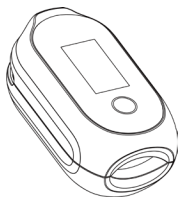
English

Pulse Oximeter User Manual



(Model: PF-10BW, PF-10AW)

Download the APP software

You can view the measurements and record list in the ViHealth App. Scan the below QR code to download the APP software for iOS and Android system.

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 patient 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 patient 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.
- Keep this device away from pets, pests or 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.
- The biocompatibility testing has been performed on the materials in contact with the person in accordance with ISO10993.
- Be placed on the limited training of a lay operator with respect to the ability to intervene and maintain basic safety and essential performance.
- The PATIENT is an intended OPERATOR.
- **Do Not** dispose of the appliance with the normal household waste at the end of its life, but hand it in at an official collection point for recycling. By doing this you will help to protect the environment.
- Warning about suffocation caused by charging cables.

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.

1 Overview

1.1 Intended Use

This Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through a patient's finger. It is applicable for measuring(spot-checking) SpO2 and pulse rate of adult patients in homes and medical clinics.

1.2 Contraindications

No contraindications.

1.3 Views

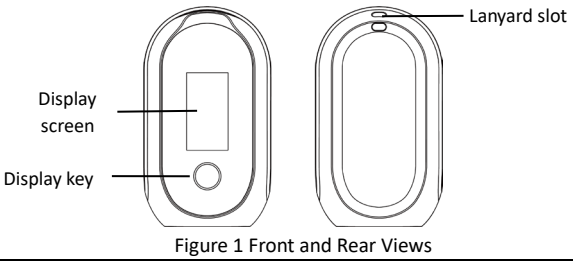


Figure 1 Front and Rear Views

1.4 Features

- Display SpO_2, PR, PI, and Plethysmogram
- Auto power On/Off
- Change between PR and PI
- Over-limit indication and sound
- Mute sound
- Four direction display
- Setting menu (including over-limit setting)
- Pulse beep
- Wireless function
- Continuous measuring mode

2 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.

3 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 seconds.
- On the menu interface, if there is no key operation for about 30 seconds, the device will automatically exit the menu and then shut down.
- On the recording and playback screen, if there is no key operation for 6 seconds, the device will automatically shut down.

4 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.

Finger Placement

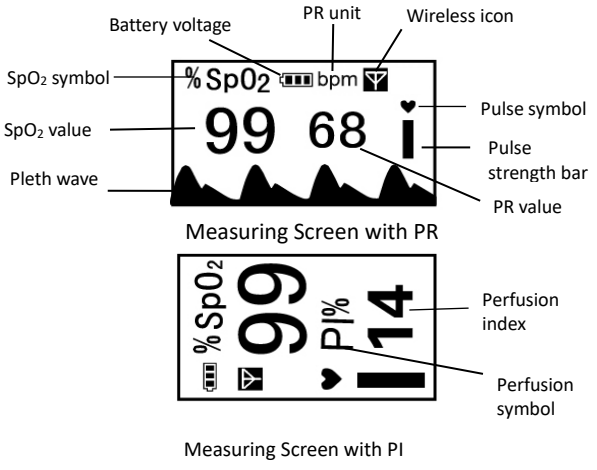
2. Wait for 2 seconds, the Oximeter will power on and start to measure.
3. The display screen shows the measurement.
4. Get the finger out, and the device will automatically power off.

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.

5 Screen

5.1 Indications and Icons

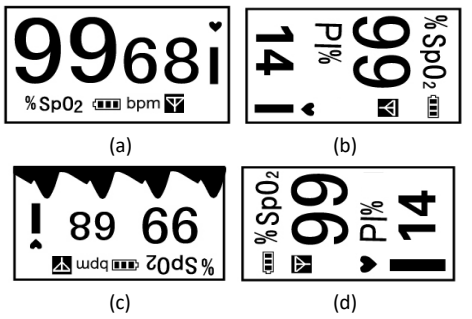


- Icon : indicates the wireless connection is set up between the mobile device and Oximeter.

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

5.2 Four Directions of the Screen

The Oximeter supports to show the screen in four directions. **A short pressing of the Display Key can change display direction by 90°, and change PR/PI at the same time.** The four display directions are as shown below.



- For display screens of figure (b) and (d), the PI% display value will be replaced with PR display value after 20 seconds if no key operation.
- The display direction is remembered at each startup, it will display the screen layout (display direction) from the last time it was used.

6 Menu Setup

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

SpO_2 Lo 89	Reminder On	Save exit menu
PR Hi 100	Beep On	Restore default
PR Lo 30	Display Always	
Setting menu >>	Setting menu >>	<<Setting menu

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 exit from the setup menu.

Menu settings:

- **Over-limit settings:** If the SpO_2 or PR value is over the defined limits, the value will flash.
- **"Reminder":** The device supports reminders triggered by user-defined oxygen level or PR threshold. It is on by default.
- **"Beep"**:Pulse beep option. If it is set to on, every pulse beat makes a beep.
- **"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 key.
- **"Restore default":** Shortly press Display Key to choose "Restore default" and long press Display Key to reset all parameters to their default values.

7 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	14 hours for typical use (max)	
Charge time	About 3 hours	
SpO_2		
SpO2 range	Measuring range: 0% - 100%	
SpO_2 Accuracy (Arms)	±2% (70% - 100%); ±3% (50% - 69%); No definition (0% - 49%)	
Pulse Rate range	30bpm - 250 bpm	
Pulse Rate accuracy	±2 bpm or ±2%, whichever is greater	
SpO_2 Low limit setting range	85% - 99% Default setting: 90%	
Pulse Rate low limit setting range	30bpm - 60 bpm Default setting: 50bpm	

Pulse Rate high limit setting range	100bpm - 240 bpm Default setting: 120bpm
Sensor	Dual-wavelength LED sensor with wavelength
Wavelength	Red light: 663 nm; Infrared light: 890 nm
Maximal average optical output power	≤2mW
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%.
SpO_2 data averaging time	8s
SpO_2 data update period	1s
Data update	<10s
Recorded parameters	SpO_2, Pulse Rate
Frequency range	2.402-2.480GHz
Max RF power	-10dBm
Expected service life	3 years

9 Maintenance and Cleaning

9.1 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.
- If the Oximeter has not been used for more than 7 days, please charge the Oximeter before use.
- 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.**
- **Do not service and maintain while the device is in use.**

9.2 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.**

10 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	Charge the device.
No display	Charge the device.
"- -"is displayed on the screen.	Place the finger correctly inside and try again. Keep calm.

11 Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
	Refer to instruction manual
	Type BF Applied Part
	No alarm system
MR	MR unsafe
IP22	Indicates that the product is protected against solid foreign objects of 12,5 mm Ø and greater; and protected against vertically falling water drops when enclosure tilted up to 15°.
CE 0197	Indicated that the product complies with the EU Medical Device Regulations (Regulation (EU) 2017/745)Article 120,Annex II of 93/42/EEC and Regulation (EU)2023/607.
MD	Medical device
EC REP	Authorized representative in the European community
UK CA	UKCA marking
UK REP	UK Responsible Person
	Non-ionizing radiation
	Indicates that the marked item or its material is part of a recovery or recycling process.
	Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

FCC Statement

FCC Warning:
FCC ID: 2ADXK-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:
(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 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
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 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 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse 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 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Pulse 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 Pulse 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 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
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.			

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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Vous êtes responsable de remettre tous les appareils électriques et électroniques usagés à des points de collecte correspondants.
Pour en savoir plus:
www. quefairedemesdechets.fr

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