CREATIVE MEDICAL

Fingertip Oximeter

User Manual

Instructions to User

Dear Customers,

Thank you for purchasing this quality product. 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 manual is published in English and we have the ultimate right to explain the Manual. No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent. We reserve the right to improve and amend it at any time without prior notice.

For user's convenience, we share the latest version analysis software of the Oximeter on our website, the user can enter into our website (www.creative-sz.com) to download the corresponding latest version data manager software. Please contact the manufacturer or your local distributor if anything about software downloading.

Version of the Manual: Ver 1.1

Revised date: August 28th, 2019

Notes

- 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 patients or other rights of third parties that may result from its use.

Instructions for Safe Operation

- ☞ Check the device to 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.

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.

Warnings

🔊 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.

🖐 DO NOT clip this device on edema or tender tissue.

🖐 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.

Attentions

⚠ 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 7 for instructions regarding cleaning and disinfection.

⚠ 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°.

⚠ Please 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.

And it also follows 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.

FCC Rules are specifically for PC-60NW

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.

Table of Contents

1 Overview

1.1 Appearance

Display Key — ○

Rubber Cushions

Display Screen —

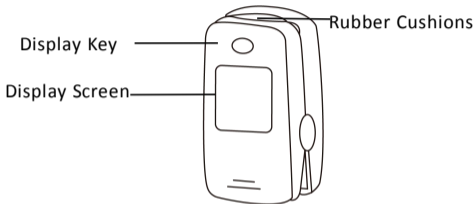**Figure 1 Front View**

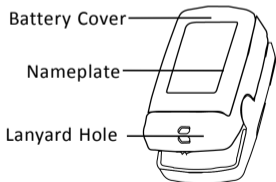Battery Cover —

Nameplate —

Lanyard Hole —

Figure 2 Rear View

Note: the appearance is for demonstration only, please refer to the oximeter you purchased.

1.2 Name and Model

Name: Fingertip Oximeter
Model:
POD-1a/POD-2a/POD-3a/POD-1/POD-2/POD-3**/**
PC-60A/POD-1W/PC-60B/PC-60B1/PC-60B2/PC-60B3/
PC-60B5/PC-60NW-1/PC-60C/PC-60C1/PC-60C2/
PC-60D/PC-60D2/PC-60E/PC-60N/PC-60NW/
PC-60F/PC-60FW/PC-60FL

1.3 Intended Use

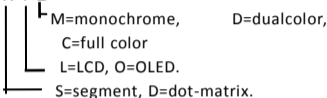This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO$_2$) through a patient's finger. It is applicable for spot-checking SpO$_2$ and pulse rate of adult and pediatric patients in homes and medical clinics. Models with external sensor options and over-limit Indication may be used for longer periods of time dependent on the suitability of the sensor selected.

1.4 Feature List

Explanation of abbreviations:

"√" this function is available, " × " without this function.

Display type: X-Y-Z

       └─ M=monochrome, D=dualcolor,
        C=full color
      └── L=LCD, O=OLED.
    └──── S=segment, D=dot-matrix.

Note: The finger clip of PC-60D & 60D2 are suitable for small fingers, especially for pediatric patients. The only difference between these two Oximeters is battery type. PC-60D installs rechargeable button cell battery which could use many times after being charged by the charger.

Configuration of PC-XXXX Fingertip Oximeters

Model Function	POD-1a	POD-2a	POD-3a	POD-1	POD-2	POD-3
Display type	S-L-M	S-L-D	S-L-C	S-L-M	S-L-D	S-L-C
SpO₂	√	√	√	√	√	√
PR	√	√	√	√	√	√
PI (Perfusion index)	×	×	×	×	×	×
Plethysmogram	×	×	×	×	×	×
Pulse bar	√	√	√	√	√	√
Auto on	√	√	√	√	√	√
Auto off	√	√	√	√	√	√
Low voltage indication	√	√	√	√	√	√
Two directions display	√	√	√	√	√	√
Wireless function	×	×	×	Optional	×	×

