OXYGEN SATURATION MONITOR

PULSOX®-300

Instruction Manual

This instrument must be used according to the instructions of the doctor.

KONICA MINOLTA

Safety Symbols

Warnings and precautions noted in this manual and the instrument are indicated by the following markings, designed to prevent accidents caused by erroneous handling of the equipment.

This indicates text consisting of a warning or precaution relating to safety. Please read the text carefully and use the equipment safely.

This indicates an action which is prohibited.
The prohibited action should never be carried out, under any circumstances.

This indicates instructions concerning an action.
Always follow the instructions carefully.

This indicates an action which is prohibited.
Never disassemble the product or unit.

This symbol indicates that has no alarm function is prescribed in IEC60417-5319.

This symbol indicates type BF equipment.
The instrument provide a particular degree of protection against electric shock, particularly the leakage current and reliability of the protective earth connection with an F-TYPE APPLIED PART.
F-TYPE APPLIED PART indicates applied part isolated from all other parts of the instrument to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated mains voltage is applied between the applied part and earth.

This symbol indicates D.C.

Authorized Standards

For North America

UL, C_ UL:

Electrical Safety
E112871

For Europe

CE (Medical Device Directive):

This instrument complies with EN60601-1, EN60601-1-2, EN ISO 14971, EN ISO 13485.

Safety Precautions

To ensure correct use of this instrument, read the following points carefully and adhere to them. After you have read this manual, keep it in a safe place where it can be referred to anytime a question arises.

WARNING

(Failure to adhere to the following points may result in death or serious injury.)

- The instrument is designed for measurement of the oxygen saturation (SpO_2) of arterial blood and the pulse rate. Do not use it for any other purposes, such as warning of sleep apnea and breathing abnormalities.
- Do not use the instrument in places where flammable or combustible gases (anesthetic gas etc.) are present. Doing so may cause a fire.
- Do not disassemble or modify the instrument and accessories. Doing so may cause a fire or electric shock.
- The instrument should not be operated if it is damaged, or smoke or odd smells occur. Doing so may result in a fire. In such situations, turn OFF the power immediately, remove the battery, and contact the nearest authorized service facility.
- Do not put the batteries on a fire, short-circuit them, heat them or disassemble them. Doing so may cause explosion or heat generation, resulting in fire or injury.

CAUTION

(Failure to adhere to the following points may result in injury or damage to the instrument or other property.)

Do not use batteries other than those specified by KONICA MINOLTA SENSING, INC. When installing batteries in the instrument, make sure that they are correctly oriented according to the ⊞ mark.

If alkali fluid from the battery comes in contact with eyes, skin, or clothing, immediately wash the affected area and see a physician for treatment.

Do not use probes other than those specified by KONICA MINOLTA SENSING, INC. Use of alternative probes may cause the probe to overheat, resulting in burns.

Do not operate the instrument for long periods of time with a probe attached to a patient. Low-temperature burn, redness or rash may result. If you feel pain or itchiness, stop use of the instrument immediately and consult a doctor. A doctor should also be consulted before using the instrument on patients with high fever, those with peripheral blood circulation problems or those with sensitive skins.

Contents

Foreword

Safety Notes

CAUTION: U.S.Federal law restricts this device to sale by or on the order of a physician.

The instrument is designed for measurement of the oxygen saturation (SpO_2) of arterial blood and the pulse rate. Do not use it for any other purposes, such as warning of sleep apnea and breathing abnormalities.

The Oxygen Saturation Monitor PULSOX-300 is designed to measure oxygen saturation (SpO_2 value) in arterial blood and pulse rate by attaching a probe to an adult finger, in a non-invasive method.
PULSOX-300 is intended for spot check use.

- The compact, lightweight and portable body has a large LED display for easy operation.

Package Contents

Before using the instrument, make sure that the following items are present.

1) PULSOX-300 main body × 1
2) Wristband WB-300 × 1
3) AAA-size alkaline battery × 1
4) Instruction manuals
   - PULSOX-300 instruction manual × 1
   - Separate manual (Using manual for Probes) × 1

   ⁎ The probe is optional.

About Probe

The following probe types can be used with this instrument.

