OMRON

Fingertip Pulse Oximeter
P300 Intelli IT (HPO-300T)

Instruction Manual

All for Healthcare

IM-HPO-300T-ENFR-01-08/2020

General Description

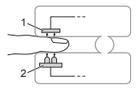
Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO_2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO_2 level.

Measurement Principle

Principle of the pulse oximeter is as follows: The pulse oximeter works by applying a sensor to a fingertip. The sensor contains a dual light source and a photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is an infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in the finger sensor collects and converts the light into an electronic signal which is proportional to the light intensity. The arteriole normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO_2.

Diagram of Operation Principle

1. Red and Infrared-ray Detector
2. Red and Infrared-ray Light Source



Intended Use

The Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, adolescent and child patients in hospitals, hospital-type facilities and home-care environments.

Precautions For Use

- Before use, carefully read the manual.
- Always consult with the physician when using the device.
- Operation of the device may be affected by the use of an electrosurgical unit (ESU).
- The device must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
- Do not use the device in MRI or CT environments.
- Do not use the device in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
- Do not use the device in an explosive atmosphere.
- The device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- In order to ensure a correct sensor alignment and a skin integrity, the maximum application time at a single site for this device should be less than half an hour.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- This device complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
- Portable and mobile RF communications equipment can affect the medical electrical device and should not be used no closer than 30cm to any part of the device. Otherwise, degradation of the performance of this device could result.
- This device is not intended for use during patient transport.
- This device should not be used adjacent to or stacked with other equipment.
- It may be unsafe to:
  - use accessories, detachable parts and materials not described in the instructions for use
  - interconnect this device with other equipment not described in the instructions for use
  - disassemble, repair or modify the device
- The materials that contact with the patient's skin contain medical silicone and pass the ISO10993-5 tests for in vitro cytotoxicity and ISO 10993-10 tests for irritation and skin sensitization.
- When the signal is not stable, the reading may be inaccurate. Please do not refer to the result, and try the measurement again.
- The patient is an intended operator.
- The pulse waveform is normalized.

Contraindication

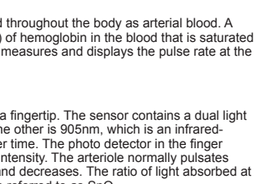
Not found yet.

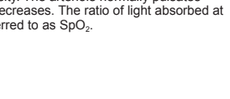
Inaccurate Measurements may be Caused by

- Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- High ambient light. Shield the sensor area if necessary.
- Excessive patient movement.
- High-frequency electrosurgical interference and defibrillators.
- Venous pulsations.
- When the device is used on the same arm as a blood pressure cuff, arterial catheter, or intravascular line.
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- The patient is in cardiac arrest or is in shock.
- Fingernail polish or false fingernails.
- Weak pulse quality (low perfusion).
- Low hemoglobin.

Product Features

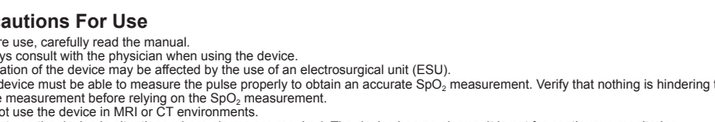
- Simple to operate and convenient to carry.
- Small volume, light weight and low power consumption.
- Colorful color OLED displays SpO_2, PR and pulse waveform.
- 2 display modes.
- 2pcs AAA-size alkaline batteries (LR03); battery indicator.
- **Bluetooth®** for data transmission.
- Automatically power on/off.
- Weak or unstable signal prompt provides more accurate measurements.
- When no signal or low signal is detected, it will display "Finger Out" and will power off automatically in 8 seconds.





Battery Installation

1. Install two AAA alkaline batteries.
   1.1. Push up the battery case along the arrow to open the battery case.
   1.2. Install two AAA alkaline batteries into the battery case. Match the plus (+) and minus (-) signs in the case. If the polarities are not matched, damage may be caused to the device.
   1.3. Push down the battery case to close.



