MONIDOR

MONIDOR VITALS™ USER MANUAL

For device version 1.2.x

Contents

1. INTRODUCTION

This document is the digital user manual for Monidor Vitals, a software designed by Monidor Oy.

Read this manual carefully before use. A free paper version of this manual can be obtained by sending an e-mail to the following address Info@monidor.com . A copy will be delivered within 5 days of receipt of your request.

It is recommended that you read this and the user manual of the pulse oximeter manufacturer carefully before use.

This software can only be used with devices approved by Monidor Oy. The use of the software with any other devices is forbidden.

The installation shall be done with the assistance of the manufacturer or by an authorised person. The installation instructions (D0448_Setup guide for Monidor Vitals) are to be found from material provided by the manufacturer.

1.1 Intended use

Monidor Vitals (ref. number: V017456) is a SW application, which transfers, stores and displays pulse rate and SpO2 values measured by connected pulse oximeter and provides alarms. Monidor Vitals is intended for continuous near real-time remote monitoring and data collection and recording.

The Monidor Vitals system includes a wireless patient monitor used on a designated mobile device that is not a medical device, server software hosted on a commercial server or cloud server, and terminal software used on commercial Android or Windows devices.

The system works in combination with 3150 WristOx2 pulse oximeter, which is a CE marked medical device.

Monidor Vitals is intended for use by medical staff who are authorised to monitor the patient's vital signs with a pulse oximeter. It is intended for use in patients whose oxygen saturation and heart rate need to be monitored. Users should note that Monidor Vitals is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

Monidor Vitals is not intended to be used in intensive care units or critical care units, or for observing such patient conditions where failure to detect changes in the condition in timely manner would be likely to lead or contribute to death or irreversible injury.

1.2 Intended conditions of use

Monidor Vitals is intended to be used in medical care facilities, such as hospitals, health centres, doctor`s offices and clinics. Monidor Vitals is approved for use in a home healthcare environment by healthcare professionals who have received training in its use.

Monidor Vitals is not intended to be used in intensive care or critical care units.

1.3 Operating principle

Monidor Vitals wireless patient monitoring software retrieves electronic information from the pulse oximeter via Bluetooth. This data is then transmitted to the Monidor Vitals Server so ftware over IP networks, making it available to remote terminals.

The Monidor Vitals wireless patient monitor should remain within Bluetooth range of the pulse oximeter.

Monidor Vitals server software is executed on a server which is accessible from both the wireless patient monitor and terminal devices.

Terminal software, both Android and Windows, runs on general-purpose terminal devices running Android or Windows, respectively.

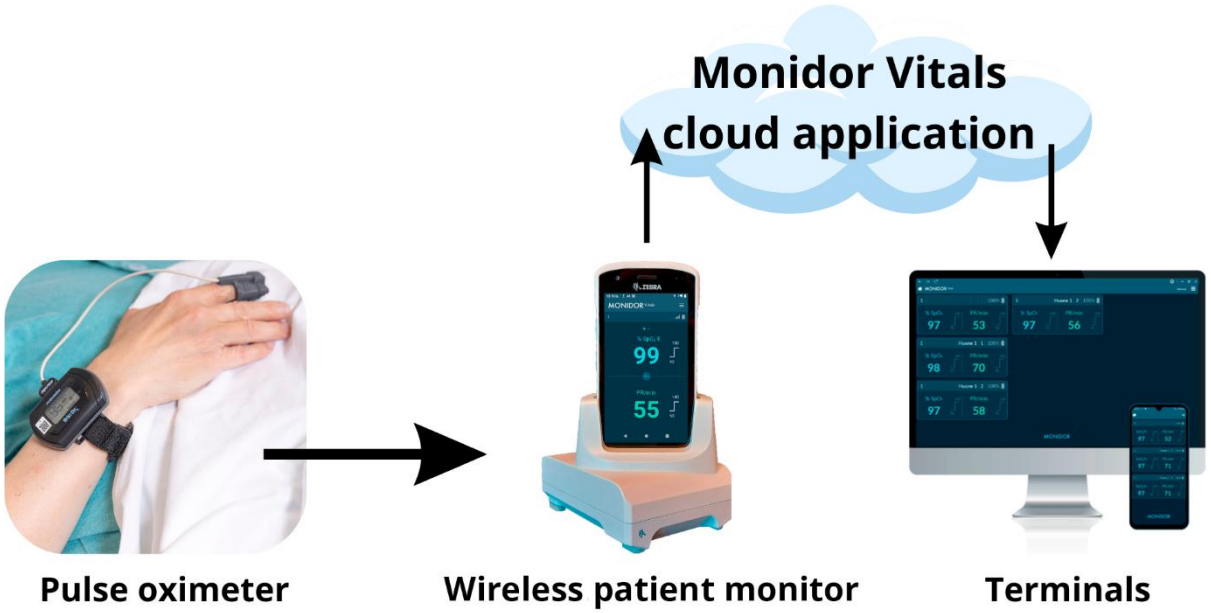


Figure 1: Monidor Vitals data flow

1.4 System requirements

Reliable network connection (to the server)

Wireless patient monitor:

Only devices approved by Monidor Oy may be used as wireless patient monitors.

NOTE: Mobile devices that function as wireless patient monitors are not medical devices.

Monidor Oy currently approves the following mobile devices as patient monitors:

- Zebra TC26-HC
- Zebra HC25
- Ascom Myco 4

Mobile terminal:

- Display: min 5 inches. HD colour (1280 x 720)
- CPU: 1,4 GHz 4 cores
- Camera: 2 MP
- Memory: 2 GB
- Operating system: Android 9 or later
- Network connectivity: Wi-Fi or mobile data (4G or 5G)

Windows terminal:

- Display: min 14 in. HD colour (1280 x 720)
- CPU: 1,5 GHz 4 cores
- Memory: 4 GB
- Operating System: Windows 10 or 11
- Network connectivity: Ethernet, Wi-Fi or mobile data (4G or 5G)

Supported browsers:

- Chrome version 78 or later
- Microsoft Edge version 97.0.1072.55 or newer
- Firefox version 70 or newer
- Monidor Vitals application for Android 2.5.0 or newer
- Monidor Vitals application for Windows 2.0.0 or newer

Other browsers may also be supported.

Supported pulse oximeters:

- Nonin WristOx2®, Model 3150 Pulse Oximeter

1.5 Service life

5 years

1.6 Symbols used for marking the device

The symbols used on the device comply with EN ISO 15223- 1;2021. The symbols are described in Table 1.

Table 1: Description of the symbols used in the device.

