Vibeat

Fingertip Oximeter User Manual

(Model: POD-1W)

Shenzhen Creative Industry Co., Ltd.
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Manufacture date: See the label on the product
Revision Date: April 24, 2022
Manual Version: V1.0 PN: 255-05155-00

Notes

- Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the Oximeter.
- The contents contained in this manual are subject to change without notice.
- Information furnished by our company is believed to be accurate and reliable. However, no responsibility is assumed by us for its use, or any infringements of users or other rights of third parties that may result from its use.

Instructions for Safe Operation

- 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.
- 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.
- Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to service this device.
- The oximeter must not be used with devices and accessories not specified in User Manual.

Warnings and Cautions

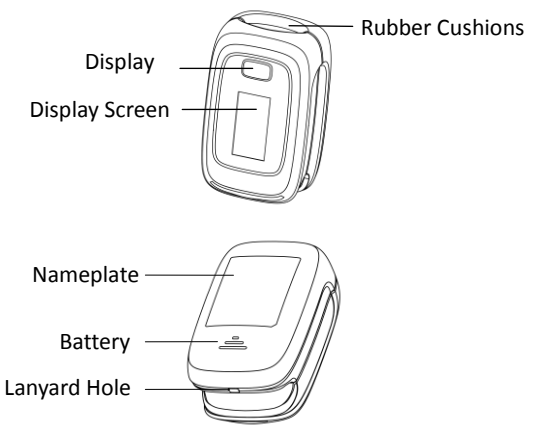
- Explosive hazard—**DO NOT** use the Oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO **NOT** use the Oximeter while the user is under MRI or CT scanning. This device is NOT MRI Compatible.
- Discomfort or pain may appear if using the Oximeter continuously 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.
- 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.

1 Overview

1.1 Intended Use

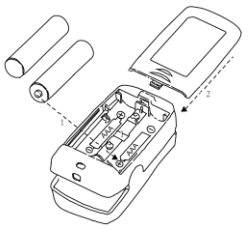
This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through a user's finger.

1.2 Views



2 Battery Installation

1. Refer to Figure 2, insert two AAA size batteries into the battery compartment properly, and note the polarity markings.
2. Replace the cover.



Attentions:

- Make sure that the batteries are correctly installed. Incorrect installation may cause the device not to work.
- Remove batteries if the device is not being used for more than 7 days to prevent and avoid potential damage from the battery leaking. Any such damage is not covered under the product warranty.

3 Start/Stop Measuring

1. Open the clip and put finger inside the clip (make sure the finger is in the correct position), and then release the clip.
2. Wait for 2 seconds, the oximeter will power on and start to measure.

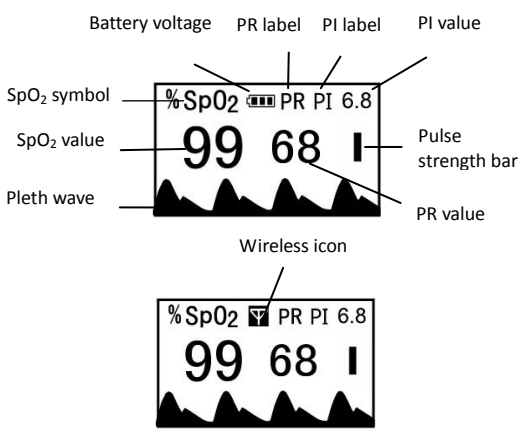
3. The display screen shows the measurement.
4. Get the finger out, and the device will automatically power off.

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 lamb, 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.
- If the measurements over the limits, there is a reminder sound. You can press the Display key to mute it, or wait for 10 seconds till the sound disappears by itself.

4 Screen

4.1 Indications and Icons



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

Status of	Definition
Flashing in blue	The oximeter is connecting with the mobile devices.
Blue on	The connection between the oximeter and mobile devices is established.
No display of "" icon	1. The oximeter fails to set up wireless connection with mobile device within 3 minutes. 2. Hardware failure of wireless function.

- Icon /: low battery voltage.
- Flashing value: indicates the value is over the defined limits. There also accompanies the reminding sound.

5 Menu Setup

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

SpO_2 alm Lo	90
PR alm Hi	120
PR alm Lo	50
Setting menu >>	

Beep	On
Exit	
<< 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 item.
4. Move the setting item to "Exit", and long pressing Display Key to store the modification and exit from the setup menu.

