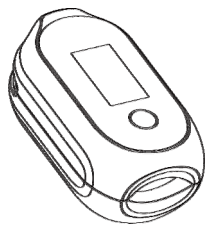# Fingertip Oximeter
User Manual

(Model: PF-10AW、PF-10AW1、PF-10BW、PF-10BW1)

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.

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.

☝ 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.

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.
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.
Note: The Grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. such modifications could void the user's authority to operate the equipment.
The device has been evaluated to meet general RF exposure requirement.
This equipment complies with FCC's RF radiation exposure limits set forth for an uncontrolled environment. This device and its antenna(s) must not be co-located or conjunction with any other antenna or transmitter.

1 Overview

1.1 Intended Use

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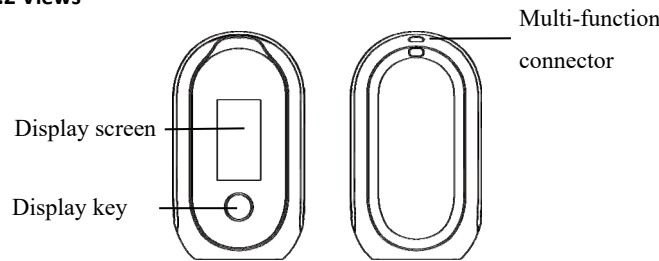
1.2 Views

Figure 1 Front and Rear Views

1.3 Features

- Display SpO₂, 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 (PF-10AW, PF-10AW1, PF-10BW and PF-10BW1 only)
- Continuous or spot check measuring mode
- Record list

2 Charging

Charge the battery before using.
Connect the device to computer USB or USB charging adapter with USB cable.

🔋 : 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 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.
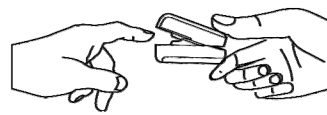
Finger Placement

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.

5 Screen

5.1 Indications and Icons
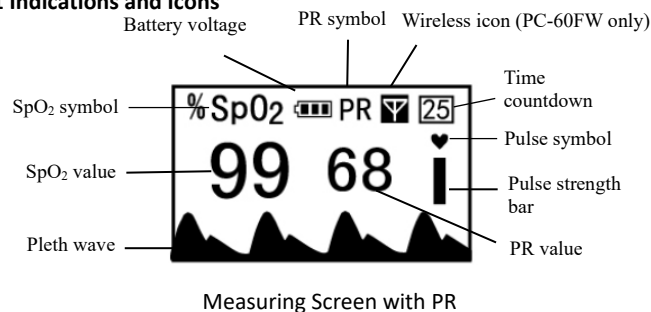
Measuring Screen with PR
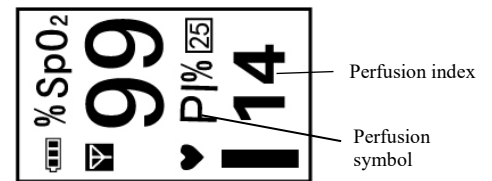
Measuring Screen with PI

- Icon ▼ : indicates the wireless connection is set up between the mobile device and oximeter (PF-10AW, PF-10AW1, PF-10BW and PF-10BW1 only).

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	The oximeter fails to set up wireless connection with mobile device within 3 minutes.
	Hardware failure of wireless function.

- Icon 25 : indicates the counting-down time if the oximeter works at Spot check mode. The total measuring time for Spot check mode is 30 seconds.
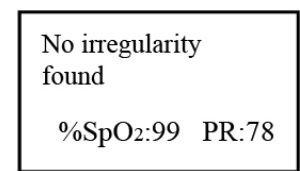
5.2 Four Directions of the Screen

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.

(a)　　　　(b)

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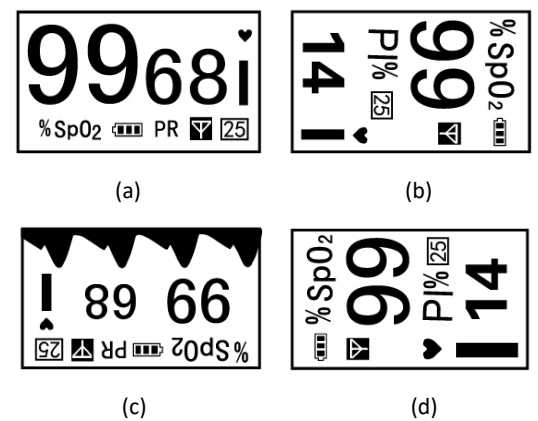
- For display screens of figure (b) and (d), the PI% display value will be replaced with PR display value after 20 seconds if no key operation.
- The display direction is remembered at each startup, it will display the screen layout (display direction) from the last time it was used.

