



CREATIVE  
MEDICAL

# Fingertip Oximeter

## *User Manual*

Shenzhen Creative Industry Co., Ltd.

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## **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.

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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](http://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 1.3

Revised date: April 13<sup>th</sup>, 2020

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## 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 patents 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

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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 at ambient temperature above 37°C, burns 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.

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## 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

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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.
- 🚫 The 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.

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## **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.

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## **FCC Rules are specifically 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.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment complies with FCC radiation exposure limit without restriction

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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

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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

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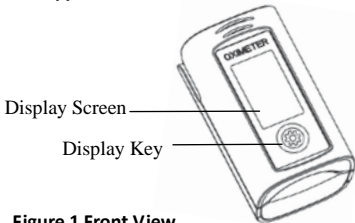
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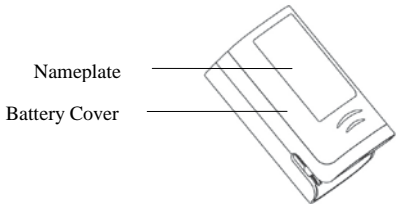
# 1 Overview

## 1.1 Appearance



**Figure 1 Front View**





**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:** PC-60FW

## **1.3 Intended Use**

This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO<sub>2</sub>) through a patient's finger. It is applicable for spot-checking SpO<sub>2</sub> and pulse rate of adult and pediatric patients in homes and medical clinics.

## **1.4 Feature List**

**Explanation of abbreviations:**

"V" this function is available, "X" without this function.

Display type: *D-O-D means dot-matrix dual color OLED*

<b>Function</b> \ <b>Model</b>	<i>PC-60F</i>	<i>PC-60FW</i>	<i>PC-60A</i>
<b>Display type</b>	<i>OLED</i>	<i>OLED</i>	<i>LCD</i>
<b>SpO<sub>2</sub>, PR, PI</b>	✓	✓	✓
<b>Plethysmogram</b>	✓	✓	X
<b>Auto on/off</b>	✓	✓	✓
<b>Pulse bar graph</b>	✓	✓	✓
<b>PR and PI shifts</b>	✓	✓	✓
<b>Over-limits indication</b>	✓	✓	✓

<b><i>Over-limits indication sound</i></b>	√	√	×
<b><i>Indication sound mute</i></b>	<i>Manual</i>	<i>Manual</i>	<i>Manual</i>
<b><i>Four directions display</i></b>	√	√	<i>Two</i>
<b><i>Setting menu</i></b>	√	√	×
<b><i>Over-limits setting</i></b>	√	√	×
<b><i>Pulse beep</i></b>	√	√	×
<b><i>Wireless function</i></b>	×	√	×
<b><i>Measuring mode</i></b>	<i>Continuous, Spot check</i>	<i>Continuous, Spot check</i>	×
<b><i>Record list</i></b>	√	√	×

***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 SpO<sub>2</sub> 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 out, the display will be cleared and the Oximeter shuts down automatically.*

*② Continuous mode: measurement will start automatically when finger is inserted into the oximeter, SpO<sub>2</sub> and PR readings will be displayed until the finger is removed from the oximeter. Once finger is removed the Oximeter will automatically turn off.*

**➤ 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.*

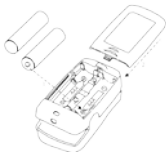
*③ When batteries are removed from the device all readings will be deleted.*

*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**

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 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.

Figure 3 Battery Installation

### 3 Operation

1. Open the clip and put finger inside the rubber



Figure 4

cushions of the clip (make sure the finger is in the correct position), and then clip the finger, as shown in figure 4.

2. Next enter into data display screen:

✧ *A short time press of the Display Key can change display direction, the four display directions are as shown in figure 5A, 5B, 5C, & 5D. For display screens of figure 5B and 5D, the PI% display value will be replaced with PR display value after 20 seconds if no key operation.*



Figure 5A

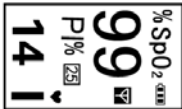


Figure 5B



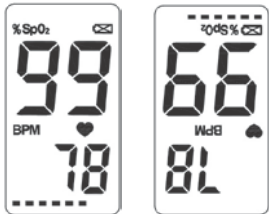
Figure 5C




Figure 5D

✧ For PC-60A, the display screen is as shown in below

*figure.*



- ✧ *For PC-60F and PC-60FW, the display direction is remembered at each startup, it will display the screen layout (display direction) from the last time it was used.*

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

No irregularity found
%SpO <sub>2</sub> :99 PR:78

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

*Figure 5E*

- ✧ *When the measurement ends up for Spot check mode, the measured SpO<sub>2</sub>, PR value and the analysis result of pulse rhythm will be displayed on the screen, as shown in figure 5E.*

*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 6. In record list screen, short time press Display key to shift the records page.*

**Menu** (PC-60F and PC-60FW)

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

SpO <sub>2</sub> 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. Transmitting data to PC when it is on. “on” and “off” can be optional. The factory default is “on”.

