

Zacurate® 500BL

Fingertip Pulse Oximeter

User Manual

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Letter to Users

Thank you for choosing our Zacurate® 500BL Fingertip Pulse Oximeter. The Zacurate® 500BL is accurate, reliable and highly rated for its simple design and ease of use. 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 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/500b1>

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1 Standard Packing List

- 1.Pulse oximeter.....1PC
- 2.AAA Battery.....2PCS
- 3.Lanyard.....1PC
- 4.User Manual.....1PC

2 Safety

2.1 Contraindications

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

2.2 Warnings

- Do not use the oximeter in an environment with any flammable gases, flammable anesthetic, or other flammable substances.
- Keep the oximeter away from young children. Small items such as the battery door, battery and lanyard may pose as choking or entanglement hazards.
- Do not attempt to charge the included batteries as that can cause leakage, fire disaster or explosion. Dispose used batteries in accordance with local laws and regulations.

2.3 Precautions

- Please read the user manual carefully before use.
- Do not use the oximeter in situations where alarms are required. This oximeter has no alarms.
- This oximeter is not designed to be used by newborn babies.
- This oximeter is not for continuous monitoring.
- In order to ensure proper sensor alignment and skin integrity, the maximum application time at a single site for the oximeter should be less than half an hour.
- Do not use the oximeter on edema or fragile tissue.
- Do not use the oximeter on the same arm that a blood pressure

(Continued)

cuff, arterial duct or intravenous injection is placed.

- Do not immerse the oximeter in liquid.
- Do not stare at the light emitting components of the oximeter to avoid potential eye damage and/or blindness. Note that infrared light is invisible to your eyes.
- Do not disassemble, repair or modify the oximeter.
- Follow local disposal and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- This fingertip pulse oximeter is not a medical device and is not intended to diagnose and/or treat any medical condition or disease.

(Continued)

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 SpO₂ and pulse rate measurements because of a medical condition should not use this fingertip pulse oximeter and should consult with their physician.

- The following conditions may negatively affect the performance of the oximeter and cause inaccurate measurements:
 - ◆ Flickering or very bright light
 - ◆ Moisture in the oximeter
 - ◆ Excessive user movement
 - ◆ Weak pulse strength
(low blood perfusion)

(Continued)

- ◆ Venous pulsations
- ◆ Low hemoglobin
- ◆ Presence of intravascular dyes such as cardiogreen or methylene blue
- ◆ Significant levels of dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin
- ◆ Artificial nails or fingernail polish
- ◆ Presence of high-frequency electro-surgical interference or defibrillators
- ◆ Placement of device on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

(Continued)

- ◆ The user has hypotension, severe vasoconstriction, severe anemia, or hypothermia
- ◆ The user is in cardiac arrest or is in shock

3 About This Product

3.1 Overview

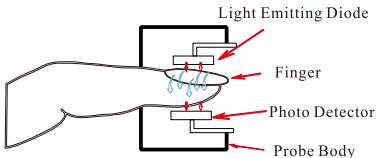
SpO₂ stands for peripheral capillary oxygen saturation. Oxygen saturation is defined as the ratio of oxyhemoglobin (HbO₂) to the total concentration of hemoglobin (i.e. Oxyhemoglobin + reduced hemoglobin) present in the blood. It is an important physiological parameter involved in respiration and circulation. 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 SpO₂ level and pulse rate. It has also been proven to be highly precise and

reliable in clinical tests.

3.2 Measurement Principle

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 Zacurate® 500BL uses a proprietary algorithm to collect data from pulsatile arterial blood and excludes 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.



Schematic Illustration of Operating Principle

3.3 Intended Use

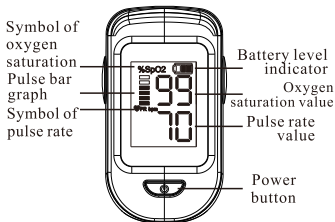
The Zacurate® 500BL Fingertip Pulse Oximeter is a portable non-invasive device intended for spot-

checking of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR) of adult and children (>2 years old). The device is for sports and/or aviation use.

3.4 product Features







- Easy to operate. Measure your SpO₂ non-invasively.
- Small, light and portable.
- LED screen displays SpO₂, Pulse Rate and Pulse Bar.
- Low power consumption. Battery level indicator.
- When no or low signal is detected, the device will power off automatically in about 8 seconds.

