FS10/FS20

Pulse Oximeter

CE 0123

User Manual

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Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter.

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

Read this manual carefully before using the fingertip pulse oximeter.

This product is a reusable medical device. The using life is 2 years.

1.Safety

1.1.1 Contraindications

Do not use oximeter in a magnetic resonance (MR or CT)environment.

1.1.2 Warnings

Keep the oximeter away from young children. Small parts such as the battery door, battery and lanyard may trigger choking hazards.

1.1.3 Cautions

- Do not use oximeter in the present of flammable anesthetics.
- The oximeter needs to be used according to information provided in the user manual.
- The equipment is NOT intended for neonate and infant.
- Do not use a damaged oximeter which may affect measurement performance.
- Do not place the oximeter on the same hand/arm when using a blood pressure cuff or monitor.
- Do not use the oximeter for more than 5 minutes without relocating the device to another finger.
- Do not place the oximeter on edema or fragile tissues.
- Do not use the oximeter as the only basis for making medical decision,it is intended only to be used as addtional information that you can give to your licensed health care professional.
- Do not use the oximeter in high frequency environment such as electrosurgical equipment.
- Do not place the oximeter in liquid.
- Follow local disposal and recycling laws for the oximeter and its components,including the battery.
- Do not stare the light(the infrared is invisible) which emitted from the oximeter is harmful to the eyes.
- For clinical limitations and contraindications, please carefully review the medical literature
- The equipment is just a clinical diagnosis of auxiliary equipment. The physiological data displayed on the equipment are for reference only and can not be directly used for diagnostic interpretation.
- Not suitable for the users with arrhythmia / heart failure / Low perfusion (PI <0.3) / finger trembling.
- Not suitable for the users with large finger size or exceeding pulse oximeter's finger measurement cavity size.
- Please don't use the thumb and tail finger to measure .
- Discomfort or pain may appear if using the equipment ceaselessly,especially for microcirculation barrier patients, it recommended that the equipment should not be used on the same finger more than 5 minutes.
- The oximeter is designed to measure the percentage of arterial oxygen saturation of functional hemoglobin. Any of the following conditions may reduce the performance of the oximeter.
  - ◆ Flicking or very bright light
  - ◆ Moisture in the oximeter
  - ◆ The individual weight less than 20kgs
  - ◆ Week pulse quality(low perfusion)
  - ◆ Venous pulsations
  - ◆ Low hemoglobin
  - ◆ Cardiogreen and other intravascular dyes
  - ◆ Carboxyhemoglobin
  - ◆ Methemoglobin
  - ◆ Dysfunctional hemoglobin
  - ◆ Artificial nails or fingernail polish
  - ◆ The Finger is too cold
  - ◆ Patients with abnormal circulation of finger endings caused by copd.

2.The Basics

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter for respiration. A number of diseases relating to respiratory system may cause the decrease of SpO2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body. And the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients SpO2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical of medical field.

2.1 Principle

Principle of the oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrunm Absorprtion characteristic of Reductive hemoglobin(Hb) and oxyhemoglobin(HbO2) in glow&near-infrared zones. Opertation Principle of the device is:Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning Recording Technology, So that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor.Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

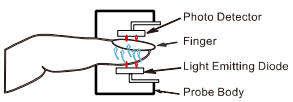


Figure 1.Oximeter schematic diagram

2.2 Introduction

2.2.1 Intended Use

The Pulse Oximeter is a portable, convenient, non-invasive device, used for monitor arterial hemoglobin oxygen saturation (SPO2) and pulse rate. The personal application are adult patients (weight: >30kgs) and pediatric patients(weight:20-30kgs). We recommend index finger, middle finger and ring finger are suitable position for monitor. It's intended for spot-checking or attended-care monitoring in Home Health Care and Medical Facility.

Warning:

This pulse Oximeter is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.

CAUTIONS:

- This pulse oximeter is intended for use in hospital, clinical institution, healthcare community.
- The pulse oximeter is NOT designed for newborn and infant. For adults and children,it recommended that the finger thickness should between 8-25.4mm.

NOTES:

- The probe is the hole in the middle of the equipment to which the finger insert.
- The probe is the Applied part of the equipment.

2.2.2 Features

- The pulse oximeter is small in volumes, light in weight and easy to carry.
- One button and easy to operate.
- There are three modes: power off , sleep and measure.
- Automatically turning into sleep mode within 8 seconds after there is no signal.

