MONIDOR

VITALS™ USER MANUAL

For device version 1.1.0

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 an access point used on a designated access point mobile device, which is not a medical device, server software hosted on commercial server or cloud, 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 not intended to be used in intensive care or critical care units.

1.3 Operating principle

The Monidor Vitals Access Point retrieves electronic information from the pulse oximeter via B luetooth. This data is then transmitted to the Monidor Vitals Server software over IP networks, making it available to remote terminals.

The Monidor Vitals access point mobile device should remain within Bluetooth range of the pulse oximeter.

Monidor Vitals server software is executed on a server which is accessible from both access point and terminal devices.

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

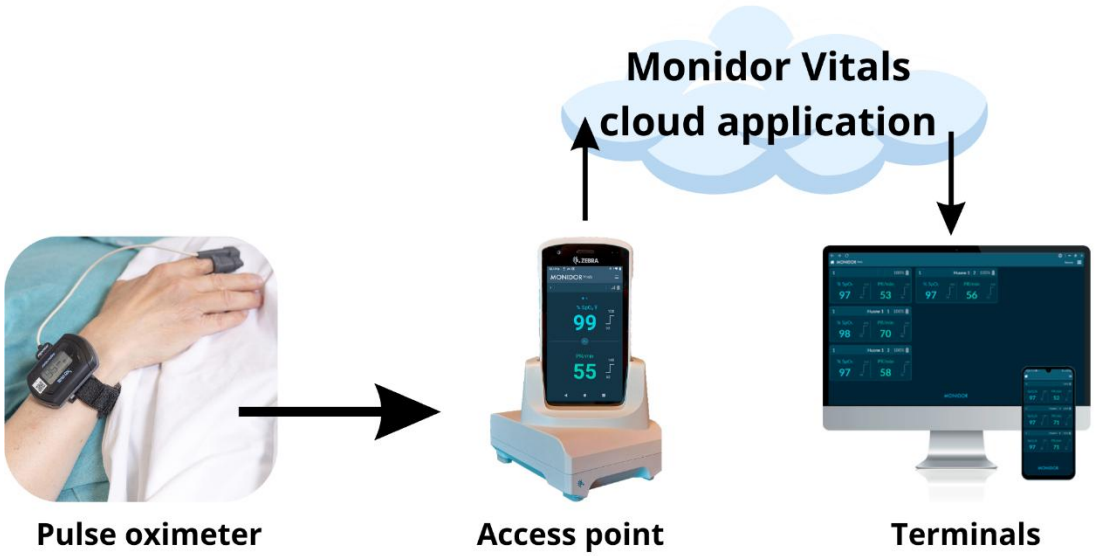


Figure 1: Monidor Vitals data flow

1.4 System requirements

Reliable network connection (to the server)

Access Point Mobile Device:

Only a device approved by Monidor Oy is allowed to use as an access point mobile device.
NOTE: Access point mobile device is not a medical device.
The following mobile devices are currently approved as access points by Monidor Oy:

- Zebra TC26-HC Mobile device

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

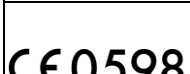
1.5 **Service life**

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 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 access point 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 at the access point and in the remote monitoring application in terminals.

Please refer to the pulse oximeter's own safety instructions.

- Monidor is not responsible for the safety of the user's terminal devices (e.g. tablet, mobile phone or PC).
- The access point mobile device is not a medical device.
- The access point mobile device must not be placed within the reach of the patient.
- 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.
- To ensure continuous data transmission, the access point mobile device must be placed close enough to the connected pulse oximeter within Bluetooth range but not within the reach of the patient.
- Time and date settings of access point mobile device and terminal devices must be set correctly.
- If the batteries of the pulse oximeter or the battery of the access point mobile device run out, the measured values cannot be transmitted to the remote monitoring system.
- 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.

- The use of the device for remote monitoring of the patient's vital signs must not reduce the observation of the patient's condition at the patient's side.
- 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 access point to modify the settings.
- The Monidor Vitals access point software runs on a Zebra TC26-HC Mobile Computer; read the user manual.

Notes on connected devices:

- Read the user manual of Nonin WristOx2® Model 3150 BLE.
- 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".

⚠ WARNING: Modifying this device is prohibited.

⚠ WARNING: Due to possible network connection problems, alarms are not always transmitted to the terminals. The access point is the primary source of alarms.

⚠ WARNING: Setting the sound pressure level of the remote monitoring terminal or access point mobile device lower than the ambient levels can impede operator recognition of alarm conditions.

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.

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 access point 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 on the access point device by pressing the blue button on the side of the device. The blue button can be found on both sides of the device, and the barcode reader is activated by pressing either one.
3. The access point is placed in the patient room.
4. The access point displays the values measured by the pulse oximeter (Figure 4) and sends them to the Monidor Vitals cloud application.

