult a Healthcare Professional

Users should consult a healthcare professional in the following situations:

- if measured values are outside normal ranges,

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

Using the System

Installation

The corpuls auryx 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 'corpuls auryx App' in the search field.
- Press the search button.

3. Select the app:

- Select the corpuls auryx 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 corpuls auryx 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)

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6. Open the app:

- Once the installation is complete, locate the corpuls auryx 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 corpuls auryx 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. 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. Depending on your operating system, different rights may be required.

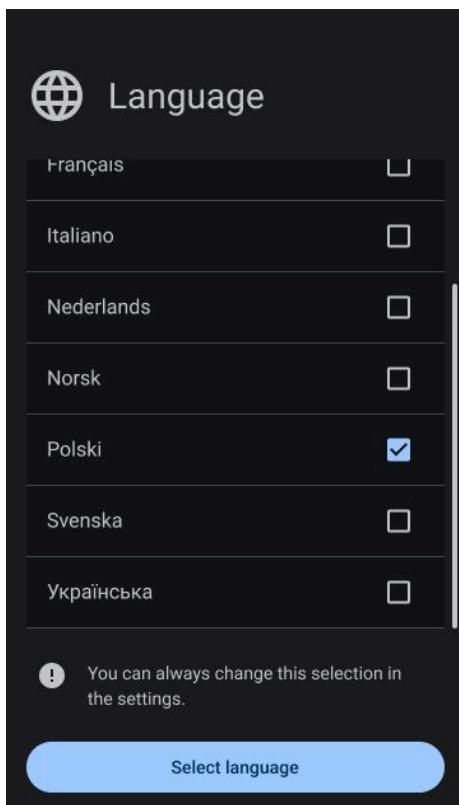
- Bluetooth: Required to receive data from a sensor.
- Location: Required to operate a Bluetooth interface.

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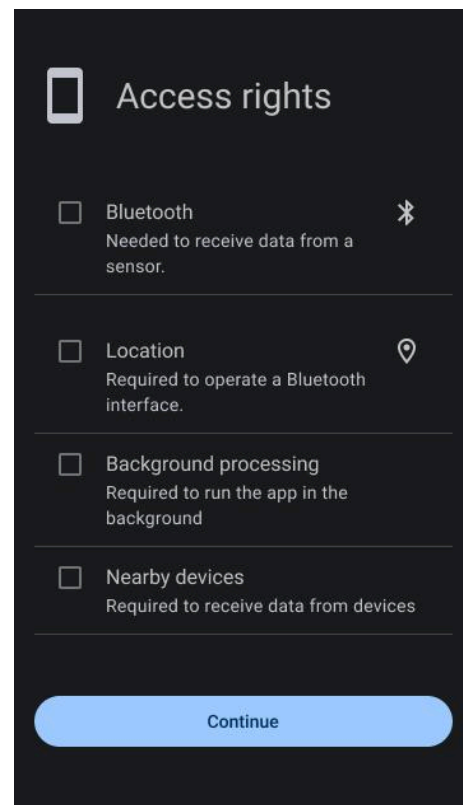
- Background permission: Required to run the app in the background.
- Nearby devices: Required to receive data from devices.

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

	<p>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.</p>
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Onboarding Screen - Select Language: Choose the preferred language for the application from the available options.



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.

1. Read through the linked data privacy policy carefully.:

<https://support.cosinuss.com/health-app/privacy/>.

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2. After reading the privacy policy go back to the corpuls auryx 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. 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.

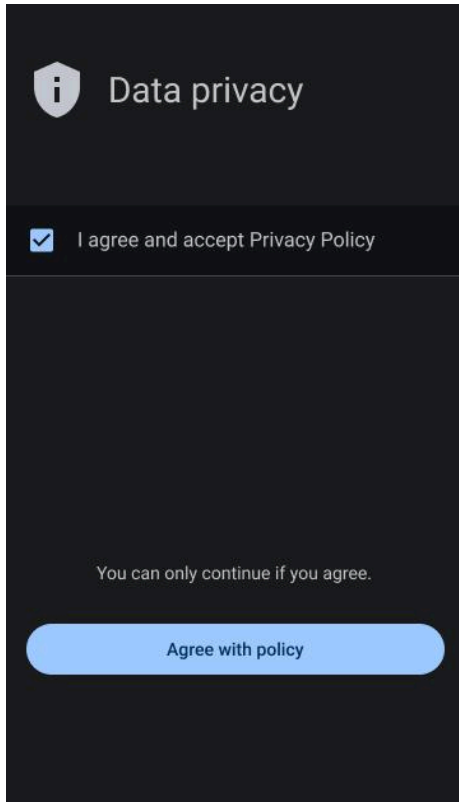
Preset threshold values

Pulse rate (green)	SpO2 (blue)	Body temperature (orange)
<ul style="list-style-type: none"> • Upper limit: 110 bpm • Lower limit: 50 bpm 	<ul style="list-style-type: none"> • Upper limit: 100 % • Lower limit: 90 % 	<ul style="list-style-type: none"> • Upper limit: 40 °C • Lower limit: 35 °C

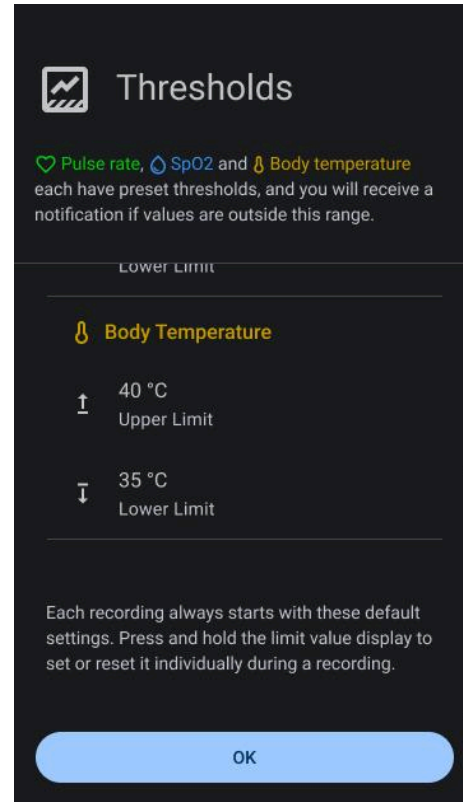
You can set user-defined limits during a measurement by pressing and holding the limit value display.

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

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



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

Safety Notes

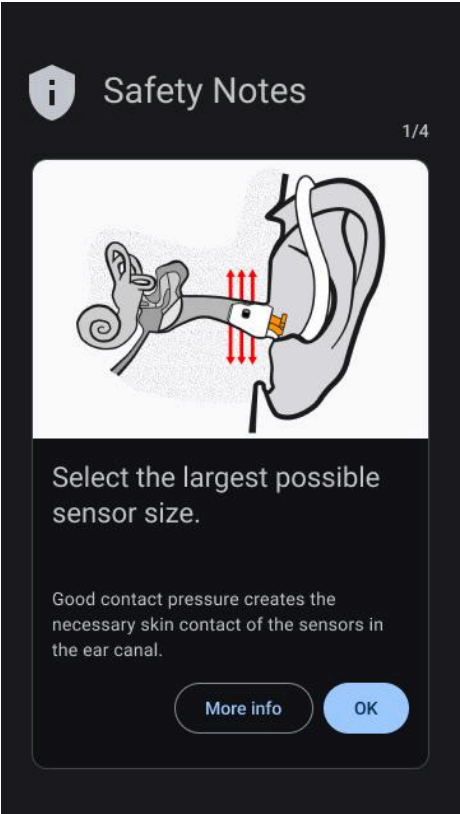
In the onboarding process, we provide important information on the correct handling of the sensor used. This step is crucial to ensure that the sensors work accurately and reliably.

If you use the corpuls auryx vital signs device, please note the following instructions:

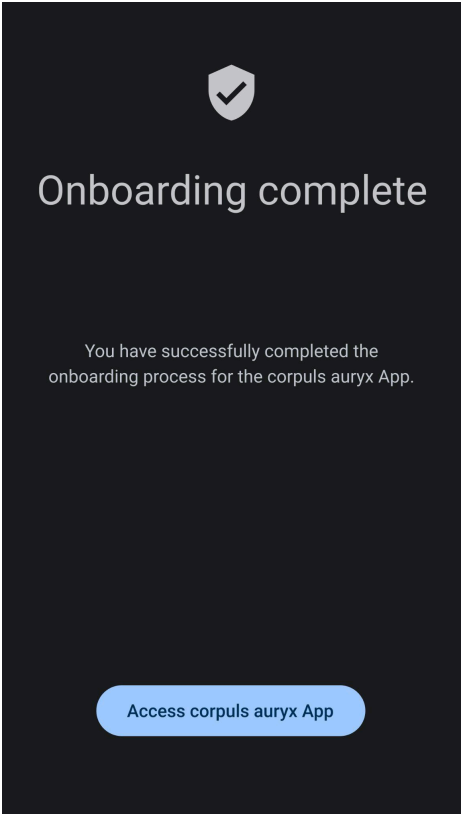
- Select the largest possible sensor size.
- Push the sensor head deep into the ear canal.
- The patient should not speak or chew during the measurement.
- The displayed temperature value is the value directly measured in the ear canal.

If you have read and understood the instructions, you have successfully completed the setup process and can start using the corpuls auryx App.

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Onboarding Screen - Safety Notes: Acknowledge safety instructions relevant to your device for proper usage.



Onboarding Screen - Completion: Marking the completion of the onboarding process, allowing users to begin using the app.

Audio signal verification

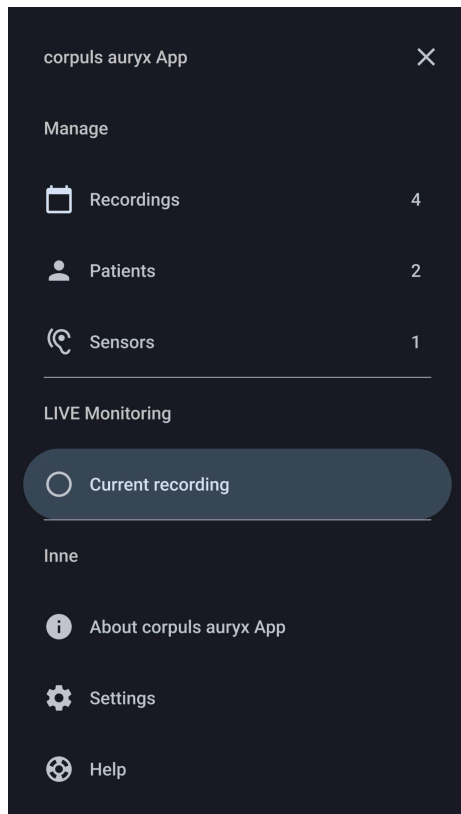
Upon first use, the app will guide the operator through an audio signal verification procedure. The operator must play each alarm signal (high and medium). The operator is prompted to confirm that the sounds are clearly audible.

User Interface Overview

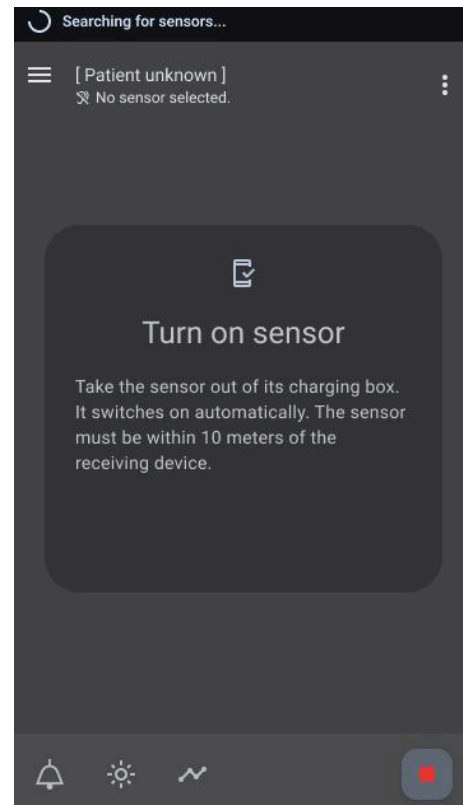
Navigation Drawer

The navigation drawer in the corpuls auryx App allows users to easily access different sections of the app. Here’s a detailed description of each item in the navigation:

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**Navigation Drawer:**

Access various sections of the app through the main navigation drawer.

**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)

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The 'Current recording' section of the corpuls auryx App displays the live monitor of the ongoing recording.

- **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)

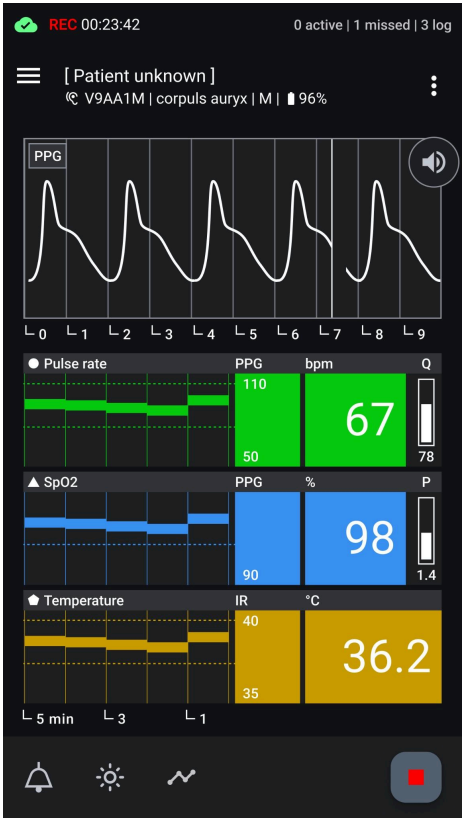
- **Function:** Review and customize app settings.
- **Usage:** Personalize the app according to individual preferences and requirements.

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.

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Main Recording Screen



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, display modes,trend interval and stop recording button).

- 1. **Status Bar:**
 - Located at the top of the screen.
 - Displays alarm banner, recording status, data transmission 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.
 - **Display Modes:** Toggle between light and dark modes for screen visibility.
 - **Timeline Trend Graph:** Opens a menu where you can set the display intervals of the timeline to 1, 5, or 10 minutes. This allows you to view measurements further in the past or examine values averaged over longer periods.
 - **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 corpuls auryx 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.

Searching... X sensor(s) available



Icon: Progress indicator.

Text: Searching... X sensor(s) available, Recording duration.

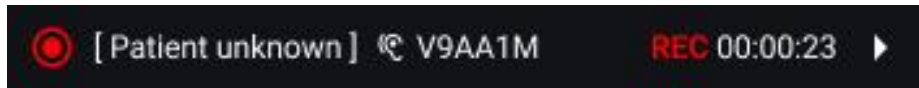
Color: Background.

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.

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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.

Data Transmission Status:

If data transmission to a server has been configured, the connection status is displayed during an ongoing measurement instead of the "Recording Active" icon.

Connection Active: Green cloud with check mark



Connection Unstable: Yellow cloud



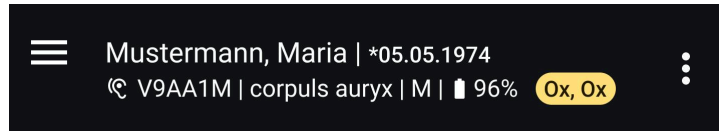
No Connection: Red crossed-out cloud



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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:

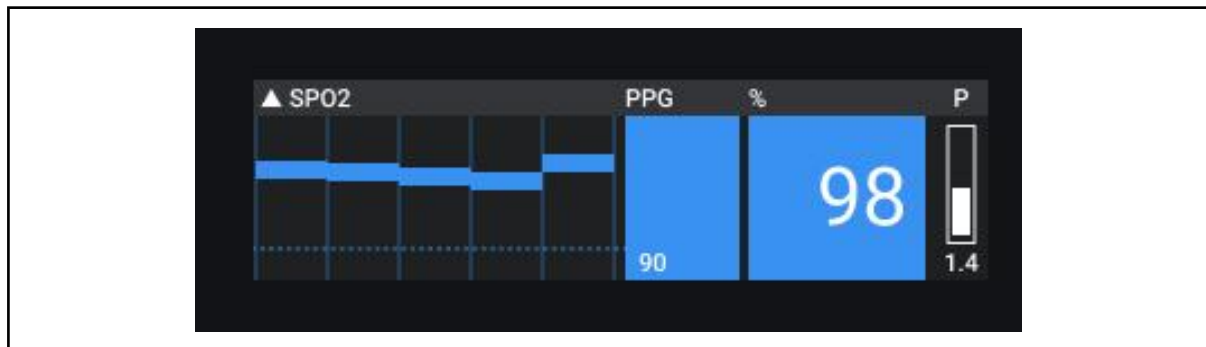
- **Turn On Audio Output:** Activates the audio output for alarms, represented by the bell icon.

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- **Turn Off Audio Output:** Deactivates the audio output for alarms, represented by the bell cancel icon.
- **Pause Audio Output for 2 Minutes:** Temporarily pauses the audio output for alarms for 2 minutes, represented by the bell cancel temporary icon.
- 2. **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.
- 3. **Timeline Trend Graph:**
 - Opens a menu where you can set the display intervals of the timeline to 1, 5, or 10 minutes. This allows you to view measurements further in the past or examine values averaged over longer periods.
- 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.