Model Function	60A	60B	60B1	60B2	60B3	60B5
Display type	S-L-M	S-L-M	D-O-D	D-O-M	D-O-D	D-L-D
SpO$_2$	√	√	√	√	√	√
PR	√	√	√	√	√	√
PI(Perfusion index)	✕	√	√	√	√	√
Plethysmogram	✕	✕	√	√	√	√
Pulse bar	√	√	√	√	√	√
Auto on	✕	√	√	√	√	√
Auto off	√	√	√	√	√	√
Over-limit indication	✕	√	√	√	√	√
Low voltage indication	√	√	√	√	√	√
Two directions display	✕	✕	4	√	4	√
Waterproof & drop resistant	✕	✕	√	✕	✕	✕

Big numerical display	$\times$	$\times$	$\times$	$\times$	$\times$	√

Model Function	60C	60C1	60C2	60D	60D2	60E
Display type	D-O-C	D-O-C	D-O-C	D-O-C	D-O-C	D-O-C
SpO$_2$, PR, PI	√	√	√	√	√	√
Plethysmogram	√	√	√	√	√	√
Auto on & off	√	√	√	√	√	√
Pulse bar	$\times$	$\times$	√	√	√	√
Over-limit indication	√	√	√	√	√	√
Setting menu	$\times$	√	$\times$	$\times$	$\times$	$\times$
Pulse beep	$\times$	√	$\times$	$\times$	$\times$	√
Low voltage indication	√	√	√	√	√	√
Four directions display	√	√	√	√	√	√
Orientation-sensor	$\times$	√	$\times$	$\times$	$\times$	√
External probe connection	$\times$	$\times$	$\times$	$\times$	$\times$	√

Big numerical display	√	√	×	×	×	×

Note: the new PC-60D2 is applicable for measuring SpO$_2$ and PR of pediatric.

Model Function	POD-1 W	60N	60NW (Color)	60NW-1 (Dual)	New 60D2
Display type	S-L-M	D-O-C	D-O-C	D-O-D	D-O-D
SpO$_2$, PR, PI	SpO$_2$, PR,	√	√	√	√
Plethysmogram	×	√	√	√	√
Pulse bar	√	√	√	√	√
Auto on	√	√	√	√	√
Auto off	√	√	√	√	√
Setting menu	×	√	√	√	×
Pulse beep	×	√	√	×	×
Low voltage indication	√	√	√	√	√

Four directions	2	√	√	√	√
Orientation-sensor	×	×	√	×	×
External probe	×	√	√	×	×
Wireless function	√	×	√	√	×

Model Function	PC-60F	PC-60FW	PC-60FL
Display type	D-O-D	D-O-D	S-L-M
SpO$_2$, PR, PI	√	√	√
Plethysmogram	√	√	×
Auto on/off	√	√	√
PR and PI shifts	√	√	√
Pulse bar	√	√	√
Over-limits indication	√	√	√
Over-limits indication sound	√	√	×

Indication sound mute	Manual	Manual	×
Four directions display	√	√	2
Setting menu	√	√	×
Over-limits setting	√	√	×
Pulse beep	√	√	×
Wireless function	×	√	×
Measuring mode	Continuous, Spot check	Continuous, Spot check	×
Record list	√	√	×

Description:

➢ Indication sound mute

For the model with both over-limits indication function and pulse beep function, 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.

➢ *Measuring mode*

① *Spot check mode: the measurement starts automatically when the finger is inserted into the finger clip properly, 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. Once the finger is our, the display will be cleared and the Oximeter shuts down automatically.*

② *Continuous mode: the measurement starts automatically when the finger is inserted into the finger clip properly, the measuring never ends up along with SpO₂ and PR readings update until the finger is out, then causing the Oximeter shuts down automatically.*

➢ *Record list*

① 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.

② 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.

③ if the batteries are removed from the device, then the records will be not kept or volatile.

④ on power off status, long pressing the Display key brings up the record recall screen. On record recall screen, short time pressing 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.

2 Battery Installation
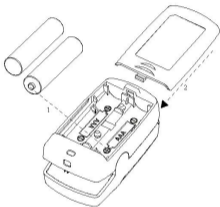
Figure 3 Battery Installation

1. Refer to Figure 3, insert two AAA size batteries into the battery compartment properly, and note the polarity markings.

