



## Viatomtech SA-10BW Continuous Pulse Oximeter Fingertip User Manual

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## Viatomtech SA-10BW Continuous Pulse Oximeter Fingertip User Manual



### Download the APP software

You can view the measurements and record list in the APP.

Scan the below QR code to download the APP software for iOS and Android system.

Please pair the APP with your oximeter according to the number displayed in the lower right corner of the screen after the oximeter is turned on.



## Instructions for Safe Operation

**M It's not a medical device. This device is for Sports and Aviation use only and not intended for medical use.**

- M The Oximeter is not intended for medical use.
- M The Oximeter is not an apnea monitor and should not be used for arrhythmia analysis.
- M Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor.
- M Make sure that there is no visible damage that may affect user's safety or measurement performance with regard to sensors and clips. It is recommended that the device should be inspected minimally before each use. If there is obvious damage, stop using the device.
- M Special attention should be paid while the oximeter is used constantly under the ambient temperature over 37°C, burning hurt may occur because of over-heating of the sensor at this situation.
- M Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to service this device.
- M The oximeter must not be used with devices and accessories not specified in User Manual.

## Warnings and Cautions

- Explosive hazard—**DO NOT** use the Oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- **DO NOT** use the Oximeter while the user is under MRI or CT scanning. This device is NOT MRI Compatible.
- Discomfort or pain may Appear if using the Oximeter continuously on the same location for a long time, especially for user with poor microcirculation. It is recommended that the Oximeter should not be Applied to the same location for longer than 2 hours. If any abnormal condition is found, please change the position of Oximeter.
- When using the device for continuous prolonged monitoring, the position to which the oxygen probe (sensor) is attached should be checked every 2 hours when the ambient temperature exceeds 37°C, and it is advisable to change the position of the wearing device or move it every 2 hours in the event of skin changes. More frequent examinations may be required for certain patients, such as neonates, patients with perfusion disorders or skin sensitivities.
- It is not recommended to use the device continuously when the ambient temperature (including the patient's body temperature) exceeds 41°C, as prolonged and continuous use may increase the risk of unanticipated skin changes such as sensitization, reddening, blistering, or pressure necrosis.
- The light (the infrared light is invisible) emitted from the device is harmful to the eyes. Do not stare at the light.
- The Oximeter is not a treatment device.
- Local laws and regulations must be followed when disposing of the device.

- Keep the Oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- The device should be kept out of the reach of children.
- If the oximeter gets wet, please stop using it and do not resume operation until it is dry and checked for correct operation. When it is carried from a cold environment to a warm and humid environment, please do not use it immediately. Allow at least 15 minutes for Oximeter to reach ambient temperature.
- DO **NOT** operate the button on the front panel with sharp materials or sharp point.
- DO **NOT** use high temperature or high-pressure steam disinfection on the Oximeter. Refer to Chapter 8 for instructions regarding cleaning and disinfection.
- Pay attention to the effects of lint, dust, light (including sunlight), etc.
- Please keep the cable away from children. It can cause strangulation.

## FCC Rules

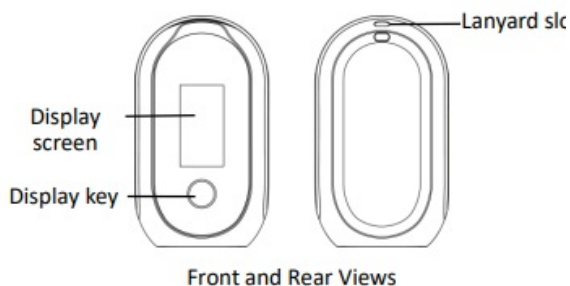
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

## Overview

### Intended Use

This Pulse Oximeter is intended for measuring the pulse rate and oxygen level (SpO2) through a user's finger.

### Views



## Features

- Display oxygen level, PR, and Plethysmogram
- Auto power On/Off
- Setting menu
- Pulse beep
- Wireless function

## Charging

Charge the battery before using.