Symbol	Explanation of symbols
	Please refer to the user manual or the electronic instruction manual.
	Medical device.
CE 0598	CE marking, includes the reference number of the notified body.
	Unique device identifier (01) UDI-DI Product identification number (11) UDI-PI/release date: release date of the software version, (year, month, day) (10) UDI-PI/batch number: version number
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

2. SAFETY INSTRUCTIONS

Monidor Vitals is intended for continuous near real-time remote monitoring, data collection and storage.

When initiating the use of Monidor Vitals, the patient's clinical condition should be assessed to ensure that they do not require immediate intensive care and are not at risk of rapidly deteriorating into an unstable state. The patient must not be at risk of death or serious deterioration.

The wireless patient monitor is connected to the pulse oximeter via Bluetooth, with a safe signal range of about 10 m, depending on possible obstacles (doors and walls). Without this connection, the pulse oximeter values will not be displayed in the remote monitoring application and related alarms will not be triggered. The pulse oximeter does not provide any alarm signals; alarms are only indicated on the wireless patient monitor and in the remote monitoring application on the terminal devices.

The warnings associated with the use of Monidor Vitals are listed in Table 2.

Table 2: Warnings

⚠	WARNING: Modifying this device is prohibited.
⚠	WARNING: Due to possible network connection problems, alarms are not always transmitted to the terminals. The wireless patient monitor is the primary source of alarms.
⚠	WARNING: Setting the sound pressure level of the remote monitoring terminal or wireless patient monitor lower than the ambient levels can impede operator recognition of alarm conditions.
⚠	WARNING: Note that the default settings for Monidor Vitals alarms may vary between hospital wards. Always check the default settings and operating procedures for the ward in question before use.

Incidents related to the device that have led to or could have led to a risk to the health of the patient, user or other person should be reported to your local competent authority and to Monidor at info@monidor.com . The list of competent authorities is in Chapter 7.

Notes on Monidor Vitals:

- Monidor is not responsible for the safety of the user's terminal devices (e.g. tablet, mobile phone or PC).
- A mobile device that functions as a wireless patient monitor is not a medical device.

- Wireless patient monitor must not be placed within the reach of the patient (applies only to Zebra TC26-HC and Zebra HC25 devices).
- Mobile devices for terminal SW are not medical devices. Monidor is not responsible for the safety of these mobile devices
- Stable internet connection is required to use remote monitoring software. Use mobile network unless there is a reliable Wi-Fi available.
- To ensure continuous data transmission, the wireless patient monitor must be placed close enough to the connected pulse oximeter within Bluetooth range.
- The time and date settings on the wireless patient monitor and terminal devices must be set correctly.
- If the pulse oximeter batteries or the wireless patient monitor battery run out, the measured values cannot be transmitted to the remote monitoring system.
- During a power outage, the wireless patient monitor will operate for approximately 10 hours on battery power, provided it is fully charged.
- The user should always evaluate the accuracy of the information displayed on the screen before making treatment decisions.
- The user must ensure that the patient information is correct.
- The installation of Monidor Vitals remote monitoring is only allowed on Monidor Oy approved devices and systems.
- The equipment must not be used during the MRI scan.
- Regardless of the use of Monidor Vitals remote monitoring, the care personnel need to regularly observe the patients according to local practices and policy.
- Using Monidor Vitals for remote monitoring of a patient's vital signs should not replace observation of the patient's condition at their bedside.
- The user should be aware that a visual impairment may interfere with the use of the device.
- The user should be aware that colour blindness may make it difficult to use the device.
- It is possible to set a PIN code query on the wireless patient monitor to modify the settings.
- Monidor Vitals patient monitoring software runs on Zebra TC26-HC, Zebra HC25 and Ascom Myco 4 mobile devices; read the user manual.
- The devices must not be placed in the immediate vicinity of heat sources.
- The charging cable for the wireless patient monitor may pose a strangulation hazard.
- The devices or their parts, such as the charger, must not be used for any other purpose.
- The devices may only be cleaned by a healthcare professional in accordance with the relevant instructions for use.

Notes on home healthcare use:

- The clinician must assess and determine, on a patient-by-patient basis, whether the use of remote monitoring is appropriate for home healthcare.
- In a home environment, care must be taken to ensure that children and pets cannot touch the devices.

- The device should never be left with the patient for self-use. Between home visits, the patient and family are instructed not to operate or adjust the device.

Notes on connected devices:

- Read the user manual of Nonin WristOx2® Model 3150 BLE pulse oximeter and refer to its safety instructions.
- When using Monidor Vitals software with a Nonin WristOx2® Model 3150 BLE pulse oximeter, the following section of the pulse oximeter's user manual does not apply: Warning "Do not use the device when alarms are required".

2.1 **Safety standards**

719/2021 Medical Devices Act (FIMEA)

Monidor Vitals satisfies all safety standards for medical device software in compliance with EN 82304-1:2017

3. BASIC USE

3.1 Deployment

1. Check and, if necessary, replace the batteries of the pulse oximeter and attach the sensor to the patient.
2. Connect the pulse oximeter to the wireless patient monitor by scanning the pulse oximeter QR code (Figure 2) or by selecting from the list (Figure 3). The QR code is scanned using the barcode reader function of the patient monitor by pressing the button on the side of the device. For more information on the barcode reader function, refer to the user manual of the mobile device used as a wireless patient monitor.
3. The wireless patient monitor displays the values measured by the pulse oximeter (Figure 4) and sends them to the Monidor Vitals cloud application. Ensure that the patient monitor is connected to remote monitoring by checking that the device card is visible in the remote monitoring application and that the patient monitor is not alerting about a connection problem.
4. The wireless patient monitor is placed in the patient room.

Figure 2: Connecting the wireless patient monitor to the pulse oximeter by scanning the pulse oximeter QR code.

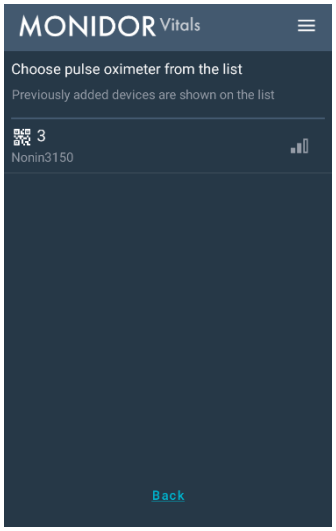


Figure 3: Connecting the wireless patient monitor to the pulse oximeter by selecting from the list.

