PULSE OXIMETER

USER'S MANUAL

Models:

☐ C101H1 ☐ C101A2 ☐ PO-A2AO
☐ PO-B1AO ☐ PO-A2AT ☐ PO-A3AO
☐ PO-H1AO ☐ PO-C5AO ☐ PO-C5AT
☐ PO-C6AO ☐ PO-C6AT

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Responsibility of the Manufacturer
IMDK only considers 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 international 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 "Lambert-Beer"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 905nmNear-infrared light irradiation on the nails by photosensor measured signal.
Peak wavelength and maximum output energy of red and infrared light of optical sensor:
Red light(wavelength is 660nm,11.0Mw),
Infrared light(wavelength is 905nm,5Mw)

This information about wavelength range can be especially useful to clinicians To obtain data by electronic circuits and microprocessors, are displayed in LED Easy to read on. Operation schematic diagram:
1: Infrared / red light emitting tube
2. Light receiving tube

1.Section1 Safety
1.1 Safety Information
Carefully read this manual about all safety information, operation and specification before using the 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: -20°C~+55°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 25 seconds**
■ 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:
a) High-frequency electrosurgical
b) Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or intravascular line
c) The patient has severe vasoconstriction severe anemia or hypothermia The patient is in cardiac arrest or is in shock
d) Fingernail polish or false fingernails may cause inaccurate SpO2 readings

1.2 Warnings
WARNING: Always consult your physician regarding clinical decisions. Do not rely on pulse oximeter as the only basis for medical decisions. Incorrect clinical decisions may result in harm.
WARNING: Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor.
WARNING: DO go to the hospital for further examination when persistent inaccurate readings occurs.

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.
WARNING: Misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.
WARNING:DO NOT service and maintain the device while in use.

1.3 NOTE
1) Fluorescent 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) Displayed and transmitted SpO2 and pulse rate data values are affected by data averaging and other signal processing, the DATA UPDATE PERIOD.
6) The device was calibrated Display Arterial oxygen saturation(SpO2) and Pulserate(PR).
7) 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 characterized by the amplitude of the waveform. If the signal is low 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.
8) There are several reasons for a weak signal:
a) Low perfusion
b) Dirty sensor or LED light
c) The oximeter improper positioning
d) Cold temperatures and general health can cause low blood pressure
9) Do not open the oximeter. It contains small parts which might be swallowed by children.
10) The pictures and interfaces in this manual are for reference only
11) This Manual is prepared based on the most complete configuration. Some configurations and functions may be not available in your.
12) No ALARM SYSTEM that includes the capability to detect an SpO2 or pulse rate PHYSIOLOGICAL ALARM CONDITION is provided.
13) The pulse oximeter is for single patient use only.
14) Any serious incident in relation to the pulse oximeter should be reported to manufacturer and local competent authority of the member state in which you and/or your patient is established.

1.4 Definitions and 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 appropriate collection site according to local regulations for separate collection after its useful life.

	The symbol indicates that the device complies with REGULATION (EU) 2017/745
EC REP	Authorized representative in the European community
SN	Serial Number
	Date of manufacture
	Manufacturer
LOT	Batch code
	Caution
MD	Medical device
UDI	Unique device identifier

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 three years.
When plugging your finger into the Oximeter,your nail surface must be upward.
Declaration: Please use the 70% isopropanol to clean the rubber before each test and clean the tested finger with it 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.
• Select relevant datum from display screen.
• If there is no signal input ,oximeter can shut off automatically.
• Please replace new batteries when display indicates the batteries are in low power.

