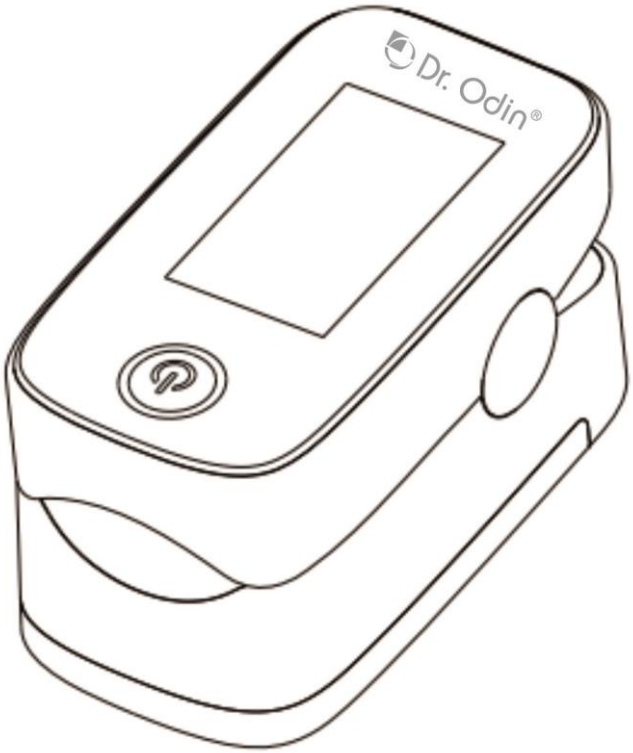
Pulse Oximeter User Manual
YM-201



Version: 2.0

Date: 2020-07-08

1. Product Introduction and Operation Guide

1.1 Front View

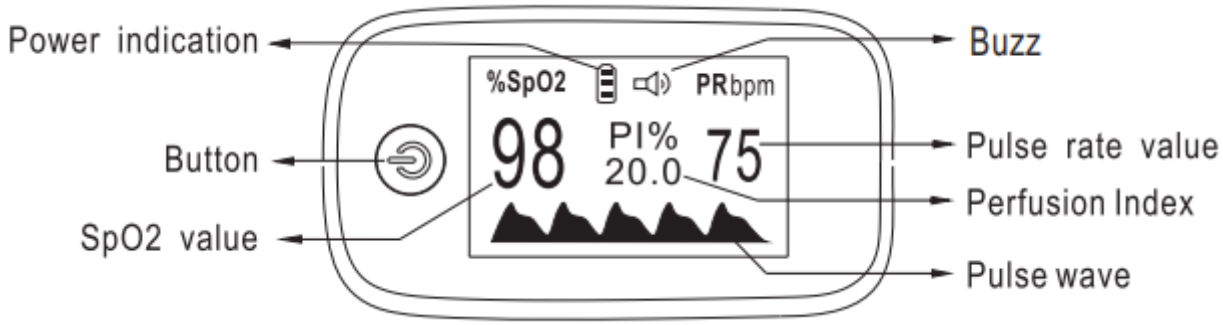


Figure 1 Front View of YM201/YM301

1.2 Operation Method

A. Open the battery cover, and put the two AAA batteries into the battery compartment in correct polarities, then replace the cover;

B. Press the bottom of the equipment and open the probe, then insert one finger into the probe;

C. Press the button to turn the equipment on, and the measure interface will appear;

D. After about 8 seconds, the measurement result can be read directly from the display screen;

E. Before reading the parameters, make sure that stable numbers of the pulse oximeter interface has sustained more than 4 second;

F. The equipment will turned off automatically within 8 seconds when the finger left the probe.

1.3 Battery Installation

A. Put the two AAA batteries into battery compartment in correct polarities (Figure2).

B. Push the batter y cover horizontally along the arrow shown as right.

WARNINGS:

- Battery polarities should be correctly installed, otherwise, damage may be caused to the equipment.
- Please remove the batteries if the equipment will not use for a long time.