"Beep": Pulse beep option. If it is set to on, every pulse beat makes a beep.

6 Record List

- A single group of stable readings will be recorded in the record list each time when the oximeter shuts down regardless of spot-check or continuous mode. However, if the time from displaying valid readings to the end of measurement is less than 5 seconds, then no recording will be done.
- Up to 12 groups of records can be stored in the record list, the newest record is marked as M1, and the oldest record is marked as M12. The new record will override the previous record.
- When batteries are removed from the device all readings will be deleted.
- On power off status, long pressing the Display key shows the record list screen. On record list screen, a short pressing on the Display key can shift the records display, and if there is no key operation for 6 seconds, then the oximeter will power off automatically again.

S:	98	99	98	97
P:	68	77	82	75
	M1	M2	M3	M4

7 Technical Specifications

A. SpO_2 Measurement

Sensor: dual-wavelength LED sensor with wavelength: Red light: 663 mm, Infrared light: 890 mm.
Maximal average optical output power: ≤2mW
SpO_2 display range: 35% - 100%
SpO_2 measuring accuracy: ≤ 2% for SpO_2 range from 70% to 100%

B. Pulse Rate measurement

PR display range: 30 bpm – 250 bpm
PR measuring accuracy: ±2bpm or ±2% (whichever is greater)

C. Perfusion Index (PI) Display range

0% - 20%

D. Over-limit settings

SpO_2:

Low limit setting range: 85% - 99%, step: 1%
Default setting: 90%

Pulse Rate:

Low limit setting range: 30 - 60 bpm, step: 1bpm;
High limit setting range: 100 - 240 bpm, step: 5bpm;
Default setting: high: 120bpm; low: 50bpm

E. Audible & visual alert function

When measuring, if SpO_2 value or pulse rate value exceeds the preset limit, the device will alert with beep automatically and the value which exceeds limit will flash on the screen.

F. Power supply requirement

2 x LR03 (AAA) alkaline batteries
Supply voltage: 3.0VDC**,** Operating current: ≤40mA

G. Environmental Conditions

Operating Temperature: 5°C - 40°C

Operating Humidity: 30% - 80%
Atmospheric pressure: 70kPa - 106kPa

H. Low Perfusion Performance

The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%.

I. Ambient Light Interference

The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

J. Dimensions: 56 mm (L) × 34 mm (W) × 30 mm (H)

Net Weight: approx. 60g (including batteries)

K. Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied parts.

The degree of protection against harmful solid foreign objects and ingress of liquid:

The equipment is **IP22** with protection against harmful solid foreign objects and ingress of liquid.

Electro-Magnetic Compatibility: Group I, Class B

8 Maintenance and Cleaning & Disinfection

8.1 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 lightens.
- 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.
- Please take out the batteries if the Oximeter will not be used any more than 7 days.
- The recommended storage environment of the device: ambient temperature: -20 ºC - 60 ºC, relative humidity 10% - 95%, atmospheric pressure: 50 kPa - 107.4 kPa.
- The Oximeter is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle.

Caution:

- **High-pressure sterilization cannot be used on the device.**
- **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 it.**

8.2 Cleaning and Disinfecting Instruction

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

Caution:

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

9 Troubleshooting

Problem	Solution
The SpO_2 and Pulse Rate value are unstable	Place the finger correctly inside and try again. Keep calm.
Cannot turn on the device	Change or re-install the batteries.
No display	Change the battery.

10 Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
	Indicates a device that is not to be disposed of as unsorted municipal waste.
	Follow Instructions for Use.
	Type BF Applied Part
	No alarm system
	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
IP22	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.

11 FCC

FCC Warning:

FCC ID: A49POD-1W

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:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, 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 a 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, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Appendix EMC

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

Table 1

Guidance and manufacturer's declaration-electromagnetic emission		
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Fingertip 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 Fingertip Oximeter suitable for use in all establishments, including domestic establishments and those directly network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC61000-3-3	N/A	

