Zacurate® 500D

Finger Pulse Oximeter

User Manual

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Version 2.0

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Contents

Letter to Users

Thank you for choosing our Zacurate® 500D Deluxe Finger Pulse Oximeter. By listening intently to our customers and applying some simple technological innovations, you will come to see that the 500D is one of the most user-friendly, reliable and comfortable pulse oximeters that you will ever own. Before using this product, please read the user manual carefully and follow the instructions stated herein. Please also check that all accessories are complete as listed in the packing list and whether any component is damaged during shipping. If there is any damage and/or if you have any concerns, please contact us at cs@beyondmedshop.com or phone: 1-832-939-8290 with the following information:

1. Product model
2. Serial number of the product
3. Your contact information and address

The manual is updated periodically and the latest manual can be downloaded at http://www.beyondmedshop.com/products/500d

Standard Packing List

1. Pulse Oximeter……1 PC
2. AAA Battery……2 PCS
3. Lanyard……1 PC
4. Silicone Cover……1 PC
5. User Manual……1 PC

Chapter 1 Precautions, Warnings and Symbol

1.1 Precautions

- Do not attempt to repair the pulse oximeter by yourself. Only certified engineers should maintain and repair it.
- Change the contact position between the oximeter probe and the finger periodically if your finger feels sore or is uncomfortable.
- Stop immediately if you have broken skin or the blood circulation of your finger is affected during prolonged use.
- This product is not designed to be used by newborn babies.
- Seek medical care if the measured value goes beyond the

normal range and you are sure that the device is not malfunctioning.

- The pulse oximeter uses infrared light (invisible to your eyes) to measure your SpO_2 level. Hence, please do not stare at the light emitting components of the oximeter to avoid potential eye damage and/or blindness.
- **This pulse oximeter is not a medical device and is not intended to diagnose and/or treat any medical condition or disease. It is intended for non-medical use by healthy people to monitor their pulse rate and blood oxygen levels. It is for sports and/or aviation use. People who need SpO_2 and pulse rate measurements because of a medical condition should consult with their physician.**

The following factors may affect the performance and accuracy of the oximeter:

- ❖ The oximeter is used in an environment with high-frequency devices, such as high-frequency electric knives and/or CT apparatuses.

- Ambient light intensity that is too bright. Hence, please avoid direct exposure to strong light (such as beams from operating lamps or sunlight) during measurement.
- The probe of the oximeter is placed on the same arm that a blood pressure cuff, arterial duct or intravenous injection is placed.
- The user suffers from hypotension, severe vascular atrophy, severe anemia, or low oxygen.
- The user is in sudden cardiac arrest or shock state.
- The user is wearing nail polish or artificial nails.

1.2 Warnings

Warning: Do not use the oximeter in an environment with any flammable gases, flammable anesthetic, or other flammable substances.

Warning: Keep unit and lanyard away from children as the included lanyard may pose as an entanglement or choking hazard to small children. Adult supervision is required; never leave children unattended with unit or lanyard.

Warning: Do not throw the batteries into fire, as that may cause an explosion.

Warning: Do not attempt to charge the included batteries, as that could cause leakage, fire disaster, or even explosion. Dispose the used batteries in accordance to the local laws and regulations.

Warning: Do not use the oximeter in an MRI or CT environment.

Caution: Do not operate the oximeter if it is wet. Avoid moving the oximeter from a cold to a hot and humid environment.

Caution: Install the batteries properly before powering on the oximeter for normal use. Please remove the batteries if you are not planning to use the oximeter for an extended period of time.

Caution: Close the battery cover when the device is in use.

1.3 Symbol

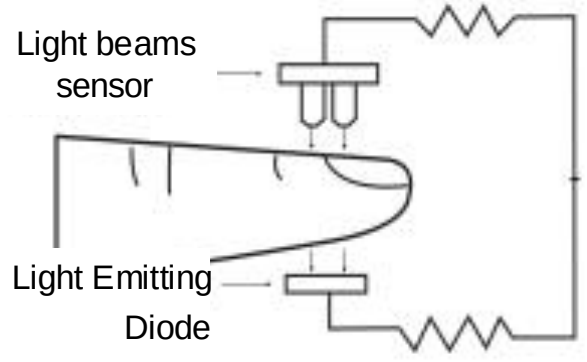
Symbol	Description
	BF-type application part
	Caution: Please refer to this manual
%SpO_2	Symbol of oxygen saturation
bpmPR	Symbol of pulse rate

	Manufacturer information
	Temperature limitation
	Electrical waste materials should be sent to dedicated collection points for recycling
Warning	A personal injury or device damage may result if the device is not used correctly
Caution	Important information on the proper usage of the device
Attention	Necessary information to protect the device against damage

Chapter 2 About This Product

2.1 Overview

SpO_2 stands for peripheral capillary oxygen saturation. Oxygen saturation is defined as the ratio of oxyhemoglobin (HbO_2) to the total concentration of hemoglobin (i.e. Oxyhemoglobin + reduced hemoglobin) present in the blood. It is an important physiological parameter involved in respiration and circulation. The Pulse Oximeter feature herein is small, portable, non-invasive and easy to use. The user only needs to insert a finger into the chamber to measure his/her SpO_2 level and pulse rate.