Note
- Please remove the batteries if the device will not be used for long periods of time.
- Please replace the batteries when the battery indication starts flashing.
- Only use two AAA alkaline batteries with this device. Do not use other types of batteries. Do not use new and used batteries together. Do not use different brands of batteries together.

Warning: Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
- Keep the device away from young children. Small items such as the battery case and batteries are choking hazards.

Download the "OMRON connect" app on the Smart Device

1. Enable **Bluetooth®** on the smart device.
2. Download and install the "OMRON connect" app onto the smart device.
3. Press the power button to access the measurement interface. Press and hold the power button for more than 2 seconds to enter the pairing setting interface.
4. Open the app on your smart device, and follow the pairing instructions.

connect OMRON

To get started go to:
omronconnect.com/setup

Bluetooth®

Uploading the Data via Bluetooth

When taking a measurement, open the app for uploading the data.
When the " " symbol stops flashing during a measurement, the device is connected with the app successfully.

Note
- When the reading is stable, the data is uploaded to the app. The device will power off automatically after the data shows on the display about 15 seconds.
- The device stores data up to 30 without using the app during the measurement. When taking a measurement with the app, all stored data will be uploaded on the app. The device deletes from the oldest data if the measurement is taken more than 30 times without using the app.

Operation Instructions

Open the app when taking a measurement.

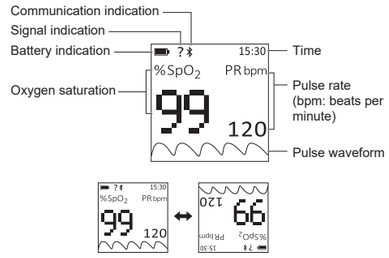
1. Place one of fingers other than a thumb or a little finger, into the rubber opening of the device. The device will turn on automatically. It goes from the startup screen to the measurement interface.

2. Keep hands still for the measurement. Do not shake the finger during a measurement. It is recommended not to move the body while taking a measurement.

3. Read the data.

Note
- If the measurement falls below the threshold (SpO_2<90%), the color of the measurement becomes orange.
  If it continues to become orange, we recommend to consult with the physician.
- If the display shows the "?" symbol, it means the signal is unstable. Please keep hands still and retry.
- If the battery power reduces to half, the " " appears. If it becomes low, the " " flashes in red. We recommend to replace 2 AAA alkaline batteries with new ones.
- The " " symbol stops flashing when the device is connected with the app successfully.
- The time will automatically be adjusted when the device is connected with the app.

4. Press the power button once to switch the display mode.



Maintenance and Storage

- Replace the batteries in a timely manner when the battery indication flashes in red.
- Clean surface of the device before it is used in diagnosis for patients.
- Remove the batteries if the device is not operated for a long time.
- It is best to store the device in -20°C ~ 60°C, 10% ~ 93% RH (no condensation).
- Keep in a dry place. Extreme moisture may affect the lifetime of the device and may cause damage.
- Dispose of batteries properly; follow any applicable local battery disposal laws.

Cleaning and Disinfecting the Device

It is recommended to clean and disinfect the silicone touching the finger inside of the device with a soft cloth dampened with recommended alcohol of 70% isopropyl or 70% ethanol before and after each use.
Excessive disinfection may cause damage to the device and is therefore not recommended for this device unless otherwise indicated in your hospital's servicing schedule.
Do not pour or spray liquids onto the device and do not allow any liquid to enter any openings in the device. Allow the device to dry thoroughly before reuse.
The Fingertip Pulse Oximeter requires no routine calibration or maintenance other than replacement of batteries.

Caution: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.
- Never use EtO (ethylene oxide) or formaldehyde for disinfection.

The use-life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:
1. Any of the problems in the "Possible Problems and Solutions" cannot be solved.
2. The device cannot be powered on in any case and not due to the battery issues.
3. There is a crack on the device or a damage on the display resulting that readings cannot be identified; the internal spring does not put appropriate pressure on the finger; or the power button is unresponsive.

