SIBEL

anne® VIEW

INSTRUCTIONS FOR USE

support.sibelhealth.com

IFU P/N 443-00003G

Table of Contents

Section 1. Important Safety Information

1.1 Device Description

The ANNE View application is a bedside patient monitoring device that receives vital signs and physiological data from compatible devices for display and transmission to central monitoring platforms. The ANNE View application operates on the ANNE Tablet. When connected to the ANNE Chest Sensor, the ANNE View application displays electrocardiography (ECG), skin temperature, heart rate, respiratory rate, fall detection, and body position data. When connected to the ANNE Limb Sensor, the ANNE View application displays photoplethysmography (PPG), SpO2, pulse rate, and perfusion index data. The ANNE View application is also compatible with optional third-party devices for SpO2, non-invasive blood pressure, and body temperature measurements. The ANNE View application alarms when physiological data are outside of the configured thresholds.

1.2 Indications for Use

The ANNE View application is intended for the display of physiological data from the ANNE Chest and ANNE Limb devices. The application is also compatible with third-party, FDA-cleared devices for the display of noninvasive blood pressure, SpO2, pulse rate, and body temperature measurements. The ANNE View application notifies healthcare professionals when physiological data fall outside selected parameters. The ANNE View application displays the orientation of patients to aid in the prevention of pressure ulcers for at-risk patients. The system notifies the user when the patient's position has not changed for a preset threshold of time. The ANNE View application communicates to compatible central monitoring platforms, including the Central Hub, for the display and storage of multiple patients' physiological data. The Central Hub has the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The ANNE View and Central Hub are intended for use by trained, qualified healthcare professionals in the clinical or home healthcare environment. The device is not intended for use on critical care patients.

1.3 Contraindications

- ANNE View is not intended for use on critical care patients and is not a remote diagnostic device.
- While the data displayed by ANNE View may be applicable for use as an aid to diagnosis and treatment, ANNE View does not provide diagnostic or interpretive statements to either the patient or the clinician.
- The electrocardiogram is not for diagnostic or interpretative purposes. It should not be relied on for assessing QRS morphology.

1.4 Warnings

- ANNE View should not be used in the presence of strong electromagnetic fields such as high frequency surgical equipment.
- ANNE View is not intended to be used as an apnea monitor. Do not rely on the respiration monitoring to detect cessation of breathing.
- Setting alarm limits to extreme values may prevent certain alarm conditions from being detected and from being enunciated with audible and visual alarm signals.
- Do not attempt to disassemble, repair, or modify the device.

- Do not plug in any unauthorized cables to the hardware ports located on the tablet device.
- Turning all audio alarms off may result in clinically actionable physiological conditions to be missed. Ensure that audio alarms are re-enabled upon leaving the bedside if there is no connected central monitoring system.
- Use proper clinical judgment when determining the prioritization of concurrent physiological and technical alarm conditions.
- Ensure that a new monitoring session is started for each patient. Continuing the previous monitoring session with a new patient will result in physiological information to be associated with the previous patient. Continuing the previous monitoring session with a new patient may result in inappropriate alarm setting for the new patient, resulting in false positive or false negative alarm generation.
- The patient monitor is intended to be located at the patient bedside. Placing the patient monitor away from the patient bedside may result in communication drops with wireless sensors. Placing the patient monitor away from the patient bedside may decrease the effectiveness of the alarm system.
- Clean the patient monitor with the cleaning agents as prescribed in this manual. Using unvalidated cleaning agents may damage the patient monitor, causing it to malfunction.

1.5 Precautions

- Do not use this product if the ANNE Tablet is damaged.
- Temporary interruption of data streaming is possible. Similar devices may cause signal interference during data transmission. If you experience this effect, avoid operating near interfering devices.
- The battery used in the tablet may present a risk of fire, explosion, or chemical burn if mistreated. Do not expose the sensors or tablet to excessive heat or fire. Do not crush, puncture, or incinerate as doing so can result in fire, explosion, or the release of toxic gases. Do not use or charge if the sensors appear to be leaking, discolored, deformed, or in any way abnormal.
- Dispose of all non-consumable components in accordance with local regulations. Alternatively, components may be returned to your authorized distributor for recycling or proper disposal. Sibel Health's European distributors have been registered as a B2B (business-to-business) producer of Category 8 (Medical Equipment without implanted or infectious devices).
- ANNE View is intended to be operated by a qualified healthcare professional. The patient is not an intended operator.
- ANNE View has no cardiac arrhythmia detection capabilities.
- In order to maintain monitoring of the patient the patient monitor should be transported with the patient during transfers.

1.6 Glossary

Table 1: Glossary

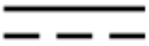
Abbreviation	Definition
ADT	Admission Discharge Transfer
BPM	Beats Per Minute
BRPM	Breaths Per Minute
DIA	Diastolic
ECG	Electrocardiogram

HR	Heart Rate
ID	Identifier
IP	Ingress Protection
IR	Infrared
LED	Light-emitting diode
ME	Medical Equipment
MRI	Magnetic Resonance Imaging
NFC	Near Field Communication
NIBP	Non invasive Blood Pressure
PI	Perfusion Index
PIN	Personal Identification Number
PLETH, PPG	Photoplethysmogram
PR	Pulse Rate
RF	Radio Frequency
RH	Relative Humidity
RR	Respiratory Rate
SpO2	Oxygen Saturation
SYS	Systolic
TEMP	Temperature

1.7 Symbols and Markings

Table 2: Symbols and markings

Symbol	Title	Description
	eIFU	Indicates the need for the user to consult the instructions for use or the electronic instructions for use.
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read
	Class II Equipment	Equipment meets the safety requirements specified for Class II equipment according to IEC 61140
	MRI Unsafe	This device is not safe for use with MRI equipment
Rx ONLY	Prescription Use Only	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

	Does not contain natural latex rubber	Natural rubber latex was not used as a material in the manufacture of this medical device, its container, and/or packaging
	Manufacturer	Indicates the medical device manufacturer
	Direct current	Direct current
	Alternating current	Alternating current
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	Federal Communications Commission Mark	FCC marking indicates the electronic device, which sold in the United States, is certified and the electromagnetic interference from the device is under the limits that are approved by the Federal Communications Commission
	Batch code	Indicates the manufacturer's batch code so that the batch or lot in which the device was manufactured can be identified
	Date of Manufacture	Indicates date when medical device was manufactured
	Catalogue number	Indicates the manufacturer's catalogue number so the medical device can be identified
	Serial Number	Device serial number
	WEEE (Waste Electrical and Electronic Equipment)	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. The WEEE marking must appear on any electrical and electronic equipment placed on the EU market.
	TELEC Certification	The classification and technical standards for the specified radio equipment listed in the official online technical regulations compliance certification system
IPN_1N_2	Ingress Protection	N1 0 Non-protected 1 Protected against solid foreign objects of 50 mm diameter and greater 2 Protected against solid foreign objects of 12.5 mm diameter and greater 3 Protected against solid foreign objects of 2.5 mm diameter and greater 4 Protected against solid foreign objects of 1.0 mm diameter and greater 5 Dust-protected 6 Dust-tight N2 0 Non-protected 1 Protection against vertically falling water drops 2 Protection against vertically falling water drops when enclosure tilted up to 15° 3 Protected against spraying water 4 Protected against splashing water 5 Protected against water jets

		6 Protected against powerful water jets 7 Protected against the effects of temporary immersion in water 8 Protected against the effects of continuous immersion in water When a characteristic numeral is not required to be specified, it is replaced by the letter "X" ("XX" if both numerals are omitted).
RoHs compliant	RoHs (Restriction of Hazardous Substances)	Regulates the use of toxic materials with the purpose of making electronics manufacturing safer at every stage of its life cycle
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	Bluetooth®	Indicates that the sensors use Bluetooth® as the wireless communication protocol
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Temperature limits	Operating temperature range
	Atmospheric pressure limitation	Operating pressure range
	Humidity limitation	Operating humidity range
	Non-ionizing electromagnetic radiation	Equipment includes RF transmitters that generate non-ionizing electromagnetic radiation
	Indoor use only	Identifies electrical equipment designed for indoor use
	Audio On	Indicates audible alarm tone is on.
	Audio Pause	Indicates audible alarm tone is paused temporarily.
	Audio Off	Indicates audible alarm tone is turned off permanently.
	Keep Away From Rain / Keep Dry	The transport package shall be kept away from rain and in dry conditions or keep dry when applied to a device.
	Acknowledgement	To identify the control whereby a bell may be acknowledged or to indicate that the bell has been acknowledged. The alarm condition may be indicated below or beside the bell.
	Alarm off	To identify the control for alarm off or to indicate that the alarm system is in the alarm off state.
QTY	Quantity Symbol	Indicates the number of units or pieces in the package.

EC REP	Authorized representative in the European Union	Indicates the authorized representative in the European Union.
CE 2460	CE Mark	Indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.
	Importer	Indicates the entity importing the medical device into the locale.
MD	Medical Device	Indicates the item is a medical device.

1.8 Storage and Handling

- Storage temperature range: -15°C – 45°C (5°F – 113°F)
- Storage relative humidity range: 5 – 95% RH (non-condensing)
- Storage pressure range: 30 kPa to 120 kPa
- Operating temperature range: 10°C – 40°C (50°F – 104°F)
- Operating humidity range: 5 – 95% RH (non-condensing)
- Operating range: 30 kPa to 120 kPa

1.9 Security Recommendations

There are steps you can take to help make the operating environment more secure.

- Do not connect the ANNE Tablet to sensors outside of the system components.
- Do not connect the ANNE Tablet to sensors with sensor IDs you do not recognize.
- Do not connect to unknown open wireless networks while operating the system. Avoid public/free Wi-Fi hotspots, and use only secure Wi-Fi networks.
- Always confirm the sensor ID displayed on the tablet with the one displayed on the system before use.
- Limit the information you enter into the ANNE Tablet to only information required for use of the system.
- Use strong PINs and passwords.

1.10 Manufacturer Information

- If a replacement is needed for any component of ANNE View, contact your customer support representative.
- Contact your customer support representative for any of the following issues:
    - Assistance in setting up, using, or maintaining ANNE View
    - To report unexpected operation or events

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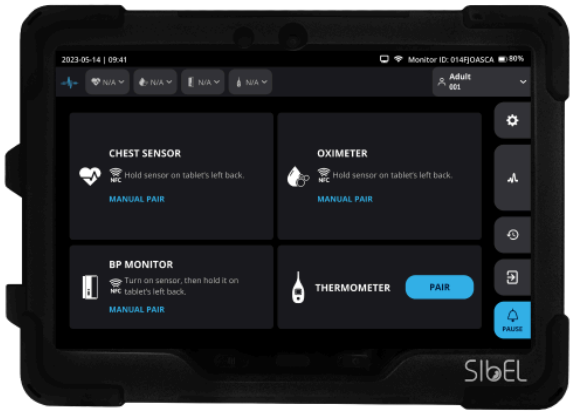
Website: www.sibelhealth.com

MDSS GmbH
Schiffgraben 41, Hannover 30175
Germany

Section 2. System Items

The system includes ANNE View Patient Monitor and the accessories listed below:

ANNE View Patient Monitor



Tablet Charger

Note:

- The tablet is provided with a case and should remain in the case during use.
- The Central Hub is not sold in all countries. Contact your local sales representative for availability.
- Power adapters provided may vary by country.

Section 3. Tablet & Battery Status

3.1 Turn On & Unlock Tablet

To turn on:

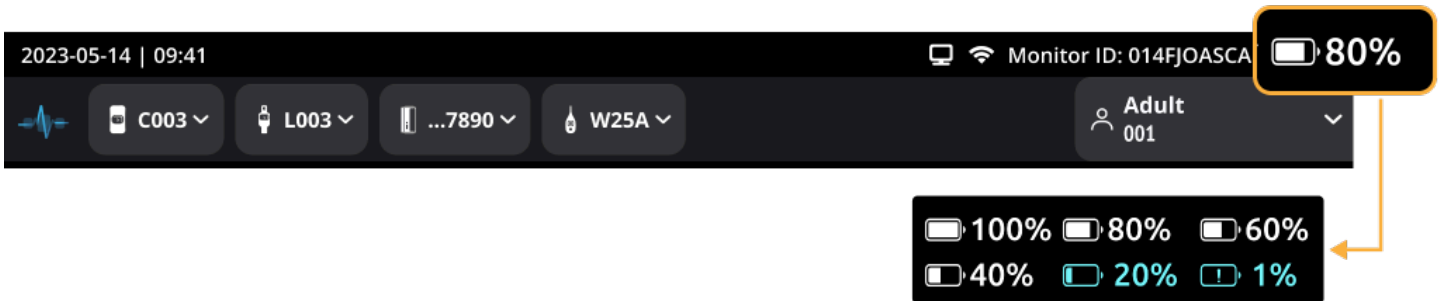
Press and hold the power button.

To unlock:

Press the home button.

3.2 Tablet Battery Status

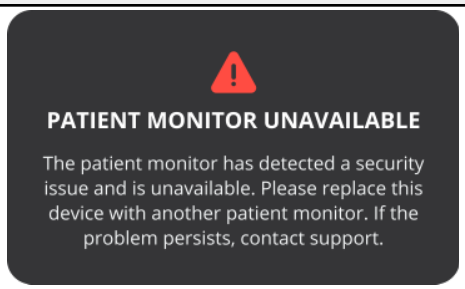
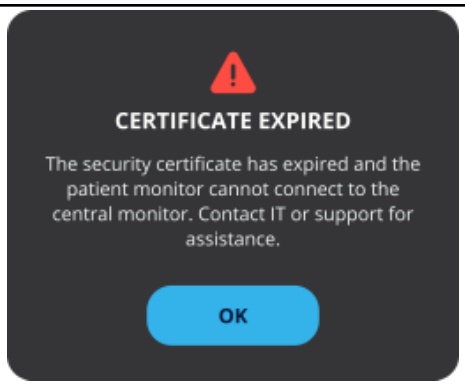
The tablet battery status is represented on the top bar above the patient information. It shows the percentage of battery left for the tablet.



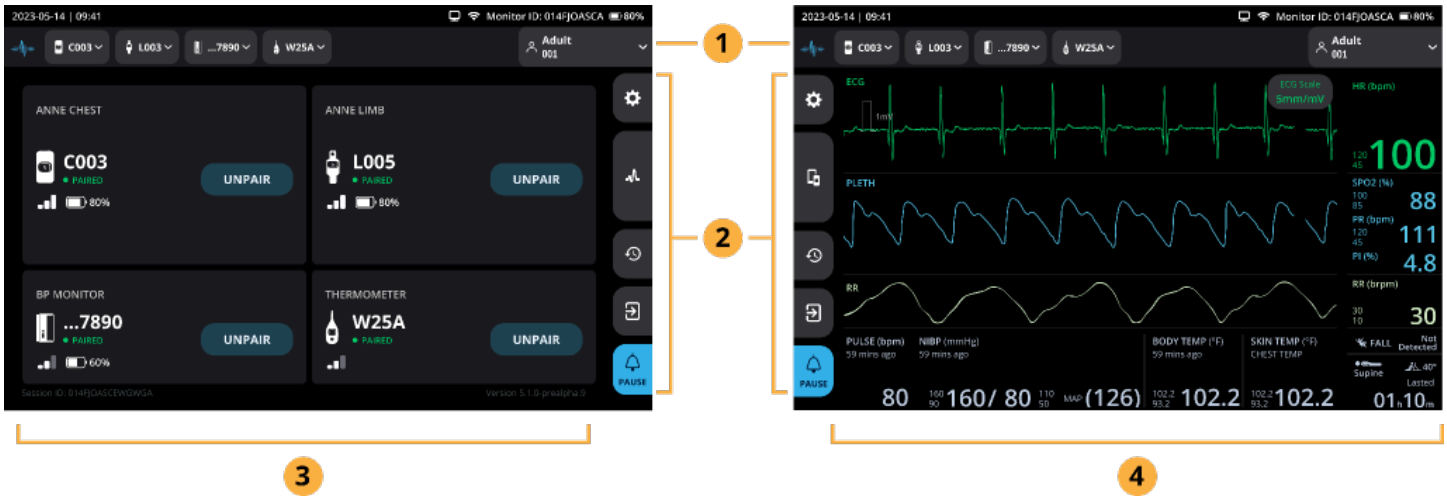
Keep the tablet plugged in during use whenever possible.

