OxySmart

Fingertip Oximeter

User Manual

Model:*PC-60F*

Notes

- 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 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 the instructions regarding cleaning and disinfection.
- The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid.
- 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: 2012 Medical electrical equipment-Part 1: General requirements for basic

safety and essential performance;
ISO 80601-2-61: 2017 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.

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1 Overview

1.1 Appearance

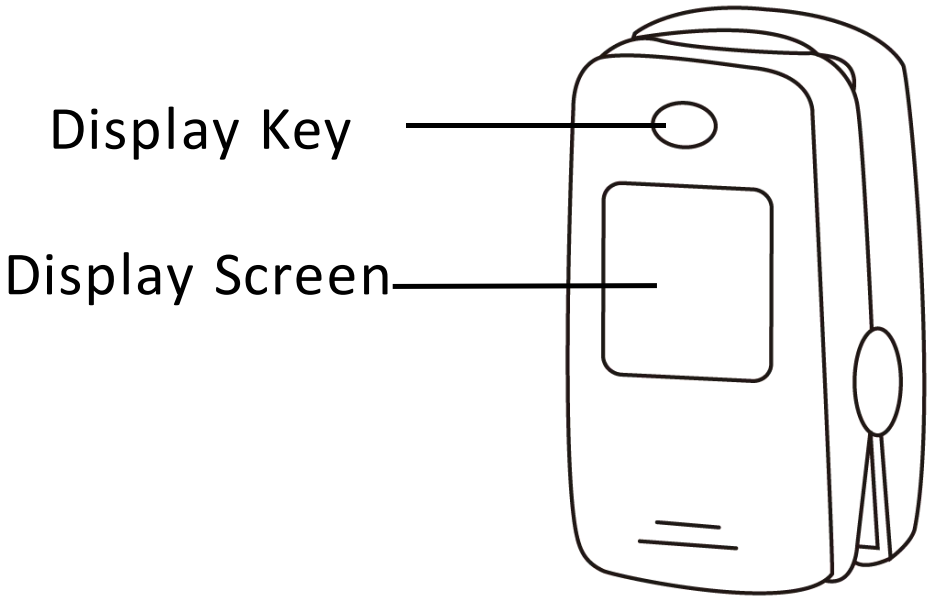

Figure 1 Front View

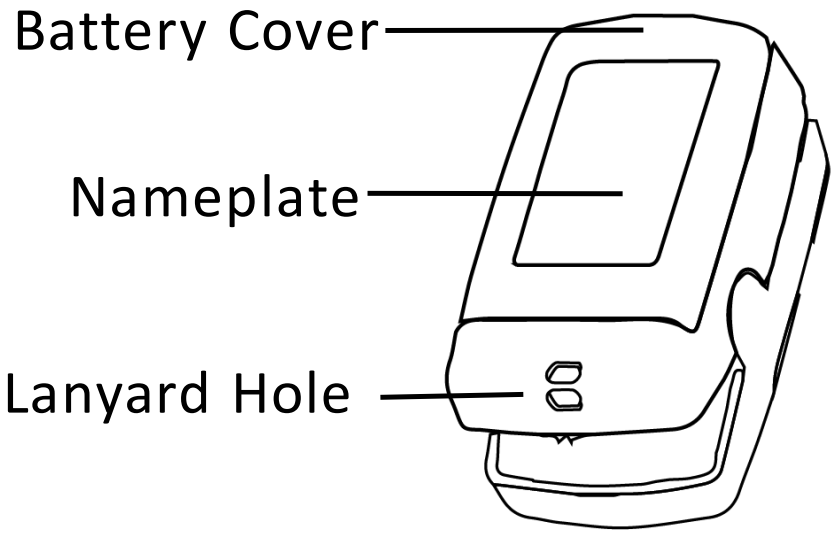

Figure 2 Rear View

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

1.2 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 checking SpO_2 and pulse rate of adult and pediatric patients in homes and medical clinics.