Specifications

1. **Product category**
   Pulse oximeter
2. **Product description**
   Fingertip pulse oximeter
3. **Model(code)**
   P300 Intelli IT (HPO-300T)
4. **Display Type**
   OLED display
5. **SpO_2**
   Display range: 0%~100%
   Measurement range: 70%~100%
   Accuracy (A_{rms}): ±2% (70%~100%), no definition (0%~69%)
   Low Perfusion Accuracy (A_{rms}): ±3% (70%~100%), no definition (0%~69%),
   PI (Pulse Amplitude Index) ≥0.1%, tested using the functional tester
   Resolution: 1%

   Note
   - The device is calibrated to display SpO_2. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples is measured over the SpO_2 range of 70%~100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO80601-2-61, Medical Electrical Equipment–Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
   - A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. A functional tester is used to measure how accurately the pulse oximeter is reproducing the specified calibration curve and the PR accuracy.
   - The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.
   - ±1 A_{rms} represents approximately two-thirds of measurements at zero bias.
6. **Pulse Rate**
   Display range: 28bpm~255bpm
   Measurement range: 30bpm~250bpm
   Accuracy (A_{rms}): ±2bpm (30bpm~99bpm), ±2% (100bpm~250bpm), no definition (outside of 30bpm~250bpm)
   Low Perfusion Accuracy (A_{rms}): ±2% (30bpm~250bpm), no definition (outside of 30bpm~250bpm),
   PI (Pulse Amplitude Index) ≥0.1%, tested using the functional tester
   Resolution: 1bpm
7. **Probe LED Specifications**

	Wavelength	Radiant Power
RED	660±3nm	3.2mw
IR	905±10nm	2.4mw

   Note
   - The information about wavelength range can be especially useful to clinicians.
8. **Power Requirements**
   Two AAA alkaline batteries (LR03)
   Power consumption: Less than 40mA
   Battery Life:
   It is used for 2000 measurements and 30 seconds per one measurement.
9. **Environment Requirements**
   Operating environmental conditions: 10°C ~ 40°C, 30% ~ 85% RH (no condensation), 700hPa ~ 1060hPa
   Storage/transport environmental conditions: -20°C ~ 60°C, 10% ~ 93% RH (no condensation)
10. **Equipment data update period**
    The average data update period is 8s.
11. **Classification**
    Type of protection against electric shock: Internally Powered Equipment
    Degree of protection against electric shock: Type BF applied part (applied part: the rubber hole of the device)
    Degree of protection against ingress of dust and water: IP32
    Mode of operation: Continuous operation (classification based on IEC60601-1)
12. **Wireless Communication**
    Frequency range: 2.4 GHz (2400 - 2483.5 MHz)
    Modulation: GFSK
    Effective radiated power: <20 dBm
13. **Transmission method**
    Bluetooth® Low Energy
14. **Weight**
    Approximately 60 g (including batteries)
15. **Dimensions**
    Approximately 32 mm (w) × 61.5 mm (h) × 31.5 mm (l)
16. **Internally stored data**
    Up to 30

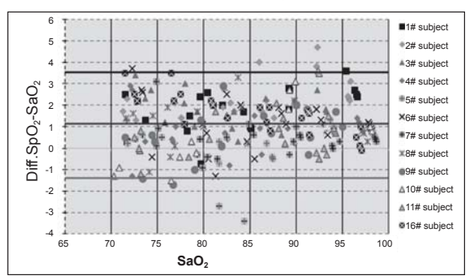
Clinical Study Summary

The following details are provided to disclose actual performance observed in the clinical validation study of 12 healthy adult volunteers (ages 18-45yr, mixed-gender, light to dark skin pigmentation). The A_{rms} value analysis statement and Bland-Altman plot of data is shown as following:

A_{rms} Value Analysis Statement

Item	90--100	80--<90	70--<80
#pts	80	85	82
Bias	1.25	1.10	1.02
A_{rms}	1.64	1.66	1.70