- Finger Clip Probe SR-5C
- Spot Check Probe SP-5C
- Monitor Probe LM-5C
- Personal Probe SD-5C

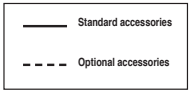
◆ As shown in the table below, the measuring point varies with the probe used, so select the one that is suitable for your purpose.

Probe type	Patient	Allowed measuring point
SR-5C	Adult	Finger (hand)
SP-5C		
LM-5C		
SD-5C		

◆ For the usage method, please refer to “Connecting the probe” (page 13) on this manual and the probe’s instruction manual.

System Diagrams and Accessories

The instrument consists of the following items.

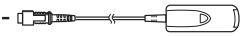


Optional accessories

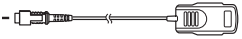
PULSOX-300

Extension cable **EC-300**

Finger Clip Probe **SR-5C**

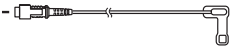


Spot Check Probe **SP-5C**



Monitor Probe **LM-5C**

Personal Probe **SD-5C**

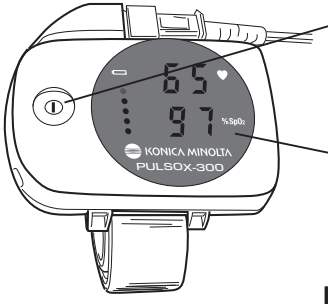


Standard accessories

Wristband **WB-300**

AAA-size alkaline battery

Names of Parts



Power button

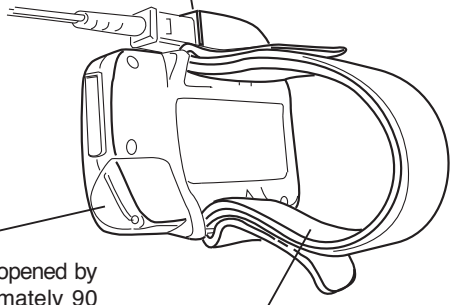
Used to start/end measurement.

Display (LED)

Measurement results and messages are displayed.

Probe connector

Connect the probe to this connector.



Battery cover

The cover can be opened by turning it approximately 90 degrees.

Wristband

Used to set the instrument on your wrist.

Notes on Use

- This instrument should be used under the following operating conditions.
  - Temperature of 0 to 40°C (32 to 104°F), relative humidity of 30 to 85%, with no condensation.
  - Atmospheric pressure of 700 to 1060 hPa (altitude of –400 to 3000m).
- This is a precision instrument. To avoid the possibility of it being damaged, the instrument should not be dropped nor should heavy objects be placed on top of it.
- Do not expose this instrument to rain and water.
- This instrument has no alarm function. Do not use this instrument if an alarm function is necessary.
- This instrument is designed for use on adults. When using the instrument on infants or babies, please note that the designed measurement accuracy cannot be guaranteed.
- Do not use the instrument on a point where there is excessive vibration. In addition, to avoid excessive impact on the instrument, it should be handled gently. Failure to observe this may cause breakdown.
- Accurate measurement data may not be obtained in the following cases.
  - When body movement is excessive
  - When the probe is not attached properly
  - When blood circulation at the measuring point is poor (due to pressure on arm/finger, peripheral circulatory insufficiency)
  - When ambient light (e.g. panel light, fluorescent light, infrared heat lamp, direct sunlight) is too strong
  - When influenced electromagnetically by other electronic devices (e.g. near electrical appliances like TV, medial device)
  - When a mobile telephone is used during measurement

- When influenced by abnormal hemoglobin like carbon monoxide hemoglobin (HbCO) and methemoglobin
- When pigments such as cardiogreen, intravascular dyes and indocyanine greenare present in the blood
- When finger nails are polished

- Tables 1 and 2 below show the errors which occur due to these hemoglobins.

Difference from the SaO_2 value to displayed value

<Table 1>

SaO_2	HbCO		
	1%	5%	10%
50	-0.1	-0.7	-1.5
70	-0.1	-0.7	-1.5
90	-0.2	-0.8	-1.6
100	-0.2	-0.8	-1.7

Measured value is always lower than the actual value.

