

Fingertip Pulse Oximeter

Model No.:EHP029

General Description

The Easy@Home Fingertip Pulse Oximeter EHP029 is a handheld non-invasive device intended for spot-checking of oxygen saturation of hemoglobin (SpO₂) and Pulse Rate for adult, adolescent and children.

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 SpO₂. A pulse oximeter also measures and displays the pulse rate at the same time as it measures the SpO₂ level.

Read and follow the operating procedures closely as shown in the instructions. Otherwise malfunction, equipment damage, or personal injury may occur. The manufacturer warranty does not include safety and reliability issues due to user negligence.

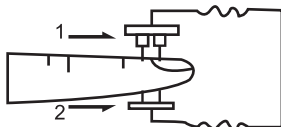
Note: Solely for use with sporting and aviation activities. Intended to monitor heart rate during exercise.

Measurement Principle:

Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to either pointer finger. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is 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. Systolic blood pressure is the first number measuring the pressure in your blood vessels when your heart beats; the second number is diastolic blood pressure measuring the pressure in your blood vessels as well, but when the heart is resting in between beats. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO₂.

Diagram of Operation Principle

- 1.Red and Infrared-ray Emission Tube
- 2.Red and Infrared-ray Recept Tube



Precautions for Use

- 1.Operation of the fingertip pulse oximeter may be affected by using an electrosurgical unit (ESU).
- 2.The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO₂ measurement. Before relying on the SpO₂ measurement, verify that nothing is hindering the pulse measurement.
- 3.Do not use the fingertip pulse oximeter in an MRI or CT environment.
- 4.Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
- 5.Do not use the fingertip pulse oximeter in an explosive atmosphere.
- 6.The fingertip pulse oximeter is intended only as an adjunct assessment. It must be used in conjunction with other methods of assessing signs and symptoms.
- 7.In order to ensure correct sensor alignment and skin integrity, the maximum application time for this device should be less than half an hour.
- 8.Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- 9.Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- 10.This equipment 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 environments, it is possible that high levels of such interference due to proximity close proximity or strength of a source might disrupt the performance of this device.
- 11.Portable and mobile RF communications equipment can affect electrical equipment.
- 12.This equipment is not intended for use during person transport outside a facility
- 13.This equipment should not be used adjacent to or stacked with other equipment.
- 14.Do not disassemble, repair or modify the equipment without authority.
- 15.These materials that contact with the skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.

Rx only: "Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner."

Inaccurate Measurements May be Caused by

- 1.Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin);
- 2.Intravascular dyes such as indocyanine green or methylene blue;
- 3.Strong ambient light. Shield the sensor area if necessary;
- 4.Excessive movement;
- 5.High-frequency interference and defibrillators;
- 6.Venous pulsations;
- 7.Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- 8.Hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- 9.Cardiac arrest or shock;
- 10.Fingernail polish or false fingernails;
- 11.Weak pulse quality (known as low perfusion);
- 12.Low hemoglobin;

Contraindication

This device is not for continuous monitoring.

Product Features

- 1.Dual color OLED displays SpO₂, PR, Pulse bar, and waveform.
- 2.Level 1-10 adjustable brightness.
- 3.6 display modes.
- 4.2 pack AAA-size alkaline batteries (included in box); low-battery indicator.

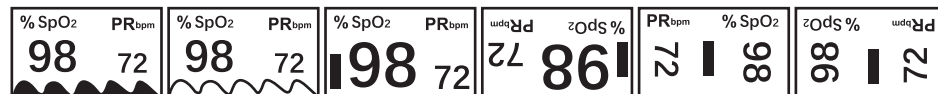
- 5.When it shows "Finger out", the pulse oximeter will power off automatically in 8 seconds.

Operation Instructions

- 1.Install two AAA batteries according to the Battery Installation instructions.
- 2.Place one of your fingers into the rubber opening of the pulse oximeter.
- 3.Press the switch button one time on front panel to turn the pulse oximeter on.
- 4.Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
- 5.Read the data from the display screen.

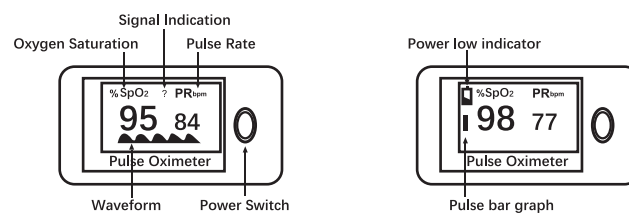
Tips:

- 1.Pressing the power switch for longer than one second will adjust the brightness of the oximeter. There are 10 levels of brightness. The default is level four.
- 2.After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 6 display modes.