Connect the device to computer USB or USB charging adapter with USB cable.

Note: The device cannot be used during charging, and if choosing a third party charging adaptor (Class II), select

one that complies with IEC60601-1 or IEC60950-1.

: Fully charged.

: The filled part represents the remaining power. If the filled part moves from left to right, the device is charging. :

Low battery. Please charge the device

**Note:** Please use the accessories that are original or Approved by our company.

## POWER ON/OFF

POWER ON:

Wear the device, it will turn on automatically.

## POWER OFF:

Take the device off.

- It will turn off automatically after 2
- On the menu interface, if there is no key operation for about 30 seconds, the device will automatically exit the menu and then shut
- On the recording and playback screen, if there is no key operation for 6 seconds, the device will automatically shut

## Start/Stop Measuring

1. Open the clip and put finger inside the clip (make sure the finger is in full contact with the deep inner side of the clip), and then release the clip.
2. Wait for 2 seconds, the oximeter will power on and start to measure. Finger Placement
3. The display screen shows the measurement.
4. Get the finger out, and the device will automatically power



## Attentions for measuring:

Do not shake the finger and relax during measurement.

Do not put wet finger directly into sensor.

Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.

Do not let anything block the emitting light from device, i.e. do not use finger nail polish/paints.

Existence of high intensive light sources, such as fluorescence light, ruby lamp, infrared heater or strong sunshine, etc. may cause inaccuracy of measurement result. Please put an opaque cover on the sensor or change the measuring site if necessary.

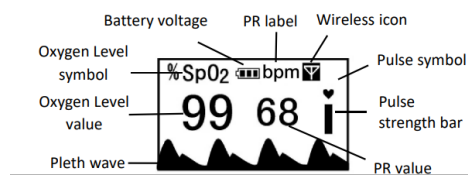
Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.


Nail polish may affect the measuring accuracy, and too long fingernail may cause failure of measurement or inaccurate result.


If the first reading Appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

## Screen

### Indications and Icons



Icon : indicates the wireless connection is set up between the mobile device and oximeter.

Status of 	Definition
Flashing	The oximeter is disconnected from the mobile devices.
On	The connection between the oximeter and mobile devices is established.

### Menu Setup

During measuring, long pressing Display key can enter the setup menu screen.

SpO <sub>2</sub> Lo 89 PR Hi 100 PR Lo 30 Setting menu >>	Reminder On Beep On Display Always Setting menu >>	Save exit menu Restore default <<Setting menu
--	---	---

### Menu operating procedures:

1. Shortly press Display Key to choose the setting item;
2. Long press Display Key to active the setting item, then shortly press it to modify the setting parameter;
3. Long press Display Key to confirm the modification and exit from this setting
4. Move the setting item to “Save exit menu”, and long press Display Key to exit from the setup

### Menu settings:

- **“Reminder”**: The device supports reminders triggered by user-defined oxygen level or PR It is on by default.
- **“Beep”** Pulse beep option. If it is set to on, every pulse beat makes a
- **“Display”**: The display screen is always on by default. You can set the display to automatically turn off after 5 minutes, 3 minutes, or 1 minute. Wake the screen by pressing the display
- **“Restore default”**: Shortly press Display Key to choose “Restore default” and long press Display Key to reset all parameters to their default values.