<Table 2>

SaO_2	Methemoglobin		
	1%	5%	10%
50	+0.2	+1.3	+3.2
70	-0.6	-2.3	-3.2
90	-1.5	-6.0	-9.6
100	-1.8	-7.5	-12.2

Displayed value is sometimes higher than the actual value if SaO_2 is around 50%.

Notes on Storage

- This instrument should be stored under the following storage conditions.
  - Temperature of –10 to 60°C (14 to 140°F), relative humidity of 10 to 95%, with no condensation.
  - Atmospheric pressure of 700 to 1060 hPa (altitude of –400 to 3000m).
- When storing the instrument:
  - Do not store the instrument in an area where it will be exposed to water.
  - Do not store the instrument in an area where direct sunlight, pressure, temperature, humidity, ventilation, sunlight, dust, strong magnetic fields, and/or saline or sulphurous atmospheres may affect the instrument.
  - Do not store the instrument on an inclined surface or on a surface which may be subject to vibrations or physical shock. (Also avoid vibrations or physical shock during transportation.)
  - Do not store the instrument in areas where chemicals are stored or where gas may be emitted.
- To avoid any problems occurring the next time the instrument is used, make sure the instrument, cords, probes and other accessories are cleaned and stored safely.
- If the instrument will not be used for more than 2 weeks, remove the batteries from the battery to avoid the possibility of damage due to leakage of electrolyte.

Disposal Method

- When disposing of the used battery, insulate the polarity terminals with insulating tape etc. If the terminals of the battery come into contact with metal objects, heat generation, explosion or fire may result.
- Make sure that the battery is either disposed of or recycled correctly in accordance with local laws and regulations.

Preparations

Before starting measurements using this instrument, follow the procedure given below to ensure that measurements are stable.

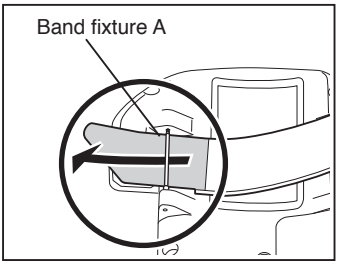
1) Attaching the Wrist Band

Attach the Wrist Band WB-300 (supplied as a standard accessory) to the instrument. Since the WB-300 is made of elastic material, it allows for flexibility and comfort of fitting on the wrist.

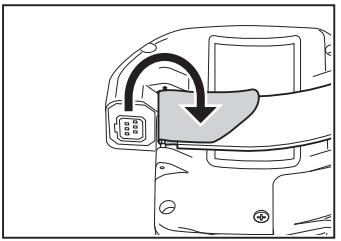
Procedure

1 Place the instrument with its rear side up.

2 Pass the angled tip of the hook-and-loop tape of the wristband outward through band fixture A.
- ◆ When doing so, make sure that the Velcro tape section faces upward.

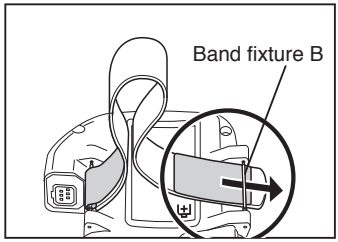


3 Fold up the inserted hook-and-loop section, and stick it firmly to the band.



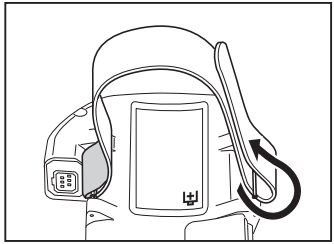
4 Pass the other end of the band outward through band fixture B.

- Take care not to twist the band.



5 Fold back and secure the band with the hook-and-loop tape section.

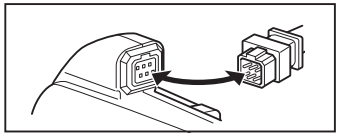
- When attaching the instrument to an arm, adjust the band length and fitting at this hook-and-loop tape section.



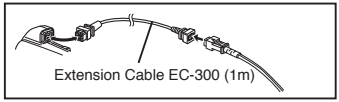
2) Connecting the probe

Connect the probe's connector plug into the Probe Connector on the instrument.

- Make sure that probe's connector plug is oriented correctly.
- Do not connect it in with excessive force. Doing so may damage the connector.
- Do not touch the connector terminals by hand. Contact failure may occur.