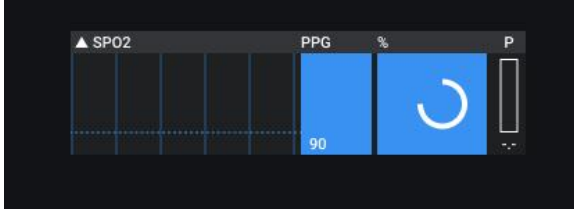
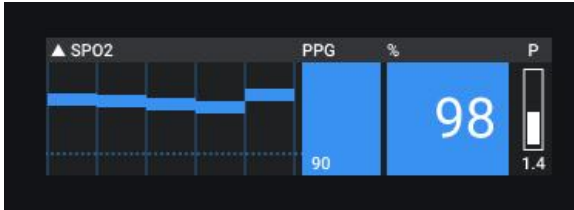
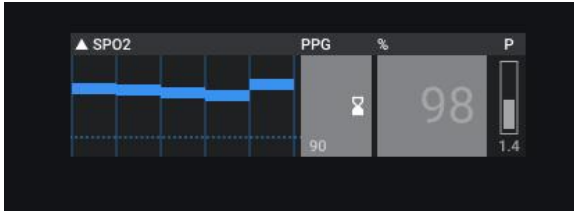
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- **Current Value:**
 - **Numerical Display:** The current measurement value transmitted by the sensor.
- **Perfusion / Quality Index:**
 - **Visual Representation:** Displayed as a bar with the current value.

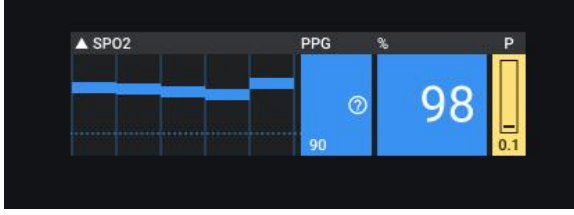
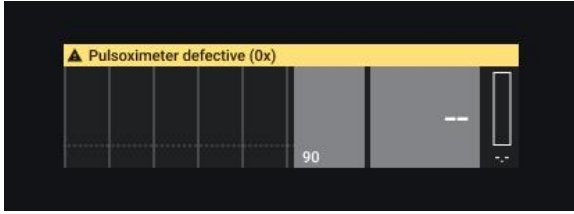
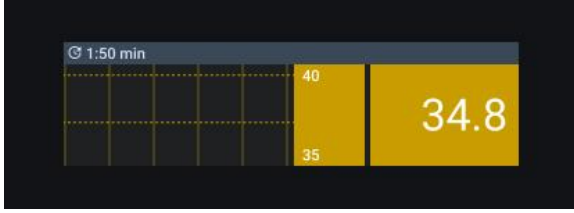
Additional Information:

- **Status Changes and Notifications:**
 - The item will also display any status changes and notification colors to alert the user of important updates.

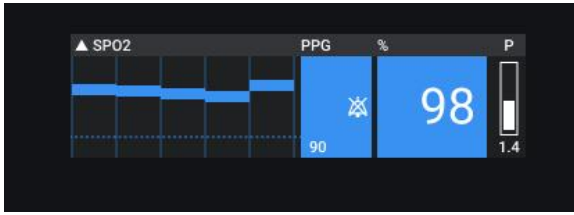
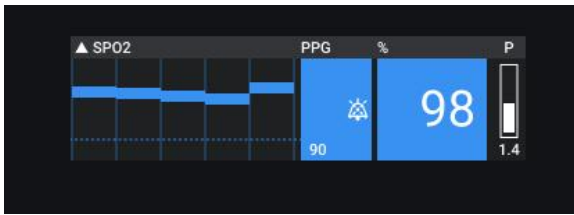
States of the Vital Sign Item:

<p>Initializing (Empty):</p> <ul style="list-style-type: none"> • Meaning: In the current data, there are no displayable values. • Display: Default layout with a processing indicator. 	
<p>Enabled:</p> <ul style="list-style-type: none"> • Meaning: Values are incoming and displayed. • Display: Normal display of all components. 	
<p>Timed Out (Waiting):</p> <ul style="list-style-type: none"> • 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. 	

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<p>Sensor Out of Range:</p> <ul style="list-style-type: none"> • Meaning: No values incoming from the current sensor. • Display: After 30 seconds, the last values disappear. 	
<p>Quality Poor:</p> <ul style="list-style-type: none"> • Meaning: Quality index has passed its thresholds. • Display: Quality index area blinks yellow, and a 'Poor measurement quality' notification is triggered. 	
<p>Vital Signs Threshold:</p> <ul style="list-style-type: none"> • Meaning: Current value has exceeded its thresholds. • Display: Current value area blinks red, and the corresponding notification is triggered. 	
<p>Device Error:</p> <ul style="list-style-type: none"> • Meaning: Parameter is affected by a device error. • Display: Title area appears red and displays the defect and error code. 	
<p>Warm-Up Phase (only applicable for Temperature):</p> <ul style="list-style-type: none"> • Meaning: The thermometer unit in a sensor is using direct measurement, awaiting stable temperature reading. • Display: No alarms 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. 	

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<p>Audio Off:</p> <ul style="list-style-type: none"> • Meaning: User has turned off the acoustic output. • Display: The bell cancel symbol appears in the current value area. 	
<p>Audio Paused:</p> <ul style="list-style-type: none"> • Meaning: User has paused the acoustic output. • Display: The bell cancel temporary symbol appears in the current value area. 	

Alarm system

Characteristic of the Alarm System

The app incorporates an alarm system designed to monitor physiological and technical conditions and provide notifications to the operator.

This system is not a distributed alarm system, as all alarm processing, threshold evaluation, and signaling occur locally within the app on each device.

The alarm system is designed for use on a mobile device that is carried by the operator or kept within a maximum distance of 1 meter. Alarm signal perception (audio and visual) is dependent on this operating condition.

The alarm system performs three main functions:

1. Source — collects data directly from the connected sensor(s), which serves as the input for alarm evaluation.
2. Integrator — evaluates the sensor data against the configured alarm thresholds and determines the priority and type of alarm (e.g., high, medium, low).
3. Communicator — signals the alarm to the operator using audio and visual modalities, including indefinite silencing, temporary pausing, acknowledgment of active alarms,

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confirmation of missed alarms and complete logging of alarm events, state changes and user actions.



Operator Position Requirement

The application is intended to be carried on the operator's body or kept within a maximum distance of 1 meter. Safe and effective use of the alarm system requires that the operator is able to perceive visual and audible alarm signals at all times. If the device is placed further away, alarm signals may not be perceived in time.

Alarm conditions

Alarms are classified according to their priority and urgency:

- High-priority alarms – indicate critical conditions that require immediate operator attention. These alarms are latched, meaning the audio and visual signals continue until the operator acknowledges them.
 - If a high-priority alarm is not acknowledged, it is added to the Missed Alarms list, where the operator must confirm it. This ensures that hazardous situations are always reviewed and documented.
- Medium-priority alarms – indicating that prompt operator action is required (re-planning of current workflow is expected)
- Low-priority alarms – indicate operator awareness is required/ future action might be needed

Each alarm type may relate to:

- Physiological conditions — measurements from the sensor that indicate patient-related events (e.g., pulse rate, oxygen saturation).
- Technical conditions — issues related to the device or sensor (e.g., no signal from sensor, measurement errors).

Prioritization of alarm signals

The prioritisation of alarm conditions is defined hierarchically. The hierarchy of alarm signals are defined within each alarm group and do not change. Multiple conditions can exist simultaneously.

Priority	Type	Condition
High	Physiological alarm conditions	<ul style="list-style-type: none"> - SpO2 low - pulse rate high - pulse rate low

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		<ul style="list-style-type: none"> - heart rate high - heart rate low - temperature high - temperature low
Medium	Technical alarm conditions	<ul style="list-style-type: none"> - Bluetooth deactivated - No signal - In-ear sensor - Poor perfusion - Poor quality - SpO2 missing - Pulse rate missing - Low battery - In-ear sensor - Low battery - ECG - Low battery - mobile device - Device error PPG (multiple error codes) - Device error thermometer (multiple error codes) - Device error other (multiple error codes)
Low	System state / Informational signals	<ul style="list-style-type: none"> - Warm-up phase Thermometer - System volume is below 50%

Alarm Priority Logic

High-Priority Alarm Logic

High-priority alarms indicate conditions requiring immediate operator attention.

High-priority alarms generate both audio and visual alarm signals. These alarms are latched and must be acknowledged by the operator.

- The visual alarm indication remains active for as long as the alarm condition persists.
- The audio signal continues until the alarm is acknowledged, unless temporarily silenced in accordance with the alarm pause function.
- Once the alarm condition resolves, the event is transferred to the alarm history log.
- If a high-priority alarm is not acknowledged before the condition resolves, it is additionally listed in the “Missed Alarms” section and requires operator confirmation.
- This behavior ensures that critical alarm conditions are always reviewed and documented.

Medium-Priority Alarm Logic

Medium-priority alarms indicate conditions requiring operator awareness but not immediate emergency response.

Medium-priority alarms generate both audio and visual alarm signals.

- The operator may acknowledge the alarm to silence the audio signal while the condition remains active.

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- The visual alarm indication remains active for as long as the alarm condition persists.
- When the parameter returns within the defined limits, the alarm condition automatically resolves.
- Resolved medium-priority alarms are transferred to the alarm history log.
- Medium-priority alarms are not listed in the “Missed Alarms” section, regardless of acknowledgment status.
- This design supports operator awareness while reducing unnecessary alarm burden.

Low-Priority Alarm Logic

Low-priority alarms indicate informational or advisory conditions.

Low-priority alarms generate visual alarm signals only.

- No audio signal is generated.
- Operator acknowledgment is not required.
- When the parameter returns within the defined limits, the alarm condition automatically resolves.
- Resolved low-priority alarms are transferred to the alarm history log.
- Low-priority alarms do not appear in the “Missed Alarms” section.

Signal modalities

Alarms are signaled to the operator using:

- Audio signals – indicate active alarms; the volume depends on the device’s settings. The operator may:
 - Pause audio alarms temporarily (2 minutes), or
 - Silence audio alarms indefinitely.

These functions apply globally to all active and subsequent alarms and informational signals. It is not possible to pause or silence individual alarm conditions separately.

- Visual signals – remain visible for the duration of the alarm condition and indicate alarm type, priority and state. Visual alarms cannot be silenced and remain displayed while the alarm condition exists.

Operators can acknowledge active alarms, the audio signal is then silenced for ongoing conditions. Missed alarms appear in the Missed Alarms list, where they must be confirmed by the operator to ensure all critical events are reviewed.

Audio Alarm Signal Characteristics

The alarm system uses distinct acoustic patterns to differentiate alarm priorities.

High-Priority Audio Alarm Signal

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- Pattern: Burst of 10 pulses
- Repetition: Repeats at defined intervals while the alarm condition persists
- Behavior: Continues until the alarm is acknowledged or the condition resolves
- Intended meaning: Immediate operator action required

Medium-Priority Audio Alarm Signal

- Pattern: Burst of 3 pulses
- Repetition: Repeats while the alarm condition persists
- Behavior: Continues until the alarm is acknowledged or the condition resolves
- Intended meaning: Prompt operator attention required

Low-Priority Audio Alarm Signal

- Pattern: No tone
- Repetition: No repetition
- Intended meaning: Informational or minor deviation

Alarm volume



Alarm Volume

If the alarm volume is set below the ambient noise level, alarm conditions — including high priority alarms — may not be recognized.



System Volume

If the device volume is below 50%, high-priority alarms may not be audible. In this case, the app will trigger a low-priority alarm to notify the operator.



Alarm signals may not be perceived if:

- the mobile device volume is muted or set too low,
- external audio devices (e.g., headphones or speakers) are connected,
- the device speaker is defective,
- the user is in a noisy environment

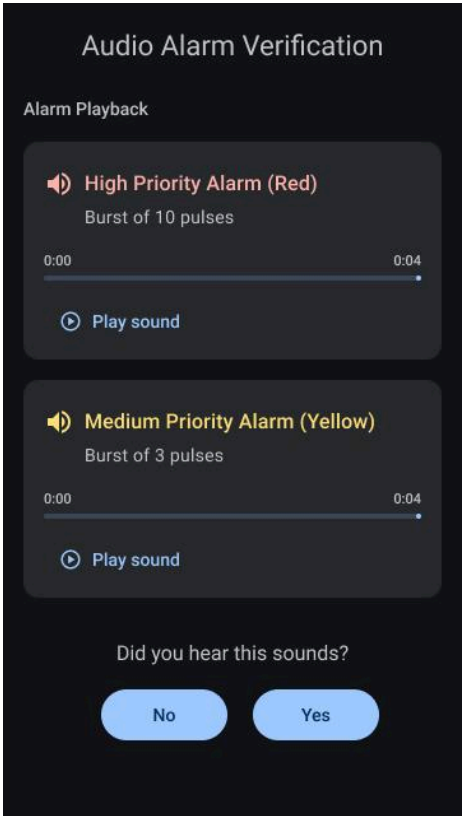
Ensure the alarm volume is set sufficiently above the surrounding noise level before use. Failure to perceive audio alarms may reduce the effectiveness of alarm signal recognition. In this case, visual signals remain active.

Audio Signal Verification (Onboarding)

Upon first use, the app will guide the operator through an audio signal verification procedure. The operator must play each alarm signal (high and medium). The operator is prompted to confirm that the sounds are clearly audible.

This procedure ensures that the operator can perceive audio alarms according to the intended environment of use.

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Audio Alarm Verification Screen - Onboarding:
Layout of the Audio Alarm Verification screen, presented once during the onboarding process. This screen allows playback of the high- and medium-priority alarm sounds, enabling the operator to verify that the mobile device correctly reproduces the acoustic signals and that the alarm tones are clearly audible under the intended conditions of use.

Visual Alarm Signal Characteristics

Alarm banner

Visual alarm signals are displayed in the alarm banner at the top of the main monitoring screen. The banner shows the alarm with the highest active priority and includes:

- An alarm icon
- The alarm text
- A priority-specific visual signal pattern

If multiple alarms are active:

- Only the highest-priority alarm is displayed in the banner.
- Additional active alarms are indicated by a counter.
- All currently active alarm conditions can be viewed in the Alarm log (see: Alarm log)

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If alarm condition occurred too briefly:

- The alarm counter in the status bar will indicate that new missed or logged events are present in the alarm log.
- The operator can open the alarm log at any time to review all missed and logged events in full detail, ensuring that no alarm conditions or system actions are overlooked.

Highlight of Affected Measurements

The measurement(s) associated with an active alarm on the main monitoring screen are highlighted in the corresponding priority color:

- High priority: Red
- Medium priority: Yellow
- Low priority: Blue

This ensures that the operator can immediately identify which measurement triggered the alarm and respond accordingly.

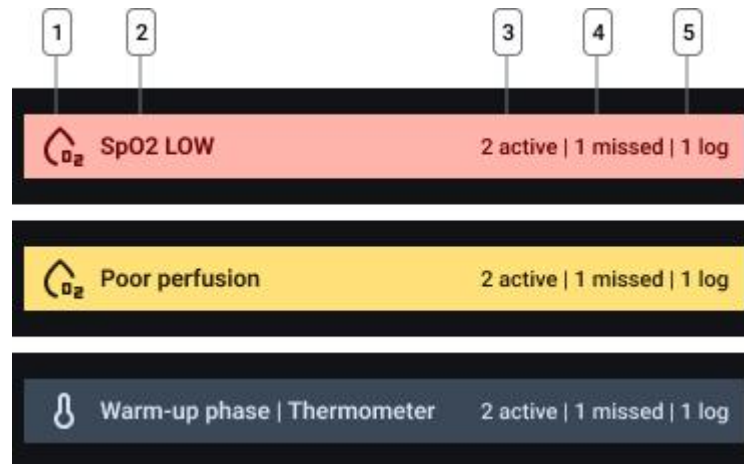
Priority-Specific Visual Patterns

- **High-Priority Visual Alarm Signal**
Color: Red
Display: Alarm icon and alarm text
Behavior: Flashing between normal and reverse display
Flash frequency: 2.1 Hz
Duty cycle: 20% to 60% ON
The high-priority visual signal remains active while the alarm condition exists.
- **Medium-Priority Visual Alarm Signal**
Color: Yellow
Display: Alarm icon and alarm text
Behavior: Flashing
Flash frequency: 0.5 Hz
Duty cycle: 20% to 60% ON
The medium-priority signal remains active while the alarm condition exists.
- **Low-Priority Visual Alarm Signal**
Color: Blue
Display: Alarm icon and alarm text
Behavior: Constant (non-flashing)
Illumination: 100% ON
The low-priority signal remains active while the alarm condition exists.

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Additional Visual Indicators

- Counter for additional active alarms
- Counter for missed alarms
- Counter for new alarm log entries



Alarm Banner – Priority Levels

Examples of the alarm banner for each priority level, illustrating the structure and key elements of the banner. The labeled components include: 1) Alarm icon indicating helping to identify the affected parameter, 2) Alarm text describing the active condition, 3) Counter displaying the total number of active alarms, 4) Indicator showing the number of currently missed alarms, and 5) Indicator displaying the number of new entries in the alarm log history.

