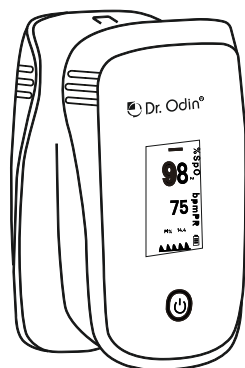




# Pulse Oximeter+PI

## TY-01 User Manual



### 1. Product Information

Product name: Finger Oximeter

### 2. Explanation of Symbols

The following symbols appear on the Finger Oximeter and its packaging.

Table 1 Finger Oximeter and Packaging Symbols

Symbol	Description	Symbol	Description
	BF applied part : including F applied part(float/insulation)		Caution, consult accompanying documents
	Keep upright		Date of manufacture
	Keep dry		Fragile, handle with care
	Humidity limitations		Temperature limitations
	Atmospheric pressure limitations		Serial Number
<b>IPX1</b>	Protective grade		Manufacturer address
			Compliance to WEEE standard

### 3. Safety Standards

The following table describes the safety standards of the Finger Oximeter.

Table 2 Safety Standards

Parameter	Specification
Protection class	Class 1, anti-shock, externally and internally powered equipment, per IEC 60601-1

Degree of protection	Type BF defibrillator-proof: per IEC 60601-1 Degree of noxious-liquid proof as IPX1 Anti-shock degree as BF applied part According to the degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide, the equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide
Sterilization and disinfection	Class 1, anti-shock, externally and internally powered equipment, per IEC 60601-1
As recommended by manufacturer	Continuous

### 4. Safety Conventions

The manual uses the following conventions for Notes, Cautions, and Warnings.

**Note**—A Note calls attention to an important point in the text.

**Caution** A Caution calls attention to a condition or possible situation that could damage or destroy the product or the user's work.

**Warning** A Warning calls attention to a condition or possible situation that could cause injury to the user and/or patient.

### 5. Safety Requirements

Warning The Finger Oximeter is only for use on one patient at a time.

The Finger Oximeter is not for diagnostic or therapeutic use.

Never use the Finger Oximeter during MRIs or CT scans.

Never use the Finger Oximeter in an environment of anesthetic gases.

FUNCTIONAL TESTER cannot be used to assess ACCURACY.

The skin temperature is initially at 35 °C for each Finger Oximeter, the APPLIED PART temperature can not exceed 41 °C. The material that the Finger Oximeter contacted to body is Non-toxic silica gel which meet the ISO10993 requirements, so can be safely used. But to some natural rubber latex sensitive user, there may be some allergic reactions. Only use accessories recommended by the manufacturer.

Using other kinds of accessories might cause damage or personal injury. Modification of the Finger Oximeter could be unsafe as applicable.

The degrade sensor may degrade the performance.

### Cautions

To avoid personal injury, only use accessories and parts produced or recommended by SUPPLIER. Otherwise, damage to the Finger Oximeter can occur. The Finger Oximeter must conform to the international standard IEC 60601-1-2 and other applicable EMC standards.

Interference takes place when electromagnetic energy is extremely high.

Ensure that any nearby instruments are also in compliance with EMC standards. Never turn on or use portable communication devices like mobile phones or portable dual-channel radios near a Finger Oximeter. When power is lost for less than or equal to 30s, the ALARM SETTINGS prior to the power loss shall be restored automatically. Ensure that qualified service representatives annually calibrate and maintain the Finger Oximeter. Periodically check the Finger Oximeter for damage. When necessary according to your local hospital waste disposal regulations. Clean and sterilize the Finger Oximeter and accessories according to local requirements. Turn off the Finger Oximeter before cleaning or sterilization. Keep all Finger Oximeter packing materials away from children, pet or pests, or dispose of them in accordance with your local environmental regulations. Inhalation or swallowing of small parts that be detached from Finger Oximeter may cause choking. Always properly dispose of the Finger Oximeter and all accessories at the end of their service life. Dispose of batteries according to your local regulations. Never incinerate batteries or expose them to high temperatures.

