# Desktop Pulseoximeter
# USER MANUAL



ABADIS 711®

*Digital Pulse Oximeter*

# Content

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| | |
|---|---|
| | Device: **Pulse Oximeter**<br>Model: **ABADIS711**<br>Class: **IIb**<br>Basic UDI-DI: **62618435ABADIS711T5**<br>REF **24.07** |

| | | |
|---|---|---|
| **Date of Writing: 05/10/2024** | **Revision Number: R005** | **Revising Date: 05/10/2026** |

## Introduction

According to the definition of medical references and sources, pulse oximetry is a device that can non-invasively monitor the oxygen saturation of arterial hemoglobin in the blood, which is known as $SpO_2$. In fact, this device measures the amount of oxygen as a percentage of hemoglobin molecules that are mixed with oxygen in relation to the total amount of hemoglobin molecules.

This monitor with spectroscopic technique is able to detect Hypoxia, Cyanosis, Tachycardia and Bradycardia. Due to its simplicity of installation, non-invasive method of monitoring, and numerous helpful features, it is intended for use by patients of all ages -adults, pediatrics, and infants- in various departments of healthcare institutions.

This device with the trade name ABADIS711 was designed and manufactured by Parsian Medical Co. and its general specifications are as follows.

### Primary requirements:

- Monitoring the vital signs

### Secondary requirements:

- Monitoring of $SpO_2$ level (%) (if required by the doctor, with an accuracy of one tenth of a percent).
- Monitoring of Pulse Rate (PR).
- Motion artifact reduction.
- Monitoring of Perfusion Index (PI) numerically.
- Monitoring of body temperature.
- Visual and audible alarms with high and medium priorities.
- Adjustable alarms with different priorities.

- Variable pitch pulse tone based on changes in blood oxygen saturation.
- Trend analysis option for each patient.
- Configurable patient profile settings for adult, pediatric, and neonate.
- Use of electricity and rechargeable battery with capacity of 5 hours with the ability to increase based on the user's needs.
- 7.8'' wide screen with display resolution for a distance of up to 4 meters with adjustable backlight.
- Durable body according to IEC 60601-1 standard for portable devices.
- Complying all requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, ISO 80601-2-61, IEC 62304 and ASTM F 2761-09 standards.

## Additional specifications:

- Possibility of portable use.
- Potential for placement on a trolley, infant incubator, serum holder and wall-mounted.
- Potential for connecting to Integrated Clinical Environment (ICE) using Ethernet networks supporting TCP and MLLP protocols in compliance with the HL7 standard.
- Potential for transferring patient information and adjusting system settings by using the USB port for connecting to a PC.

## Section 1 – Principles of Operation

### 1-1- Safety

Read this section carefully before use**.**

### 1-1-1- Intended use

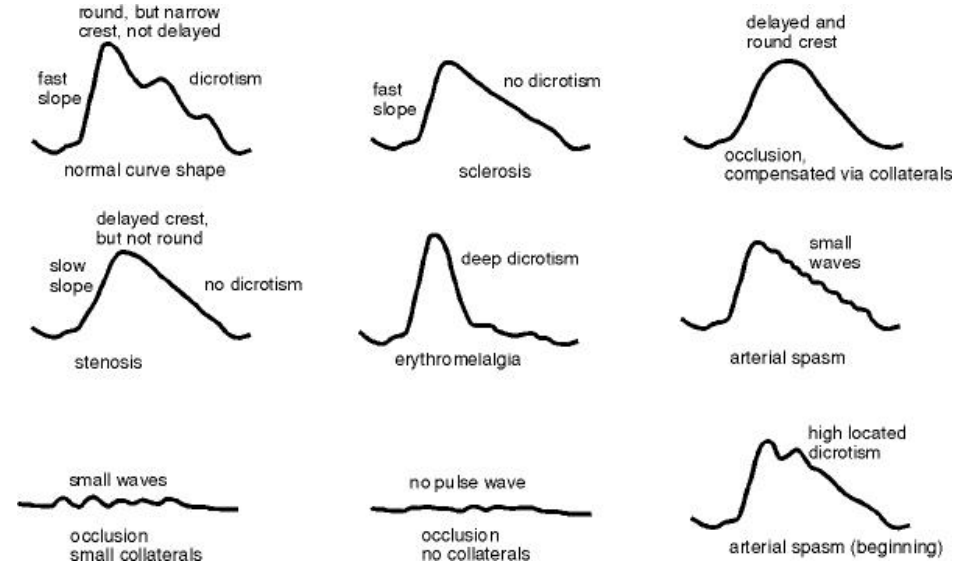
ABADIS711 is used to measure $SpO_2$, pulse rate, perfusion and body temperature. This device is calibrated to measure functional oxygen saturation.

### 1-1-2- Operating principles

- There is a difference in light absorption against red and infrared light between oxyhemoglobin and deoxyhemoglobin (photometry).
- Blood volume and the amount of light absorbed by the blood changes in each heartbeat (photoplethysmography technique).
- Red and infrared LEDs act as light sources and photodetectors act as light receivers.
- Perfusion Index (PI) in pulse oximeter is the ratio of pulsative signal to non-pulsative signal, which is expressed as a percentage (AC / DC × 100). Peripheral perfusion measurement does not require direct observation and access (for example, an unforeseen factor such as skin color is unaffected in this measurement). This makes the perfusion factor an important tool in the evaluation.

### 1-1-3- Photoplethysmography (PPG) waveform

This curve, which shows the change in arterial volume in each heartbeat, will be very useful in diagnosis. By this, the following examples help to determine the issues facing the patient in relation to this chart:




Bar graph profile also shows the maximum of the plethysmograph curve in each heartbeat.

## 1-1-4- Warnings

⚠ A warning indicates the possibility of injury to the user or patient. This suggests that follow the warnings that are issued.

⚠ Make sure to read the instructions before use.

⚠ Never use this device in the presence of flammable gases and anesthetic compounds.

⚠ This device must be used by experienced employees after reading the instructions and getting familiar with the technical specifications.

⚠ The alarm range of the device automatically resets to the standard's specified limits after each power-on. Only if needed, adjust the desired range through the corresponding menu.

⚠ Do not use this device as an apnea monitor.

⚠ Only visual messages will show up on the screen if you disable auditory alarms. Please note that audio alarms will remain disabled on the device for maximum 120 seconds based on user settings.

⚠ If the patient is in critical condition, it is better not to turn off the alarms.

⚠ Do not block the openings related to the device speaker. This will reduce the effectiveness of sound warnings.

⚠ Do not lift or move the device by its extension cable connection or sensor cable. In general, avoid any action that could damage the wires, connectors and sensors.

⚠ Use only Parsian Medical Co. sensors for this device. Using sensors from other manufacturers will cause improper performance or damage to the device.

⚠ If damage is observed in the sensor, refrain from using it. Do not attempt to sterilize sensors by autoclave.

⚠ If the LCD screen of the device is broken, take extra care to keep the liquid away from your body. These chemicals are extremely harmful and poisonous.

⚠ To improve system accuracy and avoid light interference, cover the sensor if you are using the device in a well-lit area.

⚠ Avoid placing the sensor on damaged and wounded tissue.

⚠ According to the standard ISO 80601-2-61, it is not allowed to use Functional Tester or Patient Simulator to check $SpO_2$ accuracy. To check the calibration of $SpO_2$ and Pulse rate, you can use Fluke Biomedical Co. vital signs simulators with SPOT Light Firmware v1.07 and ProSim 8 Firmware V2.08 models with Masimo settings.

⚠ If a serious incident occurs in relation to the device, please report to the Parsian Medical Co. and the competent authority of the member state in which the user and/or patient is established.

**Risk of explosion:** Do not use this device in environments containing flammable anesthetic gases or other flammable gases, especially when combined with air or a mixture of oxygen and nitrogen in enclosed environments.

## 1-2- Security

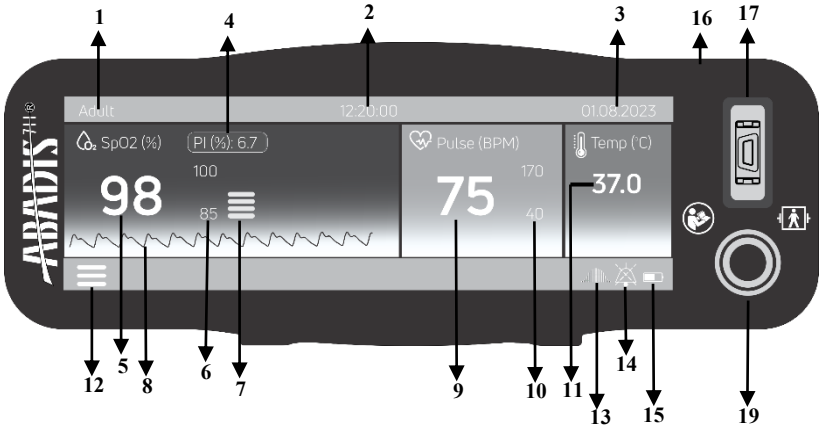
### 1-2-1- Caution

- Attention indicates the possibility of damage to the device or its inefficiency.
- This device can only be used for medical purposes.
- The ABADIS711 is equipped with a rechargeable Li-ion battery. Do not attempt to replace or remove the battery from the device. Service of the ABADIS711 should be done only by qualified personnel. Dispose the battery according to required country or regional requirements.
- Do not use the ABADIS711 during magnetic resonance imaging (MRI).
- If there is a fault in device, do not use it and send it to Parsian Medical Co. for repair as soon as possible.
- Do not unscrew the device under any circumstances. There is no part inside the device to be adjusted by the user.
- When disconnecting the extension cable from the device, press the latches to prevent the corresponding jacks from breaking.
- Do not expose the device to direct water splashes or drops (for example, in the rain).
- Check the sensor cable and the extension cable for physical damage before use.
- Avoid moving the device by pulling the cables.
- To prevent any potential injury to the patient, select an installation location where the device cannot accidentally fall on them.
- This device can be used in conjunction with defibrillators or high frequency surgical devices. However, this may affect the accuracy or availability of the parameters and measurements.
- If the power outlet used does not have a protective earth pin or this pin is not connected, it is better to connect the equipotential ground conductor pin on the back of the device to the protective earth of the power grid using a screw clamp.
- Check the device time and date in the relevant menu before using the trend menu.