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


**“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.

### **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 lamp, 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.
- when the displayed SpO2 and pulse rate is incorrect, the “—” prompts on screen, please check whether the finger is in appropriate position.

## 4 Download the 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.

### **◆ 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.

## 5 Technical Specifications

### A. SpO<sub>2</sub> Measurement

Transducer: dual-wavelength LED sensor with wavelength:

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

**Maximal average optical output power:**  $\leq 2\text{mW}$

**SpO<sub>2</sub> display range:** 35%~100%

**SpO<sub>2</sub> measuring accuracy:**

≤ 2% for SpO<sub>2</sub> 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 for PC-60A**

SpO<sub>2</sub> low limit: 90%

Pulse Rate: high limit: 120bpm

low limit: 50bpm



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

***SpO<sub>2</sub>:***

*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*

**F. Audible & visual alert function**

When measuring, if SpO<sub>2</sub> 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:  $\leq 40\text{mA}$

**I. Environmental Conditions:**

Operating Temperature:  $5^{\circ}\text{C} \sim 40^{\circ}\text{C}$

Operating Humidity:  $30\% \sim 80\%$

Atmospheric pressure:  $70\text{kPa} \sim 106\text{kPa}$

**J. Low Perfusion Performance:**

The accuracy of  $\text{SpO}_2$  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<sub>2</sub> value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

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

**Net Weight:** approx. 60g (including batteries)

**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

#### **N. Data update period**

The data update period is less than 30 seconds. The measurement of SpO<sub>2</sub> and pulse rate is based on the judgment and calculation of multiple sets of data

collected recently every 1 second, and then the average value of the recently calculated numerical queue is obtained to display the value.

## **6 Packing List**

- 1) Fingertip Oximeter
- 2) User Manual
- 3) Batteries
- 4) Pouch (optional)
- 5) Lanyard (optional)

Note: the items and its quantity are subject to change,

please refer to your subject in hand.

## **7 Repair and Maintenance**

### **7.1 Maintenance**

The expected service life (not a warranty) of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the device before using, with 75% alcohol wipes, then let it air dry or wipe it dry. Do not allow liquid to enter the device.

- Please take out the batteries if the Oximeter will not be used any more than 7 days.
- The recommended storage environment of the device:  
ambient temperature:  $-20^{\circ}\text{C} \sim 60^{\circ}\text{C}$ , 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  $\text{SpO}_2$  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  $\text{SpO}_2$  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<sub>2</sub> 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<sub>2</sub> simulator, e.g. for Index 2 series SpO<sub>2</sub> 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 SpO<sub>2</sub> simulator does not contain "KRK" R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO<sub>2</sub> 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.**

## **7.2 Cleaning and Disinfecting Instruction**

- Surface-clean sensor with a soft cloth dampened 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 dampened **ONLY** with clean water and dry with a clean, soft cloth.


**Caution:** Do not sterilize by irradiation steam, or ethylene

oxide.

Do not use the Oximeter if it is damaged.

## 8 Troubleshooting

### Problem:

1. The SpO<sub>2</sub> and Pulse Rate display instable
2. Cannot 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.

## 9 Key of Symbols

Symbol	Description
%SpO <sub>2</sub>	Pulse oxygen saturation

 <b>BPM/PR</b>	Pulse rate (beats per minute)
<b>PI%</b>	Perfusion Index (%)
	Pulse Strength Bar Graph
	Low battery voltage
	CE mark
<b>SN</b>	Serial number
	Date of manufacture
	Authorised representative in the European community



Manufacturer (including address)



BF type applied part



Attention – refer to User Manual



Wireless icon



Follow WEEE regulations for disposal

## 10 Frequently Asked Questions

1. Q: What's SpO<sub>2</sub>?

A: SpO<sub>2</sub> means the saturation percentage of oxygen in

the blood.