3.3 Patient Monitor Error Handling

Table 3: Patient monitor error handling

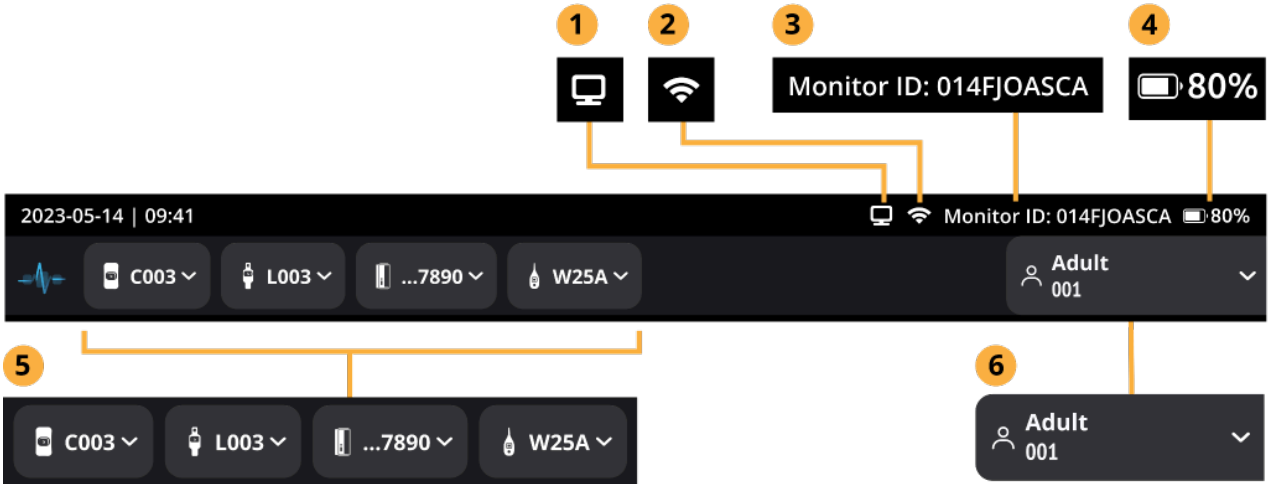
UI	Description	Solution
	The patient monitor has detected a security issue and is unavailable.	Please replace this device with another patient monitor. If the problem persists, contact support.
	The security certificate has expired and the patient monitor cannot connect to the server.	Contact support for assistance.

Section 4. User Interface Structure



① Top Bar (Section 4.1)
② Side Bar (Section 4.2)
③ Sensor Dashboard (Section 4.3)
④ Vital Dashboard (Section 4.4)

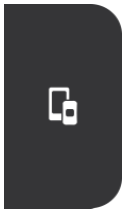
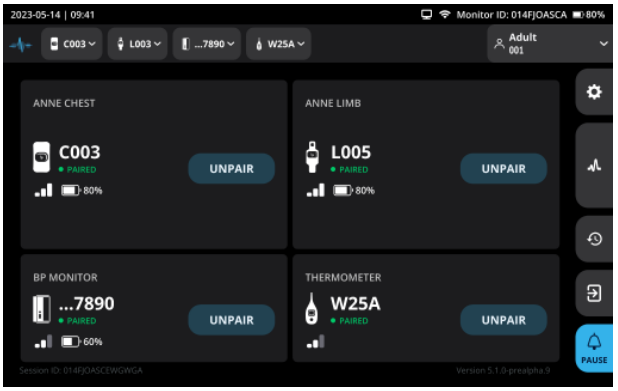
4.1 Top Bar

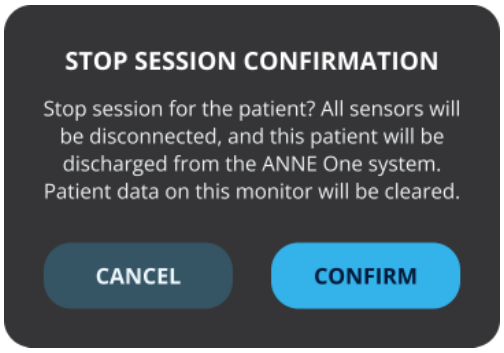


① Central Icon:The tablet is configured to a central monitoring platform.
② Wi-Fi Icon: Internet is connected.
③ Patient monitor ID: Unique identifier for the device.
④ Tablet battery status: Indicator for the tablet's battery level and charging status.
⑤ Sensor details: Displays the sensor status. Select to see more sensor info.
⑥ Patient type and ID: Select to see more patient info.

4.2 Side Bar

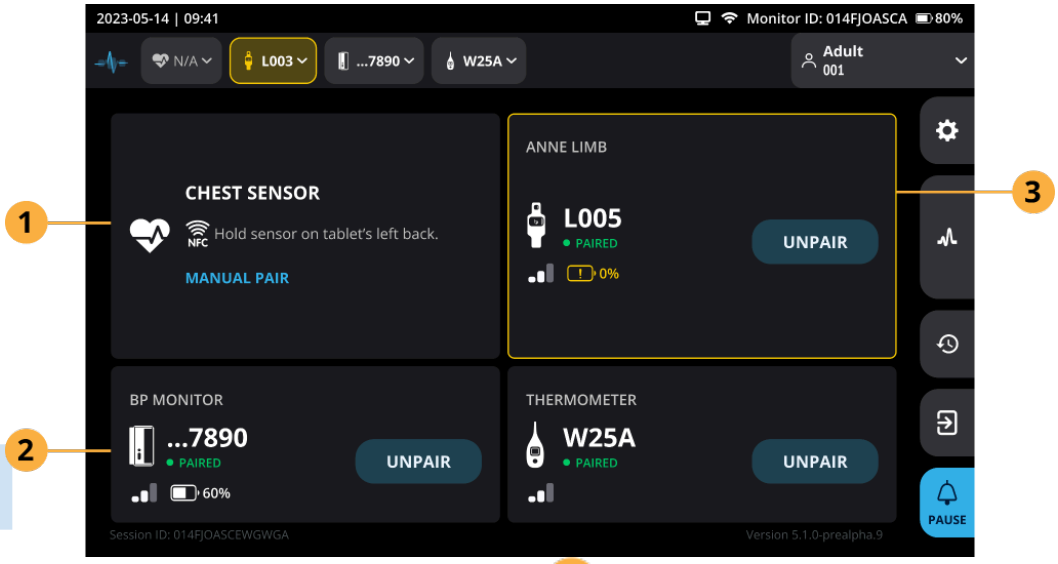
Table 4: Side bar

Button	Name	Purpose	Destination
	Settings	Update vitals settings including alarm limits and alarm control. Refer to Section 10	
	Vitals	See real time waveforms, real time vitals, and/or spot check vitals. Refer to Section 7	
	Sensors	Pair/unpair sensor(s). Check sensor status details. Refer to Section 6	

	History	See vital, alarm, and alarm settings history. Refer to Section 8	
	Stop session	Stop session for the patient and clear data. Refer to Section 11	
	Audio pause	Pause all physiological and technical alarms. Refer to Section 9.3	

4.3 Sensors Dashboard

① Unpaired status
② Paired status
③ Technical alarm status



4.4 Vitals Dashboard

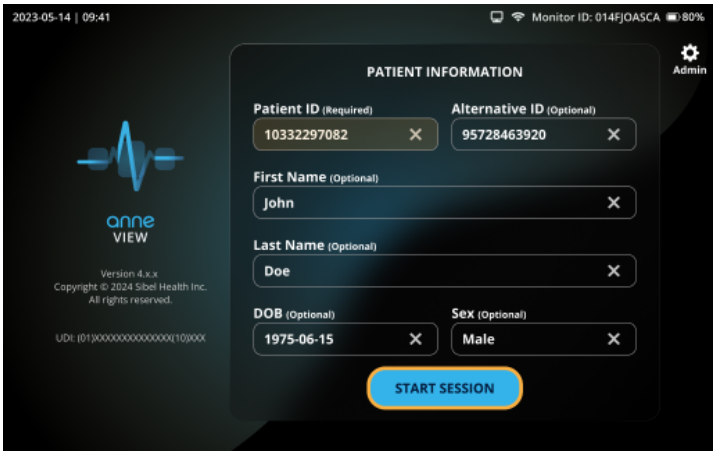
① Realtime waveform
② Realtime vitals
③ Spot check vitals

Section 5. Patient Admission

5.1 Patient Info Entry

Step 1

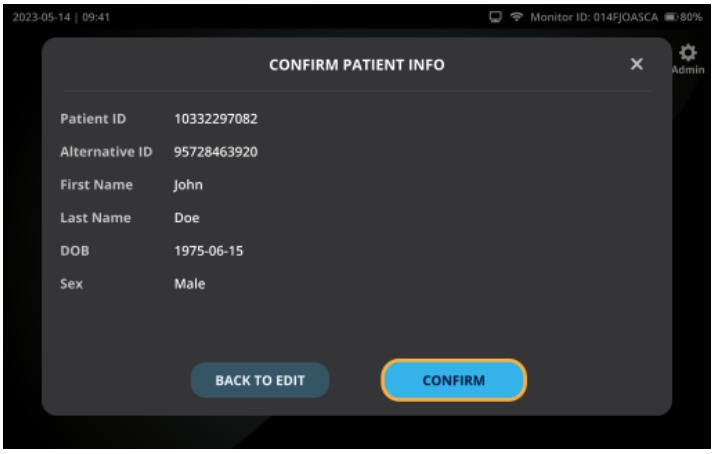
Input the patient's information. Select the "START SESSION" button to start the session.



- Patient ID (Required): Enter the unique patient identifier assigned in the EHR system. Use letters and numbers only.
- Alternative ID (Optional): Enter an additional identifier used for patient matching when a secondary ID is available. Use letters and numbers only.
- First and last name (Optional): Enter the patient's name, if available.
- DOB (Optional): Select the patient's date of birth.
- Sex (Optional): Select male, female, other, or unknown.

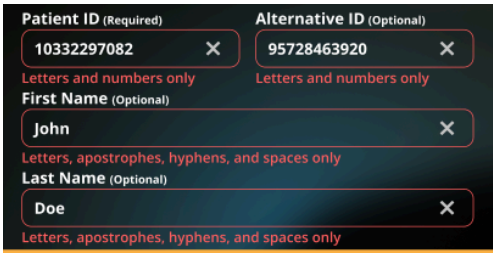
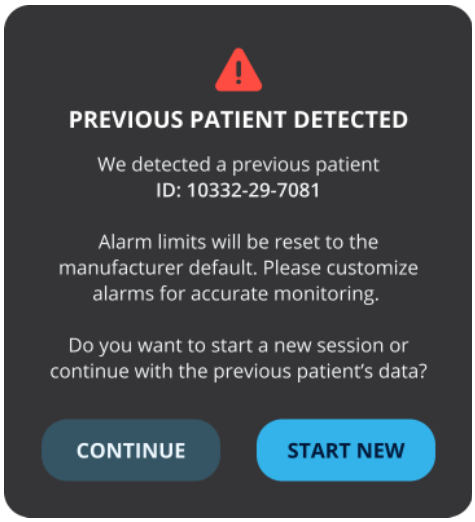
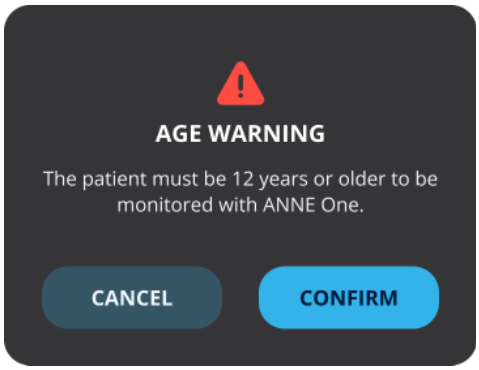
Step 2

Review the patient's information and select the "CONFIRM" button.



5.2 Error Handling

Table 5: Patient admission error handling

UI	Description	Solution
	Patient information input error	• Patient ID, Alternative ID: Letters and numbers only • First name and last name: Letters, apostrophes, hyphens, and spaces only
	If the application relaunches after 30 seconds, a popup will show to indicate the previous patient monitoring session has been detected..	Select "START NEW" to start a new session or select "CONTINUE" to continue with the previous patient's data. Alarm limits will be reset to the manufacturer default if the user starts a new patient. Please customize alarms for accurate monitoring.
	Age warning	The patient must be 12 years or older to be monitored with ANNE One.

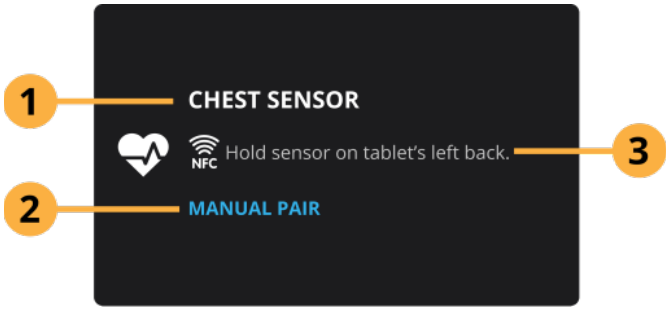
Section 6. Sensor Pairing

6.1 Sensors Dashboard User Interface

The Anne View application Sensors Dashboard displays a summary status of all sensors for a single patient in which the Anne Tablet is assigned. The Sensors page is the default screen shown after patient admission. To return to this page later, tap the  button on the left sidebar.

6.1.1 Before Sensor Pairing

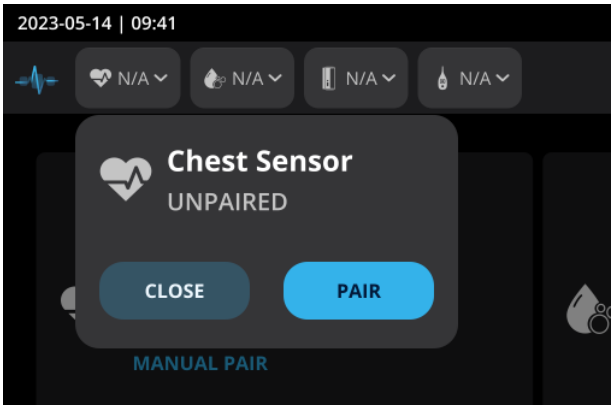
6.1.1.1 Sensor Card Overview



① Sensor type
② Manual pair button
③ NFC instruction

6.1.1.2 Sensor Details

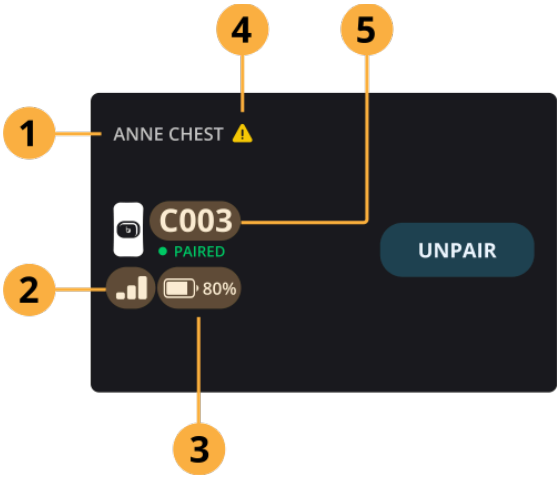
You can pair sensor(s) through the top bar by selecting each type of sensor. A dropdown including detailed sensor information and action buttons will show.



