FINGER TIP PULSE
Oximeter
USER'S MANUAL

Model:
☐ C101H1 ☐ C101A2 ☐ C101A3
☐ C101B1 ☐ C101B2

Version: V1.1
Release date: April 2020

Responsibility of the Manufacturer

IMDK only consides itself responsible for any effect on safety, reliability and performance of the equipment if: Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by IMDK, and The electrical installation of the relevant room complies with national standards, and The instrument is used in accordance with the instructions for use. The equipment compliant with IEC60601-1 requirements of electrical safety and ensure the designated device's voltage and current meet the requirements of this Manual.

Measuring principle

Oximeter is based on the measuring principle haemoglobin, oxygenation of hemoglobin in the red and infrared light absorption characteristics in the region on the basis of the application "LamnertBeer"Law of data presented.
The instrument works by photoelectric detection of blood oxygen combined with the pulse volume recording technology, specific process is as follows:
First, the emission wavelength of used fluorescent tubes 660nm Red and wavelength 940nm Near-infrared light irradiation on the nails by photosensor measured signal. This information about wavelength range can be especially useful to clinicians
To obtain data by electronic circuits and microprocessors, are displayed in OLED Easy to read on. Operation schematic diagram:

1.Infrared / red light emitting tube 2.Light receiving tube

Section1 Safety

1. 1 Safety information

Carefully read this manual about all safety informations, operation and specifications before using this oximeter.

- •Do not place the equipment in children, pets and other places can be touched
- •This device is not intended for treatment,it can't be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor
- •Do not attempt to service the pulse oximeter. Only qualified service personnel should attempt any needed internal servicing.
- •Do not use this device in situations where alarms required. Although this oximeter provides alarm function, but the alarm does not meet IEC60601-1-8.
- •The environment temperature should be guaranteed(working temperature: 5°C～40°C, transport and storage temperature: -10°C～+40°C). **When the ambient temperature is low or high, ensure that the product is recovered to room temperature before use。**
- •It is not suitable for long-time continuous patient monitoring. Continual measurement must not exceed 2 hours. Do not charge during measurement. **Transfer of blood oxygen saturation and pulse rate data value oximetry in 8-10 seconds and data update cycle, more than 20 seconds**
- •Sp02 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 shoe
  - ■Fingernail polish or false fingernails may cause inaccurate Sp02 readings

1.2 Warnings

WARNING: EXPLOSION HAZARD -Do not use the oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
WARNING: The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems
WARNING: Do not attempt to recharge normal dry-cell batteries, they may leak. And may cause a fire or even explode.
WARNING: .Do not use the pulse oximeter in an MRI or CT environment.
CAUTION:Keep the operating environment free of dust ,vibrations,corrosive,of flammable materials.and extremes of temperature and humidity .
CAUTION:The battery must be taken out from the battery compartment if the device will not be used for
A long time.
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.

1.3 NOTE:

1 .Fingernail polish or false fingernails may cause inaccurate SpO2 readings.
2. The SpO2 waveform is disproportionate to pulse.
3. Do not use this equipment on any limb with arterial cannula, intravenous infusion set or inflated blood pressure cuff.
4.The SpO2 waveform is disproportionate to pulse. Do not use any function tester to measure the SpO2 accuracy.
5.The device was calibrated.Display Arterial oxygen saturation(SpO2) and Pulse rate(PR).
6. If the detected signal is incomplete, the equipment will not display the parameter value but display the waveform as a straight line. The weak signal is represented by the amplitude of the waveform. If the signal is too low, it will affect the accuracy and function of the pulse oximeter. If your blood oxygen does not give the correct result, check the signal strength is too low.
There are several reasons for a weak signal:
Low perfusion
Dirty sensor or LED light
The oximeter improper positioning
Cold temperatures and general health can cause low blood pressure
7. The pictures and interfaces in this manual are for reference only
8. This Manual is prepared based on the most complete configuration. Some configurations and functions may be not available in your

1.4Definitions and Symbols

1.4.1 Cleaning instruments:

Use 70% of the alcohol cotton, clean silica gel sleeve, and test finger, probe and cavity cone. Please ensure that the instrument is inverted during cleaning to prevent the liquid from entering the instrument.
Don't put any liquid inside the instrument.
The instrument does not require the maintenance and calibration of the schedule except for the replacement of the battery.
Clinical test is a method commonly used to determine the oxygen accuracy. The measured arterial hemoglobin had an oxygen saturation, and the measurements were compared with the determined results of the arterial blood samples analyzed by the co-oximeter
Measure ten times a day for ten minutes. It could take five years.
When plugging your finger into the Oximeter,your nail surface must be upward.

