Fingertip Pulse Oximeter

User Manual

(Model: PC-60F, PC-60FW)

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

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Manufacture date: See the label on the product

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Manual Version：V1.0 PN：3502-2290123

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.

Declaration of Conformity

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

- IEC 60601-1: 2005 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;
- BS/EN/ISO 9919:2009 or the equivalent ISO 80601-2-61:2011 - 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.

FCC Rules (only for PC-60FW)

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 Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through a patient's finger. It is applicable for spot-checking SpO_2 and pulse rate of adult and pediatric patients in homes and medical clinics.

1.2 Views

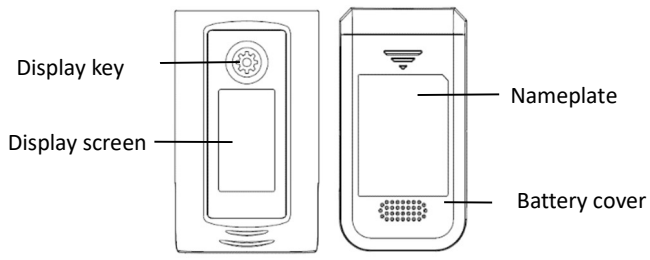


Figure 1 Front and Rear Views

1.3 Features

- Display 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 (PC-60FW only)
- Continuous or spot check measuring mode
- 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.

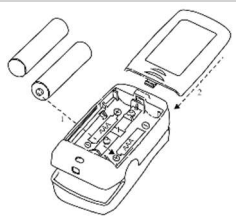


Figure 2 Battery Installation

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.
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.

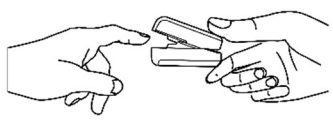


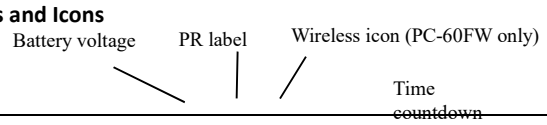
Figure 3 Finger Placement

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.

4 Screen

4.1 Indications and Icons



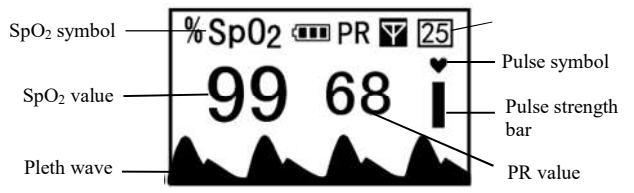


Figure 4 (a) Measuring Screen with PR

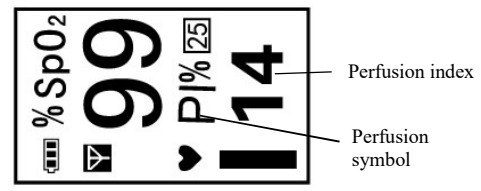


Figure 4 (b) Measuring Screen with PI

- Icon : inidicates the wireless connection is set up between the mobile device and oximeter. Only PC-60FW has this function.

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

4.2 Four Directions of the Screen

Figure 5 (a)

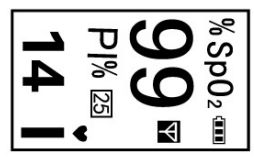


Figure 5 (b)

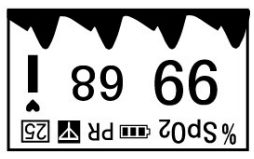


Figure 5 (c)

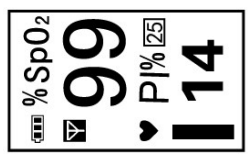


Figure 5 (d)

The oximeter supports to show the screen in four directions. The four display directions are as shown in figure 5 (a), 5 (b), 5 (c), & 5 (d).

The display direction is remembered at each startup, it will display the screen layout (display direction) from the last time it was used.

Change screen direction and **PR/PI**:

A short pressing of the Display Key can change display direction by 90° , and change PR/PI at the same time. For display screens of figure 5 (b) and 5 (d), the PI% display value will be replaced with PR display value after 20 seconds if no key operation.

4.3 Measurement End Screen (Spot Check Mode)

When the measurement ends up for Spot check mode, the measured SpO_2, PR value and the analysis result of pulse rhythm will be displayed on the screen, as shown in figure 6.

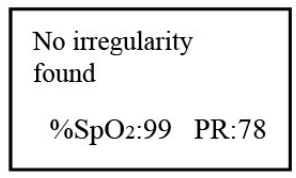


Figure 6 Results

5 Menu Setup

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

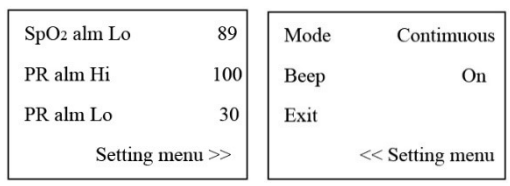


Figure 7 Menu

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.

"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 SpO_2 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, SpO_2 and PR readings will be displayed until the finger is removed from the oximeter.

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

Figure 8 Record List

7 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°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. 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.**

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 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.

10 Symbols

Symbol	Description	Symbol	Description
CE 0123	CE mark	EC REP	Authorised representative in the European community
SN	Serial number		Manufacturer (including address)
	Date of manufacture		BF type applied part
	Attention – refer to User Manual		Follow WEEE regulations for disposal

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 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.			

Quality Certificate

Name: Fingertip Oximeter

Model: _____

Date: _____

QA: _____

This prosuct has been inspected in accordance with the standards specified in the User Manual.

Shenzhen Creative Industry Co., Ltd