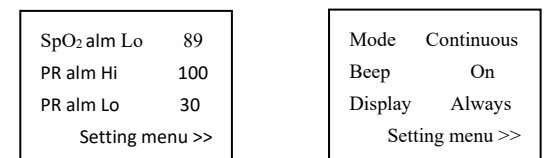### 5.3 Measurement End Screen (Spot Check Mode)

When the measurement ends up for Spot check mode, the measured SpO₂, PR value and the analysis result of pulse rhythm will be displayed on the screen, as shown below.

No irregularity found
%SpO₂:99   PR:78

Results

6 Menu Setup

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

SpO₂ alm Lo	89
PR alm Hi	100
PR alm Lo	30
Setting menu >>	

Mode	Continuous
Beep	On
Display	Always
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 SpO₂ or PR value is over the defined limits, the value will flash.

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

➢ "Mode": Set the measuring mode. "Continuous" and "Spot check" for optional, the default is "Spot check".

- Spot check mode: the measuring time lasts 30 seconds with a counting-down indication. The SpO₂ and PR readings will freeze at the end of 30 seconds, the analysis

result for the pulse rhythm will be displayed on the screen as well.

- **Continuous mode**: measurement will start automatically when finger is inserted into the oximeter, SpO₂ and PR readings will be displayed until the finger is removed from the oximeter.

➢ **"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.

7   Record List

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   75   82
     M1  M2  M3  M4
```

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.

8   Technical Specifications

Classification	
The type of protection	Internally powered equipment
The degree of protection	Type BF applied parts
Electro-magnetic	Group I, Class B

Environment		
	Operating	Storage
Temperature	5 - 40°C	-20 - 55°C
Relative humidity	30% - 80%	10% - 93%
Atmospheric pressure	700 - 1060hPa	700 - 1060hPa
Degree of dust & water	IP22	

Physical	
Dimension	64mm*38mm*28mm
Weight	37 g
Display	OLED
Wireless	Bluetooth 4.0 BLE
Vibration source	low oxygen level; high/low pulse rate

Power and supply	
Input	DC 5V ±10%
Battery	Rechargeable Lithium-polymer
Battery life	24 hours for typical use
Charge time	About 3.5 hours

SpO₂	
Oxygen level range	Measuring range: 35% - 100%
SpO₂ Accuracy (Arms)	±2% (70% - 100%); ±3% (50% - 69%);
Pulse Rate range	30bpm - 250 bpm
Pulse Rate accuracy	±2 bpm or ±2%, whichever is greater
SpO2 Low limit setting	85% - 99%
Pulse Rate low limit	30bpm - 60 bpm
Pulse Rate high limit	100bpm - 240 bpm
Perfusion Index (PI)	0% - 20%
Low perfusion	The accuracy of SpO₂ and PR measurement still
Sensor	Dual-wavelength LED sensor with wavelength
Wavelength	Red light: 663 mm; Infrared light: 890 mm
Maximal average optical	≤2mW
Ambient light	The difference between the SpO₂ value
Data update	<10s
Recorded parameters	Oxygen level, Pulse Rate

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.
- Please take out the batteries if the Oximeter will not be used any more than 7 days.
- The Oximeter is calibrated in the factory before sale, so there is no need to calibrate it during its life cycle. Any SpO₂ 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 SpO₂ 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.**

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 SpO₂ 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.

11   Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
	Indicates a medical device that is not to be disposed of as unsorted municipal waste.
	Follow Instructions for Use.
	Type BF Applied Part
MR	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
IP22	Resistant to liquid ingress
	No alarm system
CE	CE marking
EC REP	Authorized representative in the European community
UKCA	UKCA marking
UK REP	Authorized Representative in the United Kingdom
FC	This product complies with the rules and regulations of the Federal Communication Commission.
	Non-ionizing radiation
	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).

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	3A/m	3A/m	Power frequency magnetic fields should be at levels

IEC61000-4-8			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 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 the 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.

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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