- To close the dropdown, select “CLOSE”.
- To pair the sensor, select “PAIR”.

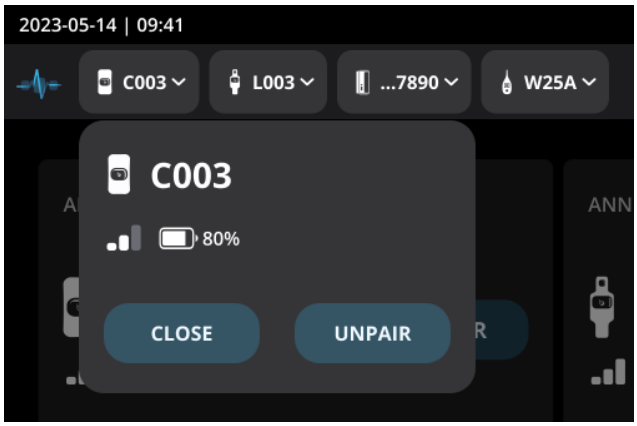
6.1.2 After Sensor Pairing

6.1.2.1 Sensor Card Overview



① Sensor type
② Sensor’s signal strength
③ Sensor’s battery level
④ Sensor expiration alert
⑤ Sensor ID

6.1.2.2 Sensor Details



You can unpair sensor(s) through the top bar by selecting each type of sensor.

- To close the dropdown, select “CLOSE”.
- To unpair the sensor, select “UNPAIR”.
  See Section 11.1 for detailed instructions.

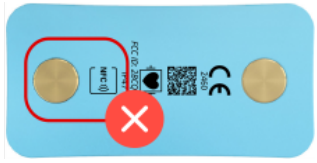
‘

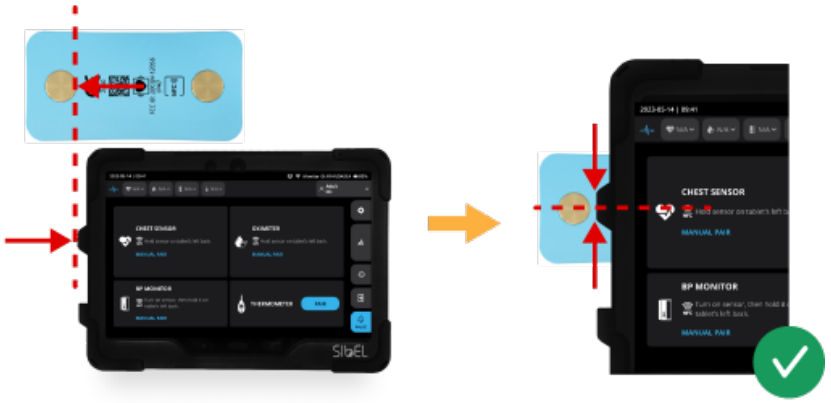
6.2 NFC Sensor Pairing

6.2.1 NFC Sensor Positioning

Anne Chest

Align the edge of the left electrode with the tablet notch. Align the center of the sensor with the tablet notch and tap the sensor against the back of the tablet.





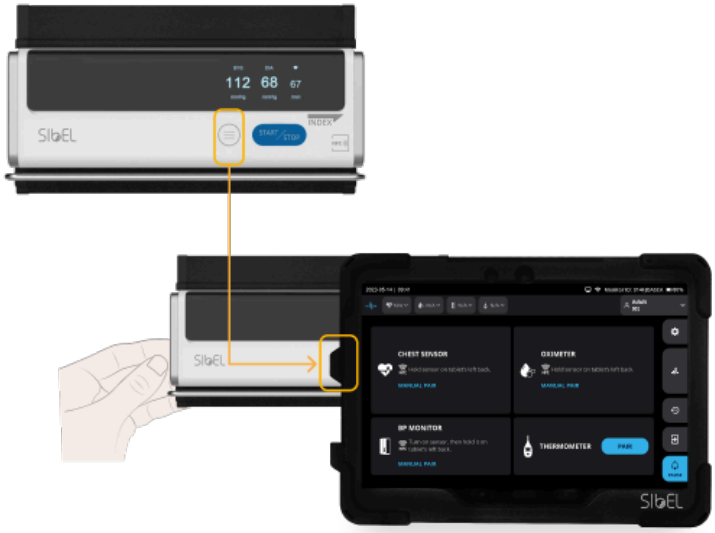
Anne Limb

Tap and hold Anne Limb near the tablet to NFC pair following the illustration on the right. Ensure the sensor’s orientation is correct.

BP Monitor

Refer to *Sibel/Viatom BP Monitor User Manual* and Sibel/*Viatom BP Monitor Quick Guide* to see more details or perform the tasks below:

- Sensor specification
- Sensor application to the patient's body

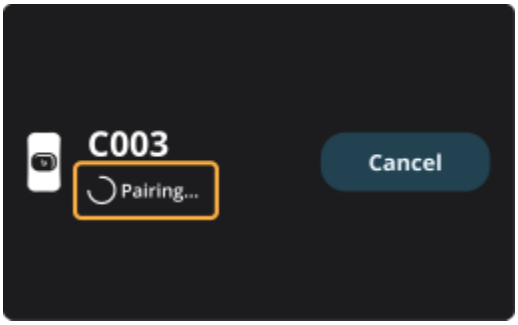


6.2.2 NFC Sensor Pairing Flow

Note:
When pairing a new sensor that has not been paired with the tablet before, a Bluetooth pairing request appears. Select Pair to continue. Selecting Cancel or not selecting Pair will result in pairing failure.

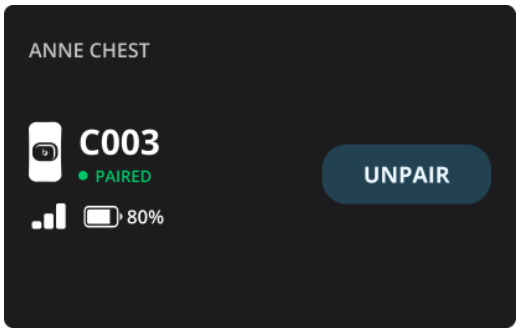
Step 1

After the tablet detects the sensor, "Pairing..." will display on the dashboard under the sensor ID.



Step 2

After pairing successfully, the dashboard will update with the paired sensor and its information, such as sensor ID, battery level, signal, etc.

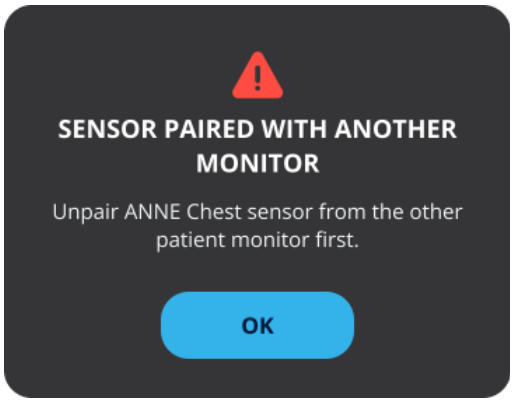
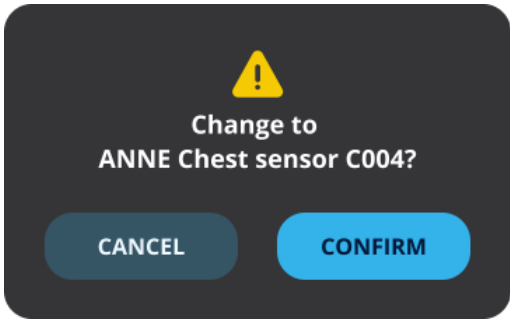
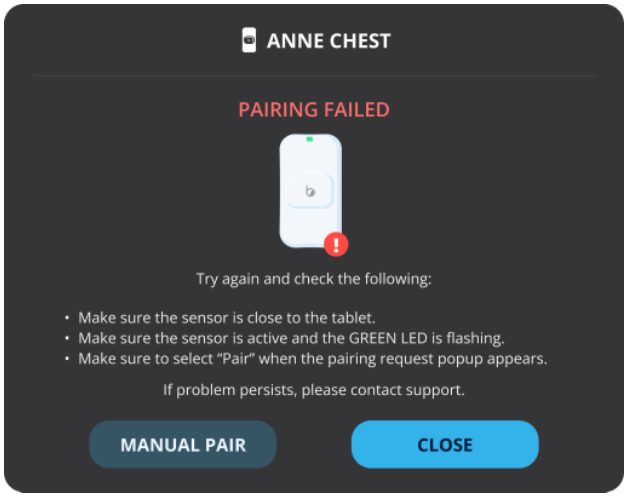


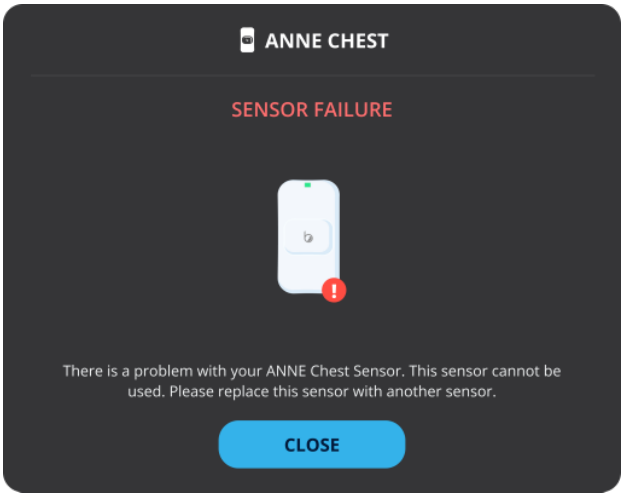
Step 3

To see the waveform and vital signs, press the "VITALS" button on the sidebar to see the data representation from the paired sensor.

6.2.3 NFC Pairing Error Handling

Table 6: NFC pairing error handling

UI	Description	Solution
	The sensor is already paired with another monitor.	Please unpair from the other patient monitor first.
	The patient monitor already has the same type of sensor paired.	Select “CONFIRM” to replace it with the newly detected sensor, or “CANCEL” to keep the current one.
	Pairing failed.	• Make sure the sensor is close to the tablet. • Make sure the sensor is active and the GREEN LED is flashing. • Make sure to select “Pair” when the pairing request popup appears. If the problem persists, please contact support.

	Sensor failure. This sensor cannot be used.	Please replace this sensor with another sensor.

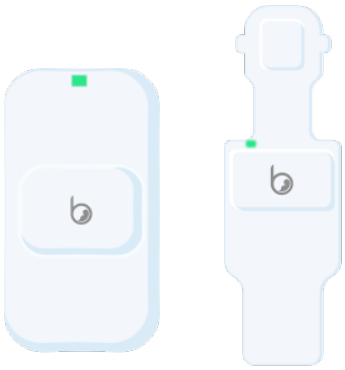
6.3 Bluetooth Sensor Pairing

6.3.1 Sensor Preparation Before Bluetooth Pairing

6.3.1.1 ANNE Chest & ANNE Limb

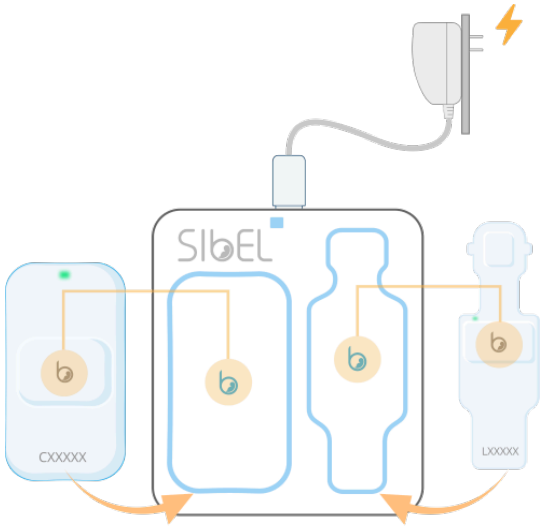
Step 1

Check if the sensors are ready. Ready-to-use Anne Chest and Limb sensors should show a short green LED blink every 3 seconds.



Step 2

If the sensors do not show any LED, charge them to activate them. To maximize sensor usage, use fully charged sensors whenever possible. A full charge takes about 5 hours. When fully charged, the sensor will show a solid green LED while on the charger.



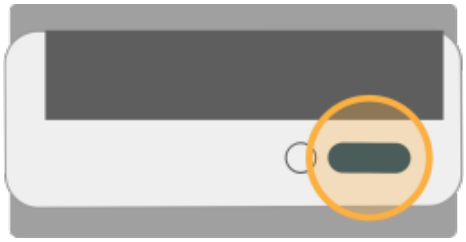
6.3.1.2 BP Monitor

Step 1

Fold back the cuff to locate the sensor ID beneath the barcode. The last 4 characters will be used for pairing.

Step 2

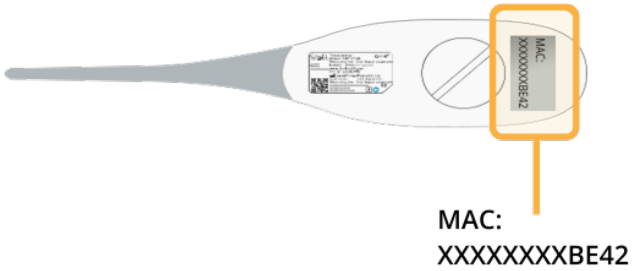
Turn on the device by pressing the power button on the front.



6.3.1.3 Thermometer

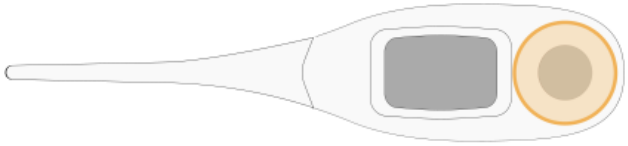
Step 1

Locate the sensor ID on the back of the ANNE Thermometer.



Step 2

Turn on the device by pressing the power button on the front.



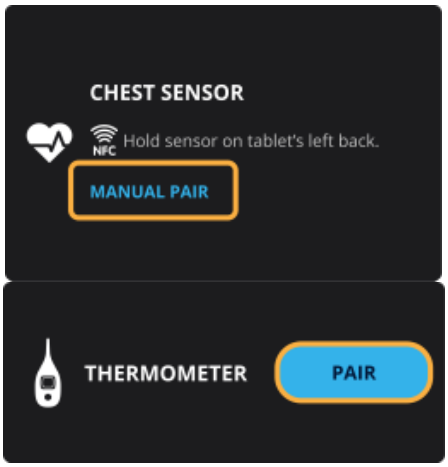
Note: The ANNE Thermometer is not sold in all countries. Contact your local sales representative for availability.

6.3.2 Bluetooth Sensor Pairing Flow

Note:
When pairing a new sensor that has not been paired with the tablet before, a Bluetooth pairing request appears. Select Pair to continue. Selecting Cancel or not selecting Pair will result in pairing failure.

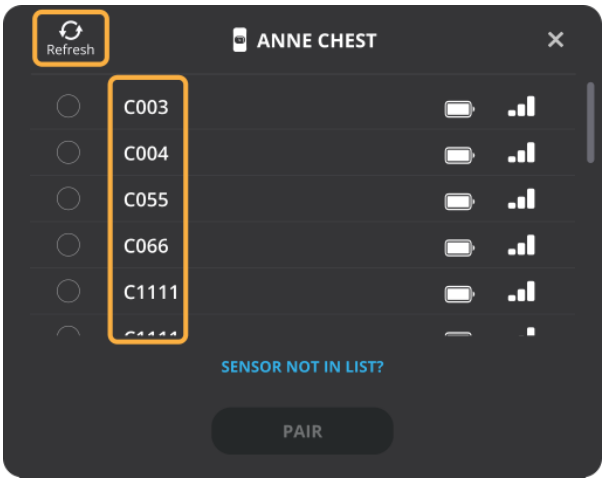
Step 1

Select the “MANUAL PAIR” or “PAIR” button in the sensor card to start pairing.