Ensure that no water condenses into or on the Finger Oximeter. Condensation can occur from changes in temperature or exposure to humidity.

### 6. Product Operation Scope

This Finger Oximeter is a kind of innovated medical detection device with non-invasive and continuous features for artery SpO2 and PR detection.

It is portable and easy to measure the SpO2 and PR value quickly and precisely.

This can be through the finger Finger Oximeter to measure human blood oxygen saturation and heart rate. This product is suitable for family, clinic, oxygen bar, sports health (use before and after exercise is not recommended for use during exercise), community health and other ranges. It's for ages from 15 to 60 years old patients. This product is not suitable for Finger Oximetering the patient's prolonged use.

### 7. 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 Finger 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 display screen will directly show measured value of hemoglobin Saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

### 8. Measurement principle

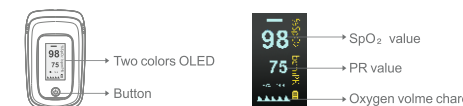
Principle of the oximeter is as follows: An experience formula of data process is established taking use of Lambert beer Law according to Spectrum Absorption Characteristics of reductive hemoglobin(R Hb) and Oxyhemoglobin (O2 Hb) in glow and near-infrared zones. Operation principle of the instrument 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 LED through process in electronic circuits and microprocessor.

### 9. Feature

1. Two colors OLED display, figure and Oxygen volume chart display together on interface;

- Adjust the display interface direction manually, according to the patient observation data needs;
- audible alarm function;
- Low Power consumption. 20 hours continuous to work.
- Low Perfusion  $\leq 0.6\%$ .
- Low voltage indicator.
- Automatic power off when no signal in 8s.
- Small and light weight, convenient to carry.
- A menu function can set up oxygen alarm limit, the upper and lower limits of PR, alarm switch, sound switch.

### 10. Appearance introduction



### 11. Operation Instructions

#### 11.1 The product Operation Instructions

- Installing two AAA batteries into battery cassette in correct polarities and cover it.
- Plug one of fingers into rubber hole of the Oximeter (it is best to plug the finger thoroughly) nail surface upward, then releasing the clamp.



- Press the switch button once on front panel.
- Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status.
- Read correspondent data from display screen.

**Note**—Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using medical 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. Disposable batteries should be unloaded when used for a long interval.

### Warning

The maximum application time for a Finger Oximeter PROBE at a single site is 4 hours. The misapplication of a Finger Oximeter PROBE with excessive pressure for prolonged periods can induce pressure injury. Ambient light (including photodynamic therapy); physical movement (PATIENT and imposed motion); diagnostic testing; low perfusion; electromagnetic interference; HF SURGICAL EQUIPMENT; dysfunctional haemoglobin; there will be windage for SpO2 value.

### 11.2 Operation Instructions

#### 11.2.1 Display Description (6 interface diagrams)

Setting interface		
Pulse Oximeter Interfaces	Without detection signal interface	A detection signal interface
Interface 1		
Interface 2		
Interface 3		
Interface 4		
Interface 5		
Interface 6		

#### 11.2.2 Button operating instructions

1. put into two AAA batteries according to the instructions, the device will turn on automatically and display interface 1; then put into finger for measuring, if there is finger for detection and without operation, it power off automatically in 8s.

2. When there is battery, but the Finger Oximeter power off, press the button, it will be opened.

3. During the measurement (there is a measurement signal and figure), press the button shortly, the interface can turn from interface 1 to interface 6 circularly. Press the button longly during the measurement; it can turn to settings menu interface.

4. In the Settings menu interface, press button longly, it can choose 8 options circularly, they are Alarm switch (Alarm Sound on/off), the add and subtract of oxygen lower limit value (SPO<sub>2</sub> Lo+/-), the add and subtract of PR limit value (PR Hi+ /-; PR Lo+ /-), PR Sound switch (BeeP) and the withdraw from the menu (Exit). The selected options foreground color will become Blue Square.