- The technology used to calculate the values in ABADIS711 is digital pulse oximetry technology. This technology calculates and displays the values of vital signs with much higher accuracy than previous technologies by using the time and frequency analysis of the calibrated data received from the sensor. 6 to 12 seconds pass between placing the sensor in normal mode and computing the initial value of the received signal. Other calculations will be performed consecutively in less than 9 seconds. In the signal analysis method used in this device, data averaging is not used, and the warning mechanism related to $SpO_2$ and Pulse Rate parameters will be activated without any delay after the completion of the calculation period**.**
- The advanced signal processing algorithm automatically increases the amount of input data required to calculate $SpO_2$ and Pulse Rate based on the measurement conditions. This algorithm automatically increases the calculation time if the measurement conditions become more difficult and worse due to low perfusion, signal disturbances, ambient light, electrocautery and other disturbances or a combination of them. If the calculation time exceeds 30 seconds, the "Interference Detected" message will be displayed on the screen, and if this delay continues, the "Pulse Search" message will be displayed. The Pulse and $SpO_2$ values are not displayed during "Pulse Search" alarm**.**
- To simulate the movement physiological disturbance, the method of shaking the finger in irregular periods of time, with a range of 1-2 cm and a frequency of 0.5-4 Hz was used. In this test, subjects were asked to tap a pressure recording pad with their fingertips. The average percentage of modulation calculated in this case is 4.18 in the stationary mode and 6.88 in the motion disturbance mode. This test was applied for different people and the results were evaluated according to the procedure specified in the standard guideline**.**
- To verify the accuracy of the device parameters in Low Perfusion mode, the Fluke Biomedical patient vital signs simulator with ProSim 8 Firmware v2.08 model, equipped with Masimo and PI settings, was used. The accuracy was assessed in

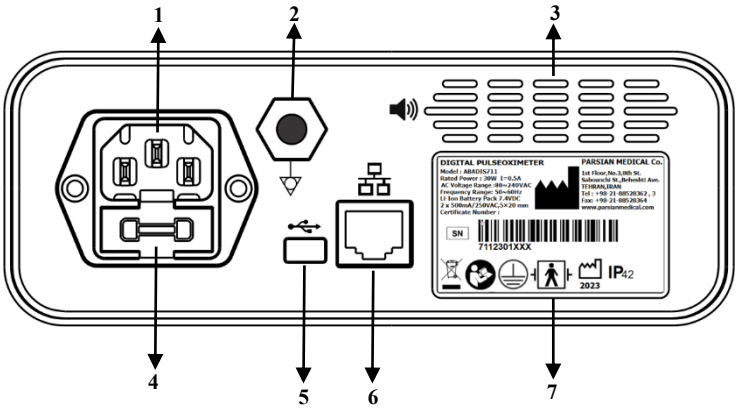
the range of 0.2 to 0.4 according to the $SpO_2$ accuracy review method specified in the ISO 80601-2-61 standard.

## 1-2-2- Signs and icons description




| | | | |
|---|---|---|---|
| 1 | Patient range | 2 | Time (hour, min, sec) |
| 3 | Date (day, month, year) | 4 | Perfusion Index |
| 5 | $SpO_2$ percentage | 6 | Upper and lower limits of $SpO_2$ |
| 7 | Bar graph | 8 | Plethysmography |
| 9 | Pulse rate | 10 | Upper and lower limits of pulse rate |
| 11 | Temperature | 12 | Menu |
| 13 | Signal quality | 14 | Alarm silence |
| 15 | Battery charge percentage | 16 | ON / OFF key and alarm indicator |
| 17 | Pulse oximeter sensor connector | 18 | Temperature sensor connector |

## 1-2-3- Backside connectors



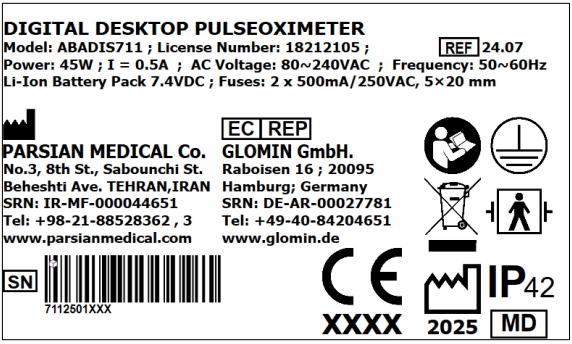

| | | | |
|---|---|---|---|
| 1 | Power connector | 2 | Equipotential ground connector |
| 3 | Speaker | 4 | Fuse Holder |
| 5 | Mini-USB | 6 | RJ45 Ethernet connector |
| 7 | System information label | | |

## 1-2-4- Symbols

| | | | |
|---|---|---|---|
| | Defibrillation-proof. Type BF applied part | 2025 | Production year |
| | Follow instructions for use | IP42 | Protection from ingress of particulates > 1 mm and against vertically falling water drops when it tilted at 15 degrees |
| | Separate collection for electrical and electronic equipment | | Manufacturer |
| SN | Device serial number | | Protective earth (Class I equipment) |

| | | | |
|---|---|---|---|
| EC REP | EU Authorized representative | REF | Catalog number |
| CE | CE Mark | MD | Medical device |

## 1-2-5- Device label




## 1-3- Sensors and accessories

Only Parsian Medical sensors are compatible with ABADIS711 to enable normal operation. The list of these sensors with degree of protection IP42 is given below.

| Accessory | Model | Patient |
|---|---|---|
| PM2019™ Sensors | 210 | Adult / Pediatric – Patients over 30 Kg |
| | 290 | Pediatric |
| | 360 | Neonatal / Patients under 30 Kg |
| Extension Cable | 110 | All |

**Warning**: Ensure that only the suggested sensors are used to prevent serious damage to the device and inaccuracies in measuring system parameters. Please refrain from using any sensors other than those recommended for this device.

The following points should be considered regarding to the sensors**:**

- The recommended sensor placement is index finger in adults and the thumb in children**.**
- Before using Y-shaped sensors, ensure physical health of the sensor position**.**
- To apply the Y-shaped sensors, place one part above the finger and the other side in front of the upper part and under the finger and gently secure both places on the finger with an adhesive**.**
- To apply the Y-shaped sensors to the ear, use the corresponding clip provided in the package with the sensor**.**

It is necessary to pay attention to the following points in this regard**:**

- Excessive movement of the patient, high intensity of ambient light, electromagnetic interference, hemoglobinopathy, low perfusion, vascular occlusion, nail polish or artificial nails will affect the accuracy of the device and sensor**.**
- Check the adult-pediatric sensors every 8 hours and pediatric-infant sensors every four hours and change their positions**.**
- Avoid place the sensor on injured tissues**.**
- If using the Y-sensor with the ear clip, be careful not to place it on the earring or the earring hole on the earlobe**.**
- The materials that are in contact with the patient's skin in this sensor are medical grade silicone that are completely compatible with the body.
- To clean the sensors, cables and connectors, use a cotton soaked in 70% isopropyl alcohol solution.

- The degree of protection of the sensors of this device against the entry of liquids is IP42.
- Sensors required calibration within one-year calibration period. Calibration tests are necessary to verify the correctness of the sensor's performance. If the sensor fails these tests, it must be replaced.

## Section 2 – Instruction for installation and usage

### 2-1- Preparation for use

1. Unpack the device carton and make sure that there is no evidence of damaging on the device and its accessories.
2. Check the sensor and the extension cable connector and make sure there is no evidence of damaging or defective pin on their connectors.
3. Open the sensor package and make sure it is intact.
4. Hold the button ⏻ for 2 seconds until the Parsian Medical Co. logo appears on the screen and hear the welcome sound.
5. After connecting the power cable to the device, make sure that the symbol is displayed on the screen.
6. Connect the extension cable to the device and then connect the sensor to this cable.
7. After about 10 seconds (response time), you should see $SpO_2$ and Pulse measures on the screen.
8. You can set the upper and lower limits of $SpO_2$ and Pulse measures by touching these limits on the screen. Check these issues and make sure it's working correctly.
9. Disconnecting the sensor from the patient's finger will be accompanied by the "Sensor Off Patient" message on the screen. Check occurrence of this alarm by disconnecting sensor from your finger.
10. Disconnecting the sensor from the extension cable or the extension cable from the device will display "Sensor Disconnected" on the screen. Check the occurrence of this condition.

## 2-2- Quick manual

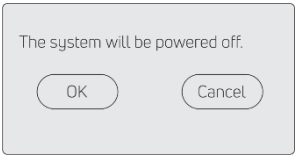
- Press the button  to turn on the device. The device turns on after displaying the logo of Parsian Medical Co. and playing the welcome sound.
- To turn off the device, press  and hold the button. Then you should choose Yes to turning system OFF.
- Use the  to access the settings menu.
- To change the patient age range, select  from the main menu or touch the corresponding option in the upper left part of the screen. Three options, Adult, Pediatric, and Neonate, will appear on the screen to select the age range of adult, pediatric, and neonate, respectively.
- By selecting  , you can enter the menu related to registering patient information per time unit (second).
- Use  to silence auditory alarms temporarily.
- Touch the battery symbol  to check the percentage of battery power.
- Temperature value will immediately be shown on the screen if the temperature sensor is connected to the specified connector on device front panel.