NOTES:

- Press the operating button to activate oximeter(measure mode) from sleep mode.
- Power off after removing the batteries.

2.3 Front View

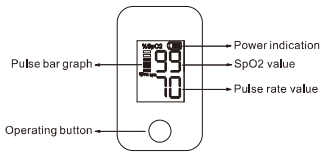


Figure 2.Front View of FS10

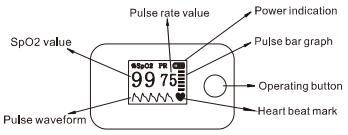


Figure 2.Front View of FS20

2.4 Functions

Function	FS10	FS20
Display	LED	OLED
Spo2 parameter measurement	Y	Y
Pulse rate parameter measurement	Y	Y
Bar graph display	Y	Y
Battery display	Y	Y
Automatically enters sleep mode	Y	Y
Pulse waveform display	—	Y

2.5 Symbols

Symbols	Definition	Symbols	Definition	Symbols	Definition	Symbols	Definition
%SpO2	The Pulse Oxygen Saturation (%)	SN	Serial Number	+	Battery positive electrode		BF type applied part
PR	Pulse Rate(BPM)		The device has no Alarm System	−	Battery cathode electrode		Manufacturer
IP22	The product is protected against harmful effects of dripping water per IEC 60529.		Date of Manufacturer		Caution, consult accompanying documents	CE 0123	This item is compliant with Medical Device Directive 93/42/EEC
	Power indication(some models have no battery capacity indicator, but have low battery indicator)						

3.Battery Installation

A.Put the two AAA batteries into battery compartment in correct polarities.
B.Push the battery cover horizontally along the arrow shown as figure 3.

WARNINGS:

- Battery polarities should be correctly installed,otherwise,damage may be caused to the equiment.
- Please remove the batteries if the oximeter will be stored for more than 30 days.
- Please remove the batteries if you want to turn off the oximeter. Otherwise it is always in power state.
- Battery may leak or explode if used or disposed off improperly.

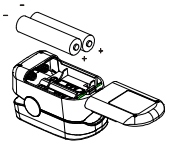


Figure3. Battery Installation

4. Operating Guide

4.1 Application Method

A.Remove the battery cover,and insert the two AAA batteries following polarity markings indicated inside of the battery compartment,then reposition the cover.
B.Hold the oximeter with the display facing toward you,slide your finger into the opening probe of the device,as shown below(Figure 4),until the fingertip touches the built-in stop guide.For best results,make sure the finger is centered with in the finger guide.
C.Press the button to activate the oximeter from sleep mode, and then measurement interface will appear in 3 seconds.
D.The measurement result will be read directly from the screen about 10 seconds.
E.The oximeter will turn into sleep mode automatically within 8 seconds after the finger left the probe.

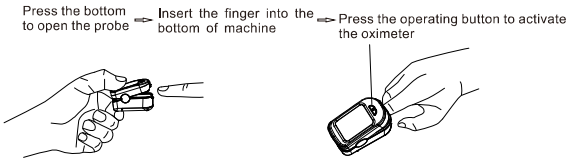


Figure 4.Operation Guide

4.2 Attention for Operation

A. Ring finger, middle finger and index finger are recommended as suitable monitor position.
B. Excessive or rapid movement may affect measurement accuracy.
C. Improper sensor placement may affect the measurement accuracy.
D. The oximeter can be reused after cleaning and disinfection.
E. The measurement comes to the best when the oximeter and the heart are at the same level.
F. (Only for FS20)The plethysmogram can be used as pulse intensity indicator. The displayed parameters might be unreliable with the discorderly plethysmogram.
G. (Only for FS10) The bar graph can be used as pulse intensity indicator. The displayed parameters might be unreliable with un-periodic change.
H. The displayed parameters will show invalid indicator as '---' if signal quality is very low.
I. The displayed parameters will show invalid indicator as '---' if oximeter fault occur.
J. The maximum continuous test time does not exceed 5 minutes.