2. Replace the cover.

• Please make sure that the batteries are correctly installed. Incorrect installation may

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cause the device not to work.

• Please 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 External SpO₂ Probe Connection

Connect the external SpO₂ probe to SpO₂ sensor connector as shown below. Ensure the "Arrow" faces upwards.
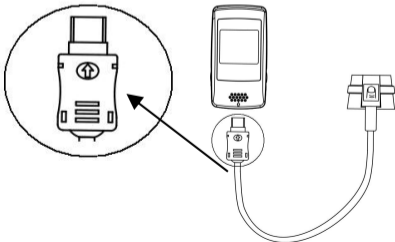
Figure 4 Probe Connection（For PC-60E, 60N, 60NW）

Note: When the external SpO_2 probe is connected, the built-in finger clip sensor will be disabled. The measurement is detected from the external SpO_2 probe. Default over-limit indication settings for SpO_2 and PR will change to: SpO_2 Low limit: 95%

Pulse Rate high limit: 160bpm

Low limit: 60bpm

4 Operation

1. Open the clip and put finger inside the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger, as shown in figure 5.
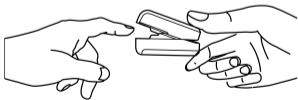
Figure 5 Put finger into the Oximeter

☀ ① For PC-60A, press the display key to start the measurement.

② For other modules (except for PC-60A), wait 2 seconds, the Oximeter will power on automatically and start to measure;

2. Next enter into data display screen:

① POD-1, POD-2 & POD-3 display screen are as shown in figure 6.

Figure 6

Note: the display direction of POD-1a, POD-2a &POD-3a is up and down.
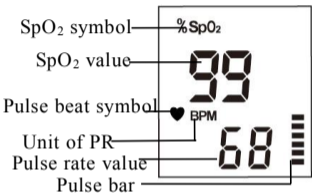
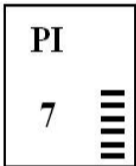② PC-60A & 60B display screen are as shown in figure 7A.

SpO₂ symbol —— %SpO₂

SpO₂ value ——

Pulse beat symbol —— ♥ BPM

Unit of PR ——

Pulse rate value ——

Pulse bar ——

Figure 7A

PI

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Figure 7B PI display screen(for PC-60B)

③ For PC-60B, short time press Display Key to turn on/off the backlight. Longtime press Display Key to display PI as shown in figure 7B, after 8 seconds, the screen will return to the screen as shown in figure 7A.

④ For other type Oximeter PC-60B1, PC-60B2, PC-60B3, PC-60B5, PC-60C, PC-60C1, PC-60C2,

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PC-60D and PC-60D2, short time press Display Key to change display direction, as shown in figure 8A& 8B (Note: 60C1 changes direction automatically, and 60C and 60C1 without pulse bar); Longtime press Display Key to shift the parameter display between PR and PI. Please refer to figure 8C.

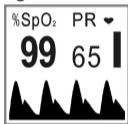⑤ For POD-1W, the display screen is as shown in figure 8G.

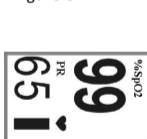
Figure 8A

Figure 8B

Figure 8C

Figure 8D

Figure 8E

Figure 8F

Figure 8G

Note:

➢ The PI% display will be shifted back to PR

display automatically after 20 seconds even if no button operation.

➢ For the model PC-60B3, there is no plethysmogram display while the display direction is shifted to the right or left direction, as shown in figure 8D; To the opposite, PC-60B1 has no plethysmogram on default measuring screen as shown in figure 8E, while the display direction is shifted to left side direction, there will be displayed plethysmogram please refer to figure 8F.

➢ For the model of PC-60B2 & 60B5, only has two change directions: up and down.

➢ For model of PC-60C, the measuring screen is shown in big font, then there is no pulse bar shown.

➢ The model PC-60B3 may have different options for manual switching display direction by button or automatic changing display direction by orientation sensor (similar to the model PC-60C1).

➢ For PC-60E, PC-60N and PC-60NW, when change display direction, PI value will automatically display on the device instead of PR value, PR value will restore after 20 seconds.