## 2-3- User manual

### 2-3-1- Turning device on and off

To turn on the device, press ⏻ button until Parsian Medical Co. logo appears on the screen and the welcome sound play.


To turn off the device, press and hold the same button. After confirmation, the Parsian Medical Co. logo and a “Power Off” message will appear on the screen.




## 2-3-2- Signal quality

Signal quality indicator is located in the screen bottom-right side. Indicator shape will progressively change from **?** to  when the sensor is connected to the device. The quality of the received signal has a direct effect on shape of this indicator; if this quantity is decreased, the user should pay particular attention to the sensor installation position. If the indicator change to **?**, the received signal is not suitable for use or making decision.

## 2-3-3- Main power and battery

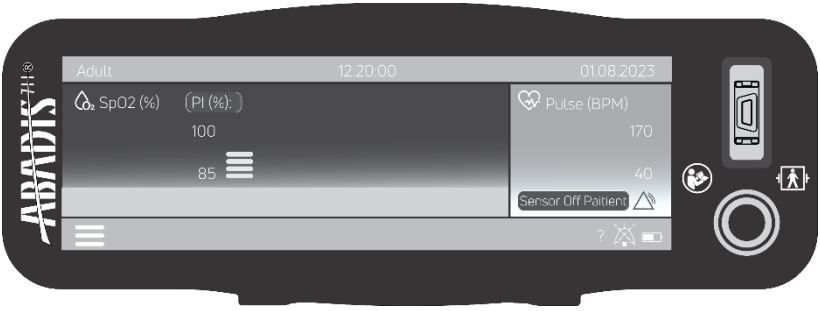
When power cable is connected to the power cord inlet on the back panel, a sign  will appears on the device's display screen. During charging, if the device is turned off, the alarm indicator will turn red, and, its color will change to green gradually as the battery charge increases**.**

Touch the battery icon  to check the remaining battery level. The battery icon provides a visual indication of the current battery charge condition as follow:

| **Displayed symbols** |  |  |  |  |  |  |  |  |  |  |  |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Charge percentage** | <10 | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 100 | connect the power cable |

## 2-3-4- Connecting the sensor to the device

After connecting the extension cable to the sensor, connect the cable connector to the device according to the direction and by pressing the corresponding jacks. If this connector is applied correctly, the “Sensor Disconnected” message will change to “Pulse Search” and then “Sensor Off Patient” (otherwise, contact the service section of company). The monitoring procedure can be initiated by attaching the sensor to the patient’s finger using the device’s default settings.

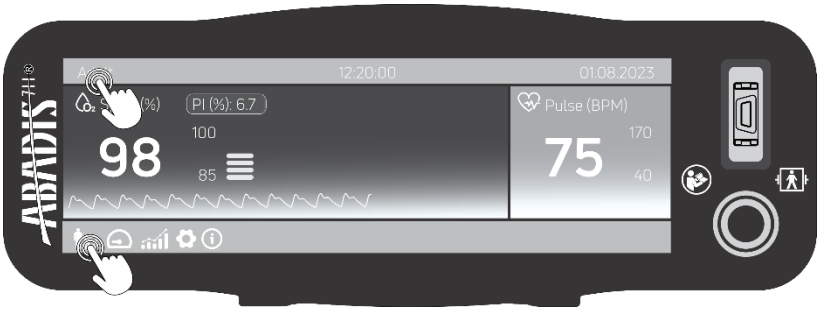

## 2-3-5- Setting menu

Access the settings menu by touching ≡ on the screen. Then, select the desired option from the choices that appear in the bottom left corner of the screen. If you touch any point outside the settings menu on the screen, you will exit from it.

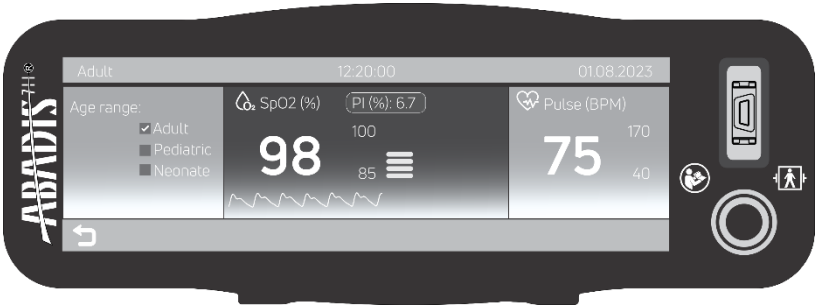
**Note**: The desired menu will automatically close after 90 seconds, if no modifications or selection are made by the user.

## 2-3-6- Patient mode

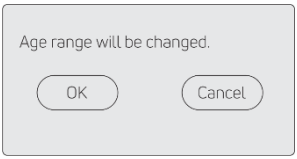
This device can be adjusted for three age ranges of the patient: Adult mode for older patients or those weighing more than 50 kg, Pediatric mode for younger patients weighing between 20 kg and 50 kg, and Neonate mode for newborn patients weighing below 20 kg. By adjusting the patient range correctly, you can observe more accurate measurements. To change the age range to adult, pediatric, or neonate, touch the corresponding option in the upper-left side of the monitor or select  from the main menu**.**




Immediately, three options, Adult, Pediatric and Neonate, will appear on the screen. Select the desired option on the screen by touching it**.**

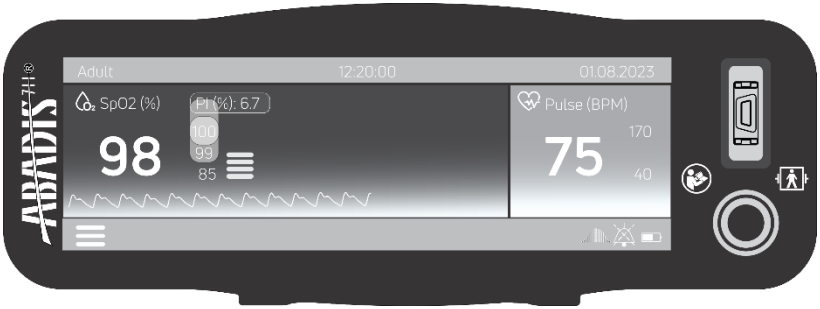


After selecting the age range of the patient and choosing the return option, the following message will appear on the screen. Select OK if you assure about your choice; otherwise, choose Cancel.




## 2-3-7- Upper and lower limits of $SpO_2$ and Pulse rates

In order to set the upper and lower limit of auditory and visual alarms of $SpO_2$ and Pulse rates, select upper and lower limits of $SpO_2$ and Pulse values**.**



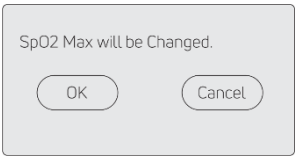

The following thresholds are suggested for each age ranges**:**

| Neonate Mode | |
|---|---|
| **Limit** | **Value** |
| High $SpO_2$ | 95% |
| Low $SpO_2$ | 85% |
| High Pulse Rate | 190 BPM |
| Low Pulse Rate | 90 BPM |

| Pediatric Mode | |
|---|---|
| **Limit** | **Value** |
| High $SpO_2$ | 100% |
| Low $SpO_2$ | 85% |
| High Pulse Rate | 170 BPM |
| Low Pulse Rate | 60 BPM |

| Adult Mode | |
|---|---|
| **Limit** | **Value** |
| High $SpO_2$ | 100% |
| Low $SpO_2$ | 85% |
| High Pulse Rate | 170 BPM |
| Low Pulse Rate | 40 BPM |

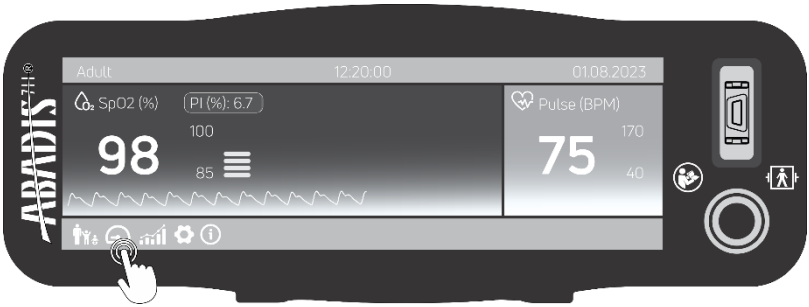
After selecting the upper or lower limit of each parameter and choosing the return, the following message will appear on the screen. Select OK if you assure of your selection; otherwise, choose Cancel.




**Warning:** Users should be warned that modifying the alarm's ranges can pose a risk to patients in specific medical situations. Remember that alarms may lose their effectiveness under high-priority condition. Note that the upper and lower alarm limits for all patient age groups (adult, pediatric, and neonate) will reset to the default values after the device is turned off and on. In this case, by setting the $SpO_2$ low limit for values below 85%, the mentioned limit will change to red color for the user's attention.

## 2-3-8- Sensitivity

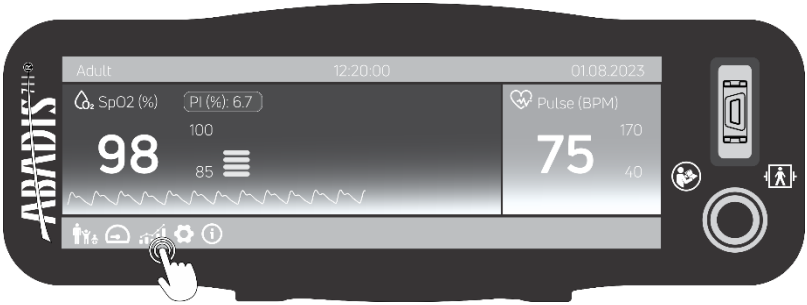
In normal mode, the device sensitivity is set in normal mode . If the patient is in a condition with a weak received signal, such as low perfusion, it is advisable to set the sensitivity to a high level. Touch on the screen. By selecting the sensitivity option high sensitivity mode will be activated.



