Operator's Manual

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Section 1

Safety

1.1 Instructions for the Safe Operation and Use of the Fingertip Pulse Oximeter

• Do not attempt to service the Fingertip Pulse Oximeter. Only qualified service personnel should attempt any needed internal servicing.

• Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status and correct alignment at least every 2 hours.

• SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area （with a surgical towel, or direct sunlight, for example) if necessary.

• The following reason will cause interference to the testing accuracy of the Fingertip Pulse Oximeter.

▪ High-frequency electrosurgical equipment.

▪ Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or intravascular line

▪ The patient has hypotension severe vasoconstriction severe anemia or hypothermia.

▪ The patient is in cardiac arrest or is in shock.

▪ Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

1.2 Warnings

WARNING: EXPLOSION HAZARD — Do not use the Fingertip Pulse Oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other

WARNING: Do not throw batteries in fire as this may causes them to explode.

WARNING: Do not attempt to recharge normal dry-cell batteries, they may leak. And may cause a fire or even explode.

WARNING: Do not use the Fingertip Pulse Oximeter in an MRI or CT environment.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.

CAUTION: The batteries must be taken out from the battery compartment if the device will not be used for a long time.

CAUTION: The device shall only be used if the battery cover is closed.

CAUTION: The batteries must be proper disposed according to local regulation after their use.

CAUTION: The device should keep away from the children, pets and pests to avoid swallowing.

1.3 Definitions and Symbols

Symbol	Description
	Type BF Equipment
LOT	Batch code*
	Date of manufacture*
SN	Serial NO*
	Information of manufacture, including name and address
	Temperature limitation
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling
	Follow instruction for use
IP22	Anti-dust& Anti-water class
Warning	The information you should know to protect patients and medical staff from possible injury
Caution	The information you should know to protect the equipment from possible damage
Note	The important information you should know

* Batch code, Date of manufacturer and Serial No are printed on the label on the battery cover.

Section 2

Introduction

2.1 General

This chapter provides a general description of the Fingertip Pulse Oximeter including:

• Brief device description

• Product features

2.2 Brief Device Description

The Fingertip Pulse Oximeter, based on all digital technology, is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2). Advanced DSP algorithm* can minimize the influence of motion artifact and improve measurement accuracy of low perfusion*.

The Oximeter can be used to measure human Hemoglobin Saturation and heart rate through finger. The product is suitable for family, hospital (including clinical use in internist/surgery, Anesthesia, pediatrics, intensive care and etc.) Oxygen Bar, social medical organizations, physical care in sports and etc.

2.3 Product Features

• Lightweight for carrying and Easy-To-Use.

• Manually adjust the direction of interface .

• Color OLED display, simultaneous display for testing value and plethysmogram*.

• Low Perfusion : 0.2%. (Advanced DSP algorithm can improve measurement accuracy, under the condition of low perfusion.)

• Visual & Sound reminder function. Real-time spot-checks.

• Low Battery voltage indicator.

• Automatically switch off.

• Standard two AAA 1.5V Alkaline Battery support more than 20 hours continuous work.

CAUTION: The device can not be used to measure the child below 3 years as the test result is not guarantee to accurate.

CAUTION: The fingertip pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

CAUTION: A function tester cannot be used to assess the accuracy of a Fingertip Pulse Oximeter monitor or sensor. Clinical testing is used to establish the SpO2 accuracy. The measured arterial hemoglobin saturation value (SpO2) of the sensor is compared to arterial hemoglobin oxygen(SaO2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO2 range of 70 -100%. Accuracy data is calculated using the root-mean-square(Arms value) for all subjects. Only about two-thirds of FINGERTIP PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by a CO-Oximeter.

Pulse simulator shall be used to assess Pulse rate Accuracy. The measured pulse rate is compared to the preset pulse rate value in simulator. Accuracy data is calculated using the root-mean-square (Arms value) for all subjects.

***DSP algorithm:** Digital signal processor algorithm.

***Low Perfusion:** In physiology, perfusion is the process of a body delivering blood to a capillary bed in its biological tissue. Under the condition of low perfusion, the measurement of non-invasive saturation of pulse-blood oxygen is low-accurate.

***Plethysmograph:** is an instrument for measuring changes in volume within an organ or whole body (usually resulting from fluctuations in the amount of blood or air it contains).