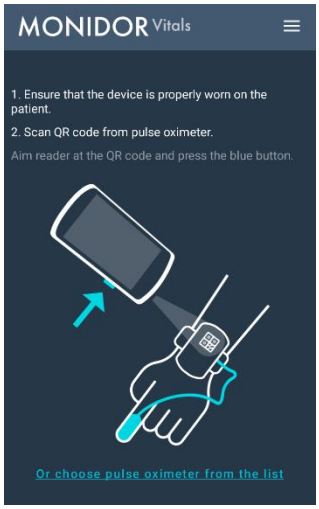


Figure 2 Connecting the access point to the pulse oximeter by scanning the pulse oximeter QR code.

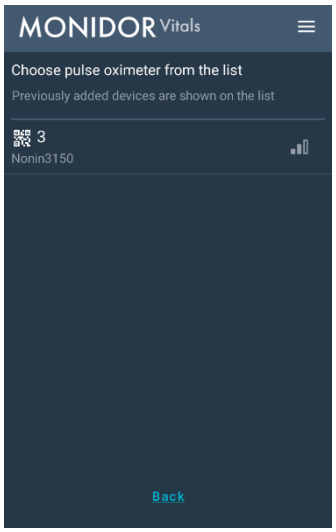


Figure 3 Connecting the access point to the pulse oximeter by selecting from the list.

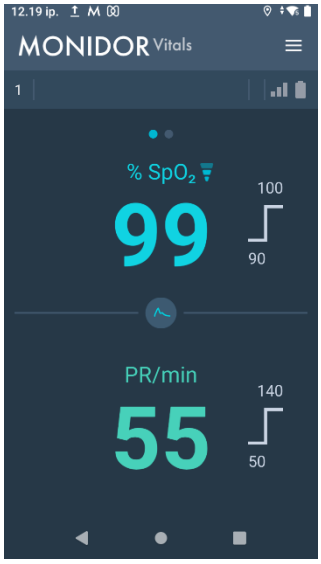


Figure 4 View of the access point

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.

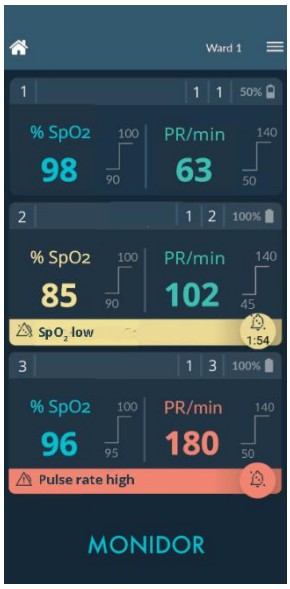


Figure 5: Monidor Vitals remote monitoring view

Card view (Figure 6):

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

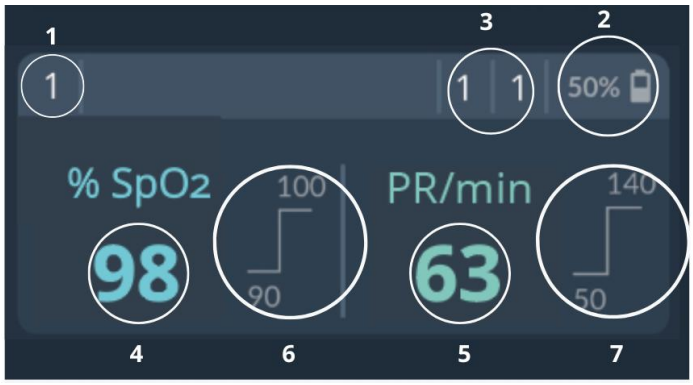


Figure 6: Device card elements

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 access point 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 access point (Figure 7) or from the remote monitoring application (Figure 8).