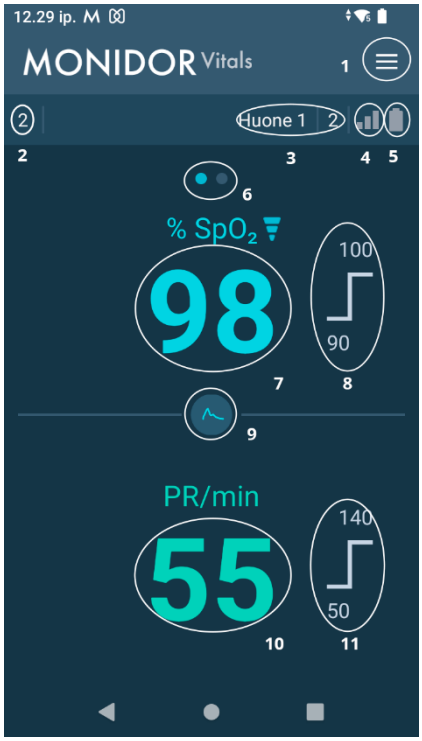


Figure 4: Wireless patient monitor main view

Components of the wireless patient monitor main view (Figure 4)

1. Menu
2. Device number
3. Room and patient location
4. Signal strength
5. Pulse oximeter battery charge status
6. Number of displays on the main view (Main view and History view)

7. Oxygen saturation (%SpO2)
8. Oxygen saturation limits
9. PPG curve symbol, which can be clicked to display the PPG curve
10. Pulse (PR/min)
11. Pulse limits

3.2 Remote monitoring view

All pulse oximetry measurements remotely monitored with Monidor Vitals in the same ward are automatically displayed in the Monidor Vitals remote monitoring application used on the terminals. Each pulse oximeter set up for a patient will appear as a separate device card in the application (Figure 5).

Alarms are automatically cleared from the screen when the cause of the alarm has been removed.

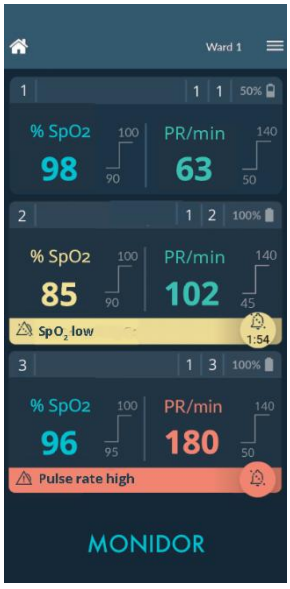


Figure 5: Monidor Vitals remote monitoring view

Card view (Figure 6):

1. Device number
2. Room and bed number
3. Battery charge status of the pulse oximeter batteries
4. Oxygen saturation (% SpO_2)
5. Pulse (PR/min)
6. Oxygen saturation limits
7. Pulse rate limits

Figure 6: Device card elements

3.2.1 Identifying the right device card

You can identify the Monidor Vitals device card by the top left corner of the device card (Figure 6). The number there corresponds to the number in the top left corner of the wireless patient monitor display and the identification number on the pulse oximeter.

3.3 Setting up a patient location

The room and bed location are set from the wireless patient monitor (Figure 7) or from the remote monitoring application (Figure 8).

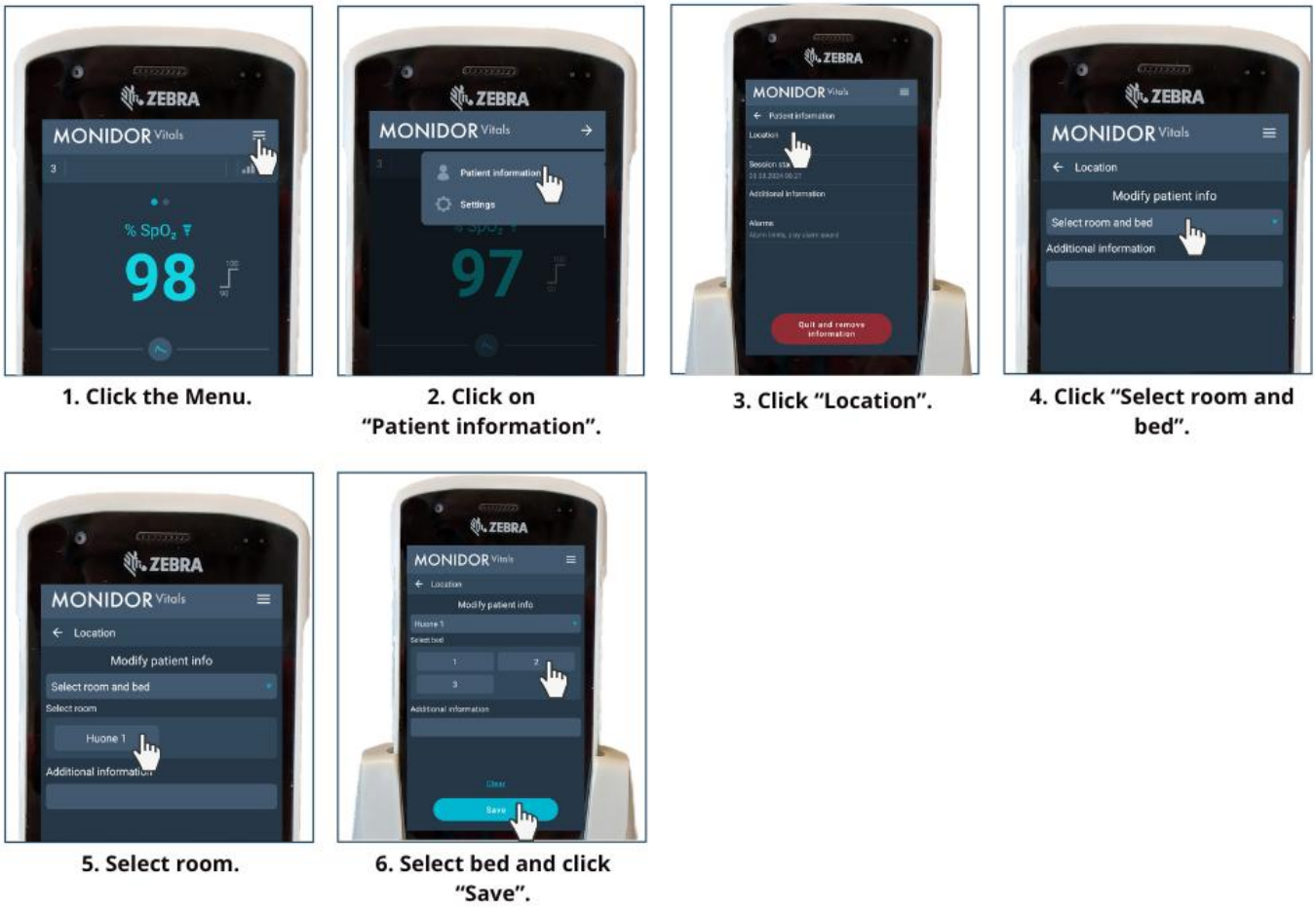


Figure 7: Setting up a room and bed locations from the wireless patient monitor.