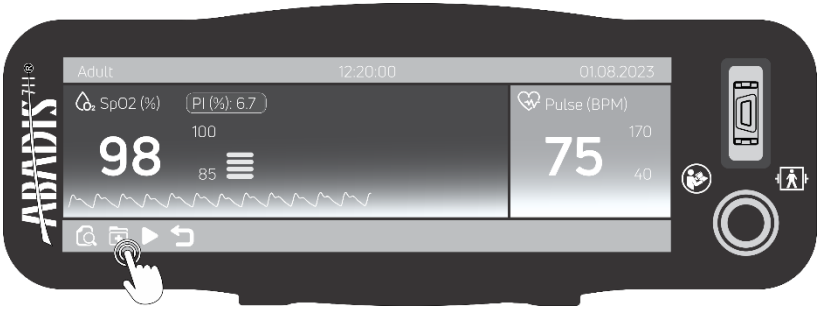
**Note:** Use caution when adjusting to high sensitivity. In this case, small noises such as motion artifact and ambient light interference will affect the calculated signal. As such, it is advised that the settings in this section be made with this in consideration.

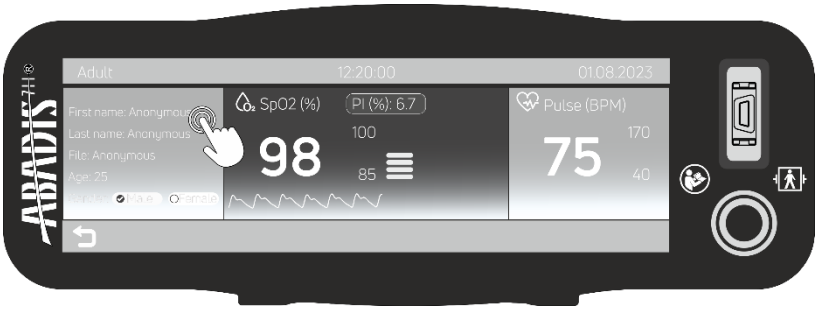
## 2-3-9- Set patient information to store parameters (Trend)

Select the settings menu ☰ on the screen and then 📊. In this case, you can store $SpO_2$ and Pulse values for each patient in the terms of time (second)**.**




Next, choose 📁. In this menu, you can enter the patient's first name, last name, file name, age, and gender using the on-screen keyboard by tapping any of the fields**.**



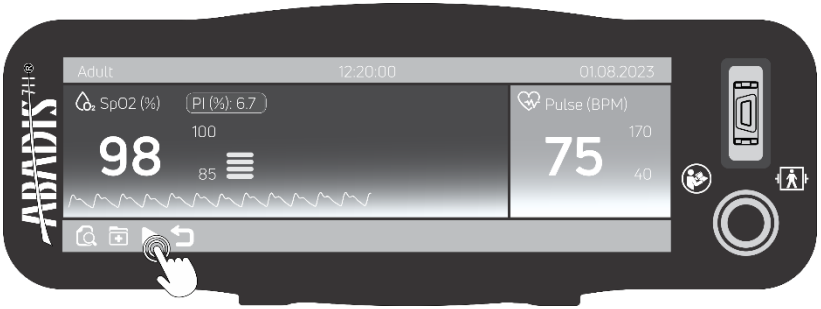



| First name |
|---|
| Last name |
| File |
| Age |
| Gender |

You can return to the previous menu by selecting or you will exit the settings menu by touching any point outside displayed menu. If trend is running, it is not possible to access this menu**.**

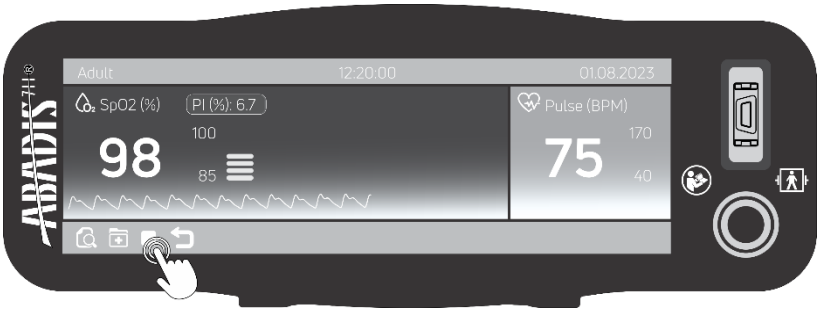
## 2-3-10- Start storing parameters (Trend)

Select settings menu on the screen and then . Enable trend by touching . Note that when this option is activated, the symbol Trend will appear on the screen**.**



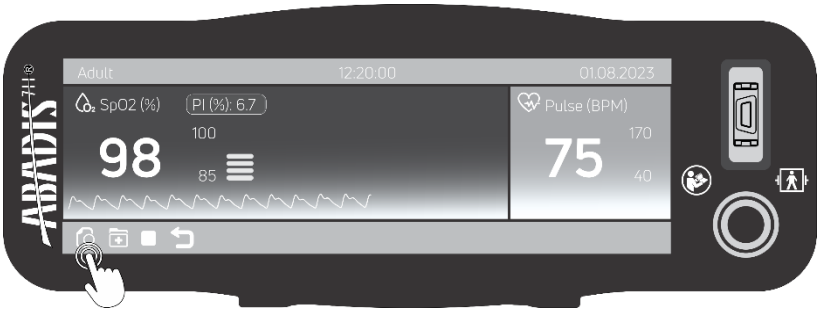
## 2-3-11- Stop trend

From settings menu ☰ on the screen, select 📊. Then disable trend mode by touching ■.

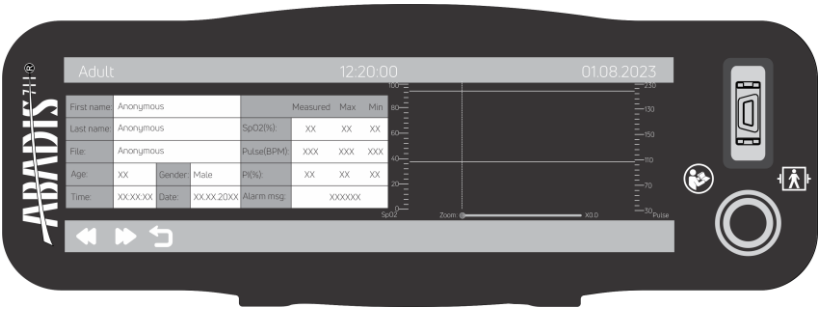



## 2-3-12- View and review trends

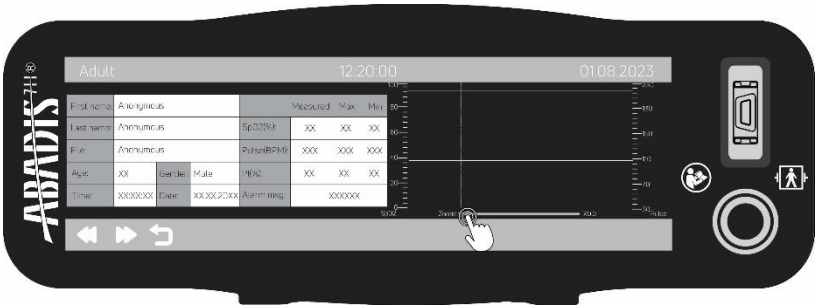
From settings menu ☰ on the screen, select 📊. Then select 🔍 to reach the corresponding menu.




In this menu, the patient's information is shown in 📁 menu both in a table and also on a graph. To move on the graph, you can use the ⏩ and ⏪. In case of continuous touching of these options, the speed of movement of the indicator on the graph will increase. This feature is useful for reviewing charts recorded over longer periods.



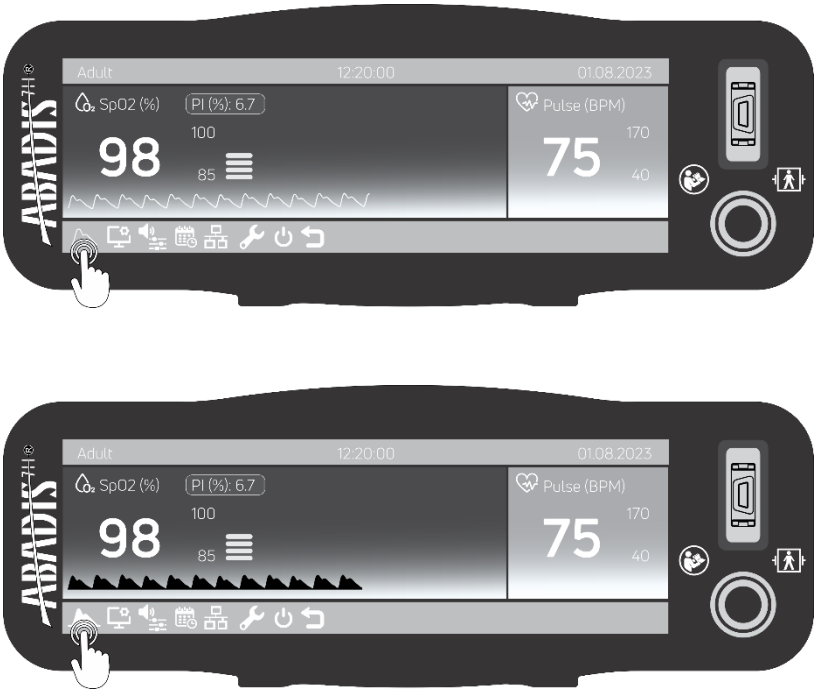

Using the Zoom scroll bar under the graph, it is possible to enlarge the desired part of the graph up to ten times. For this purpose, scroll right or left**.**




## 2-3-13- Setting the waveform shape (Plethysmograph)

From settings menu ☰ on the screen, select ⚙ .