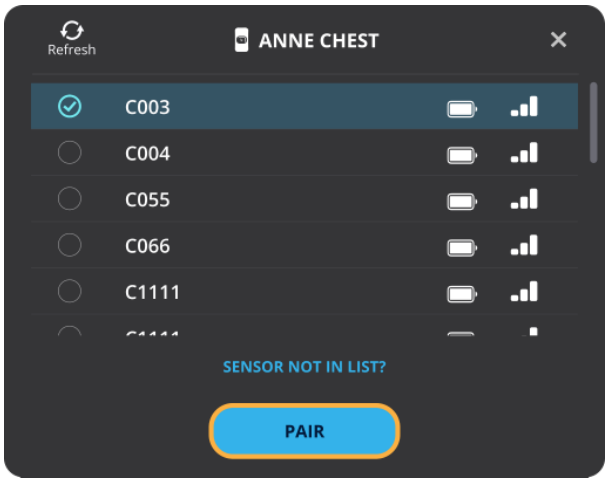
Step 2

A popup window will show the advertising sensors near the tablet. The sensor ID is located on the back of the sensor. If the sensor does not appear in the list of advertising sensors then refer to Section 6.3.1 to ensure the sensor is activated and refresh the list.



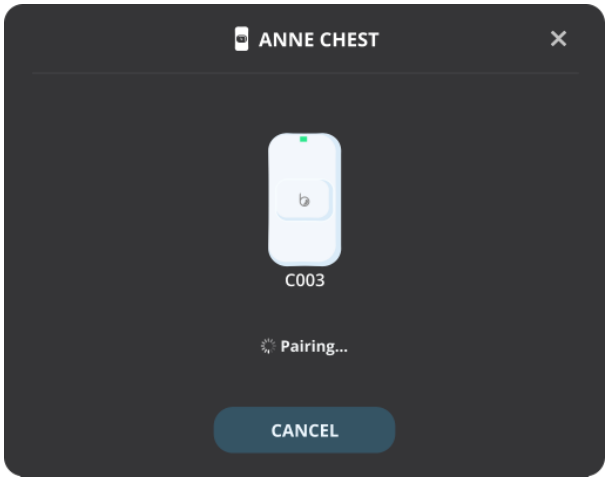
Step 3

After selecting the desired sensor, the “PAIR” button will be active (button color changes to blue). Select the “PAIR” button in the pop-up window to pair with the sensor.



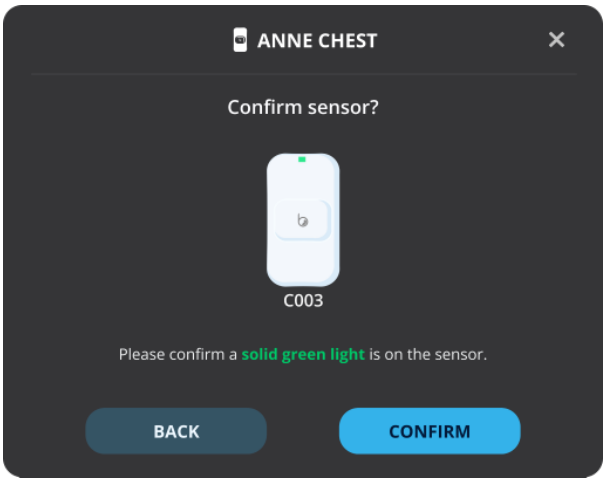
Step 4

After selecting “PAIR”, the system will start pairing with the sensor and present a loading screen with the name of the sensor and the pairing status.



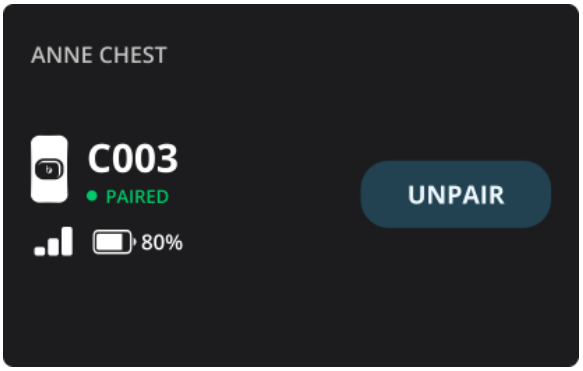
Step 5

Please confirm a solid green light is on the sensor.
(Applies ONLY to ANNE Chest and ANNE Limb Sensor)



Step 6

After pairing successfully, the dashboard will update with the paired sensor and its information, such as sensor ID, battery level, and signal.

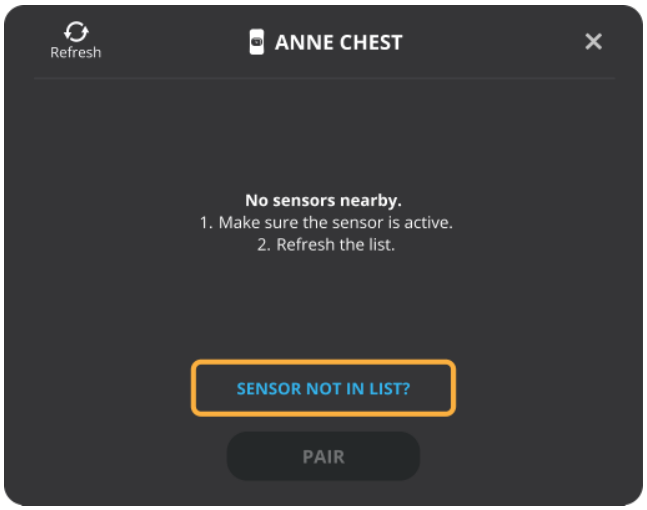


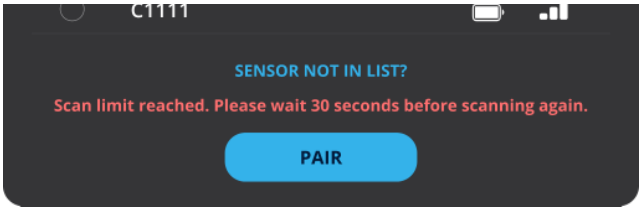
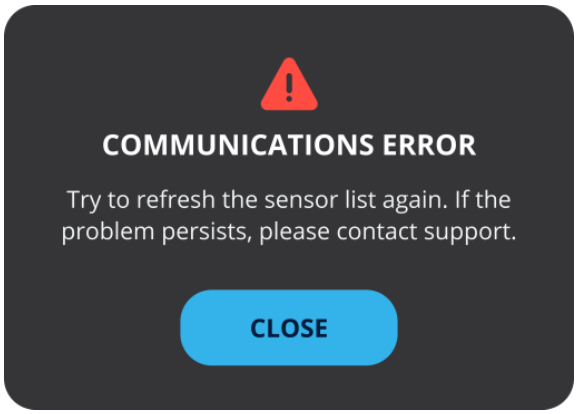
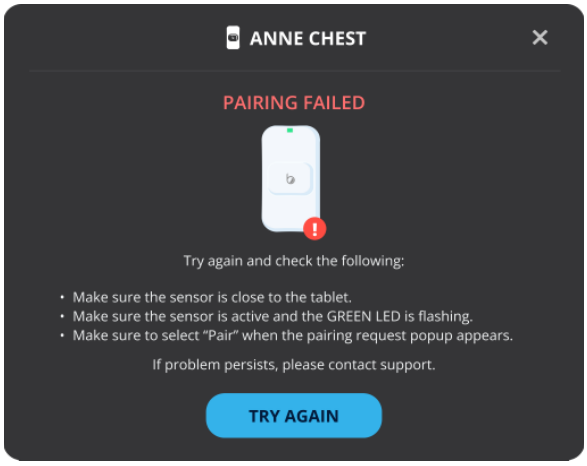
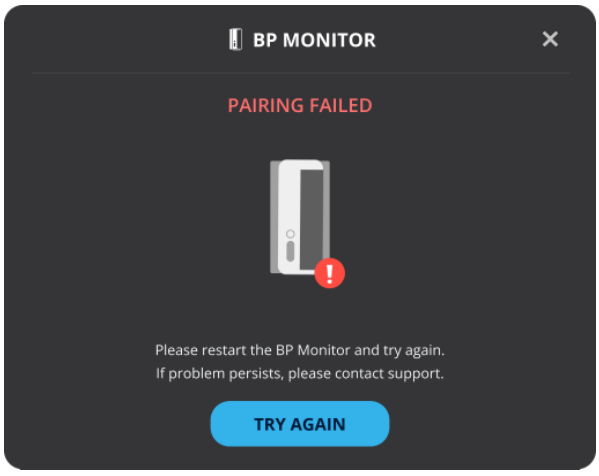
Step 7

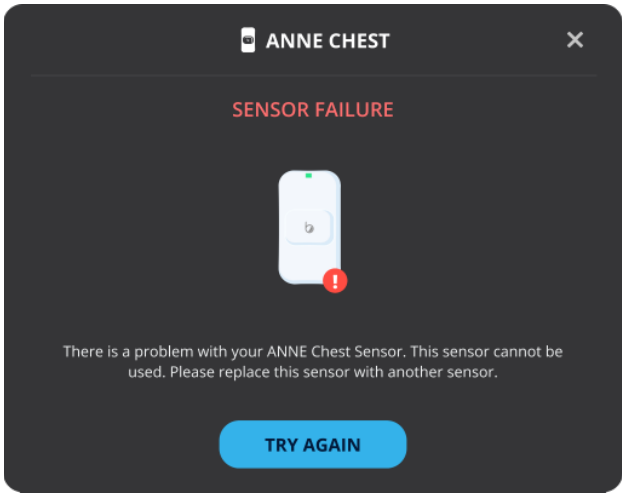
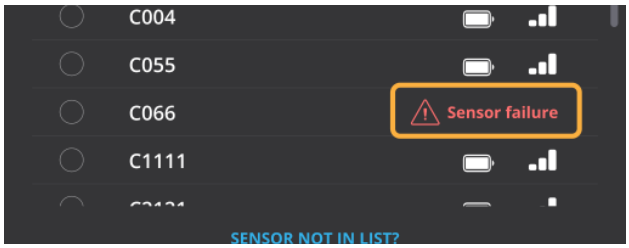
If you want to see the waveform and vital signs, press the "VITALS" button on the sidebar to see the data representation from the paired sensor.

6.3.3 Bluetooth Pairing Error Handling

Table 7: Bluetooth pairing error handling

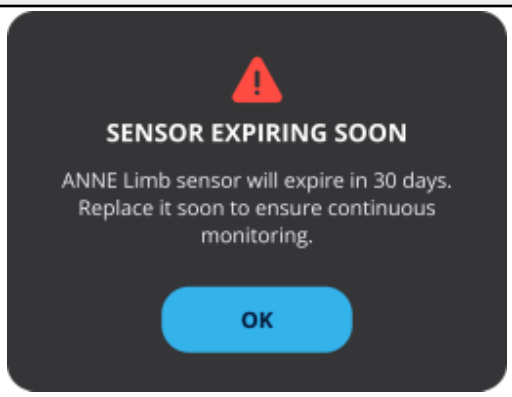
	UI	Description	Solution
ANNE Chest ANNE Limb BP Monitor Thermometer		Sensor not in the list.	1. Check that the sensor is powered on and ready to pair by looking for the blinking green LED on the top of the sensor. If it is not blinking green every 3 seconds, then place the sensor on the wireless charger to wake it up. 2. Bring the tablet close to the sensor and make sure there are no obstructions between the tablet and the sensor. 3. Use the refresh icon on the top left corner to refresh the list. 4. Scroll the list up and down to double-check if it is in the list. If the sensor still does not show up after trying STEP 1 - 4, contact support.

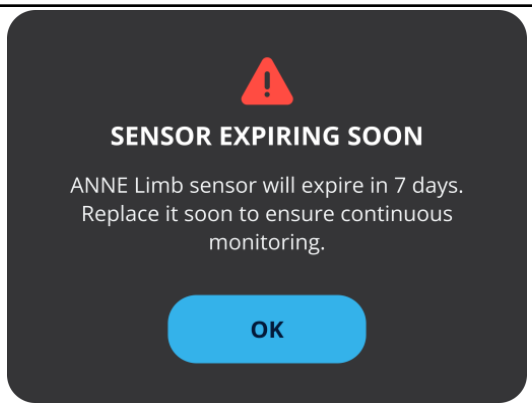
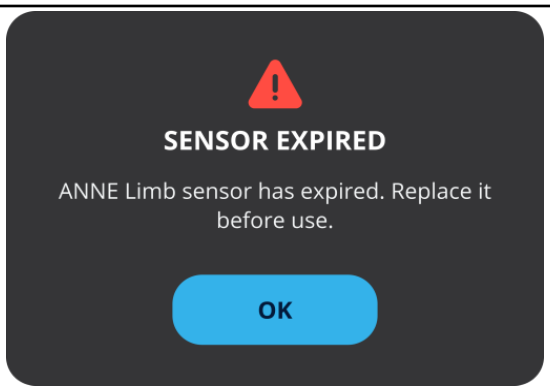
		Scan limit reached.	Please wait 30 seconds before scanning again.
		Communications error.	Try to refresh the sensor list again. If the problem persists, please contact support.
ANNE Chest ANNE Limb		Pairing failed.	1. Try again - Tap the button to try to pair the sensor again. 2. If it continues to fail, please replace the sensor and pair with the replacement sensor using the instructions in Section 6.2.1 and 6.3.2.
BP Monitor Thermometer			Please restart the BP Monitor and try again. If the problem persists, please contact support.

ANNE Chest ANNE Limb	 	Sensor failure. This sensor cannot be used.	Notify your customer support representative to replace the failed sensor.

6.4 Sensor Expiration Error Handling

Table 8: Sensor expiration error handling

UI	Description	Solution
	The sensor will reach the end of its useful service life in 30 days. Once it reaches the end of its useful service life and can no longer be used for monitoring.	Replace it soon to ensure continuous monitoring.

	The sensor will reach the end of its useful service life in 7 days. Once it reaches the end of its useful service life and can no longer be used for monitoring.	Replace it soon to ensure continuous monitoring.
	The sensor has expired.	Replace it before use.

Section 7. Vitals Dashboard

7.1 Displayed Data Parameters

- **Electrocardiogram (ECG):** Displays the electrical signal of the heartbeat as a waveform.
    - The single lead of ECG displayed is intended for heart rate monitoring and is not intended for arrhythmia or diagnostic ECG interpretation.
    - The ECG wave may resemble aVR, but differs in morphology due to electrode placement and signal processing.
- **Heart Rate (HR):** Displays the detected heart rate, measured in beats per minute (BPM).
- **Plethysmograph (PLETH):** Displays the visual indication of the patient's pulse as a waveform.
- **Functional Oxygen Saturation (SpO2):** Displays the percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin, measured in percentage (%).
- **Pulse Rate (PR):** Displays the detected pulsations per minute, measured in beats per minute (BPM).
- **Perfusion Index (PI):** Indicates pulse strength at the sensor site, measured in percentage.
- **Respiratory Rate (RR):** Displays breathing rate, measured in respirations per minute (rpm).
- **Fall Detection:** Indicates whether a fall has been detected.
    - Fall Detection can be reset by selecting the "FALLS" area.
- **Body Position**: Displays the body position of the patient and the amount of time that they have been in that position.
- **Temperature:**
    - Chest skin temperature: Skin temperature measured in Fahrenheit (°F) or Celsius (°C).
    - Thermometer: Body temperature measured in Fahrenheit (°F) or Celsius (°C).
- **Noninvasive Blood Pressure (NIBP):** Displays blood pressure (systolic/diastolic), measured in millimeters of mercury (mmHg).
- **Pulse rate from BP Monitor (PULSE):** Displays pulse rate during blood pressure measurement, measured in beats per minute (BPM).