2.Section 2 Introduction
2.1Brief Device Description
The 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 sensor and displays on the display screen after certain further processing: it can be used to measure human Hemoglobin Saturation and heart rate through finger

2.2 Intended purpose:
2.2.1 Intended use
The Pulse Oximeter is a portable non-invasive device intended for use in measuring and displaying oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adults through the finger in hospitals, hospital-type facilities, and home environments. The patient is an intended operator.
2.2.2 Product contraindications
The presence of an ongoing need for measurement of pH, PaCO2, total hemoglobin.
-Dyshemoglobinemia.
-Carboxyhemoglobinemia.
-Methemoglobinemia.
-Poor peripheral blood flow.
-During cardiac pulmonary resuscitation.
-Hypovolemic.
•For assessing the adequacy of ventilatory support.
-For detecting worsening lung function in patients on a high concentration of oxygen.
-Weak cardiac arrest peripheral pulses.
2.2.3 Side-effects:
-Tissue injury
-Skin burn
2.2.4 Intended patient population
Adult
2.2.5 Intended user
The patient is an intended operator.

Operator	
Age	-Adult (above 18 years old)
Knowledge	-Minimum: -Read and understand text and Arabic numerals; -Read this manual.
Linguistic	-English or local official language
Education	-At least 18 years old and 12 years intensive reading experience(school).
Experience	-No experience or has some experience using similar medical device. -No trained to use the device.
Permissible impairments	-Mild reading vision impairment or vision corrected to log MAR 0.2(6/10 or 20/32). -Impaired by 45% resulting in 60% of normal hearing at 50 Hz to 2 kHz.
Work responsibility	-Operation of the device. -Device maintenance and storge.

2.2.6 Clinical benefit
The Pulse Oximeter can provide good clinical practice for measuring oxygen saturation and pulse rate and allow people to measure oxygen saturation and pulse rate by themselves as easy and safe as possible.

2.2.3 Side-effects:
-Tissue injury
-Skin burn
2.2.4 Intended patient population
Adult
2.2.5 Intended user
The patient is an intended operator.

2. 3 Specifications
1) Peak wavelength and maximum output energy of red and infrared light of optical sensor:
i. Red light(wavelength is 660nm,11.0Mw),
ii. Infrared light(wavelength is 905nm,5Mw)
This information about wavelength range can be especially useful to clinicians
2) Type of protection against electric shock: Internally powered equipment
3) Degree of protection against electric shock:Type BF
4) 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°)
5) Mode of operation: Continuous
6) Expected Service Life:3 years
7) Display Type:OLED/TFT Display
8) SpO2:
a) Measurement range:35%-99%
b) Accuracy
i. 80%-99%, Accuracy:±2% ;
ii. 70%-79%, Accuracy:±3%
iii. Unspecified(≤69%)
c) Resolution: ±1%
9) PR:
a) Measurement range:30BPM-240BPM
b) Accuracy: within ±3BPM
c) Resolution: ±1BPM
10) Working Power:
Power Supply 2 * AAA 1.5V batteries ,
Electric Current: ≤ 50mA
11) Battery life: 2 *AAA 1.5 V alkaline battery can be used for 8 hours continuously;

12) Battery voltage: Low battery indicator appears before battery power is lowered to normal operation
13) Service life: 3 years
14) Shelf life:3 years
15) Dimension:

C101H1/PO-H1AO	60*36*35mm
C101A2/PO-A2AO/PO-A2AT	60*36*33mm
PO-A3AO	58*36*33mm
PO-B1AO	66*36*33mm
PO-C5AO/PO-C5AT	60*38*55mm
PO-C6AO/PO-C6AT	60*38*38mm

16) Environmental:

Working Temperature	+5°C~ +40°C
Transport and Storage Temperature	-20°C~ +55°C
Working Transport and Storage Relative Humidity	15%~95%, no condensation
Working/Transportand Storage Atmos pheric Pressure	70kPa ~106kPa

3. Section 3 Installation, Setup, and Operation
3.1 Description of the Front Panel (as figures3.1.1)

Figure 3.1.1 Parts of front & back panel

Table3.1.1 Part Definition and Description

Item	Name	Description
1	Power Button	Turn on the machine, direction change and parameter setting
2	Display Screen OLED/TFT Panel	Display the SPO2/PR /Data & Plethysmogram

SpO2 plethysmograph waveform

3.2 Display
Product introduction (Take the C101A2/ PO-A2AO/ PO-A2AT series as an example, the specific model is mainly based on purchasing the actual product)

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

3.3 Parameter Settings:
Software name:
C101** series:C8-V1.0
PO-** series: T6-V1.0

Software is embedded in the chip of PCBA during manufacture, and not connected to IT networks to communicate, therefore no additional hardware or IT networks is required.