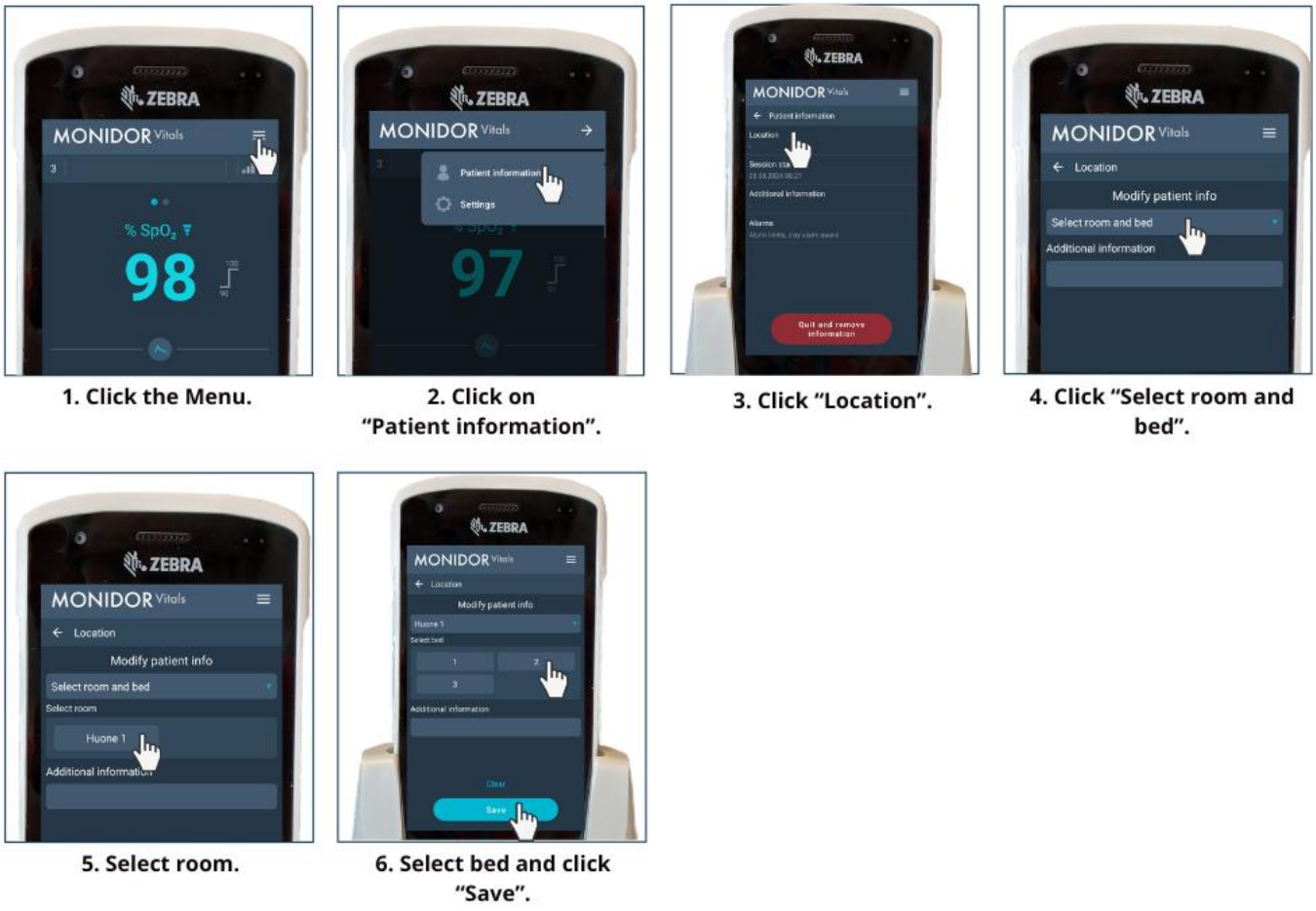


Figure 7: Setting up a room and bed locations from the access point.