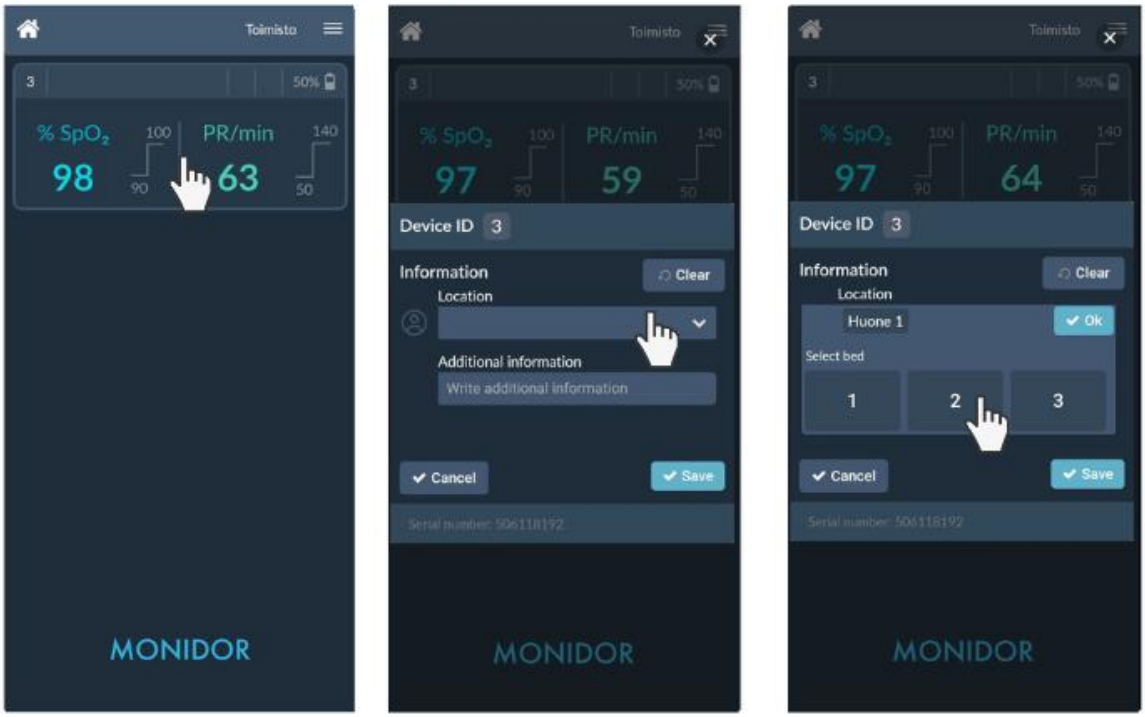
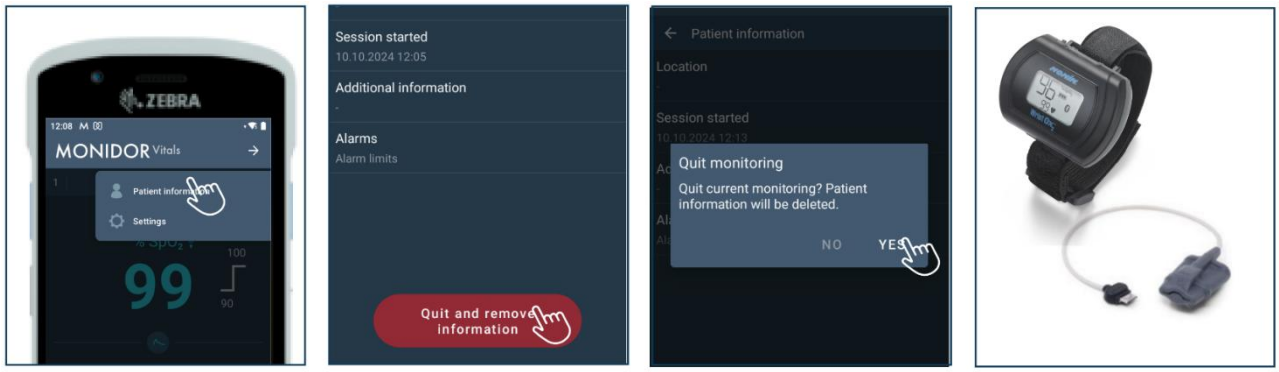


Figure 8: Setting up a room and bed locations from the remote monitoring application.

3.4 Ending remote monitoring

To end remote monitoring, the connection is disconnected from the wireless patient monitor and the data is deleted (Figure 9) so that the equipment is ready to be used for another patient. Deleting the data resets the measurement history and settings. The sensor is removed from the device and cleaned after each use.

The device card will be automatically removed from the remote monitoring view after 15 minutes.



Click the Menu and click on “Patient information”.

Click “Quit and remove information”.

Click YES.

Disconnect the sensor from the pulse oximeter. Clean the sensor and meter after each use.

Figure 9: Ending remote monitoring from wireless patient monitor

4. ALARMS

The Monidor Vitals alarm system monitors oxygen saturation (SpO2) and pulse rate and reports technical problems. The alarm system is designed to be visual and can be adjusted to be completely silent or to emit an alarm sound according to alarm priority or notification sound, depending on the needs of the unit.

Alarms are divided into three priorities:

- High priority (red)
- Medium priority (yellow)
- Low priority (light blue)

Each active alarm displays the cause as text and an alarm icon  , whose background colour indicates the priority.

Alarm sources:

- Oxygen saturation or pulse rate exceed or fall below set limits.
- Technical problems initially cause low priority alarms, which can escalate to medium priority alarms after a delay if the problem is not resolved. The escalation delay is defined in the presets (see section 4.1.).

All alarms issued by Monidor Vitals are described in Table 3.

Table 3: Description of alarms

Alarm	**Priority***	**Sound alarm wireless patient monitor****	**Sound alarm remote monitoring*****
SpO_2 very low	high	x	x
SpO_2 low	medium	x	x
SpO_2 high	medium	x	x
Pulse rate very low	high	x	x
Pulse rate low	medium	x	x
Pulse rate very high	high	x	x
Pulse rate high	medium	x	x
Pulse oximeter battery low	medium		x
	low		
Wireless patient monitor battery low	medium		x
	low		
No connection to pulse oximeter	medium		x
	low		

No connection to wireless patient monitor (x min). Data cannot be updated.	medium		
No connection to remote monitoring	medium		
	low		
No sensor detected	medium		x
	low		
Sensor error	medium		x
	low		
System error in pulse oximeter	medium		x
	low		
Weak sensor signal	medium		x
	low		
Monitoring not active	notification		
*Can be set for each ward according to Table 4 “Alarm priority”. **Can be set for each ward according to Table 5 “Sound alarms at the wireless patient monitor”. ***Can be set for each ward according to Table 5 “Sound alarms on terminal devices”.			