Declaration：Please use the medical alcohol to clean the rubber before each test and clean the
tested finger with alcohol before and after the test.(The rubber inside of the Oximeter adopts medical
rubber,which has no toxin,no harm,and brings no side effect such as allergy to the our skin).
Install two AAA batteries into battery cassette before covering its cover

- •Plug one finger into rubber hole of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp with the nail upwards.
- •Press button on the front panel;
- •Don't tremble your finger when the Oximeter is working. Your body is not recommended on moving status.
- •Press the button on the front panel, if we want change display direction;
- •Read relevant datum from display screen.
- •If there is no signal input ,oximeter can shut off automatically.
- •Ptease replace new batteries when OLED indicates the batteries are in low power.

Section 2 Introductionn

2.1 Brief Device Description

This device intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate (PR). The device measures SpO2 and PR with a SpO2 senor and displays on the OLED after certain further processing，it can be used to measure human Hemoglobin Saturation and heart rate through finger
2.2 Application:
The Oximeter intended to be used for home care and medical outpatient measure pulse oxygen saturation and pulse rate of adults .Oximetry is suitable for vascular diseases, respiratory diseases, the elderly over the age of 60, working more than 12 hours a day, extreme sports and alpine hypoxia environment of blood oxygen monitoring population and chronic alcoholism

2.3 Symbols

Symbols	Definition of symbols
📖	Follow instructions for us
🔕	No alarm
🚶	Type BF Applied Part
🔋	Battery indication
SpO2	oxygen saturation of arterial hemoglobin
PR	Pulse Rate
🗑	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
CE 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices
EC REP	Authorized representative in the European community
SN	Serial Number
🏭	Manufacturer
⚠	Refer to use manual before application

2. 4 Specifications

1. Type of protection against electric shock: Internally powered equipment
2. Degree of protection against electric shock:Type BF
3. Protection Against Ingress of Liquids: IP22(protected against ingress of water when the water is
dripping vertically and the monitor is tilted up to 15°
4. Mode of operation: Continuous
5. Expected Service Life:5 years
6.Display Type:OLED display
7.Spo2:
  Measurement range:70%-99%
  Accuracy:±2% on the stage of 70%-99%,Unspecified(≤70%)
  Resolution: ±1%
8.PR:
  Measurement range:30BPM-240BPM
  Accuracy: ±1BPM or ±1%
9. Working Power:
Power Supply :2AAA 1.5V batteries , Power consumption: less than 30mA;
Battery life: 2 AAA 1.5 V alkaline battery can be used for 30 hours continuously;
Battery voltage:Low battery indicator appears before battery power is lowered to normal operation
10.Dimension:60*35*35mm
11.Environmental:

Operation Temperature	5℃-40℃
Storage Temperature	-10℃-40℃
Operation Humidity	15%-80%
Srorage Humidity	15%-80%
Air Pressure	70-106kpa

Section 3 Installation,Setup,and Operation

3.1,Description of the Front Panel (as figure3.1.1)

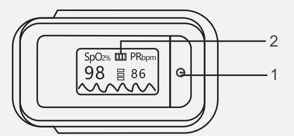


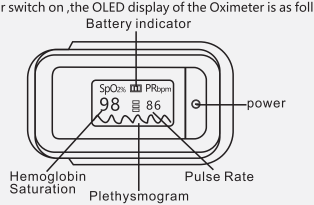
Figure 3.1.1Parts of front&back panel

Table3.1.1Part Definition and Description

Item	Name	Descriptio
1	Power button	Turn on the machine,direction change and parameter setting
2	OLED panel	Display the SPO2/PR data &Plethysmogram

3.2 Display

After switch on ,the OLED display of the Oximeter is as follow



3.3Parameter setting:

Press the power button (>0.5S), the oximeter will enter into parameter setting.
There are two submenu for choice:
When the '*' singal is shown on the "Sounds setup" ,press the button(> 0.5S)and enter into the sounds setting menu(Figure3.3.1)，you can press the button to change the data you need.
Select or to increase or decrease the number of settings.
When the '*' singal is shown on the "Aim setup" ,press the button (> 0.5S)and enter into the alarm setting menu(Figure3.3.2)，press the button to set the on/off for the alarm and beep.