Alarm Delay

To ensure reliable detection and indication of alarm conditions, the corpuls auryx App applies defined, fixed, and deterministic delays for alarm signal generation and alarm clearing. These delays depend on the type of alarm condition and are summarized below. No additional alarm condition delay is applied. Alarm conditions are evaluated immediately based on the measured values.

Alarm condition	Alarm signal generation delay	Alarm clear delay
Physiological alarm conditions		
SpO2 low	0 sec	10 sec
Pulse rate high	0 sec	10 sec
Pulse rate low	0 sec	10 sec
Temperature high	0 sec	10 sec
Temperature low	0 sec	10 sec

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Technical alarm conditions		
SpO2 unavailable	35 sec	0 sec
Pulse rate unavailable	35 sec	0 sec
Poor perfusion	15 sec	0 sec
Poor quality	15 sec	0 sec
Bluetooth disabled	0 sec	0 sec
No signal	10 sec	0 sec
Low battery (sensor)	0 sec	0 sec
Low battery (mobile device)	0 sec	0 sec
Device error	0 sec	15 sec
System Status		
Warm-Up Phase	0 sec	120 sec
System Volume < 50%	0 sec	0 sec

Alarm condition delay:

Time interval between the occurrence of a physiological or technical condition and its detection by the system as an alarm condition.

Alarm signal generation delay:

Time interval between the occurrence of an alarm condition and the generation of the corresponding alarm signal.

Alarm clear delay:

Time interval during which an alarm condition must no longer be present before the alarm signal is automatically cleared.

Alarm Signal Inactivation and Acknowledgment

This section describes how audio can be silenced, paused, or acknowledged, and how operators can use the global alarm controls.

Global Audio Settings

The global audio/alarm settings are displayed in the bottom app bar.

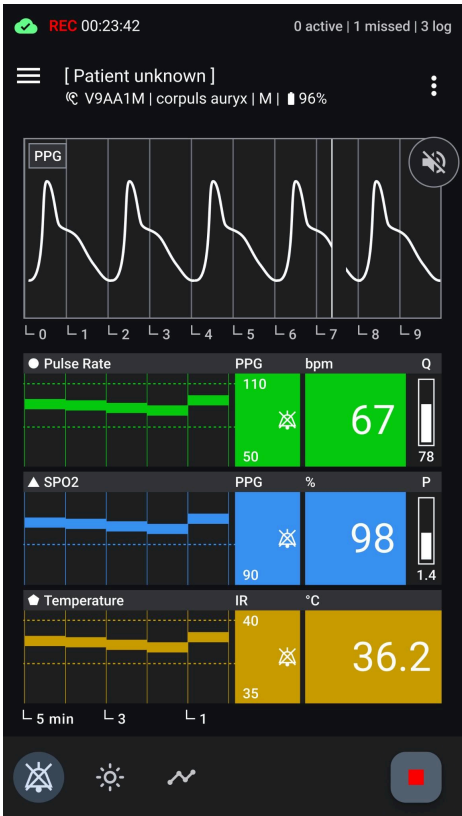
The bell icon indicates the current state of the alarms:

- Audio on/off, paused (2 min)

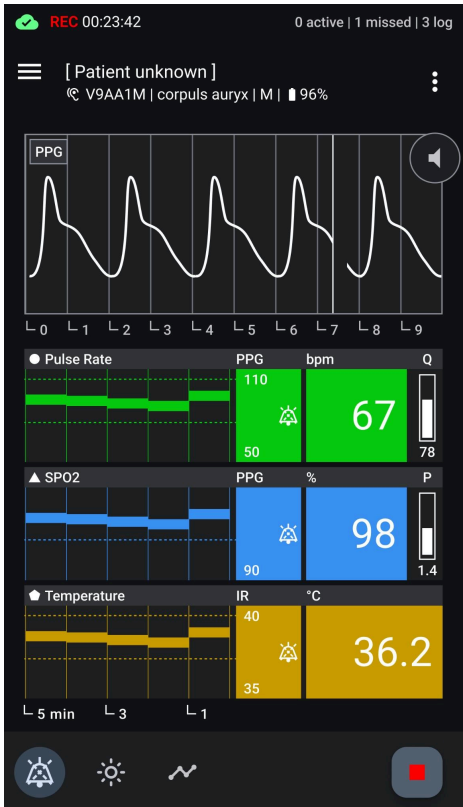
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All parameters affected by this global setting are marked with the bell icon.
Operators can tap the icon in the bottom app bar to silence, pause or enable alarms globally.

Important: Operators should check the state of the bell icon to ensure that alarms are enabled. Silenced audio alarms will not provide audible notification of active conditions.



Main Monitoring Screen – Audio Off
Main monitoring screen with alarm audio **off**. The Bottom App Bar highlights the bell cancel icon, and small indicators next to the vital signs show that no acoustic output is active.



Main Monitoring Screen – Audio Paused
Main monitoring screen with alarm audio **paused**. The Bottom App Bar highlights the bell cancel temporary icon, and small indicators next to the vital signs show that acoustic output is temporarily inactive.

Acknowledging Alarms

Acknowledging high- and medium-priority alarms indicates that the operator has recognized the alarm condition and assumes responsibility for evaluating and managing the associated clinical or technical situation.

Acknowledging high- and medium-priority alarm silences the audible signal of the acknowledged alarm condition while the condition remains active. The visual alarm indication remains displayed in a steady state with reduced visual emphasis, while maintaining priority-specific color coding.

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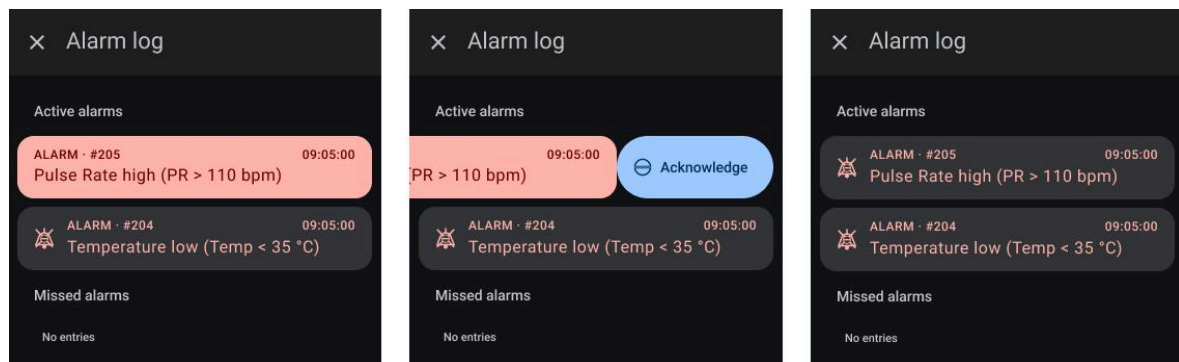
If additional alarm conditions are active, the system emits the audible signal corresponding to the highest-priority active alarm that has not been acknowledged.

Acknowledgment does not resolve the alarm condition, change its priority, or remove the visual alarm indication.

Acknowledgment applies to the currently active alarm condition(s) of the selected priority:

- Silences the audio signal for the active alarm condition.
- Visual alarms remain active at all times.
- Acknowledged alarms are visually marked and displayed with lower emphasis.
- Acknowledged alarms resolves automatically when the alarm condition ends.
- Acknowledging an alarm does not change its priority.

Important: Operators should be aware that acknowledged audio alarms may not provide audible notification of ongoing alarm conditions.



Alarm Log – Acknowledging an Active Alarm

Sequence of three images showing the active alarm section in the log. The operator can acknowledge an alarm by tapping or swiping the corresponding list entry. The images illustrate the transition from an active alarm to its acknowledged state, clearly indicating how acknowledged alarms are displayed in the list.

States

State	Description
AUDIO OFF	Audio notifications silenced globally
AUDIO PAUSED	Audio notifications temporarily paused (2 min)
ACKNOWLEDGE	Silences audio for the acknowledged currently active alarm (see below)

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Alarm presets

General

The app uses one single manufacturer-configured default alarm preset.
No additional alarm presets are available.

The app retains only the current alarm settings during an active recording session. Alarm settings are continuously displayed and cannot be stored for future recordings by the operator.

Manufacturer-Configured Default Alarm Preset

The app includes one manufacturer-configured default alarm preset.
For this preset:

- The defined alarm limits are specified in this Instructions for Use. (See: Alarm limits)
- Alarms are triggered when measured values from the connected sensor exceed the configured alarm limits.
- The system maintains the original priority classification of each vital sign according to the manufacturer-configured default limits.

The default preset represents the standard alarm configuration for all new recording sessions.

Alarm Settings During Recording

Each recording session starts with the manufacturer-configured default alarm preset.

During a recording session:

- The operator may adjust the alarm limit thresholds.
- Adjusted limits are applied immediately.
- Changing an alarm limit might cause an alarm to resolve.
- All active alarm limits are continuously displayed on the monitoring screen next to the corresponding vital sign parameter.

Changes made by the operator:

- Apply only to the current recording session.
- Are not stored after the recording session.
- Cannot be saved as a new preset.

When the recording session ends, all alarm limits automatically return to the manufacturer-configured default values.

Alarm Preset After Power Interruption or App Restart

If the app is closed, restarted, or a power interruption occurs:

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- The manufacturer-configured default alarm preset is always automatically restored.
- Any alarm limit changes made during the previous recording session are lost and cannot be recovered.
- A new recording session always starts with the default preset.

Operators shall verify the alarm settings at the start of each recording session.

Alarm limits

Independent Alarm Settings

If multiple devices are used, each device running the app monitors the same sensor independently. Alarm thresholds are specific to each device.

Operators should check alarm settings on every device to ensure alarms are recognized correctly in the environment of use.

Physiological alarm conditions	Alarm limit preset	Range for limit settings (during recording)
SpO2 low	< 90 %	70 - 100 %; step size +/- 1 %
heart rate high	> 110 bpm	55 - 200 bpm; step size +/- 5 bpm
heart rate low	< 50 bpm	10 - 105 bpm; step size +/- 5 bpm
pulse rate high	> 110 bpm	55 - 200 bpm; step size +/- 5 bpm
pulse rate low	< 50 bpm	10 - 105 bpm; step size +/- 5 bpm
temperature high	> 40 °C	36 - 41 °C; step size +/- 1 °C
temperature low	< 35 °C	24 - 39 °C; step size +/- 1 °C

Technical alarm conditions	Alarm limit preset	Range for limit settings (during recording)
Bluetooth deactivated	Activated or disabled	no limit changes possible
No Signal - In-ear sensor	Foreground: 10 seconds of continuous missing data	no limit changes possible

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	Background: 30 seconds of continuous missing data	
Poor perfusion	perfusionValue < 0.15 for at least 15 seconds	no limit changes possible
poor quality	< 45 for at least 15 seconds	no limit changes possible
Low battery In-ear sensor	Battery ≤ 20 % (MS01)	no limit changes possible
Low battery mobile device	Battery ≤ 20 %	no limit changes possible
device error PPG	error code sent from sensor (MS01) a.) defect green LED b.) defect red LED c.) defect infrared LED	no limit changes possible
device error thermometer	error code sent from sensor (MS01)	no limit changes possible

System state / operator actions	Alarm limit preset	Range for limit settings (during recording)
Warm-up phase thermometer	2 minute timeout	no limit changes possible
System volume is below 50%	system volume ≤ 50%	no limit changes possible

Alarm System Security

Access Control

- Operator vs Responsible Organization roles:
 - Only the manufacturer can modify default alarm presets, configure global alarm behavior, or change system-wide settings.
 - Clinical operators can adjust alarm thresholds during a recording session only, but changes are not saved beyond the session.
- Authentication / permissions:
 - The app does not implement user-specific authentication or role-based access control. Any person with physical access to the mobile device and

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connected sensor can operate the app and modify alarm thresholds during a recording session.

Protection of Alarm Settings

- Default alarm preset integrity:
 - The manufacturer-configured default preset cannot be overwritten or deleted by the operator.
 - Alarm thresholds automatically reset to the default preset at the start of each recording session or after power interruption.
- Global audio/alarm controls:
 - Global settings (Audio Off, Alarm Off, Pause) are displayed clearly in the interface.
 - Only the operator can configure whether these global controls are enabled or disabled.

Data Integrity and Logging

- All alarm events and operator actions (e.g., acknowledging alarms, pausing audio, threshold changes, sensor swaps) are recorded in the Alarm Log.
- Log entries are chronological, grouped by incident ID, and include:
 - Alarm state and priority
 - Timestamps
 - Operator actions
 - Thresholds and affected parameters
- This ensures a complete audit trail for patient safety and regulatory compliance.
- The alarm log is maintained after power down or app restart; the time of power interruption or device shutdown is recorded as a separate log entry with timestamp.
- The app records all events using the mobile device's storage. If a recording ends unintentionally (e.g., due to power loss or device shutdown), all entries up to that point are saved, while subsequent events are not recorded.
- The event log has no inherent capacity limit within the app and depends on the available storage space of the mobile device. Due to the small size of individual log entries, a typical smartphone provides sufficient storage for at least 1000 events per recording under normal conditions.
- If the available device storage is exhausted, no additional events can be recorded and the app cannot continue operation, resulting in an unintentional end of the recording.
- Exported data contains the complete alarm and system event history to ensure traceability and documentation.

Safe Operation

- The alarm system is designed so that silencing, pausing, or acknowledging alarms cannot disable visual alarms.
- Even if audio is silenced, visual signals and the Alarm Log provide continuous awareness of alarm conditions.

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- High-priority alarms are latched to ensure critical conditions are not missed.

Recommendations to Operators

- Verify that the global audio icon shows enabled status before starting a recording.
- Ensure all alarm thresholds and device settings are appropriate for the patient and environment at the start of each session.
- Identify any alarms that may have been missed, ignored, or not addressed in real time. Confirm them in the Missed alarms section of the log to maintain traceability.

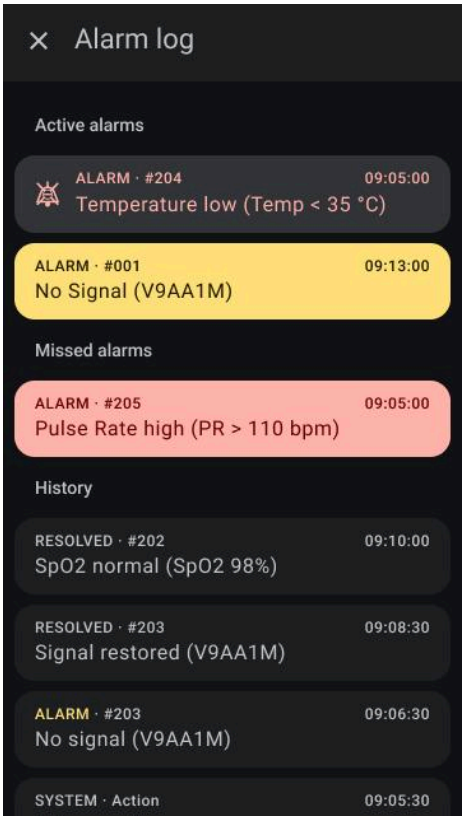
Alarm system log

The Alarm Log provides a comprehensive overview of all alarm activity during an active recording session.

Operators can access the log by tapping either the alarm banner or the current recording section at the top of the main monitoring screen.

The log is divided into three sections:

- Active Alarm Conditions
- Missed Alarms
- History Log.



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Alarm Log Overview

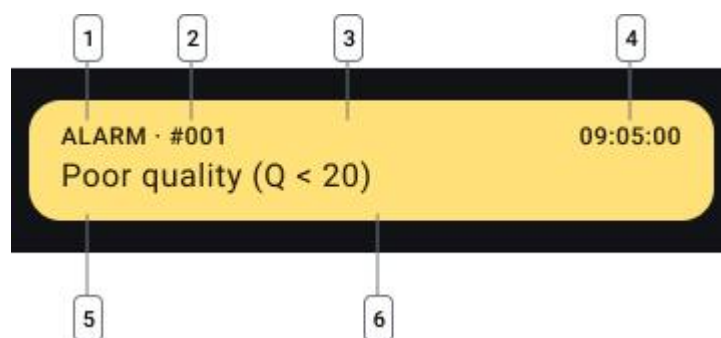
Layout of the full alarm log, showing all sections: **Active Alarms**, **Missed Alarms**, and **History Log**. Each section displays the corresponding entries, allowing the operator to review current, missed, and past alarm events in a single view.

Active Alarm Conditions

This section displays all currently active alarms.

- **Purpose:** Allows the operator to see all alarm conditions that require immediate attention without scrolling or missing any.
- **Behavior:**
 - Only high-priority alarms require acknowledgment.
 - Acknowledging a high-priority alarm:
 - Silences the audio signal for that alarm.
 - Marks the entry visually as acknowledged and stops flashing.
 - Does not affect the underlying alarm condition or its priority.
 - Medium-priority alarms may be acknowledged.
- **Information Displayed:**
 - Alarm state
 - Incident ID (grouping multiple state changes for a single alarm)
 - Priority/severity color: Red = high, Yellow = medium, Blue = low
 - Timestamp
 - Condition description
 - Affected parameter, threshold, and unit
 - Acknowledgment icon if the alarm has been acknowledged

Alarms will be kept in the active alarm section, as long as the alarm condition is ongoing. All active alarms are simultaneously recorded in the History Log, ensuring traceability.

