Acc U Rate® CMS 500D

URATE

Finger Pulse Oximeter

User Manual

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6.4   Storage and Transportation

+50 ℃
−10

Temperature
−10℃～ +50℃

93%
10%
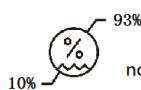
RH
10%～93%
non-condensing
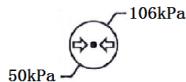
106kPa
50kPa

Atmospheric pressure
50kPa～106kPa

5

Stack height:
No more than 5
layers

Place upward

Keep away from
rain

Contents

Letter to Users

Thank you for choosing our Acc U Rate® CMS 500D Deluxe Finger Pulse Oximeter. By listening to our customers and applying some simple technological innovations, you will come to see that the CMS 500D is one of the most user-friendly, reliable and comfortable pulse oximeters that you will ever come to own. Before using this product, please carefully read the manual and follow the instructions stated herein. Check whether all accessories are complete against the packing list and whether any component is damaged during shipping. If there is any damage or if you have any concerns, please contact us at cs@cmsmobilityusa.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.cmsmobilityusa.com/cms-500d.html

Standard Packing List

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

Chapter 1 Precautions, Warnings, and Conventions

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 you are monitoring your SpO₂ levels and pulse rate for more than 2 hours.

● Stop immediately if you have broken skin or the blood circulation of your finger is affected during prolong use.

● This product is not designed to be used by newborn babies.

● The pulse oximeter uses infrared light (invisible to your eyes) to measure your SpO₂ levels. Hence, please do not stare at the light-emitting components of the Oximeter, as that could cause harm and/or potentially blind your eyes.

● This device is not intended to diagnose or treat any medical condition or disease. It is intended for non-medical use in healthy people to monitor their pulse and blood

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: IPX1

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:

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

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 ith 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 SPO_2 accuracy should state whether the tested object suffers from disease or is healthy, and should state the skin color, age, and gender of the tested object.

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.*

oxygen levels during sports and/or aviation only. People who need SpO_2 and pulse rate measurements because of a medical condition should not use the CMS 500D and should consult with their physician.

The following factors may affect the accuracy of the measurement:

◆ *The Oximeter is used in an environment involving high-frequency devices, such as high-frequency electric knives and CT apparatuses.*

◆ *Ambient light intensity 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 present an entanglement or choking hazard to small children. Adult supervision required; never leave children unattended with unit or lanyard*

> *Warning: Do not throw the batteries into fire, as that could 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 of your region.*

> *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 a long time.

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

1.3   Symbol Conventions

Symbol	Description
(BF symbol)	BF-type application part
(caution triangle)	Caution: Please see this manual.
%SpO₂	Symbol of oxygen saturation
bpmPR	Symbol of pulse rate
(manufacturer symbol)	Manufacturer information including the name and address of the manufacturer
(temperature symbol)	Temperature limitation
(recycling symbol)	When end users abandon this product, they must send the product to the collection place for recycling.
Warning	Information that you must learn about possible harm of this product to patients or medical staff

parameter range, the Oximeter gives an alert sound.

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 precision	Oxygen saturation	± 2% (70% to 100%) No requirement (≤ 69%)
	Pulse rate	±2 bpm
Alert 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
Alert 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

Compare the measured value of oxygen saturation in the case of indoor natural light and existing illumination sources with the measured value of oxygen saturation in the 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 instrument 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

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 function.

6) Some people with medical conditions such as anemia, hypotension and hypothermia can experience an inaccurate reading during use. If that may be the case for you, we suggest that you consult a physician.

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)

     Weight: 49.4g (including the height of the two AAA dry batteries)

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

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

Note: While curing disease such as (blood vessel) proliferative lesion using photodynamic therapy, avoid using the Oximeter for measurement, because the light (within the wavelength range) emitted by the probe of the Oximeter may influence non-lesion tissues of the human body.

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 conditions of alert

Parameter	Value
Oxygen saturation	Upper limit: 100 Lower limit: 94
Pulse rate	Upper limit: 130 Lower limit: 50
Alert condition	When the alert switch is on and the actual measured value goes beyond the preset alert

| Caution	Some important information that you must learn
Attention	Information that is necessary for you to protect this product against damage

Chapter 2 About The 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$_2$ and pulse rate.