5. Specifications

5.1 Classification

Type of protection against electric shock.....Internally powerted equipment
Degree of protection against electric shock.....Type BF-Applied part(non-defibrillation proof)
Operating mode.....Spot checking
Degree of protection against hazards of explosion.....Ordinary equipment :Note protected
Equipment type.....Fingertip oximeter

5.2 Measurement Specifications

Spo2 declared accuracy

Range(σ*).....70%~99% ± 2digits
0%~69%:unspecified
Resolution.....1%
Update Period.....1s
Averaging Time.....8s

PR declared accuracy

Range(σ*).....25~250: ± 3 digits
Resolution.....1bpm
Update Period.....1s
Averaging Time..... 8s

5.3 Power Requirements

Specification of batteries.....Two 1.5V(AAA)
Operatin voltage.....DC 2.5-3V

5.4 Enivornmental Specifications

Temperature

Operating.....+41° to +104° F/5° to +40℃
Storage/Transportation:.....-4° to +140° F/-20 to +60℃

Humidity

Operating.....10~95%,noncondensing
Storage/Transportation.....10~95%,noncondensing

Atmosphere Pressure

Operating.....70~106kpa
Storage/Transportation.....50~107.4kpa

5.5 Physical Specificaions

Width x Height x Depth.....About 33x36x58mm(For FS10C,FS20C,FS10D,FS20D, FS10E,FS20E,FS10F,FS20F,FS10I,FS20I,FS10K,FS20K, FS10L,FS20L,FS10M,FS20M,FS10N,FS20N)
About 37x31x63mm(For FS10A,FS20A,FS10B,FS20B)

Weight.....About 60g(including the batteries)

5.6 Display

	FS10	FS20
Display type	LED	OLED, 0.96", 128×64 pixel
Display content	SpO2%,Pulse rate,Battery indicator, Bar graph	SpO2%, Pulse rate, Battery indicator, Bar graph, Pulse waveform, Heart beat mark

5.7 LED Wavelengths

Probe LED Specifications

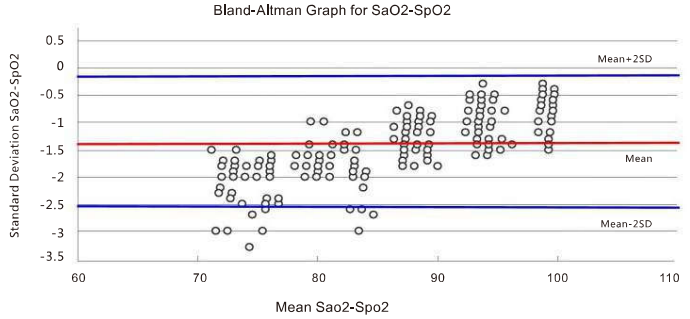
	Wavelength	Radiant Power
RED	660±6nm	1.8mW
IR	905±10nm	2.0mW

6.Technical Description

The below table shows statistic conclusion of an invasive controlled desaturation study which guided by"ISO 80601-2-61,Annex EE,Guideline for evaluating and documenting SpO2 Accuracy in human subjects".The statistic result displayed the accuracy distribution between the range of 70%~100%,which may helpful to user.

Bias Analysis / SpO2-Pulse Oximeter	SaO2-Radiometer ABL800 FLEX-CO-Oximeter			
	70-80(%)	80-90(%)	90-100(%)	70-100(%)
Mean Bias(Bs)	1.94	1.45	0.89	1.4
Precision(Sres)	2	1.55	0.98	1.53
Accuracy(Arms)	1.98	1.53	0.96	1.52

The below is the Bland-Altman graphical plot of samples from invasive controlled desaturation study.



7.Maintenance,cleaning,Disinfection

7.1 Maintenance

Keep your equipment and accessories free of dust and dirt, and follow these rules:

A. Please clean the equipment before use according to chapter 6.2; Remove the batteries inside the battery cassette if the equipment will not be operated for a long time;
B. Replace the batteries in time when the battery voltage indicate lamps were empty;
C. It is recommended that the equipment should be kept in a dry environment with no corrosive gases and good ventilation anytime. The moisture and high-light environments will affect its lifetime and even might damage the equipment.
D. It is best to preserve the product in a place where the temperature is between -20 to 60℃ and the relative humidity is less than 95%.
E. The packed equipment can be transported by ordinary conveyance. The equipment can not be transported mixed with toxic, harmful, corrosive materials.

WARING:

No modification of this equipment is allowd.