Bland-Altman Plot Graphic



Possible Problems and Solutions

Problems	Possible reason	Solution
SpO_2 or PR can not be shown normally.	1. Finger is not inserted correctly 2. Patient's SpO_2 value has variations or is inaccurate.	1. Retry by using the same or a different finger (other than a thumb or a little finger). 2. There is excessive illumination. 3. Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.
The display continues to show "---" and "Finger Out".		
SpO_2 or PR is shown unstably.	1. Finger might not be inserted deep enough. 2. Excessive patient movement	1. Retry by inserting the finger. 2. Be calm.
The display continues to show "?".		
The device cannot be powered on.	1. No battery or low power of battery 2. Batteries might be installed incorrectly. 3. The device might be damaged	1. Please replace batteries. 2. Please reinstall the batteries. 3. Please contact with local customer service center.
The display is suddenly off.	1. The device is automatically powered off when no signal is detected longer than 8 seconds. 2. The battery power is too low to work.	1. Normal 2. Replace the batteries.
Any communication issue occurs.	Follow the instructions shown in the smart device, or visit the "Help" section in the "OMRON connect" app for further help. If the problem still persists, contact your OMRON retail outlet or distributor.	

Symbol Definitions

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Type BF applied part		Atmospheric pressure limitation	IP32	The degree of protection against ingress of dust and water
	Follow instruction for use		Date of Manufacture		Manufacturer's information
SpO_2	No SpO_2 Alarm	CE 0123	European union approval	EC REP	Authorized representative in the European community
	Temperature limitation		Conformity to WEEE Directive	MD	For medical use
	Humidity limitation	SN	Serial No.		

Box Contents

1. Fingertip Pulse Oximeter
2. Two AAA alkaline batteries (LR03)
3. Instruction manual
4. Storage case

Note
- The illustrations used in this manual may differ slightly from the appearance of the actual product.
- The specifications are subject to change without prior notice.

Limited Warranty

Thank you for buying an OMRON product. This product is constructed of high quality materials and great care has been taken in its manufacturing. It is designed to give you a high level of comfort, provided that it is properly operated and maintained as described in the instruction manual.
This product is warranted by OMRON for a period of 2 years after the date of purchase.
The proper construction, workmanship and materials of this product is warranted by OMRON. During this period of warranty OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts.

The warranty does not cover any of the following:
A. Transport costs and risks of transport.
B. Costs for repairs and / or defects resulting from repairs done by unauthorised persons.
C. Periodic check-ups and maintenance.
D. Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly warranted above.
E. Costs arising due to non-acceptance of a claim (those will be charged for).
F. Damages of any kind including personal caused accidentally or from misuse.

Should warranty service be required please apply to the dealer whom the product was purchased from or an authorised OMRON distributor. For the address refer to the product packaging / literature or to your specialised retailer.
If you have difficulties in finding OMRON customer services, visit our website (www.omron-healthcare.com) for contact information.

Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.
The warranty will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer.

Electromagnetic Compatibility

HPO-300T conforms to IEC60601-1-2:2014 Electromagnetic Compatibility (EMC) standard.

Essential performance is defined as SpO_2 accuracy and pulse rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the intended use. If issues are experienced, move the device away from the source of electromagnetic disturbances.

Table 1: Electromagnetic Emissions Limits and Compliance

Emissions Test	Compliance
RF Emissions CISPR 11	Group 1, Class B
Note : Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3) are not applicable.	

Table 2: Electromagnetic Immunity

Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Rated Power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50Hz and 60 Hz	
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m 80% AM 1kHz
	380 – 390 MHz	27 V/m Pulse mod. 18Hz
	430 – 470 MHz	28 V/m FM±5Hz deviation 1kHz sine
	704 – 787 MHz	9 V/m Pulse mod. 217Hz
	800 – 960 MHz	28 V/m Pulse mod. 18Hz
	1.7 – 1.99 GHz	28 V/m Pulse mod. 217Hz
	2.4 – 2.57 GHz	28 V/m Pulse mod. 217Hz
	5.1 – 5.8 GHz	9 V/m Pulse mod. 217Hz
Note : Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6) are not applicable.		

Hereby, Beijing Choice Electronic Technology Co., Ltd., declares that the radio equipment type HPO-300T is in compliance with Directive 2014/53/EU.
The full text of the EU declaration of conformity is available at the following internet address:
www.omron-healthcare.com

Issue Date: 2021-02-09
Version: Ver1.0

CE 0123

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