User manual

MNPG48-03 09/04/2020
Fingertip Pulse Oximeter

I-TECH MEDICAL DIVISION

FOX-300

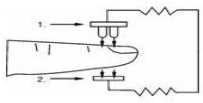
General Description

Hemoglobin Saturation is blood oxyhemoglobin (HbO2) percentage, that is the total hemoglobin quantity able to combine with oxygen (Hb) in blood. In other words, it is the Oxyhemoglobin consistency in blood. It is a very important ecological parameter for respiratory circulation system. Many respiratory diseases can result in hemoglobin saturation decreasing in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human hemoglobin saturation might be reduced: automatic organic regulation malfunction caused by anesthesia, intensive postoperative trauma, hurts resulted by some medical examination and etc. In these situation, illnesses, such as dizziness, asthenia, vomit 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, easy operation and being portable. It is only necessary for patient to put one of his fingers into the fingertip photoelectric sensor and a display screen will directly show measured value of hemoglobin saturation. Clinical experiments evidenced its high accuracy and repeatability.

Measurement principle

Oximeter principle 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 (RHb) and oxyhemoglobin (O2 Hb) in glow and near-infrared zones.
Operation principle of the instrument is photoelectric oxyhemoglobin inspection technology adopted in accordance with capacity pulse scanning and recording technology, so that two lights beams of different wavelength(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 and it will be shown on oximeter display.

Diagram of Operation Principle



1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube

Precautions for use

1. Do not use the pulse oximeter in an MRI or CT environment.
2. Do not use the pulse oximeter in situations where alarms are required. The device has no alarms.
3. Explosion hazard: do not use the pulse oximeter in an explosive atmosphere.
4. The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
5. Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
6. Before use, carefully read user manual.
7. The pulse oximeter has no SpO2 alarms; it is not for continuous monitoring, as indicated by the symbol.
8. 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 4 hours.
9. Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, immersing the sensor in liquid, significant levels of dysfunctional hemoglobin (such as carbonxy- hemoglobin or methemoglobin), intravascular dyes such as indocyanine green or methylene blue.
10. SpO2 measurements may be adversely affected in the presence of high ambient light (protect sensor area from direct sunlight), excessive patient movement, venous pulsations, placement of a sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line, patients with hypotension, severe vasoconstriction, severe anemia or hypothermia, in the presence of cardiac arrest or shock.
11. Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

Product subject to WEEE regulations concerning separate waste collection.

General features

Medical device features in small volume and low power consumption and it is used to measure human hemoglobin saturation and cardiac rate.
It's equipped with 2 batteries AAA size that can be operate continuously for 30 hours.
Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the oximeter might be influenced.
The product will automatically be powered off when no signal will be shown in the product for longer than 8 seconds.

Purpose

FOX-300 is a portable oximeter (non-invasive) used to measure blood oxygen saturation level (SpO2) and cardiac pulsation. The product is suitable for hospital first aids or dentists.
The product is not suitable to monitor patient continuously.

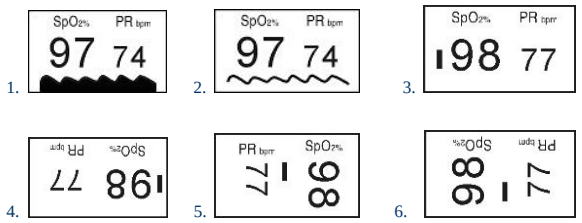
The device doesn't need any calibration or maintenance with the exception of batteries change.

Operating instructions

1. Installing two batteries AAA size into battery compartment as indicated in paragraph "Battery installation".
2. Introduce the finger in fingertip pulse oximeter (see image below).
3. Press the switch button once on front panel.
4. Avoid finger movements when oximeter is working. Your body is not recommended in moving status.
5. Read correspondent datum from display screen choosing your favorite display modes (following image).

ATTENTION! After turn on the oximeter, each time you press the power switch, the oximeter will switch to another display mode.

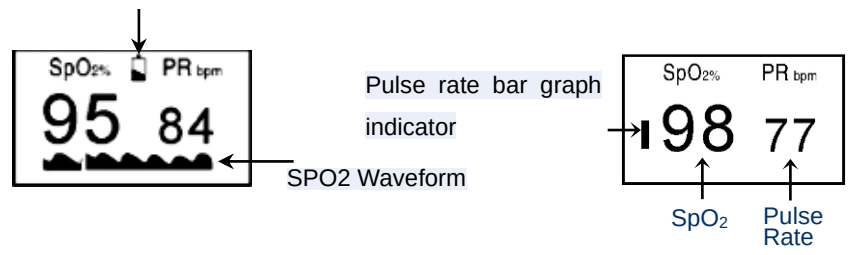
6 display modes:



Brightness regulation. 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.
Cleaning: 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.

When your finger is plugged into the Oximeter, your nail surface must be upward as shown here below.

Front panel description



Pulse rate bar graph flashes in relation with pulse rate shown on display.

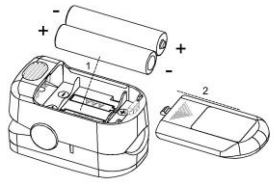
Accessories

1. One hang lace.
2. Two batteries AAA Size.
3. User manual.

Battery installation

1. Push the battery cover horizontally along the arrow shown as below.
2. Insert two batteries AAA size according to correct polarity indicated in the battery compartment.
3. Close battery cover of battery compartment.