**Alarm Log – Active Alarm Entry (Example: Medium Priority)**

Example of a single active alarm entry (medium priority) within the Active Alarm Conditions section. The entry includes: 1) Event type, 2) Incident ID, 3) Severity/priority color code, 4) Timestamp, 5) Alarm condition described in text, and 6) Associated parameter with its measured value, unit, and defined threshold.

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Incident ID

Each alarm event is assigned a unique Incident ID, which groups all related state changes for that specific alarm condition.

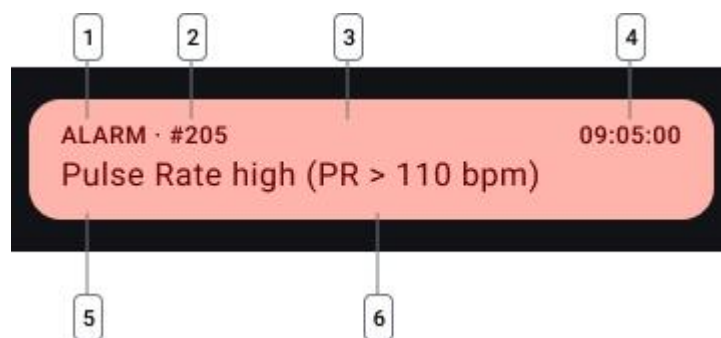
- An incident starts when an alarm condition is first detected.
- The ID increments sequentially is displayed as a hash symbol followed by a number, e.g., #000.
- Any subsequent changes (e.g., threshold exceeded, acknowledgment, condition resolved) are linked to the same Incident ID.

Missed Alarms

This section lists high-priority alarms that resolved without operator acknowledgment.

- **Purpose:** Ensures operators are informed of alarm conditions that occurred but were not acknowledged in real time.
- **Behavior:**
 - Missed alarms remain in this section until confirmed by the operator.
 - Confirming a missed alarm moves it to the History Log only.
 - Confirming a missed alarm does not affect currently active alarms.
- **Information Displayed:**
 - Same as Active Alarm Conditions

Only latched (high-priority) alarms that are resolved without acknowledgment appear in this section. Medium- and low-priority alarms do not require acknowledgment and are not listed here. Operators must confirm each missed high-priority alarm to ensure that all critical conditions have been reviewed.



Alarm Log – Missed Alarm Entry

Example of a single missed alarm entry in the Missed Alarms section. The layout is similar to active alarms, showing the event type, incident ID, priority color code, timestamp, alarm condition, and associated parameter with value, unit, and threshold. Missed alarms can be confirmed by the operator to remove them from the display.

History Log

The History Log contains both alarm conditions and system events in chronological order.

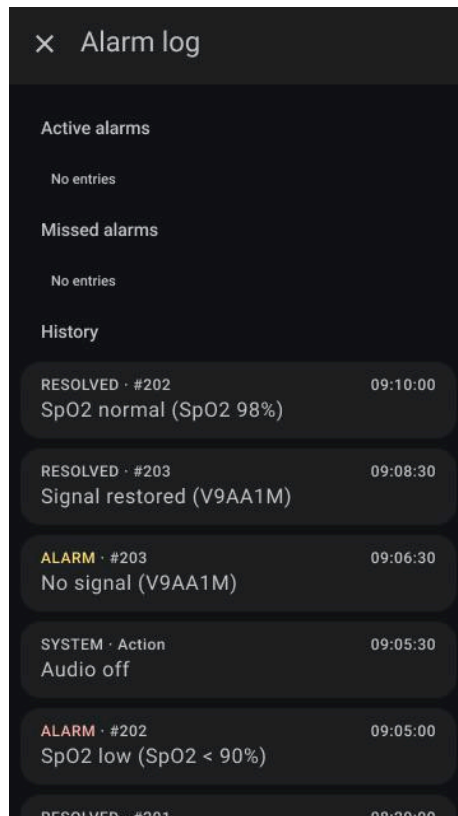
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System events include operator-initiated actions such as threshold changes, sensor replacement, and modifications to alarm or audio settings.

System events are informational entries. They do not represent alarm conditions and are not assigned a priority level.

- **Purpose:** Supports retrospective review and documentation of alarm events.
- **Behavior:**
 - Displays all alarm conditions and state changes.
 - Includes operator actions and system events
 - Entries are grouped by incident ID when multiple state changes occur for the same alarm.
 - Initial alarms are highlighted by priority/severity:
Red = high, Yellow = medium, Blue = low.
 - Entries in the History Log are read-only.
- **Information Displayed:**
 - Alarm state and type
 - Incident ID
 - Priority color / severity
 - Timestamp
 - Condition description
 - Affected parameter, threshold, and unit

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Alarm Log – History Overview

Layout of the History Log section in the alarm log. Entries display alarms' state changes, user actions, and other events in chronological order. All list entries follow the same structure as active and missed alarms, providing a complete overview of past alarm activity.

	Audio pause or silence does not remove alarms from any section. Visual signals remain active regardless of audio state.
	Operators are responsible for reviewing all entries, confirming missed high-priority alarms, and monitoring system actions.

Logged System Events

In addition to alarm conditions, the Alarm Log records operator actions and system state changes. These entries are informational and do not represent alarm conditions.

- Audio ON/OFF
- Audio PAUSED
- Threshold changes
- Sensor swap
- Start/End of Recording

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These entries are displayed chronologically in the History Log and support traceability. They are not assigned an alarm priority and do not generate alarm signals.

Export Alarm-Log

A complete recording session, including:

- Recorded vital sign data
- Alarm conditions
- System events
- Operator actions
- The full Alarm Log

can be exported from the app.

The export contains all alarm states and associated timestamps in chronological order. Instructions on how to perform the export are provided in the chapter [Manage Recordings](#)

Thresholds and Timeouts

Device Related

Connection Timeout

The corpuls auryx 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.

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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 corpuls auryx App.

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 not older than 5 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 35 seconds
Error	Current device errors.

Errors Affecting Data:

Error Code	Error Description	Affected data
0x0a	PPG-IR error	Pulse Rate, SpO2

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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

corpuls auryx

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

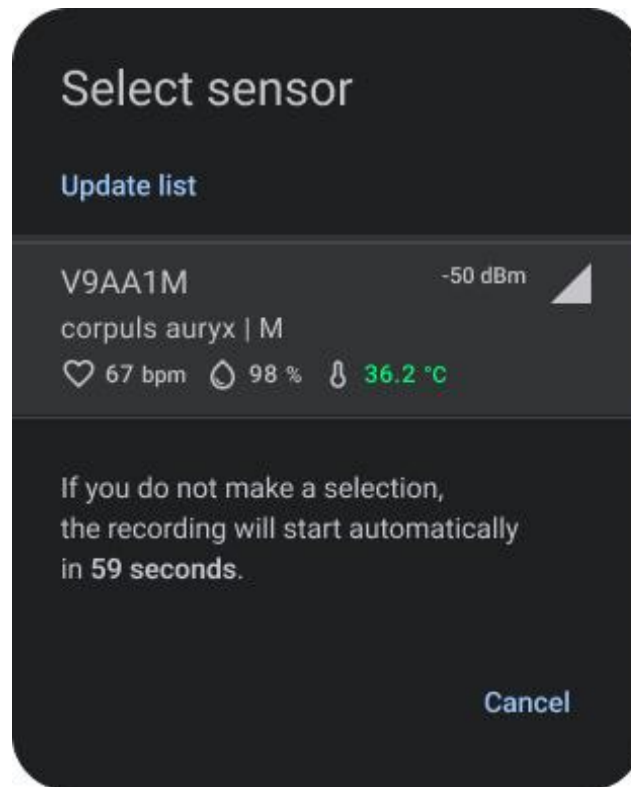
- **Segment Length:** 1 minute.
- **Segment States:**

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.

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Start Recording Pop-Up Dialog

The start recording pop-up dialog is designed to facilitate the selection and initialization of sensors for recording. It comprises several elements:



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. **List of Available Sensors:**
 - A list displaying all sensors available for selection. Each list item can have different states based on sensor conditions:
 - **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).
3. **Supporting Text:**

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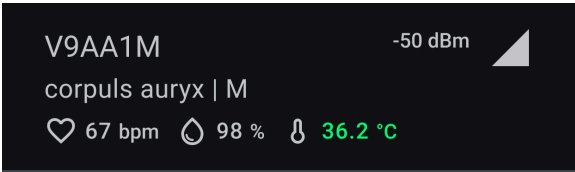
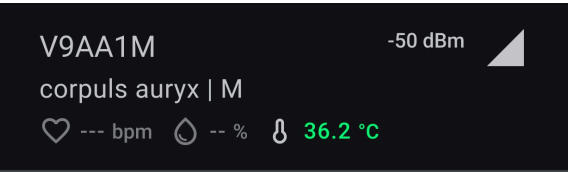
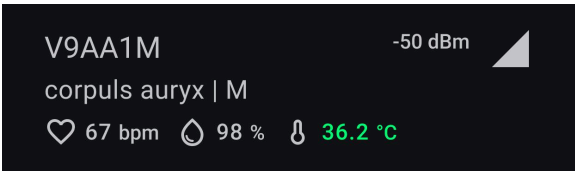
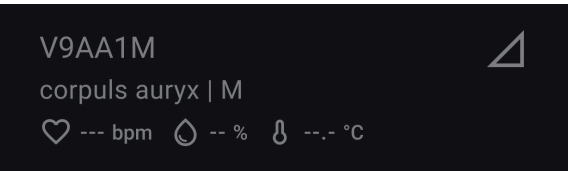
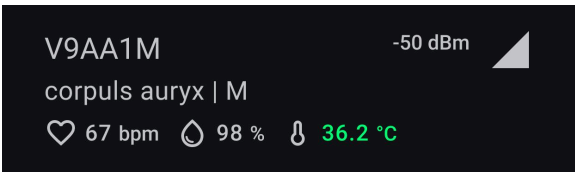
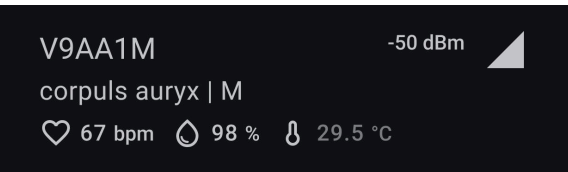
- Additional information or instructions to assist the user in making an informed selection.

4. Action Buttons:

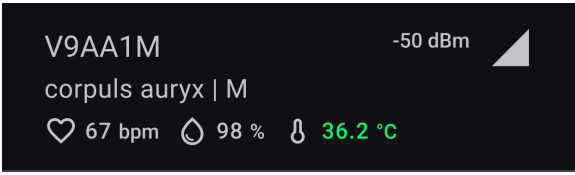
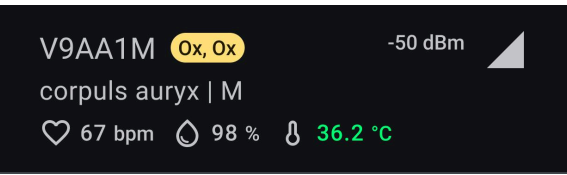
- Buttons for user actions, such as 'Cancel' to exit the dialog.

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:

	
<p>Broadcast Mode: The sensor is actively broadcasting data. Vital data preview available.</p>	<p>Other Mode: The sensor is not broadcasting data.</p>
	
<p>Enabled: The sensor is available for selection and use.</p>	<p>Disabled: The sensor is not available for selection and use.</p>
	
<p>Temperature above 30 °C: Indicates that the sensor may be applied.</p>	<p>Temperature below 30 °C: Indicates that the sensor may be unapplied and should be checked before use.</p>

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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 corpuls auryx App

Start Monitoring (Manually)

To start a measurement with the corpuls auryx 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 .

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.

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.

4. Verify Sensor Serial Number:

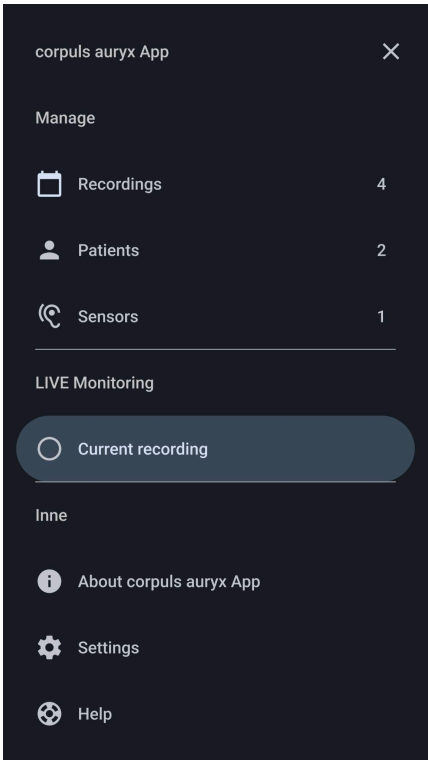
It is the user's responsibility to verify that the displayed serial number matches the serial number on the sensor being used. This ensures the accuracy of data assignment.

5. Start the Recording:

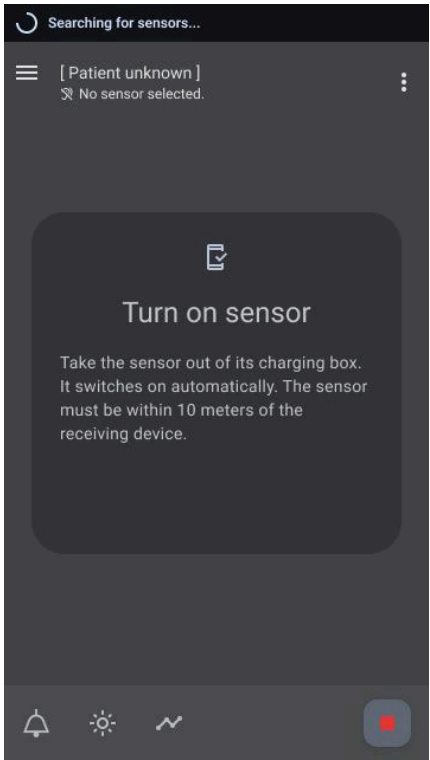
Press the 'Start' button to begin the measurement. The monitoring screen will appear and start populating with real-time data.

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	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.

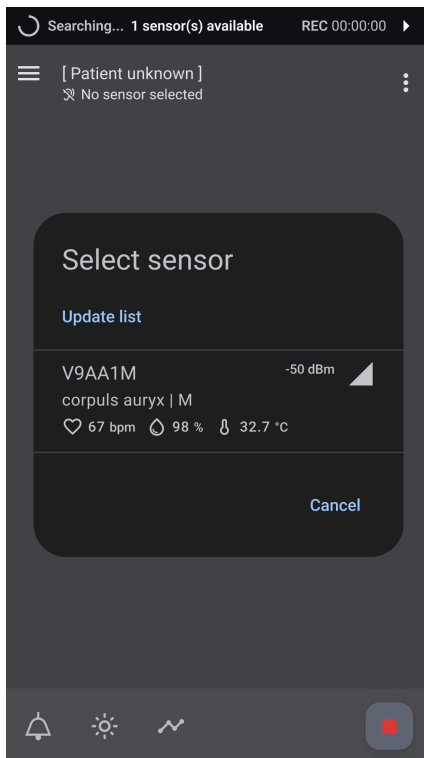


Navigation Drawer - Select Current Recording:
Allows users to start a monitoring session by selecting the current recording option.

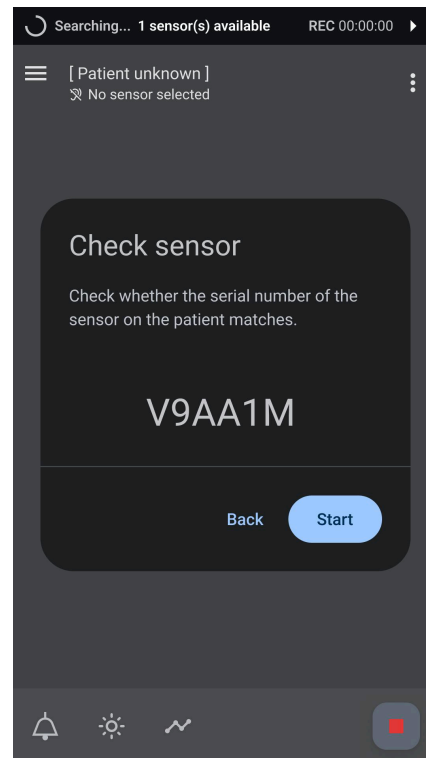


Current Recording Screen - No Sensor Available:
Displays the default screen prompting the user to turn on a compatible sensor device for the current recording.

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Current Recording Screen - Select Sensor Dialog:
Displays the select sensor dialog, allowing users to choose an available sensor device to begin monitoring.



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.

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.

