

Fingertip Pulse Oximeter

Model No.:EHP035

General Description

The Easy@Home Fingertip Pulse Oximeter EHP035 is a handheld non-invasive device intended for spot-checking of oxygen saturation of hemoglobin (SpO₂) and Pulse Rate of adult, adolescent and children in the home setting. It is approved for OTC (over the counter use) for individuals.

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 it measures the SpO₂ level.

Follow and read the operating procedure closely as found in these instructions. Otherwise abnormality, equipment damage, or personal injury may occur. The manufacturer warranty does not include these safety and reliability issues noted above due to user negligence.

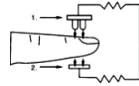
NOTE: This oximeter is for sport or aviation use only and is NOT intended for medical use.

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 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



Box Content

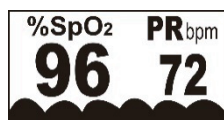
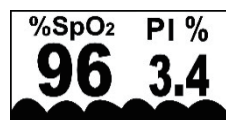
1. Fingertip pulse oximeter
2. One lanyard +
3. One Carrying Package
4. Two AAA batteries
5. One instruction manual

Product Features

1. Simple operation, easy to carry.
2. Light weight and low power usage.
3. Dual color OLED displays SpO₂, PR, PI, Pulse bar, and waveform.
4. 7 display modes
5. Level 1-10 adjustable brightness.
6. 2pcs AAA-size alkaline batteries; real-time battery status indication.
7. Multiple users.

Operation Instructions

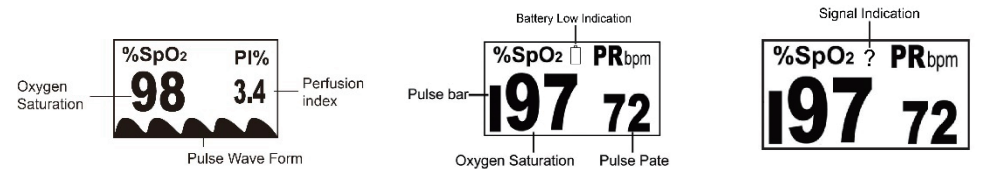
1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Short press the switch button on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. The hand should be rested on the chest at the level of the heart. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading either as it will sway results.
5. Read the data from the display screen when the wave form is steady and forming a consistent pattern. This is the optimal value for measurement. 120/80 is considered normal for blood pressure, but this may vary. For adults, a normal pulse is 60-100 beats per minute, but this may also vary. Speak with your doctor about any concerns.
6. The display modes are as follows:



Notes:

1. Short press the power button to switch the display modes.
2. Long press the power button to adjust the brightness of the oximeter. There are 10 levels of brightness. The default is level four.
3. Take out your finger, the screen displays "Finger Out". It means the measurement has ended.

Front Panel



Notes:

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

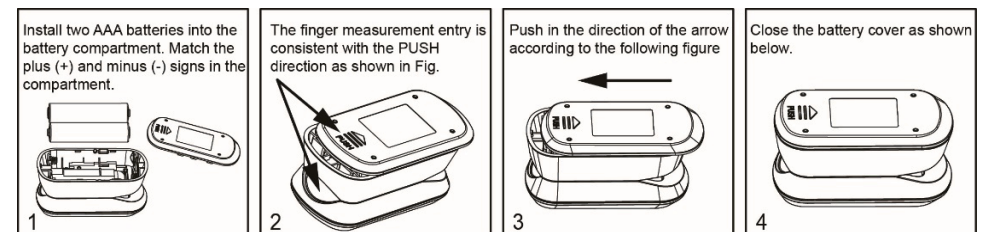
Symbol	Definition
SpO ₂ %	Oxygen saturation
PI	Perfusion Index (indication of pulse strength at sensor site)
	Pulse Wave Form (visual display of pulse)
	Pulse Bar (shows visually strength of pulse--under 30% indicates the signal is inadequate and SpO ₂ or pulse rate may be incorrect)
PR bpm	Pulse Rate-person's heartbeat per minute
	Low power indication of device
?	Indicate the signal is not stable

Battery Installation:

1. Slide the battery door cover horizontally along the arrow shown as the picture.
2. Install two AAA batteries into the battery compartment. Match the polarity the compartment. If the polarities are not matched, damage may be caused to the oximeter.
3. Close the battery door cover.

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 starting flickering.

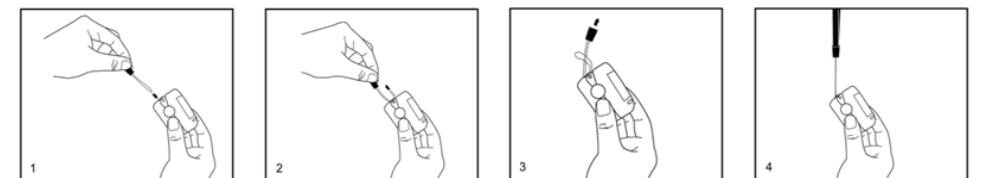


Using the Lanyard

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

Warnings!

- ◇ 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.



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. High ambient light. Shield the sensor area if necessary.
4. Excessive patient 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. The person has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The person is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (also known as low perfusion).
12. Low hemoglobin.

Maintenance and Storage

1. Replace the batteries in a timely manner when low voltage lamp is lighted.
2. Clean surface of the fingertip oximeter before it is used.
3. Remove the batteries if the oximeter will not be 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.

- Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
- Dispose batteries properly; follow any applicable local battery disposal laws.