- 3.Take out your finger, then screen displays "Finger Out". It means the measurement is ended.

Front Panel:

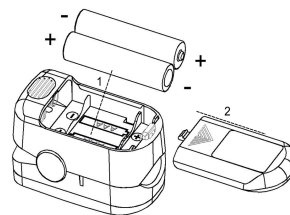


Notes:

- 1.The pulse bar less than 30% indicates signal inadequacy and the displayed SpO₂ or pulse rate value is potentially inaccurate.
- 2.If the screen displays "?", it means the signal is unstable, please take out your finger out and put it back in the oximeter, then keep your hands still and retry.

Battery Installation

- 1.Slide the battery door cover open horizontally along the arrow.
- 2.Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
- 3.Close the battery door cover by sliding back.



Notes:

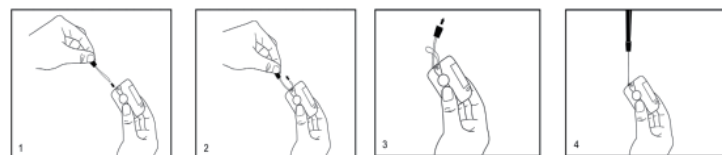
Please remove the batteries if the pulse oximeter will not be used for long periods of time, as corrosion can occur.
Please replace the battery when the power indicator starts flickering.

Using the Lanyard

- 1.Thread the thinner end of the lanyard through the loop.
- 2.Thread the thicker end of the lanyard through the threaded end before pulling it tightly.

Warning!

- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Do not hang the lanyard from the device's electrical wire.
- Please notice that the lanyard, which is tied to the oximeter, may cause strangling due to excessive length.



Maintenance and Storage

- 1.Replace the batteries in a timely manner when low voltage lamp is lit.
- 2.Clean surface of the fingertip oximeter before it is used.
- 3.Remove the batteries if the oximeter is not operated for a long time.
- 4.It is best to store the product in -13°F~-158°F (-25°C~+70°C) and ≤93% humidity.
- 5.Keep in a dry place where humidity is ≤93%. Extreme moisture may affect the oximeter lifetime and may cause damage.
- 6.Dispose of the battery properly; follow any applicable local battery disposal laws.

Cleaning the fingertip pulse oximeter

Please use medical alcohol to clean the silicone. Touch the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the finger being tested finger using alcohol before and after each test.

Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.

The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

The device lifetime is five years when it is used for 15 measurements every day and 10 minutes per

one measurement. Stop using and contact our customer service center if one of the following cases occur:

- An error in the Possible Problems and solutions section is displayed on the screen.
- The oximeter cannot be powered on in any case and not the reasons of battery.
- There is a crack on the oximeter or damage on the display resulting in readings that cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

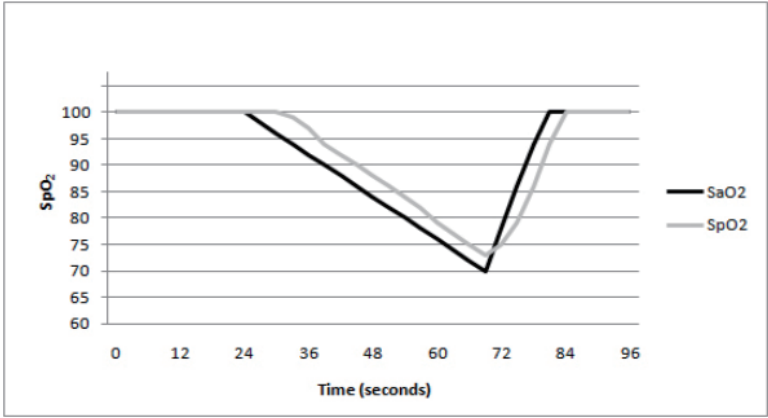
Disinfecting

The applied parts that touch the person's body are required to be disinfected after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid

disinfectants.
Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated.
Clean the pulse oximeter before disinfecting it. CAUTION: Never use EtO or formaldehyde for disinfection.