Table 2

Guidance and manufacturer's declaration-electromagnetic emission			
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge(ESD) IEC61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC61000-4-4	±2kV for power Supply lines ±1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	±1kV line (s) to line(s) ±2kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycles <70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	N/A	N/A
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Fingertip Oximeter should assure that it is used in such an electromagnetic environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC61000-4-6	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 Fingertip Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). b 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.
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, and electromagnetic site survey should be considered. If the measured field strength in the location in which The Fingertip Oximeter is used exceeds the applicable RF compliance level above, The Fingertip 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 Fingertip 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 Fingertip Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The Fingertip Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fingertip 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
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. 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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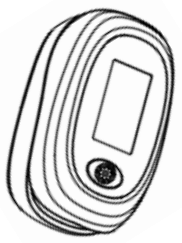
Fingertip Oximeter

User Manual

(Model: POD-2W)



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EC REP **Shanghai International Holding Corp. GmbH (Europe)**

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shholding@hotmail.com +49-40-25-2513175

Manufacture date: See the label on the product

Revision Date：June 9, 2021

Manual Version：V1.0 PN：3502-1290212

Download the APP software

App name: ViHealth

iOS: App Store

Android: Google Play

The ViHealth app is compatible with iOS versions 9.0+ and Android versions 5.0+.

Instructions for Safe Operation

- 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.
- Special attention should be paid while the oximeter is used constantly under the ambient temperature over 37 ℃, burning hurt may occur because of over-heating of the sensor at this situation.
- Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to service this device.
- 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.
- 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 instructions regarding cleaning and disinfection.
- Pay attention to the effects of lint, dust, light (including sunlight), etc.

Declaration of Conformity

The manufacturer hereby declares that this device complies with the following standards:

- IEC 60601-1: 2005+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;
- ISO 80601-2-61:2017 - Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse Oximeter equipment.
- Follow the provisions of the council directive MDD 93/42/EEC.

Caution: U.S. federal law restricts this device to sale or use by or on the order of a physician.

1 Overview

1.1 Intended Use

This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through a user's finger. It is intended for sports or aviation use only. It should not be used to diagnose or treat any medical condition.

1.2 Appearance

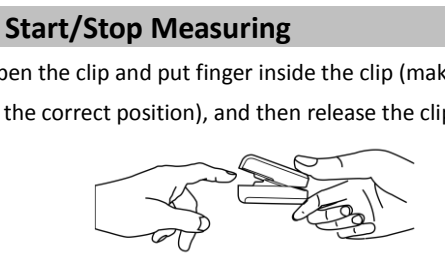


Figure 1

1.3 Features

- SpO_2, PR, PI, Plethysmogram, Pulse bar
- Auto On/Off
- Over-limit settings
- Pulse beep
- Wireless function
- Measuring mode: continuous
- Record list

2 Battery Installation

1. Refer to Figure 2, insert two AAA size batteries into the battery compartment properly, and note the polarity markings.

2. Replace the cover.

Figure 2 Battery Installation

Attentions:

- Make sure that the batteries are correctly installed. Incorrect installation may cause the device not to work.
- Remove batteries if the device is not being used for more than 7 days to prevent and avoid potential damage from the battery leaking. Any such damage is not covered under the product warranty.

3 Start/Stop Measuring

1. Open the clip and put finger inside the clip (make sure the finger is in the correct position), and then release the clip.

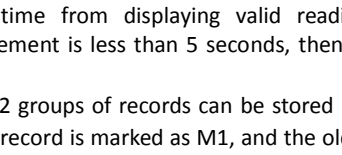


Figure 3 Finger Placement

Wait for 2 seconds, the oximeter will power on and start to measure.

If you connect device to App, you can also check readings in App.

2. Get the finger out, and the device will automatically power off.

3. Readings display screen

The screen displays as below：

Figure 4

4. Recording & Recall

Recording & Recall functions are available. At power off status, pressing display key can bring up record list display screen, as shown in figure 5. In record list screen, press display key to shift the records page.

Figure 5

- If the time from displaying valid readings to the end of measurement is less than 5 seconds, then no recording will be done.
- Up to 12 groups of records can be stored in the record list, the newest record is marked as M1, and the oldest record is marked as M12. The new record will override the previous record.
- If the batteries are removed from the device, then the records will be not kept or volatile.

4 Menu Setup

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

Figure 6 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 item.
4. Move the setting item to "Exit", and long pressing display key to store the modification and exit from the setup menu.

"Beep"：Pulse beep option. If it is set to on, every pulse beat makes a beep. when beep is on and over-limits indication sound is activated, then display key will work as the Mute key, and short time pressing it can mute the over-limits indication sound and pulse beep for 90 seconds.