2.2 Working Principles

Oxygenated blood absorbs light preferentially at 905nm (near infrared light), whereas deoxygenated blood absorbs light preferentially at 660nm (red light). A pulse oximeter works by passing a beam of red and infrared light through a pulsating capillary bed and then measure the amount of red and infrared light emerging from the tissues via a sensor. To improve accuracy, the 500D uses a proprietary algorithm to collect data from pulsatile arterial blood and excludes local noise from the

tissues. The relative absorption of light by oxyhemoglobin (HbO) and deoxyhemoglobin is then calculated according to the Beer-Lambert's law and a quantitative measurement of the users' oxyhemoglobin status i.e. Oxygen saturation level (SpO_2) is derived.

Due to the sensitivity of the pulse oximeter, finger should be kept stationary during measurement. It is recommended that you use this device for measurement before or after sports. Do not use for continuous monitoring.

2.3 Intended Use

The Zacurate® 500D Deluxe Finger Pulse Oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) of adult and children (>2 years old).

2.4 Product Features

- Lightweight, portable and easy to use
- Six different display options
- Dual-color OLED screen to show measured values, plethysmograph and bar graph
- Large font display

- Preset alarm function
- Low battery indicator
- Automatic shut down if no signal is detected after 16 seconds.
- Low power consumption. Two 1.5 V AAA batteries will allow the pulse oximeter to operate for approximately 30 hours.

2.5 Limitations

The pulse oximeter works by measuring the amount of oxygenated hemoglobin in your blood over a period of time. Spot check pulse oximeter takes 1-2 readings every second and takes an average of 4-6 readings before displaying the result. Hence, you will have to wait at least 4-6 seconds before a result will be displayed on the monitor. If the pulse oximeter fails to detect blood flow for the first few seconds, the results will be delayed accordingly.

The pulse oximeter does not work for people with naturally small fingers or low peripheral blood flow. This is because the pulse oximeter could not detect enough blood for a measurement. Please note that prolonged use of a pulse oximeter, hypotension, vasoconstriction, hypothermia and certain medications can lead to low or restricted blood flow. Nail polish can also impede the pulse oximeter from taking a reading.

Finally, it is generally accepted that the saturation percentage is unreliable on the steep part (around 60 mm Hg) of the oxyhemoglobin dissociation curve.

2.6 Innovative Features of the 500D

The 500D is designed to address and alleviate some of the above problems by

1) Increasing the sensitivity of the sensor to allow user to measure his/her SpO_2 levels and Pulse Rate (PR) even at low blood perfusion.

2) Using a self-adjusting smart spring system to fit user's finger snugly but not too tight as to impede blood flow.

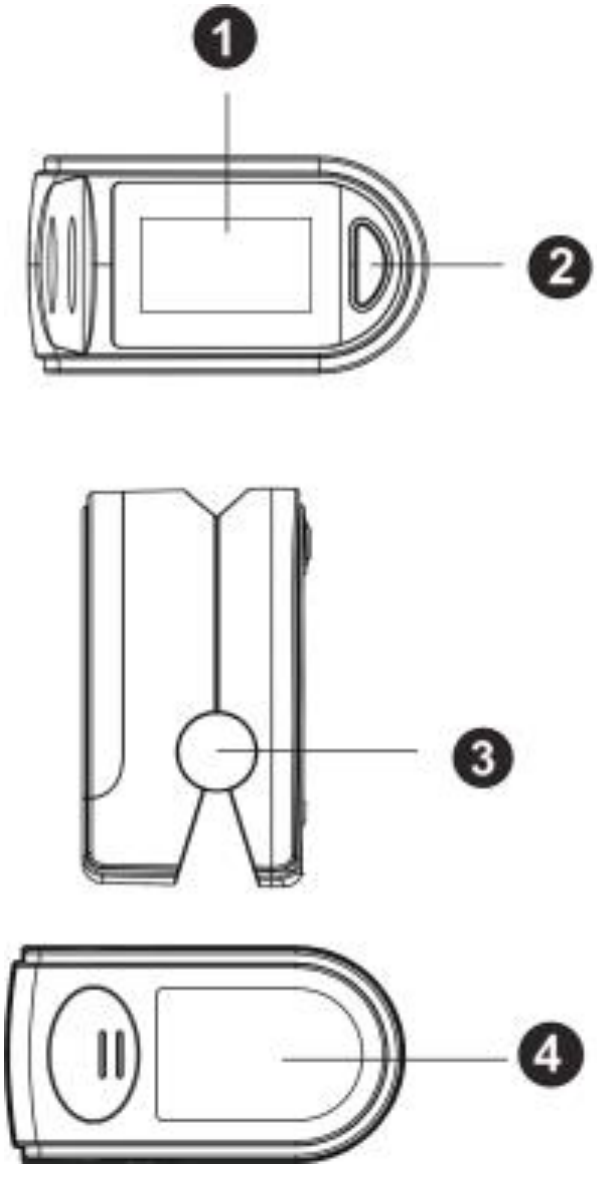
3) Using soft, hypoallergenic medical grade silicone in the finger chamber to minimize discomfort to user's finger.

4) Using solid ABS plastic to block ambient light from reaching the sensor so that the signal to background ratio and the accuracy of the measurement is dramatically increased.

5) Having a plethysmograph that allows the user to visualize and gauge the amount of blood detected by the pulse oximeter. This helps user to determine if the finger is inserted properly into the finger chamber, which in turn helps to determine the optimal time to get an accurate and reliable readings (See Chapter 3.3.3 about plethysmograph).