5. In the Settings menu interface, press button shortly, we can operate the value add and subtract or switch of current options. they are: The SpO<sub>2</sub> default alarm lower limit value is 90, the adjustable range is from 70 to 95 and pressing the button shortly can do add and subtract of 1step. The PR default alarm upper limit value is 110, the adjustable range is from 110 to 250 and pressing the button shortly can do add and subtract of 5 steps. The PR default alarm lower limit value is 50, the adjustable range is from 15 to 95 and pressing the button shortly can do add and subtract of 5 steps.

6. All the setting value will restore to default value: alarm off, oxygen lower limit value 90, PR upper limit value 110, PR lower limit value: 50, PR sound off when we replaced the battery.

7. In the Settings menu interface, choose to Exit option and press button shortly, it will quit the setting menu interface.

### 12. Alarm

The Pulse Oximeter uses the following alarm indicators: audible alarm and visual alarms.

**Note**—To correctly identify visual alarms, always observe the Finger Oximeter within 1 meter of its position.

#### 12.1 Low power alarm

when battery power is at lowest level, the battery capacity indicates empty in OLED, remind users of replacement of battery.

**Note**—When power is lost for less than or equal to 30 s, the ALARM SETTINGS prior to the power loss shall be restored automatically.

#### 12.2 Audible alarm

The audible alarm is buzzer alarm; the auditory sound pressure range is 45dB-70dB.

#### 12.3 SpO2 and PR alarm

\*Default alarming Value of PR: High Limit: 110BPM; Lower Limit: 50BPM  
\*Default alarming Value of SpO2: 90%.

\*When it is under operation conditions, if the measurement of the PR and SpO2 value exceed the setting alarm limit and the alarm switch is on, the HKM-500A will have a sound alarm and its long buzzer alarm.

\*When it is under operation conditions, if the PR sound switch is on, the measurement PR will go with a PR sound. To test the alarm according the following:

- Connect the Finger Oximeter to simulator;
- the simulator setting: SpO2 90%, PR 200bpm;
- the Finger Oximeter alarm setting: SpO2 95%, PR High Limit 110bpm;
- to verify the Finger Oximeter alarm.

#### 13. SpO2 Specifications

The update rate for the SpO2 value and pulse rate is typically 1 second. Data averaging and other signal processing on the displayed and transmitted data values of SpO2 and pulse rate is not more than 20 seconds. Depending on the magnitude of difference between the alarm limit and the displayed value, the alarm signal generation delay may be from 1 second to 20 seconds. The maximum alarm condition delay is 4 seconds, the maximum alarm signal delay is 20 seconds, the average alarm condition is 2 seconds, the average alarm signal is 10 seconds. Because Finger Oximeter measurements are statistically distributed, only approximately two-thirds of Finger Oximeter equipment measurements can be expected to fall within the Arms value measured by a CO-oximeter. The signal adequacy is indicated by waveform, and it is NORMALIZED.

**Note**—The Finger Oximeter EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION. It is not necessary to have a SpO2 calibration when the Finger Oximeter is in use.

The following table describes the SpO2 specifications.

Parameter	Specification
SpO2 measurement range	35%-99%
SpO2 accuracy	$\pm 1\%$ in the range of 90%-99%, $\pm 2\%$ in the range of 70%-89%, other scope is not defined

SpO2 Alarm range	Consistent with the display range, the set step length is 1%
Pulse rate range	30 bpm-240bpm
Pulse rate accuracy	$\pm 1$ bpm
Pulse rate Alarm range	Consistent with the display range, the set step length is 5bpm
Data update cycle	0.25s-2s
SpO2, PR average	8s
Pulse rate sound	PR tone
Peak Wavelength range <sup>2</sup>	500nm-1000nm
Maximum optical output power	150mW
Pulse rate display	Numeric
Display Specifications	two color OLED, 0.96"
Power dissipation	in normal measurement, less than 40mW; in power off state, less than 50uW;

Sensor accuracy was obtained by performing controlled hypoxia studies on healthy, non-smoking adult volunteers (according to ISO 80601-2-61).