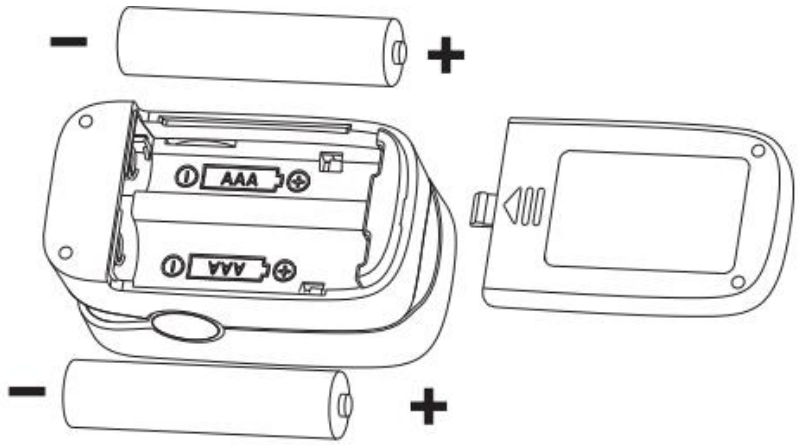


Figure 2 Battery Installation

1.4 Lanyard installation

A. Pass the thinner end of the lanyard through the hanging hole;

B. Pass the thicker end of the lanyard through the thinner end and tighten the lanyard(Figure3).

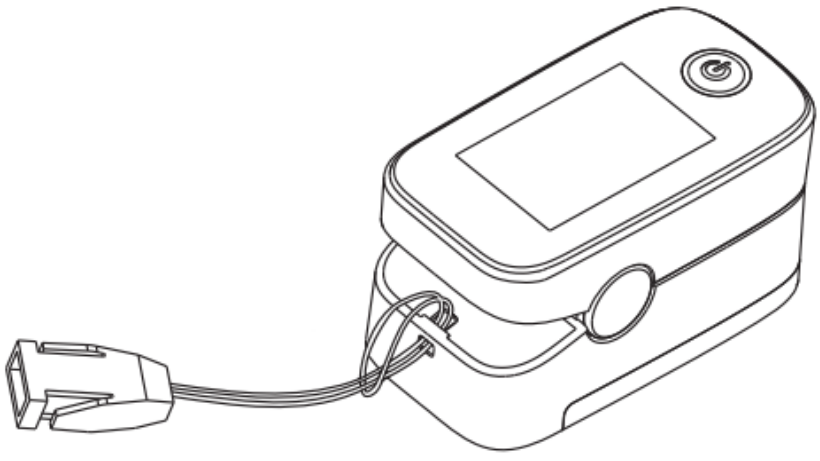


Figure3 Lanyard Installation

1.5 Attention for Operation

A. Before use check and confirm that the people or finger size were applicable;

B. Before use check and confirm that the environment should be non- combustible material, as well as to avoid high or low temperature and humidity, but also need to pay attention to the following:

a) To avoid glare and direct sunlight exposure;

b) To avoid radiation infrared or ultraviolet radiation;

c) Avoid contact with the organic solvent, mist, dust, corrosive gases;

C. The equipment should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection;

D. The equipment may not work normally on microcirculation barrier patients,Warm or rub the finger, or re-position the equipment could improve the measurement.

E. The ray between photo detector and light emitting diode should across patient's arteriole.

F. The patient should not use enamel or other makeup;

G. Avoid to insert a wet finger into the probe.

Notes:

A. The user should fully insert the finger into the probe;

B. It is recommended to let the LED light shine directly on the nail(Figure 4);

C. Don't shake the finger and try to keep still during the measurement.

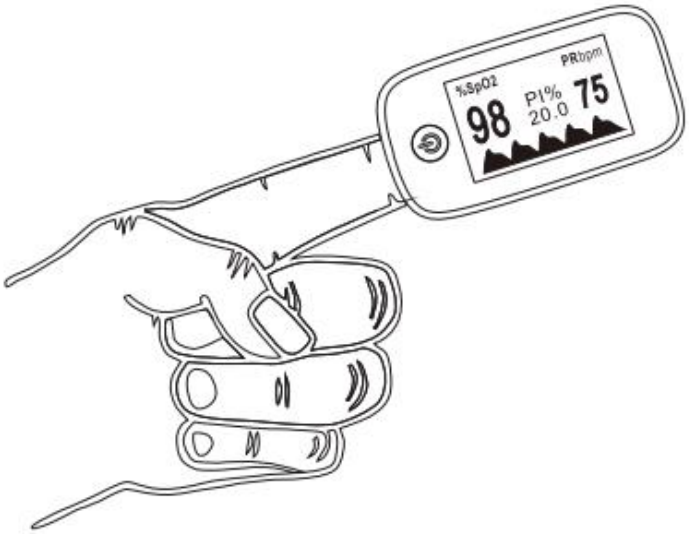


Figure4 Finger Placement Diagram

1.6 Function and menu operation

After turning on the oximeter, press and hold the power button for about 2 seconds. The oximeter will call up the parameter setting interface and set it by pressing the button. Defined here, long- press indicates that the button hold time reaches 1-2s, shor t-press indicates that the button hold time is less than 0.5s.

