tenovi

Pulse Oximeter

User Manual

Model#: TE-BPOG-A1

Date of Issue: 2025, Version: V1.0

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Precautions

- Do not attempt to maintain the Oximeter unless you are professional engineers. Only professionals with maintenance qualification are allowed to perform interior maintenance as necessary.
- Periodically change the contact position between the Oximeter probe and the finger for a measurement. Adjust the position of the probe before the measurement, and check the integrity of skin, blood circulation condition of the finger as well as the position of the finger.
- This product is not applicable to the examination of newborn babies.
- Seek for medical care in time if the measured value goes beyond the normal range while you are sure that the instrument does not malfunction.
- Do not directly expose your eyes to light-emitting components of the Oximeter, as that could cause harm to your eyes.
- Do not expose the device to lint, dust, light(including sunlight), pets, pests, or children, etc.
- This pulse oximeter is not intended to diagnose or treat any medical condition or disease. People who need SpO2 and pulse rate measurements because of a medical condition should not use the oximeter and should consult with their physician.
- Do not self diagnose and treat based on measurement results, please always consult a doctor.
- For details about clinical limitations and contraindications, please carefully consult relevant medical literatures.
- It needs more than half an hour to warm or cool from the minimum /maximum storage temperature between uses until it is ready for intended use.
- Please note the effects of degraded sensors that can degrade performance or cause other problems.
- The patient is an intended operator.
  The lay operator or lay responsible organization should contact the manufacturer or manufacturer's representative on the following issues:
- Assistance in setting up, using, or maintaining the equipment or system when needed.
- To report unexpected operation or events.
  The following factors may cause disturbance to or affect the accuracy of examination: This product is used in an environment involving high-frequency devices, such as high-frequency electric knives and CT apparatuses.
- The probe of the Oximeter is placed on the same body part or limb as with blood pressure cuff arterial duct or intravenous injection.
- The user suffers from hypotension, severe vascular atrophy, severe anemia, or low oxygen.
- The user is in sudden cardiac arrest or shock state.
- The finger with nail polish or a fake fingernail may cause wrong readings of pulse oxygen saturation.
- Please note the effects of degraded sensors that can degrade performance or cause other problems.
- Do not combine old and new batteries, different brands batteries for using.
- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the micro-circulation barrier patient. It is recommended that the sensor should not be applied to the same finger for over 2 hours.
  The person who is allergic to silicon rubber can not use this device.
- **Note:** The device has no side-effects if administered correctly and residual risk is acceptable.

Warnings

Warning: Do not use the Oximeter in an environment with any inflammable gases, inflammable anesthetic, or other inflammable substances.
Warning: Do not attempt to charge any common dry battery, as that could cause leakage, fire disaster, or even explosion. Dispose of exhausted batteries in accordance with environment protection regulations.
Warning: Do not use the Oximeter in an MRI or CT environment.
Warning: Do not operate the Oximeter when it is damp with overflow or water vapor condensation. Avoid moving the Oximeter from an excessively-cold environment to a high-temperature moist environment.
Warning: No modification of this equipment is allowed for safety.
Warning: Do not use accessories and detachable parts not specified or authorized by manufacturer. Otherwise, it may cause damage to the unit or danger to the user or patients.
Warning: Keep unit and lanyard away from children as the included lanyard may present an entanglement or choking hazard to small children. Adult supervision required; never leave children unattended with unit or lanyard.
Warning: Do not throw the batteries into fire, as that could cause an explosion.
Warning: Close the battery cover when the instrument is in use.

Symbol Conventions

Symbol	Description
	Date of manufacture
	Temperature limitation
	Humidity
	Atmospheric Pressure
	BF-type application part
	Caution: Please see this manual.
%SpO2	Symbol of oxygen saturation
bpmPR	Symbol of pulse rate
	No SPO2 alarms.
	Consult the instructions for use.
IP22	The degree of protectionagainst harmful ingress of water and particulate matter
	When end users abandon this product, they must send the product to the collection place for recycling.

Overview

Oxygen saturation is the percentage of oxyhemoglobin (HbO2) that is combined with oxygen against all combinable hemoglobin (Hb). It is an important physiological parameter involved in respiration and circulation. The oxygen saturation of arterial blood in a normal human body is 98%. Oxygen saturation is an important indicator of the oxygen condition in the human body. In general, the normal values of oxygen saturation shall not be lower than 94%. If the measured value of oxygen saturation is lower than 94%, an insufficient supply of oxygen is considered.The pulse rate is the number of pulse beats per minute. Normally, the pulse rate is consistent with the heart rate. In general, the pulse rate of every people is 60 to 90 beats per minute. The Perfusion Index (PI) usually reflects the limb perfusion status of an examined patient, and shows the detection precision of the instrument as well; that is, examination can still be performed even in the low or weak perfusion condition.The PI of a normal human body is 3% or greater.