1. Been compared to CO-oximeter measurements on arterial blood samples. To represent the general population, data from at least 10 subjects (male and female) with a wide range of skin color was taken to validate SpO2 accuracy. Accuracy data for Masimo sensors is included in the sensor package insert.

2. Information about wavelength ranges can be useful for clinicians performing photo dynamic therapy.

#### 14.1 Power Specifications

The following table describes the power specifications.

Parameter	Parameter
battery	DC 3V AAA(x2) The Finger Oximeter powers off if the battery power is almost depleted.

#### 15. Physical Specifications

The following table describes the physical specifications.

Item	Parameter
Size	37x62x31mm

#### 16. Environmental Specifications

The following table describes the environmental specifications.

Parameter	Specification
Temperature	Operating: 0°C-40°C Storage: -20 °C+ 55°C for the device
Relative humidity	Operating: 15%-80% (noncondensing) Storage: 10%-93% (noncondensing)
Barometric pressure	Operating: 59kPa-107.4kPa Storage: 22 kPa - 107.4 kPa

#### Part 3 EMC Related Summary

#### 17. EMC Related Summary

##### 17.1 NOTICE

- Finger Oximeter meets the requirement of electromagnetic compatibility in IEC60601-1-2.
- The user needs to install and use according to electromagnetism compatibility information which is attached with it.
- Portable and mobile RF communication devices may influence Finger Oximeter performance, so Finger Oximeter should be kept away from them during using.
- Guidance and manufacturer's declaration stated in the appendix.

##### 17.2 WARNING

- The user needs to install and use Finger Oximeter according to electromagnetism compatibility information which is attached with it.
- Portable and mobile frequency communication devices may influence its performance, so it should be kept off these devices.
- Finger Oximeter should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Finger Oximeter should be observed to verify normal operation in the configuration in which it will be used.
- Speaking, Finger Oximeter could not be used for transport using, like ambulances (land and air ambulances).

#### Part 4 Repair and Warranty

##### 18. Repair and Maintenance

- Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.
- No flammable substance, overtop or lower temperature and humidity existed in operation conditions.
- When the device is dabbled or there is hydraulic set existed, stop operating.
- When lower power capacity light in red pls replace the battery right away.
- Pls clean the surface before applying for detection.
- Pls take out the battery when device is not used for a period of time.
- Pls dispose the battery according to the local statute.
- If there is dust or dirt on surface, 75% density of medical alcohol can be used to clean the surface. Pls use dry fabric with little alcohol to avoid alcohol permeates into the device.

9. The transportation and storage conditions are: Temperature: -20°C~55°C; Humidity: 10%~93%.

#### 19. Troubleshooting

Trouble	Possible Reason	Solution
The SpO2 and Pulse Rate display instable	1.The finger is not places inside enough. 2.The finger is shaking or the patient is moving.	1.Place the finger properly and try again. 2.Let the patient keep calm.
The device can not turn on	1.The batteries are drained or almost drained. 2.The batteries are not inserted properly. The device's malfunction.	1.Change batteries. 2.Reinstall batteries. 3.Please contact the local service center.
The indicator light is off suddenly	1.The device will power off automatically when it gets no signal for 8 seconds. The batteries are almost drained.	1.Normal. 2.Change batteries.
The SpO2 and Pulse Rate alarm	1.The value has exceeded the high alarm limit or below the low alarm limit.	1.Place the finger properly and try again. 2.Let the patient keep calm.

#### 20. Accessory

Hang String-----1 pcs  
User Manual-----1 pcs

#### 22.1 Warranty

The unit can not be repaired by users themselves. All services must be done by the engineers approved by SUPPLIER. The unit is guaranteed for a period of 12 months, valid from the date of purchase. SUPPLIER warrants that each product we sell you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty. IMPORTED & MARKETING BY:

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