

FINGER PULSE OXIMETER FOX-250

USER'S MANUAL

Date: March, 2020

Rev.0

Section 1 Safety

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

- Do not attempt to service the pulse oximeter. Only qualified service personnel should attempt any needed internal servicing.
- Do not use the oximeter in situations where alarms are required.
- 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 reasons will cause interference:
 - High-frequency electrosurgical
 - 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 oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

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

WARNING: Do not use the pulse oximeter in an MRI or CT environment.

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.

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








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

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

1.3 Definitions and Symbols

Symbol	Description	Symbol	Description
	Type BF Equipment		Manufacturer
	Refer to the instruction manual /booklet		When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling
	Serial NO*		No SpO2 Alarm
	The CE labelling certifies the product complies with requirements of Directive 93/42/EEC on medical products.	Note	The important information you should know
Caution	The information you should know to protect the equipment from possible damage	Warning	The information you should know to protect patients and medical staff from possible injury

Section 2 Introduction

2.1 Brief Device Description

The 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 minish 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, pediatrics, ect), Oxygen Bar, social medical organizations, physical care in sports and etc.

2.2 Intended Use

This product is suitable for the hospital (including surgey, anedthesiology, paediatrics, and clinical use), oxygen bar, sports health(using them before or after sports, do not advise using them during the movement), and community health care, ect.

2.3 Contraindication

It is not for intensive care and person whose finger is injured.

2.4 Product Features

- Lightweight for carrying and Easy-To-Use.
- Manually adjust the direction of interface .
- LED display, simultaneous display for testing value and plethysmogram.
- Real-time spot-checks.
- Low Battery voltage indicator.
- Automatically standby or sleep.

Section 3 Installation, Setup, and Operation

3.1 Description of the Front Panel (as FIG.1)

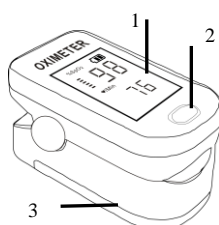


FIG.1 Parts of front & back panel

Table 1 Part Definition and Description

Item	Name	Description
1	LED Panel	Display the SPO2/PR data & Bargraph
2	Key	Start the working state
3	Battery Compartment	2*AAA 1.5V Alkaline battery

3.2 Display

After switch on, the LED display is as follows (as FIG.2):

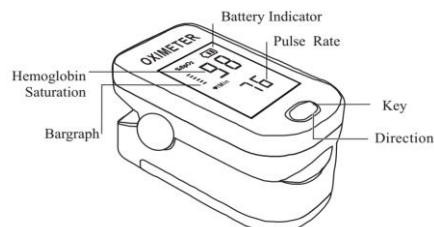


FIG.2 LED display

3.3 Operation

3.3.1 Install battery

Installing two AAA batteries into battery cassette in correct polarities and cover it (as FIG.3)

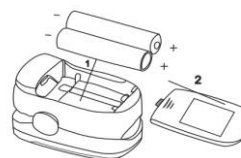


FIG.3

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

3.3.2 Turn the 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 (as FIG.4), then releasing the clamp. Press the key, oximeter will go into the working state.



FIG.4

The oximeter will automatic standby or go asleep after 8 seconds without finger in.

3.3.3 Read correspondent data from display screen.

3.3.4 Display Description of LED

The display interface of "LED" can rotate two directions after pressing the key for less than 0.5s. It is shown as below (as FIG. 5):

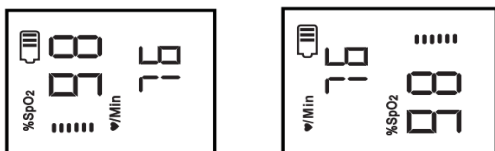


FIG.5

Note: when battery power is at lowest level, the battery capacity indicates symbol of "⊠" in LED, remind users of replacement of battery.

3.4 Install Hanging Rope

Let the thin end of the rope go through the hole, next let the big point of rope go through the thin rope hole, then tighten the rope (as FIG. 6).

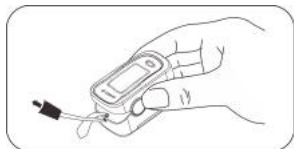


FIG.6 Install hanging rope

Section 4 Maintenance

4.1 Cleaning

Switch off the power and take out the batteries before cleaning, Cleaning exterior surface (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.

4.3 Warranty

The host product' design life is 2 years, and 1 years warranty. Under normal circumstances, the malfunction of the product during the warranty period (from the date of purchase) should be sent back to the company for maintenance, and our company is responsible for all maintenance costs (users should cover the freight themselves). Outside the warranty period, our company shall charge some maintenance fee (users should cover the freight themselves) if the product has broken down and is sent back for maintenance . The battery is beyond the scope of the warranty. If you have the purchase and sale contract, the costs of the maintenance shall be in accordance with the purchase and sale contract execution. Our company can provide the designated qualified technical personnel with files listed GB9706.1 6.8.3 C. Besides, it is recommended that users should use them no more than five years. And over the using life, the using risks may increase due to the equipment' aging.

4.4 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 -20 - 55 °C and humidity is 10%-95%..
- 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.

4.5 Troubleshooting

Table 4.5 Troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemoglobin 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.

Oxyhemoglobin 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.
The oximeter can't go into the working state	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 automatically standby or sleep when no signal is detected longer than 8 seconds. 2. Power quantity of the batteries is exhausted.	1. Normal. 2. Replace the batteries.

4.6 Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect or decontaminate the device appropriately before disposing of it in accordance with your country's law for equipment containing electrical and electronic parts.

Section 5 Specification

Physical Characteristics

Machine Dimensions: 57mm (L) * 31mm (W) * 30.5mm (D)

Machine Weight -approx: 54 g (including 2 * AAA battery)

Classification

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type BF equipment

EMC: Type B class I

Mode of operation: Continuous Operation

Enclosure Degree of ingress protection: IP22

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

Power

Internal:	2*AAA 1.5v alkaline battery
Power Consumption:	Smaller than 30mA(Normal)

Environmental

Operating Temperature:	5°C to 40°C
Storage Temperature:	- 20°C to 55°C
Relative Humidity:	15% to 85% non-condensing

Electronics Parameters

Parameter	Value	
Hemoglobin saturation Display	35-100%	
Pulse rate Display	25-250 BPM	
Perfusion Index Display	0-30%	
Resolution	Hemoglobin Saturation	1%
	Pulse rate	1 BPM
Measure Accuracy	Hemoglobin Saturation	2% (80% - 100%)
		3% (70% - 80%)
	Pulse rate	Unspecified (≤70%)
	Pulse rate	2 BPM

Technical information is subject to change without notification to allow for updates.

- This device complies with EU Directive 93/42/EEC concerning medical devices, and the DIN EN ISO 13485:2016 standard.

- This device complies with IEC 60601-1-2: 2014, ISO 80601-2-61: 2011 Clause 202, IEC 60601-1-11: 2010 Clause 12.

- Manufacturer: Promise Technology Co., Ltd.

3/F, East-Asia Building, Jida Jiuzhou Avenue, 519015 Zhuhai, Guangdong,

PEOPLE'S REPUBLIC OF CHINA

- EC-Representative: Shanghai International Holding Corp. Gmbh (Europe)

Eiffestraße 80 20537 Hamburg GERMANY

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