Instruction Manual

Fingertip Pulse Oximeter

1. General Description

Haemoglobin Saturation is percentage of Oxyhemoglobin (HbO2) capacity, compounded with oxygen, by all combinativable haemoglobin (Hb) obin (HbO2) capacity in blood. In other words, it is consistence of Oxyhemoglobin in blood. It is a very important ecological parameter for Respiratory circulation System. Many respiratory diseases can result in haemoglobin Saturation being lowered in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human haemoglobin saturation might be reduced: Automatic Organic Regulation Malfunction caused by Anesthesia, Intensive Postoperative Trauma, hurts resulted in by some medical examination and etc. In the situation, illnesses, such as light head, asthenia, vomitory and etc, might happen to patients and even endanger the patient's life. Therefore, it is very important to know Hemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in time.

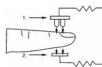
The Fingertip Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a screen will directly show display of measured value hemoglobin Saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

2. Measurement principle

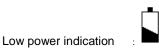
Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(R Hb) and Oxyhemoglobin (O2 Hb) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) 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 two groups of LEDs through process in electronic circuits and microprocessor.

Diagram of Operation Principle



- 1. Glow and Infrared-ray Emission Tube
- 2. Glow and Infrared-ray Receipt Tube
- 3. Technical Specifications 3.1 Display type: OLED display SPO2 display range: 0-99% PR display range: 30-254 BPM PR display mode: bargraph



3.2 Power requirements: Two AAA 1.5V Alkaline Battery

3.3 Power consumption: less than 40mA 3.4 Resolution: ±1% for SPO2 and ±1BPM for Pulse rate

3.5 Measurement Accuracy:

SPO2: 80%--99%, ±2%; 70%--80%, ±3%; ≤70% no definition.

PR: 30-235 BPM, ±2% or 2 BPM

3.6 Measurement Performance in Weak Filling Condition: required the test equipment (BIO-TEK INDEX Pulse Oximeter tester) the pulse wave is available without failure when the simulation pulse wave amplitude is at 6%.

3.7 Interference Resistance Capacity against Ambient Light: Device work normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester 3.8 It is equipped with a function switch, through which the Oximeter can be powered off in case no finger is the Oximeter longer than 8 seconds.

4. Product Properties

4.1 Operation of the product is simple and convenient

4.2 The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying

4.3 Power consumption of the product is low and the two originally-equipped two AAA batteries can be operated continuously for 30 hours.

4.4 Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the Oximeter might be influenced.

4.5 The product will automatically be powered off when no signal is in the product for longer than 8 seconds.

5. Product Operation Scope

The fingertip Oximeter can be used to measure human Haemoglobin Saturation and heart rate through finger. The product is suitable for use in family, hospital (including clinical use in internist/surgery, Anaesthesia, paediatrics, intensive care and etc.) Oxygen Club, social medical organizations, physical care in sports (It can be used before or after sports. Operation in sport procedure is not recommended) and etc.

The product is not suitable to monitor patient continuously.

6. Operation Instructions

6.1 Installing two AAA batteries into battery cassette before covering its cover.

6.2 Nip the clamp as diagram

6.3 Plug one of fingers into rubber hole of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp

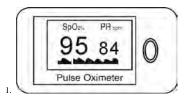
6.4 Press the switch button once on front panel.

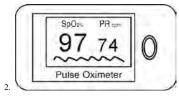
6.5 Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status

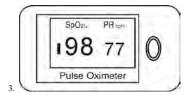
6.6 Read correspondent datum from display screen.

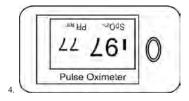
6.7 Six display modes

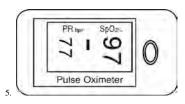
After turn on the oximeter, each time you press the power switch, the oximeter will switch to another display mode, there are 6 display modes shown as follows:

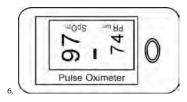












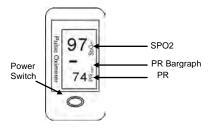
When you press the power switch for a long time (more than one second), the brightness of the oximeter will be changed by degrees, there are 10 levels on brightness; the default level is level four.

