

## FL400 Pulse Oximeter User Manual

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### Instructions to User

Dear Users, thank you very much for purchasing our product.

The Manual is written for the current Pulse Oximeter. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the Manual very carefully before using this equipment. These instructions describe the operating procedures to be followed strictly, failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operating instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation(s), the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

This product is a pulse oximeter, and can be used repeatedly. Its' useful life is 3 years. If you have any questions regarding to the use of this product, please call us at 1-847-234-0754 Monday-Friday from 8:00 AM to 5:00 PM Central Time.

### WARNING:

- An uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier users. It is recommended that the sensor should not be applied to the same finger for over 2 hours.
- For the individual users, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.
- The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and/or the maintenance persons, can not stare at the light.
- Testee can not use enamel or other makeup.
- Testee's fingernail can not be too long.
- Finger should not be moving, it should be stationary while using this pulse oximeter, otherwise it will give inaccurate results
- This device is not intended to diagnose or treat any medical conditions or disease.
- It is intended for non-medical use in healthy individuals to monitor their pulse and blood oxygen levels during sports and aviation use only.
- People who need to monitor SpO2 and pulse rate measurements because of a medical condition should not use the FL400 and should consult with their physician.

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### 1 Safety

#### 1.1 Instructions for Safe Operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect the user's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in the User's Manual. Only accessories that are provided or recommended by the manufacture can be used with this device.
- This product is calibrated before leaving the factory.

#### 1.2 Warnings

- ☐ Explosive hazard—DO NOT use the oximeter in an environment with inflammable gas such as some ignitable anesthetic agents.
- ☐ DO NOT use the oximeter while the testee is being measured by MRI and/or CT.
- ☐ The A person who is allergic to rubber can not use this device.
- ☐ The disposal of scrap instruments and their accessories and packings (including batteries, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- ☐ Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
- ☐ Please don't measure this device with function test paper for the device's related information.

#### 1.3 Attentions

- ⚠ Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.

- ⚠ If the oximeter gets wet, please stop operating it.
- ⚠ When it is carried from a cold environment to a warm or humid environment, please do not use it immediately.
- ⚠ DO NOT operate buttons on the front panel with sharp materials.
- ⚠ High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection. Do not have the oximeter submerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- ⚠ When cleaning the device with water, the temperature should be lower than 60°C/140°F.
- ⚠ As to the fingers which are too thin or too cold, it would probably affect the normal measure of the users' SpO2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- ⚠ Do not use the device on infant or neonatal users.
- ⚠ The product is suitable for children above four years old and adults (Weight should be between 15kg/33lb to 110kg/242lb).
- ⚠ The device may not work for all users. If you are unable to achieve stable readings, discontinue use.
- ⚠ The update period of data is less than 5 seconds, which will vary changeable according to different individual pulse rate.
- ⚠ If some abnormal conditions appear on the screen during the test process, pull out the finger and reinsert to restore normal use.
- ⚠ The device has normal useful life for of three years since the first electrified use.
- ⚠ The hanging rope attached to the product is made from Non-allergic material, if particular group are sensitive to the hanging rope, stop using it. In addition, pay attention to the use of the hanging rope, do not wear it around the neck to avoiding cause harm to the user.
- ⚠ The instrument does not have a low-voltage alarm function, it only shows the low-voltage, please change the battery when the battery energy is used up.
- ⚠ The instrument does not have an alarm function. Do not use the device in situations where alarms are required.
- ⚠ Batteries must be removed if the device is going to be stored for more than one month, or else batteries may leak.
- ⚠ A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

### 1.4 Indication for Use

It is intended for non-medical use in healthy individuals to monitor their pulse and blood oxygen levels during sports and aviation use only. This device is not intended for continuous monitoring. The device can be multi-used. People who need to monitor SPO2 and pulse rate measurements because of a medical condition should not use the FL400 and should consult with their physician. This device is not intended to diagnose or treat any medical conditions.