Data transmission

The user could effectively transmit the data to App via Bluetooth.

Attention to the operation

- The finger should be put into the sensor correctly.
- 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.
- 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.
- Existence of high intensive light sources, such as fluorescence light, ruby lamb, 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.
- 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.

5 Wireless

The wireless icon Definition

Status of	Definition
Flashing in blue	The oximeter is connecting with the mobile devices.
Blue on	The connection between the oximeter and mobile devices is established.
No display of "" icon	1. "Wireless" function is disabled; 2. The device fails to setup a wireless connection with the surrounding host within 3 minutes; 3.Hardware failure of wireless transmission function while the "Wireless" function is enabled.

5.1 Connecting to the device

1. Keep the device on measuring.
2. Run ViHealth App on your smart device.
3. Click the device icon when ViHealth finds your Pulse Oximeter.
4. Follow the screen guide to start pairing.
5. Once paired, you can log on to ViHealth.

Caution: Do NOT pair the device in your smart device settings.

For more details about ViHealth App, please refer to the ViHealth App user manual.

5.2 Real-time Monitoring

The ViHealth app supports monitoring SpO2 and HR in real-time on the Dashboard screen .

5.3 Syncing Data to Apple Health

To enable/disable syncing measurement data to Apple Health App, tap [Setting]-> [Apple Health]->[On/Off].

The measurement data will be transferred to Apple Health App when ViHealth App is running.

Note: Refer the ViHealth user manual for more details.

6 Technical Specifications

A. SpO_2 Measurement

Sensor: dual-wavelength LED sensor with wavelength:

Red light: 663 nm, Infrared light: 890 nm.

Maximal average optical output power: ≤2mW

SpO_2 display range: 35% - 100%

SpO_2 measuring accuracy: ≤ 2% for SpO_2 range from 70% to 100%

B. Pulse Rate measurement

PR display range: 30 bpm – 240 bpm

PR measuring accuracy: ±2bpm or ±2% (whichever is greater)

C. Perfusion Index (PI) display range

0% - 20%

D. Over-limit settings

SpO_2:

Low limit setting range: 85% - 99%, step: 1%

Default setting: 90%

Pulse Rate:

Low limit setting range: 30 - 60 bpm, step: 1bpm;

High limit setting range: 100 - 240 bpm, step: 5bpm;

Default setting: high: 120bpm; low: 50bpm

E. Audible & visual alert function

When measuring, if SpO_2 value or pulse rate value exceeds the preset limit, the device will alert with beep automatically and the value which exceeds limit will flash on the screen.

F. Power supply requirement

2 x LR03 (AAA) alkaline batteries

Supply voltage: 3.0VDC**,** Operating current: ≤40mA

G. Environmental Conditions

Operating Temperature: 5 ℃ - 40 ℃

Operating Humidity: 30% - 80%

Atmospheric pressure: 70kPa - 106kPa

H. Low Perfusion Performance

The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%.

I. Ambient Light Interference

The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

J. Dimensions: 56 mm (L) ×34 mm (W) ×30 mm (H)

Net Weight: approx. 60g (including batteries)

K. Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied parts.

The degree of protection against harmful solid foreign objects and ingress of liquid:

The equipment is **IP22** with protection against harmful solid foreign objects and ingress of liquid. So that means the equipment is protected against solid foreign objects of 12.5mm and greater, and protected against vertically falling water drops when enclosure tilted up to 15° .

Electro-Magnetic Compatibility: Group I, Class B

7 Maintenance and Cleaning&Disinfection

7.1 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 lightens.
- 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.
- Please take out the batteries if the Oximeter will not be used any more than 7 days.
- The recommended storage environment of the device: ambient temperature: -20 ℃ - 60 ℃, relative humidity 10% - 95%, atmospheric pressure: 50 kPa - 107.4 kPa.
- The Oximeter is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. Any SpO_2 simulators should not be used to validate the accuracy of the Oximeter, they can only be used as functional testers to verify its precision. The SpO_2 accuracy claimed in this manual is supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark skinned subjects in an independent research laboratory.