2.2   Working Principles and Usage

Oxygenated blood absorbs light at 660nm (red light), whereas deoxygenated blood absorbs light preferentially at 905nm (infra-red). 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 CMS 500D uses a proprietary algorithm to collect data from pulsatile arterial blood and ignores local noise from the tissues. The relative absorption of light by oxyhemoglobin (HbO) and deoxyhemoglobin is then processed according to the Beer-Lambert's law and a qualitative measurement of the users' oxyhemoglobin status i.e. Oxygen saturation level (SpO$_2$) derived.
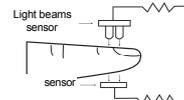
Due to the sensitivity of the pulse oximeter, you should keep your finger stationary during measurement. It is recommended that you use this instrument for measurement before or after sports. Do not use for continuous monitoring.

2.3   Applicable Scope

This device is intended for non-medical use in healthy people to monitor their pulse and blood oxygen levels for sports and/or aviation only. However, you are not advised to use this instrument during sports activities as finger movement may lead to inaccuracies. It is suitable for users between 15 to 60 years old. Do not use it for continuous monitoring.

2.4   Product Features

● Lightweight, portable, and easy to use.

● Six different displays options.

● Dual-color OLED screen to show measured values, plethysmogram and bar graphs

● Large-font display

- *Preset alarm function*
- *Battery low-voltage indication*
- *Automatically 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 haemoglobin in your blood over a period of time. Spot check pulse oximeter takes a reading 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, then 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 would not have enough blood to take a measurement. Please note that prolong 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 CMS 500D

The CMS 500D attempts to ameliorate some of the above problems by
1) Increasing the sensitivity of the sensor so that it can measure the user's SpO$_2$ and Pulse Rate (PR) even at low blood perfusion.
2) Using a self-adjusting smart spring system to fit the finger snugly but not so tight as to impede blood flow.
3) Using soft, hypoallergenic medical grade silicon in the finger chamber so that the pulse oximeter will not cause discomfort to your 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 see and gauge the amount of blood detected by the pulse oximeter. This will allow the user to know if the finger is properly inserted into the finger chamber and if the pulse oximeter is taking the measurements properly (See Chapter 3.3.3 about the plethysmograph).

The Oximeter fails to display the blood oxygen saturation levels and/or pulse rate.	1. **The finger is not placed properly between the sensor and the LED lights.** 2. **The user's blood perfusion is too low to be detected.**	1. **Place the finger at the correct position.** 2. **Make sure nothing is restricting your blood flow**
The displayed value of the oxygen saturation or pulse rate fluctuates.	1. **The finger is not placed properly between the sensor and the LED lights.** 2. **The user is moving his finger or body**	1. **Place the finger at the correct position.** 2. **Ensure that the user's body is stationary.**
The Oximeter cannot be powered on.	1. **The batteries are empty, or are not installed at all.** 2. **The batteries are incorrectly installed.** 3. **The Oximeter is damaged.**	1. **Replace the batteries.** 2. **Correctly install the batteries according to the polarity indication.** 3. **Contact the distributor.**
The screen is suddenly off.	1. **If the Oximeter does not detect any signal within 16 seconds, it will automatically power off.** 2. **The batteries are empty**	1. **This is normal. Just turn on the pulse oximeter again.** 2. **Replace the batteries.**

5.3   Tips to getting a good reading.

1) Make sure that your finger is put deep into the probe such that the fingertip is directly in between the LED sensor and the LED light source.
2) Make sure your finger is stationary in the probe while you are measuring your SpO2 levels
3) If your fingernails are too long, this may obstruct the sensor from the LED lights. Please make sure that your fingernails are kept short.
4) Excessive ambient infra-red light, especially for people who use the pulse oximeter in an overly bright lit room can interfere with the sensor.
5) Poor circulation can affect oximeter readings. Warm your hands and fingers before taking your measurements. Remember your pulse oximeter is measuring your SpO$_2$ and

Caution: Do not allow liquid to flow into the instrument during cleaning.

Caution: Do not immerse any part of the instrument into any liquid.

4.2   Disinfection

Before measurement with the instrument, wipe the silicon finger pad using a piece of dry soft cloth dipped with 75% medical alcohol. Clean the finger to be measured using the medical alcohol for disinfection purposes before and after use.

⚠️ Do not disinfect the instrument by using high-temperature/high-pressure disinfecting gas.

