



ToronTek Pulse Oximeter

Model: H50+ Pulse Oximeter

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Precautions

- Do not attempt to maintain the Oximeter unless you are a professional engineer. Only personnel with proper maintenance qualifications are allowed to perform internal maintenance as necessary.
- Periodically change the contact position between the Oximeter probe and the finger during measurement. Adjust the position of the probe before measurement, and check the integrity of the skin, blood circulation of the finger, and finger position.
- This product is not intended for the examination of newborn infants.
- Seek medical care promptly if the measured values fall outside the normal range, provided the instrument is functioning correctly.
- Do not directly expose your eyes to the light-emitting components of the Oximeter, as this may cause eye injury.
- Do not expose the device to lint, dust, direct light (including sunlight), pets, pests, or children.
- This pulse oximeter is not intended to diagnose or treat any medical condition or disease. Individuals requiring SpO2 and pulse rate measurements for medical reasons should not use the oximeter and should consult their physician.
- Do not self-diagnose or treat based on measurement results; always consult a healthcare professional.
- For details about clinical limitations and contraindications, please refer to relevant medical literature.
- Allow at least 30 minutes for the device to warm up or cool down from minimum or maximum storage temperatures before use.
- Be aware that degraded sensors may reduce performance or cause incorrect readings.
- The patient is the intended operator.

The non-professional user or responsible organization should contact the manufacturer or manufacturer's representative for the following:

- Assistance in setting up, using, or maintaining the equipment when needed.
- To report unexpected operation or incidents.

The following factors may affect measurement accuracy:

- Use of the product in environments with high-frequency devices, such as electro-surgical units or CT scanners.
- Placement of the Oximeter probe on the same limb as a blood pressure cuff, arterial line, or intravenous injection.
- User conditions such as hypotension, severe vascular atrophy, severe anemia, or low oxygen levels.
- Sudden cardiac arrest or shock.
- Fingers with nail polish or artificial nails, which may cause inaccurate readings.
- Degraded sensors that may impair performance or cause incorrect readings.

- Do not mix old and new batteries, or batteries of different brands.
- Continuous use may cause discomfort, especially in patients with microcirculation issues. Do not leave the sensor on the same finger for more than 2 hours.
- Persons allergic to silicone rubber should not use this device.

Note: The device has no known side effects when used correctly, and residual risks are considered acceptable

Warnings

Warning: Do not use the Oximeter in environments containing flammable gases, flammable anesthetics, or other flammable substances.

Warning: Do not attempt to charge standard dry batteries, as this may cause leakage, fire, or explosion. Dispose of exhausted batteries in accordance with environmental protection regulations.

Warning: Do not use the Oximeter in MRI or CT environments.

Warning: Do not operate the Oximeter when it is damp or covered with water vapor

condensation. Avoid moving the Oximeter from extremely cold environments to high-temperature, humid environments.

Warning: No modifications to this equipment are allowed for safety reasons.

Warning: Do not use accessories or detachable parts not specified or authorized by the manufacturer. Unauthorized components may damage the unit or pose a risk to users or patients.

Warning: Keep the unit and lanyard away from children. The included lanyard may present an entanglement or choking hazard. Adult supervision is required; never leave children unattended with the unit or lanyard.

Warning: Do not dispose of batteries by throwing them into fire, as this may cause an explosion.

Warning: Always close the battery cover when the instrument is in use.

Symbol Conventions

Symbol	Description
	Type BF applied part
	Caution: Please see this manual.
%SpO2	Symbol of oxygen saturation
bpmPR	Symbol of pulse rate
	No SPO2 alarms.
	Consult the instructions for use.
	Temperature limitation
IP22	The degree of protection against harmful ingress of water and particulate matter
	When end users abandon this product, they must send the product to the collection place for recycling.
	Date of Manufacture
	Information of manufacturer
CE 0598	This product complies with the MDR 2017/745 requirements.
EU REP	Authorized European Representative
MD	Medical device
	Humidity
	Atmospheric Pressure
	Information of Importer

Overview

Oxygen saturation (SpO₂) represents the percentage of oxyhemoglobin (HbO₂) relative to total hemoglobin (Hb) capable of binding oxygen. It is an important physiological parameter that reflects the body's respiratory and circulatory status. In a healthy adult, arterial oxygen saturation is approximately 98%. Oxygen saturation serves as a key indicator of the body's oxygen supply, and values below 94% generally indicate insufficient oxygenation.

The pulse rate represents the number of heartbeats per minute and is usually consistent with the actual heart rate. In a typical adult, the normal pulse rate ranges from 60 to 90 beats per minute.

Intended Use

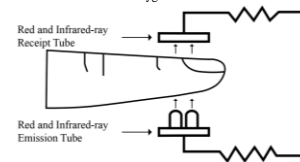
The Fingertip Pulse Oximeter is a non-invasive device designed for spot-checking functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. This portable fingertip device is suitable for use by adults and pediatric patients in both home and hospital settings.

Scope of Application

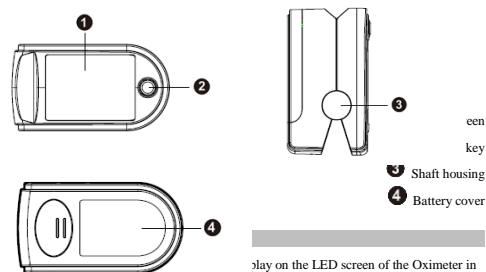
The Fingertip Pulse Oximeter is suitable for use in a wide range of settings, including homes, hospitals, oxygen bars, social medical care institutions, and sports or wellness environments. It is intended for spot-check measurements before or after physical activity; it is not recommended for use during exercise. This device is designed for intermittent monitoring and should not be used for continuous patient care.