1.3 Configuration

- SpO2, PR, PI
- Plethysmogram
- Auto on/off
- PR and PI shifts
- Pulse bar
- Over-limits setting
- Pulse beep
- Measuring Mode: Continuous / Spot Check
- Record list

2 Battery Installation

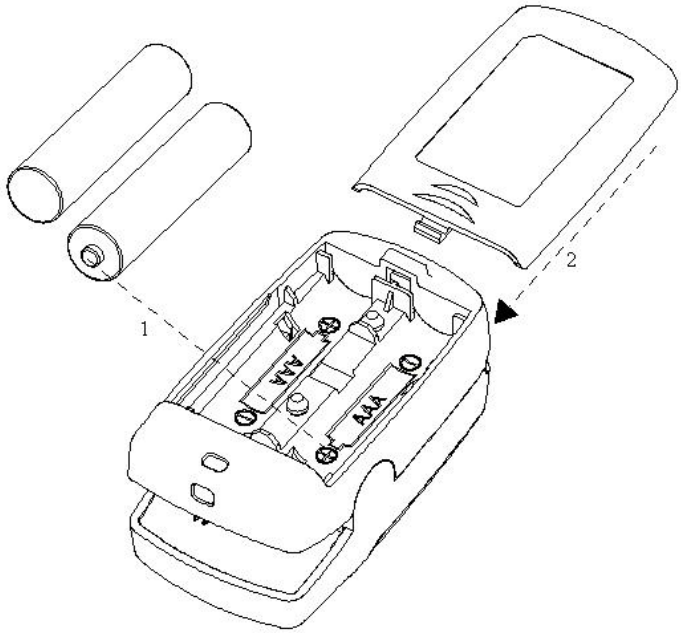

Figure 3 Battery Installation

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 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 Operation

1. Start. 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 4.

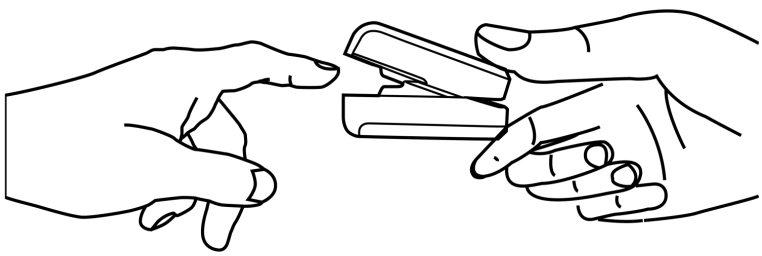

Figure 4 Put finger into the Oximeter

Wait 2 seconds, the Oximeter will power on automatically and start to measure;

2. END. When finger is out, the Oximeter shuts down automatically.

3. Readings display screen

The screen displays as below：

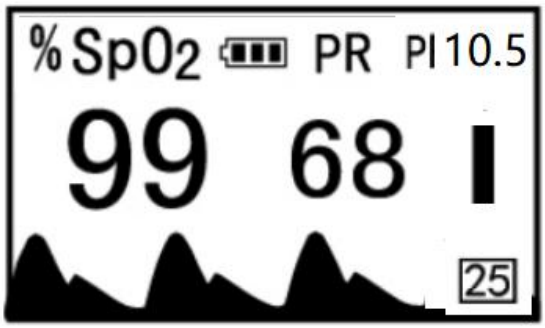

Figure 5

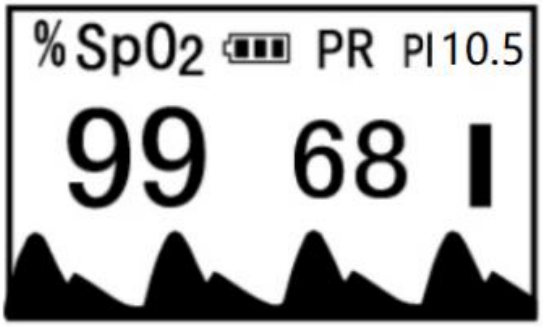

Figure 6

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.

4. Recording & recall

Recording & recall functions are available. At power off status, pressing Display key can bring up record list display screen, as shown in figure 7. In record list screen, press Display key to shift the records page.