## Chapter 5 Maintenance and Troubleshooting

5.1   Maintenance

- Replace the batteries if they are low on power. Clean the Oximeter and the fingertip before use to ensure accurate reading.
- Remove the batteries from the battery slot and properly store them if you do not plan to use the Oximeter for a long period of time.
- Store the Oximeter between 14 -122°F (-10 ° to +50°C) and at humidity levels no greater than 93%.
- Periodically check the Oximeter for damage.
- Avoid using the Oximeter in an environment with inflammable gases or using it in an environment where the temperature or humidity is excessively high or low.
- Check the accuracy of the oxygen saturation and pulse rate readings by using an appropriate calibration apparatus.

5.2   Troubleshooting

Problems	Possible Cause	Solution

Chapter 3 Product Structure, Parameter Settings and Operation Steps

3.1   Schematic Structural Diagram

❶ OLED screen

❷ Power-on key/functional key

❸ ABS plastic casing

❹ Battery cover
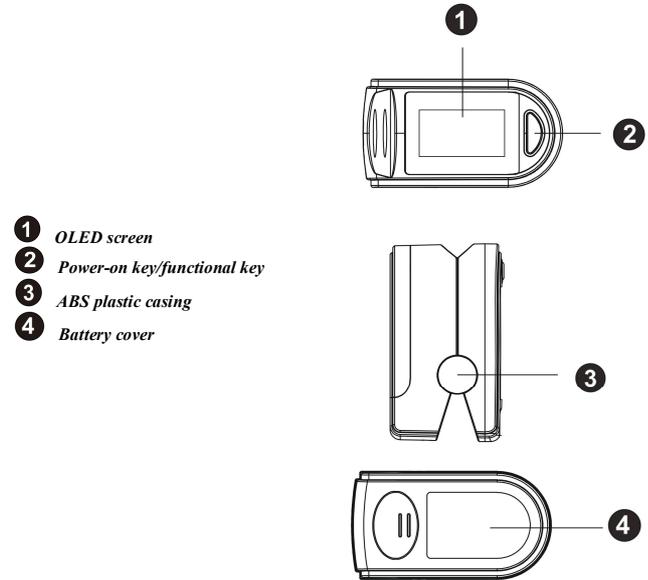
Note: The photo in this manual may differ from the actual model.

3.2   Schematic Diagram of Display

The following figure shows the information display on the OLED screen of the Oximeter in normal detection state:
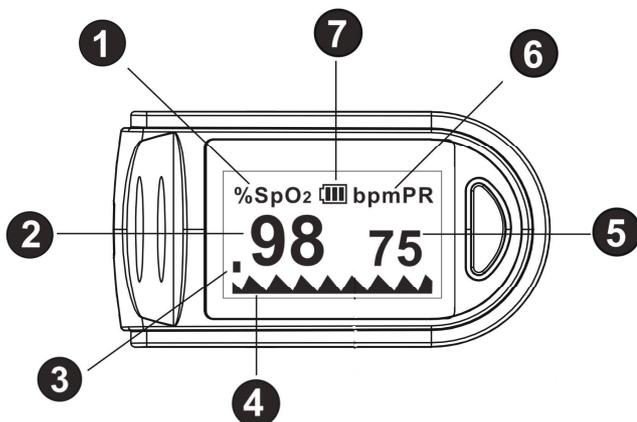
❶ *Symbol of oxygen saturation*

❷ *Measured value of oxygen saturation*

❸ *Bar graph*

❹ *Plethysmogram*

❺ *Measured value of pulse rate*

❻ *Symbol of pulse rate*

❼ *Battery power indication*

3.3   Operation Guide

3.3.1   Operation Steps

(1)   Installing the batteries

Install the two AAA batteries into the battery slot according to polarity indication and mount the battery cover.

3.4.4   Brightness Setting

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

3.4.5   Alarm Range Setting

To change the alarm range settings, PRESS the power-on key/functional key to move "" to Alm Setup and HOLD the power-on key/functional key to enter in Menu Interface 2. "*" should be at Sounds Setup. Press the power-on key/functional key to move "*" to the option you desire to change. SpO₂ Alm Hi and SpO₂ Alm Lo refer to the upper and lower limit of the SpO₂ 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.*

While the "" symbol stays on the +/- option, hold the functional key to set the option to + or -. In + mode, select the corresponding upper or lower limit option and hold the functional key to increase the upper or lower limit; in - mode, hold the functional key to decrease the upper or lower limit. Move "*" to the Exit option, and hold the functional key to return to the monitoring interface.*

Chapter 4 Cleaning and Disinfection

4.1   Cleaning

To clean the instrument, power off and remove the batteries first. Then clean the outer surface of the instrument (including the LED screen) using a piece of dry soft cloth dipped with 75% medical alcohol. **Do not immerse the unit in alcohol!**

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

Attention: Do not rub the body of the instrument using materials such as steel wire balls or polished metal objects.