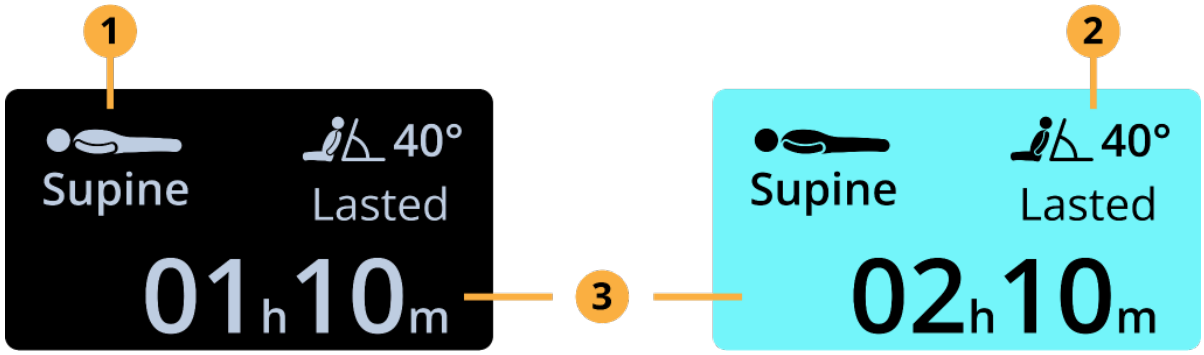
Note: ANNE View will display a question mark (-?-) instead of a value when any of the data parameters are outside of their specified ranges or when data quality is poor.

7.2 ECG Scale Adjustment

Press the ECG scale button to switch the ECG scale to 5mm/mV, 10mm/mV, 20mm/mV, or 40mm/mV.

7.3 Body Position

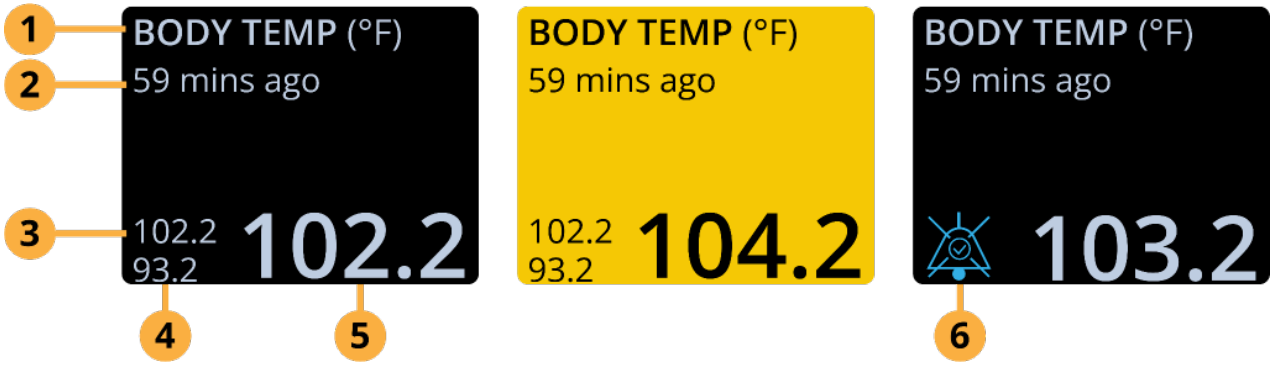
The body position parameter reflects the patient's body position and the amount of time they have been in that position. If the patient changes the position, the icon and timer will be automatically refreshed.



Normal state, Alarm state overview

① Body position: Supine position, Prone position, Upright position, Right lateral position, Left lateral position
② Body angle
③ Body position timer: Measured in hh:mm

7.4 Vitals



Normal state, Alarm state, Acknowledgement state overview

① Vital name
② Last measurement timestamp
③ Upper limits
④ Lower limits
⑤ Vital value
⑥ Acknowledgement icon

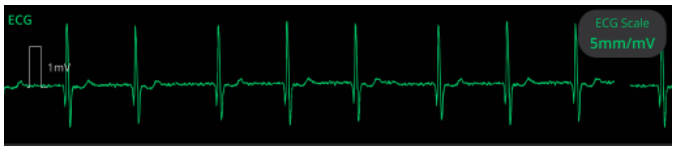
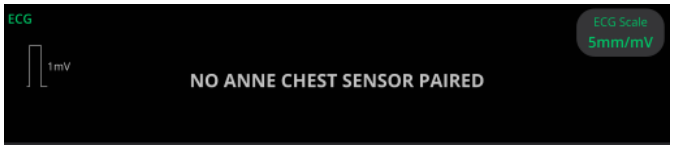
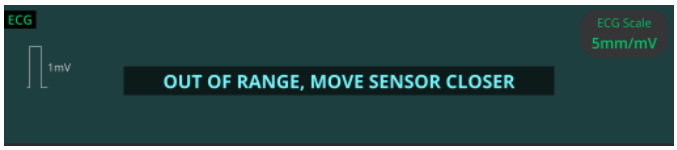
Table 9: Vitals

Vitals	Unit	Measured by	Note
Heart rate	Beats per minute	ANNE Chest Sensor	
Respiratory rate	Breaths per minute		
Fall detection	N/A		If a fall is detected, the “FALL” state will be changed into “Detected”.
Body position	N/A		Patient’s body position and the amount of time they have been in that position.
Body Angle	Degrees		Patient’s upright torso angle.
Oxygen saturation	Percentage	ANNE Limb Sensor	SpO2 data from ANNE Limb should not be used while the patient is ambulatory.
Pulse rate	Beats per minute		Pulse rate data from ANNE Limb should not be used while the patient is ambulatory.
Perfusion index	Percentage		
Skin temperature	°C or °F	ANNE Chest Sensor	There is a 30-minute delay for skin temperature alarm. The display units (°C or °F) can be changed under the admin settings.
Body temperature	°C or °F	Thermometer	Display time since last reading. The display units (°C or °F) can be changed under the admin settings.
Non-invasive blood pressure (Systolic and Diastolic)	mmHg	BP Monitor	Displays time since last reading.
Pulse	Beats per minute		Displays time since last reading.

7.5 Waveform Status

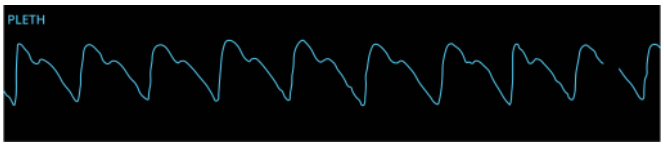
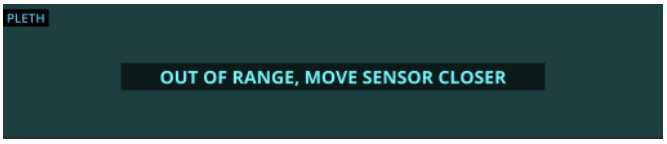
ECG (Electrocardiogram): Measured by ANNE Chest Sensor

Table 10: Waveform status - Anne Chest - ECG

Electrocardiogram	Status	Recommended user action
 **Note**: The default ECG scale is 10mm/mV and the sweep speed is 25 mm/s +/-10%.	ECG Active	N/A
	No ANNE Chest Sensor paired	Pair the ANNE Chest Sensor.
	ANNE Chest Sensor is not detecting good contact with the skin.	The sensor is not detecting good contact with the skin. 1. Adjust the sensor placement. 2. Replace the sensor adhesive. 3. Switch the sensor.
	ANNE Chest Sensor is not detected nearby. Data will not be available.	Bring the sensor closer to the tablet. The application will automatically attempt to reconnect to the sensor after the signal is detected.
	ANNE Chest Sensor has reported a sensor failure. The sensor should be replaced immediately.	Switch the sensor.
	ECG Loading	The ECG waveform displays when data becomes available.

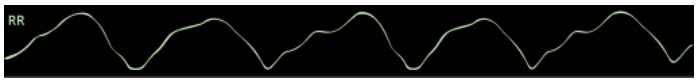
PLETH (Photoplethysmogram): Measured by ANNE Limb Sensor

Table 11: Waveform status - Anne Limb - PLETH

Photoplethysmogram	Status	Recommended user action
	PLETH Active	N/A
	No ANNE Limb Sensor paired.	Pair the ANNE Limb Sensor.
	ANNE Limb Sensor in use is not detecting good contact with the skin.	If an ANNE Limb Sensor is in use, the sensor is not detecting good contact with the skin. 1. Adjust the sensor placement. 2. Replace the sensor adhesive. 3. Switch the sensor.
	ANNE Limb Sensor is not detected nearby. Data will not be available.	Bring the sensor closer to the tablet. The application will automatically attempt to reconnect to the sensor after the signal is detected.
	ANNE Limb Sensor has reported a sensor failure. The sensor should be replaced immediately.	Switch the sensor.
	PLETH Active	See the PLETH waveform as soon as data is available.

RR (Respiratory rate): Measured by ANNE Chest Sensor

Table 12: Waveform status - Anne Chest - RR

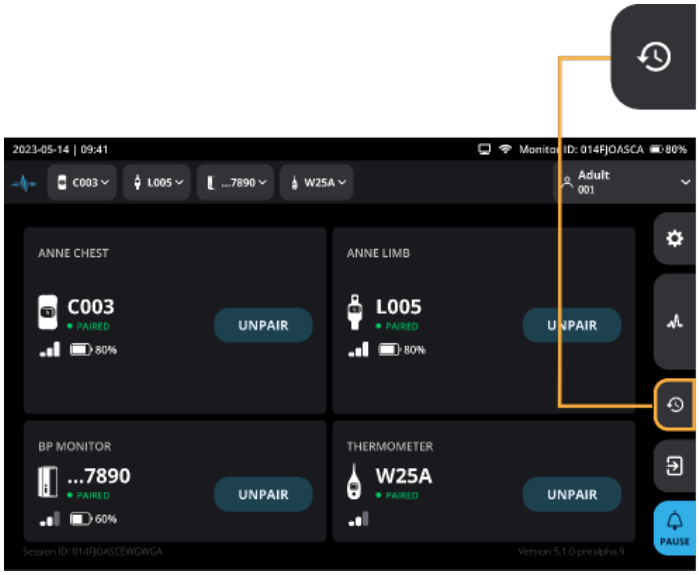
Respiratory rate	Status	Recommended user action
	RR Active	N/A
	No ANNE Chest Sensor paired	Pair the ANNE Chest Sensor.
	ANNE Chest Sensor is not detecting good contact with the skin.	The sensor is not detecting good contact with the skin. 1. Adjust the sensor placement. 2. Replace the sensor adhesive. 3. Switch the sensor.
	ANNE Chest Sensor is not detected nearby. Data sync will not be available.	Bring the sensor closer to the tablet. The application will automatically attempt to reconnect to the sensor after the signal is detected.
	ANNE Chest Sensor has reported a sensor failure. The sensor should be replaced immediately.	Switch the sensor.
	RR Loading	See the RR waveform as soon as data is available.

Section 8. History

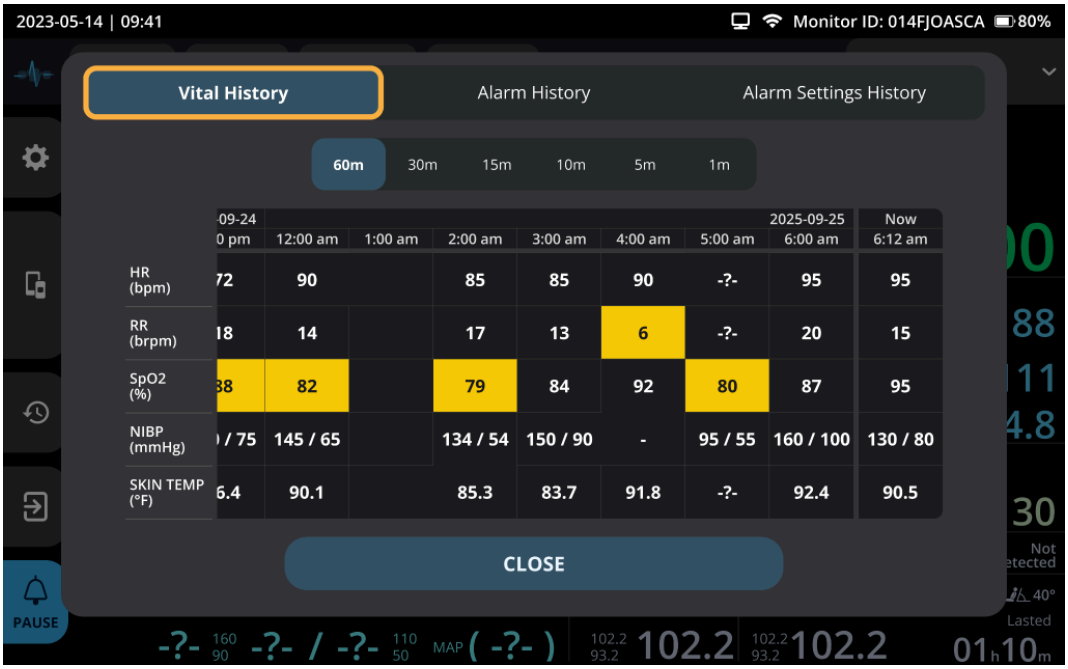
Press the  button from the sidebar to view the history of sensor monitoring.

History is available only during an active monitoring session. Data is not retained after the session ends. All local patient data is deleted when the user ends the active session. Use this feature to review earlier patient data within the current session.

If the patient moves out of range during monitoring, vital signs data will resume and backfill once the connection to the ANNE View Patient Monitor is restored. Sensor-derived alarms during this out-of-range period are not recorded.



8.1 Vital History



The *Vital History* tab displays a time-based summary of recorded physiological data for the monitoring session. The table is organized by parameter rows and time columns, with the rightmost column showing the time when the popup was opened. This column always appears last and does not update in real time.

Each cell represents the data state at a specific point in time:

Table 13: Vital history data

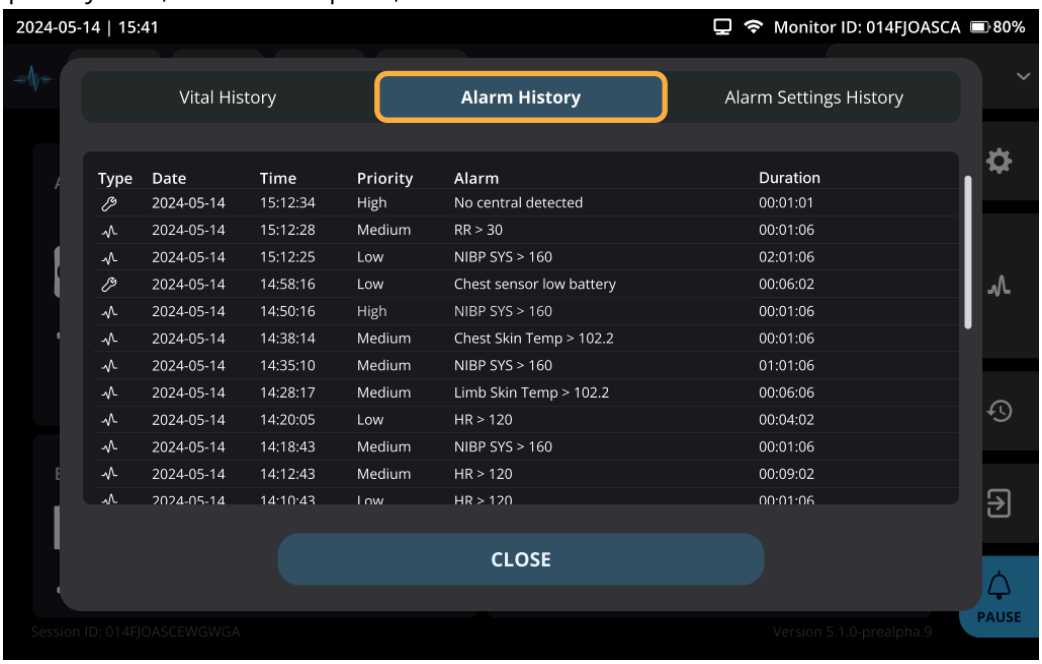
UI	Name	Description
	Empty cell	No sensor was paired at that time, and no data is available.
80	Numeric value highlighted in yellow	Data outside of set alarm limits in the interval.
83.7	Numeric value	Continuous values show the first reading within the last minute. Spot-check values show the most recent measurement taken within the interval.
-?-	“–?–” symbol	A sensor was paired, but data could not be obtained at that time (for example, if the sensor was out of range, lead off, poor skin contact etc.).