4.1 Alarm presets

When the Monidor Vitals system is implemented, presets are defined for the ward to control alarm functions and general settings. These ensure that the system meets the unit's needs right from the start.

The presets define, among other things, alarm limits and delays, priority levels, the use of alarm sounds, and the delay for low-priority escalation. The administrator has the right to change the default settings if necessary. The default settings may differ from the factory settings, which are based on the alarm system in accordance with the EN 60601-1-8 standard.

The responsible organization shall configure alarm presets specific to each department according to the intended use environment. In environments where the user may be located far from the patient and the wireless patient monitor (the primary alarm source), such as in a home healthcare environment, it may be appropriate to disable audible alarm sounds.

Table 4 shows the adjustment range and factory settings for alarm limits, priorities, and audible alarm delays that can be defined with the presets.

Table 4: Adjustment range and factory settings for preset alarm limits, priorities and audible alarm delay.

Alarm	**Alarm limit** (factory setting in brackets)	**Alarm priority** (factory setting in brackets)	**Audible Alarm delay** (factory setting in brackets)
SpO_2 high	71–100 % SpO_2 (100)	Low, (Medium), High	0–5 min (15 s)
SpO_2 low	70–99 % SpO_2 (90)	Low, (Medium), High	0–5 min (15 s)
SpO2 very low Δ lower than the "SpO_2 low" alarm limit	-10– -1 % SpO_2 (-5)	Medium, (High)	0–1 min (5 s)
Pulse rate very high Δ higher than the 'Pulse rate high' alarm limit	1–50 PR/min (20)	Medium (High)	0–1 min (5 s)
Pulse rate high	75–210 PR/min (140)	Low, (Medium), High	0–5 min (15 s)
Pulse rate low	30–100 PR/min (50)	Low, (Medium), High	0–5 min (15 s)
Pulse rate very low Δ lower than the "Pulse rate low" alarm limit	-30– -1 PR/min (-20)	Medium, (High)	0–1 min (5 s)

Table 5 shows the adjustment range and factory settings for technical alarms and general settings. The low priority escalation delay is the time after which low priority alarms are changed to medium priority alarms.

Table 5: Adjustment range and factory settings for technical alarms and general settings that can be defined with presets.

Technical alarms	**Adjustment range** (factory setting in brackets)
Technical alarm, low priority alarm delay	0–15 min (5 min)
Technical alarm, medium priority alarm delay	0–5 min (15 s)
General settings	
Enabling sound alarms and notifications	Automatic / On demand (Automatic)
Repeat interval for medium priority alarms	5 s –15 min (30 s)
Repeat interval for high priority alarms	5 s –15 min (15 s)

Mute duration on terminal device	1–15 min (2 min)
Delay for escalation of low priority alarms	1–30 min (15 min)
Low priority alarm sounds enabled	Yes /No (No)
Sound alarms at the wireless patient monitor	Sound alarms / Silent (Sound alarms)
Sound alarms on terminal devices	Sound alarms / Sound notifications / Silent (Sound alarms)
Minimum volume of the wireless patient monitor	60–100 % (60 %)

4.2 **Alarm sounds**

Alarms of different priorities can be distinguished by both colour and sound (Figure 10).

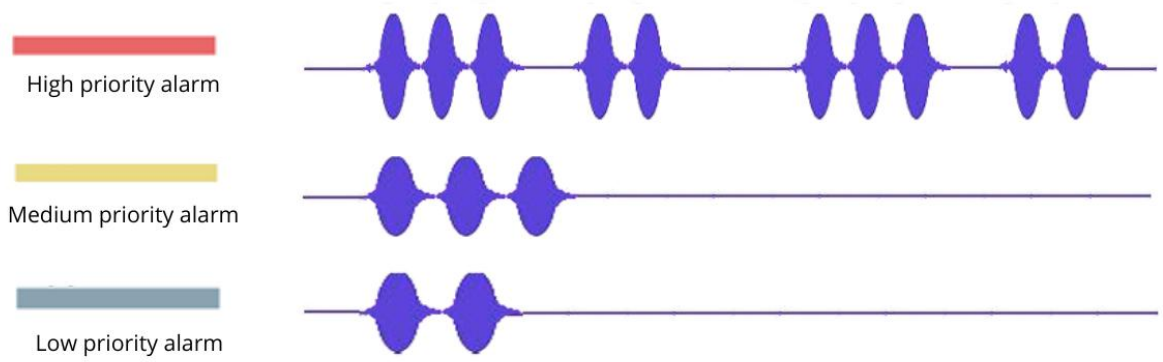


Figure 10: Alarm sounds

Maximum sound pressure levels of wireless patient monitor are shown in table 6.

Table 6: Maximum sound pressure levels at wireless patient monitor

Zebra TC26-HC	
Alarm volume setting	**Maximum sound pressure level**
High volume (100 %)	High priority alarm **77** dB(A) Medium priority alarm **69** dB(A) Low priority alarm **68** dB(A)
Low volume (60 %)	High priority alarm **72** dB(A) Medium priority alarm **67** dB(A) Low priority alarm **61** dB(A)
Tested according to EN 60601-1-8:2007+A1+A11+A2:2021, clause 6.3.3.2, with the alarm volume at maximum (100 %) and minimum (60 %).	
Zebra HC25	
Alarm volume setting	**Maximum sound pressure level**
High volume (100 %)	High priority alarm **77** dB(A) Medium priority alarm **70** dB(A) Low priority alarm **71** dB(A)
Low volume (60 %)	High priority alarm **75** dB(A) Medium priority alarm **69** dB(A) Low priority alarm **64** dB(A)
Tested according to EN 60601-1-8:2007+A1+A11+A2:2021, clause 6.3.3.2, with the alarm volume at maximum (100 %) and minimum (60 %).	
Ascom Myco 4	
Alarm volume setting	**Maximum sound pressure level**
High volume (100 %)	High priority alarm **71** dB(A) Medium priority alarm **69** dB(A) Low priority alarm **65** dB(A)
Low volume (60 %)	High priority alarm **61** dB(A) Medium priority alarm **52** dB(A) Low priority alarm **46** dB(A)
Tested according to EN 60601-1-8:2007+A1+A11+A2:2021, clause 6.3.3.2, with the alarm volume at maximum (100 %) and minimum (60 %).	

NOTE: Volume levels may vary from one device to another, so their exact level cannot be guaranteed. The values in Table 6 apply only to the device tested.

NOTE: Audio frequencies may vary depending on the device and cannot be guaranteed.