Caution:

- **High-pressure sterilization cannot be used on the device.**
- **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 it.**

7.2 Cleaning and Disinfecting Instruction

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

Caution:

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

8 Troubleshooting

Problem	Solution
The SpO_2 and Pulse Rate value instable	Place the finger correctly inside and try again. Keep calm.
Cannot turn on the device	Change or re-install the batteries.
No display	Change the battery.
No display of the wireless icon ""	Hardware failure of wireless transmission function.

If the above problem still exists, please contact the local service center.

9 Symbols

Symbol	Description	Symbol	Description
%SpO_2	Pulse oxygen saturation		Date of manufacture
♥BPM/ **PR**	Pulse rate (beats per minute)	EC REP	Authorised representative in the European community
PI%	Perfusion Index (%)		Manufacturer (including address)
	Pulse Strength Bar Graph		BF type applied part
/	Low battery voltage		Attention — refer to User Manual
CE	CE mark		Follow WEEE regulations for disposal
SN	Serial number		Wireless icon
	No alarm system		

10 Frequently Asked Questions

1. Q: What's SpO_2?

A: SpO_2 means the saturation percentage of oxygen in the blood.

2. Q: What's the normal range of SpO_2 value for healthy people?

A: The normal range varies by individual, but usually over 95%, otherwise, please consult your physician.

3. Q: What's the normal range of PR value for healthy people?

A: Usually, the normal range is 60bpm~100bpm.

4. Q: Why do the display value of SpO_2 and PR vary with time?

A: The measured SpO_2 and PR value changes in correspondence with the change of user's physiological conditions.

5. Q: What to do if there is no SpO_2 and PR reading?

A: Do not shake the finger, and keep calm during the measurement. Please also avoid the Oximeter and the cuff on the same limb for blood pressure and oxygen saturation measurement simultaneously.

6. Q: How to confirm that the SpO_2 reading is true or accurate?

A: Hold breath for a while (50 seconds or more), if the SpO_2 value significantly decreases, it means that the SpO_2 reading truly reflects the physiological condition change.

7. Q: When to replace the batteries?

A: The icon of low battery will appear on the screen when the battery voltages are low. By then, batteries need to be replaced.

8. Q: What to do if the Oximeter is moistened or sprayed by water?

A: Remove the batteries immediately and dry the Oximeter completely with a hair dryer.

9. Q: What factors will affect the SpO_2 accuracy?

A: a) Intravascular dyes such as indocyanine green or methylene blue;

b) Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight;

c) Vascular dyes or external used color-up product such as nail enamel or color skin care;

d) Excessive user movement;

e) Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;

f) Exposure to the chamber with High pressure oxygen;

g) There is an arterial occlusion proximal to the sensor;

h) Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing;

i) Low perfusion condition (Perfusion Index is small).

Please contact the local distributor or manufacturer if necessary.

Appendix EMC

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

Table 1

Guidance and manufacturer's declaration-electromagnetic emission		
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Oximeter should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The Fingertip 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 Fingertip Oximeter suitable for use in all establishments, including domestic establishments and those directly network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC61000-3-3	N/A	

Table 2

Guidance and manufacturer's declaration-electromagnetic emission			
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge(ESD) **IEC61000-4-2**	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst **IEC61000-4-4**	±2kV for power Supply lines ±1 kV for input/output lines	N/A	N/A
Surge **IEC 61000-4-5**	±1kV line (s) to line(s) ±2kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines **IEC61000-4-11**	<5% U_T (>95% dip in U_T) for 0.5 cycle <40% U_T (60% dip in U_T) for 5 cycles <70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	N/A	N/A
Power frequency (50Hz/60Hz) magnetic field **IEC61000-4-8**	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Fingertip Oximeter should assure that it is used in such an electromagnetic environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC61000-4-6	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 Fingertip Oximeter, including cables, than the recom led separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] 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.
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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, and electromagnetic site survey should be considered. If the measured field strength in the location in which The Fingertip Oximeter is used exceeds the applicable RF compliance level above, The Fingertip 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 Fingertip 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 Fingertip Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The Fingertip Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fingertip 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
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. 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.			

Vibeat

Fingertip Oximeter User Manual

(Model: S5W)

Shenzhen Creative Industry Co., Ltd.
Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, P. R. China

Manufacture date: See the label on the product
Revision Date: April 24, 2022
Manual Version: V1.0 PN: 255-05155-00

Notes

- **It's not a medical device. This device is for Sports and Aviation use only and not intended for medical use.**
- Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the Oximeter.
- The contents contained in this manual are subject to change without notice.
- Information furnished by our company is believed to be accurate and reliable. However, no responsibility is assumed by us for its use, or any infringements of users or other rights of third parties that may result from its use.