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Interrupt Auto-Recording:

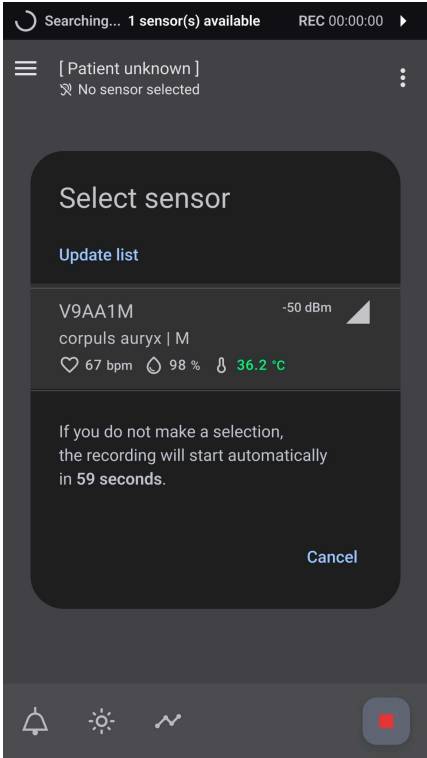
Users can interrupt this process by manually selecting a sensor from the list if needed.

5. Start the Recording:

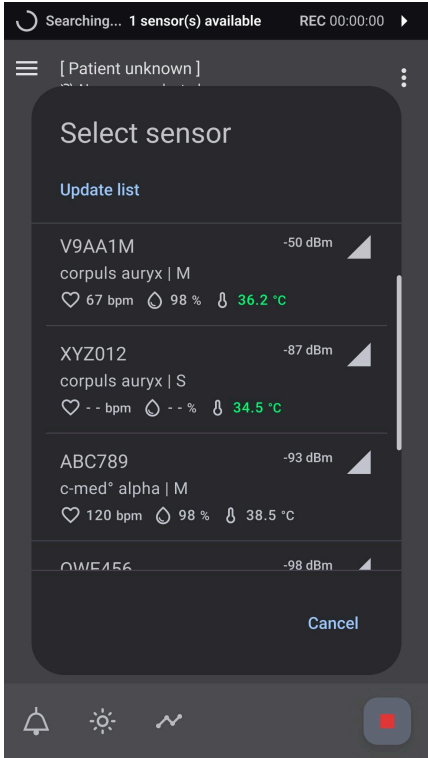
After the 60-second countdown, the recording starts automatically. The monitoring screen will appear and start populating with real-time data.

	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.
	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.

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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.



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. When selected, the corpuls auryx App will automatically switch these sensors to BLE Broadcasting mode to ensure all data is displayed on the monitoring screen.

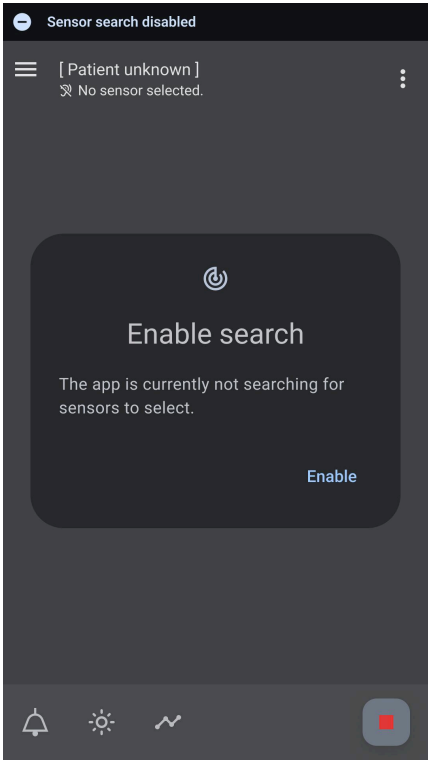
Partly Defective Sensors

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. 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.

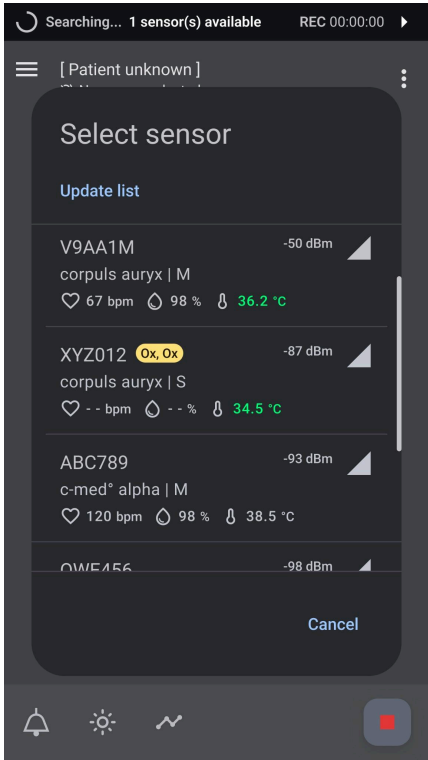
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Cancel Start Monitoring

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. Additionally, the dialog will automatically close if no sensors are available nearby.



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.



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 corpuls auryx App, 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’ alarm.

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2. Check Current Vital Signs:

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

- 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 corpuls auryx 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%.

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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.

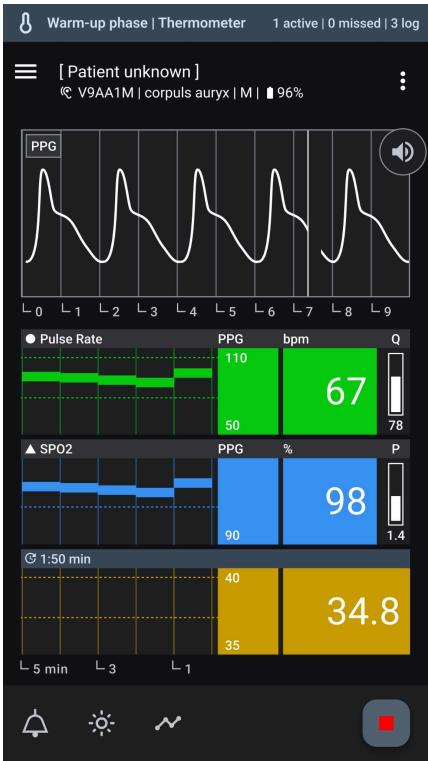
3. Reviewing the Trend of Vital Signs Over Time

When reviewing the trend of vital signs over time in the corpuls auryx App:

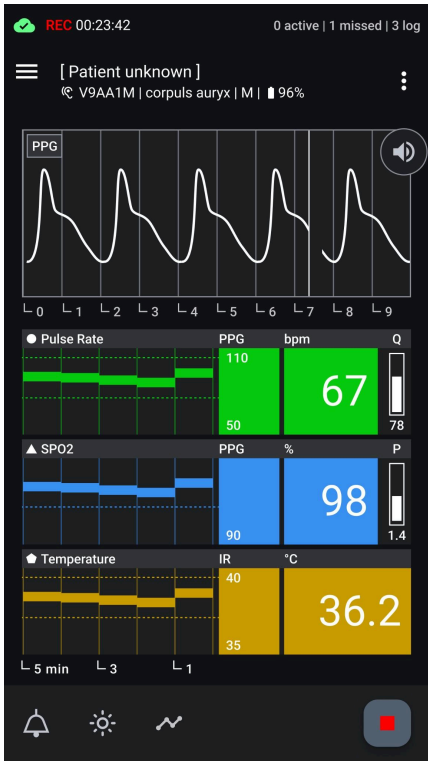
- Historical values for each vital sign are shown as a trend curve on the left next to the current values.
- Each segment represents the averaged value of the parameter over time.
- Thresholds are marked with dotted lines on the curve.
- Segment Status:
 - Segments can be within or above thresholds.
 - 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.



Performing Monitoring - Warm-Up Phase:



Performing Monitoring - Active Recording Screen:

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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.

Displays the current recording with all vital signs and metadata actively being monitored.

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Act and Adapt During Monitoring

Check Sensor Functionality:

To ensure effective monitoring in the corpuls auryx 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
 - Low Battery Warning
 - Connection Loss

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 corpuls auryx 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% 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.

- **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.

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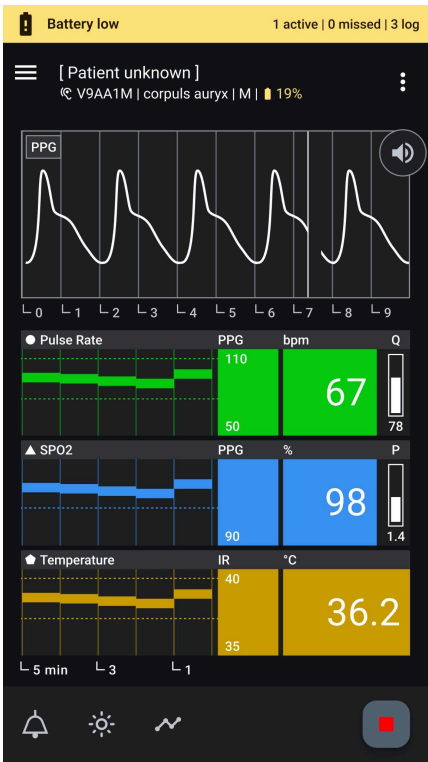


The displayed ppg signal is normalized. The amplitude cannot be used to draw conclusions about the perfusion. The perfusion index must be considered.

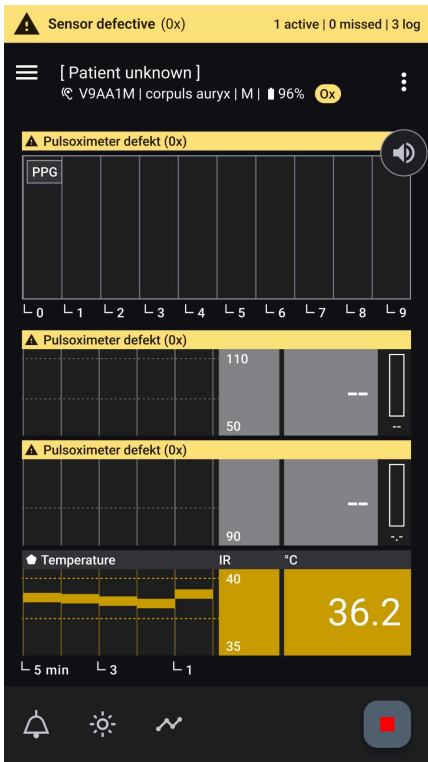
Check for Vital Signs Outside Thresholds:

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.

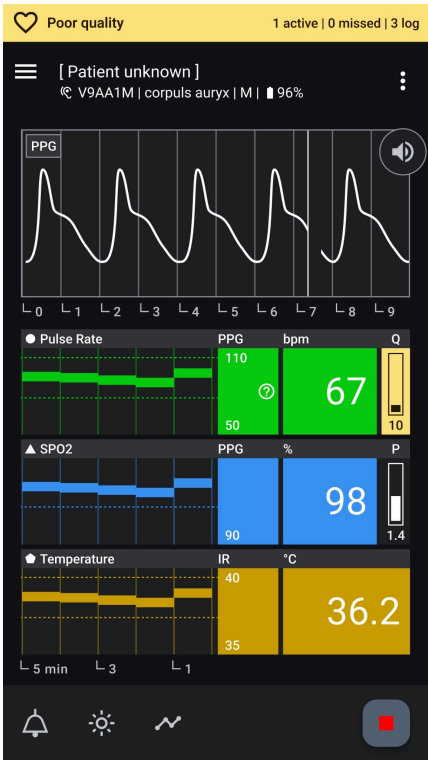


Sensor functionality - Sensor Low Battery:
Displays the screen during monitoring indicating that the sensor device has a low battery state.

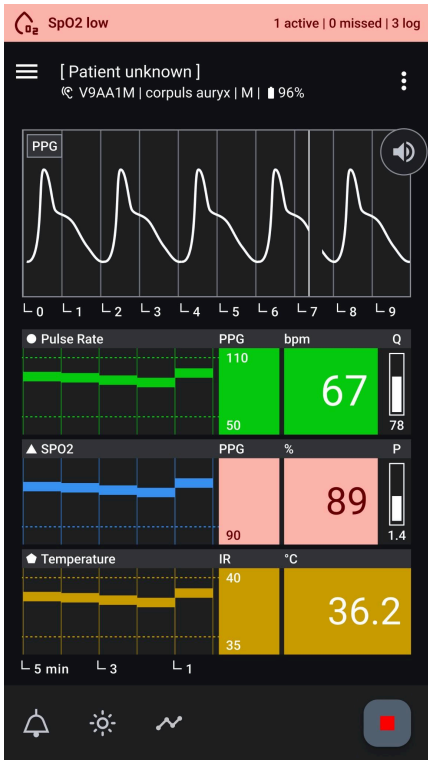


Sensor functionality- Device Error:
Displays the screen during monitoring where a device error, such as a defective pulse oximeter, is impacting specific vital signs.

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Data validity - Invalid Data:
Shows the screen where data is marked as invalid due to poor measurement quality, indicating unreliable vital sign readings.



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 corpuls auryx App offers a light and dark display mode. 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.

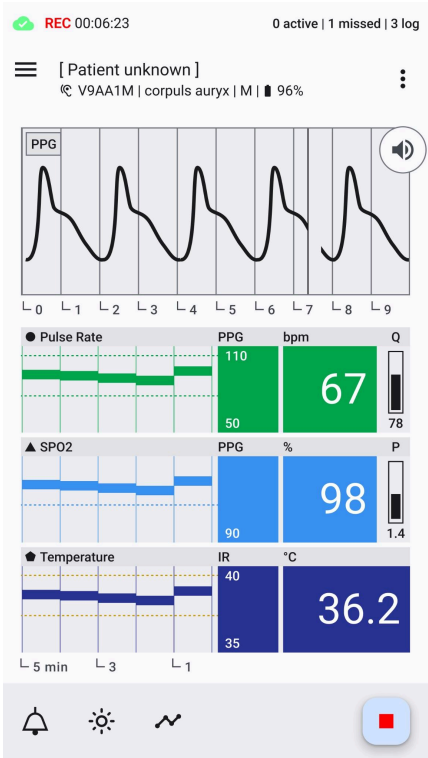
SpO2 Dropout Pulse Tone

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

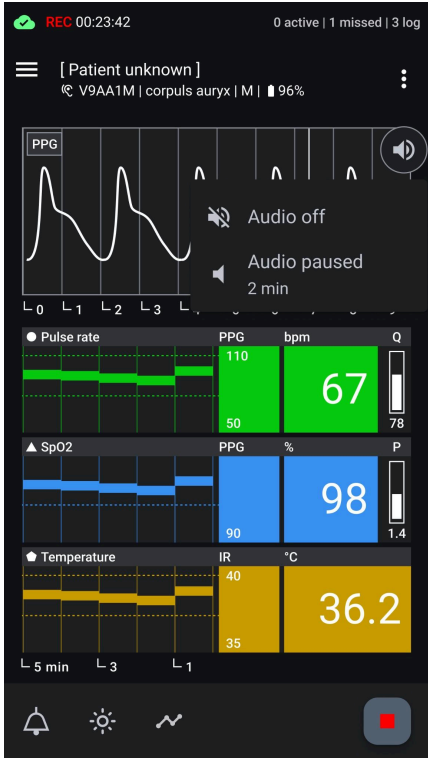
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clearly from the normal pulse tone and indicates a technical or physiological issue affecting SpO2 measurement.

- **Toggle Audio:**
 - The signal can be turned on or off by clicking the ‘Audio’ button next to the PPG curve.



Display Mode Switch - Dark to Light:
Shows the transition of the display mode from dark to light, enhancing readability for different lighting conditions.

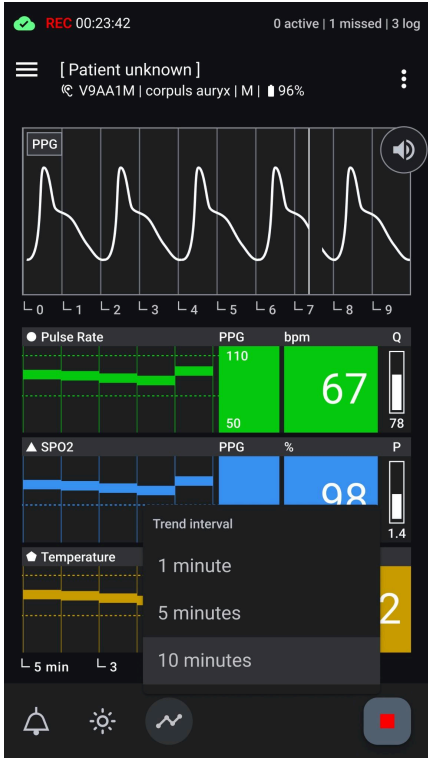


Acoustic Pulse Wave Signal Controls:
Displays the options to turn on, off, or pause the acoustic pulse wave signal for notifications during monitoring.

Timeline Trend Graph:

Opens a menu where you can set the display intervals of the timeline to 1, 5, or 10 minutes. This allows you to view measurements further in the past or examine values averaged over longer periods.

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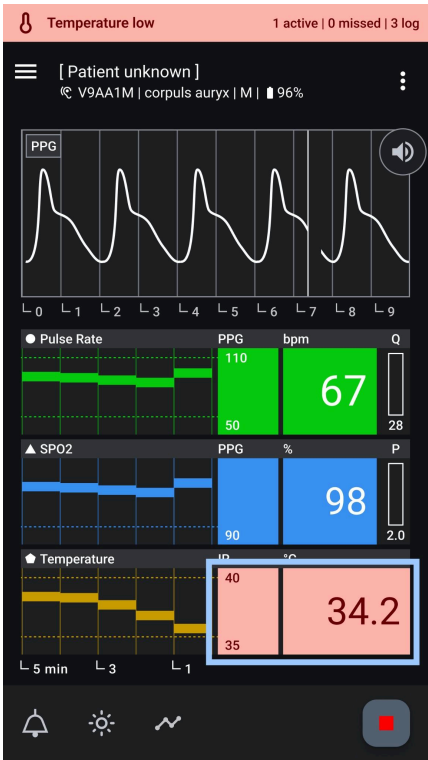
Adjusting the Trend Graph Timeline – Displays the menu with options to adjust the timeline of the trend graph.