4.2.1 Sound notifications

Instead of a sound alarm, Monidor Vitals emits a sound notification on the terminal devices if sound notifications have been selected in the presettings. The sound notification is a short melody with a rising pitch.

4.3 Alarms in remote monitoring

All alarms are displayed on the terminals in the remote monitoring application. The measured data and alarms are displayed in remote monitoring with a 1–15 second delay. The cause of the alarms is displayed in the remote monitoring as a text on a red, yellow or light blue background (Figure 11). The alarm text can be seen, when the user is within 1 metre of the terminal device. Unmuted alarms are displayed at the top of the priority list.

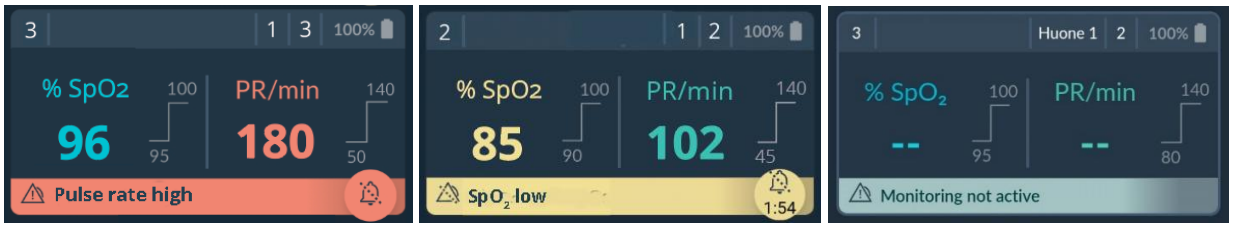


Figure 11: Display of alarms on the remote monitoring device card.

During an alarm, the card frame also flashes.

Frequency of flashing:

- High priority alarm 1,4 Hz
- Medium priority alarm 0,7 Hz
- Low priority alarm does not flash

The flashing edge of the high or medium priority alarm on the device card in the remote monitoring application is detectable when the user is within four metres of the terminal.

Alarms and notifications are also displayed in the notification window (Figure 12) when the application is running in the background.

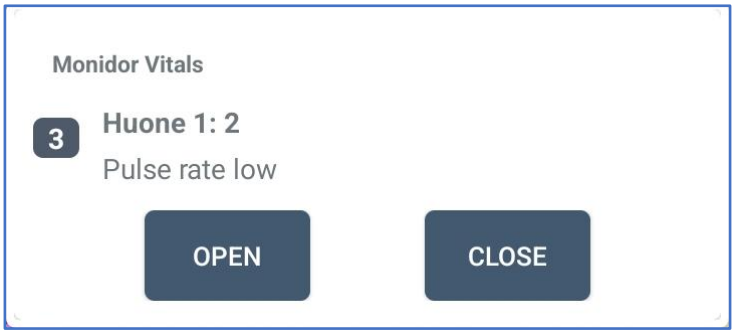


Figure 12: Notification window

4.3.1 Enable sound alarms and notifications on the terminal device

Depending on the alarm presettings, sound alarms or notifications are either played automatically on Android devices or must be enabled separately for the devices on which you want to hear alarm or notification sounds. Check the presetting of your ward.

The Windows application always plays all sound alarms or notifications, so sounds cannot be subscribed separately with the Windows application.

Instructions for enabling sound alarms and notifications with the Android application are shown in Figure 13.

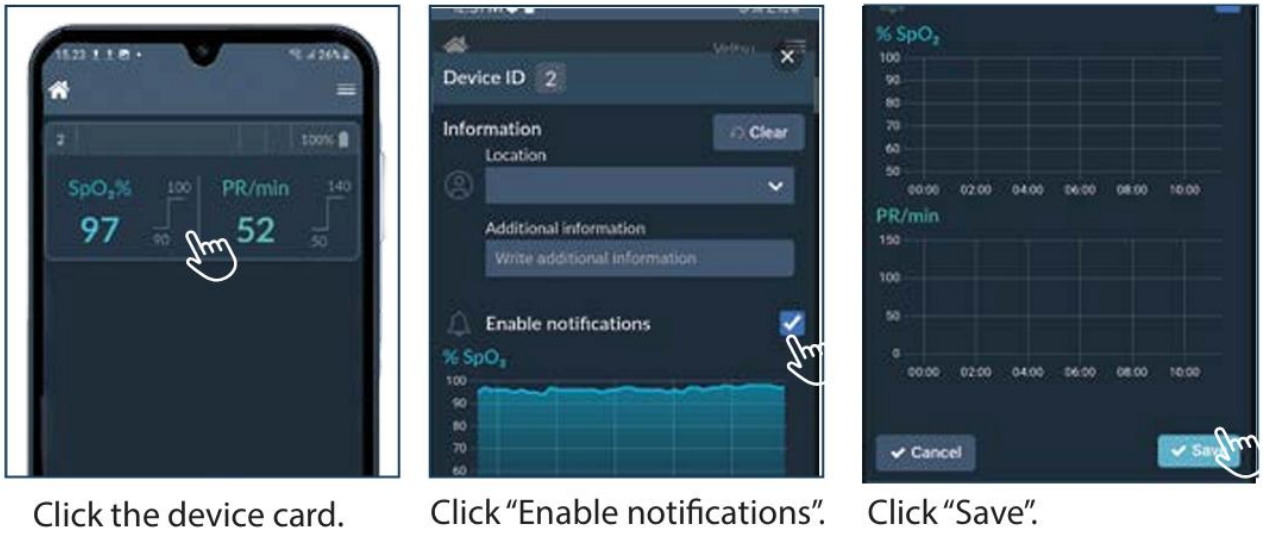


Figure 13: Enabling sound notifications on the Android terminal device.

4.4 Alarms at the wireless patient monitor

All alarms are displayed on the wireless patient monitor. The alarm text on the patient monitor application is detectable when the user is within one meter of the device.

Figure 14: Display of alarms on wireless patient monitor

4.5 Alarm delays

When the wireless patient monitor detects an alarm, it immediately displays a visual alarm. The wireless patient monitor sends alarms to remote monitoring every 15 seconds, so the alarm is sent to remote monitoring within 1–15 seconds. Visual alarms are typically visible in remote monitoring within 12 seconds. Alarm sound delays are set in the presets (see Table 4). Remote monitoring alarm delays are described in Table 7.

Table 7: Remote monitoring alarm delays

	Alarm delays	
	Visual alarm	**Audible alarm**
From wireless patient monitor to remote monitoring (incl. network delay)	max 12 sec*	max 31 sec**
* Alarm delays have been measured in a simulated manner by measuring the time from when the alarm message is sent from the wireless patient monitor device to when the visual alarm is displayed on the remote monitoring and the alarm sound is heard. Due to network connections, the delay may be longer. **Measured with default settings.		