	“–” symbol	A sensor was paired, but no measurement was recorded.

Note: If missing data becomes available, it will appear after you close and reopen the popup.

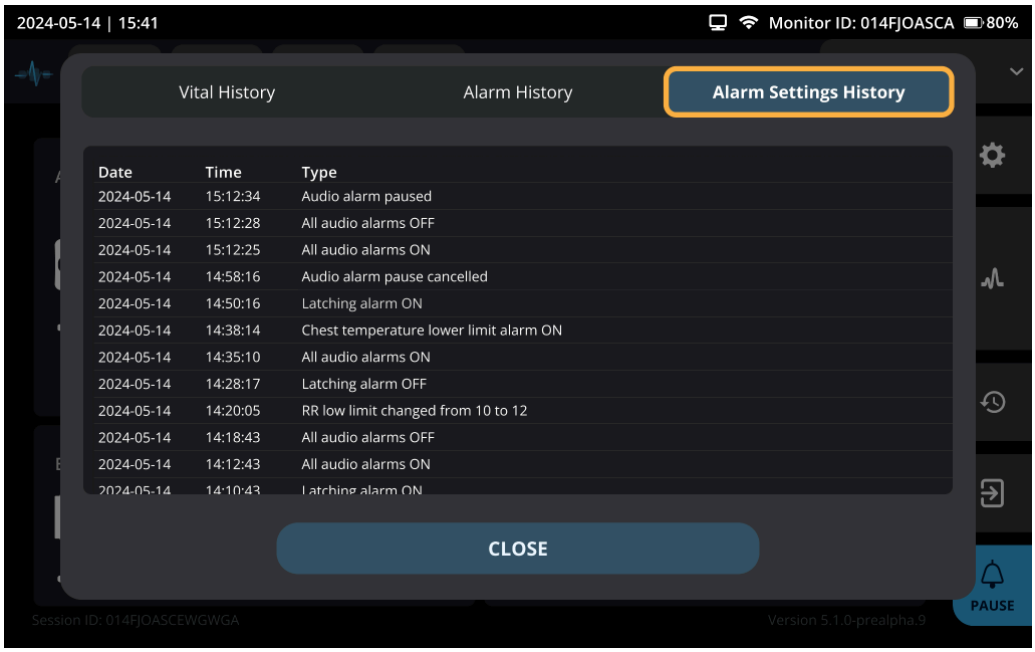
8.2 Alarm History

The *Alarm History* tab displays a list of all alarms that occurred during the monitoring session, including the alarm type, date, time, priority level, alarm description, and duration of the alarm.



8.3 Alarm Settings History

The *Alarm Settings History* tab displays a list of all alarm settings changes made during the monitoring session. The types of alarm settings include audio alarm actions (ON, OFF, paused), alarm acknowledgement, individual alarm controls (such as latching or body position alarms), and any adjustments to high or low alarm limits. This view helps track how alarm behaviors and limits were modified over time.



Section 9. Alarm Handling

The ANNE View application uses both audible and visual alarms to signal various alarm conditions, including physiological alarms and technical alarms. These alarm conditions are categorized into medium and low priorities, each with unique audible and visual alarm signals. The color of an alarm message, yellow and cyan, corresponds to the priority of the associated alarm condition. Alarm messages are displayed within the alarm dropdowns on the top navigation bar, and active alarm conditions are highlighted in the parameter boxes. You can modify the high and low alarm limits for a patient, enable/pause audio alarm signals, or turn on/off latching alarms, turn on/off audio alarm signals.

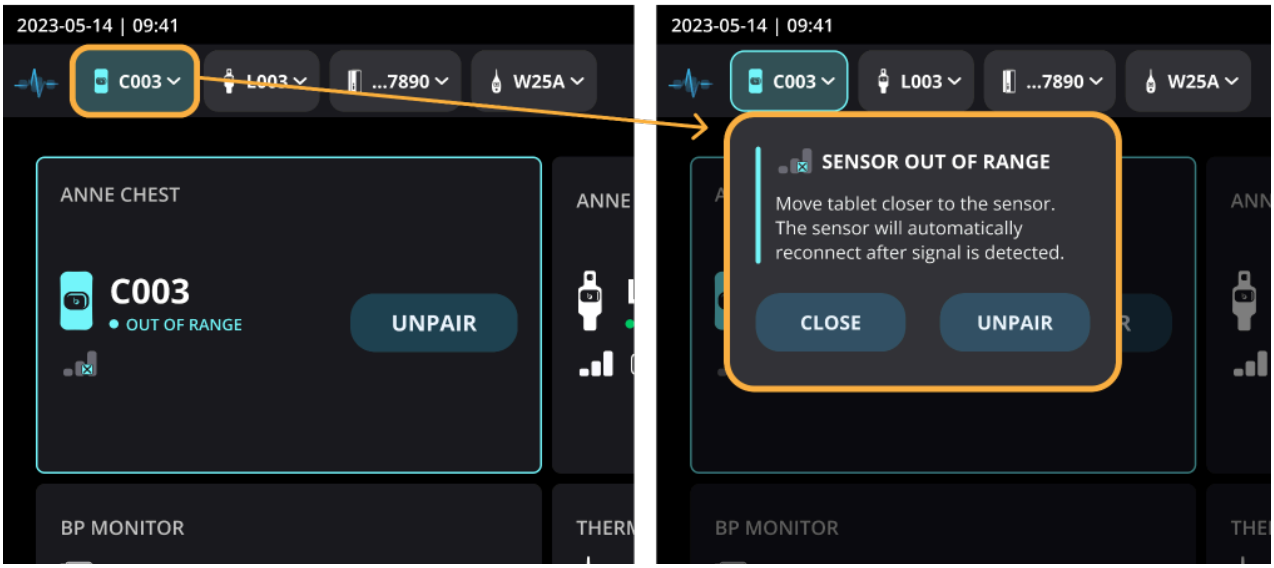
Note:

- The typical operator's position is in front of the monitor. The visual alarm signal indicating the specific alarm condition and its priority are legible from the operator’s position or at least 1 meter from the monitor.
- Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.
- To ensure the alarm system is functioning normally, periodically generate lead off or poor skin contact technical alarms by removing the sensor from the patient prior to halting the monitoring session. Verify that an appropriate alarm message is presented and an audible tone is heard.

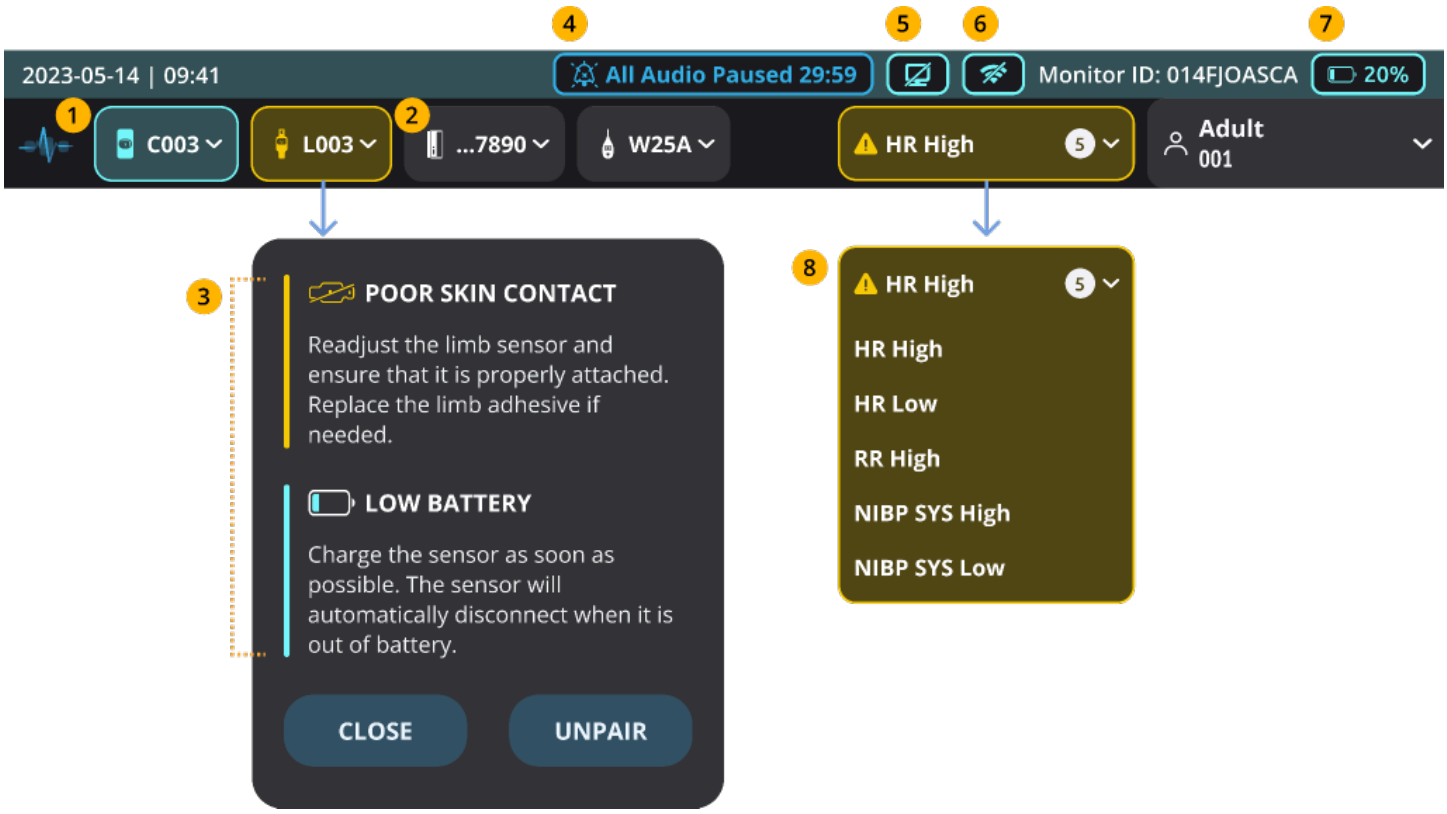
9.1 Interpretation of Alarm UI on Dashboard

Section 9.1 shows the user interface design of the error messages and the methods of recognition. Each error has a specific icon to indicate different meanings. Being familiar with the icon glossary table in Section 9.2 with the descriptions and recommended user action is necessary to quickly solve the problem for future use.

Note: When the system detects issues that may affect the quality of the data, the application may temporarily halt displaying the vitals data. Resolving the error states as soon as possible will aid in restoring the data quality and allow you to resume the use of the system.



Alarm states on dashboard screen



Alarm handling user interface overview

① If the frame color is CYAN: At least one of the error severities is LOW.

② If the frame color is YELLOW: The highest error severity is MEDIUM.

③ Technical alarm name & solution description: The color of the alarm dropdown depends on the highest priority alarm. Alarm message's order is ranked by the priority level from high to low. Follow the instructions to solve the errors.

④ Audio Alarm Status: Audio alarm of all physiological alarms and technical alarms is switched from ON to PAUSED for 30 minutes.

⑤ No Central: Displays the technical alarm icon when the target server is not connected.

⑥ No Network: Displays the technical alarm icon when network (Wi-Fi) is not available.

⑦ Low Battery: Displays technical alarm when the patient monitor battery is less than 20%.

⑧ Physiological alarm name & solution description: Alarm message's order is ranked by the priority level from high to low. Check the patient's condition. Check if the alarm limits are correct.

9.2 Alarm Glossary

Note:

- When Alarm Validation is enabled, the Patient Monitor confirms that an alarm limit has been violated for 95% of the time over a 15-minute validation period before annunciating an alarm. If there are enough invalid samples, the validation period may extend up to 22.5 minutes.
- Alarm validation can be globally set up through Admin Settings. See 443-00005F ANNE View IT IFU.

9.2.1 Physiological Alarms

Table 14: Physiological alarms

Alarm name	Alarm description	Alarm Validation	Recommended User action	Priority
HR High	HR value is above the upper alarm limit.	Yes	Check the patient's condition. Check if the alarm limits are correct.	Medium
HR Low	HR value is below the lower alarm limit.	Yes	Check the patient's condition. Check if the alarm limits are correct.	Medium
RR High	RR value is above the upper alarm limit.	Yes	Check the patient's condition. Check if the alarm limits are correct.	Medium
RR Low	RR value is below the lower alarm limit.	Yes	Check the patient's condition. Check if the alarm limits are correct.	Medium
SpO2 High	SpO2 value is above the upper alarm limit.	Yes	Check the patient's condition. Check if the alarm limits are correct.	Medium
SpO2 Low	SpO2 value is below the lower alarm limit.	Yes	Check the patient's condition. Check if the alarm limits are correct.	Medium
PR High	PR value is above the upper alarm limit.	Yes	Check the patient's condition. Check if the alarm limits are correct.	Medium
PR Low	PR value is below the lower alarm limit.	Yes	Check the patient's condition. Check if the alarm limits are correct.	Medium

NIBP SYS High	NIBP SYS value is above the upper alarm limit.	No	Check the patient's condition. Check if the alarm limits are correct.	Medium
NIBP SYS Low	NIBP SYS value is below the lower alarm limit.	No	Check the patient's condition. Check if the alarm limits are correct.	Medium
NIBP DIA High	NIBP DIA value is above the upper alarm limit.	No	Check the patient's condition. Check if the alarm limits are correct.	Medium
NIBP DIA Low	NIBP DIA value is below the lower alarm limit.	No	Check the patient's condition. Check if the alarm limits are correct.	Medium
Body Temp High	Body Temp value is above the upper alarm limit.	No	Check the patient's condition. Check if the alarm limits are correct.	Medium
Body Temp Low	Body Temp value is below the lower alarm limit.	No	Check the patient's condition. Check if the alarm limits are correct.	Medium
Chest Skin Temp High	Chest Skin Temp value is above the upper alarm limit.	No	Check the patient's condition. Check if the alarm limits are correct.	Medium
Chest Skin Temp Low	Chest Skin Temp value is below the lower alarm limit.	No	Check the patient's condition. Check if the alarm limits are correct.	Medium
Fall Detected	A fall has been detected.	No	Check if the patient has fallen.	Medium
Body Position > 2 Hours	The patient has been in the current position for more than 2 hours.	No	Check the patient's condition.	Low

9.2.2 Technical Alarms

Table 15: Technical alarms

Sensor	Alarm name	Alarm description	Alarm Validation	Recommended user action	Priority
Anne Chest Anne Limb BP Monitor	Critical sensor battery	Battery of the sensor has fallen below 10%. There is less than one hour of battery life remaining on ANNE Chest Sensor and ANNE Limb Sensor.	No	Switch the sensor and put it on the charger.	Medium