Intended Use

The Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The portable fingertip device is indicated for adult and pediatric patients at home and hospital environments. Intended user: Professional or lay person.

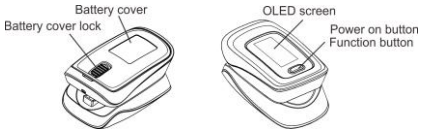
Scope of Application

It is applicable to a wide range of fields, such as families, hospitals, oxygen bars, social medical care institutions, and sports & health. Use this instrument for measurement before or after sports. You are not advised to use this instrument during sports activities. Do not use it for continuous care for patients.

Working Principles

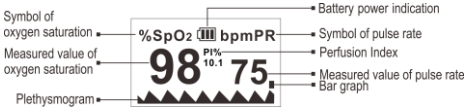
The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole land diastole, as blood volume increases and decreases.

Appearance of Structure



Screen Display

The following figure shows the information display on the OLED screen of the Oximeter in normal detection state:
Note: Battery power indication and Bluetooth symbol will alternately displayed.



Press and release the button to turn on, hold the button for about one second. The Oximeter shows a parameter setting interface. Press or hold the button to perform corresponding operations. Hold it to set an item, or press it to switch an option or switch the display mode. Press means no more than 0.5 seconds, while Hold means more than 0.5 seconds.

Alert Sound Setting

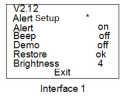
Hold the functional button while the Oximeter is in powered-on state. Parameter setting interface 1 is displayed, as shown in the following figure.To press and release the button can move "*" to the corresponding option, and hold the functional button to set Alert to on and set Beep to off. When Alert is set to on and the measured values of the blood oxygen saturation and pulse rate go beyond the upper limit or lower limit, the Oximeter gives off an alert sound. When Alert 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 tick will be heard along with pulse beats during pulse rate measurement. When Beep is set to off, no sound will be output along with pulse beats during pulse rate measurement. While the "*" symbol stays on the Restore option, hold the functional button to restore factory settings.

Brightness Setting

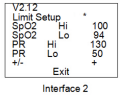
On parameter interface 1, press the functional button to select the Brightness option and then hold the functional button to set the brightness to a value ranging from 1 to 5. The greater the value, the greater the brightness of the screen.

Alert Range Setting

On parameter interface 2, press the functional button to switch between options. On this interface, you can set the upper limit and lower limit of SpO2 Alert and PR Alert. While the "*" symbol stays on the +/- option, hold the functional button to set the option to + or -. In + mode, select the corresponding option and hold the functional button to increment the upper or lower limit; in - mode, hold the functional button to decrement the upper or lower limit. Move "*" to the Exit option, and hold the functional button to return to the monitoring interface.



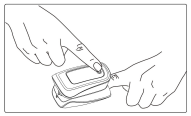
Interface 1



Interface 2

Operation Guide

Stick one finger completely into the measuring parts of the Oximeter, keep the fingernail surface upward, and release the clip. Then press the power button to power on the Oximeter.



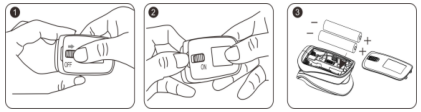
⚠ If you do not yet completely insert your finger into the cavity, the measurement result may be inaccurate.

⚠ Do not vibrate your finger during measurement, ensure that your body does not move. Wait for about 20 seconds or until you hear your gateway beep and turn green.

NOTE:The Oximeter will automatically shut down 10 seconds later after your finger leaves away.

Replace battery

⚠ Replace the batteries in low power when the icon (▭) flickers on screen. Open the battery cover with your fingers, you can replace the batteries according to the correct battery polarity.



Cleaning

Power off the instrument and remove the batteries before cleaning. Ensure that the appearance of the instrument is neat, dust-free, and dirt-free. Clean the outer surface of the instrument (including the OLED screen) using 75% medical alcohol and a piece of dry soft cloth before changing patients.
Caution: Avoid liquid flowing into the instrument during cleaning.
Caution: Do not immerse any part of the instrument into any liquid.

Disinfection

Before measurement with the instrument, wipe the silicon rubber finger pad using a piece of dry soft cloth dipped with 75% medical alcohol. Clean the finger to be measured using the medical alcohol for disinfection purposes before and after use.

⚠ Do not disinfect the instrument by means of high-temperature/ high-pressure or gas disinfection.