### Technical Specifications

Classification		
The type of protection against electric shock	Internally powered equipment	
The degree of protection against electric shock	Type BF Applied parts	
Electro-magnetic compatibility	Group I, Class B	
Environment		
	Operating	Storage
Temperature	5 – 40°C	-20 – 55°C
Relative humidity (non-condensing)	30% – 80% (non-condensing)	10% – 93% (non-condensing)
Atmospheric pressure	700 – 1060hPa	700 – 1060hPa
Degree of dust & water resistance	IP22	
Physical		
Dimension	64mm*38mm*28mm	
Weight	About 37 g	
Display	OLED	
Wireless	Bluetooth 4.2 BLE	
Power and supply		
Input	DC 5V ±10%	
Battery	Rechargeable Lithium-polymer	
Battery life	≤15 hours for typical use	

<b>Charge time</b>	About 3 hours
<b>Oxygen level</b>	
<b>Oxygen level range</b>	Measuring range: 0% – 100%
<b>Oxygen level Accuracy (Arms)</b>	±2% (70% – 100%); ±3% (50% – 69%); No definition (0% – 49%)
<b>Pulse Rate range</b>	30bpm – 250 bpm
<b>Pulse Rate accuracy</b>	±2 bpm or ±2%, whichever is greater
<b>Oxygen level Low limit setting range</b>	85% – 99% Default setting: 90%
<b>Pulse Rate low limit setting range</b>	30bpm – 60 bpm Default setting: 50bpm
<b>Pulse Rate high limit setting range</b>	100bpm – 240 bpm Default setting: 120bpm
<b>Low perfusion performance</b>	The accuracy of oxygen level and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6 %.
<b>Sensor</b>	Dual-wavelength LED sensor with wavelength
<b>Wavelength</b>	Red light: 663 nm; Infrared light: 890 nm
<b>Maximal average optical output power</b>	≤2mW
<b>Ambient light interference</b>	The difference between the oxygen level value measured in the

## Maintenance and Cleaning

### Maintenance

The expected service life (not a warranty) of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please change the batteries when the low-voltage indicator
- Please clean the surface of the device before using, with 75% alcohol wipes, then let it air dry or wipe it dry. Do

not allow liquid to enter the device.

- If the Oximeter has not been used for more than 7 days, please charge the Oximeter before
- The Oximeter is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. Any oxygen level simulators should not be used to validate the accuracy of the Oximeter, they can only be used as functional testers to verify its

#### **Caution:**

- **High-pressure sterilization cannot be used on the**
- Do not immerse the device in liquid.
- **It is recommended that the device should be kept in a dry environment. Humidity may reduce the life of the device, or even damage**










#### **Cleaning and Disinfecting Instruction**

- Surface-clean sensor with a soft cloth dampened with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a mild bleach
- Then surface-clean with a cloth dampened ONLY with clean water and dry with a clean, soft

#### **Caution:**

- **Do not sterilize by irradiation steam, or ethylene**
- **Do not use the Oximeter if it is**

#### **Symbols**

Symbol	Description
	Manufacturer
	Date of manufacture
<b>SN</b>	Serial number
	Indicates a device that is not to be disposed of as unsorted municipal waste.
	Follow Instructions for Use.
	No alarm system
	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
<b>IP22</b>	Resistant to liquid ingress
	This product complies with the rules and regulations of the Federal Communication Commission.
	Non-ionizing radiation
	This product complies with verpackG.
--	Indicator of poor signal, displayed when there is no available reading.

## FCC Statement

FCC Warning:

FCC ID: 2ADXX-1659

Any Changes or modifications not expressly Approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on,

## Appendix EMC

The equipment meets the requirements of IEC 60601-1-2:2014.

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 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 re-orienting or relocating The Pulse Oximeter.

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile RF communication the equipment			
The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or 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.			
Rated maximum output power of transmitter W(Watts)	Separation distance according to frequency of transmitter M(Meters)		
	150kHz to 80MHz $d=1.2 \sqrt{P}$	80MHz to 800MHz $d=1.2 \sqrt{P}$	80MHz to 2,5GHz $d=2.3 \sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.38	0.73
1	N/A	1.2	2.3

10	N/A	3.8	7.3
100	N/A	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be determined 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.</p> <p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range Applies.</p> <p>NOTE 2: These guidelines may not Apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

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## Illustration

All illustrations provided in this manual are for reference only, and the settings or data in the illustrations may not be exactly the same as the actual display you see on the product.

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