By choosing or you can change the plethysmograph waveform shape. In addition, every time you touch the chart on screen, the waveform shape will change.



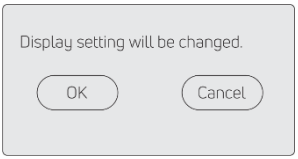

Select to return to the main menu. If you touch any point outside the settings menu on the screen, you will also exit from this menu.

## 2-3-14- Screen settings

Choose settings menu on the screen and select and then .


In this menu, the intensity of the backlight can be changed from ten percent (10%) to one hundred percent (100%) in each ten percent steps. For this purpose, scroll left or right**.**


If you wish to cancel or exit the settings, select  to return to the previous menu. If you touch any point outside the settings menu on the screen, you will also exit it. Select OK if you assure of your selection; otherwise, choose Cancel.



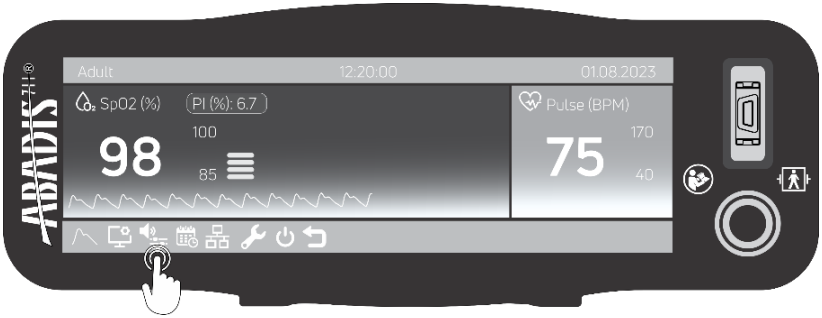

In this device, the screen content can automatically adjust by rotating the device vertically or horizontally, unless the user decides to disable this feature and choose screen orientation

manually. For this purpose, select the desired mode in the screen settings menu  one of the “Vertical”, “Horizontal”, or “Auto rotate” options and then confirm your decision.



## 2-3-15- Sound setting

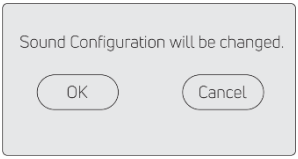
From settings menu on the screen, select the option . Then choose to change the audio setting.



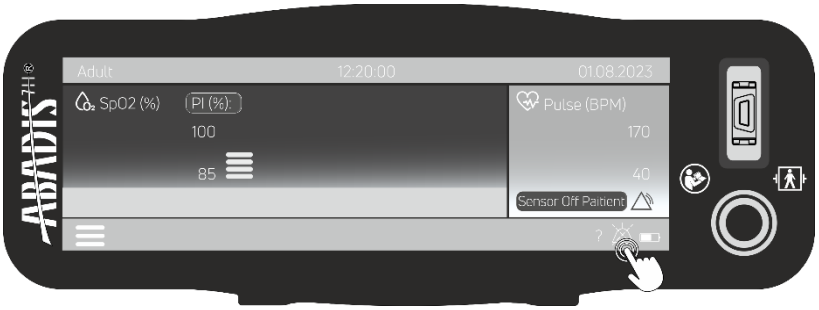

In this menu, the volume of the sound alarms (Alarm level), heartbeat sound (Beep level) and temporarily inactivation the generation of alarm signal (Alarm paused period) can be adjusted according to the following table by scrolling each option right or left.


| | Range | Step | Unit |
|---|---|---|---|
| Alarm level | 10 – 100 | 10 | Percentage |
| Beep level | 0 - 100 | 10 | Percentage |
| Alarm paused period | 0 - 120 | 30 | Second |

If you wish to cancel or exit the settings, select  to return to the previous menu. If you touch any point outside the settings menu on the screen, you will also exit it. Select OK if you assure of your selection; otherwise, choose Cancel.

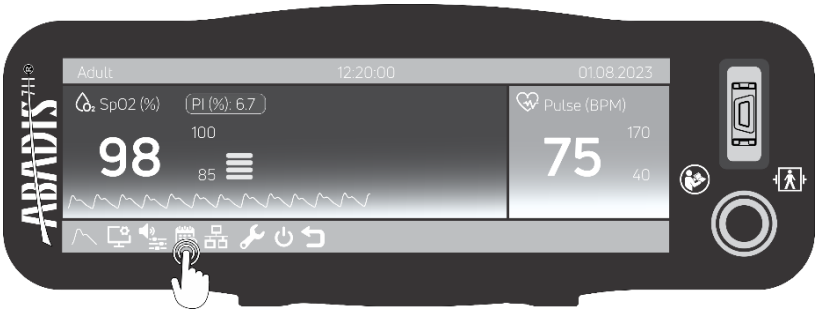



Additionally, selecting  causes temporarily inactivation the generation of alarms audio (alarm paused) for a period of time (adjustable interval up to 120 seconds). Selecting this option again terminates it.

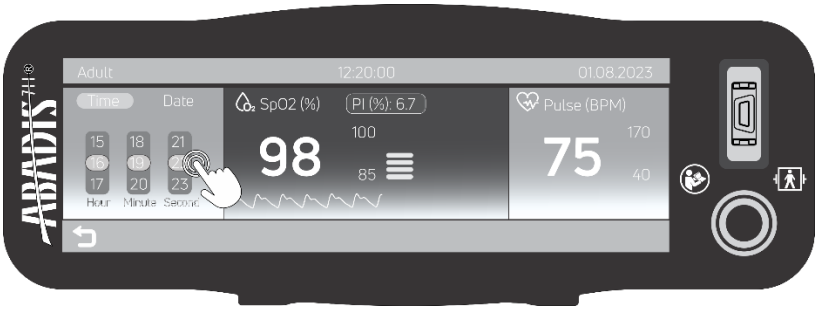



## 2-3-16- Set time and date

Select settings menu  on the screen and then  . Choose  to set the time and date .

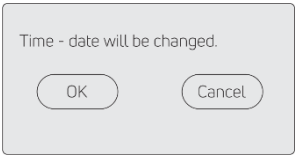


In this menu, you can change the time by setting the Hour, Minute, and Second with scrolling related items up and down.




You can also set Day, Month, and Year in the date tab in the same menu.


If you wish to cancel or exit the settings, select  to return to the previous menu. If you touch any point outside the settings menu on the screen, you will also exit the settings menu. Select OK if you assure of your choice; otherwise, choose Cancel.



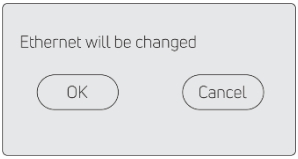
## 2-3-17- Ethernet

In settings menu ≡ on the screen, select ⚙. You can change the network settings 🖧 menu.


In this menu, you can change Device IP, Server IP, Ward Location, Room and Bed numbers.

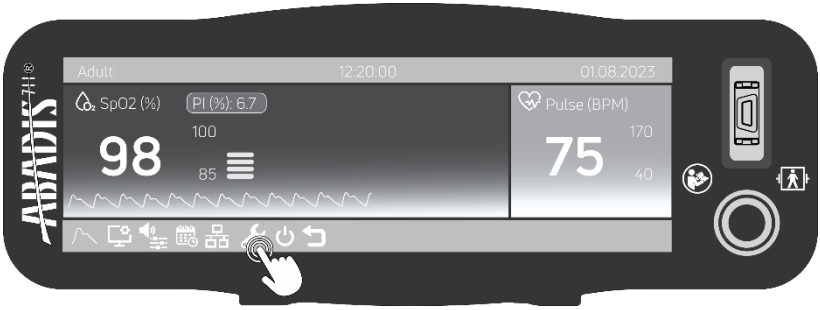

In this case, Device IP and Port in the first row are related to device settings and in the second row are related to the specifications of the HL7 server that receives the information sent by the devices. Based on the HL7 standard, all required parameters such as ward name (Location Ward), room number (Room), and bed number (Bed) will also be sent and utilized in the integrated clinical environment (ICE). By connecting the device to the Ethernet network, it will automatically communicate with the HL7 server and all the required fields will be sent to the server according to the mentioned standard.

Select  to return to the previous menu. If you touch any point outside the settings menu on the screen, you will also exit the settings menu. Select OK if you assure of your selection; otherwise, choose Cancel.



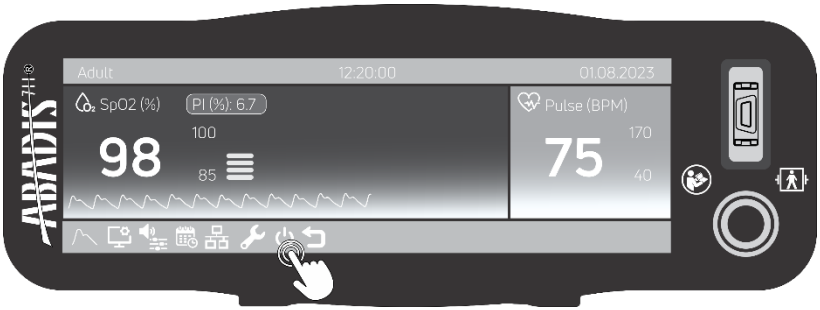

## 2-3-18- Service

Only authorized service personnels are granted access to  menu. It contains special parameters regarding the device hardware.