PI （Perfusion Index ） is the ratio of the pulsatile blood flow to the non-pulsatile static blood flow in a patient's peripheral tissue, such as finger tip, toe, or ear lobe. Perfusion index is an indication of the pulse strength at the sensor site

Section 3

Installation,Setup,and Operation

3.1 Description of the Front Panel (as figure 3.1.1)

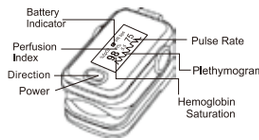
Figure 3.1.1 Parts of front & back panel

Table 3.1.1 Part Definition and Description

Item	Name	Description
1	Power button	Turn on the machine
2	OLED Panel	Display the SPO2/PR data & Plethysmogram
3	Battery Compartment	

3.2.Display

After switch on, the OLED display of the Fingertip Pulse Oximeter is as follows:



3.3 Parameter setting

When the device is under measuring interface, press the direction button for 1 second in order to enter into menu page (figure 3.3.1 and figure 3.3.2). There are two submenus for choice:

3.3.1 Remind Setup

Press the direction button for 1 second and enter into the Reminder Setup. User can adjust the setting through moving the "*" symbol to the back of the Sound Reminder, Beep, Restore or Brightness.

• Sound Reminder

Press the direction button for 1 second, move the "*" symbol to the back of Sound Reminder, long press the direction button to turn it on/off.

(Note: If the measured value exceeds the maximum or minimum value of SPO2 or PR, there will give off sound when sound reminder is turned on.)

• Beep

Press the direction button for 1 second, move the "*" symbol to the back of Beep, long press the direction button to turn it on/off.

(Note: When Beep is turned on, the sound emitted during the test indicates the pulse rate sound)

• Restore

When the "*" symbol show behind "Restore", long press the direction button can be changed to "OK", which causes the device to restore factory data setting.

• Demo

Press the direction button for 1 second, move the "*" symbol to the back of Demo, long press the direction button to turn it on/off.

• Brightness

When the "*" symbol show on "Brightness", long press the direction button to change the Brightness value from 1 to 5.

3.3.2.Limit Value Setting

When the * symbol show on the Reminder Setup, long press the direction button until enter into the Reminder Limit setup menu (figure 3.3.2). User can press the direction button to select the items. And press the direction button for 1 second to change the data you need.

On the Reminder Limit setup menu page (figure 3.3.2), when the * symbol show behind the "+/-". Press direction button for 1 second to change the "+" to "-" or change the "-" to "+".

When "+" shows on the right side, press the direction button for 1 second, move the "*" after the Spo2 Hi or PR Hi setting, can increase the value to a higher value (until it reaches to the highest.)

When "-" shows on the right side, press the direction button for 1 second, move the "*" after the Spo2 Lo or PR Lo value setting, can reduce the value to a lower value (untill it reaches to the lowest).

Figure 3.3.1

Figure 3.3.2

Note:

1..The sound reminder have 1 second delay after the incorrect result being detected.

2. The customer can preset the limit value to the 98 or 99 to check whether it is normal for sound reminder setting.

3.4 Operation

3.4.1 Install battery

Installing two AAA batteries into battery cassette in correct polarities and cover it.

WARNING: Do not attempt to recharge normal alkaline batteries, they may leak and may cause a fire or even explode.

3.4.2 Turn the Fingertip Pulse Oximeter on

Put one of fingers into rubber hole of the Oximeter (it is best to put the finger thoroughly) with nail surface upward, then releasing the clamp.

Press power button for 2 seconds to turn the Fingertip Pulse Oximeter on.

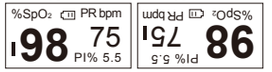
3.4.3 Read correspondent data from display screen.

3.4.4 Display Description of OLED

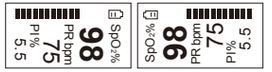
The display interface of "OLED" can rotate four directions with six different display modes after pressing the direction button. It is shown as below:

Type 1 Type 2

Type 3 Type 4



Type 5 Type 6



Note:

1. when battery power is at lowest level, the battery capacity indicates symbol of "▭"in OLED, remind users of replacement of battery.

2. The plethymogram can been regarded as correct if the wave is fluctuated regularly.

Section 4

Cleaning and Disinfection

4.1 Cleaning

Switch off the power and take out the batteries before cleaning, Keep the exterior surface of the device clean and free of dust and dirt. Cleaning exterior surface (OLED display screen included) of the unit with a dry and soft cloth. Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid alcohol permeates into the device.

4.2 Disinfection

Disinfecting the machine after using by the patient if multiple patient use the machine in the hospital.

Use 75% density of medical alcohol to clean the surface that contacting with the patient.