Chapter 3 Product Structure, Operation Instructions and Parameter Settings

3.1 Schematic Structural Diagram



1 OLED screen

2 Power-on key/function key

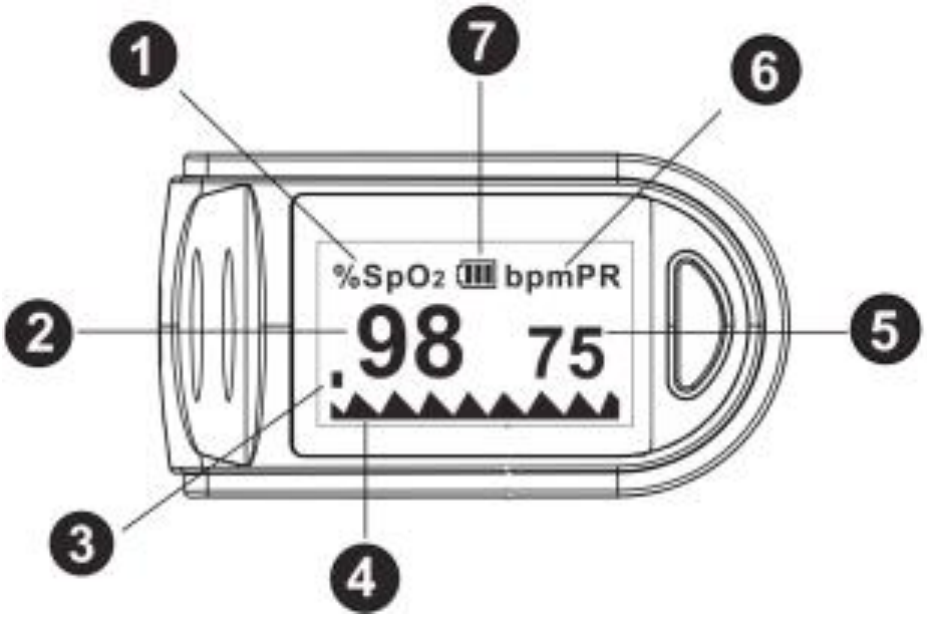
3 Shaft housing

4 Battery cover

Note: The illustration in this manual may differ slightly in appearance from the actual product.

3.2 Schematic Diagram of Display

The following figure shows the information display on the OLED screen of the Oximeter in normal detection state:



1 Symbol of oxygen saturation

2 Measured value of oxygen saturation

3 Bar graph

4 Plethysmograph

❺ Measured value of pulse rate

❻ Symbol of pulse rate

❼ Battery power indicator

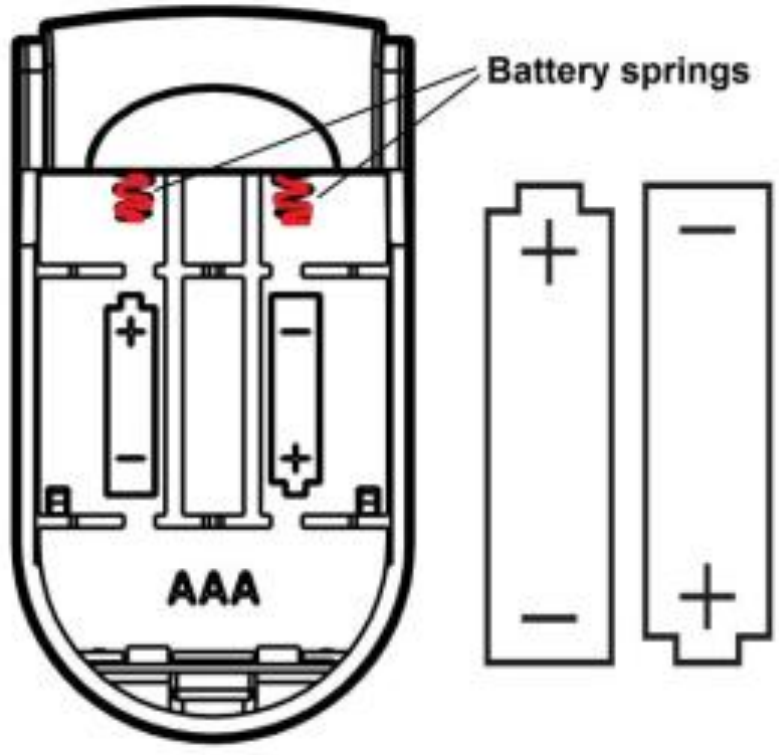
3.3 Operation Instructions

3.3.1 Operation Steps

(1) Installing the Batteries

Install two AAA batteries in opposite polarity by matching the plus (+) and (-) signs in the battery compartment. Mount the battery cover by sliding the cover in place until you hear a click sound.