2. Q: What's the normal range of SpO<sub>2</sub> 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<sub>2</sub> and PR vary with time?

A: The measured SpO<sub>2</sub> and PR value changes in correspondence with the change of patient's physiological

conditions.

5. Q: What to do if there is no SpO<sub>2</sub> 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<sub>2</sub> reading is true or accurate?

A: Hold breath for a while (50 seconds or more), if the SpO<sub>2</sub> value significantly decreases, it means that the SpO<sub>2</sub> 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<sub>2</sub> 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***

<i>No.</i>	<i>Description</i>
<i>1</i>	<i>No irregularity found</i>
<i>2</i>	<i>Suspected a little fast pulse</i>
<i>3</i>	<i>Suspected fast pulse</i>
<i>4</i>	<i>Suspected short run of fast pulse</i>
<i>5</i>	<i>Suspected a little slow pulse</i>
<i>6</i>	<i>Suspected slow pulse</i>
<i>7</i>	<i>Suspected occasional short pulse interval</i>
<i>8</i>	<i>Suspected irregular pulse interval</i>

9	<i>Suspected fast pulse with short pulse interval</i>
10	<i>Suspected slow pulse with short pulse interval</i>
11	<i>Suspected slow pulse with irregular pulse interval</i>
12	<i>Poor signal. Measure again</i>

## **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.

<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment-guidance</b>
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,

Harmonic emissions IEC61000-3-2	N/A	including domestic establishments and those directly network that supplies buildings used for domestic purposes.
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) <b>IEC61000-4-2</b>	$\pm 8$ kV contact $\pm 15$ kV air	$\pm 8$ kV contact $\pm 15$ kV 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 <b>IEC61000-4-4</b>	$\pm 2$ kV for power Supply lines $\pm 1$ kV for input/output lines	N/A	N/A
Surge <b>IEC 61000-4-5</b>	$\pm 1$ kV line (s) to line(s) $\pm 2$ kV line(s) to earth	N/A	N/A

<p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p><b>IEC61000-4-11</b></p>	<p>&lt;5% <math>U_T</math> (&gt;95% dip in <math>U_T</math>) for 0.5 cycle</p> <p>&lt;40% <math>U_T</math> (60% dip in <math>U_T</math>) for 5 cycles</p> <p>&lt;70% <math>U_T</math> (30% dip in <math>U_T</math>) for 25 cycles</p> <p>&lt;5% <math>U_T</math> (&gt;95% dip in <math>U_T</math>) for 5 s</p>	<p>N/A</p>	<p>N/A</p>
<p>Power frequency(</p>	<p>3A/m</p>	<p>3A/m</p>	<p>Power frequency</p>



<p>50Hz/60Hz) magnetic field <b>IEC61000-4-8</b></p>			<p>magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE: <math>U_T</math> is the a.c. mains voltage prior to application of the test level.</p>			

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.

<b>Immunity test</b>	<b>IEC60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment -guidance</b>
			Portable and mobile RF communications equipment should

<p>Conducted RF IEC61000-4- 6</p>	<p>3 Vrms 150 kHz to 80 MHz</p>	<p>N/A</p>	<p>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. <b>Recommended</b></p>
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Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<b>separation distance</b> $d=1.2 \sqrt{P}$ $d=1.2 \sqrt{P}$ 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
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			<p>manufacturer and <math>d</math> is the recommended separation distance in metres (m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in</p>
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			each frequency range . <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol. 
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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, an 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.

<b>Rated maximum</b>	<b>Separation distance according to frequency of transmitter M(Meters)</b>
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	150kHz to 80MHz	80MHz to 800MHz	80MHz to 2,5GHz
	$d=1.2 \sqrt{P}$	$d=1.2 \sqrt{P}$	$d=2.3 \sqrt{P}$
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 product has been inspected in accordance with the standards specified in the User Manual.

Shenzhen Creative Industry Co., Ltd

## Shenzhen Creative Industry Co., Ltd.



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

Tel: +86-755-2643 3514

Fax: +86-755-2643 0930

E-mail: [info@creative-sz.com](mailto:info@creative-sz.com)

Website: [www.creative-sz.com](http://www.creative-sz.com)



Shanghai International Holding Corp.  
GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg Germany