Instructions for Safe Operation

- 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.
- 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.
- Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to service this device.
- The oximeter must not be used with devices and accessories not specified in User Manual.

Warnings and Cautions

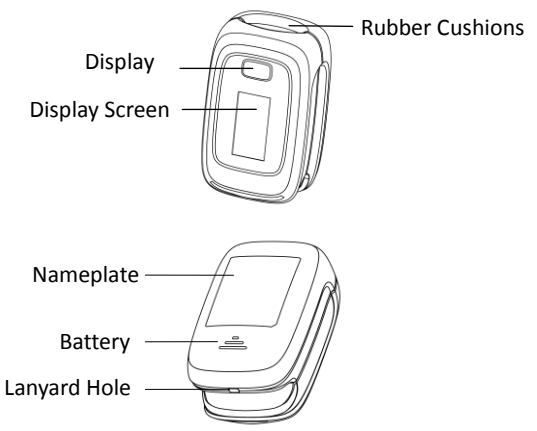
- Explosive hazard—**DO NOT** use the Oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO **NOT** use the Oximeter while the user is under MRI or CT scanning. This device is NOT MRI Compatible.
- Discomfort or pain may appear if using the Oximeter continuously 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.
- 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.

1 Overview

1.1 Intended Use

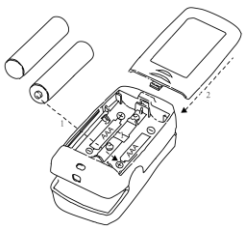
This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through a user's finger.

1.2 Views



2 Battery Installation

1. Refer to Figure 2, insert two AAA size batteries into the battery compartment properly, and note the polarity markings.
2. Replace the cover.

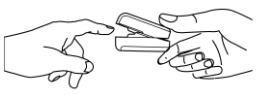


Attentions:

- Make sure that the batteries are correctly installed. Incorrect installation may cause the device not to work.
- Remove batteries if the device is not being used for more than 7 days to prevent and avoid potential damage from the battery leaking. Any such damage is not covered under the product warranty.

3 Start/Stop Measuring

1. Open the clip and put finger inside the clip (make sure the finger is in the correct position), and then release the clip.
2. Wait for 2 seconds, the oximeter will power on and start to measure.



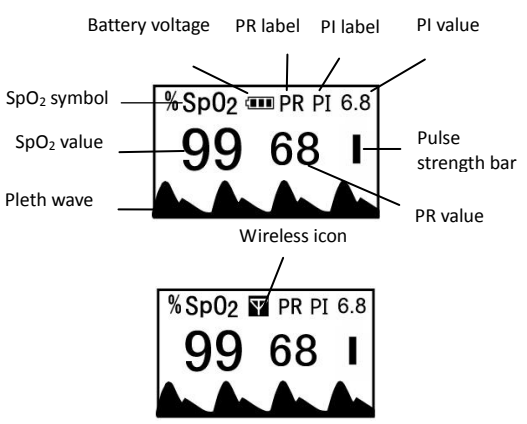
3. The display screen shows the measurement.
4. Get the finger out, and the device will automatically power off.

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 lamb, 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.
- If the measurements over the limits, there is a reminder sound. You can press the Display key to mute it, or wait for 10 seconds till the sound disappears by itself.

4 Screen

4.1 Indications and Icons



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

Status of	Definition
Flashing in blue	The oximeter is connecting with the mobile devices.
Blue on	The connection between the oximeter and mobile devices is established.
No display of "" icon	1. The oximeter fails to set up wireless connection with mobile device within 3 minutes. 2. Hardware failure of wireless function.

- Icon /: low battery voltage.
- Flashing value: indicates the value is over the defined limits. There also accompanies the reminding sound.

5 Menu Setup

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

SpO_2 alm Lo	90
PR alm Hi	120
PR alm Lo	50
Setting menu >>	

Beep	On
Exit	
<< 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 item.
4. Move the setting item to "Exit", and long pressing Display Key to store the modification and exit from the setup menu.

"Beep": Pulse beep option. If it is set to on, every pulse beat makes a beep.