*Connecting the extension cable EC-300 between the PULSOX-300 and the probe extends the probe cable to a total length of 1m.

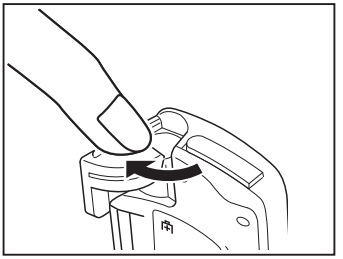


3) Installing the battery

Procedure

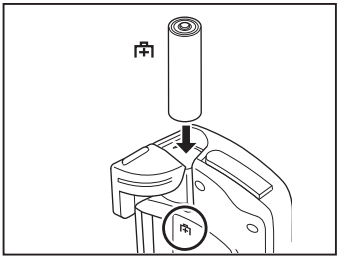
1 Turn the battery cover clockwise approximately 90 degrees to open the cover.

- When turning the cover, keep the flat part of your finger on the cover's catch. This facilitates opening the cover with minimum force.



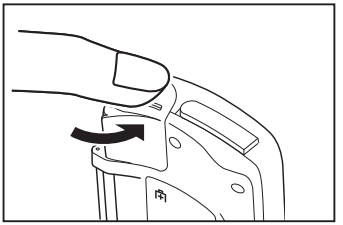
2 Insert the battery into the battery compartment according to the polarity mark (⊞)shown on the rear of the instrument.

- This instrument requires one AAA-size battery.



3 Turn the battery cover counter-clockwise approximately 90 degrees to close it.

- Introduction of a new mechanism locks the cover automatically when it is closed.



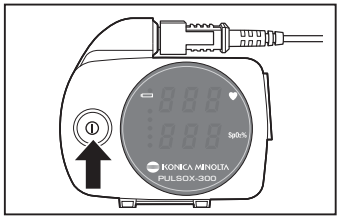
Measurement

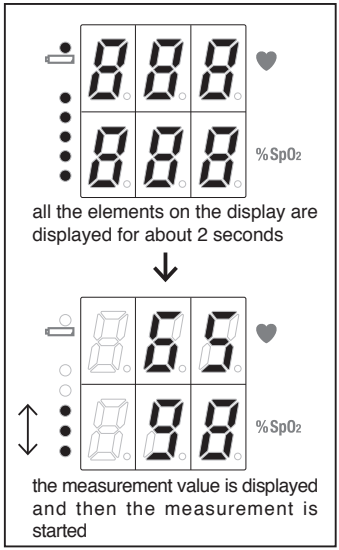
1) Starting the Measurement

1 Attach the probe to a finger of an adult patient.

2 Press the Power button.

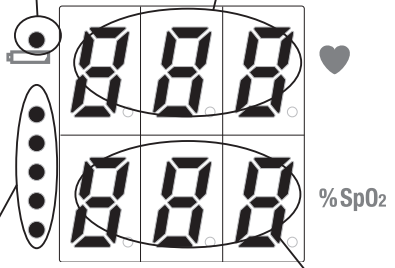
- The Power is ON, all the elements on the display are displayed for about 2 seconds, and then the display changes to the measurement display.
- Until the measurement value has been calculated and displayed, "---" will be displayed as the values of the oxygen saturation (SpO_2) and the pulse rate.





2) Reading the display

When the instrument is turned ON, all the elements of the LED will light up.
The pulse level, pulse rate and SpO_2 value are displayed during measurement.



Battery indicate

Flashing when battery is nearly empty.

Pulse rate (P.R.)

If an error occurs, an error message mainly about P.R. will be displayed.

Pulse Level Meter

Indicate the pulse level.

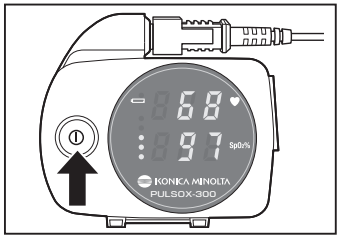
* For stable measurement, make sure that the pulse level meter lights up two or more segments by adjusting the measuring point or rubbing or warming it up to improve blood circulation.

Oxygen saturation (SpO_2) value

If an error occurs, an error message mainly about SpO_2 will be displayed.

3) Ending the Measurement

Press the Power button, the measurement is finished and the Power is off.