Notes: battery polarities must be correctly respected in order to avoid device damages. Please remove the battery if FOX-300 will not be used for long time.



Hang lace installation

1. Thread hang lace end through the hanging hole.
2. Close hang lace around itself.

Maintenance and Storage

1. Replace the batteries timely when low voltage lamp is lighted.
2. Clean fingertip oximeter surface before each test.
3. Remove batteries from battery compartment if the device will not be operated for a long time.
4. Preserve product in a place where ambient temperature is between -20°C and +55°C and relative humidity less than 93% .
5. It is recommended keeping the product in a dry environment. A wet ambient might

damage the product.

6. Product subject to WEE regulations.

Calibration (only authorized distributors)

1. Functional tester cannot be used to assess oximeter accuracy and calibration.
2. Index 2 made by Bioteck company is a functional tester. Set Tech to 1, R curve to 2 then user can use this particular calibration curve to measure oximeter.
3. Test method used to assess SpO2 accuracy is a clinical testing. Arterial hemoglobin and oxygen saturation levels have to be compared to the levels determined from arterial blood sampling with a CO-oximeter.

Declarations

FOX-300 complies with IEC 60601-1-2 norm pour EM emission.

The materials which user can come into contact is no toxicity and no action on tissues, comply with ISO10993-1, ISO 10993-5 and ISO 10993-10.

Technical specifications

1. Display:

OLED Display.

2. SpO2:

measurement range ：70-99%;

accuracy： 80%-99%, ±3%; 70%-80%, ±3%；≤69% no definitions.

3. Pulse rate:

measurement range: 30 ~ 235 BPM;
accuracy: 30 ~ 99bpm, ± 2bpm; 100 ~ 235bpm, ± 2%;
pulse intensity: Bar graph indicator.

4. Power requirements:

two alkaline batteries AAA Size;

power consumption: less than 30 mA;

low power indication

battery life: batteries could be continuously operated as long as 30 hours.

5. Dimension:

length: 58 mm;

width: 32 mm;

height: 37 mm;

weight: 33 g (batteries excluded).

6. Environment requirements:

work temperature: 5～ 40 °C;

storage temperature: -20～55 °C;

relative humidity: ≤80%in function, without condensation

≤93% in storage, without condensation.

7. Measurement performance in low perfusion condition: use the test equipment (BIO-TEK INDEX Pulse Oximeter tester) pulse wave is available without failure when the simulation pulse wave amplitude is at 0.6%.

8. Interference resistance capacity against ambient light: device works normally with mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

EMC Table

Guide and manufacture's declaration– electromagnetic emissions

FOX-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the *Pulse Oximeter* should assure that it is used in such environment.

Emission test	Compliance	Electromagnetic environment - guide
Emissions RF CISPR 11	Group 1	FOX-300 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.
Emissions RF CISPR 11	Class B	FOX-300 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.

POSSIBLE PROBLEMS AND SOLUTIONS

Problem	Possible reason	Solution
SpO_2 or Pulse Rate (PR) cannot be shown normally	1. Finger is not introduced correctly. 2. Patient's oxyhemoglobin value is too low to be measured.	1. Try again by introducing the finger . 2. Make more attempts in order to make sure about no problem existing in the product. In doubt consult your own doctor.
SpO_2 or PR is shown unstably.	1. Finger might not be introduced deep enough. 2. Finger is trembling or patient's body is on the move.	1. Try again by introducing the finger. 2. Try not to move.
Finger pulse oximeter cannot be powered on. .	1. Check battery indication 2. Batteries might be installed incorrectly. 3 Finger pulse oximeter might be damaged.	1. Please replace batteries. 2. Please reinstall batteries. 3. Please contact manufacturer/distributor.
Display suddenly power off.	1. The product is automatically powered off when no signal is detected longer than 8 seconds. 2. Low power/ Discharged battery.	1. Correct working. 2. Replace batteries.
"Error3" or "Error4" displayed on screen.	1. Discharged battery. 2. Receiving tube being shielded or damaged together with broken connector. 3.Internal electronics damaged.	1. Replace battery. 2. Clean sensor area with alcohol. Please contact manufacturer/distributor. 3. Clean sensor area with alcohol. Please contact manufacturer/distributor.
"Error7" displayed on screen.	1. Discharged battery. 2. Emission tube damaged. 3. Internal electronics damaged.	1. Replace battery. 2. Clean sensor area with alcohol. Please contact manufacturer/distributor. 3. Clean sensor area with alcohol. Please contact manufacturer/distributor.

Symbol Definitions

Symbol	Definition
	Device with type BF applied parts
	Attention, refer to user manual before application
SpO_2%	Hemoglobin saturation
BPM	Cardiac rate (BPM)
	Low power indication
	Not suitable to monitor patient continuously
SN	Serial No
	Month-Year of production
	Directive WEE

CE 0123 Device in compliance with the 93/42/EEC (as amended by 2007/47/EC)

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

Room 4104, No. A12 Yuquan Road, Haidian District, 100143 Beijing, PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corporation GmbH (Europe), Eiffestraße 80, 20537 Hamburg, Germany.

Distribuited by: I.A.C.E.R. Srl Via S.Pertini 24/a – 30030 Martellago (VE) Italy

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