Customizing Vital Sign Thresholds

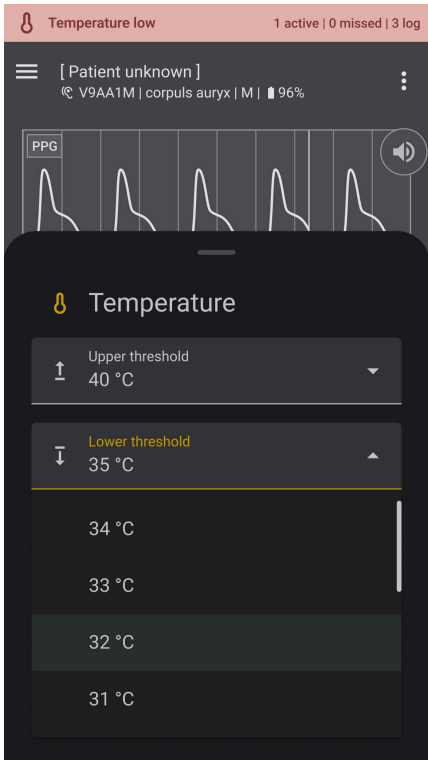
Users can adapt individual vital sign thresholds to meet their specific needs, context and use case, helping to prevent alarm fatigue and provide individualized care. Here’s how to customize these thresholds:

- **Functionality:**
 - **Adapt Thresholds:** Long-press on the area where the thresholds are displayed (to the left of the current values).
 - **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.
 - **Confirm or Reset:** The user can either confirm their new custom thresholds or reset the values to default settings.
 - **Custom Threshold Indicator:** Custom thresholds will be marked with a small indicator to show they have been customized.

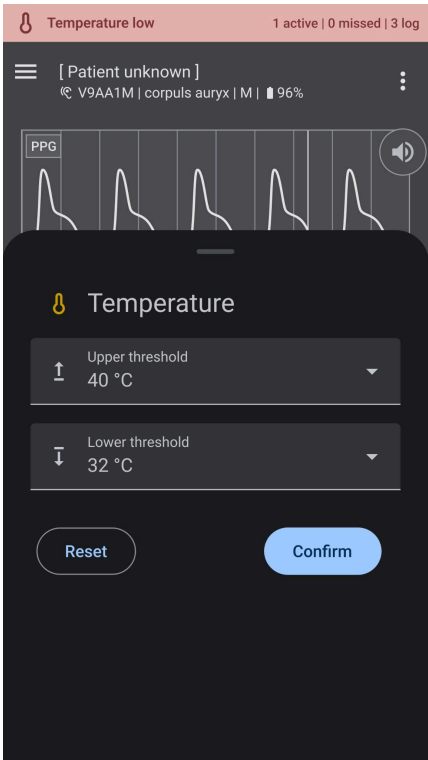
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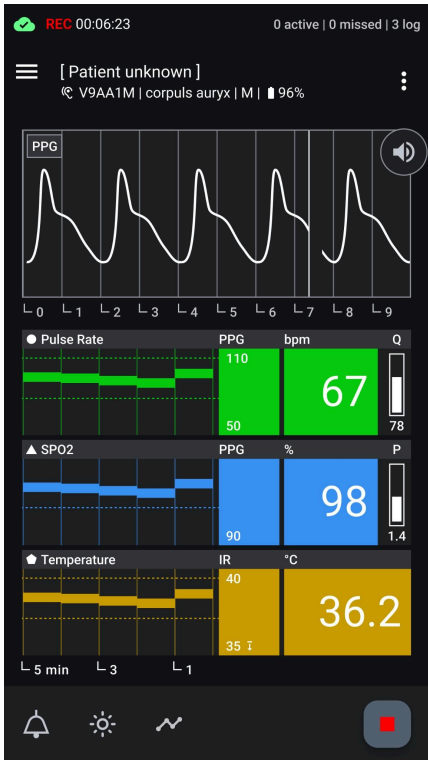
Customizing Vital Sign Thresholds:
Shows the options for adjusting vital sign thresholds, which can be accessed by a long press on the threshold area.



Selecting New Vital Sign Threshold Values
Displays the dropdown menu for choosing a new value for vital sign thresholds.



Confirming Vital Sign Threshold Selection:



Customized Vital Sign Display:

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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.



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.

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:

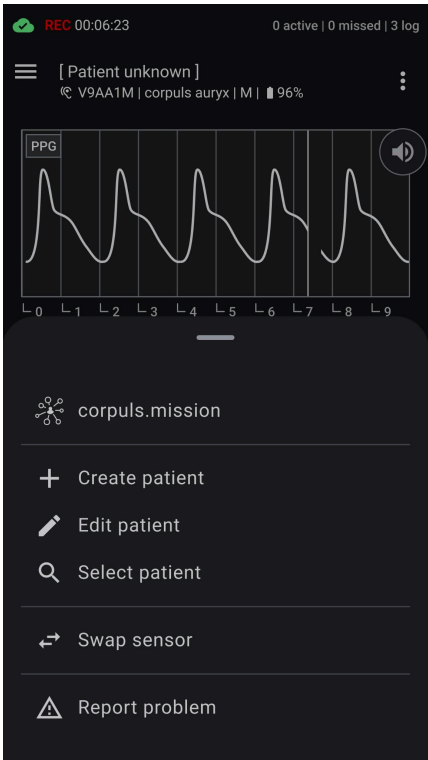
- The 'Swap Sensor' dialog will appear, displaying a list of available sensors. Choose another sensor from the list by identifying it through its serial number and signal strength.

4. Continued Recording:

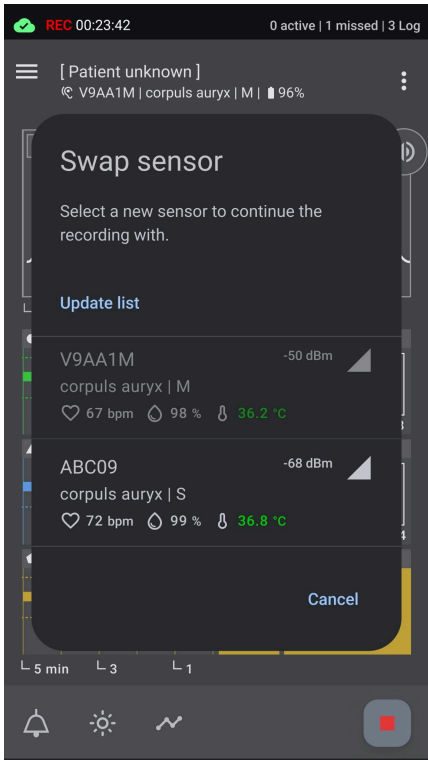
- The current recording will continue uninterrupted during the sensor selection process.

This functionality ensures flexibility and continuity in monitoring by enabling swift sensor replacements without interrupting ongoing recordings.

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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.



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 corpuls auryx 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. Click on it to open the input mask for reporting problems.

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.

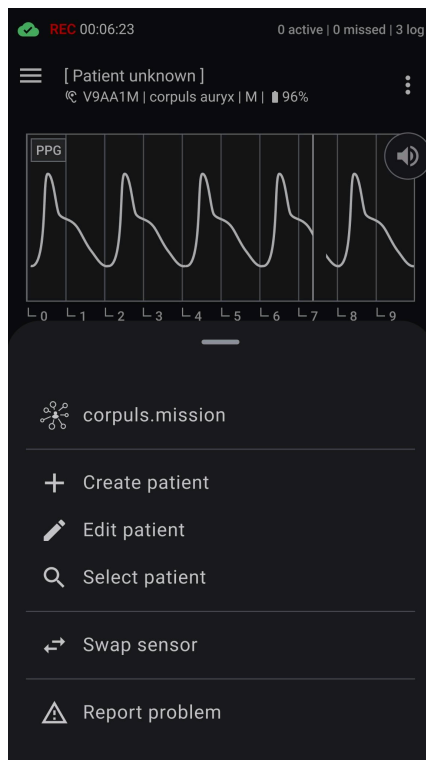
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- **Add Photos (Optional):** Optionally, attach photos to visually illustrate the problem.
- **Contact Information (Optional):** For personalized feedback, provide your name and email address.

Additional Information

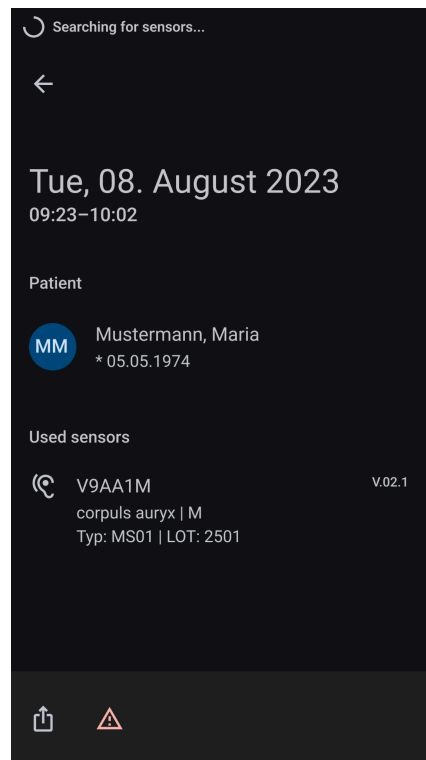
- **CSV File:** Click on the 'Additional information on CSV file' link to learn about the data contained in the attached CSV file and its use.
- **Photos:** Use the link to get instructions on correctly uploading photos to assist in problem analysis.

This reporting feature ensures that we can promptly address any issues and enhance your experience with our app.



Bottom Sheet - Report Problem:

Displays the bottom sheet with the option to report a problem, enabling users to report issues directly from the app.



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.

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Problem Report Input Mask:

Shows the input mask for reporting a problem, where users can enter details about the issue they are experiencing.

Forwarding Data to the Telemedicine Solution corpuls.mission

The **“Share with corpuls.mission”** function in the corpuls auryx App allows you to forward an ongoing recording to a connected telemedicine solution.

Only vital and raw data are forwarded. Patient data, as well as technical and physiological notifications and alarms, are not forwarded.

Server configuration options can be found in the **Settings** menu.

How to Forward a Recording

1. Open the current recording in the °Health app.
2. Tap the three dots in the top app bar to open the menu.
3. If server authentication is configured, select the **“corpuls.mission”** option.
4. A card with a QR code will appear, summarizing the recording. Other participants can also open the session in corpuls.mission by scanning the QR code.
5. Confirming this card forwards the recording to corpuls.mission.
6. The corpuls.mission application will open on your mobile device.

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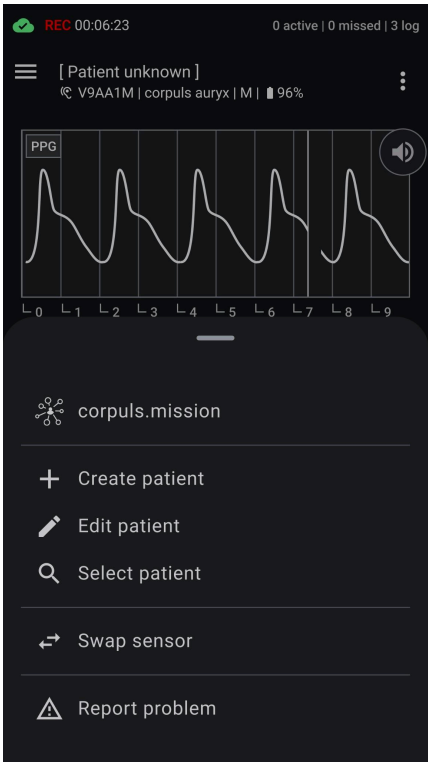
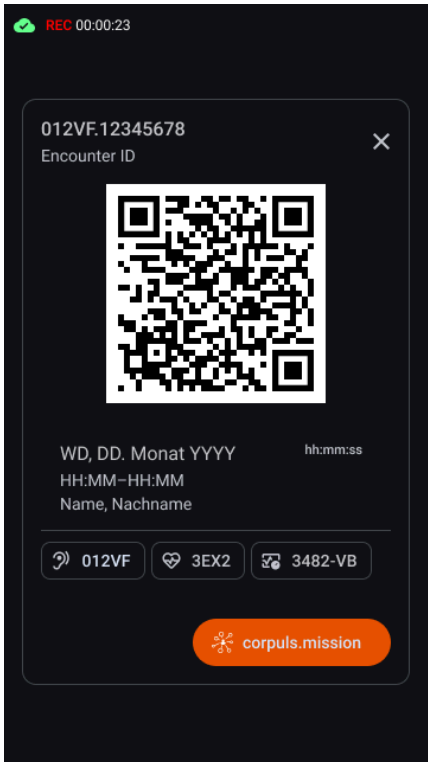
Notes and Error Messages

If not all prerequisites are met, the “Share with corpuls.mission” option will be disabled or an appropriate message will be displayed, for example:

- corpuls.mission not found. Please install or update the app.

Data Privacy and Security

The transmission of measurement data occurs exclusively within authorized and linked server environments. Sharing with third parties or unlinked systems is not possible. This feature ensures that measurement data are secure, unambiguous, and can only be accessed by authorized medical professionals.



Menu – corpuls.mission Forwarding:
Displays the “More” menu with the active “corpuls.mission” option, which allows the current recording to be securely forwarded to the telemedicine solution.

corpuls.mission Forwarding – QR Card:
Displays the generated card with QR code and the button to forward the current measurement, as summarized on the card, to the telemedicine solution.

	Note on Active Data Transmission After forwarding starts, it is possible that the recorded measurement data or the associated session ID (Encounter ID) may not yet be fully available on
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	<p>the server.</p> <p>In this case, data transfer or synchronization is still in progress. Please wait until the transfer is complete before attempting to open or share the session in corpuls.mission again.</p> <p>The app will automatically continue transmission once a stable server connection is established.</p>
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Add Information to Recording

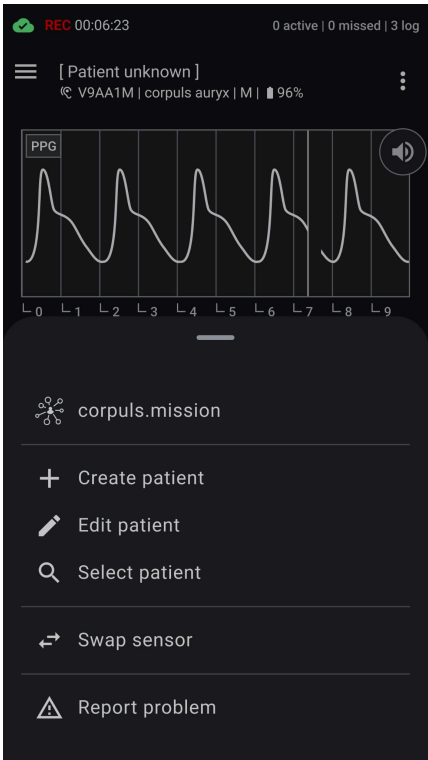
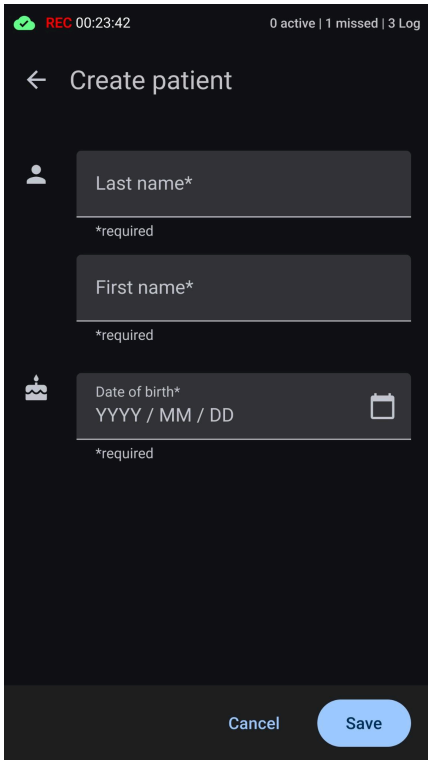
Adding Patient Information

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.
- **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.
 - 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.

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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.

Input Mask - Patient Information:
Displays the form for entering or updating patient details, including fields for name, date of birth, and other relevant information.

