

FINGER PULSE OXIMETER FOX-350

USER' S MANUAL

Date: March, 2020

Rev.0

Section 1 Intended Use and Safety

1.1 Intended Use

This product is suitable for the hospital (including surgery, anesthesiology, 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.

1.2 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 user's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status and correct alignment every hour.
- SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area if necessary.
- The following reasons will cause interference.
 - Improper placement or alignment.
 - Placement of a sensor on an extremity with a high pressure cuff.
 - Extremely low perfusion.
 - The user has hypotension severe vasoconstriction severe anemia or hypothermia.
 - Excessive motion.
 - Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

1.3 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.
WARNING: This oximeter is not a Apnea monitor, should not be used for arrhythmia analysis.
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.

1.4 Definitions and Symbols

Symbol	Description	Symbol	Description
	Type BF Equipment		Information of manufacture, including name and address
	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*	Warning:	The information you should know to protect users from possible injury
Caution:	The information you should know to protect the equipment from possible	Note:	The important information you should know

Section 2 Introduction

2.1 Display Parameter and Brief Device Description

(Functional oxygen saturation), is the amount of oxyhemoglobin expressed as a percentage of the Functioning Hemoglobin. Functioning Hemoglobin is capable of carrying oxygen and includes oxygenated hemoglobin (HbO2) and deoxygenated hemoglobin (Hb).

PR(Pulse Rate), measured in beats per minute(bpm), is the frequency of heart beats.

PI(Perfusion Index) is the ratio of the pulsatile blood flow to the non-pulsatile static blood in peripheral perfusion. Perfusion index is an indication of the pulse strength at the sensor site.

Plethysmogram The amount of light absorbed by the varying quantities of arterial blood changes with the pulse beats, the waveform is named Plethysmogram, This waveform and its variation is used for assigning signal integrity, physiological and artifactual changes such as perfusion changes, dysrhythmia, motion artifact, and electrical interference.

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 reduce the influence of motion artifact and improve measurement accuracy of low perfusion.

Section 3 Installation, Setup, and Operation

3.1 Description of the Front and Back Panel (as Figure 3.1.1 and Table 3.1.1)



Figure 3.1.1 Parts of front & back panel

Table 3.1.1 Part Definition and Description

Item	Name	Description
1	Button	Start the working state and set parameters
2	OLED Panel	Display the SPO2/PR & Bargraph, Plethysmogram, PI
3	Battery Compartment	2xAAA 1.5V Alkaline battery

3.2 Install battery

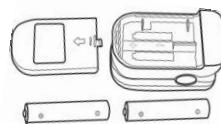


Figure 3.2.1

Installing two AAA batteries into battery cassette in correct polarities and cover it(as Figure 3.2.1).

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

3.3 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 Figure 3.3.1), then releasing the clamp.

Press the button, oximeter will go into the working state.

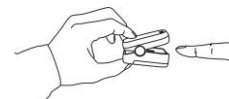


Figure 3.3.1

3.4 Read data from display screen

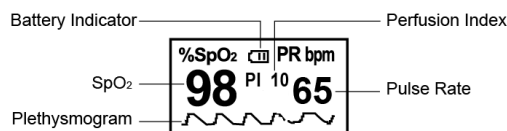


Figure 3.4.1 OLED display

The main screen can rotate four display directions after short press the button as shown below:

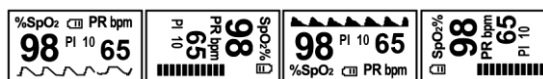


Figure 3.4.2

Note: when battery power is at lowest level, the battery capacity indicates

symbol of "□" in OLED, remind users of replacement of battery.

3.5 Operate the Menu

There are two ways to operate the button according to the pressing time: long-press is longer than **half a second** and short-press is shorter than **half a second**.

Short-press is used to select a item by moving a * to the line of this item, long-press is used to change the item's value, status, open a new page or make it take effect.

From the main screen, long-press on the button will make the oximeter display Settings Pages as shown in Figure 3.5.1 or Figure 3.5.2. Selecting "Page 1/2" or "Page 2/2" and long press will make this two pages display alternately.

Settings	
Page 1/2	*
Alm	on
Beep	off
Demo	off
Reset	OK
Brightness	4
Exit	

Figure 3.5.1

Settings	
Page 2/2	*
SpO2 Alm Hi	100
SpO2 Alm Lo	94
PR Alm Hi	130
PR Alm Lo	50
+/-	+
Exit	

Figure 3.5.2

The Items in Page1 are:

Items	Default	Options	Description
Alm	on	on, off	Turn on or off the sounds when the value if out of the limit set in page 2.
Beep	off	on, off	Set Pulse Beep on or off.
Demo	off	on, off	Enter Demo mode, long press to quit it.
Reset	OK	OK, Blank	Reset all settings as default value.
Brightness	4	1-5	Set the screen's brightness.
Exit	N/A	N/A	Return to the Main Screen or Enter Demo mode when it is selected as 'on'.

The Items in Page2 are:

Items	Default	Options	Description
SpO2 Alm Hi	100	50-100	The upper limit of SpO2.
SpO2 Alm Lo	94	50-100	The lower limit of SpO2.
PR Alm Hi	130	25-250	The upper limit of PR.
PR Alm Lo	50	25-250	The lower limit of PR.
+/-	+	+, -	Increase or decrease the number.
Exit	N/A	N/A	Return to the Main Screen.

3.6 Turn off the Oximeter

The oximeter will turn off automatically after 8 seconds after removing the finger out of the device.

Section 4 Maintenance

4.1 Cleaning

Switch off the power and take out the batteries before cleaning. 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

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

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. 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's 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 users.
- 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
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Oxyhemoglobin or heart rate can not be shown normally.	1. Finger is not plugged correctly. 2. User'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 user's body is in movement status.	1. Retry by plugging the finger. 2. Try not to move, Let the user 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) x 31mm (W) x 30.5mm (D)

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

Classification

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type BF equipment

EMC: Group 1 Class 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 alkaline battery
Power Consumption:	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	
SpO2(Oxygen saturation)	35-100%	
PR (Pulse Rate)	25-250 bpm	
Resolution	SpO2 (Oxygen saturation)	1%
	PR (Pulse Rate)	1 bpm
	PI (Perfusion Index)	0.1% (<10%) 1% (10% - 20%)
Measure Accuracy: A_{rms} *	SpO2(Oxygen saturation)	2% (80% - 100%) 3% (70% - 80%) Unspecified (<70%)
	PR (Pulse Rate)	2 bpm
	PI (Perfusion Index)	1%

* A_{rms} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- Arms of the reference measurements in a controlled study.

Applicable models

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.

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