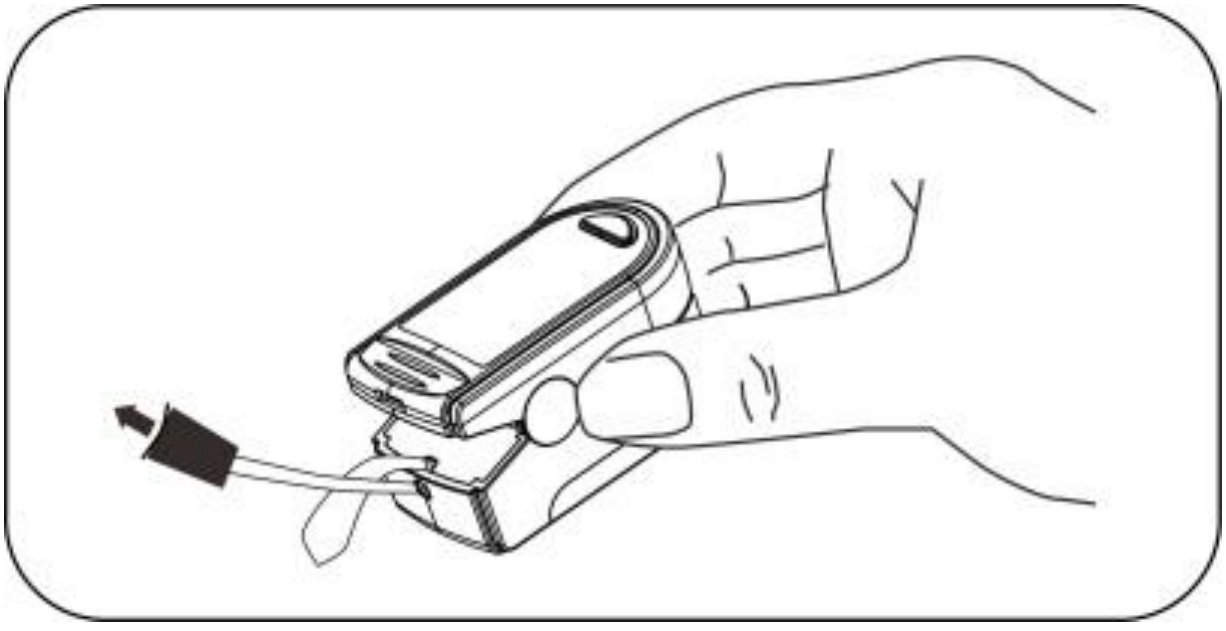
Important note on battery alignment – Battery springs are unconventionally located on the same side. Install batteries in opposite polarity as illustrated below.



Incorrectly installed batteries may damage the device.

(2) Installing the Lanyard

Remove the silicone cover. Thread the thin end of the lanyard through the lanyard hole, and thread the coarse end of the lanyard through the thin end of the lanyard, and tighten the lanyard. Put the silicone cover back on.

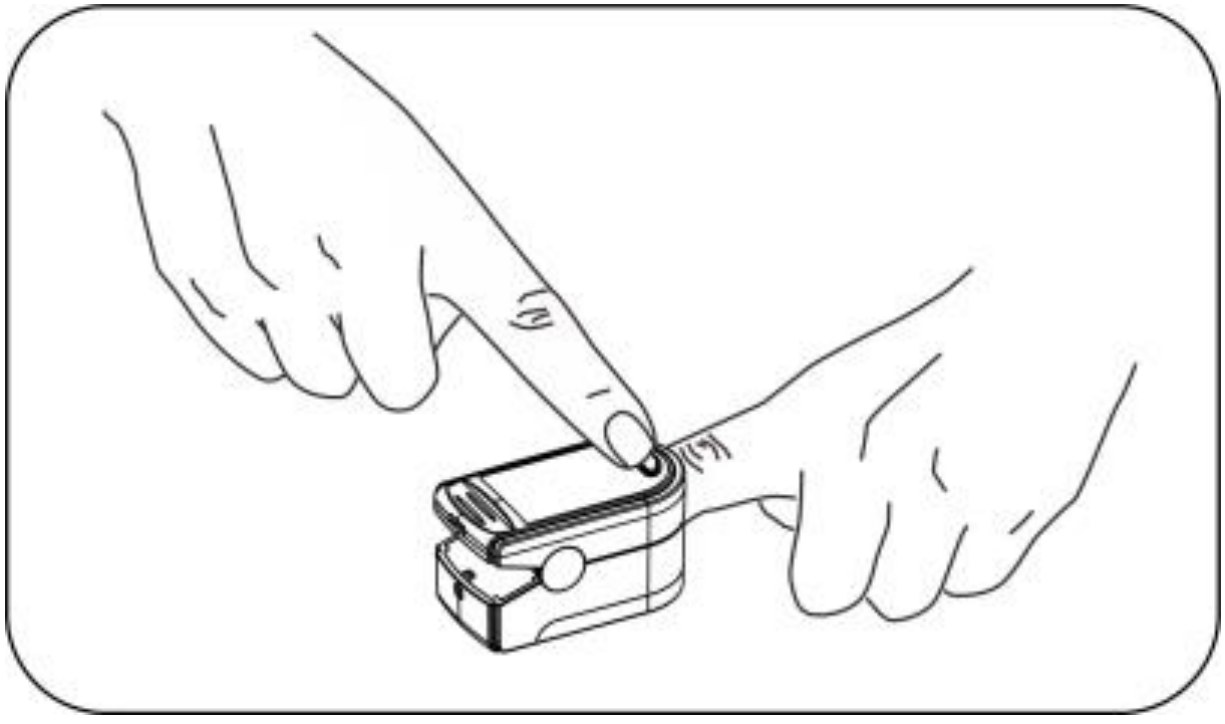


(3) Switching On the Power Supply of the Pulse Oximeter

Insert one of your fingers into the finger chamber of the pulse oximeter.

Note: The fingernail should be facing the top chamber (which contains the sensor). Finger should also be inserted completely into the chamber. Otherwise, measurement will be inaccurate.

Press the power-on key to turn the pulse oximeter on.



Note: Before each use, it is recommended to clean finger and the silicone padded finger chamber. The silicone is non-toxic, soft and hypoallergenic.