Cleaning the fingertip pulse oximeter

Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the finger being tested 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 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 the manufacturer if one of the following cases occurs:

- Troubleshooting error notifications are displayed on screen.
- The oximeter cannot be powered on if you have ruled out any possible battery issues.
- There is a crack on the oximeter or damage on the display resulting in readings not being able to be identified; the spring is invalid; or the key is unresponsive or unavailable.

Disinfecting

The applied parts touching the finger should be disinfected once after each use. The recommended disinfectants include: alcohol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

Note: Disinfection may cause equipment damage. Therefore only disinfect rubber cushion of the clip.

CAUTION: Never use EtO or formaldehyde for disinfection.

Precautions for Use

- Before use, please read the manual carefully.
- The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO₂ measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO₂ measurement.
- Explosive hazard—do not use the fingertip pulse oximeter in an environment with flammable gas such as ignitable anesthetic agents.
- The fingertip pulse oximeter is intended only as an adjunct in assessment. It may be used in conjunction with other methods of assessing.
- In order to ensure correct sensor alignment and skin integrity, the maximum application time for a single use session of this device should be less than half an hour. It is not for continuous monitoring.
- 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 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 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 electrical equipment.
- This equipment is not intended for use during transport.
- This equipment 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 equipment with other equipment not described in the instructions for use
 - disassemble, repair or modify the equipment
- These materials that contact with the patient's 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.
- When the signal is not stable, the reading may be inaccurate. Please do not rely on.

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: 30bpm~250bpm

Measure range: 30bpm~250bpm

Accuracy: 30bpm~99bpm, ±2bpm; 100~250bpm, ±2%

Resolution: 1bpm

4. Perfusion Index

Display range: 0.1%~20.0%

Measure range: 0.2%~20.0%

Accuracy: 0.2%~1.0%, ±0.2digits; 1.1%~20.0%, ±20%

Resolution: 0.1%

5. Probe LED Specifications

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

6. Power Requirements

Two AAA alkaline Batteries

Power consumption: Less than 40mA

Battery Life: Two AAA 1.5V, 1200mAh alkaline batteries could be continuously operated as long as 24 hours.

7. 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;

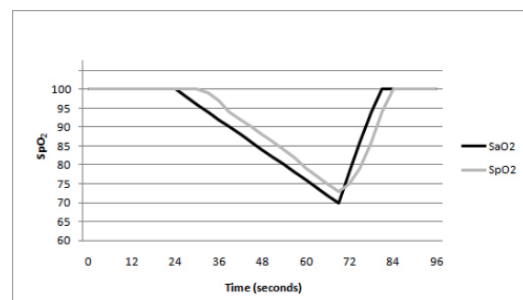
≤93% no condensation in storage/transport

Atmosphere pressure: 70kPa~106kPa

8. Equipment Response Time

As shown in the following figure.

Response time of slower average is 8s.



9. Classification

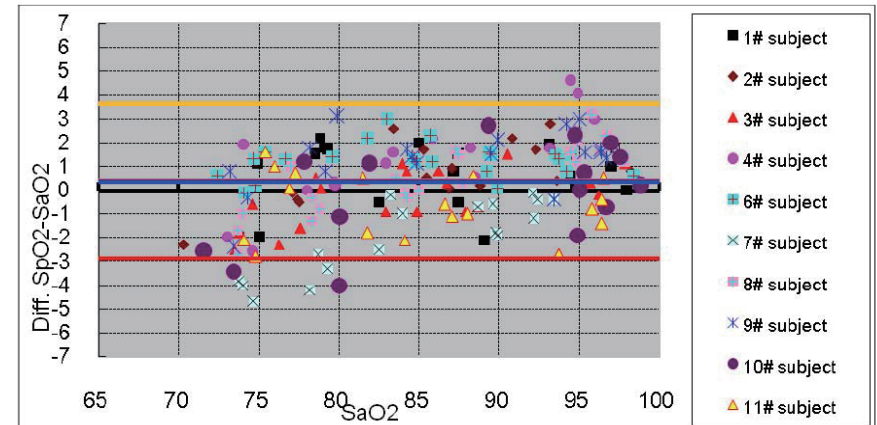
According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART (The application part is rubber inside of the Pulse Oximeter);
According to the degree of protection against ingress of water: IP22
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 for EHP035 is shown as following:

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

Troubleshooting

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 is too low to be measured	1. Retry by inserting the finger. 2. Lower brightness. 3. Try more times. If you are sure there is nothing wrong with the device itself, consult your doctor.
SpO ₂ or PR is shown unstably	1. Finger might not be inserted deep enough. (The nail position should fully cover the sensor position.) 2. Excessive movement	1. Retry by inserting the finger. 2. Be calm.
The oximeter cannot be powered on	1. No battery or low power of battery 2. Batteries might be installed incorrectly 3. The oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact manufacturer customer service
Indication signals are suddenly off	1. The product 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
"Error7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	Please contact manufacturer customer service support.

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part.		Attention
IP22	Protected against dripping water.	SpO ₂ %	Oxygen saturation
PR bpm	Pulse rate (BPM)	PI	Perfusion Index
	No SpO ₂ Alarm		Low power indication
	Storage temperature and relative humidity		Serial No.
	Power Switch		Follow instruction for use
	Waste electrical and electronic equipment		Date of Manufacture
?	Indicate the signal is not stable		

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Questions or comments?

Please call toll-free: 1-855-822-6999 M-F 9 a.m.-5 p.m. CST

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