If the pulse oximeter connected to Monidor Vitals is turned off outside the Bluetooth connection when the alarm is on, the wireless patient monitor will continue the alarm until monitoring is stopped from the wireless patient monitor. On the terminals, the device card for the remote monitoring application is displayed for 30 minutes and the audible alarms are stopped after 15 minutes if the connection to the wireless patient monitor is lost.

4.6 Muting an alarm

Please note! The mute function is not available if Monidor Vitals is set to silent.

The alarm sound of a visible alarm can be muted by clicking on the bell icon  .

The bell icon gives you the option of 2 minutes and 5 minutes (only in wireless patient monitor) for the duration of the mute (Figure 15).

A muted alarm is indicated by a mute icon  .

Muting an alarm sound from a wireless patient monitor will mute the alarm sound from all devices. Muting an alarm sound from remote monitoring will only mute the alarm sound on that device.

You can cancel the mute by clicking on the bell icon again and selecting “Unmute”.

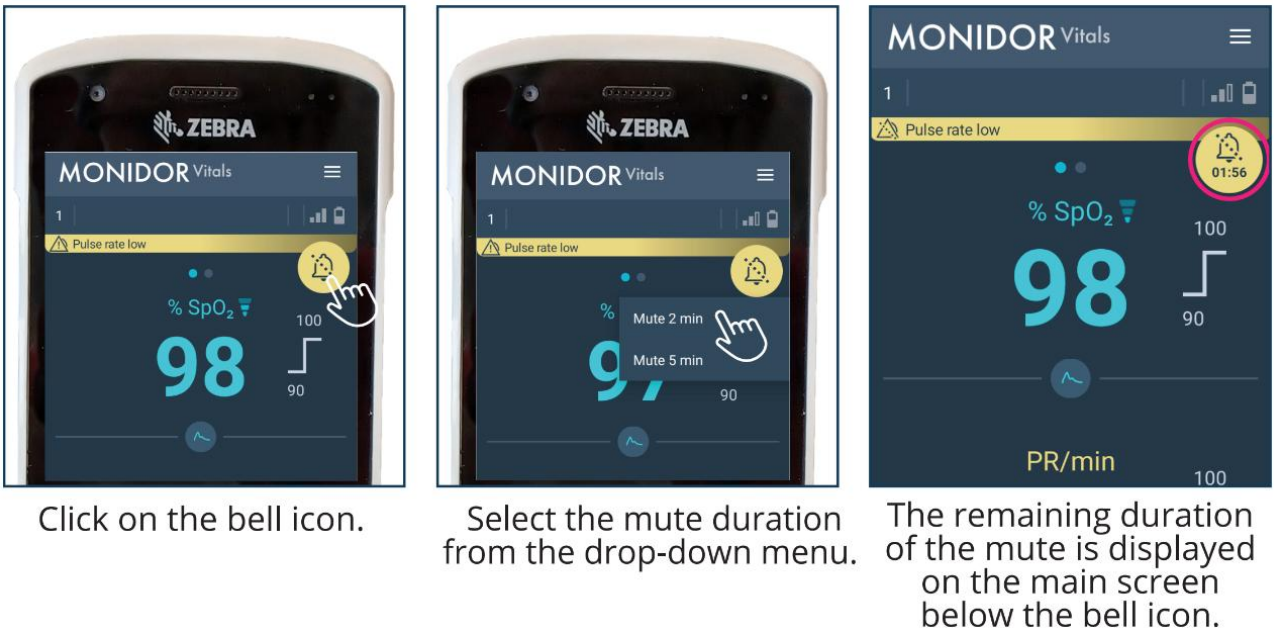


Figure 15: Muting an alarm sound from the wireless patient monitor

4.7 Setting alarm limits

Monidor Vitals has preset alarm limits which trigger an alarm when exceeded or not reached, unless the user has set different alarm limits. The factory-set alarm limits and alarm limit adjustment ranges are specified in Table 8. The default settings may differ from the factory settings in the unit's presets. Check the default settings used in the unit.

The user can adjust the alarm limits from high to low values, but the alarm limits for very high and very low values are automatically set in relation to the alarm limits for high and low values. Alarm limits can only be set at the wireless patient monitor.

NOTE: If the battery of the wireless patient monitor device runs out, the alarm limits will be reset to the unit's default settings when it is restarted.

Table 8: Alarm limits

Alarm	Adjustment interval	Factory setting	Automatic
SpO_2 high	71–100	100	-
SpO_2 low	70-99	90	
SpO_2 very low		85	Δ lower than the "SpO_2 low" alarm limit*

Pulse rate very high		160	Δ higher than the 'Pulse rate high' alarm limit*
Pulse rate high	75-210	140	
Pulse rate low	30-100	50	
Pulse rate very low		30	Δ lower than the "Pulse rate low" alarm limit*
* Δ is defined in the presets for each very high or very low alarm.			

Alarm limits are set using sliders or by entering the desired values in the numeric fields (Figure 16).

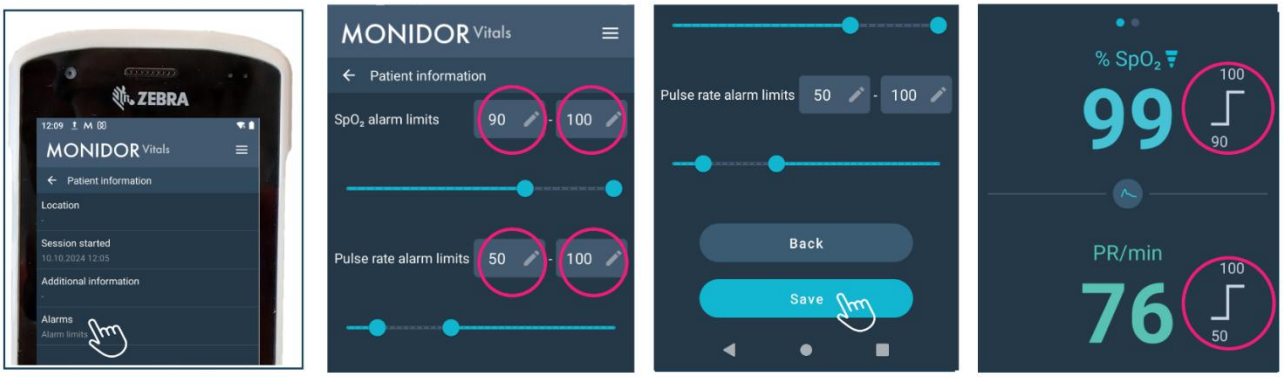


Figure 16: Setting alarm limits at the wireless patient monitor.

