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FINGER PULSE OXYMETER USERS MANUAL V1.1

Section 1 Safety

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

- There are no alarms in this device.
- 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 every hour.
- 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 Oxymeter 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 Oxymeter in an MRI or CT environment.
WARNING: This Oxymeter 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.
NOTE: Inaccurate Respiration Rate (RR) measurements may be caused by: Improper placement or alignment, Low perfusion, Motion, During arrhythmia.

1.3 Definitions and Symbols

Symbol	Description	Symbol	Description
	Type BF Equipment.		Information of manufacturer, 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.
SN	Serial NO.	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.

Section 2 Introduction

2.1 Display Parameter and Brief Device Description

SpO2 (Functional oxygen saturation), is the amount of oxy-hemoglobin 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.

RR (Respiratory Rate), measured in respirations per minute (rpm), the act of breathing is controlled by the brain, which tells the body to breathe based on oxygen and carbon dioxide levels in the blood, and certain factors, such as exercise, drugs, and alcohol, can affect a person's breathing rate. An abnormally high or low respiratory rate may indicate certain medical conditions such as bradypnea, apnea, or tachypnea.

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

The Pulse Oxymeter, based on all digital technology, is intended for non-invasive 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.

2.2 Intended Use

This product is suitable for the clinic, oxygen bar, sports health (using it before or after sports, not advised using them during the movement), and community health care, etc.

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)

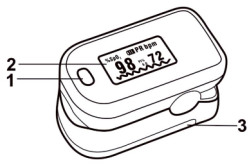

Figure 3.1.1 Parts of front & back panel

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 & Bar-graph, Plethysmogram, PI.
3	Battery Compart-ment	2xAAA 1.5V Alkaline battery

3.2 Install battery

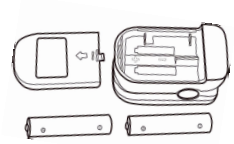

Figure 3.2.1

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

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

3.3 Turn the Pulse Oxymeter "ON"

Put one of fingers into rubber hole of the Oxymeter (as much area as possible) with nail surface upward (as Figure 3.3.1), then release the clamp.

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

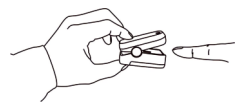

Figure 3.3.1

Keep your tested hand still during measurement.

3.4 Read corresponding data from display screen

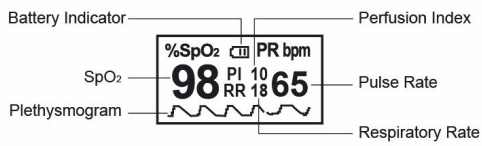

Figure 3.4.1 OLED display

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

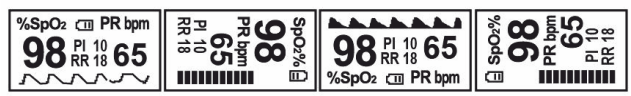

Figure 3.4.2

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 Oxymeter 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.

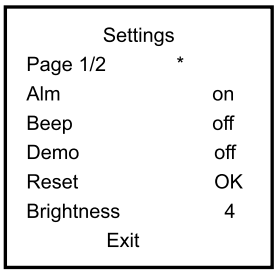

Figure 3.5.1

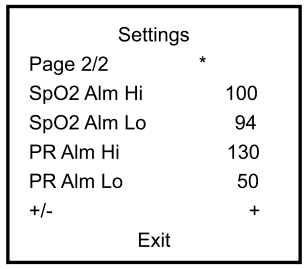

Figure 3.5.2

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 Oxymeter

The Oxymeter 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

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's design life is 2 years, with 1 year warranty. Battery is not included in the scope of the warranty.

Besides, it is recommended that users should use the device for not more than four years. as the risk may increase due to the long term use.

4.4 Maintenance

- Replace the batteries timely when battery indication is low. Clean surface of the Pulse Oxymeter before it is used in diagnosis for patients.
- Remove the batteries inside the battery cassette if the Oxymeter 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 Oxymeter 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 Oxymeter might be damaged.	1. Please replace batteries. 2. Please reinstall the batteries.
The screen is 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 disposal 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
RR (Respiration Rate)		10-70 rpm
Resolution	SpO2 (Oxygen saturation)	1%
	PR (Pulse Rate)	1 bpm
	PI (Perfusion Index)	0.1% (<10%) 1% (10% - 20%)
	RR (Respiration Rate)	1 rpm
Measure Accuracy: Arms*	SpO2 (Oxygen saturation)	2% (80% - 100%) 3% (70% - 80%) Unspecified (<70%)
	PR (Pulse Rate)	2 bpm
	PI (Perfusion Index)	1%
	RR (Respiration Rate)	2 rpm

*Arms 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

OXYGARD PULSE OXYMETER OG 05

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