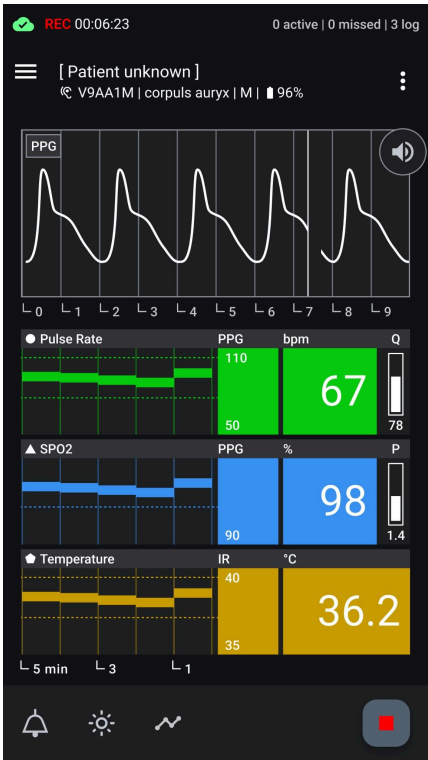
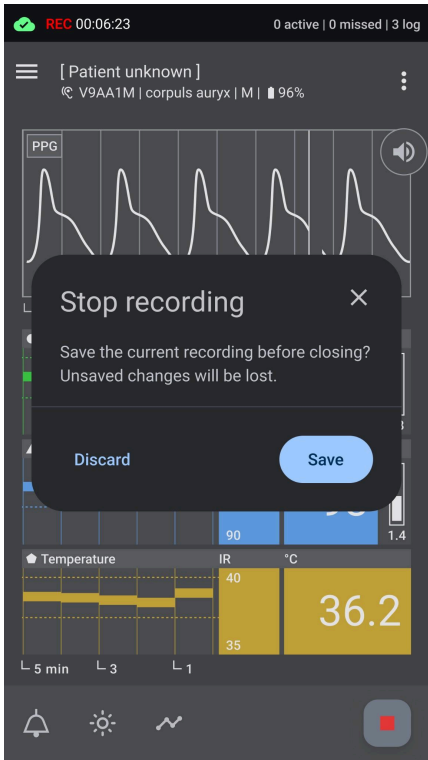
Stopping a Recording

To stop a recording in the corpuls auryx App, follow these steps:

- **Stop Recording:**
 - Click the 'Stop' button in the bottom app bar
 - A dialog box will appear.
 - Click 'Save' to confirm that you want to stop and save the recording.
 - Click "Discard" to end the recording without saving it.
 - Click "X" in the upper right corner to close the dialog and go back to monitoring.
- **Post-Recording Actions:**
 - You can find all saved recordings navigating to the 'Recordings' section.
 - In the 'Recordings' section, you can view or export the recordings.

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This ensures that all data is securely saved and easily accessible for future reference or further analysis.



Stop Recording Button:
Press the red square icon on the far right of the bottom app bar to stop the current recording.

Stop Recording Dialog:
Select between Saving the recording or discard the recording without saving it. Close the dialog to cancel the dialog.



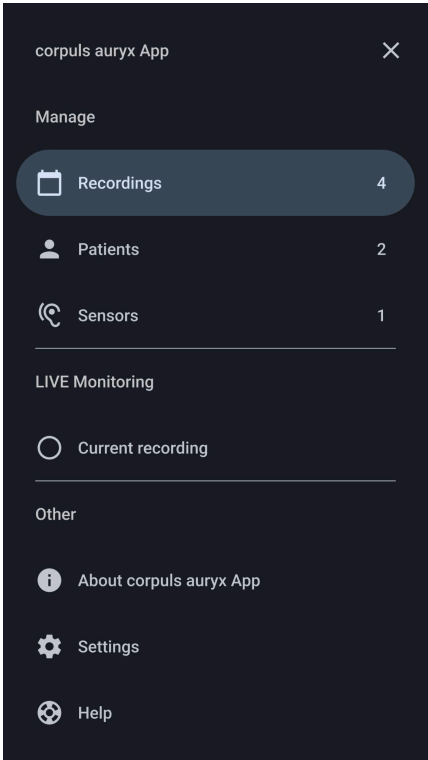
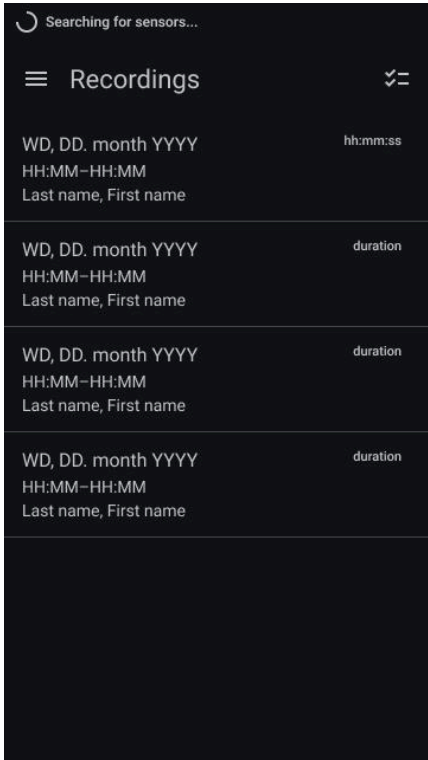
If the app is closed during an active recording, the recording will be stopped and saved automatically.

Manage Recordings

List View of all Recordings

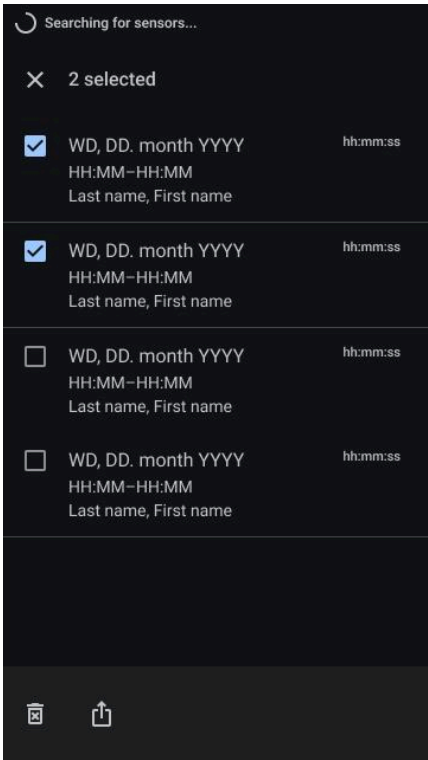
All recordings are accessible under the ‘Recordings’ menu in the navigation bar. Recordings are displayed in chronological order, with the newest recordings appearing at the top. Each recording can be uniquely identified by its date, start and end times, and the patient's name (if available). To view detailed information for a recording, simply click on its entry in the list.

To select multiple recordings at once, tap the Checklist button in the top App Bar. This enables multi-selection mode, allowing you to choose multiple recordings for further actions. For example you could delete multiple recordings at once.

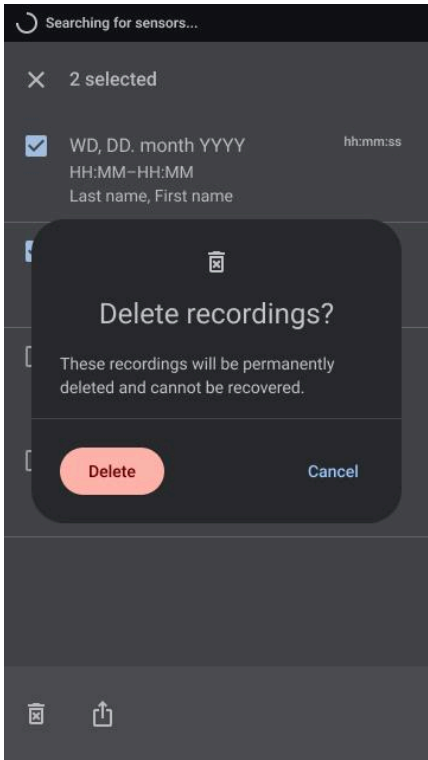


Manage Recordings - Navigation Drawer: Navigate to the 'Recordings' section in the navigation drawer to manage your recordings.	‘Recordings’ Screen: Displays a list of all recorded sessions, allowing you to review and manage past recordings.
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Multiple selection mode
After tapping on the Checklist-Button in the list view, you can select multiple recordings.



Delete multiple recordings
Tap on delete to delete the selected recordings.

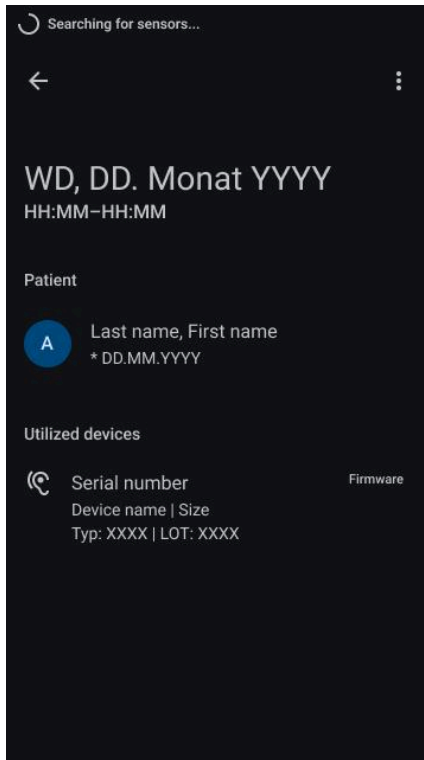
Detail View of a Recording

In the detail view of a recording, you can access all pertinent information, including patient details and the sensors utilized for the recording. By taping on the More-Menu icon in the top app bar you can perform the following actions from the menu:

- **Patient management:** You can create, select or edit patient information of this recording.
- **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.

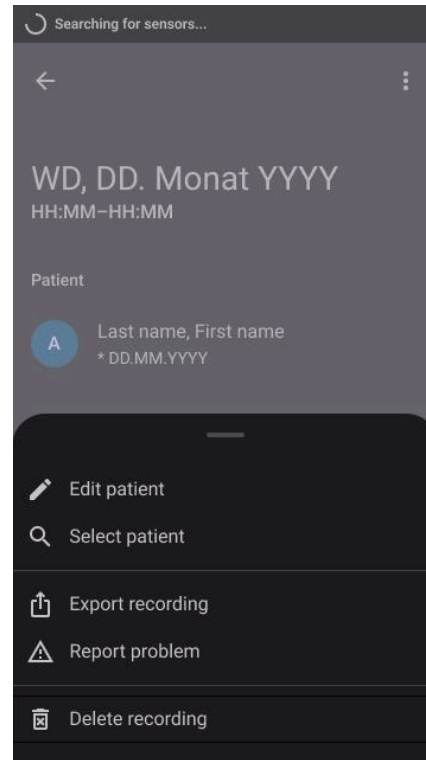
	Sharing Anonymized Patient Data When sharing patient records, personal data such as names or birthdates are excluded from the export to ensure anonymization.
	Handling Health Data Responsibly Please handle health data with responsibility and ensure compliance with applicable privacy and security guidelines.

- **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.
- **Delete Recording:** Tap on the delete recording button to delete the recording. These recordings will be permanently deleted and cannot be recovered.



Detailed Recording Screen:

Provides an in-depth view of a selected recording, including timestamps, metadata and more options in the bottom sheet.



More Menu Recording:

Provides an in-depth view of a selected recording, including timestamps, metadata and more options in the bottom sheet.

Manage Patients

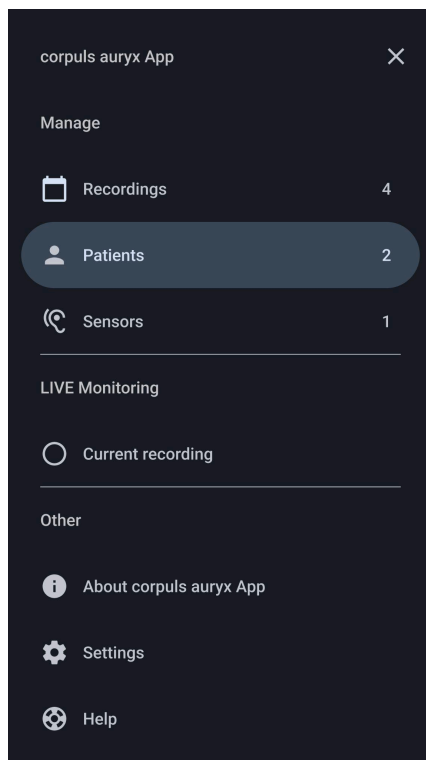
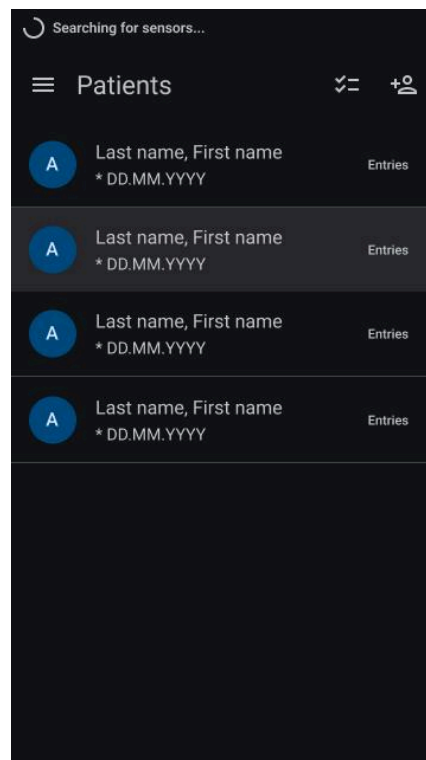
List of all Patients

In the monitoring app, users can manage all previously created patient profiles by selecting the 'Patients' option from the navigation menu in the sidebar. This opens a list view displaying all existing patients, sorted alphabetically. 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.

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- **View Patient Details:** Click on a patient entry in the list to access the detailed view of that patient.
- **Select multiple patients:** To select multiple patients at once, tap the Checklist button in the top App Bar. This enables multi-selection mode, allowing you to choose multiple patients for further actions. For example you could delete multiple patients (including their recordings) at once.



Manage Patients - Navigation Drawer:

Navigate to the 'Patients' section in the navigation drawer to manage your patients.

Patients Screen:

Displays a list of all patients, allowing you to identify, select and create patients.

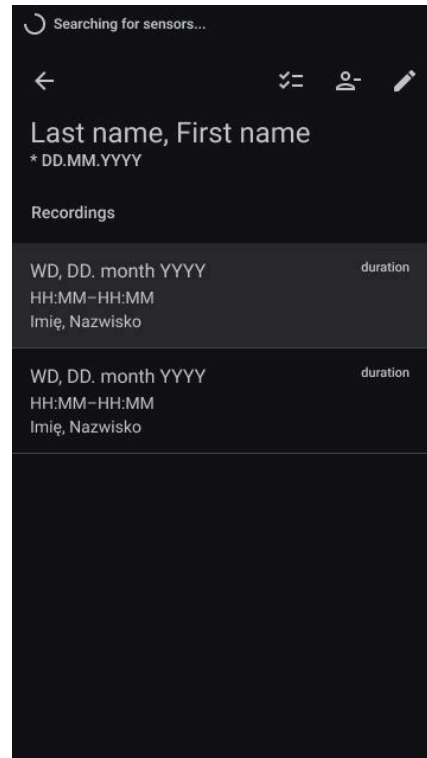
Patient Detail View

In the detailed view of the selected patient, you can access patient information including their last name, first name, and date of birth. 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.

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- **Delete Recordings:** Tap on the checklist icon button to enable selection mode. Select the designated recordings and press the bin icon button.
- **Delete patient:** Tap on the delete patient icon button and confirm your decision to delete the patient including the recordings.



Detailed Patient Screen:

Provides an in-depth view of a selected patient, including recordings that have already been performed.

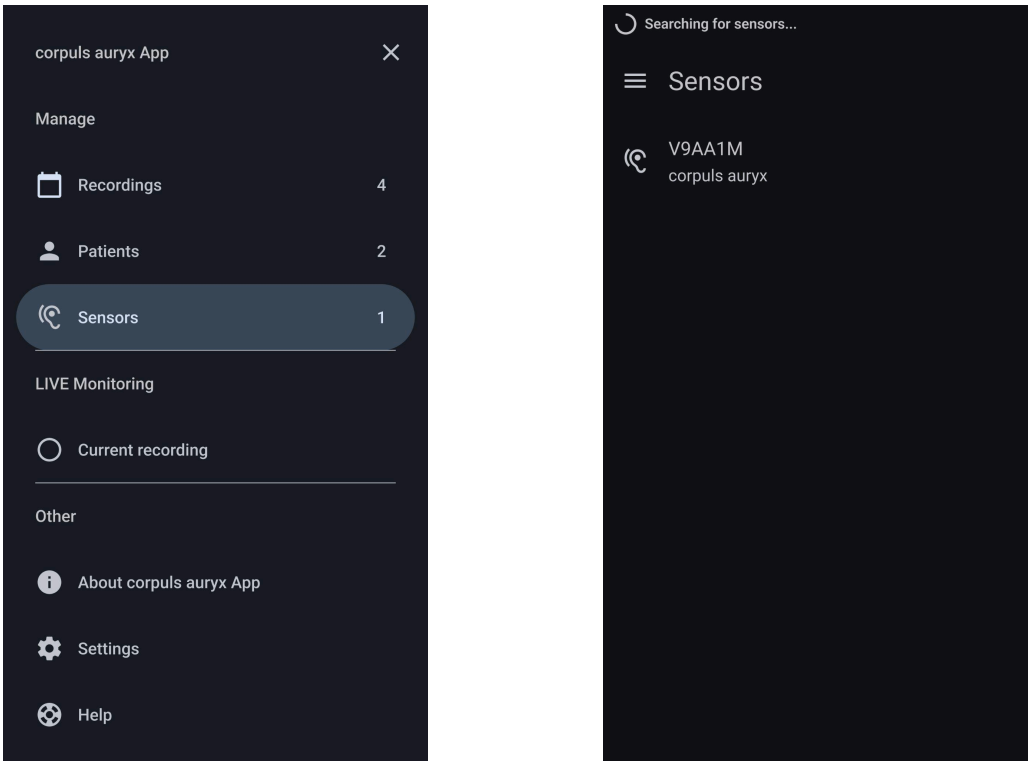
Manage Sensor Devices

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

- **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.