On parameter interface 1

- Move"*" to the corresponding option, and hold the button to set Alm or Beep to on or off.
- When Alm is set to on and the measured SpO2 or PR Values go beyond the upper limit or lower limit, the oximeter gives off an alert sound.
- When Alm is set to off and the measured values go beyond the limit, the Oximeter will not give any alert sound.
- When Beep is set to on, a ticking sound synchronized with the pulse is emitted

during the measurement, and when Beep is set to off, no sound is output.

- While the "*" symbol stays on the Restore option, hold the button to restore factory settings.
- Press the button to select a Brightness level ranging from 1 to 5. The greater the value, the greater the brightness of the screen.

On parameter interface 2

- Press the button to switch between options. On this interface, you can set the upper limit and lower limit of SpO2 Alm and PR Alm.
- While the "*" symbol stays on the +/- option, hold the button to set the option to + or -. In + mode, select the corresponding option and hold the button to increment the upper or lower limit; in - mode, hold the button to decrement the upper or lower limit.
- Move "*" to the Exit option, and hold the button to return to the monitoring interface.

Interface 1

Settings	
Alm setup	*
Alm	on
Beep	off
Demo	off
Restore	ok
Brightness	1
Exit	

Interface 2

Settings	
Sounds setup	*
SpO2 Alm Hi	100
SpO2 Alm Lo	94
PR Alm Hi	120
PR Alm Lo	50
+/-	+
Exit	

Figure5 The setting interfaces of the oximeter

2. Specification

2.1 Classification

Type of protection against electric shock.... Ⅱ (Internally powered equipment)

Degree of protection against electric shock.....Type BF-Applied part

Operating mode .....Spot checking

Degree of protection against hazards of explosion.....P22

2.2 Power Requirements

Specification of alkaline batteries.....Two AAA (LR03)

Operating current.....25-50mA

2.3 Physical Specifications

Width*Height*Depth.....57×30×31 mm

Weight.....28g (Bare machine)

2.4 Measurement Specifications

Spo2 declared accuracy .....70%~100%: ±2digits

0% ~ 69%: unspecified

SpO2 Display Range.....30%~99%

SpO2 Resolution.....1%

PR declared accuracy .....25-250bpm: ±3digits

PR Resolution.....1bpm

2.5 Environmental Specifications Temperature

Temperature

Operating.....+50~+104° F / +10~ +40° C

Storage/Transportation.....-4~+140° F / -20~+60° C

Humidity

Operating.....15~95%, noncondensing

Storage/Transportation.....10~95%, noncondensing

Atmosphere Pressure

Operating.....70~106kpa

Storage/Transportation.....50~107.4kpa

2.6 Display

Display type.....OLED display:

YM201: 0.96",Yellow&Blue

YM301: 1.3",Blue

Display content: SpO2%, Pulse Rate, PI%, Bar Graph Battery Indicator,Pulse Wave

Notes:

1) The claim for oxygen saturation accuracy should be supported by clinical studies covering the entire claimed range,The fraction of inspired oxygen (FiO2) delivered to test subjects is varied to achieve a series of targeted steady-state saturation periods over the specified SpO2 accuracy range (e.g. 70 % to 100 %),then the SpO2 accuracy is calculated by comparing SpO2 readings of the pulse oximeter to the values of SpO2 determined with a Co- Oximeter.

2) The clinical trial included 11 subjects, including 6 males and 5 females, with an age range of 18 to 46 years, the subjects skin color included dark black, medium black, light color and white.

3. Maintenance, Cleaning, Disinfection

3.1 Maintenance

The equipment's design life expectancy is about 2 years, keep your equipment and accessories free of dust and dirt, and follow these rules:

A. Please clean the equipment before use according to chapter 6.2; Remove the batteries inside the battery cassette if the equipment will not be operated for a long time;

B. Replace the batteries in time when the battery voltage indicate lamps were empty;

C. It is recommended that the equipment should be kept in a dry environment with no corrosive gases and good ventilation anytime. The moisture and high-light environments will affect its lifetime and even might damage the equipment.

D. It is best to preserve the product in a place where the temperature is between -20 to 60℃ and the relative humidity is less than 95%.