➤ For PC-60E, upward/downward shift the Oximeter quickly can turn on/off the pulse beep. The default pulse beep is OFF.

⑥ For New PC-60D2, the default measuring screen is as shown in figure 9A, short time press Display Key to change display direction, as shown in figure 9A, 9B, 9C, & 9D; Longtime press Display Key to shift the parameter display between PR and PI, as shown in figure 9E.
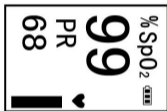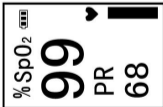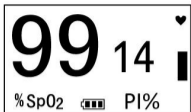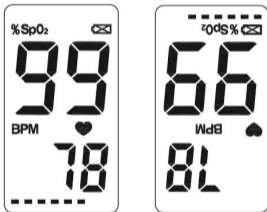

Figure 9A

Figure 9B

Figure 9C

Figure 9D

Figure 9E

⑦ *For PC-60FL, the display screen is as shown in below figure.*

⑧ ***Description for PC-60F and PC-60FW***

✧ *short time press Display Key can change display direction, the four display directions are as shown in figure 10A, 10B, 10C, & 10D. For*

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*display screens of figure 10B and 10D, the PI%
display value will be replaced with PR display
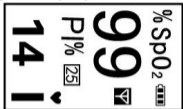value after 20 seconds if no key operation.*

*Figure 10A*   *Figure 10B*

Figure 10C   *Figure 10D*

✧ *For PC-60F and PC-60FW, the display dirextion is
remembered at each startup, that is, the screen
layout (display direction) of the last time will be
used as the initial screen layout when powering
on the Oximeter next time.*

✧ *The only difference between PC-60F and
PC-60FW is that PC-60F has no wireless function*

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and thus no wireless icon " *" on the screen.*

✧ *Icon "* 25 *" on display screen means the counting-down time if the Oximeter works at Spot check mode. The total measuring time for Spot check mode is 30 seconds.*

✧ *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 in figure 10E.*

No irregularity found %SpO₂:99 PR:78

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

Figure 10E   *Figure 11*

Other result descriptions see Appendix I.

✧ *Recording & recall functions are available for PC-60F and PC-60FW. At power off status, long time pressing Display key can bring up record list display screen, as shown in figure 11. In record list screen, short time press Display key to shift*

the records page.

⑨ **Menu** (PC-60C1, PC-60N, PC-60NW-1 Dual, PC-60NWColor, PC-60F and PC-60FW)

Long time pressing display key can enter the setup menu screen.

SpO₂ alm Lo 85
PR   alm Hi   120
PR   alm Lo   50
Pulse beep   on
Save, exit menu
Restore default

Wireless   on
SpO₂ alm Lo   85
PR   alm Hi   120
PR   alm Lo   50
Save, exit menu
Restore default

Wireless   on
SpO₂ alm Lo   85
PR   alm Hi   120
PR   alm Lo   50
Pulse beep   on
Save, exit menu
Restore default

PC-60 C1& 60N   PC-60NW-1 Dual   PC-60NW Color

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

Mode	Continuous
Beep	On
Exit	
<< Setting menu	

PC-60F and PC-60FW

"Wireless" : the wireless on-off button.

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Transmitting data to PC when it is on. "on" and "off" can be optional. The factory default is "on".

"Pulse beep" / "Beep"：Pulse beep option. If it is set to on, every pulse beat makes a beep. Only for model PC-60NW, the pitch tone of this beep changes according to SpO_2 value (within 90~99%).

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

Menu setup: Short time press Display Key to choose the setting item; Longtime press Display Key to active the setting item, then short time press it to modify the setting parameter; Next, longtime press Display Key to confirm the modification and exit from this setting item. At last, move the setting item to "Save, exit menu", and long time pressing Display Key to store the modification and exit from the setup menu.

Note: if wireless connection is setup, the icon " 📶 " will be displayed on the screen.