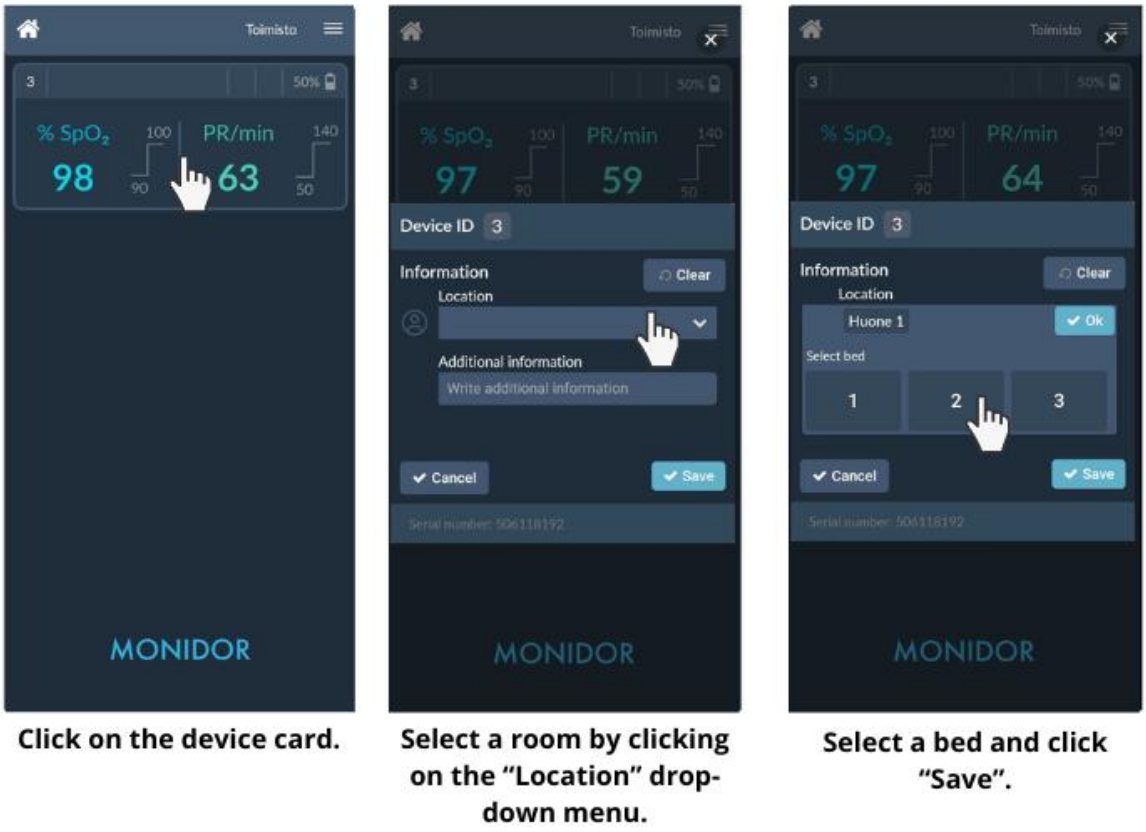
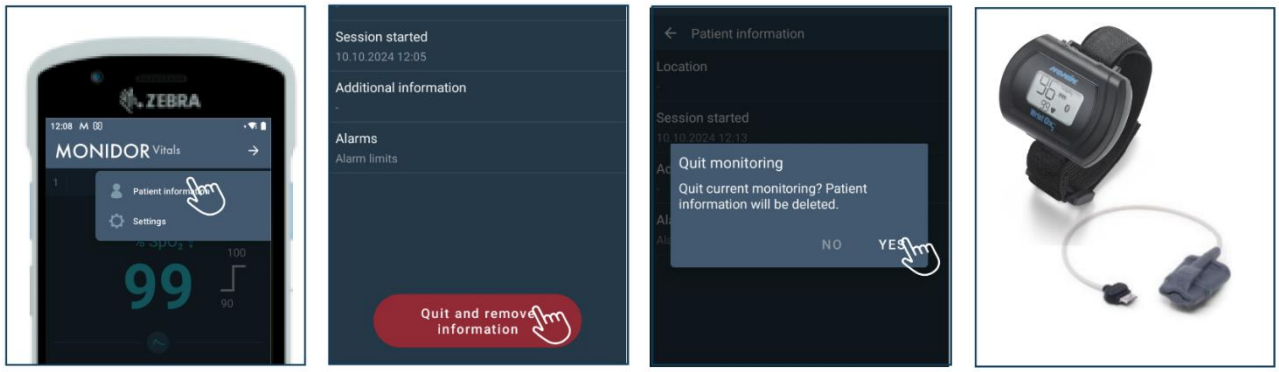


Figure 8: Setting up a room and bed locations from the remote monitoring application.

3.4 Ending remote monitoring

To end remote monitoring, the connection is disconnected from the access point 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

4. ALARMS

Monidor Vitals provides visual and/or audible alarms when the patient's oxygen saturation (SpO_2) or pulse rate values deviate from the limits, as well as for technical reasons. The alarms are divided into high priority (red), medium priority (yellow) and low priority (light blue) alarms.

In active alarms, the reason for the alarm is described in text and the alarm icon  is displayed on a coloured background according to the alarm priority.

All alarms issued by Monidor Vitals are described in Table 2.

Table 2: Description of alarms

Alarm	**Priority**	**Sound alarm Access point**	**Sound alarm Remote monitoring**
SpO2 Low	high	x	x
	medium	x	x
SpO2 High	medium	x	x
Pulse rate low	high	x	x
	medium	x	x
Pulse rate high	high	x	x
	medium	x	x
Pulse oximeter battery Low	medium		x
	low		
Access point battery low	medium		x
	low		
No connection to pulse oximeter	medium		x
	low		
No connection to access point (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		