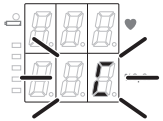
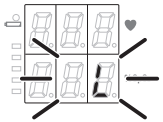
About Auto Power-Off function

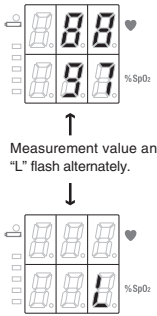
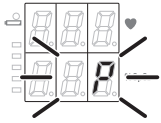
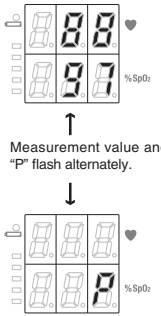
The instrument has an auto power-off function that operates independently. If no probe is connected to the PULSOX ("C" blinks) or no probe is attached to the patient ("L" blinks) continuously for more than 2 minutes, the Power is automatically switched off.

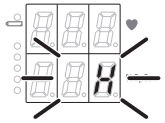
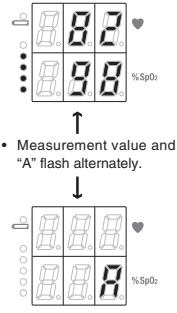
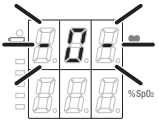
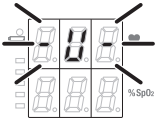
Trouble Shootings

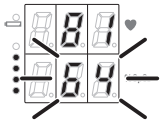
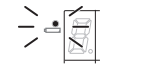
Error Messages

The instrument display error messages when the error occurs. Check and correspond to them correctly.

Error Messages	Cause	Solution
 • "C" blinks. • Power is automatically switched off if no probe is connected to PULSOX for more than 2 seconds continuously.	• There is no probe connected to the PULSOX-300 or the probe is improperly connected to the PULSOX-300. • If using the optional Extension Cable EC-300, the cable may not be connected to the instrument or the probe correctly.	• Connect the probe to the PULSOX-300 properly. When using the optional Extension Cable EC-300, connect the cable to the instrument and the probe correctly. • If this message reappears even though the probe is properly connected to the PULSOX-300, the probe is malfunctioning (e.g., wire breakage inside the probe). Use another probe.
	• The connected probe is not for a PULSOX- 300.	• Use a probe that is specifically designed for the PULSOX-300.
 • "L" blinks. • Power is automatically switched off if no probe is attached to the patient for more than 2 seconds continuously.	• Insufficient light for measurement. • The light emitted from the LED enters the sensor directly. • Strong light enters the probes sensor directly.	• Check that the probe is properly attached to the patient. • Be sure that the light-source and sensor sections are properly lined up. • If the part being measured is thick, insufficient light will be transmitted. Attach probe to a thinner part. • Clean the light-source and sensor sections. • Take measures to prevent direct entry of strong light to the probe. • If this message reappears even though the above points have been checked, the probe may be malfunctioning. Use another probe.

Error Messages	Cause	Solution
 • Measurement value and "L" flash alternately.	• The light power required for the measurement is not obtained. The measurement value is displayed; however, the accuracy of the measurement values cannot be guaranteed.	• Check that the probe is properly attached to the patient. • Be sure that the light-source and sensor sections are properly lined up. • If the part being measured is thick, insufficient light will be transmitted. Attach probe to a thinner part. • Clean the light-source and sensor sections. • Take measures to prevent direct entry of strong light to the probe. • If this message reappears even though the above points have been checked, the probe may be malfunctioning. Use another probe.
 • "P" blinks.	• Pulse signal required for measurement is not being received.	• Check that the probe is properly attached to the patient. If the probe is properly attached but this message still appears, the circulation in the area being measured may not be good. Move the probe to an area from which a sufficiently strong pulse signal can be received. • If a sufficiently strong pulse signal cannot be obtained regardless of the area to which the probe is attached, the probe may be malfunctioning. Use another probe.
 • Measurement value and "P" flash alternately.	• The pulse is weak and the pulse signals required for measurement are not obtained. The measurement value is displayed; however, the accuracy of the measurement values cannot be guaranteed.	• Attach the probe to the body correctly. If this message is displayed when the unit is attached to the patient correctly, the measurement conditions are regarded as blood circulation or other circulatory problems. If this occurs, search for a location where adequate pulse signals can be obtained. Attach the probe again or warm up the measurement location. • In particular, when the pulse is weak, this error tends to occur. For improved measurement accuracy, if the probe is exposed to strong light, wrap it with a piece of black cloth, etc. Also make sure that the patient rests calmly to avoid influence of body movement.