Attention: Ensure that there is no washing liquid on the surface of

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

3.4.2   Alarm Setting

```
V2.01.C1                    V2.01.C1
Alm Setup        *          Sounds setup    *
Alm          on             SpO2 Alm Hi    100
Beep         off            SpO2 Alm Lo     94
Demo         off            PR Alm Hi      130
Restore      ok             PR Alm Lo       50
Brightness    4             +/-             +
        Exit                        Exit

    Interface 1                 Interface 2
```

To turn the alarm on/off, PRESS the power-on key/functional key to move "" to Alm. HOLD the power-on key/functional 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) go beyond the stated upper or lower limit (See 3.3.6 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 Settings

To turn the beeping sound on/off while measuring your pulse rate, PRESS the power-on key/functional key to move "" to Beep. HOLD the power-on key/functional 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/functional key to move "" to DEMO. HOLD the power-on key/functional key to switch the option from on to off or vice versa.*

3.4.5   Restoring Factory Settings

PRESS the functional key to move "" to the Restore option. HOLD the power-on key/functional key to restore pulse oximeter to factory settings. "OK" will be displayed. Move "*" to the Next option, and hold the functional key to reset oximeter to factory mode.*

⚠ *Ensure that the batteries are installed with correct polarities to avoid damaging the instrument.*
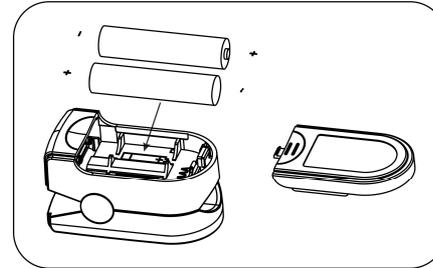
(2)   Installing the lanyard

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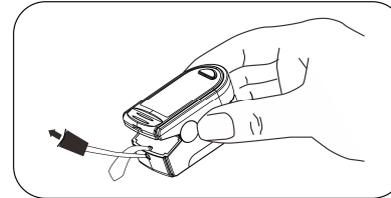

(3)   Switch on the power supply of the pulse Oximeter

Stick one finger completely into the silicon padded finger chamber of the Oximeter. The fingernail should be facing upward. Release the clip and press the power key to power on the Pulse Oximeter.

⚠ *If you do not insert your finger completely into the chamber, the measurement will be inaccurate.*
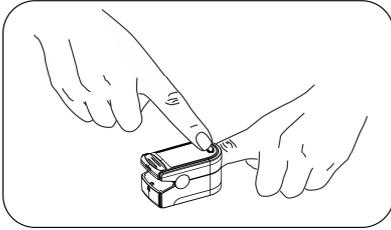
Note: Before each test, clean the measured finger and the silicon part of the Oximeter that contacts the finger with medical alcohol. The silicon is non-toxic, soft and hypoallergenic.

(4)   Reading measured data of Oxygen Saturation and the Pulse Rate from the OLED screen

Do not move your finger during measurement. Keep your body as still as possible. After the readings become stable, read the measured values of the oxygen saturation and pulse rate on the LED screen.

(5)   Switch off the power supply of the Oximeter

The Oximeter will automatically shut down 16 seconds after you remove your finger or if it does not detect a signal.

3.3.2   Switching the Display

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

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

3.3.3   Plethysmograph
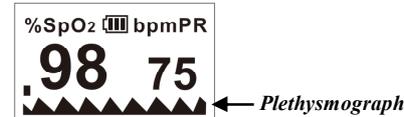
← Plethysmograph

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 flowing through the blood vessels. If the wave amplitude is low, this means that your blood perfusion is too low for a reliable read. You should retake your measurement and make sure that your finger is positioned right under the LED lights.

3.4   Parameter Settings

3.4.1   Power-On Key/Functional Key Operations

PRESS (<0.5 sec) the Power-On/functional key to turn on the pulse oximeter.