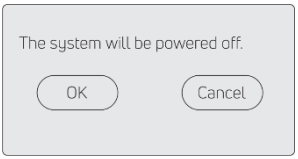



## 2-3-19- Turn off the device using the setting menu

To turn off the device without using the on and off button, from  , select menu  . Then, select  icon.



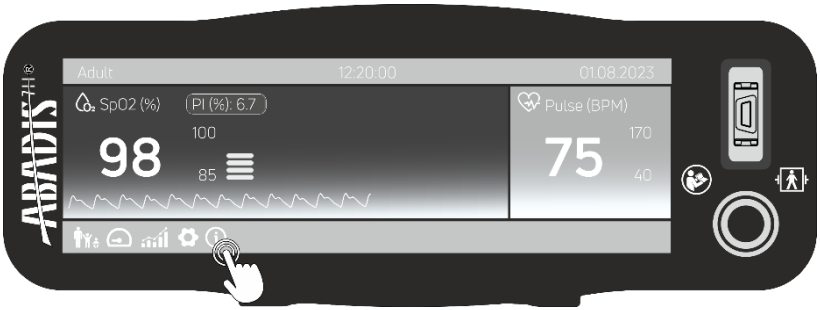

If the displayed message is confirmed, the Parsian Medical Co. logo and a “Power Off” message will appear on the screen.





## 2-3-20- System information

This menu is used to check the general specifications of the device including hardware and software versions and serial number. In this case, select ≡ on the screen, choose the settings menu and then ⓘ.



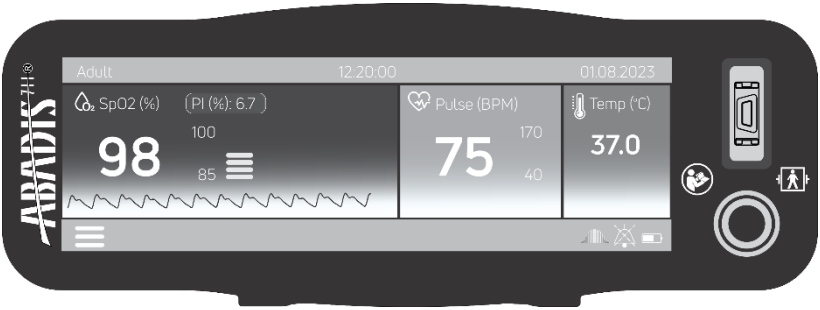

The following items will be displayed. Select  to return to the main men or touch any other point on the screen than menu area.


| | |
|---|---|
| Desktop Digital Pulse Oximeter | Equipment name |
| Model | Equipment model |
| UDI-DI | The unique device identification in the EU |
| S/N | Serial number |
| H/W Ver | Hardware version |
| S/W Ver | Software version |
| Parsian Medical Co. | Manufacturer |
| SRN | Manufacturer single registration number in the EU |
| www.parsianmedical.com | Website of manufacturer |

By scanning the QR code displayed on the screen with your mobile phone, you can access the device's user manual online.

## 2-3-21- Temperature

For measure body temperature, just connect the temperature sensor. For this purpose, YSI 400 series sensors or compatible approved sensors can be used. After connecting the temperature sensor to related connector on the front panel, the measure will be displayed on screen with an accuracy of one tenth based on the Celsius unit.




## 2-3-22- USB port communication

To connect the device to the computer via the USB port, you need to use a special USB cable, with a plug on each end —one Mini-B and one A— which the corresponding receptacle is on a computer. Once connected to the computer and after installing the necessary software, you can save the device information to the computer. For instructions on connecting via USB, refer to the manual.

## 2-3-23- Data accuracy assurance

To ensure the accuracy of measured factors, calculate the pulse rate manually and compare it with displayed Pulse rate. If there is a significant difference, the $SpO_2$ factor may not be displayed correctly. In such a case, pack the device, including the sensor and extension cable, then contact Parsian Medical Co. service department to send it back for servicing.

## 2-4- Collect

- To turn off the device, hold the button ⏻ for 2 seconds and confirm power off message. The device will turn off after displaying the Parsian Medical logo and the Message “Power Off.”
- Disconnect the connector of extension cable from front panel, by pressing the mechanism on both sides of this connector.
- After disconnecting extension cable, put it in package next to the device.

## 2-5- Disposing conditions

In order to dispose the device, keep in mind that all conditions related to the disposal of electronic waste must be taken into account. The components of this device, such as the liquid crystal in the LCD screen and lithium batteries, contain hazardous chemicals that must be disposed of in accordance with specified conditions and regulations related to this type of waste. The relevant symbol for this waste indicated on the backside panel.

## Section 3 – Technical performance

# 3-1- Technical specification

**Note:** All specifications are nominal values.

| **Sensor's LEDs** | |
|---|---|
| Nominal Wavelengths and Nominal Power Output Values | (RED) 660nm – 1.8mw<br>(IR) 905nm – 2.0mw |

| **Display** | |
|---|---|
| Type | High quality TFT full colors liquid crystal display (LCD) with LED backlight and capacitive touch |
| Data Displayed | $SpO_2$, Pulse Rate, Plethysmograph Waveform, Temperature, Alarms and Status Messages |
| NOTE: There is no display delay from the calculated value. | |

| **Measurement Range** | |
|---|---|
| $SpO_2$ | 0% - 100% |
| Pulse Rate | 30 - 250 BPM (Beat per Minute) |
| Temperature | 32.0 - 138.9 °F (0.0 - 60.0 °C) |
| Perfusion | 0.2% - 20% |

| **Resolution** | |
|---|---|
| $SpO_2$ (Functional) | 1% |
| Pulse Rate | 1 BPM |
| Temperature | 0.1°C |

| **Accuracy** | | | |
|---|---|---|---|
| $SpO_2$ (Functional) | No motion and normal perfusion | (91-100 %) | +/- 1% |
| | | (81-90 %) | +/- 2% |
| | | (70-80 %) | +/- 3% |
| Pulse Rate | No motion and normal perfusion | (30-250 BPM) | +/- 3 BPM |
| $SpO_2$ (Functional) | Neonate*<br>No motion and normal perfusion | (70-100 %) | +/- 3% |
| $SpO_2$ (Functional) | Motion or Low perfusion | (70-100 %) | +/- 3% |
| Pulse Rate | Motion or Low perfusion | (35-245 BPM) | +/- 5 BPM |
| Temperature | Not including sensor accuracy | (0- 40 °C) | 1 – 2% |

- Pulse Rate accuracy performed by using ProSim 8 Firmware v2.08 Fluke Biomedical patient simulator.
- Neonatal testing was completed on healthy adult subjects and 1% was added to the % Arms to account for fetal hemoglobin effects.
- Only 2/3 of measurements are expected to fall within the **declared range** of $SpO_2$ accuracy.

| **Data Values** | |
|---|---|
| Data averaging | 8 seconds |
| Data update period | From 8 to 30 seconds* |
| Alarm condition delay | None |
| Alarm signal generation delay | None |

* Based on measurement conditions data update period varies from 8 to 30 seconds.

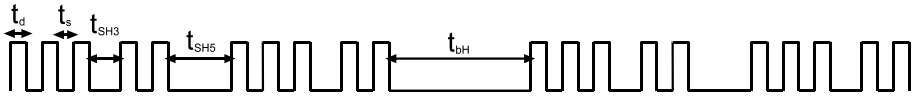
| **Alarm Limits** | |
|---|---|
| Low $SpO_2$ | 0% - 99% |
| High $SpO_2$ | 1% - 100% |
| Low Pulse Rate | 30 - 229 BPM |
| High Pulse Rate | 31 - 230 BPM |

| **Physical Characteristic** | |
|---|---|
| Dimension (WHD) | 25 × 8 × 22 cm |
| Weight | 1 Kg |

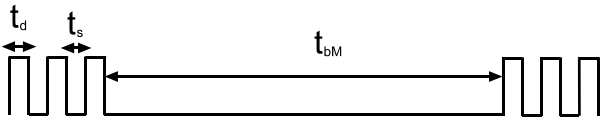
| **Environmental** | | |
|---|---|---|
| Operating | Temperature | -5 °C to 40 °C (23 °F to 113 °F) |
| | Relative humidity | 5% RH to 95% RH, non-condensing 503 mbar to 1059 mbar |
| | Pressure | Approximate elevation of -378 to 594 (-1240 to 1950 ft) |
| Storage | Temperature | -29 °C to 60 °C (-20 °F to 140 °F) |
| | Relative humidity | 5 to 95% RH, non-condensing 503 mbar to 1059 mbar |
| | Pressure | Approximate elevation of -378 to 5946 (-1240 to 1950 ft) |

| Characteristic of Auditory Alarm Signals According to IEC 60601-1-8:2006 | | | | | |
|---|---|---|---|---|---|
| Pulse Frequency | | | 700 Hz | | |
| Effective Pulse Duration ($t_d$) | High Priority | 50 ms | Pulse Spacing ($t_S$) | High Priority | 50 ms |
| | Medium Priority | 170 ms | | Medium Priority | 130 ms |
| $t_{SH3}$ | | 150 ms | $t_{bH}$ | | 10 s |
| $t_{SH5}$ | | 550 ms | $t_{bM}$ | | 20 s |

High Priority




Medium Priority




| Electrical Characteristics | |
|---|---|
| Power Requirement | 80~264 VAC |
| Frequency Range | 47~63 Hz |
| Rated Power | 30 W |
| Fuse | 2 x 500 mA/250 VAC, 5 x 20 mm |
| Battery | Li-Ion 7.4 V, Rechargeable, Maximum Protection |
| Battery Operating Time | 5 hours |
| Battery Charging Time | 3 hours |