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This information allows you to easily identify and manage sensor devices used within the app.



Manage Sensors - Navigation Drawer:
Navigate to the 'Sensors' section in the navigation drawer to manage your sensors.

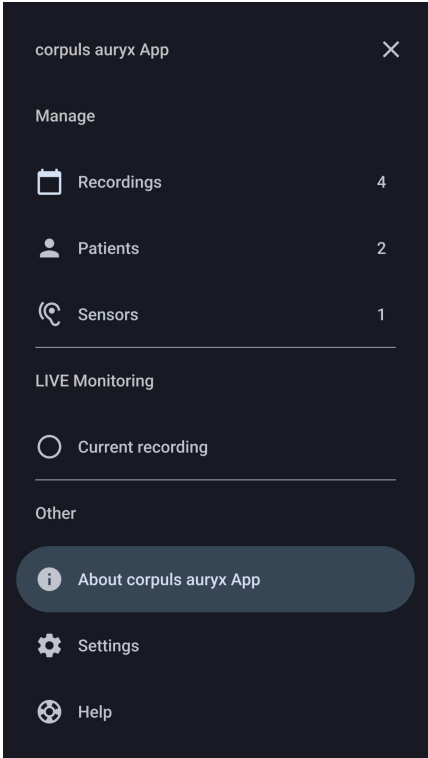
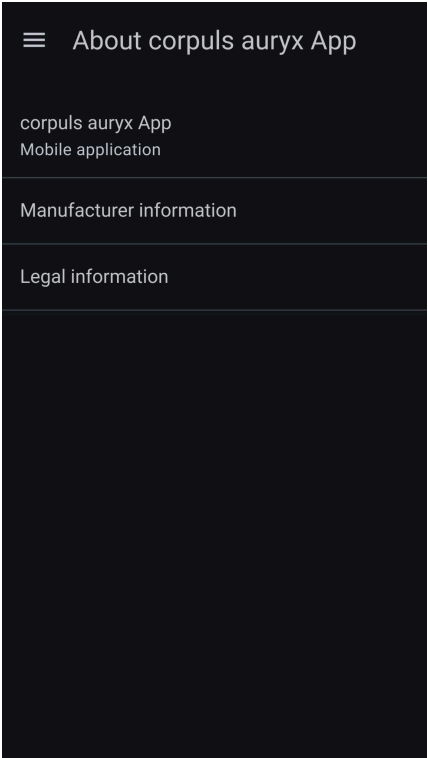
Sensors Screen:
Displays a list of all sensors that have been recorded allowing you to identify certain sensors.

Other App Sections

About corpuls auryx App

Explore the 'About corpuls auryx App' section for comprehensive information about the software, regulatory markings, and contact details for the manufacturer.

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About corpuls auryx App:
Navigate to the 'About' section in the navigation drawer to access detailed information about the corpuls auryx App.

About Screen - corpuls auryx App:
Displays information about the app and manufacturer.

Software Information

Version Information:
View details about the current version of the corpuls auryx App.

Unique Device Identification:
Find the unique identification number associated with your instance of corpuls auryx App for tracking and support.

CE Marking and Other Regulatory Symbols:
Learn about the CE marking and other significant regulatory symbols related to the corpuls auryx App.

Manufacturer Information

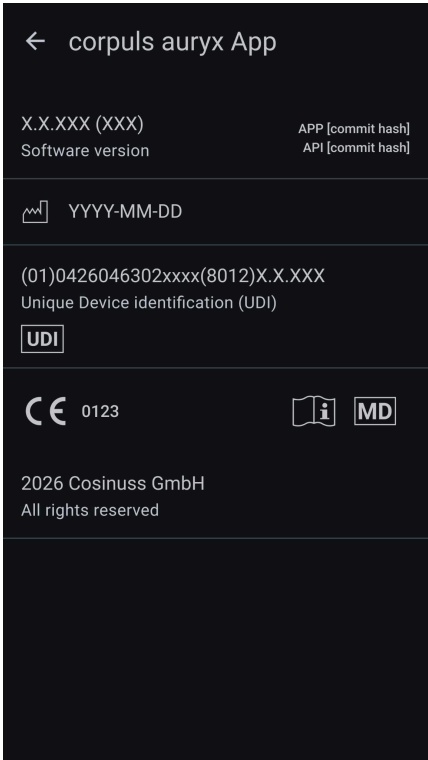
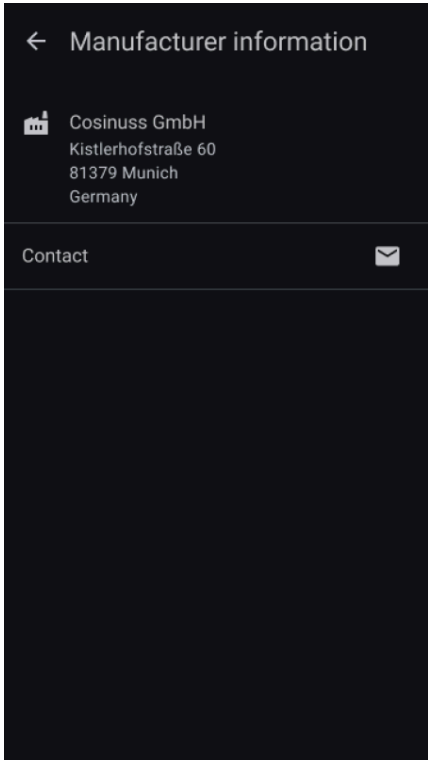
Manufacturer Details:

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Obtain information about the manufacturer of the corpuls auryx App, ensuring transparency regarding the software's origin.

Contact Information:

For any issues, questions, or support needs, please submit a support ticket at: <https://support.cosinuss.com/submit-a-ticket/>.



Software Information - corpuls auryx App:
Displays details about the app's version, unique device identification, CE marking, and other important regulatory markings.

Manufacturer Information - The corpuls auryx App:
Provides details about the manufacturer of the corpuls auryx App and contact information for support and inquiries.

Legal Information

Contains country-specific regulatory information and safety instructions regarding the intended use and distribution of the corpuls auryx App.
Select your country to view the relevant legal information and regulatory requirements in the respective official language.

Settings

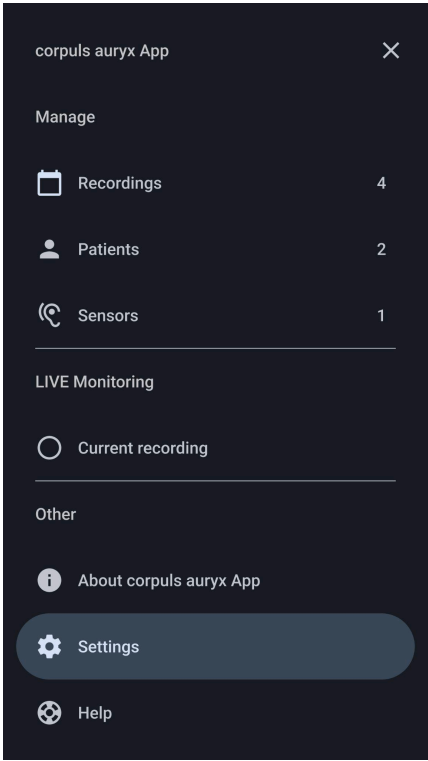
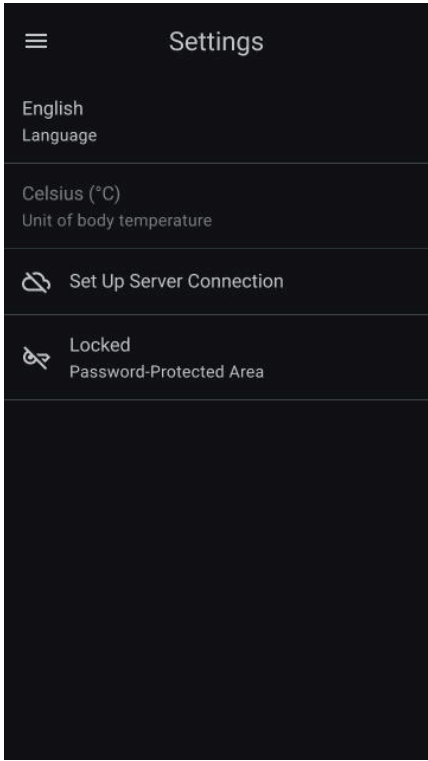
Language Selection:

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

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Measurement Units:

Customize the app to display measurements in units that best suit your preferences, ensuring ease of understanding and use.



Settings - Navigation Drawer:
Navigate to the 'Settings' section in the navigation drawer to review and adjust app settings.

Settings Screen:
Settings include access rights, language selection, and measurement units.

Server Connection:

Establish a connection to an authorized server by entering the server URL and your access credentials. Your recorded measurement data will then be automatically forwarded whenever an internet connection is available.

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✕ Set up server connection

Enter your login details to establish the connection.

Server URL

 https://

 User name

*** Password

Cancel

Connect

Server Configuration – Input Form:
Displays the input form for configuring forwarding to a server.

The app shows the current transmission status in the status bar using a cloud icon (e.g., active, unstable, or inactive).

Connection Active: Green cloud with check mark



Connection Unstable: Yellow cloud



No Connection: Red crossed-out cloud



A valid authentication is required to access server-based functions and forward data. Please ensure that your user account is correctly set up and linked to the corresponding server project.

Possible Notes and Error Messages:

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- “Session expired. Please log in again.”
→ Log in again in the app using your access credentials.
- “Linked project missing. Sharing not possible. Please contact your system administrator.”
→ The project is not properly linked to your user account.

Service Note:

For initial setup of access or in case of authentication issues, please contact the manufacturer: Cosinuss GmbH.

Integration with corpuls.mission:

If the configured server is linked to corpuls.mission, the “**Share with corpuls.mission**” function is additionally enabled. This allows secure forwarding of recordings to the connected telemedicine solution.

	<p>Note on Data Transmission:</p> <p>The app automatically and periodically synchronizes measurement data with the configured server. Older recordings that have not yet been transmitted will also be uploaded.</p> <p>Do not close the app immediately after a measurement to ensure the transfer completes. Also, ensure sufficient data allowance, especially for large datasets or when using mobile network internet access.</p>
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Help

Electronic Instructions for Use (eIFU):

The button provides access to an electronic version of the IFU available at <https://eifu.cosinuss.com>. 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.

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

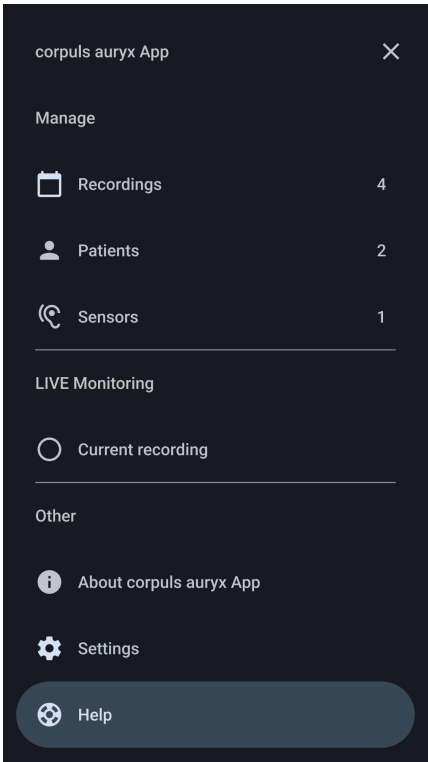
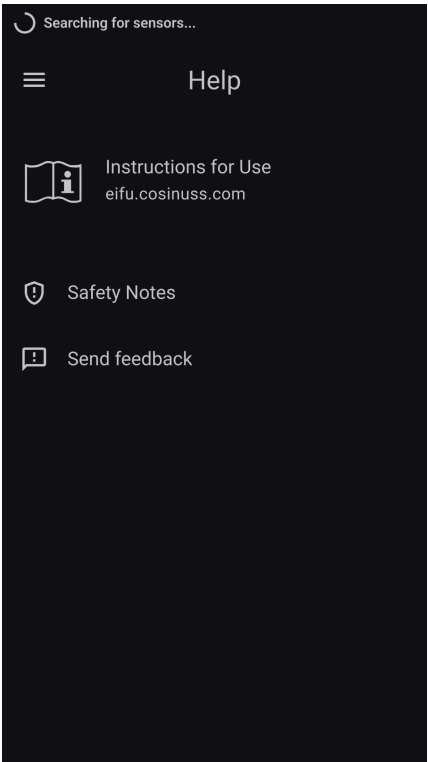
Safety Notes:

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.

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Help - Navigation Drawer:
Navigate to the 'Help' section in the navigation drawer to access user manuals, training materials, safety notes, and feedback options.

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 13 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,	While the software should work on devices running Android 13 or later, full support and testing are focused on the latest devices. If you encounter any issues,

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	<p>please contact our support team for assistance: support@cosinuss.com</p>	<p>please contact our support team for assistance: support@cosinuss.com</p>
Cross-Platform Consistency	<p>The iOS and Android versions of the app are built from the same codebase, ensuring identical functionality, features, and intended use across both platforms.</p>	
Software lifecycle	<p>The app is maintained through regular updates to ensure safe and effective use. Software updates and security patches are provided for 2 years from release. The app is compatible with the last 3 major versions of iOS and Android.</p> <p>If the app is discontinued or replaced, you will be notified, and it will be removed from the App Store and Google Play Store. Measures are in place to ensure continued safety, and all relevant documentation and versions are archived in accordance with regulatory requirements.</p>	
Screen Sizes	<p>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.</p>	
Hardware Requirements	<p>The software requires a modern multi-core processor. Performance may vary based on the specific hardware configuration.</p> <p>Minimum of 2 GB of RAM is required for smooth operation. More RAM may be needed for optimal performance.</p>	
Bluetooth Requirements	<p>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.</p> <p>Ensure that Bluetooth is enabled on your device.</p> <p>For specific Bluetooth compatibility questions, please contact our support team: support@cosinuss.com</p>	
Storage	<p>Ensure at least 150 MB of free storage space for installation and operation.</p> <p>Additional space may be required for updates and data.</p>	
Compatible sensor device	<p>Name: corpuls auryx Typ: MS01 Firmware: 2.4.1 or higher</p>	
	<p>Name: c-med° alpha Typ: MS01 Firmware: 2.4.1 or higher</p>	

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Known device restrictions	Some Android devices (e.g., Nokia 7.2, Samsung A15, Huawei P30 lite) may have intermittent BLE scanning, causing gaps in Phytoplethymographic (PPG) measurements; iOS devices generally scan reliably.
Acoustic performance requirements	<p>The auditory alarm is generated by the loudspeaker(s) of the mobile device. To ensure reliable perception the intended equipment shall meet the following acoustic performance requirements:</p> <ul style="list-style-type: none"> - the alarm shall produce a minimum sound pressure level of 65 dB(A) at a distance of 1 meter, - reproduce all alarm-relevant frequency components within the range of 500 Hz to 4 kHz, - maintain burst timing with no temporal distortion exceeding $\pm 20\%$, - and provide at least mono audio output.

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Compliance Declaration

corpuls auryx App is a Class IIb 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 corpuls auryx 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 corpuls auryx App interface.	The devices are not compatible.	See chapter ' Components ' for compatible devices
	Patient out of range/No signal.	Ensure the patient is within 10 m of your receiving device. Sensor device should appear as 'connected' on the corpuls auryx App display.
	Bluetooth wireless failure.	Check system status of the sensor and the corpuls auryx App on the App display. Check if the sensor is indicating to be functioning correctly, and is within 10 m of BLE range.

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		Reset sensor device and app if necessary by following the instruction manuals.
	No vitals are displayed due to defect compatible device	Check if there is/was an technical alarm regarding the vital (e.g. "Pulserate missing"), contact support - manufacturer of compatible device
	Low Battery of compatible device	Check if there is/was an technical alarm regarding the battery status of the compatible device. Charge the compatible device
	Low Battery of mobile device	Check if there is/was an technical alarm regarding the battery status of the mobile device. Charge the mobile device
Data not updating	No data from the sensors getting through to corpuls auryx App.	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 corpuls auryx 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.

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	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 ' Components ' 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

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	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
	SENSOR (IN-EAR) enabled		BATTERY LOW
	SENSOR (IN-EAR) disabled		ERROR
	AUDIO ON		POOR QUALITY
	AUDIO OFF		TIMED OUT
	AUDIO PAUSED		PATIENT

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	ACKNOWLEDGE Control		DATE OF BIRTH
	ACKNOWLEDGED State		ADD / CREATE
	PROGRESS INDICATOR		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

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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 and user manuals of compatible devices are available at: training.cosinuss.com.

- End of document -

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