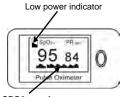
Declaration: Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using alcohol before and after each test. (The rubber inside of the Oximeter belongs medical rubber, which has no toxin, and no harmful to the skin of human being).

When your finger is plugged into the Oximeter, your nail surface must be upward.



7. Brief Description of Front Panel





SPO2 waveform

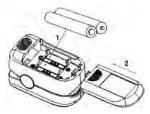
It is apparent the heart rate bargraph display corresponds with pulse rate.

8. Product Accessories

8.1 One hang lace8.2 Two batteries8.3 One User manual

9. Battery Installations

9.1 Put the two AAA batteries into battery cassette in correct polarities.9.2 Push the battery cover horizontally along the arrow shown as below:



Notes: Battery polarities must be correctly installed. Otherwise, damage might be caused to device.

Please put or remove batteries in right order, or is likely to damage the device bracket.

Please remove the battery if the Oximeter will not be used for long time

10. Hang Lace Installations

10.1 Thread thinner end of the hang lace through the hanging hole

10.2 thread thicker and of the lace through the threaded end before pulling it tightly

11. Maintenance and Storage

11.1 Replace the batteries timely when low voltage lamp is lighted

11.2 Clean surface of the fingertip Oximeter before it is used in diagnosis for patients

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

11.4 It is best to preserve the product in a place where ambient temperatures $-10\text{-}40~^{\circ}\text{C}$ (14-104 $^{\circ}\text{F}$) and humidity is 10%-80%

It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.

Please follow the law of the local government to deal with used battery

12.Possible Problems and resolutions

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Problems	Possible reason	Solution	
Oxyhemoglobi nor heart rate can not be shown normally	1. Finger is not plugged correctly 2. Patient's Oxyhemoglobi n value 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	
Oxyhemoglobi nor heart rate is shown unstably	 Finger might not be plugged deep enough Finger is trembling or patient's body is in movement status 	1. Retry by plugging the finger 2. Try not to move	
The Oximeter can not be powered on	 Power of batteries might be inadequate or not be there at all Batteries might be installed incorrectly The Oximeter might be damaged 	 Please replace batteries Please reinstall the batteries Please contact with local customer service centre 	
Indication lamps are suddenly off	 The product is automatically powered off when no signal is detected longer than 8 seconds Power quantity of the batteries is started being inadequate 	1. Normal 2. Replace the batteries	
"Error3" or "Error4" Displayed on screen	 Low power Receiving tube being shielded or damaged together with broken connector. Mechanical 	 Change new battery Please contact with local customer service center Please 	

	Misplace for receive-emissi on tube 4. Amp circuit malfunction.	contact with local customer service center 4 Please contact with local customer service center
"Error7" displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunction.	 Please change battery Please contact with local customer service center Please contact with local customer service center

13. Detailed descriptions of product functions:

13.1Display mode: OLED 13.2 SPO2: Measurement range:: 70-99% Accuracy : ±2% on the stage 80%-99%;±2% on the stage 70%-80%; 13.3 Pulse:

of

of

Measure range: 30-235 BPM

Accuracy: ±2 BPM or ±2% (larger) 13.4 Pulse Intensity

Bargraph Indication

13.5 Power Requirements:

Two AAA alkaline Batteries

13.6 Battery life

Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours. 13.7 Outline dimension: Length: 58mm Width: 32mm Height: 34mm Weight: 50g (including two AAA batteries) 13.8 Environment requirements: Operation Temperature: 5-40°C Storage Temperature: -10-40°C Ambient Temperature: 15%-80% in operation 10%-80% in

storage

Declaration: EMC of this product comply with IEC60601-1-1-2 standard.

14 .Symbol Definitions

Symbol	Definition
<u>*</u>	The equipment type is BF
Λ	Refer to user manual before application
%SpO ₂	Hemoglobin saturation
BPM	Heart rate (BPM)
	Low power indication
SN	Serial No