NOTE: System power is designed to work without interruption. It means you can disconnect main power and the system will switch to the internal battery automatically without any delay.

| Electromagnetic Effects | |
|---|---|
| The oximeter board complies with the requirements of IEC 60601-1-2:2014 electromagnetic compatibility. The following basic EMC standards were applied to verify conformance. | |
| IEC 60601-1-2:2014 electromagnetic compatibility | Environment |
| IEC 60601-1-2:2014 electromagnetic compatibility CISPR 11 Group 1, class B | Emissions |
| IEC 60601-1-2:2014 electromagnetic compatibility | Immunity |

| IEC (International Electrotechnical Commission) Classifications | |
|---|---|
| Type of protection | CLASS I |
| Degree of protection | Type BF |
| Mode of operation | Continuous |
| Degree of protection against ingress of liquids | Ordinary (IP42) |
| Recommended methods of sterilization or disinfection | Using a soaked swab with alcohol for the external parts of system, $SpO_2$ sensor and extension cable for appropriate cleaning instructions. |
| Degree of safety of application in the presence of a flammable anesthetic | Not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide. |
| ⚠ Do not use functional tester to assess the accuracy of pulse oximeter probes and monitor. | |

| List of Relevant Standards | | |
|---|---|---|
| 1 | IEC 60601-1:2024 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| 2 | IEC 60601-1-2:2014 | Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| 3 | IEC 60601-1-8:2006 | Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| 4 | ISO 80601-2-61:2017 | Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment |
| 5 | IEC 62304:2006 | Medical device software - Software life cycle processes |
| 6 | ISO 14971:2019 | Medical devices - Application of risk management to medical devices |

## 3-2- Alarm signals

### 3-2-1 Auditory and visual alarm signals

The system is capable of announcing audio and visual alarms to reduce the risk of patient injury during vital signs monitoring. The alarms in this system are categorized into two types: physiological and technical. They are presented in the following tables based on their priority of announcement:

| Physiological Alarms | | |
|---|---|---|
| **Priority** | **Visual** | **Audible** |
| High | $SpO_2$ High (Red) | ✓ |
| | $SpO_2$ Low (Red) | ✓ |
| | Pulse High (Red) | ✓ |
| | Pulse Low (Red) | ✓ |
| | Low Perfusion (Red) | ✓ |

| Technical Alarms | | |
|---|---|---|
| **Priority** | **Visual** | **Audible** |
| High | Low Battery (Red) | ✓ |
| Medium | Sensor Disconnected (Yellow) | ✓ |
| | Sensor Off Patient (Yellow) | ✓ |

| System Message | | |
|---|---|---|
| **Priority** | **Visual** | **Audible** |
| NO | Defective Sensor (Yellow) | × |
| | Pulse Search (Yellow) | × |
| | Too Much Ambient Light (Yellow) | × |
| | Insufficient Light (Yellow) | × |
| | Interference Detected (Yellow) | × |

The alarm indicator flashes red color when a high-priority alarm occurs, and yellow color when a medium-priority alarm occurs. When the alarm terminates, the alarm indicator turns to green color.

### 3-2-2- Sensor alarms

If the sensor is disconnected from the connecting cable or the cable from the connector, the message “Sensor Disconnected” will be displayed, and if the sensor is disconnected from the patient's hand, the message “Sensor Off Patient” will be displayed. In general, the alarms related to the sensor, along with the description of each alarm, are presented in the following table:

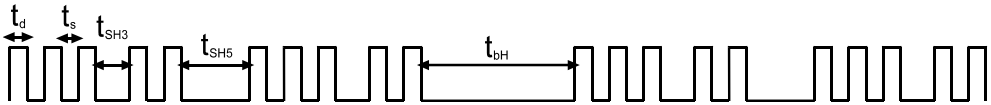
| Alarm | Description |
|---|---|
| Sensor Disconnected | The sensor is not connected to the system. |
| Sensor Off Patient | The sensor is not connected to the patient. |
| Defective Sensor | The sensor is defective. |
| Pulse Search | Search for vital signs |
| Too Much Ambient Light | The intense light of the environment has caused interference. |
| Insufficient Light | The light intensity of LEDs is low. |
| Interference Detected | Optical interference has been detected. |

## 3-2-3- Characteristics of auditory alarm signals

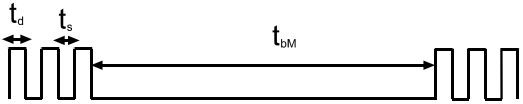
This system auditory alarms are divided into two modes: High Priority and Medium Priority. Accordingly, the values related to the characteristics of the produced audio signal for each priority are as follows**:**

| Pulse frequency | | | 700 Hz | | |
|---|---|---|---|---|---|
| Effective pulse duration ($t_d$) | High Priority | 50 ms | Pulse spacing ($t_S$) | High Priority | 50 ms |
| | Medium Priority | 170 ms | | Medium Priority | 130 ms |
| $t_{SH3}$ | | 150 ms | $t_{bH}$ | | 10 s |
| $t_{SH5}$ | | 550 ms | $t_{bM}$ | | 20 s |

High Priority:



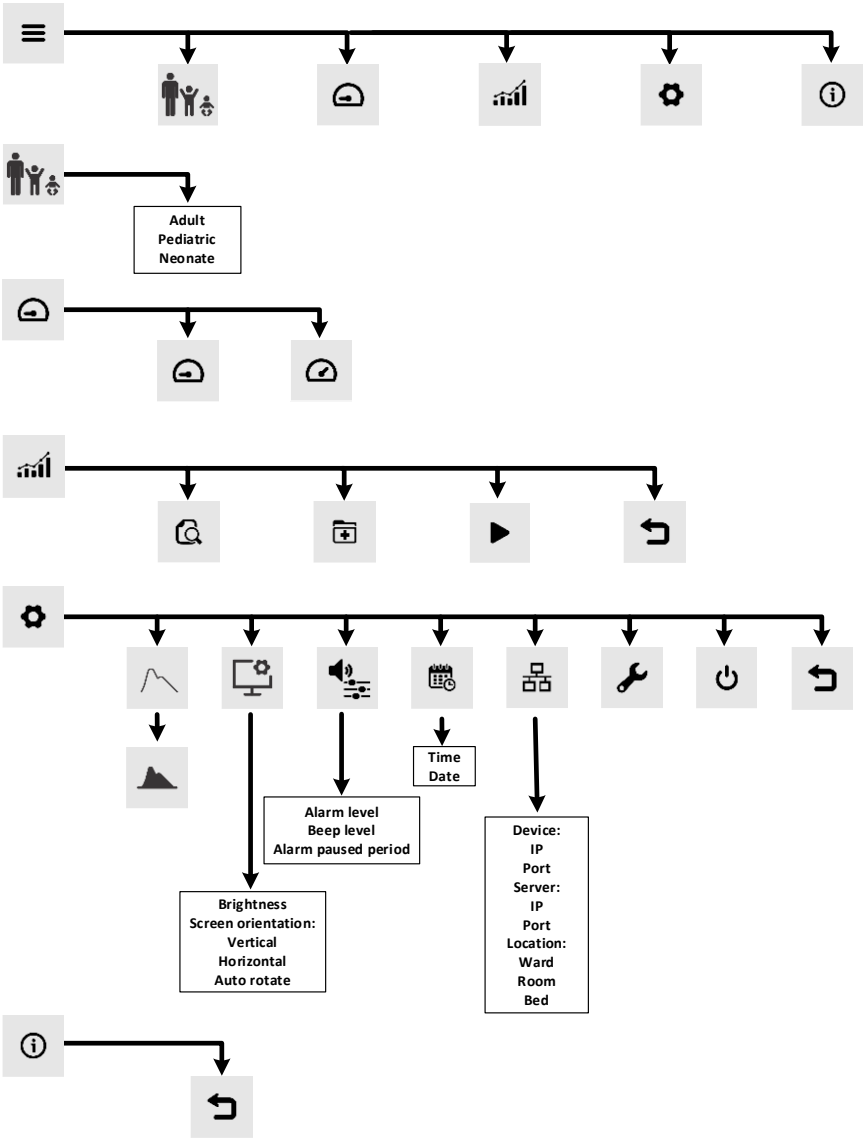

Medium Priority:




The sound pressure level of the auditory alarm signal at a distance of 1 meter from the device is proportional to the percentage of the output sound (adjustable in 10 intervals) in the range of 55 dB to 62 dB**.**

## 3-3- Menu keys and settings

All the device settings along with the sub-category menus are briefly presented in the figure below.



**Warning:**

Do not unscrew the device; there is no hardware setting for the user inside the device. For device service, please directly contact Parsian Medical Co.

**Attention:**

The delivered device does not need calibration. All services related to calibration will be provided by Parsian Medical Co.

## 4-1- Battery maintenance

If the system on battery mode is not used for a long time, battery may be discharged during transportation or storage. If the battery is not charged for more than a month, recharge it for at least 5 hours before using it again**.**

## 4-2- Cleaning the device and reusable sensors

To clean the device, use a cotton or sanitary gauze soaked in 70% alcohol, and make sure that the liquid does not leak into the device. Keep the following things in mind when cleaning:

- This device cannot be autoclaved or cleaned with steam.
- Do not immerse the device in washing liquids.
- Solvent detergents can cause damage to the external surfaces (housing) of the device.

You can stablish the same method to clean and disinfect sensors and extension cables. However, when cleaning the sensors, make sure all blood and liquids are completely cleaned, leaving no trace of colored liquid or dirt on the LEDs.