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

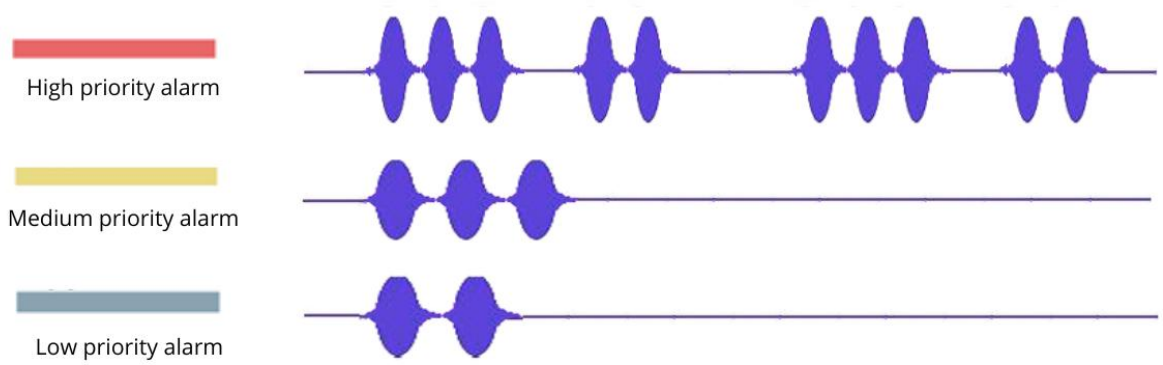


Figure 10: Alarm sounds

Maximum sound pressure levels are shown in table 3.

Table 3: Maximum sound pressure levels at access point

Setting the alarm volume	**Maximum sound pressure level**
High volume (100 %)	High alarm priority **78** dB(A) Medium alarm priority **74** dB(A) Low alarm priority **70** dB(A)
Low volume (50 %)	High alarm priority **67** dB(A) Medium alarm priority **62** dB(A) Low alarm priority **60** 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 (50 %). Testing carried out on a ZEBRA TC26-HC Mobile device.	

NOTE: Volume levels may vary from one device to another, so their exact level cannot be guaranteed. The values in Table 3 apply only to the device tested.

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

High and medium priority alarms indicate that the patient's oxygen saturation (SpO_2) or pulse rate values are out of range. The high priority alarm repeats every 15 seconds, and the medium priority alarm repeats every 30 seconds.

Low-priority alarms indicate technical problems related to the operation of the equipment. These technical alarms are displayed both on the access point screen and in the remote monitoring application on the terminals. The reason for the technical alarm is shown on the

card as a text on a light blue background. Low-priority technical alerts do not produce an alert sound by default. Low priority alarms become medium priority alarms after 15 minutes.

4.1 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.

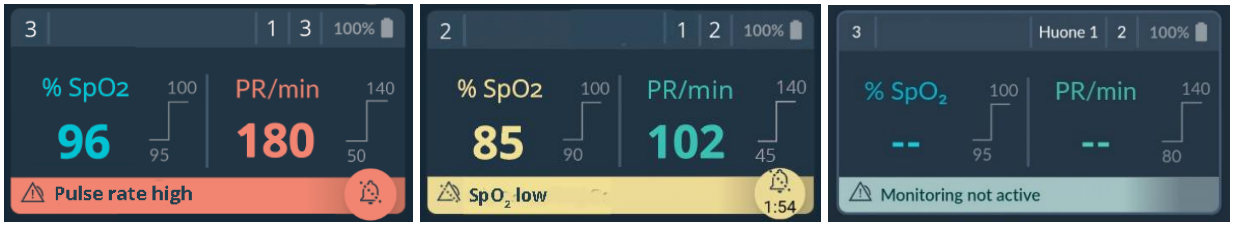


Figure 11: Display of alarms on the remote monitoring device card.

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.

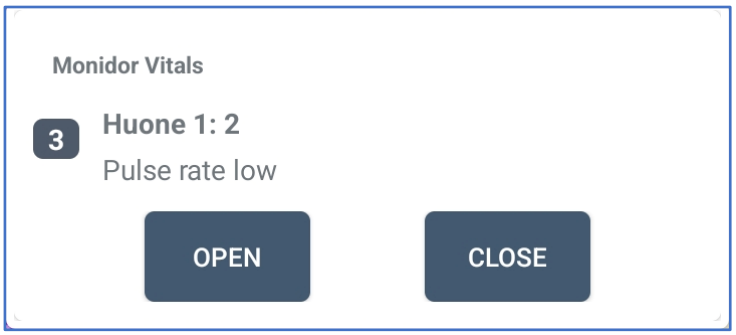
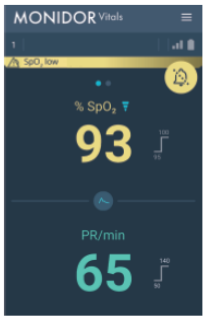


Figure 12: Notification window

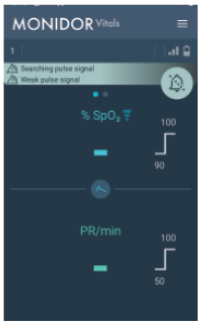
4.2 Alarms at the access point

All alarms are displayed on the access point. The low priority alarm tone will therefore not be sounded at the access point. The alarm text in the access point application is detectable when the user is no more than one metre away from the device.