Error Messages	Cause	Solution
 • "H" blinks.	• The pulse is too strong for correct measurement.	• Attach the probe to the body correctly. If this message is displayed when the unit is attached to the patient correctly, the measurement conditions are regarded as blood circulation or other circulatory problems. If this occurs, search for a location where more stable pulse signals can be obtained. • If this message reappears even though the above points have been checked, the probe may be malfunctioning. Use another probe.
 • Measurement value and "A" flash alternately.	• Motion artifact The measurement value is displayed; however, the accuracy of the measurement values cannot be guaranteed.	• Attach the probe to the patient properly. If this message still reappears even though the probe is attached properly, keep the measuring point as stationary as possible or attach the probe to another part of the body where body movement is relatively low.
 • "-O-" blinks.	• The pulse rate exceeds the upper limit (230 bpm) of the measurement range.	• Measurement cannot be performed when the upper limit of the measurement range is exceeded.
 • "-U-" blinks.	• The pulse rate belows the lower limit (30 bpm) of the measurement range.	• Measurement cannot be performed when the lower limit of the measurement range is not reached.

Error Messages	Cause	Solution
 • Measurement value blinks.	• The SpO_2 value is below the lower limit (70% SpO_2) of the measurement range. The measured value will still be displayed, but its accuracy cannot be guaranteed.	(This message indicates that the measured value is outside the accuracy guaranteed range.)
 • "bt out" will not be shown when the battery is completely exhausted.	• Battery Out	• Replace the battery with new one. • In this case, the measurement data is not left if the battery is removed.
 • Battery indicator is flashing.	• Battery power is nearly empty.	• Battery will be empty in about 30 seconds. Remove battery and replace with new one.
 • Display for about 3 seconds and the Power is switched off.	• Other trouble occurred in the measurement circuit of the instrument.	• Turn the Power Off, and turn ON again. • If these message reappear even though the above points have been checked, the instrument may be malfunctioning. Contact to the nearest distributor or authorized service facilities.

Check Points before repairing

Before taking any actions, check the following points first.

◆ If the abnormality continues to reappear, the instrument might be faulty, so contact the nearest distributor or authorized service facility.

Problem	Checkpoint	Solution	Ref.Page
· No display appears when the Power is turned ON.	· Is battery power exhausted?	· Turn the Power OFF and replace the battery (AAA-size) with new one.	P.14
	· Is battery oriented correctly?	· Make sure that the battery are oriented correctly	P.14
· Display disappeared in the middle of measurements.	· Is no probe connected to the PULSOX or is no probe attached to the patient for more than 2 minutes continuously?	· For auto power off function, if no probe is connected to the PULSOX or no probe is attached to the patient for more than 2 minutes continuously, the Power is automatically switched off.	P.17

Maintenance and Inspection

• Before using the instrument, make sure that there is no damage to the instrument, no damage or wire-breakage in the probe cable and the instrument operates correctly and safely.

Cleaning

• Dampen a soft cloth with neutral detergent or water, wipe the instrument with it, then wipe off carefully with a dry cloth. In this way, make sure the instrument is cleaned and never use solvent. When cleaning, take care not to touch the connector terminals. Touching them may break terminal pins, resulting in breakdown or damage.

Specification

■ **Dual-wavelength pulse type (665nm/880nm) arterial blood oxygen saturation measuring instrument**
- Name: Oxygen Saturation Monitor
- Model name: PULSOX-300

■ **Functions:**
- Measuring range: SpO_2: 0 to 100% SpO_2
  Pulse rate: 30 to 230 bpm
- Accuracy: SpO_2: ±2% SpO_2 (70 to 100% range, 1S.D.)
  Pulse rate: ±2 bpm (30 to 100 range)
  or ±2% of value (100 to 230 range)

※ PULSOX-300 has been clinically validated for use on adults.