## 4-3- Repair rules

All repairs must be done by Parsian Medical Co. Other repairer services are only permitted with manufacturer authorization. Otherwise, warranty and after-sales service will not be valid for device.

## 4-4- Packing and sending the device

Send the device directly to the company at the address provided, or via local authorities.

Address: 1st Floor, No. 3, 8th St., Sabounchi St., Beheshti Ave., Tehran, Iran
Tel: +98-21-88528362,3
Fax: +98-21-88528364
Website: www.parsianmedical.com
Email: info@ parsianmedical.com

**Attention:**

**Please clean the device and send it with the following items**.

**-A note providing a description of the observed errors and problems**.

**-Client information , including address, phone number, email address, or postal code**.

## 4-5- Inaccuracy in measurement

Inaccurate measurement may occur according one of the following conditions:

- Improper operation or use of the sensor.
- Significant level of improper hemoglobin function (such as carboxyhemoglobin or methemoglobin, intravenous items such as indocyanine or methylene blue).
- Exposure of the sensor to the direct radiation of operating room lights (especially those that use Xenon lamps), bilirubin reducing lamps, fluorescent lamps, ultraviolet lamps, heating lamps or direct light Sun, which can be solved by covering the sensor with dark cover.
- Excessive patient movement.
- placing sensor along with blood pressure cuff, vascular or intravascular catheter.
- Loss of the heartbeat signal occurs in the event of one of the following situations:
  1- The sensor is connected too tightly.
  2- There is a bilirubin reducing lamp or direct sunlight or operating room light.
  3- The patient has one of the conditions of Hypothermia or Hypotension.
  4- An arterial blockage has been occurred.
  5- The patient is in cardiac arrest or shock.

## 4-6- Quick troubleshooting

| Problem | Cause of occurrence | Troubleshooting instructions |
|---|---|---|
| The device does not turn on. | The battery's runtime has noticeably decreased. | Connect the device to the mains and keep it connected for at least 3 hours until it is fully charged. |
| | The battery needs to be replaced. | Contact Parsian Medical Co. |
| | The power cable is damaged. | Check the charger using an ohmmeter and replace it if there is a problem. |
| The battery does not keep the charge and is discharged quickly. | The battery needs to be replaced. | Contact Parsian Medical Co. |
| Factors are not displayed when the sensor is connected to the hand. | The system is damaged. | Contact Parsian Medical Co. |
| | The sensor is damaged. | Contact Parsian Medical Co. |
| | The extension cable is damaged. | Contact Parsian Medical Co. |
| When the device is connected to the patient, vital signs are interrupted or not displayed. | The sensor is exposed to ambient light. | Keep the sensor away from ambient light. |
| The sound of the speaker is not heard properly. | There is an obstacle blocking the sound. | Try to remove that obstacle. |
| | The speaker is broken. | Contact Parsian Medical Co. |
| Not enough background light. | The intensity of the foreground light needs to be adjusted. | Go to the corresponding menu and change the intensity of the background light to reach the desired level. |
| Unable to connect to the network. | The settings of the IP values are not correct. | Go to the relevant menu and check the settings again. |

## Section 5 – Preventive maintenance

The term "preventive maintenance" refers to a set of activities that are implemented in order to increase the efficiency and postpone repairs. These activities include control, inspection and periodical quantitative and qualitative review of the device, verifying output accuracy through calibration tests usually conducted annually. Additionally, safety reviews are conducted to minimize the risks associated with device defects, ensuring the well-being of both patients and personnel and perform activities such as cleaning, oiling or replacing parts that have problems. With this definition and a cautionary note that the content of this section pertains to the medical engineering department or the maintenance of hospitals and health facilities, the quantitative and qualitative preventive maintenance activities of this device are presented as follows. The recommended intervals for preventive maintenance typically range from six months to one year for calibration**.**

## 5-1- Quantitative activities

- Check the external part of the device for cleanliness and favorable physical conditions. Make sure that the plastic case is intact, all hardware is available, and there are no signs of liquid spills, contamination, or damage or breakage.
- Ensure that the device is accompanied by the necessary documents**.**
- All labels on the device must be intact and clearly legible**.**
- Make sure that there are all accessories of the device based on the contents of this document.
- Match the glass fuse and their nominal value with the value written next to the fuse base. Then make sure of their correct operation using an ohmmeter.
- Make sure there is a spare for the fuse.
- It is essential to ensure the correctness of the ground connection in the devices. For this purpose, the test has been done by connecting one of the ohmmeter sensors to the applied ground terminal backside of the device and then connecting the other

sensor to the corresponding part of this connection on the ground pin of the device cable and observing the ohmic value of the electrical connection.

- Check all sensor cables along with their protective cover in terms of general condition. Carefully examine the cables to find any breaks on their insulation and their firmness in the connectors at both ends and their non-rotation, and by bending the ends of the cables from their possible inefficiency or by be sure to use an ohmmeter.
- Check all electrical connectors for normal conditions. All electrical pins or connections must be smooth, clean and shiny. Check that the connector is easily installed in its place. If keyed connectors are used, make sure the keyed connection is correct.
- If disposable sensors are used, check that there is enough reservoir in the warehouse. Also check the connections of reusable sensors and test them according to normal working conditions.
- Make sure ON / OFF switch functions properly.
- Make sure the performance of the screen by checking its pixels.
- Make sure that the LEDs on the sensors are clean and that there is no color or blood on them by opening the clips of the clip-on sensors.

## 5-2- Quality activities

- It is possible to measure the accuracy of the pulse rate factor by comparing it point by point with an electrocardiograph device or a pulse simulator. For this purpose, in the range of 30 to 250 beats per minute, compare the root mean square (rms) of the values displayed by the device with one of these two systems, which must be equal. If a simulator is being used, the company recommends utilizing Fluke Biomedical patient vital signs simulators with SPOT Light Firmware v1.07 and ProSim 8 Firmware v2.08 models with Masimo settings.
- Make sure that the plethysmograph waveform is accurate.

- Connect the sensor to your finger and activate audio and visual alarms. Specify that alarms occur within ±1% of $SpO_2$. By temporarily turning off the alarm sound using the corresponding option on the screen, make sure to active it after the indicated period of time. Separate the sensor from the finger and make sure that the "Sensor Off Patient" alarm is activated.
- Check the sound adjustment mechanism in the corresponding menu by establishing one of the conditions for auditory alarms.
- Verify that the alarm limits are reset to in the default interval, as specified by the standard, after the device is powered off and then turned it on. (the lower $SpO_2$ limit should return to 85).
- Verify the battery status of the device after it has been fully charged. Ensure that the device operates on battery power for no less than one hour.
- Ensure that the battery symbol is displayed on the screen when the charger is disconnected from the device while it is in operation.
- Make sure that the red battery symbol is activated on the screen when the battery charge is low. For this purpose, disconnect the power cable from the device and allow the device to operate for a period of time to deplete some the internal battery's power.
- Verify the functionality associated with temporarily deactivating the device's audio alarms by selecting the corresponding option  on the screen.
- If you have a reference temperature in your lab, check the displayed temperature by connecting a temperature sensor. The accuracy provided should not be more than ±2% of the actual value.
- Set the time and date from the relevant menu. Turn off the device, disconnect it from the charger, and then turn it back on to ensure that the battery and its electronic circuit are functioning correctly.
- To verify the accuracy of $SpO_2$ within the intervals specified in the tables this manual, use the methods outlined in the relevant standard (ISO 80601-2-61:2017).

- According to the mentioned standard, use of Patient Simulator or Functional Tester to check the accuracy of $SpO_2$ is not acceptable in any way and the methods mentioned in the standard should be used for this purpose. However, to check the accuracy of $SpO_2$, the company recommends utilizing Fluke Biomedical company's vital signs simulation devices with SPOT Light Firmware v1.07 and ProSim 8 Firmware v2.08 models.

## Section 6 – Warranty

### 6-1- Warranty information

This device is covered by a one-year warranty from the time of delivery, provided by Parsian Medical Co., guaranteeing its performance in all typical medical environments. Please note that batteries are not included in this warranty.

To extend the warranty, the device must be returned to the company again. After undergoing tests and necessary part replacements, the warranty will be extended for an additional year, based on the terms of agreement**.**

This warranty does not apply to devices that have been improperly used, sustained physical damage, or not been operated in accordance with the conditions of the accompanying documents**.**

Devices that have been modified, opened, or have been inspected by service personnel other than the employees of Parsian Medical Co. are out of the scope of this warranty**.**

This warranty does not cover accessories and other devices that are connected to this system (sensors and extension cables)**.**

This warranty is issued to the buyer by Parsian Medical Co. and supersedes any oral agreements on this matter. It does not cover unforeseen events.

## Device and Accessories

| No. | Part Name | Presence | No. | Part Name | Presence |
|---|---|---|---|---|---|
| 1 | ABADIS711 | ☐ | 8 | Quick Manual | ☐ |
| 2 | Extension Cable | ☐ | 9 | Wall-mount Bracket | ☐ |
| 3 | Adult Sensor | ☐ | 10 | Trolley | ☐ |
| 4 | Pediatric Sensor | ☐ | 11 | USB Cable | ☐ |
| 5 | Neonate Sensor | ☐ | 12 | Ethernet Cable | ☐ |
| 6 | Power Cable | ☐ | 13 | Software Pack | ☐ |
| 7 | User Manual | ☐ | 14 | Temperature Sensor | ☐ |

## Serial Numbers

| No. | Part Name | Serial Number |
|---|---|---|
| 1 | ABADIS711 | |
| 2 | Extension Cable | |
| 3 | Sensor | |

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