The difference between parameter setting and display interface is as follows Figure 3.3.1:

Figure 3.3.1 Display interface

The Device has two display screens: OLED and TFT. It can display blood oxygen saturation (SpO2) and pulse rate (BPM). It takes about 30s to get a stable result for each measurement, and the SpO2 and PR values displayed on the screen are refreshed every second.
The specific operation steps are as follows:
1) Install two 1.5V (AAA) batteries according to positive and negative labels, and cover the battery cover;
2) Put your finger into the clip with silicone pad (preferably fully inserted into the finger, with the nail facing upwards) and release the clamp;
3) Press the power button on the front panel to turn on;
4) It is best to shake your fingers during use, and the human body should not be in motion;
5) Observe the change of the display screen and read the relevant data;
6) The device has four display modes, as shown in Figure 3.3.1. After the oximeter is turned on, click the switch button to switch to another display mode. Users can adjust the display mode according to their preferences.;
7) On the user display interface, long press the power button for about 2s to enter the parameter setting ,(as shown in Figure 3.3.1 Parameter Setting)
When moving to "Current Parameter" showing "**", press the button (> 0.5s) to enter the current parameter setting item.
Select "+"," to set the parameter range;
"Alm":"on/off ——Alarm tone on/off (no alarm)
"Beep":"on/off —— Sound on/off
8) When the device detects no finger insertion/no signal input, it will shut down after 8s.

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,t hey may leak and may cause a fire or even explode.
To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations.

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.
Note: Don't tremble your finger when the Oximeter is working. Your body is not recommended on moving status.

3.4.3Read correspondent data from display screen.

3.4.4Display Description of OLED/TFT
The display interface of 'OLED/TFT' can rotate four directions with four different display modes after pressing the power button for less than 0.5s.It is shown as Figure 3.3.1 Display Interface.
•Two color OLED display, TFT colorful 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

4.Section 4 maintenance and solution
4.1Maintenance 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 -20°C~+55°C(-4°F~131°F) and humidity is 15%-95%.
•It is recommended that the product should be kept dry anytime. A wet product would affect its life time and even damage the product
•Patients follow the law of the local government to deal with used batteries.
•The instrument does not require the maintenance and calibration of the schedule.
•Please turn off the device if the device is damaged. DO NOT attempt to repair this device yourself, as this will void the warranty. Contact your dealer and only have repairs carried out by authorized service partners.

The use life of the pulse oximeter is 3 years, stop using the device after the end of the life.
And stop using and contact local service center if one of the following cases occurs:
• The oximeter cannot be powered on in any case and not the reason of battery.
• There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

4.2Replace the Battery
1) Release battery cover. Before changing the battery be sure the system is already power off.
2) Press the battery holder lock to release the battery.
3) Remove the battery and replace with 2 new one, type AAA according to positive and negative marks
4) Slide the battery cover back in until it snaps in place. Do not dispose of used batteries in household waste. Follow local government local collection sites.

4.3Cleaning instruments
The pulse oximeter is a reusable device, please follow below instruction to clean the device each day.
Use 70% isopropanol 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.
Declaration: Please use the 70% isopropanol to clean the rubber before each test and clean the tested finger with it 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).

4.4Accessory
No accessory.

4.5 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.