CAUTION: Don't use strong solvent. For example, acetone.

CAUTION: Never use an abrasive such as steel wool or metal polish.

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquids on the device while cleaning.

CAUTION: Don't remain any cleaning solution on the surface of the device.

Section 5

Troubleshoot**ing and Maintenance**

5.1 Maintenance

• Replace the batteries timely when battery indication is low. Clean surface of the Pulse Oximeter before it is used in diagnosis for patients.

• Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.

• It is better to preserve the product in a place where ambient temperature is -25-55℃ and humidity is 15%-80%.

• Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.

• No flammable substance, overtop or lower temperature and humidity existed in operation conditions.

5.2 Troubleshooting

Table 5.2.1 troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemo-globin or heart rate can not be shown normally	1. Finger is not plugged correctly. 2. Patient's perfusion is too low to be measured.	1. Retry by plugging the finger 2. Try some more times, if you can make sure about no problem existing in the product, Please go to a hospital timely for exact diagnosis
Oxyhemo-globin or heart rate is shown unstably	1. Finger might not be plugged deep enough 2. Finger is trembling or patient's body is in movement status	1.Retry by plugging the finger 2.Try not to move, let the patient keep calm
Oxyhemo-globin or heart rate is abnormal and cause sound reminder	1. Finger is not plugged correctly. 2. Patient's SPO2&PR is abnormal.	1. Retry by plugging the finger 2. go to the hospital for further examination
The oximeter can not be powered on	1. Power of batteries might be inadequate or not be there at all 2.Batteries might be installed incorrectly 3.The Oximeter might be damaged	1.Please replace batteries 2.Please reinstall the batteries 3.Please contact with local customer service center
The screen are suddenly off	1.The product is automa-tically powered off when no signal is detected longer than 16 seconds 2.Power quantity of the batteries is exhausted	1.Normal 2.Replace the batteries

Section 6

Specification

Fingertip Pulse Oximeter Specifications:

Physical Characteristics

Machine:

Dimensions :

62 mm (L) x 34mm (W) x 31mm (D)

Weight approx: 50g

（including 2 x AAA battery）

Classification：

Anti-electric Shock Type：

Internally powered equipment

Anti-electric Shock Degree：Type BF equipment

EMC：Type B

Mode of operation: Continuous Operation

Enclosure Degree of ingress protection: IP22

IP22 means shell of this product can withstand the water dropping to the surface when the shell deviate 15 degree from horizontal surface.

Power

Internal	2xAAA 1.5v a lkaline battery
Power Consumption	Smaller than 30mA (Normal)

Environmental

Operating Temperature	5°C to 40°C
Storage Temperature	－10°C to 50°C
Relative Humidity	15% to 80% non-condensing
Air Pressure	86Kpa-106Kpa

Sound Reminder Limit default value:

Parameter	Value
Hemoglobin saturation	Upper limit: 100/ bottom limit:94
Pulse rate	Upper limit: 130 / bottom limit:50

Electronics Parameters

Parameter		Value
Hemoglobin saturation display		35-100%
Pulse rate Display		30-250 BPM
Resolution	Hemoglobin Saturation	1%
	Pulse rate	1 BPM
Measure Accuracy	Hemoglobin Saturation	±2% (90%-100%) ±3% (70%-90%), Unspecified (<70%)
	Pulse rate	± 1 BPM
PI	Display	0-20%
	Resolution	0.1%
	Measure Accuracy	0-1%: 0.1% 1-20%: 1%

Probe LED Specification

	Wave Length	Radiant Power
RED	660±2 nm	1.8 mW
Infra RED	905±2 nm	2. 0 mW

Manufacturer's Declaration of the EMC

Guidance and manufacturer's declaration - electromagnetic emission - for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emission		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment- guidance
RF emissions CISPR 11	Group 1	The Pulse Oximeteruses 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 Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

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The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximetershould assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete orceramic tile. If floors are covered withsynthetic material, the relative humidityshould be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ outputlines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles at 0° 0% UT; 250/300 cyclee	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pulse Oximeter requires continued operation during power mains interruptions, it is recommended that the Pulse Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity -for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	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 Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	6Vrms in ISM banda between 150 kHz to 80 MHz 80 MHz to 2.7 Ghz	10V/m	

NOTE l At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations. Electromagnetic 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 FMradio 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 pulse Oximeter is used exceeds the applicable RF compliance level above, the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulse OxImeter

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM-for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the pulse oximeter
The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter / m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres(m) can be estimated 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 l 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

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