High priority alarm



Medium priority alarm



Low priority alarm i.e. techincal alarm

Figure 13 Alarms at the access point

4.3 Alarm delays

When the access point has detected an alarm, it will immediately display a visual alarm. The delay for the high priority alarm sound at the access point is 5 seconds and the delay for the medium priority alarm sound is 15 seconds. The delay for high priority alarm sound is 5 seconds and 15 seconds for medium priority alarm sound.

The access point sends alarms to remote monitoring every 15 seconds, so the alarm is sent to remote monitoring terminals within 1 to 15 seconds. Visual alarms typically appear in the remote monitoring within 12 seconds or less and audible alarms are heard within 31 seconds of the alarm being sent from the access point. The alarm delays for remote monitoring are described in Table 4.

Table 4: Remote monitoring alarm delays

	Alarm delays	
	Visual alarm	**Audible alarm**
From access point 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 access point 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.		

4.4 Muting an alarm

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 access point) for the duration of the mute (Figure 14).

A muted alarm is indicated by a mute icon.

Muting an alarm sound from an access point 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”.

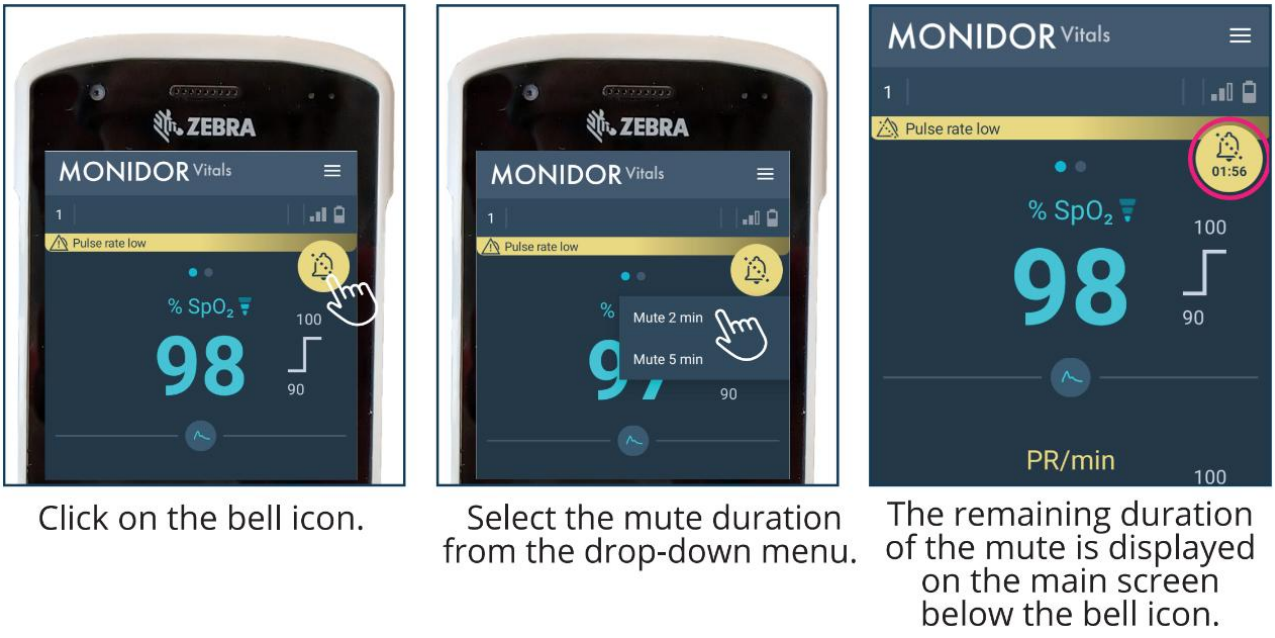


Figure 14: Muting an alarm sound from the access point

4.5 Setting alarm limits

Monidor Vitals has factory-set alarm limits. The user can also set different alarm limits. If the measured values exceed or fall below the alarm limits in use, an alarm will be triggered. The factory set alarm limits and alarm limit adjustment intervals are defined in Table 5. The user can adjust the medium priority alarm limits and the high priority alarm limits are automatically set relative to the medium priority alarm limits. Alarm limits can only be set at the access point.

NOTE: If the battery of the access point mobile device runs out, the alarm limits are restored to factory defaults upon device restart.

Table 5: Alarm limits and adjustment intervals

Alarm	Adjustment interval medium priority	Factory-set alarm limits	High priority (automatic)
SpO2 Low	70-95	90	medium - 5
SpO2 High	95-100	100	-
Pulse rate low	30-100	50	medium - 20
Pulse rate high	75-210	140	medium + 20

Alarm limits are set using sliders or by entering the desired values in the numeric fields (Figure 15).