4.Wireless icon" 📶 "/" ▅ ":

The icon of "📶"	Definition
" 📶 " flashes blue	The device is being to establish a wireless connection with the surrounding host.
" 📶 " long lights blue	Successful wireless connection between the device and a host is established.
No display" 📶 " 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.
▬	Wireless icon of POD-1W (the number of lines indicates signal intensity)

Data transmission

The user could effectively transmit the data to

computer through the wireless function. Refer to the "Oximeter Data Manager" for detailed information.

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.

- The orientation-sensor works on the basis of the gravity. A small movable metal ball is built in the orientation-sensor for detecting the orientation of the Oximeter. When you

want to change the Oximeter's display direction, if you move the Oximeter too slowly, the movable metal ball will also move slowly because of not enough acceleration. Consequently the response of orientation detection would be delayed. Acceleration needs to be provided to the orientation-sensor for quick sensing the orientation change.

- 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.

Note: Due to the working principle of orientation sensor used in the Oximeters, such as the model PC-60B3, there is a small metal ball which is movable within its compartment of the orientation-sensor. Therefore you may hear a slight "clatter" sound when you wave or shake the Oximeter, this is normal!

5 Download the APP software

◆ **Downloading the APP software for Android**

smart phone

The terminal devices such as Android smart phone can be used to receive data from the Oximeter in real-time, and store the received data, review the stored data as well. You have to download the corresponding APP software on the smart phone. Please follow the procedure to download:

1. Scan below QR code.
2. Open the link from the QR code.
3. Download the software "PC-60NW.apk" and install.
4. Run the software to connect the Oximeter for real-time data transfer.

The below QR Code is appliable to the Fingertip Oximeter with wireless function.

Instruction for Measurement

☞ Make sure the APP software is successful to

connect with the Oximeter.

☞ Refer to the manual of this APP software for detail operation.

✧ Note: APP software for PC and Android smart phone is also available for download from below link:

http://www.creative-sz.com/software/

Figure 10A

(QR code for Oximeter with and wireless

Figure 10B

(QR code for Oximeter with and wireless V4.0)

NOTES:

① The two-dimensional barcode QR code shown in Figure 9A is for Oximeter with wirelessV2.0 and

Figure 9B is for Oximeter with wireless V4.0. That's to say, if your Oximeter is PC-60NW or PC-60B5, you need to scan at Figure 10A to download the corresponding APP software, while for POD-1W, you need to scan at Figure 10B.

② Please make sure the version of Android system for your smart phone should be V4.3 or higher, and include the wireless module of V4.0, otherwise, the downloaded APP software will not be compatible with the Oximeter.

③ Please make sure the APP software performs successful wireless connection with the Oximeter.

◆ **Downloading the APP software for iOS system**

For smart phone or Pad with iOS system (such as iPhone, iPad), please follow this procedure to download:

1. On Apple App Store, enter "Shenzhen Creative" into the search box. Note: if you use an iPad to search, please select "iPhone only" as well for

searching.

2. Once the search results are listed, select the

App name "@health" with icon , then

download it from App software.

◆ **Downloading the APP software for both iOS system and Android system**

you can scan the below QR code to download the newest APP software.

6 Technical Specifications

A. SpO₂ Measurement

Transducer: dual-wavelength LED sensor with wavelength:

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

Maximal average optical output power: ≤2mW

SpO₂ display range: 35%~100%

SpO₂ measuring accuracy:

≤ 2% for SpO₂ range from 70% to 100%

B. Pulse Rate measurement

PR display range: 30bpm~240bpm

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

C. Perfusion Index(PI) Display range

0%~20%

D. Preset over-limits

SpO₂ low limit: 90%

Pulse Rate: high limit: 120bpm

low limit: 50bpm

E. Over-limit indication settings for PC-60C1,N,NW:

SpO₂:

low limit setting range: 85%~95%

Default setting: 85%

Pulse Rate:

Low limit setting range: 30~60bpm;

High limit setting range: 100~240bpm;

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

F. Over-limit settings for PC-60F, PC-60FW

SpO₂:

low limit setting range: 85%~99%, step: 1%

Default setting: 90%

Pulse Rate:

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

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

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

G. Over-limit settings for PC-60E

SpO₂:

default low over-limit:

For internal sensor: 90%

For external sensor: 95%

Pulse Rate:

For internal sensor:

High limit: 120bpm;   Low limit: 50bpm

For external sensor:

High limit: 160bpm;   Low limit: 60bpm

H. 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.

H. Power supply requirement:

2 x LR03 (AAA) alkaline batteries

Supply voltage: 3.0VDC

Operating current: ≤40mA

I. Environmental Conditions:

Operating Temperature:	5°C ~40°C
Operating Humidity:	30%~80%
Atmospheric pressure:	70kPa~106kPa

J. 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%.

K. 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%.

L. **Dimensions:**

① 60 mm (L) × 33 mm (W) × 30 mm (H) (for POD series)

② 59 mm (L) × 34 mm (W) × 30 mm (H) (for 60B series)

③ 66 mm (L) × 36 mm (W) × 33 mm (H) (for 60C series)

④ 60 mm (L) × 39 mm (W) × 32 mm (H) (for 60D series)

⑤ 61 mm (L) × 34 mm (W) × 33 mm (H) (for 60E)

⑥ 56 mm (L) × 34 mm (W) × 30 mm (H) (for

60F/FW)

Net Weight: approx. 60g

M. 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

7 Packing List

1) Fingertip Oximeter
2) User Manual
3) Batteries
4) Pouch (Optional)
5) Lanyard (Optional)
6) External SpO$_2$ probe (Optional)

Note: the items and its quantity are subject to

change, please refer to your subject in hand.

8 Repair and Maintenance

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: -20ºC ~60ºC, relative

humidity 10%~95%, atmospheric pressure: 50kPa~107.4kPa.

- 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.

- If it is necessary to verify the precision of the Oximeter routinely, the user can do the verification by means of SpO_2 simulator, or it can be done by the local third party test house. Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO_2 simulator, e.g. for Index 2 series SpO_2 simulator from Fluke Biomedical Corporation, please set "Make" to

"DownLoadMake: KRK", then the user can use this particular R-curve to test the Oximeter. If the SpO₂ simulator does not contain "KRK" R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO₂ simulator.

⚠ **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:

1. The SpO_2 and Pulse Rate display instable
2. Can not turn on the device
3. No display
4. Display direction doesn't change or changes insensitively.
5. No display of the wireless icon "📶"

Solution

1. Place the finger correctly inside and try again.
2. Changing batteries.
3. Let the patient keep calm.
4. Please shake the Oximeter with a certain force to make the movable metal ball move freely. If the problem still exists, maybe the orientation-sensor is not working properly.
5. Hardware failure of wireless transmission function.
6. If the above problem still exists please contact the local service center.

10 Key of Symbols

Symbol	Description
%SpO$_2$	Pulse oxygen saturation
♥BPM/**PR**	Pulse rate (beats per minute)
PI%	Perfusion Index (%)
☰/❙	Pulse Strength Bar Graph
⊠/▭	Low battery voltage
$C\epsilon$	CE mark
SN	Serial number
⌂	Date of manufacture
EC REP	Authorised representative in the European community
▟	Manufacturer (including address)
🖈	BF type applied part

🌐	Attention – refer to User Manual
☒	Follow WEEE regulations for disposal
⛛	Wireless icon

11 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 patient'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 patient 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 I Result Description

No.	Description
1	No irregularity found
2	Suspected a little fast pulse
3	Suspected fast pulse
4	Suspected short run of fast pulse
5	Suspected a little slow pulse
6	Suspected slow pulse
7	Suspected occasional short pulse interval
8	Suspected irregular pulse interval
9	Suspected fast pulse with short pulse interval
10	Suspected slow pulse with short pulse interval

| 11 | *Suspected slow pulse with irregular pulse interval* |
| 12 | *Poor signal. Measure again* |

Appendix II 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	**Complianc e**	**Electromagnetic environment-guidanc e**

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	Complia nce level	Electromagne tic environment -guidance
Electrostati c discharge(E SD) **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
			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.
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	
Radiated RF IEC61000-	3 V/m 80 MHz	3 V/m	

4-3	to 2.5 GHz		**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 determ 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 d 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

▲ CE_{0123}

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