(4) Reading Oxygen Saturation Level and Pulse Rate from the OLED screen

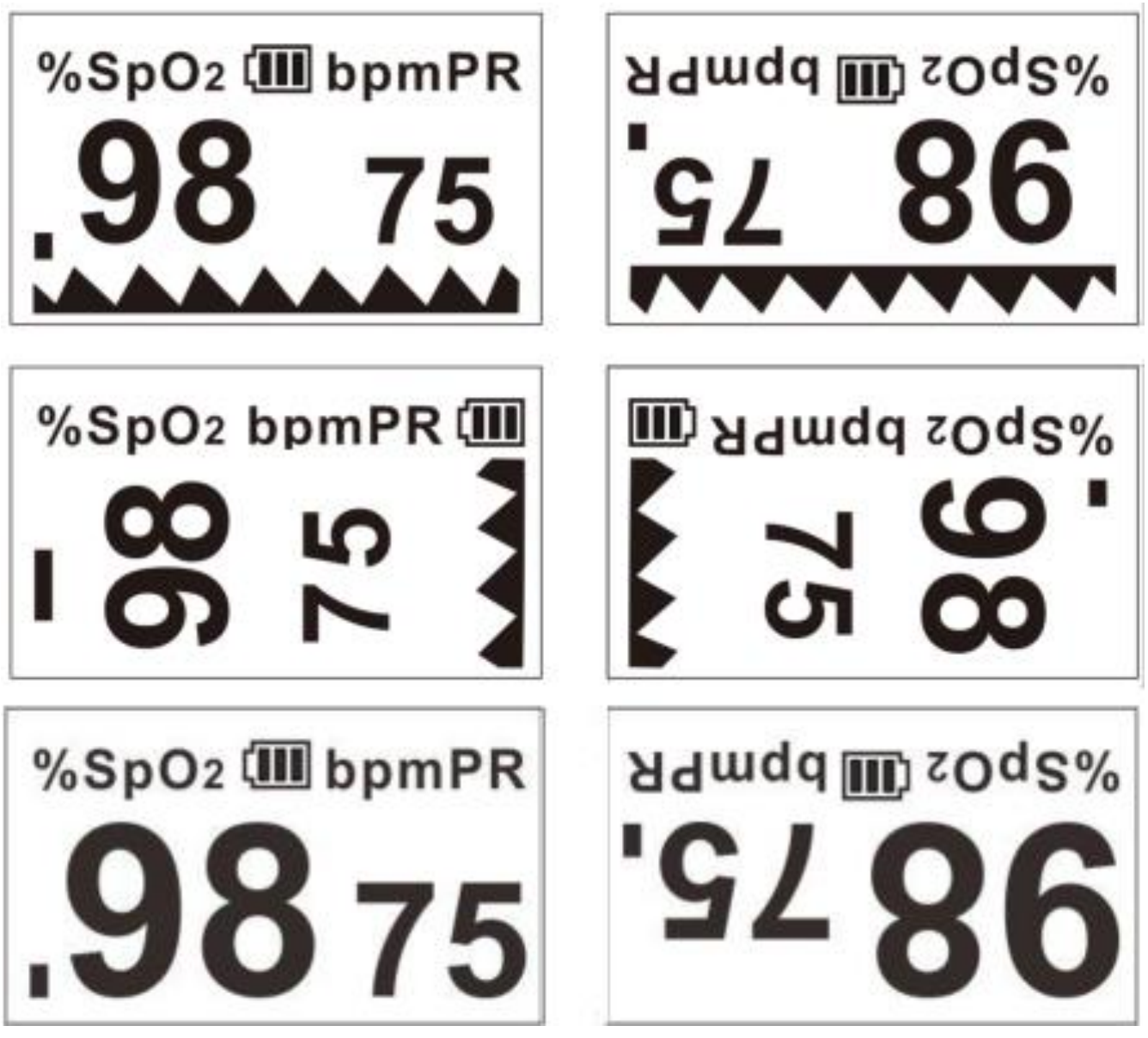
Do not move your finger and hand during measurement. Keep your body as still as possible. Once the reading stabilizes, read the measured values of the oxygen saturation level and pulse rate on the OLED screen.

(5) Switching Off the Power Supply of the Oximeter

The oximeter will automatically shut down in 16 seconds after finger is removed from the chamber or if no signal is detected by the device.