### 2 Overview

The pulse oxygen saturation is the percentage of HbO2 in out of the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO2 more easily and accurately, our company developed the Pulse Oximeter. At the same time, the device can measure the pulse rate

#### 2.1 Classification:

Class II b, (MDD93/42/EEC IX Rule 10)

#### 2.2 Features

- Operation of the product is simple and convenient.
- The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying.
- Power consumption of the product is low and the two originally equipped AAA batteries can be operated continuously for 20 hours.
- The product will automatically be powered off when no signal is in the product within 5 seconds.
- The product will enter standby mode when no signal is in the product within 5 seconds.

#### 2.3 Environment Requirements

Storage Environment

- a) Temperature: 40°C~+60°C
- b) Relative humidity: ≤95%
- c) Atmospheric pressure: 500hPa~1060hPa

Operating Environment

- a) Temperature: 10°C~40°C
- b) Relative Humidity: ≤75%
- c) Atmospheric pressure: 700hPa~1060hPa

### 3 Principle and Cautions

#### 3.1 Principle of Measurement

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 (Hb) and Oxyhemoglobin (HbO2) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto a human nail tip through perspective clamp finger-type sensor. Then A measured signal can then be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

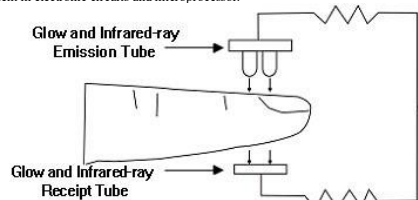


Figure 1 Operating principle

### 3.2 Caution

- The finger should be placed properly (see the attached illustration of this manual, Figure 7), or else it may cause inaccurate measurement.
- The SpO2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
- The SpO2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
- Make sure the optical path is free from any optical obstacles like rubberized fabric.
- Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
- Strenuous action of the subject or extreme electro-surgical interference may also affect the accuracy.

### 4 Technical Specifications

1) **Display Format:** Digital tube Display;

**SpO2 Measuring Range:** 0% - 100%;

**Pulse Rate Measuring Range:** 30 bpm - 250 bpm;

**Pulse Intensity Display:** collocation display

2) **Power Requirements:** 2 × 1.5V AAA alkaline battery, adaptable range: 2.6V-3.6V.

3) **Power Consumption:** Smaller than 25 mA.

4) **Resolution:** 1% for SpO2 and 1 bpm for Pulse Rate.

5) **Measurement Accuracy:** ±2% in stage of 70%-100% SpO2, and meaningless when stage being smaller than 70%. ±2 bpm or ±2% (select larger) for Pulse Rate.

6) **Measurement Performance in Weak Filling Condition:** SpO2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).

7) **Resistance to surrounding light:** The deviation between the value measured in the condition of man-made light, indoor natural light and that of darkroom is less than ±1%.

8) It is equipped with a switch function. The Oximeter can be powered off when the finger is off the oximeter within 5 seconds.

#### 9) Optical Sensor

Red light (wavelength is 660nm, 6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

### 5 Accessories

- One hanging rope;
- Two AAA batteries
- One Carrying case
- One User Manual.

### 6 Installation

#### 6.1 View of the Front Panel

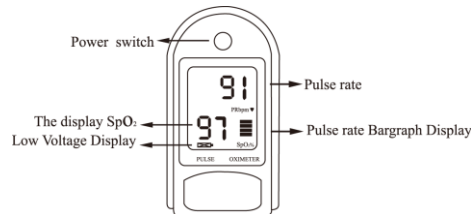


Figure 2 Front view

#### 6.2 Battery

- Step 1. Refer to Figure 3, and insert the two AAA size batteries properly in the right direction.
- Step 2. PLEASE LOOK AT + / - SIGN BEFORE INSTALLING THE BATTERY
- Step 3. Replace cover by sliding battery cover back on in line with inside tab.