7.2 Disposal

Dispose of the pulse oximeter in accordance with local envionment and waste disposal laws ahd regulations.

8.Cleaning/Disinfection

CAUTIONS

- Never immerse or soak the oximeter.
- We recommend that the oximeter be cleaned and disinfected after use every time or determined by your hospital's policy,to avoid long term damage to the oximeter.
- Never use cleaning agents/disinfectants other than the recommended.
- The sensor component is not cleaned and disinfected during testing.

8.1 Cleaning

The recommended cleaning agents include: water

A. Shut down the pulse oximeter and remove the battery.
B. Clean the oximeter with cotton or soft cloth moistened with water.
C. After cleaning,wipe off the water with a soft cloth .
D. Allow the oximeter to air dry.

8.2 Disinfection

The recommended disinfectants include:ethanol 70%,isopropanol 70%.

A. Shut down the pulse oximeter and remove the battery.
B. Clean the oximeter as instructed above.
C. Disinfect the oximeter with cotton or soft cloth moistened with one of the recommended disinfectants.
D. After disinfection, be sure to wipe off the disinfectant left on the oximeter with a soft cloth moistened with water.
E. Allow the oximeter to air dry.

9.Accessories

- One lanyard
- Two AAA batteries
- One user manual
- One certificate card

Note:

For particular configuration of accessories please refer to the product package list.

10.Troubleshooting

10.1 Troubleshopting

WARNINGS :

- Necessary maintenance must be performed by qualified service personal ONLY.
- Users are NOT permitted to maintain the equipment by themselves.
- There are NO replaceable components in the equipment.

Trouble	Possible Reason	Solution
The Oximeter can't turn to measure mode	The batteries are completely exhausted	Please replace batteries
	An incorrect battery installation	Verify and correct the batteries installation
	The oximeter breakdown	Please contact local service
The display is off suddenly	The device will turn into sleep mode automatically if there is no signal in 8 seconds	Press the button again to reactivate the oximeter
	The batteries are completely exhausted	Replace batteries
The Spo2 and Pulse Rate display unstable	The luminescent or photoelectric window is sheltered by some object	Check the luminescent and photoelectric window
	Excessive movement	Stop moving finger,hand and body
	The finger is not placed inside deep enough	Place the finger properly and try again.
	Finger size is not within the recommended range	Change another finger
	Excessive ambient light	Avoid the excessive light
	Pulse rate value of the cyclical fluctuations	The measurement is normal,and the patient is arrhythmia.
The Spo2 and PR are not displayed normally	The finger is not properly positioned	Place the finger properly and try again.
	The patient's SpO2 is too low to be detected	Try again,GO to a hospital for a diagnosis if you are sure the device works all right

Appendix A

The equipment complies with the requirement of standard EN60601-1-2 "Elecrtromagnetic Compatibility-Medical Electrical Equipment".

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 ensure 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	±8kV contact ±8kV, ±15kV air	±8kV contact ±8kV, ±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%
Power frequency (50/60Hz) magnetic field	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

The Pulse Oximeter is intended for use in the electromagnetic environment specified below.
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHZ	3 Vrms 150 kHz to 80 MHZ	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. $d=[\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7GHz	10V/m	$d=[\frac{3.5}{E_1}]\sqrt{P}$ 80MHz to 800 MHZ $d=[\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.7 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). Field strengths from fixed RF transmitters, as determined by an electromagneti.

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.

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Pulse 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 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	

Recommended separation distances between portable and mobile RF communications equipment and the Medical 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 Medical Pulse Oximetercan 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 power 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	0.04	0.07
0,1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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 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.

11. Applicable models

FS10A,FS20A,FS10B,FS20B,FS10C,FS20C,FS10D,FS20D,FS10E,FS20E,FS10F,FS20F,FS10I,FS20I,FS10K, FS20K,FS10L,FS20L,FS10M,FS20M,FS10N,FS20N

Notes:
1. The illustrations used in this manual may differ slightly from the appearanceof the actual product.
2. The specifications are subject to change without prior notice.

12. FCC statements

① Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
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
(2) this device must accept any interference received, including interference that may cause undesired operation.

② 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 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.

③ RF warning for Portable device:
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

13.Using APP

① Turn on the Oximeter by inserting finger.

② Enable your phone's Bluetooth.

③ Run App, select the device. For the initial use, you need to add the new device.