Specifications:

1. Display Type:
OLED display
2. SpO2:
Display range: 0%~100%
Measurement range: 70%~100%
Accuracy: 70%~100%±2%; 0%~69% no definition
Resolution: 1%
3. Pulse Rate:
Display range: 0bpm~250bpm
Measurement range: 30bpm~250bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%
Resolution: 1bpm
4. 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.
5. Power Requirements:
Two AAA alkaline Batteries
Power consumption: Less than 40mA
6. Environment Requirements:
Operation Temperature: 41°F~104°F (5°C ~40°C)
Storage Temperature: 13°F~158°F (-25°C ~+70°C)
Ambient Humidity:15%~93% no condensation in operation; ≤93% no condensation in storage/transport;
Atmospheric pressure: 70kPa~106kPa
7. Equipment data update period.
Data update period of slower average is 8s.



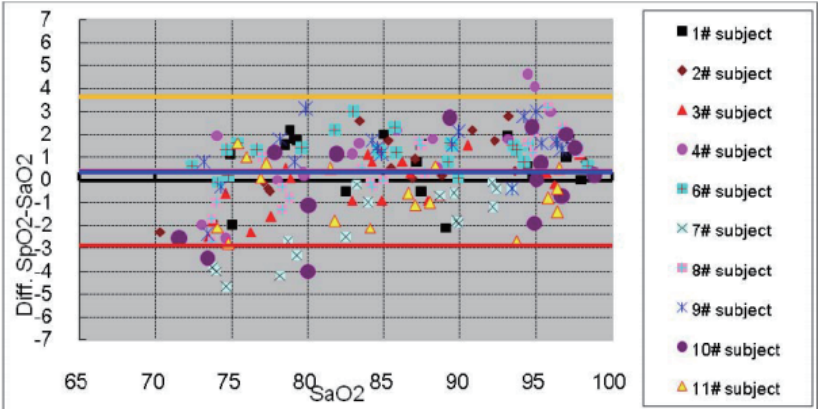
8. Classification:
- According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
- According to the degree of protection against electric shock: TYPE BF APPLIED PART, (applied part: the rubber hole of the device);
- According to the degree of protection against ingress of water: IP22
- According to the mode of operation: CONTINUOUS OPERATION

Clinical Study Summary

The following details are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot of data is shown as below:

ARMS Value Analysis Statement			
Item	90--100	80--<90	70--<80
#pts	78	66	63
Bias	1.02	0.40	-0.48
ARMS	1.66	1.46	1.93

Bland-Altman Plot Graphic



Possible Problems and Solutions

Problems	Possible reason	Solution
SpO2 or PR cannot be shown normally	1.Finger is not inserted correctly 2.Person's Oxyhemoglobin value is too low to be measured	1.Retry by inserting the finger 2.Try more times. If you can make sure no problem exists in the product, please go to a hospital or doctor in a timely way for exact diagnosis

SpO2 or PR is shown unstably	1.Finger might not be inserted deep enough. 2.Finger is trembling or person's body is moving.	1.Retry by inserting the finger 2.Try not to move
The oximeter cannot be powered on	1.Battery power might be inadequate or not be there at all. 2.Batteries might be installed incorrectly. 3.The oximeter might be damaged.	1.Please replace the batteries 2.Please reinstall the batteries 3.Please contact our customer service team.
Indication lamps are suddenly off	1.The product is automatically powered off when no signal is detected longer than 8 seconds 2.Battery power may be inadequate.	1.Normal 2.Replace the batteries
"Err7" is displayed on screen	1.Low power 2.Emission tube damaged. 3.Current control circuit malfunctions.	1.Please replace battery 2.Please contact our customer service team 3.Please contact our customer service team

Possible Problems and Solutions

Symbol	Definition	Symbol	Definition
	Type BF applied part		Storage temperature and relative humidity
	Attention		Manufacturer's information
	Date of Manufacture	IP22	Protected against dripping water
%SpO2	Oxygen saturation		European union approval
PR bpm	Pulse rate (BPM)		Authorized representative in the European community
	Low power indication		Consult accompanying documents.
	No SpO2 Alarm		Waste electrical and electronic equipment
	Serial No.		Indicate the signal is not stable

Box Contents

- Fingertip pulse oximeter
- One lanyard
- Two AAA batteries
- One instruction manual

Notes:

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

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Any questions,please call us toll-free
at 1-855-822-6999.

Monday-friday 9:00 a.m.-5:00 p.m. Central Time

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项目：EHP-029血氧仪美版说明书

尺寸：290x399mm 颜色： C=100

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