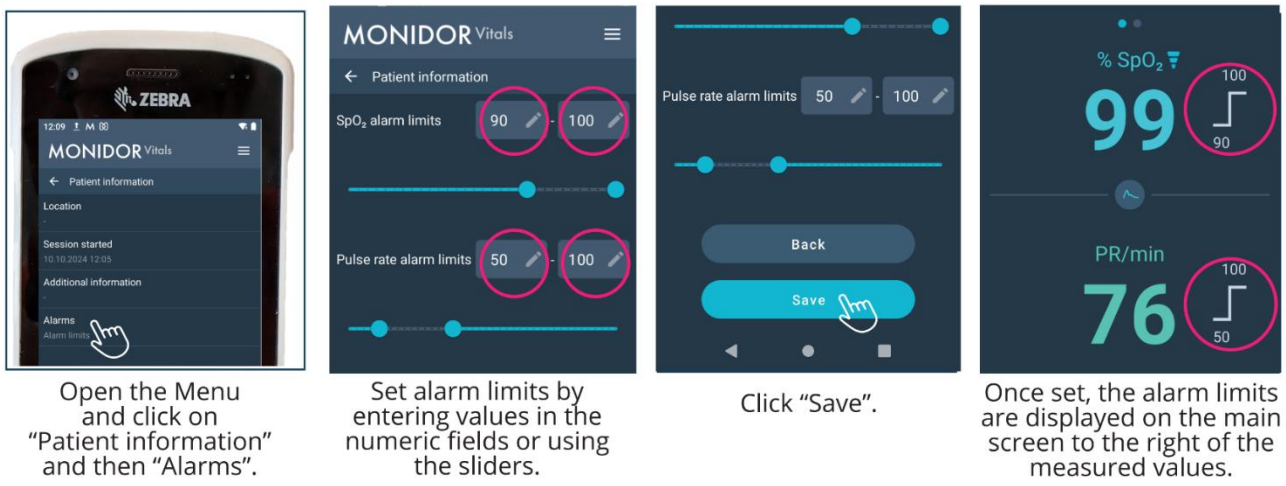


Figure 15: Setting alarm limits at the access point.

4.6 Causes of technical alarms

Table 6 shows the causes of technical alarms.

Table 6: Causes of technical alarms

Technical alarm	**Cause**
Pulse oximeter battery Low	The batteries in the pulse oximeter are running out.
Access point battery low	The access point is running out of battery. The access point is not in the charging cradle or the charging cradle power cable is not in the socket.
No connection to pulse oximeter	The access point is not connected to the pulse oximeter, the access point is not close enough to the pulse oximeter or the batteries in the pulse oximeter have run out.
No connection to remote monitoring	The access point 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.

4.7 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 access point and at the remote monitoring terminal.
4. If the alarm tone is heard within the delay time, the alarm function is working correctly.

5. HISTORY VIEW AT THE ACCESS POINT

The history view of oxygen saturation and pulse values can be viewed from the access point 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 16)

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.

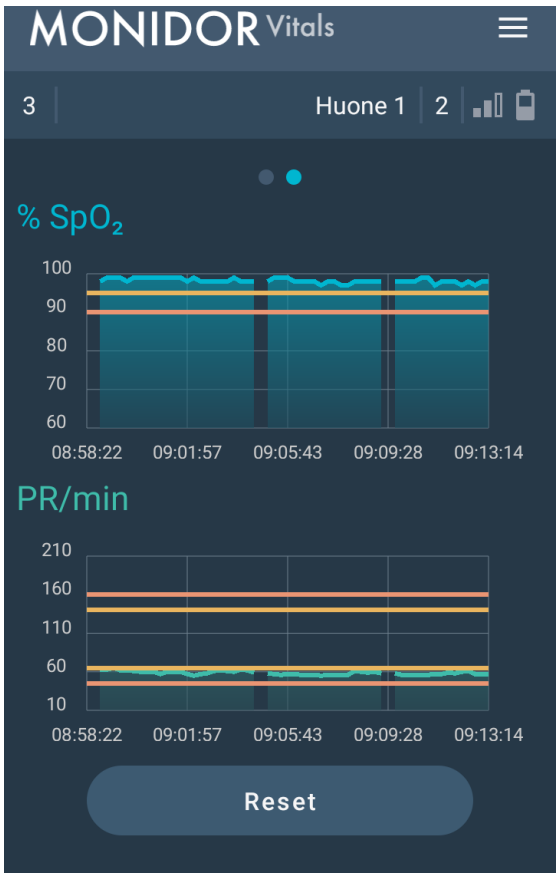


Figure 16: History view

6. POSSIBLE PROBLEM SITUATIONS

- If the access point or remote monitoring device cannot connect to the Wi-Fi network, check that the access point device and remote monitoring device are on the correct time. It is recommended that the automatic time setting on the access point be kept on. If the access point 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 access point, technical support should be contacted.