3.5 Front Panel



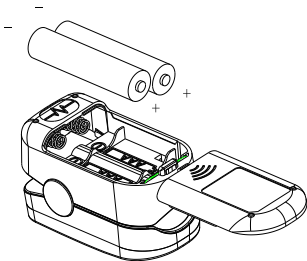
3.6 Symbol

Symbol	Definition	Symbol	Definition
%SpO ₂	Oxygen saturation (%)	+	Battery positive electrode

PR	Pulse rate (BPM)	-	Battery negative electrode
	Battery Level Indicator		BF Type Applied Part
	Follow Instruction for Use		Not for Continuous Monitoring (No SpO ₂ Alarm)
IPX2	Degree of protection against ingress of liquid		Item should not be treated as household waste
	Item is compliant with Medical Device Directive 93/42/EEC		

4 Battery Installation

1. Slide open the battery door cover.
2. Install two AAA batteries into the battery compartment as shown in the figure below.
3. Close the battery door cover.



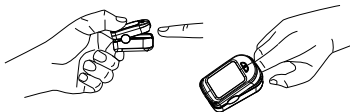
WARNINGS

- Incorrectly installed batteries may damage the device.
- Remove the batteries if the oximeter will not be used for more than 30 days.
- Replace batteries when the battery level indicator is low.
- Batteries may leak or explode if used or disposed of improperly.

5 Operation Instructions

1. Install two AAA batteries according to the 'Battery Installation' instructions.
2. Insert one of your fingers into the finger chamber of the pulse oximeter.
3. Press the power button on the front panel to turn the pulse oximeter on.
4. Keep your hand and finger still for the reading. It is recommended that you do not move your body while taking a reading.
5. The measurement result will be displayed on the screen within 10 seconds.
6. The oximeter will power off automatically in about 8 seconds when finger is removed or when no

signal is detected.



5.1 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 sensor and the LED light source.
2. Avoid making any body movement, especially your finger while taking measurement.
3. The pulse bar graph 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 SpO₂ and Pulse Rate value is potentially incorrect. Readjust your finger to ensure proper placement.

4. Long fingernails may obstruct the light sensor and prevent accurate measurement. Please keep fingernails short while using the device.
5. Excessive ambient infra-red light, especially in an overly bright lit room, can interfere with the sensor, preventing an accurate measurement.
6. Poor blood circulation can affect oximeter readings. Warm your hands and fingers before taking your measurements. Note that the pulse oximeter is measuring your SpO₂ and PR based on your blood

flow. If the blood flow in your finger drops below a perfusion index of 0.3, the pulse oximeter will not be able to get a reading.

7. Some people with medical conditions such as anemia, hypotension and hypothermia may experience an inaccurate reading during use. In such case, we suggest that you consult a physician.

6 Maintenance

6.1 Maintenance and Storage

1. Clean the finger chamber and surface of the oximeter before use.
2. Replace the batteries when the battery level indicator is low.
3. Remove the batteries if the oximeter will not be used for more than 30 days.
4. Store the product in a cool and dry place. Extreme moisture may damage the oximeter or affect its lifespan.

The lifespan of the pulse oximeter is estimated to be two (2) years with proper maintenance and storage.

6.2 Cleaning and Disinfection

It is recommended to clean the

oximeter before and after each use. The 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 70% isopropyl alcohol.

1. Make sure that the oximeter is powered off. Remove the battery.
2. Wipe the finger chamber and the surface of the oximeter using lightly dampened soft cloth.
3. Allow the oximeter to air dry thoroughly before use.

CAUTIONS

- Do not immerse or soak the oximeter in any liquid.

t pour or spray liquid onto the oximeter.

- Do not allow any liquid to enter any openings in the oximeter.
- Do not use cleaning agents or disinfectants other than the recommended.

6.3 Disposal

Dispose battery and pulse oximeter properly. Follow applicable local environment and waste disposal laws and regulations.

7 Troubleshooting

Problems	Possible Reason	Solution
The oximeter cannot be powered on	Batteries are drained	Please replace the batteries
	Batteries may be installed incorrectly	Please refer to 'Battery Installation' instruction
	The oximeter may be damaged or defective	Please contact local distribution center
The display screen turns off suddenly	The oximeter powers off automatically when no signal is detected for more than 8 seconds	This is normal. Just turn the oximeter on again
	Batteries are drained	Replace the batteries

(Continued)

SpO ₂ or Pulse Rate reading is unstable or changes erratically	Pulse is too weak	Warm finger or switch finger
	Excessive body movement	Please do not move during measurement
	Finger may not be inserted deep enough	Insert finger deep into the chamber
	Excessive ambient light	Avoid using the oximeter in an overly bright lit room

(Continued)

The oximeter fails to display SpO ₂ and/or Pulse Rate	Finger is not inserted correctly	Make sure that finger is placed right between the sensor and LED lights.
	User's blood flow is too low to be measured	Make sure that nothing is hindering the user's blood flow

8 Specifications

8.1 Display Specifications

Display type	LED
Display content	SpO ₂ %, PR bpm, battery level indicator, pulse bar graph.