6 Record List

- A single group of stable readings will be recorded in the record list each time when the oximeter shuts down regardless of spot-check or continuous mode. However, if the time from displaying valid readings to the end of measurement is less than 5 seconds, then no recording will be done.
- Up to 12 groups of records can be stored in the record list, the newest record is marked as M1, and the oldest record is marked as M12. The new record will override the previous record.
- When batteries are removed from the device all readings will be deleted.
- On power off status, long pressing the Display key shows the record list screen. On record list screen, a short pressing on the Display key can shift the records display, and if there is no key operation for 6 seconds, then the oximeter will power off automatically again.

S:	98	99	98	97
P:	68	77	82	75
	M1	M2	M3	M4

7 Technical Specifications

A. SpO_2 Measurement

Sensor: dual-wavelength LED sensor with wavelength: Red light: 663 mm, Infrared light: 890 mm.
Maximal average optical output power: ≤2mW
SpO_2 display range: 35% - 100%
SpO_2 measuring accuracy: ≤ 2% for SpO_2 range from 70% to 100%

B. Pulse Rate measurement

PR display range: 30 bpm – 250 bpm
PR measuring accuracy: ±2bpm or ±2% (whichever is greater)

C. Perfusion Index (PI) Display range

0% - 20%

D. Over-limit settings

SpO_2:

Low limit setting range: 85% - 99%, step: 1%
Default setting: 90%

Pulse Rate:

Low limit setting range: 30 - 60 bpm, step: 1bpm;
High limit setting range: 100 - 240 bpm, step: 5bpm;
Default setting: high: 120bpm; low: 50bpm

E. Audible & visual alert function

When measuring, if SpO_2 value or pulse rate value exceeds the preset limit, the device will alert with beep automatically and the value which exceeds limit will flash on the screen.

F. Power supply requirement

2 x LR03 (AAA) alkaline batteries
Supply voltage: 3.0VDC**,** Operating current: ≤40mA

G. Environmental Conditions

Operating Temperature: 5°C - 40°C

Operating Humidity: 30% - 80%
Atmospheric pressure: 70kPa - 106kPa

H. Low Perfusion Performance

The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%.

I. Ambient Light Interference

The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

J. Dimensions: 56 mm (L) × 34 mm (W) × 30 mm (H)

Net Weight: approx. 60g (including batteries)

K. Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied parts.

The degree of protection against harmful solid foreign objects and ingress of liquid:

The equipment is **IP22** with protection against harmful solid foreign objects and ingress of liquid.

Electro-Magnetic Compatibility: Group I, Class B

8 Maintenance and Cleaning & Disinfection

8.1 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 lightens.
- 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.
- Please take out the batteries if the Oximeter will not be used any more than 7 days.
- The recommended storage environment of the device: ambient temperature: -20 ºC - 60 ºC, relative humidity 10% - 95%, atmospheric pressure: 50 kPa - 107.4 kPa.
- The Oximeter is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle.

Caution:

- **High-pressure sterilization cannot be used on the device.**
- **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 it.**

8.2 Cleaning and Disinfecting Instruction

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

Caution:

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

9 Troubleshooting

Problem	Solution
The SpO_2 and Pulse Rate value are unstable	Place the finger correctly inside and try again. Keep calm.
Cannot turn on the device	Change or re-install the batteries.
No display	Change the battery.

10 Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
	Indicates a device that is not to be disposed of as unsorted municipal waste.
	Follow Instructions for Use.
	Type BF Applied Part
	No alarm system
	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
IP22	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.

11 FCC

FCC Warning:

FCC ID: A49POD-1W

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:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, 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 a 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, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Appendix EMC

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

Table 1

Guidance and manufacturer's declaration-electromagnetic emission		
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Fingertip 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.
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Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC61000-3-3	N/A	

Table 2

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Electrostatic discharge(ESD) IEC61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC61000-4-4	±2kV for power Supply lines ±1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	±1kV line (s) to line(s) ±2kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycles <70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	N/A	N/A
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Fingertip Oximeter should assure that it is used in such an electromagnetic environment.			
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Conducted RF IEC61000-4-6	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 Fingertip Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). b 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.
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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, and electromagnetic site survey should be considered. If the measured field strength in the location in which The Fingertip Oximeter is used exceeds the applicable RF compliance level above, The Fingertip 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 Fingertip 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 Fingertip Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The Fingertip Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fingertip 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
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. 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.