4.6 Possible problems and effective solutions

Problem	Possible reason	Solution
SpO2 or PR is shown normally	1.Finger is not plugged correctly 2.Patient's o Oxyhemoglobin value is too low to be measured	1.Retry by plugging the finger 2.Try more times. If you can make sure that the oximeter is in the product, please go to hospital timely for exact diagnosis
SpO2 or PR is shown unstably	1.The finger might not be plugged deep enough 2.Finger is trembling or the patient is on movement status	1.Please plug the finger deeply 2.Please remain at rest
The Oximeter can not be turned on	1.Low battery power 2.Batteries might be installed improperly 3.The Oximeter might be damaged	1.Please replace the batteries 2.Please reinstall the batteries 3.Please contact with local customer service centre
The screen suddenly turns off the display	1.The product automatically shuts off when no signal is detected in 8 seconds 2.Inadequate power	1.Normal 2.Replace the batteries 3.Contact the manufacturer or local distributor

The MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

4.7 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 the probe has no SpO2 value in the number, no red light emission will be detected by the probe. Poor probe. Replace the new 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 point 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.

4.8 Disposal
At the end of its service life, the device must be disposed of in accordance with applicable local rules and regulation.
Precaution:
-The device shall be cleaned to reduce infection risk before disposal.
-The Pulse Oximeter(Model: C101** series &PO-** series) which is not sharps shall not be placed in sharps box.
- Attention shall be paid to broken shell which may have sharp corners and edges that could result in an unacceptable RISK cause injury or damage.

⚠It is required that you should not dispose of WEEE as unsorted municipal waste and collect such WEEE separately.
In accordance with Directive 2012/19/EU and national disposal regulations regarding old electrical and electronic devices, please be advised that such items must be disposed of in a special way within the European Union (EU). These regulations require the environmentally friendly recycling/disposal of old electrical and electronic devices. Such items must not be disposed of as domestic refuse. This has been expressed using the icon of the "crossed out trash can".
The Pulse Oximeter (Model: C101** series &PO-** series) contains batteries and recyclable electronic waste. To protect the environment, do not dispose of it in household waste as unsorted municipal waste, but collect separately and take it to an appropriate local collection center.
The Pulse Oximeter (Model: C101** series &PO-** series) is classified as small equipment (5th category) according to ANNEX IV of Directive 2012/19/EU.
Before disposing of your Pulse Oximeter (Model: C101** series &PO-** series), please take away the batteries from Pulse Oximeter (Model: C101** series &PO-** series) and dispose of the batteries and Pulse Oximeter (Model: C101** series &PO-** series) separately.
You can take away the batteries as follows:
> > Battery remove diagram

① Open the battery cover
② Remove the batteries:
Batteries represent a hazard to health and the environment! Never open, damage, or swallow batteries or allow them to pollute the environment. They may contain toxic, ecologically hazardous heavy metals. The removed batteries shall be disposed of at the point of sale or in the corresponding containers provided at collection points by local public waste authorities and treated according to 2006/66/EC. The batteries and recyclable electronic waste shall be disposed of in a separate waste container.
Packaging materials must be disposed of according to local regulations. Consult the authorized collection points for more information.
In Germany:
For the recyclable electronic waste disposal, you can search the authorized collection points at the following website:
https://www.ear-system.de/ear-verzeichnis/sammel-und-ruecknahmestellen
For batteries, you can search the authorized collection points at the following website:
https://www.ear-system.de/ear-verzeichnis/batgherstellerlifno-back
Search method: using your postcode or the name of the city and state where you live to find collection points near you.

Other countries
For country-specific information on disposal, contact your local dealers or importer.

5. Section 5. Applicable Models
Model: C101H1, C101A2, A2AO, A2AT, PO-A2AO, A2AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO, PO-C6AT
Note:
1) The picture in the manual may be slightly different from actual appearance.
2) Technical parameters are subject to change without prior notice.

6. Section 6. Contact Information
If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor or manufacturer

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