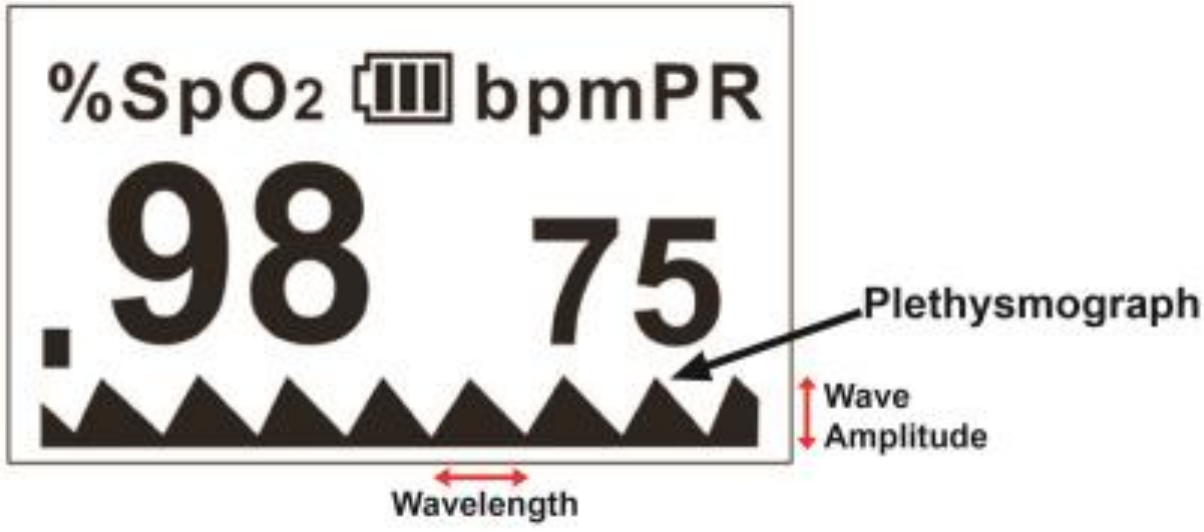
3.3.2 Switching the Display

Press (<0.5 sec) the function key while in measurement mode to change the display layout. The six different layouts are shown in the figure below. Choose the layout that is the most convenient for you.



Replace the batteries when the batteries are low and the symbol ( ) flickers on the OLED screen.

3.3.3 Plethysmograph



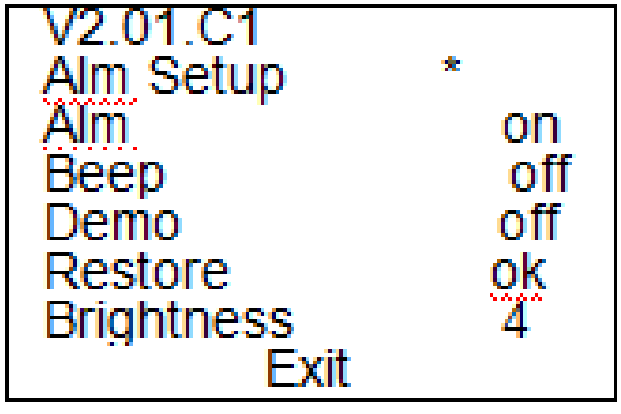
The plethysmograph indicates the amount of blood flow detected by the pulse oximeter. Each wave corresponds to a heartbeat and the wave amplitude corresponds to the amount of blood detected by the pulse oximeter. The pulse oximeter is optimized when the height of the wave amplitude is consistent throughout as shown in the figure above. That is when you should take a reading. If the wave amplitude is very small, warm your hands to increase blood flow and retake your measurement.

3.4 Parameter Settings

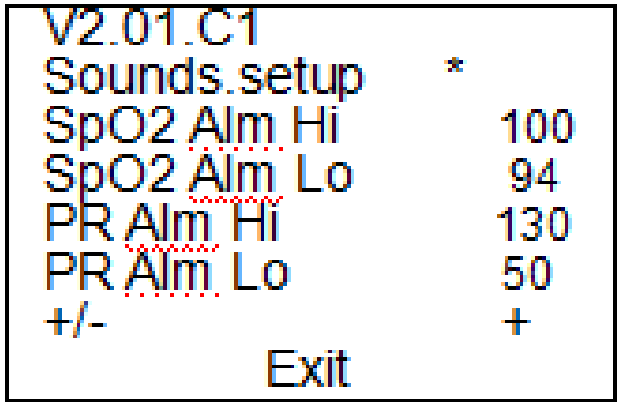
3.4.1 Power-On Key/Function Key Operations

PRESS (<0.5 sec) the power-on/function key to turn the pulse oximeter on. Once it is turned on, **HOLD** (>0.5 sec) the power-on/function key to enter the menu interface. **PRESSING** (<0.5 sec) the power-on/function key will allow you to scroll through options while **HOLDING** (>0.5 sec) will select an item. " * " indicates the option you are currently at (Please see figure below).

3.4.2 Alarm Setting



Interface 1



Interface 2

To turn the alarm on/off, **PRESS** the power-on key/function key to move " * " to **Alm. HOLD** the power-on key/function key to switch the

option from **on** to **off** or vice versa. When **Alm** is set to **on** and the measured values of the blood oxygen saturation (SpO_2) and/or pulse rate (PR) exceed the stated upper or lower limit (See 3.4.7 Alarm Range Setting to set parameters for Alarm), the alarm will go off. When **Alm** is set to **off**, the alarm is deactivated. The alarm will not go off regardless of your SpO_2 and/or PR values.

3.4.3 Beep Setting

To turn the beeping sound on/off while measuring your pulse rate, **PRESS** the power-on key/function key to move " * " to **Beep. HOLD** the power-on key/function key to switch the option from **on** to **off** or vice versa. When **Beep** is set to **on**, a tick will be heard along with pulse beats during pulse rate measurement. When **Beep** is set to **off**, no sound will be heard during pulse rate measurement.

3.4.4 Demo Mode

To turn demo mode on, **PRESS** the power-on key/function key to move " * " to **Demo. HOLD** the power-on key/function key to switch the option from **on** to **off** or vice versa.

3.4.5 Restore Factory Settings

PRESS the power-on key/function key to move " * " to **Restore**. **HOLD**

the power-on key/function key to restore pulse oximeter to factory settings. "**ok**" will be displayed.

3.4.6 Brightness Setting

To change brightness of the display, **PRESS** the power-on key/function key to move " * " to **Brightness. HOLD** the power-on key/function key to set the brightness. There are 5 brightness settings. 5 is the brightest. The factory default setting is 4. Please note that a brighter setting will drain the battery faster.