Maintenance

- Remove the batteries from the battery slot and properly store them if you do not plan to use the Oximeter for a long period of time.
- Avoid using the Oximeter in an environment with inflammable gases or using it in an environment where the temperature or humidity is excessively high or low.
- Check the accuracy of the oxygen saturation and pulse rate readings by using an appropriate calibration apparatus once a year.
- Keep the transmitting and receiving windows free of obstructions before and after use.
- No service /maintenance while the equipment is in use.

Troubleshooting

Problem	Possible Cause	Solution
The unit fails to power on.	Low Battery	Change The Batteries
	Polarities of the batteries are reversed.	Make sure the batteries are installed correctly.
	The unit is damaged.	Contact the manufacturer
The unit doesn't display any information.	The emitting light doesn't power on..	Contact the manufacturer

Product Accessories

One hanging rope;
Storage bag;
Two AAA batteries;
One user manual;

Technical Specifications

1. Dimensions: 62.0 mm (Width) × 37.0 mm (Depth) × 32.0 mm (Height)
Weight: 52 g (including two AAA dry batteries)
2. Peak wavelength range of the light emitted from the probe: red light 660 nm ± 3; infrared light 905 nm ± 5.
3. Maximum optical output power of the probe: 1.2 mW for infrared light (905 nm).

4. Manufacturing date: see the label Expected service life of the device including parts and accessories: 5 years.
5. Normal working condition

Working Temperature	5°C to 40°C (41°F to 104°F)
Relative Humidity	15% to 80%, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa
Rated Voltage	DC 3.0 V

6. Default values and conditions of alert

Parameter	Value
Oxygen Saturation	Upper Limit: 100 Lower Limit: 94
Pulse Rate	Upper Limit: 130 Lower Limit: 50
Alert Condition	When the alert switch is on and the actual measured value goes beyond the preset alert parameter range, the Oximeter gives an alert sound along with flicker (threshold value for prompting can be set up)

Technical parameters (Software version: V2.12)

Parameter		Value
Display Range	Oxygen Saturation	35%-100%
	Pulse rate	25 bpm tp 250 bpm
Resolution	Oxygen Saturation	1%
	Pulse rate	1 bpm
Measurement precision	Oxygen Saturation	±2% (70% to 100%) No requirement (≤ 69%)
	Pulse rate	±2 bpm
Alert range	Oxygen Saturation	Upper limit: 50% to 100% Lower limit: 50% to 100%
	Pulse rate	Upper limit: 25 bpm to 250 bpm Lower limit: 25 bpm to 250 bpm
Alert error	Oxygen Saturation	± 1% of the preset value
	Pulse rate	The greater of ±10% of the preset value and ±5 bpm
Battery		High-performance dry battery can be used for about 685 times at normal temperature
Service life		5 Years

Technical statement

- The device has no alarm system for SpO2 or pulse rate physiological alarm condition.
- When the signal detected by the pulse oximeter is inadequate or weak, the SpO2 and Pulse rate readings on display are: "--" and "---".
- FUNCTIONAL TESTER can not be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
- The pulse oximeter has a specific calibration curve which is accurate for the combination of the pulse oximeter and pulse oximeter probe. If the functional tester can measure the error comes from the main part of the pulse oximeter, the accuracy of the pulse oximeter that replicates this calibration curve can be verified.
- MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel designated by the manufacturer in parts repair.
- The pulse rate waveform is normalized. When the pulse rate waveform tends to be smooth and stable, the measurement value is optimal. Data update period: less than 30s, data averaging: every 8 data.

Note 1: The Pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a co-oximeter.

Note 2: The statistic conclusion of an controlled desaturation study which guided by"ISO 80601-2-61, Annex EE, guideline for evaluating and documenting SpO2 accuracy in human subjects". The statistic result displayed the accuracy distribution between the range of 70%-100%.

Safety Type

Anti-electric-shock type: internal power supply device
Anti-electric-shock degree: Type BF applied part
Running mode: Continuous working Waterproof grade: IP22

Keep the transmitting and receiving windows free of obstructions before and after use.

Storage and Transportation

Packaged products should be stored in well-ventilated rooms without corrosive gas and with an ambient temperature of –10°C to +50°C, a relative humidity 10%- 93% (without condensation), and an atmospheric pressure of 50–106 kPa.

Statement

Lay responsible organization must contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and accessories as appliable.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authorities of your Member State.

Customer Service

Tenovi, Co.
Address: 1 Cate St. Suite 100, Portsmouth, NH 03801 USA
Website: www.tenovi.com

EMC Information-Guidance and Manufacture's

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."
2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1

Declaration – electromagnetic emission	
Emission Test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable

Table 2

Declaration – electromagnetic immunty		
Immunity Test	IEC 60601 test level	Compliance level Compliance level
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
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

Declaration – IMMUNITY to proximity fields from RF wireless communications					
Immunity Test	IEC60601 test level				Compliance Level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

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