■ **Display**

Display type: Liquid crystal display
- Oxygen saturation (SpO_2)
- Pulse rate number
- Pulse level meter (5 steps)
- Battery indication
- Error messages indication

■ **Warning functions**
- SpO_2: Low SpO_2 warning (flashing display)
- Battery indication (flashing when the battery is nealy empty)
- Error message indication

■ **Operating conditions**

temperature/humidity range
0 to 40°C (32 to 104°F); 30 to 85% relative humidity with no condensation

atmospheric pressure/altitude range
700 to 1060hPa (altitude: –400 to 3000m)

■ **Storage conditions**

temperature/humidity range
–10 to 60°C (14 to 140°F); 10 to 95% relative humidity with no condensation

atmospheric pressure/altitude range
700 to 1060hPa (altitude: –400 to 3000m)

■ **Power**

1 AAA-size battery: 1.5V ⎓ 100mW (Service life under continual usage: approx. 16 hours with alkaline battery)

■ **Dimensions (W × H × D)**

68 × 58 × 15 mm

■ **Weight**

56g (including battery/excluding wrist band and probes)

■ **Usable life**

6 years [Verified by KONICA MINOLTA SENSING, INC. (based on own data)]

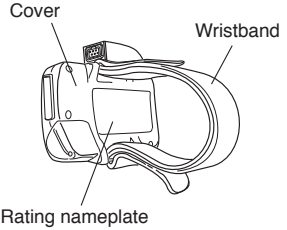
Probes (SR-5C, SP-5C, LM-5C, SD-5C)

- LED-SPD probe
- Type
  - Finger Clip Probe SR-5C
  - Spot Check Probe SP-5C
  - Monitor Probe LM-5C
  - Personal Probe SD-5C

    ✻ It can be used with one of Extension Cable EC-300

- Components that touch the body

Cover:	Polycarbonate
Wrist band:	Polyethylene terephthalate, nylon 6
Rating nameplate:	Polyethylene terephthalate



Equipment classification (based on "UL 60601-1/EN 60601-1")

- Protection against electric shock: Internally powered
- Type of applied part: BF
- Not suitability for use in the presence of flammable anaesthetic mixture with air or oxygen or nitrous oxide.
- The instrument is not protected against entry of water.
- Only the cleaning method has been stipulated (no disinfection/sterilization methods have been stipulated).
- Mode of operation of Equipment: Continuous while in Use (IEC 60601-1)

Appendix

Calculation Method for Displayed Values

<Pulse level meter>

The pulse level meter displays the transmitted light amount ratio calculated by the following equation. The pulse level is indicated in eight levels (0 to 15%, full scale if over 10%).

$$\text{Pulse level (\%)} = \frac{\text{Transmitted light amount that varies due to the pulse}}{\text{Transmitted light amount that does not vary due to the pulse}} \times 100$$

<Oxygen saturation (SpO_2)>

Updates the moving average of the oxygen saturation over the last 12 seconds at one-second intervals.

<Pulse rate (P.R.)>

Updates the moving average of the last 8 pulse rates at one-second intervals.

EMC Guidance

Guidance and manufacture's declaration - electromagnetic emissions		
The Oxygen Saturation Monitor Model PULSOX-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PULSOX-300 should assure that it is used in such anenvironment.		
Emissions test	Compliance	Electriomagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Model PULSOX-300 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 electromagnetic equipment.
RF emissions CISPR 11	Class B	The Model PULSOX-300 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Not applicable	

Guidance and manufacture's declaration - electromagnetic immunity			
The Oxygen Saturation Monitor Model PULSOX-300 is intended for use in the elec-tromagnetic environment specified below. The customer or the user of the Model PULSOX-300 should assure that it is used in such anenvironment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electromagnetic Discharge (ESD) IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile, if fllors are covered with synthetic materisl, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC61000-4-4	Not applicable		
Surge IEC61000-4-5	Not applicable		
Voltage dips, short Interruptions and Voltage variations on power supply Input lines IEC61000-4-11	Not applicable		
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at level characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration - electromagnetic immunity

The Oxygen Saturation Monitor Model PULSOX-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PULSOX-300 should assure that it is used in such anenvironment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the PULSOX-300, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d \quad 1.2\sqrt{P}$ 80MHz to 800MHz $d \quad 2.3\sqrt{P}$ 800MHz to 2.5GHz 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 inmeters (m). Field strength 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: 
Radiated RF IEC61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	

NOTE 1 At 80MHz and 800MHz, 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone 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 PULSOX-300 is used exceeds the applicable RF compliance level above, the PULSOX-300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PULSOX-300.