3.4.7 Alarm Range Setting

To change the alarm range settings, **HOLD** the power-on key/function key to enter Menu Interface 1.With the " * " next to **Alm Setup**, **HOLD** the power-on key/function key to enter Menu Interface 2. " * " should be at **Sounds Setup**. Press the power-on key/function key to move " * " to the option you desire to change. **SpO_2 Alm Hi** and **SpO_2 Alm Lo** refer to the upper and lower limit of the SpO_2 levels that you wish the alarm to go off at respectively. **PR Alm Hi** and **PR Alm Lo** refer to the upper and lower limit of the Pulse Rate levels that you wish the alarm to go off at respectively.

To increase or decrease a value, first set **+/-** to " +" or " -" respectively. Move " * " to **+/-**. Then **HOLD** the power-on key/function key to set

the option to + or -. While in + mode, select the corresponding upper or lower limit option and hold the power-on key/function key to increase the upper or lower limit; in - mode, hold the power-on key/function key to decrease the upper or lower limit.

Move " * " to the **Exit** option, and hold the power-on key/function key to return to the monitoring interface. Or move " * " to the **Sounds Setup** option, and hold the power-on key/function key to switch to Menu Interface 1.

3.5 Tips to getting a good reading

1. Make sure that your finger is inserted deep into the chamber so that the fingertip is placed directly in between the LED light source and the LED sensor.
2. Avoid making any body movement, especially your finger while taking measurement.
3. Long fingernails may obstruct the light sensor and prevent accurate measurement. Please keep fingernails short while using the device.
4. Excessive ambient infra-red light, especially in an overly bright

lit room, can interfere with the sensor, preventing an accurate measurement.

5. Poor blood circulation can affect oximeter readings. Warm your hands and fingers before taking measurements. Note that the pulse oximeter is measuring your SpO_2 and PR based on your blood flow. If the blood flow in your finger drops below a certain level, the pulse oximeter will not be able to get a reading.
6. Some people with medical conditions such as anemia, hypotension and hypothermia may experience inaccurate reading during use. In such case, we suggest that you consult a physician.
7. The pulse bar graph and plethysmograph are useful features that can be used to determine the reliability of a reading. If the height of the pulse bar is less than 30%, this indicates signal inadequacy and the displayed SpO_2 or pulse rate value is potentially incorrect. Adjust your finger so that it is directly between the LED lights and sensor. If the wave amplitude of the plethysmograph is very small, warm your hands to increase blood flow and retake your measurement. If the waveform is

not consistent, try to keep your hand and body as still as possible.

Chapter 4 Cleaning and Disinfection

It is recommended to clean the pulse oximeter regularly. The pulse oximeter can be disinfected as needed.

To clean, use a soft cloth lightly dampened with water.

To disinfect, use a soft cloth lightly dampened with isopropyl alcohol.

1. Make sure that the device is off and remove the batteries.
2. Wipe the outer surface of the device (including the OLED screen) and the finger chamber using lightly dampened soft cloth.
3. Allow the device to air dry thoroughly before use.

Caution: Do not use any strong dissolving agent such as acetone.

Caution: Do not rub the body of the device using materials such

as steel wire balls or polished metal objects.

Caution: Do not immerse or soak any part of the device in any liquid.

Caution: Do not pour or spray liquid onto the device.

Caution: Do not allow any liquid to seep into the device during cleaning.

Caution: Do not disinfect the device using high-temperature and/or high-pressure disinfecting gas.

Chapter 5 Maintenance and Troubleshooting

5.1 Maintenance

- Remove the batteries from the battery compartment if the pulse oximeter will not be used for an extended period of time.
- Replace the batteries if they are low on power.
- Clean the pulse oximeter and the fingertip before every use to ensure accurate reading.
- Store the pulse oximeter between 14°F and 122°F (–10°C and +50°C) and at humidity levels no greater than 93%.
- Periodically check the pulse oximeter for damage.
- Do not use the pulse oximeter in an environment with flammable gases and/or where the temperature or humidity is excessively high or low.

5.2 Troubleshooting

Problems	Possible Cause	Solution
The oximeter fails to display the blood oxygen saturation levels and/or pulse rate.	1. Finger is not inserted correctly. 2. User's blood perfusion is too low to be measured.	1. Make sure that finger is placed right in between the sensor and LED lights. 2. Make sure that nothing is restricting the user's blood flow.
The SpO_2 or Pulse Rate reading is unstable or fluctuates.	1. Finger may not be inserted deep enough. 2. Excessive body movement. 3. Pulse is too weak.	1. Insert finger deep into the chamber. 2. Please do not move during measurement. 3. Warm finger or

		switch finger.
The oximeter cannot be powered on.	1. Batteries are drained. 2. Batteries are incorrectly installed. 3. The oximeter is damaged or defective.	1. Replace the batteries. 2. Please refer to section 3.3.1 for battery installation instruction. 3. Please contact the distributor.

The display screen turns off suddenly.	1. The oximeter powers off automatically when no signal is detected for more than 16 seconds. 2. Batteries are drained.	1. This is normal. Just turn the oximeter on again. 2. Replace the batteries.