7. LIST OF COMPETENT AUTHORITIES

Denmark
Danish Medicines Agency
Axel Heides Gade 1, 2300 København S, Denmark
Tel. +45 7222 7400
E-mail: dkma@dkma.dk, www.laegemiddelstyrelsen.dk

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State Agency of Medicines
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Tel. +372 737 41 40
Fax +372 737 41 42
E-mail: info@ravimiamet.ee, www.ravimiamet.ee

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Finnish Medicines Agency
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Tel. +358 29 522 3341
Fax +358 29 522 3002
www.fimea.fi

France
National Agency for the Safety of Medicine and Health Products
143-147 bd Anatole France, 93285 Saint Denis cedex, France
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www.ansm.sante.fr

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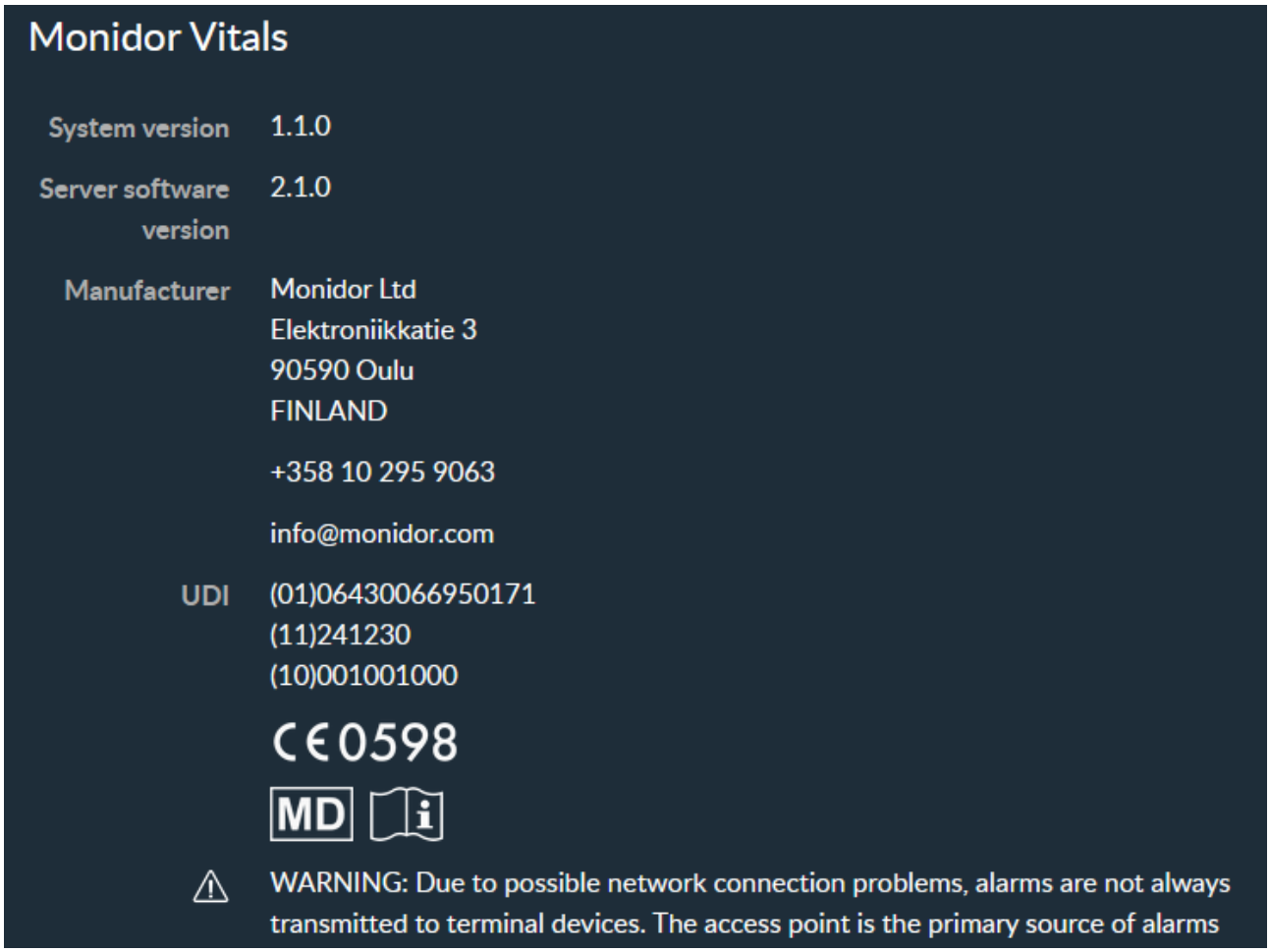

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