E. The packed equipment can be transported by ordinary conveyance. The equipment not be transported mixed with toxic, harmful, corrosive materials.

WARNINGS:

- No modification of this equipment is allowed.

3.2 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment. Recommended cleaning agents are:

a) Mild soap (diluted).

b) Ethanol (70%).

To clean your equipment, follow these rules:

a) Shut down the pulse oximeter;

b) Clean the display screen using a soft, clean cloth dampened with a glass cleaner;

c) Clean the exterior surface of the equipment and probe using a soft cloth dampened with the cleaner;

d) Wipe off all the cleaning solution with a dry cloth after cleaning if necessary;

e) Dry your equipment in a ventilated, cool place. To avoid damage to the equipment, follow these rules:

CAUTIONS:

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment in the liquid.
- Do not pour liquid onto the equipment or accessories.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).
- If you spill liquid onto the equipment, contact us or your service personnel.

3.3 Disinfection

Clean the pulse oximeter before disinfecting it. The recommend disinfectant is ethanol 70%. Disinfection step are the same as cleaning.

CAUTION

- Never use ETO or formaldehyde for disinfection.

3.4 Disposal

Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations.

4. Accessories

One lanyard.

Two AAA batteries(Optional).

One user manual.

One certificate card.

5. Toubleshooting

Trouble	Possible Reason	Solution
	The battery is drained away or almost drained away.	Please replace batteries.
	The battery installation is incorrect.	Install the battery over again.
	The device works abnormally.	Please contact the product distributor.
	The finger size is too big or small.	Select the suitable size finger to measure.
	Excessive ambient light.	Aviod the excessive ambient light irradiation.
	User's blood perfusion is very low.	Warm the finger and try again.
	The equipment is set to shut down automatically in 8 seconds when there is no correct physiological Signals.	Normal.
	The battery is almost drained away.	Replace batteries.
	The finger is not inserted deep enough.	Replace the finger and try again.
	The finger is shaking or the body is moving.	Try to keep still.
	Not used in the work environment required by this manual.	Please use in normal working environment.
	The device works abnormally.	Please contact the product distributor.

6. Appendix A EMC

The equipment complies with the requirement of standard EN 60601-1-2:2014“Electromagnetic Compatibility – Medical Electrical Equipment”.

1	**Guidance and manufacturer´s declaration – electromagnetic emission**		
2	The model YM201/YM301 is intended for use in the electromagnetic environment specified below. The customer or the user of the model YM201/YM301 should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment – guidance**
4	RF emissions CISPR 11	Group 1	The Model YM201/YM301 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.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 61000-3-2	Not applicable	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Model YM201/YM301 are intended for use in the electromagnetic environment specified below. The customer or the user of the Model YM201/YM301 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips,short interruptions and voltage variations on power supply input lines	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT)	N/A	N/A

IEC 61000-4-11	for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity			
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Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD)	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV	± 8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with

IEC 61000-4-2	air	±2 kV, ±4 kV, ±8 kV, ±15 kV air	synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	N/A	N/A
Power frequency	30 A/m, 50/60Hz		Power frequency magnetic

(50/60 Hz) magnetic field IEC 61000-4-8		30 A/m, 50/60Hz	fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The YM201/YM301 is intended for use in the electromagnetic environment specified below. The customer or the user of the YM201/YM301 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Models YM201/YM301, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

<table>
<tr>
<td>Radiated RF

IEC 61000-4-3</td>
<td>10 V/m

80 MHz to 2.7 GHz</td>
<td>10 V/m</td>
<td>Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td>
</tr>
<tr>
<td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td>
</tr>
</table>

a. The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the YM201is used exceeds the applicable RF compliance level above, the YM201should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the YM201/YM301.

d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

WARRANTY

WARRANTY CARD

Model No..... Lot No.....

Invoice No..... Date of Purchase.....

Purchased by :..... Contact No. :.....

Address.....

Dealer Name.....

Dealer Sign & Stamp

Dr. Odin®

Marketed By:

Passim Medichem Agencies

Plot No. 186, Industrial Area, Phase -2, Chandigarh-160002.

Corporate Office: #902, 9th floor, WallFort House, S.V. Road,

Near Citi mall, Goregaon (W), Mumbai-400 062 India

Customer care No.:

+91 9878785333, 9359490504

(Timing: 9 am. To 7 pm., Mon. –Sat.)

Website: www.drodin.in

Email ID: customercare@drodin.in

Certificates

PN: Finger Pulse Oximeter

Date: _____