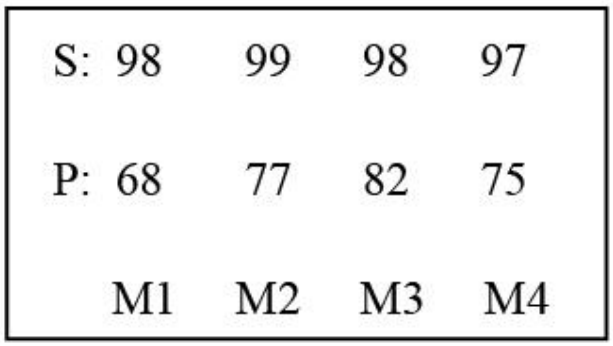

Figure 7

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.

If the batteries are removed from the device, then the records will be not kept or volatile

5. Menu

When finger is in oximeter, long time pressing

display key can enter the setup menu screen.

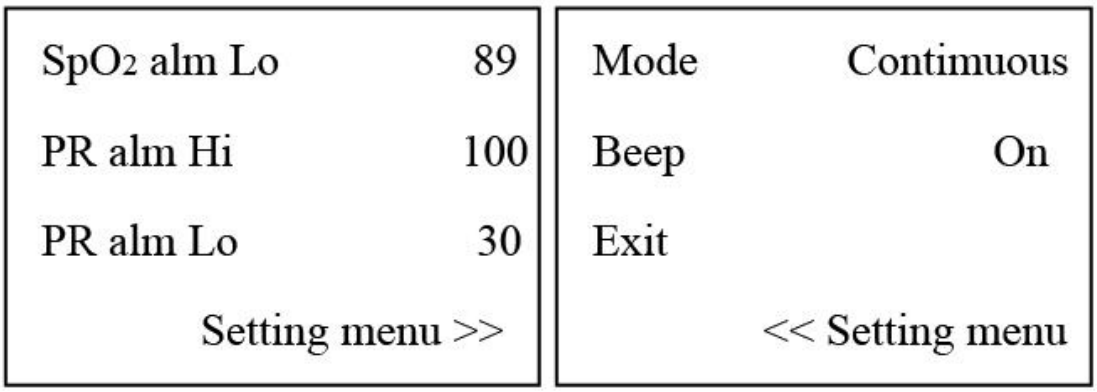

Figure 8

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.

“Mode”: *to set the measuring mode: “Continuous” or “Spot check”.*

“Beep”： Pulse beep option. If it is set to on, every

pulse beat makes a beep.

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.

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.

- 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.

4 Technical Specifications

A. SpO_2 Measurement

Transducer: 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: 30bpm~240bpm

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

C. Perfusion Index(PI) Display range

0%~20%

D. Preset over-limits

SpO_2 low limit: 90%

Pulse Rate: high limit: 120bpm

low limit: 50bpm

E. Over-limit settings

SpO_2:

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_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.

G. Power supply requirement:

2 x LR03 (AAA) alkaline batteries

Supply voltage: 3.0VDC

Operating current: ≤40mA

H. Environmental Conditions:

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

I. 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%.

J. 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%.

K. Dimensions:

56 mm (L) × 34 mm (W) × 30 mm (H)

Net Weight: approx. 60g

L. Display:

OLED

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

5 Packing List

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

Note: the items and its quantity are subject to change, please refer to your subject in hand.

6 Repair and Maintenance

6.1 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 SpO_2 simulator does not contain "KRK" R-curve, please ask the manufacturer for

helping to download the given R-curve into the SpO_2 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.**

6.2 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.

7 Troubleshooting

Problem:

1. The SpO_2 and Pulse Rate display instable
2. Can not turn on the device
3. No display

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. If the above problem still exists please contact the local service center.

8 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
	CE mark
SN	Serial number
	Date of manufacture
	Authorised representative in the European community
	Manufacturer (including address)
	BF type applied part
	Attention – refer to User Manual
	Follow WEEE regulations for disposal

9 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 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.
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 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.

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 meters (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.

Version: A

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