Anne Chest Anne Limb	Sensor failure	Sensor has reported a sensor failure. The sensor should be replaced immediately.	No	1. Notify support and ask for a replacement sensor. 2. Select the “UNPAIR” button to unpair the failed sensor. 3. Take off the current sensor and replace it with a new sensor. (See Section 6.2 or 6.3) 4. Pair the replaced sensor through ANNE View App by selecting the “PAIR” Button. (See Section 6.1.1.2)	Medium
Anne Chest	Lead off	Sensor is not detecting good contact with the skin. The display will stop showing ECG waveform, RR waveform, heart rate (HR), and respiratory rate (RR) vital values while a lead-off alert is active.	Yes	1. Adjust the sensor placement. 2. Replace the sensor adhesive. 3. Switch the sensor.	Medium
Anne Limb	Poor skin contact	Sensor is not detecting good contact with the skin. The display will stop showing PLETH waveform, SpO2, PI, and PR vital values while a poor skin contact alert is active.	Yes	1. Adjust the sensor placement. 2. Replace the sensor adhesive. 3. Switch the sensor.	Medium
Anne Chest Anne Limb	Invalid HR, RR, SpO2, PI, PR	Invalid parameter	Yes	Check the patient's conditionand ensure the sensor is properly attached. Replace the sensor or adhesive if needed.	Medium

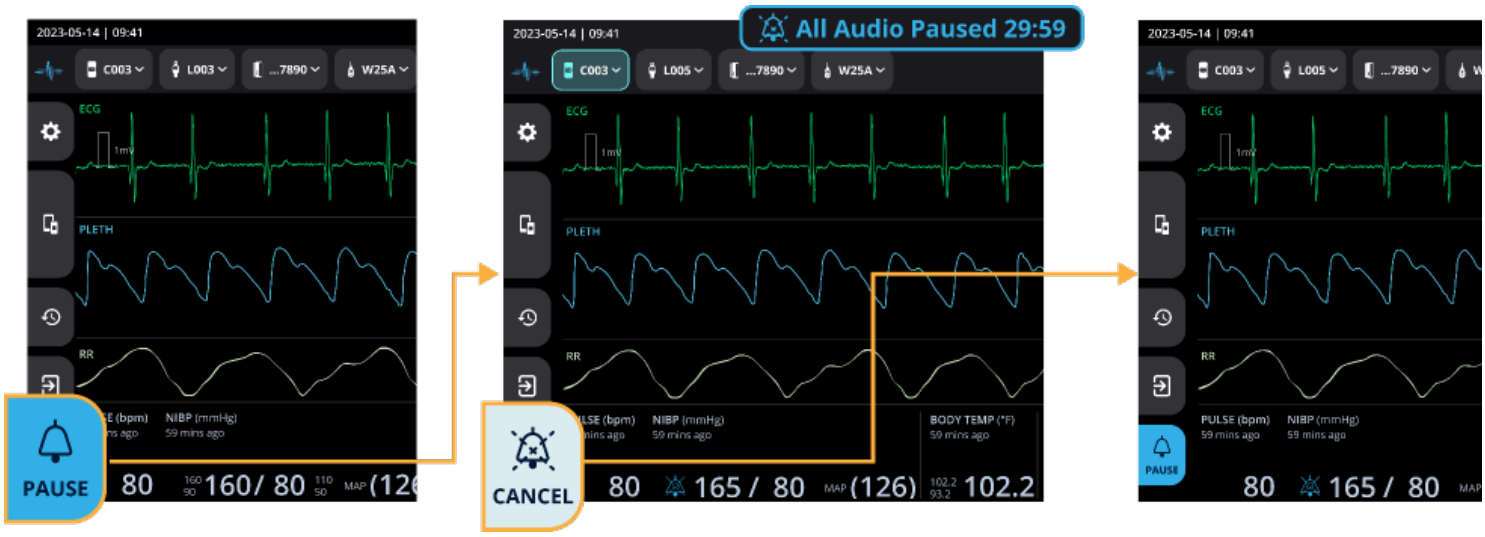
BP Monitor	Loose sleeve	If the BP2A sensor is not properly secured on the patient, the dropdown window will appear after tapping the corresponding sensor ID on the top bar.	No	Readjust the sensor and ensure that it is properly attached to the patient.	Low
BP Monitor	Movement detected	If movement is detected during the measuring process, the dropdown window will appear after tapping the corresponding sensor ID on the top bar.	No	Try again and ask the patient to remain still and not talk during the measurement.	Low
BP Monitor	Weak pulse	If there is any clothing that may be interfering with the BP monitor, the dropdown window will appear after tapping the corresponding sensor ID on the top bar.	No	Try again. Make sure to remove any clothing underneath the cuff area. Adjust the sensor location if needed.	Low
BP Monitor	Sensor failure	The BP2A device has a sensor failure.	No	Restart the sensor and try again. If the problem persists, contact support.	Low
Anne Chest Anne Limb BP Monitor	Low battery	Battery of the sensor has fallen below 20%. There are approximately five hours of battery life remaining on ANNE Chest Sensor. There is less than five hours of battery life remaining on ANNE Limb Sensor.	No	Switch the sensor and put it on the charger.	Low
Anne Chest Anne Limb	Sensor out of range	Sensor is not detected nearby. Data sync will not be available. The application will automatically attempt to reconnect to the sensor after the signal is detected.	No	Bring the sensor closer to the tablet. Make sure there is no physical barrier between the sensor and the tablet (e.g. a wall). After they are close to each other, the App will automatically attempt to reconnect to the sensor.	Low

Anne Chest Anne Limb	Low signal	Sensor wireless signal is low.	Yes	Move the tablet closer to the sensor.	Low
Patient monitor	No Central	No central detected.	Yes	Check whether the central system (i.e. the target server) is connected to the network.	Low
Patient monitor	No Network	No Wi-Fi network available.	Yes	Check if the Wireless network is available.	Low
Patient monitor	Low tablet battery	Battery level of the tablet has fallen below 20%. There is less than two hours of battery life remaining.	No	Charge the tablet.	Low

9.3 Alarm Audio Management

9.3.1 Audio Pause (All)

Pressing on the “PAUSE” button will start the timer to count down for 30 minutes pausing all audio alarms on the device. The audio pause duration cannot be adjusted.



The audio alarm is automatically back ON:

1. if the time is up
2. if the user clicks on the “CANCEL” button within a 30 minutes pause, the audio will also turn back ON.

Note:

Password:
Your organization will have configured the device with a password.
Existing alarms:

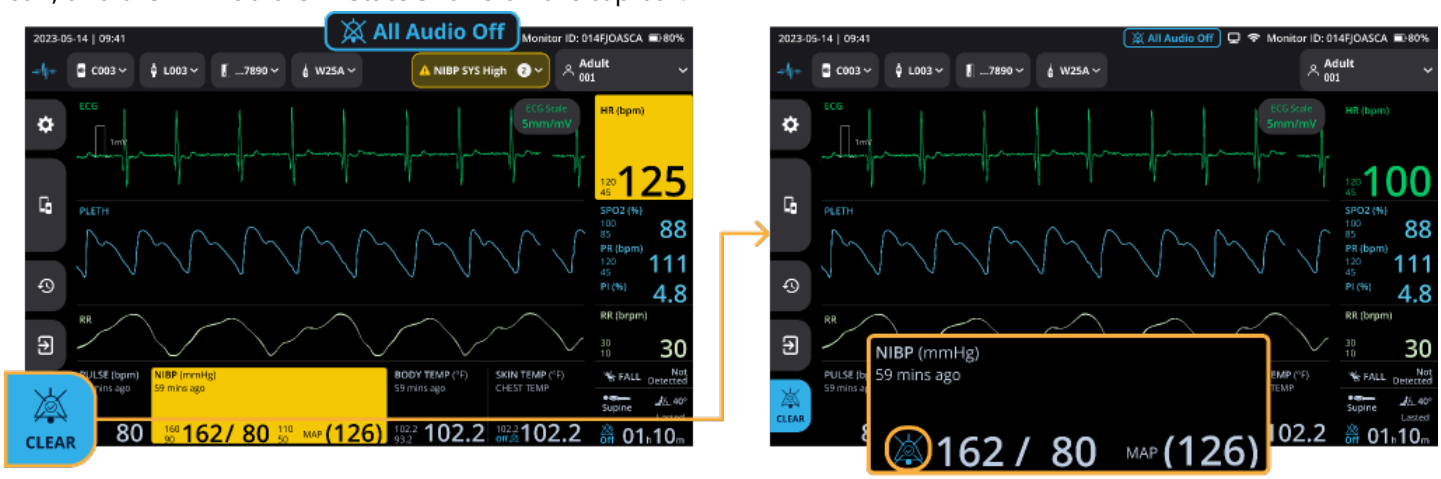
- The audio alarm of all physiological alarms and technical alarms is switched from ON to PAUSED for 30 minutes.
- Visual alarms are not affected. High or medium priority alarms remain flashing.
- Latched alarms are reset and fall detection alarm is reset if a fall was detected.

New alarms:

- Audio alarm of all physiological alarms and technical alarms is back ON.
- Visual alarms are not affected.

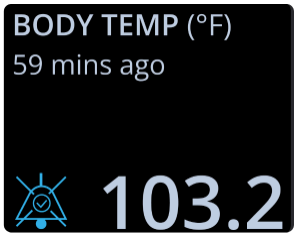
9.3.2 Audio Alarm Off

If the audio alarm is configured OFF for the device, the “PAUSE" button changes into “CLEAR” with an acknowledge icon, and the “All Audio Off” state shows on the top bar.



9.3.3 Alarm Acknowledgement

For spot check values (BODY TEMP and NIBP), use “PAUSE” or “CLEAR” to acknowledge alarms with outdated readings.



For latching alarms (alarms that remain active until manually acknowledged), use the “PAUSE” or “CLEAR” button to remove the visual and audio alarm after the alarm condition has resolved.

Note:
When Audio Off is active:

- All physiological and technical alarm sounds are disabled.
- Visual alarms remain active and continue to display.
- All alarm audio is disabled regardless of any active Audio Pause.
- Audio Pause button remains enabled in order to clear latched alarms where alarm conditions no longer exist.

9.3.4 Alarm Off

When the parameter alarms are turned off, the ALARM OFF symbol will appear, and neither audio nor visual alarms will be presented.

Table 16: Alarm off conditions

Vital type	UI	Alarm off condition
Chest skin temperature		When the sensor is first paired, the Chest Temperature alarm is automatically disabled (set to OFF) for a 30-minute buffer period.
Body position		The Body Position alarm is set to OFF. Go to settings to turn on body position alarms if needed.

Chest Lower Limit Alarm		The CHEST Skin Temperature Lower alarm is set to OFF by default. Go to settings to turn on chest temperature lower limit alarms if needed.

9.4 Alarm Ranges and Defaults

Table 17: Alarm presets

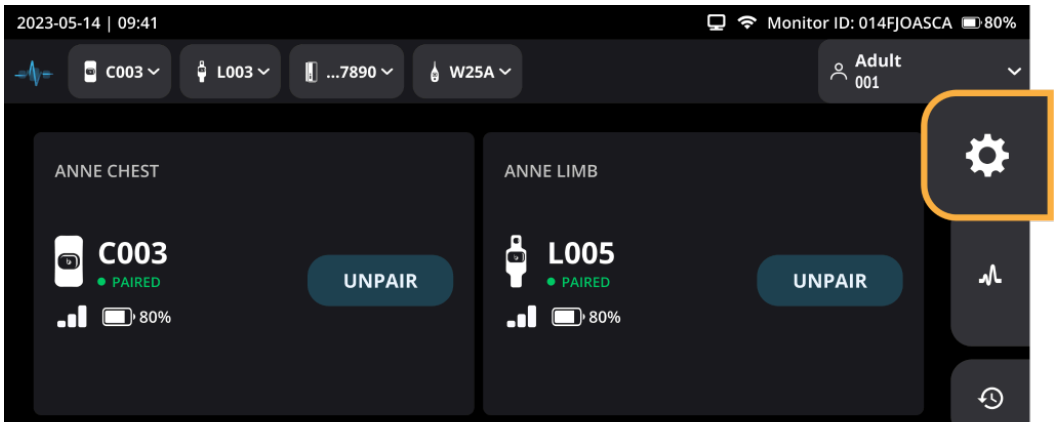
Parameter	Increment	Lower-limit Defaults	Upper-limit Defaults	Valid Lower-limit Range	Valid Upper-limit Range
HR (BPM)	1	45	120	30 ~ (*Upper limit* - 5)	(*Lower limit* + 5) ~ 270
RR (BRPM)	1	10	30	8 ~ (*Upper limit* - 2)	(*Lower limit* + 2) ~ 35
SpO2 (%)	1	85	100	70 ~ (*Upper limit* - 2)	(*Lower limit* + 2) ~ 100
PR (bpm)	1	45	120	30 ~ (*Upper limit* - 5)	(*Lower limit* + 5) ~ 240
SYS (mmHg)	1	90	160	0 ~ (*Upper limit* - 5)	(*Lower limit* + 5) ~ 300
DIA (mmHg)	1	50	110	0 ~ (*Upper limit* - 5)	(*Lower limit* + 5) ~ 300
BODY TEMP (°F)	0.1	93.2	102.2	89.6 ~ (*Upper limit* - 1.8)	(*Lower limit* + 1.8) ~ 111.2
BODY TEMP (°C)	0.1	34.0	39.0	32 ~ (*Upper limit* - 1)	(*Lower limit* + 1) ~ 44
SKIN TEMP (°F)	0.1	93.2	100.4	73.9 ~ (*Upper limit* - 1.8)	(*Lower limit* + 1.8) ~ 109.0
SKIN TEMP (°C)	0.1	34.0	38.0	23.3 ~ (*Upper limit* - 1)	(*Lower limit* + 1) ~ 42.8

Note:

- *Upper limit* stands for the currently set upper limit for each parameter.
- *Lower limit* stands for the currently set lower limit for each parameter.

Section 10. Settings

Press the button from the sidebar to update the alarm limits and alarm controls.



10.1 Alarm Limits

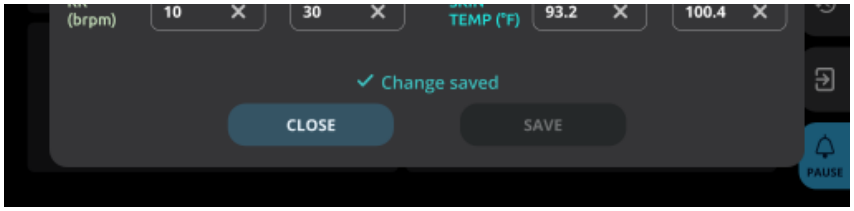
Warning: Setting alarm limits to extreme values may prevent certain alarm conditions from being detected and from being enunciated with audible and visual alarm signals.

Step 1

Press the “Alarm Limits” tab on the top of the pop-up screen. Set the Low limit and High limit values. And press the “SAVE” button.

Step 2

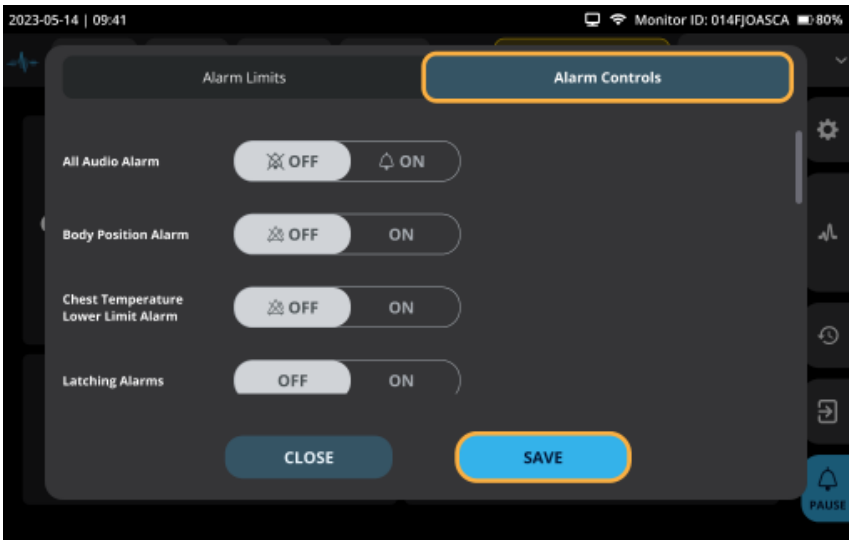
Once the new Alarm Limits is successfully changed, you will be able to see the “Change saved” text.