8.2 Measurement Specifications

SpO ₂	
Display range	0% to 99%
Resolution	1%
Accuracy	70% to 99% $\pm 2\%$ 0% to 69% no definition

(Continued)

PR	
Measurement range	25bpm to 250 bpm
Resolution	1 bpm
Accuracy	± 3 bpm

8.3 Environmental Specifications

Operat- ing	Temperature ($^{\circ}\text{C}$)	0 to 40
	Humidity (non-condensing)	15% to 95%
	Atmospheric pressure (kPa)	70 to 106

Storage/ trans- portation	Temperature (°C)	-20 to 60
	Humidity (non-condensing)	10% to 95%
	Atmospheric pressure (kPa)	50 to 107.4

8.4 Power Requirements

Alkaline batteries	Quantity	2
	Specifi- cation	1.5 V, AAA
	Operating voltage	DC2.3~3V

(Continued)

	Run time	600 spot checks on two full power batteries at ambient temperature of 25°C.
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8.5 Physical Specifications

Width x Height x Depth	About 33×36×58mm
Weight	~60 g (including batteries)

9 Technical Description

The table below shows the statistical distribution of an invasive controlled desaturation study performed according to 'ISO80601-2-61-2011, Annex EE, Guideline for evaluating and documenting SpO₂ accuracy in human subjects'.

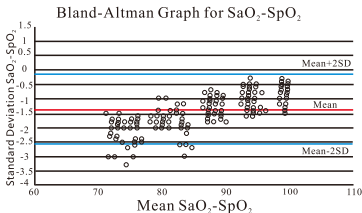
The statistical distribution displays the accuracy distribution in the range of 70% ~ 100%, which may be helpful to user.

Bias Analysis SpO₂-Pulse Oximeter	SaO₂-Radiometer ABL800 FLEX-CO-Oximeter			
	70-80 (%)	80-90 (%)	90-100 (%)	70-100 (%)

(Continued)

Mean Bias (Bs)	1.94	1.45	0.89	1.40
Precision (Sres)	2.00	1.55	0.98	1.53
Accuracy(Ams)	1.98	1.53	0.96	1.52

Bland-Altman graphical plot of samples from invasive controlled desaturation study.



10 Declaration

The equipment complies with the requirement of standard EN 60601-1-2:2007 “Electromagnetic Compatibility – Medical Electrical Equipment”.

Guidance and manufacturer's declaration – electromagnetic immunity			
The pulse oximeter is intended for use in the electromagnetic environment specified below.			
Im- munity test	IEC 60601 test level	Com- pliance level	Electromagnetic environment – guidance

(Continued)

Electro-static discharge (ESD) IEC 61000 -4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000 -4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

(Continued)

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The pulse oximeter is intended for use in the electromagnetic environment specified below.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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(Continued)

Conducted RF IEC 61000 -4-6	3 Vrms 150 kHz to 80 MHZ	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the pulse oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
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(Continued)

Radiated RF IEC 61000 -4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Recommended separation distance $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800MHz to 2.5 GHz <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the</p>
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(Continued)

		<p>transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: </p>
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(Continued)

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pulse oximeter is used exceeds the

(Continued)

applicable RF compliance level above, the pulse oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pulse oximeter.

- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Guidance and manufacturer's declaration – electromagnetic emissions

The pulse oximeter is intended for use in the electromagnetic environment specified below. The user of the pulse oximeter should ensure that it is used in such an environment.

(Continued)

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The pulse oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage.
Harmonic emissions IEC 61000-3-2	N/A	

(Continued)

Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	power supply network that supplies buildings used for domestic purposes.
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Recommended separation distances between portable and mobile RF communications equipment and the pulse oximeter

The pulse oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pulse oximeter as recommended below, according to the maximum output power of the communications equipment.

(Continued)

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}] \sqrt{P}$	800 MHz to 2,5 Ghz $d = [\frac{7}{E_1}] \sqrt{P}$
0,01	/	0.02	0.03
0,1	/	0.06	0.11
1	/	0.18	0.35
10	/	0.57	1.1
100	/	1.8	3.5

(Continued)

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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