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

Measurement Principle

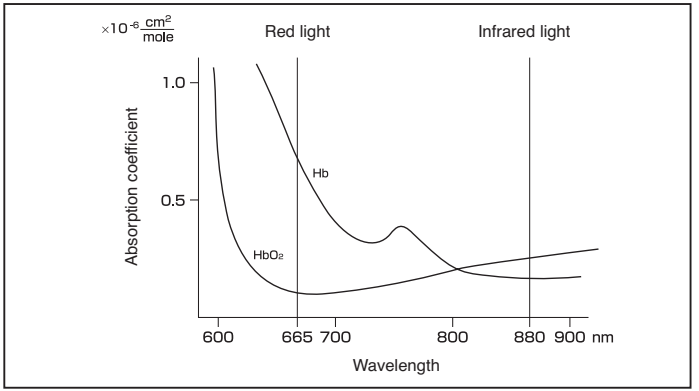
This instrument measures the oxygen saturation (SpO_2) in arterial blood and pulse rate continuously in a non-invasive method by applying optical principles.
With this instrument, SpO_2 is defined by the following equation.

$$SpO_2 = \frac{C\ (HbO_2)}{C\ (HbO_2) + C\ (Hb)} \times 100\ (\%\ SpO_2)$$

where
C (Hb): Concentration of reduced hemoglobin
C (HbO_2): Concentration of oxyhemoglobin

The light-absorption characteristics of reduced hemoglobin (Hb) are very different from those of oxyhemoglobin. This instrument measures the changes in the absorption of red and infrared lights passing through the tissue to determine the SpO_2 of the blood. Thus, this method is free from the effects of skin color, muscles, bones, and veins.

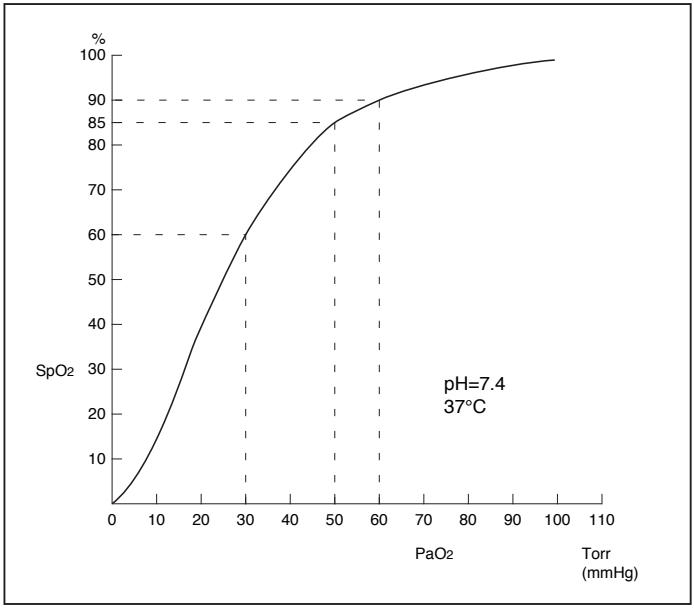
■ **Spectral Absorption of Hb and HbO_2**



Relation between Oxygen Saturation and Partial Pressure

The relation between oxygen saturation (SpO_2) and oxygen partial pressure (PaO_2) is shown in the graph below. SpO_2 is the oxygen saturation as measured by pulse oximeters.

■ **Oxygen Saturation vs. Oxygen Partial Pressure**



The curve of the above graph may shift to the right or left according to the pH of the blood or the body temperature.

- Shift to right: acidosis, high body temperature
- Shift to left: alkalosis, low body temperature

Manufacturer

KONICA MINOLTA SENSING, INC.

3-91, Daisen-nishimachi, Sakai-ku, Sakai-shi, Osaka 590-8551, Japan

9222-1732-34 AJFAKK Printed in Japan