If the wireless patient monitor is set to silent in the default settings, it is possible to temporarily enable alarm sounds from the patient monitor's "Alarms" settings.

4.8 Causes of technical alarms

Table 9 shows the causes of technical alarms.

Table 9: Causes of technical alarms

Technical alarm	Cause
Pulse oximeter battery Low	The batteries in the pulse oximeter are running out.
Wireless patient monitor battery low	The wireless patient monitor is running out of battery. The wireless patient monitor is

	not in the charging cradle or the charging cradle power cable is not in the socket.
No connection to pulse oximeter	The wireless patient monitor is not connected to the pulse oximeter, the wireless patient monitor is not close enough to the pulse oximeter or the batteries in the pulse oximeter have run out.
No connection to remote monitoring	The wireless patient monitor or terminal is not connected to the remote monitoring server. The alarming device is not connected to the network or the automatic time setting on the device is not turned on.
No sensor detected	The pulse oximeter does not detect the sensor. The sensor is not correctly connected to the pulse oximeter, the sensor connector is damaged, or the sensor is incorrect.
Sensor error	The pulse oximeter has detected a sensor error. Sensor disconnected, misaligned or incompatible with the pulse oximeter.
System error in pulse oximeter	There is an internal system error in the pulse oximeter.
Weak sensor signal	The pulse signal is insufficient. The pulse oximeter does not detect a pulse or there is excessive movement in the sensor area.

4.9 Verifying the functionality of the alarm system

The operation of the alarms should be verified before first use, and whenever a malfunction of the alarm system is suspected. The operation of the alarms is verified as follows:

1. Start monitoring.
2. Set the pulse rate limit to produce a medium or high priority alarm. For example, set the lower pulse rate limit to 40.
3. Wait for the alarm tone to be heard both at the wireless patient monitor and at the remote monitoring terminal.
4. If the alarm tone is heard within the delay time, the alarm function is working correctly.

5. OTHER FUCTIONS

Monidor Vitals collects the oxygen saturation and pulse values measured during monitoring and stores them in the history view. The history view can be viewed both on the wireless patient monitor and in the remote monitoring application. The PPG curve, on the other hand, can only be viewed on the wireless patient monitor.

5.1 History view at the wireless patient monitor

The history view of oxygen saturation and pulse values can be viewed from the wireless patient monitor by swiping the main view to the left. In the history view, the upper graph shows the patient's SpO_2 measurement values during the monitoring period. The lower graph shows the patient's pulse measurement values during the same monitoring period. (Figure 17)

The yellow line represents the medium priority and the red line the high priority alarm limits.

The history view is cleared when the remote monitoring is ended (see chapter 3.4.) or if the history view is cleared by clicking ”Reset” at the bottom of the history view.

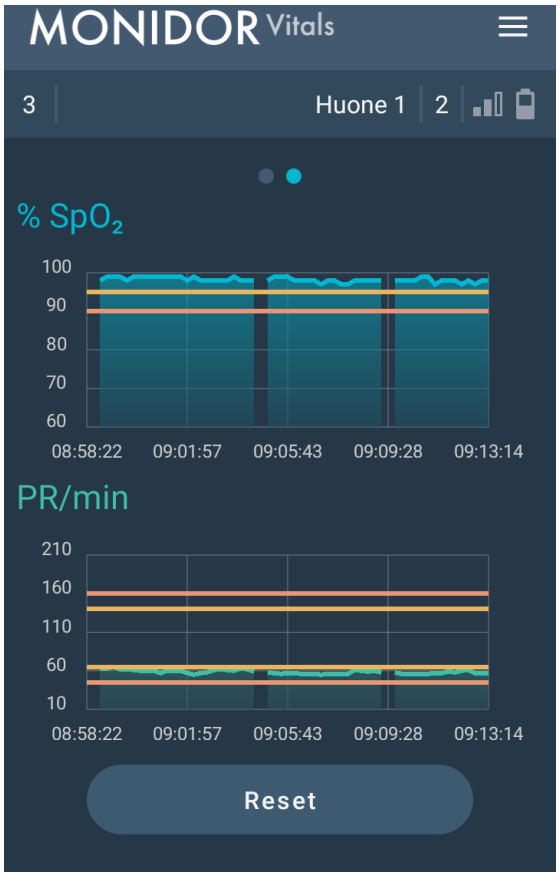


Figure 17: History view at the wireless patient monitor

5.2 History view at the remote monitoring terminals

The history view of oxygen saturation and pulse rate can be displayed in the remote monitoring application by clicking on the device card. The upper graph in the history view shows the patient's SpO_2 measurement values during the monitoring period. The lower graph shows the patient's pulse rate measurement values during the same monitoring period (Figure 18). The history view is scalable.

The history view is cleared when monitoring is stopped (see section 3.4) or if the history view is cleared from the access point.

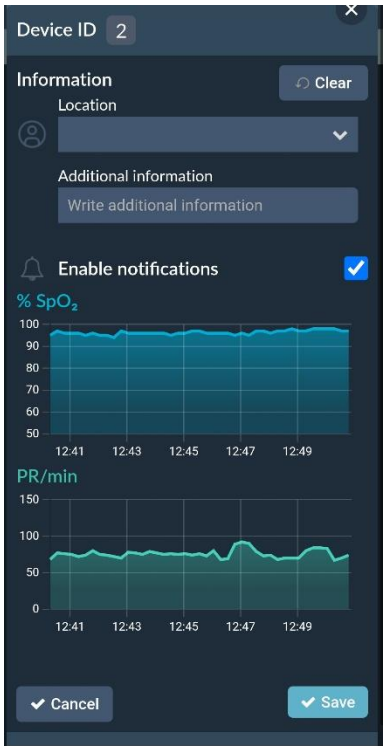


Figure 18: History view at the remote monitoring terminals

5.3 PPG curve

The PPG (photoplethysmogram) can be viewed on the wireless patient monitor by clicking the curve symbol in the middle of the main screen (Figure 19).

Display the PPG curve by clicking on the curve symbol in the middle of the main view.

The PPG curve is displayed between the SpO2 and pulse values in the center of the screen.

Figure 19: PPG curve at the wireless patient monitor

6. POSSIBLE PROBLEM SITUATIONS

- If the wireless patient monitor or remote monitoring device cannot connect to the Wi-Fi network, check that the wireless patient monitor device and remote monitoring device are on the correct time. It is recommended that the automatic time setting on the wireless patient monitor be kept on. If the wireless patient monitor or remote monitoring device cannot connect to the network and its clock is correct, the user should contact the hospital or organisation's IT support.
- If a connection cannot be established between the pulse oximeter and the wireless patient monitor, technical support should be contacted.

7. LIST OF COMPETENT AUTHORITIES

Denmark
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Device Label

MONIDOR