10.2 Alarm Controls

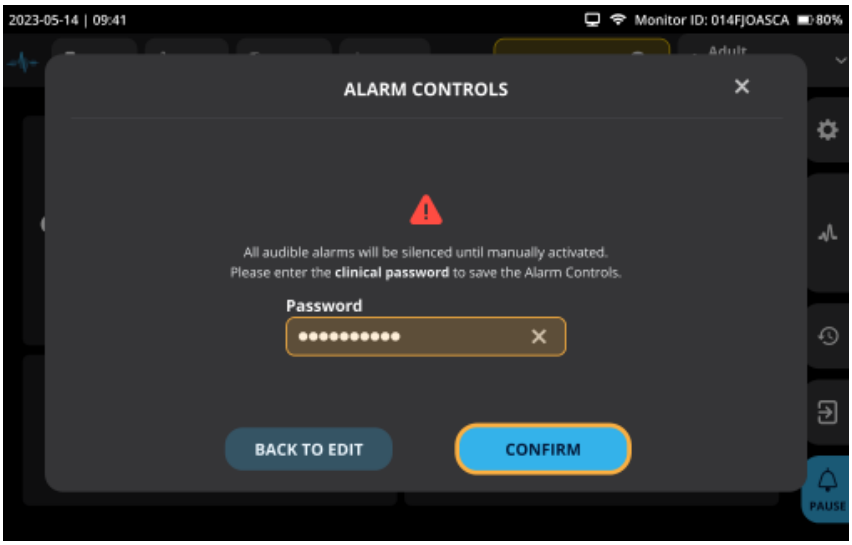
Step 1

Press the “Alarm Controls” tab on the top of the pop-up screen. Press the ON/OFF button for all audio, body position, temperature, and latching alarms. And press the “SAVE” button.



Step 2

Enter the **clinical password** to save the Alarm Control settings.



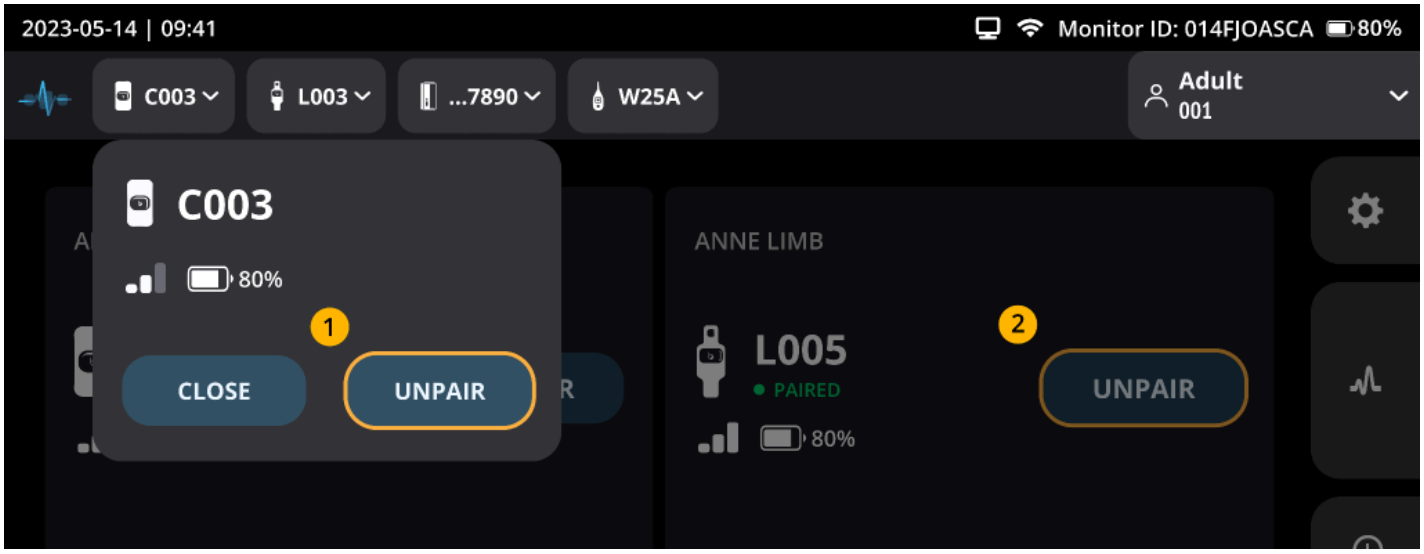
Section 11. Stop Session

Use Stop Session to end monitoring for the current patient on the ANNE View Patient Monitor when monitoring is no longer required.

11.1 Unpair Sensors

Step 1

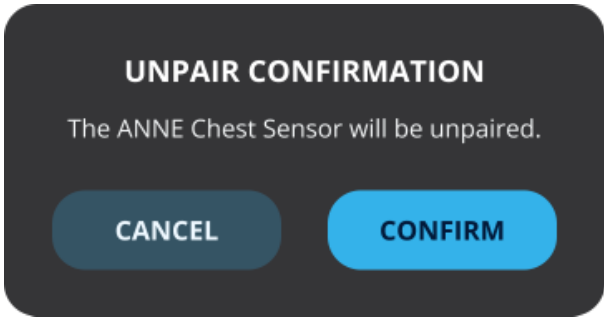
To unpair or replace the sensors, select the “UNPAIR” button to disconnect the sensors (either through top bar dropdown windows or the data collection dashboard).



Step 2

A confirmation message will pop up

- Select the “CONFIRM” button to confirm the unpair action
- Select the “CANCEL” button to cancel the unpair process

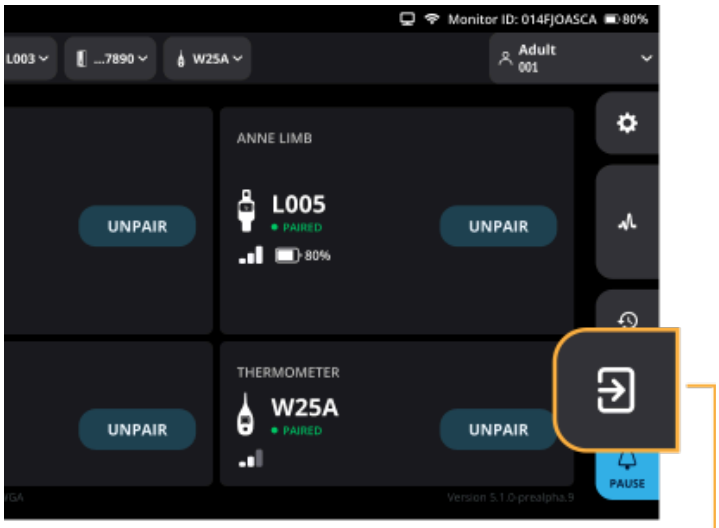


Step 3

After unpairing, the “PAIR” button will show up, and the data will stop streaming for the unpaired sensor.

11.2 Stop Session

Manual stop session:



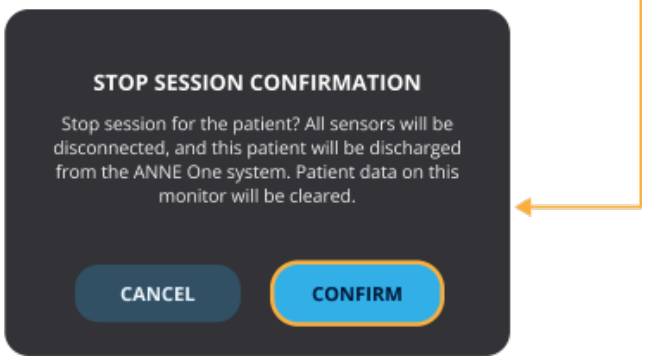
Step 1

To end the current patient monitoring session, select the “ ” button.

Step 2

A confirmation message will pop up before ending the session.

- Select the “CONFIRM” button to confirm the end session action.
- Select the “CANCEL” button to cancel the end session process.

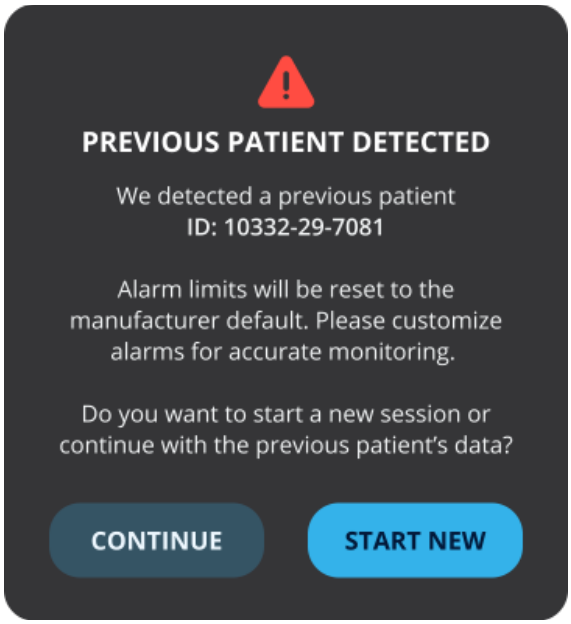


Note: All sensors will be disconnected after your confirmation.

If the patient relaunches after 30 seconds (e.g. due to a reset or restart):

“Previous Patient Detected” popup will appear.

- Match the patient ID in the popup with the patient to confirm if the patient is still the same one using the tablet. Select “CONTINUE” to resume the monitoring session.
- If the monitor will be used for a new patient, select “START NEW”.



Note:
After confirming stop session OR start new:

- All sensors will be disconnected after confirmation.
- Physiological alarm limits will be reset to the manufacturer’s default after the session is stopped or when a new session is started if a previous patient is detected.

Section 12. Cleaning

The Patient Monitor is compatible with the following cleaning agents for reprocessing:

- Isopropyl Alcohol Solutions (e.g. IPA Wipes)
- Quaternary Ammonium Compounds (e.g. CaviCide®)
- Chlorine and Chlorine Compounds (e.g. Clorox® Disinfecting Bleach)
- Oxygen-Releasing Agents (e.g. OxyCide®, Hydrogen Peroxide)
- Oxivir Excel Wipe
- Rely + On Vikon
- Dismozon Plus

Section 13. Product Specifications

13.1 ANNE View Technical Specifications

Table 18: ANNE Tablet specifications

	ANNE Tablet
Dimensions (L x W x H, cm)	18.98 x 25.6 x 2.8 cm
Weight (grams)	653 grams
Screen Size (inches)	10.1” Touchscreen
Screen Resolution (pixels)	1920 x 1200
Wi-Fi	802.11 a/b/g/n/ac/ax 2.4G+5GHz
Power supply	USB-C 10W power adapter 5V, 2A
Battery Type	Rechargeable lithium-ion battery
Operation Time (per full charge)	5 hours
Charging Time (to full charge)	6.5 hours
Water Resistance	Tablet: IPX0
Mains Isolation	When plugged into the provided power supply: Class II When unplugged: Internally powered

Table 19: Audio alarm specifications

Alarm pause time	30 minutes
Audio alarm sound pressure range	ANNE View: Med priority - 53.0dB ~ 65.8dB
Audio alarm sound measurement radius	1 meter

ANNE One offers a distributed information system wherein ANNE View serves as the primary alarming unit. The ANNE View application establishes communication with the central monitoring platform to facilitate the display and storage of physiological data from multiple patients over the same network. ANNE View is located within the patient environment, and the central monitoring platform may or may not be located within the patient environment.

The following is the essential performance of ANNE View:

- Visual and audible alarms for high and medium priority physiological alarm conditions are generated
- Input signals in the range of ±5mV are reproduced on the output with an error of < ±20% of the nominal value of the output or ±100 µV, whichever is greater

Table 20: Alarm condition delays, methods, and statistics to or from a distributed information system

Mean Alarm Condition Delay	
ANNE View delay (mean)	2.03 s

ANNE View to the central monitoring platform delay (mean)	4.25 s
Maximum Remote Alarm Signal Generation Delay and Methods	
ANNE View delay (mean)	2.06 s
ANNE View to the central monitoring platform delay (mean)	4.26 s
Methods used	From the onset of the alarm condition to the time the alarm signal leaves the source
Statistics of the distribution of the sum when the sum of the maximum alarm condition delay plus the maximum alarm signal generation delay is greater than 10 s	
ANNE View statistics	Sample size: 583 Patient Monitor min: 0.031 s Patient Monitor max: 30 s Mean: 2.04 s Standard deviation: 3.99 s 25th percentile: 0.061 s 50th percentile: 20.10 s 75th percentile: 1.00 s

13.2 Electromagnetic Emissions Declaration

Use of ANNE View in electromagnetic environments beyond those specified in this manual may result in a degradation or loss of essential performance. The end user of the device should ensure that it is used in such an environment.

Table 21: Electromagnetic environment

Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	ANNE One uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	ANNE One is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

13.3 FCC Compliance Notification

ANNE One has been verified for RF exposure and found to comply with Council Recommendation 1999/519/EC and FCC OET-65 RF exposure requirements. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However,

there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The ANNE Tablet complies with Part 15C of FCC Rules (FCC ID: A3LSMT630).Operation of the device is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

13.4 Guidance and Declaration – Electromagnetic Immunity

(For ME equipment ME system that are not life-supporting)

Use of ANNE View in electromagnetic environments beyond those specified in this manual may result in a degradation or loss of essential performance. The end user of the device should ensure that it is used in such an environment.

Table 22: ANNE One electromagnetic immunity

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	0.5 kV differential mode 1 kV common mode	0.5 kV differential mode 1 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions, and voltage variations on power-supply input lines IEC 61000-4-11	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip in 25 cycles >95% dip in 5 seconds	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip in 25 cycles >95% dip in 5 seconds	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60 Hz) magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF	3 Vrms 150 kHz to 80 MHz 3 V/m	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ANNE View device than the recommended separation distance calculated

IEC 61000-4-3	80 MHz to 2.5 GHz		from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ 125 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted disturbances induced by RF fields	Test levels: 3V 0.15-80 MHz 6 V ISM bands between 0.15 MHz to 80 MHz	Test levels: 3V 0.15-80 MHz 6 V ISM bands between 0.15 MHz to 80 MHz	Conducted disturbances induced by RF fields should be at levels characteristic of a typical location in a typical professional healthcare facility environment or domestic establishment.
Proximity Fields from RF wireless communications	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	Proximity fields from RF wireless communications should be at levels characteristic of a typical professional healthcare facility environment or domestic establishment

	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 6785 MHz	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Note 3: UT is the a.c. mains voltage prior to application of the test level.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

13.5 Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and ANNE One

(For ME equipment/ME systems that are not life-supporting)

ANNE One is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and ANNE One as recommended below, according to the maximum output power of the communications equipment.

Table 23: Separation distance

Rated max output power of transmitter (W)	Separation distance according to frequency of transmitter (meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

13.6 Communication Specifications

ANNE Tablet

Table 24: ANNE Tablet - Bluetooth

Bluetooth	
Type	Version 5.2
Max. RF Output Power	~84 mW (~19.2 dBm)
Frequency	2402 – 2480MHz

Table 25: ANNE Tablet - Radio compliance

Radio Compliance	
FCC ID	A3LSMT630
Model	SM-T630

Table 26: ANNE Tablet - Wi-Fi

Wi-Fi	
Wi-Fi Standards	IEEE 802.11a/b/g/n/ac/ax
Frequency Bands	2.4 GHz, 5 GHz, Dual-Band
Channel Width	80 MHz
Encryption Standards	WPA, WPA2, WPA3

Authentication Protocols	802.1X, EAP

The following communication capabilities are included as part of the tablet hardware and are enabled on the ANNE tablet for its use in the ANNE One system:

- Wi-Fi (802.11 a/b/g/n/ac/ax 2.4G+5GHz)
- NFC

Other Included Sensors

For communication specifications of 3rd party devices, please refer to the original manufacturer's manual originally provided with the device.