Chapter 6 Technical Description and Safety Type

6.1 Technical Specifications

1. Dimensions: 58.0 mm (Width) × 32.0 mm (Depth) × 33.2 mm (Height) (Approximately 2.28 inch x 1.25 inch x 1.30 inch)

   Weight: 49.4g/1.7oz (including the weight of two AAA batteries)

2. Peak wavelength range of the light emitted from the probe: red light 660 nm ± 3nm; infrared light 905 nm ± 5nm.

3. Maximum optical output power of the probe: 1.2 mW for infrared light (905 nm).

4. Working power supply and current

Internal Power Supply	Two 1.5 V dry batteries
Working Current	30 mA

5. Normal working condition

Working Temperature	5°C to 40°C (41°F to 104°F)
Relative Humidity	15% to 80%, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa
Rated Voltage	DC 3.0 V

6. Default values and alarm conditions

Parameter	Value
Oxygen saturation	Upper limit: 100 Lower limit: 90
Pulse rate	Upper limit: 130 Lower limit: 50

Alarm condition	When the alarm is set to on and the measured values exceed the preset alarm parameter range, the alarm will go off.

7. Technical parameters

Parameter		Value
Display range	Oxygen saturation	35% to 100%
	Pulse rate	25 bpm to 250 bpm
Resolution	Oxygen saturation	1%
	Pulse rate	1 bpm
Measurement accuracy	Oxygen saturation	± 2% (70% to 100%) No requirement (≤ 69%)
	Pulse rate	±2 bpm
Alarm range	Oxygen saturation	Upper limit: 50% to 100% Lower limit: 50% to 100%
	Pulse rate	Upper limit: 25 bpm to 250 bpm Lower limit: 25 bpm to 250

		bpm
Alarm error	Oxygen saturation	± 1% of the preset value
	Pulse rate	The greater of ±10% of the preset value and ±5 bpm

8. Capability to resist ambient light interference

   Comparing the measured value of oxygen saturation taken in indoor natural light or other illumination sources to that taken in darkroom condition, the deviation is smaller than ± 1%.

6.2 Technical Description

6.2.1 Oxygen Saturation Accuracy

The accuracy is ±2% (in the absence of movement) between 70% to 100%.

Note: The oxygen saturation accuracy is a root mean square of the difference. The measured values of the device are distributed according to statistical probability. Only about two thirds of the

measured values of the Pulse Oximeter fall within ±Arms of the measured values of a carbon-monoxide-blood-gas analyzer.

6.2.2 Determination of Oxygen Saturation Accuracy

The claimed oxygen saturation is supported by coverage of the entire range of clinical research measurements.

6.2.2.1 Data Collection

In the clinical test process, data points are recorded with comparable density in the claimed entire range.

6.2.2.2 Data Analysis

For each claimed range, the oxygen saturation accuracy of the pulse Oximeter should be represented in the form of mean root square of the difference between the measured values of oxygen saturation and the reference value. The formula is as follows:

$$\text{Arms}=\sqrt{\frac{\sum_{i=1}^{n}(SPO_{2i}-S_{Ri})^{2}}{n}}$$

Arms: accuracy

n : test sample quantity

SPO_{2i} : measured value of pulse oxygen saturation during the first measurement using the finger pulse Oximeter

S_{Ri} : reference value of pulse oxygen saturation during the i^{th} measurement using the carbon-monoxide-blood-gas analyzer

6.2.2.3 Characteristics of Population under Clinical Research

The summary clinical research report for evaluating SPO2 accuracy should state whether the tested subject suffers from disease or is healthy, and should state the skin color, age, and gender of the tested subject.

6.2.3 Data updating interval: Data averaging and other signal processing will have an influence on the display and transmission of SpO_2 and the pulse rate. The range of prompt signal generation delay is 1 to 20 seconds depending on alert parameter settings and the difference between displayed values. The maximum alert status delay is 4 seconds, the maximum alert signal generation delay is 20 seconds, the average alert status delay is 2 seconds, and the average alert signal generation delay is 10 seconds.

6.2.4 When the signal detected by the Oximeter is incomplete or weak, the readings of the oxygen saturation and pulse rate on the screen of the Oximeter are "--" and "--".

6.2.5 The oxygen volume graph of the Oximeter has been normalized.

6.2.6 Manufacturing date: See the label.

Service life: 5 years

Note: The functional tester shall not be used to evaluate the accuracy of the probe of the pulse Oximeter or the accuracy of the pulse oxygen monitor.

Note: The pulse Oximeter has a specific calibration curve, and is precise for the combination of the mainframe and probe of the pulse Oximeter. If the functional tester can measure the portion of overall errors of the mainframe-probe system of the Oximeter attributable to the mainframe of the Oximeter, the functional tester can test the accuracy of a pulse Oximeter that duplicates the calibration curve.

Note: The product is not suitable for continuous long-term monitoring. When the probe of the Oximeter fails, the Oximeter

displays "--" and "---".

6.3 Safety Type

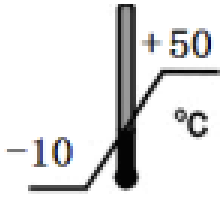
Anti-electric-shock type: internal power supply device

Anti-electric-shock degree: BF-type application part

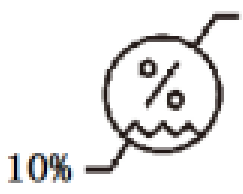
Running mode: continuous working

Waterproof grade: IP22

6.4 Storage and Transportation



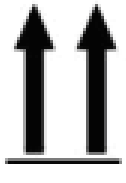
Temperature
-10℃～ +50℃



RH
10%～93%
non-condensing

Atmospheric pressure
50kPa～106kPa

Stack height:
No more than 5 layers



Place upward

Keep away from rain

ZacVrate

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