Figure3.3.1

Figure3.3.2

3.4 Operation

3.4.1 Install battery

Installing two AAA batteries into battery cassette in correct polarities and cover it .
WARNING:Do not attempt to recharge normal alkaline batteries,they may leak and may cause a fire or even explode.

3.4.2 Turn the Pulse Oximeter on/off

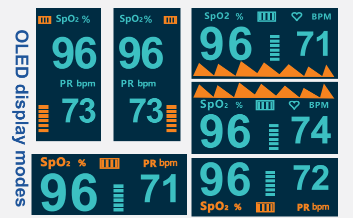
Put one of fingers into rubber hole of the Oximeter(it is best to put the finger thoroughly)with nail surface upward,then releasing the clamp.

Press power button to turn the Pulse Oximeter on.The oximeter will automatically be powered off when no finger in the device for longer than 16 seconds.

3.4.3 Read correspondent data from display screen.

3.4.4 Display Description of OLED

The display interface of "OLED" can rotate four directions with six different display modes after pressing the power button for less than 0.5s.It is shown as below:



Features
OLED display

- •Two color OLED display, more display modes
- •Low-power consumption, continuously four direction adjustable
- •Low voltage indicator
- •Automatically power off in 8 seconds when there is no signal
- •Small in volume, light in weight and convenient to carry

Section 4 maintenance and solution

4.1 Maintenance and Preservation

- •Replace the batteries timely when low voltage lamp is on.
- •Clean the surface of fingertip oximeter before it is used to diagnose patients.
- •Remove the batteries inside If you will not operate the Oximeter for a long time.
- •It would be better to preserve the product in -10~40 C (14-104 F) and humidity is 10%-80%.
- •It is recommended that the product should be kept dry anytime. A wet ambience might affect its life time and even damage the product.
- •Please follow the law of the local government to deal with used batteries.

4.2 Product declaration

Guidance and manufacture's declaration-electromagnetic radiation for other EQUIPMENTS and SYSTEMS

The Pulse Oximeter is designed to be used in specified electromagnetic environment. Users of the Pulse Oximeter must use it in the following environments.		
Radiation Test	Compliance	Electromagnetic environment-guidance
RF interference CISPR 11	Group 1	RF signal of Pulse Oximeter is simply created by its Internal function.Therefore,its RF interference is very Low and is not likely to cause any interference to nearby Electronic equipment
RF interference CISPR 11	Class B	The Pulse Oximeter applies to all establishments,including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

4.3 Possible problems and effective solutions

Problem	Possible reason	Solution
SPO2 or PR can not be shown normally	1.Finger is not plugged correctly 2.Patient" s Oxyhemoglobin value is too low to be measured	1.Retry by plugging the finger 2. Try more times. If you can make sure there is no problem in the product, please go to hospital timely for exact diagnosis
Sp02or PR is shown unsteady	1.The finger might not be plugged deep enough 2.Finger is trembling or the patient is on movement status	1.Retry by plugging the finger 2.Please remain at rest
The Oximeter can not be turned on	1.Inadequate power or power off 2.Batteries might be installed incorrectly 3.The Oximeter might be damaged	1.Please replace the batteries 2.Please reinstall the batteries 3.Please contact with local customer service centre
Indication lamps are suddenly off	1.The product automaticaliy shuts off when no signal is detected in 8 seconds 2.Inadequate power	1.Normal 2.Replace the batteries

4.4 Oximeter probe fault

The fault of the probe is one of its own faults, and the other is caused by the external factors of the probe.

1. if there is no SPO2 value in the oximeter, no red light emission will be detected by the probe. Poor probe. Replace the backup probe, SPO2 value returned to normal, determine the probe fault
2. the oximeter has no SPO2 value and has red light emission. It may be that the photocell is insensitive to the light, the photoelectric tube is aging or the wire is broken Failure
3. probe external factors mainly in noise, jitter or patient finger keratinization serious, probe launch, receiving part and unclean leakage. As long as the interference source is found, the probe is cleaned and the connecting mouth is properly used, the spot can be eliminated.

Section 5. Applicable models

C101H1,C101A2,C101A3,C101B1,C101B2.
Note:1. The picture in the manual may be slightly different from the actual instrument.
2.Technical parameters are subject to change without prior notice.

Section 6. Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor or manufacturer.

Shenzhen IMDK Medical Technology CO.,Ltd
CZone,10F,Building 16,Yuanshan Industrial B
Area,GongmingStreet,Guangming District,Shenzhen. China
Post: 518106 Tel:+86-755-36637905

EC REP MedNet EC-REP GmbH, Borkstrasse 10, 48163 . Münster, Germany