⚠ Please take care when you insert the batteries as the improper insertion may damage the device.

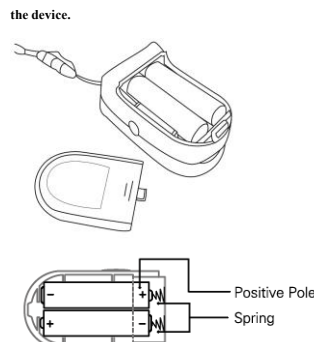


Figure 3 Batteries installation

### 6.3 Mounting the Hanging Rope

- Step 1. Put the end of the rope through the hole.
- Step 2. Put another end of the rope through the first one and then tighten it.



Figure 4 Mounting the hanging rope

### 7 Operating Guide

- 1) Insert the two batteries properly to the direction, and then replace the cover.
- 2) Open the clip as shown in Figure 5.



Figure 5 Put finger in position

- 3) Let the user's finger put go into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
- 4) Press the switch button once on the front panel.
- 5) Do not shake the finger and keep the user at ease during the process. Meanwhile, human body is not recommended to be in movement status.
- 6) Get the information directly from screen display.
- 7) In boot-strap state, press button, and the device is reset.

⚠ Fingernails and the luminescent tube should be on the same side.

### 8 Repairing and Maintenance

- Please change the batteries when the low-voltage is displayed on the screen.
- Please clean the surface of the device before using. Wipe the device with medical alcohol first, and then let it dry in air or clean it by dry clean fabric.
- Please take out the batteries if the oximeter is not in use for a long time.
- The best storage environment of the device is - 40°C to 60°C ambient temperature and not higher than 95% relative humidity.
- Users are advised to calibrate the device intermittently. It also can be performed at the state-appointed agent or just contact us for calibration.

⚠ High-pressure sterilization cannot be used on the device.

⚠ Do not immerse the device in liquid.




















⚠ It is recommended that the device should be kept in a dry environment.

Humidity may reduce the useful life of the device, or even damage it.

### 9 Troubleshooting

Trouble	Possible Reason	Solution
The SpO2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The user's SpO2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the user is moving.	1. Place the finger properly and try again. 2. Let the user keep calm
The device can not be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The malfunction of the device.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The display is off suddenly	1. The product will enter standby mode when no signal is in the product within 5 seconds 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

### 10 Key of Symbols

Symbol	Description
	Type BF
	Refer to instruction manual/booklet
SpO <sub>2</sub> %	The pulse oxygen saturation(%)
PRbpm 	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)
	1. no finger inserted 2. An indicator of signal inadequacy
	battery positive electrode
	battery negative electrode;
	Power switch
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
IP22	Ingress of liquids rank
	Manufacturer
	Manufacture Date
	Storage and Transport Temperature limitation
	Storage and Transport Humidity limitation
	Storage and Transport Atmospheric pressure limitation
	This side UP
	Fragile, handle with care
	Keep dry
	Recyclable

11 Function Specification	
Display Information	Display Mode
The Pulse Oxygen Saturation(SpO <sub>2</sub> )	Digital
Pulse Rate (BPM)	Digital
Pulse Intensity (bar-graph)	Digital bar-graph display
<b>SpO<sub>2</sub> Parameter Specification</b>	

Measuring range	0%-100%, (the resolution is 1%).
Accuracy	70%-100%: ±2% ,Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 880nm)
<b>Pulse Parameter Specification</b>	
Measuring Range	30bpm-250bpm (the resolution is 1 bpm)
Accuracy	±2bpm or ±2% select larger
<b>Pulse Intensity</b>	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.
<b>Battery Requirement</b>	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
<b>Battery Useful Life</b>	
Two batteries can work continually for 24 hours	
<b>Dimensions and Weight</b>	
Dimensions	57(L) × 31(W) × 32(H) mm
Weight	About 50g (with the batteries)