Working Principles

The pulse oximeter measures blood oxygen saturation by placing a sensor on a pulsating arteriolar vascular bed. The sensor contains a dual light source and a photodetector. One light source emits red light at a wavelength of 660 nm, while the other emits infrared light at 905 nm. Skin, bone, tissue, and venous blood typically absorb a constant amount of light over time. The photodetector in the finger sensor collects the transmitted light and converts it into an electrical signal proportional to the light intensity. As the arteriolar bed pulsates during systole and diastole, the volume of arterial blood changes, causing variable light absorption that the device uses to calculate oxygen saturation.



Appearance of Structure



normal detection state:



Operation Guide

Insert one finger fully into the oximeter's finger chamber, ensuring that the fingernail is facing upward. Release the clip and press the power-on/functional button to power on the device.

Warning: Ensure that your finger is fully inserted into the chamber. Incomplete insertion may result in inaccurate measurements.

Warning: Do not move or vibrate your finger during measurement, and keep your body

still. Once the readings stabilize, read the measured values of oxygen saturation (SpO₂) and pulse rate (PR) on the display.

Note: The oximeter will automatically power off approximately 10 seconds after your finger is removed.

Replacing the Batteries

Warning: Replace the batteries in low power when the icon flickers on screen.



Open the battery cover with your fingers. Insert new batteries, ensuring they are aligned according to the correct polarity. Close the battery cover securely before using the device.

Cleaning

Power off the instrument and remove the batteries before cleaning. Ensure that the device is clean, dust-free, and free of dirt. Wipe the outer surface of the instrument, including the OLED screen, with a soft cloth dampened with 75% medical alcohol before use with a different patient.

Caution:

- Avoid allowing liquid to enter the instrument during cleaning.
- Do not immerse any part of the instrument in liquid.

Disinfection

Before use, disinfect the silicone finger pad by wiping it with a soft cloth dampened with 75% medical alcohol. Clean the finger to be measured with medical alcohol both before and after use.

Warning: Do not disinfect the instrument using high-temperature/high-pressure or gas sterilization methods

Maintenance

- Remove the batteries from the battery compartment and store them properly if the oximeter will not be used for an extended period.
- Avoid using the oximeter in environments with flammable gases or where temperature or humidity is excessively high or low.
- Verify the accuracy of oxygen saturation and pulse rate readings annually using an appropriate calibration device.
- Ensure that the transmitting and receiving windows remain free of obstructions before and after use.
- Do not perform any service or maintenance while the equipment is in operation.

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

Lanyard; Storage bag; Two AAA batteries; One user manual; Quick guide

Technical Specifications

- Dimensions: 58 mm (Width) × 32 mm (Depth) × 33.2 mm (Height)
Weight: About 49.5 g (including two AAA dry batteries)
- Peak wavelength range of the light emitted from the probe: red light 660 nm ± 3; infrared light 905 nm ± 5.
- 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. Fuse parameters

Current	1A
Voltage	63V
Size	3.2*1.6*0.75mm

7. 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	The actual measured value goes beyond the default alert parameter range, the Oximeter gives an alert sound along with flicker.

8. Technical parameters (Software version: V2.12)

Parameter	Value
Display range	Oxygen saturation 35% to 100%
	Pulse rate 25 bpm to 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
Battery	times High-performance dry battery can be used for about 685 times at normal temperature

- The device does not include an alarm system for SpO₂ or pulse rate physiological alarm conditions.
- When the signal detected by the pulse oximeter is inadequate or weak, the SpO₂ and pulse rate readings on the display will appear as “-” and “-”.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or the pulse oximeter monitor.
- The pulse oximeter uses a specific calibration curve that is accurate for the combination of the pulse oximeter and its probe. If the functional tester identifies errors originating from the main unit, the accuracy of the pulse oximeter replicating this calibration curve can be verified.
- The manufacturer will provide, upon request, circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist authorized service personnel in performing repairs.
- The pulse rate waveform is normalized. When the waveform is smooth and stable, the measurement value is considered with data averaging over every 8 readings. optimal. Data update period is less than 30 seconds.

Note 1: Pulse oximeter measurements are statistically distributed; only approximately two-thirds of measurements are expected to fall within ±Arms of the values measured by a co-oximeter.

Note 2: The statistical conclusions are based on controlled desaturation studies guided by ISO 80601-2-61, Annex EE, which outlines guidelines for evaluating and documenting SpO₂ accuracy in human subjects. The results show accuracy distribution in the 70%–100% range.

Safety Type

Anti-electric-shock type: Internal power supply device- *Degree of protection against electric shock:* Type BF applied part- *Operating mode:* Continuous-*Waterproof rating:* IP22

Storage and Transportation

Packaged products should be stored in well-ventilated areas free from corrosive gases, with an ambient temperature of -10 °C to +50 °C, relative humidity of 10%-93% (non-condensing), and atmospheric pressure of 50–106 kPa.

Disposal of Unit

Users or the responsible organization must contact local authorities to determine the appropriate method for disposing of potentially biohazardous parts and accessories, as applicable. Any serious incident involving the device should be reported to both the manufacturer and the competent authorities in your jurisdiction.

After-sale Service

- After-sale service: GLOCOMMERCE INC- Address: 22-140 McGovern Dr, Cambridge – ON-N3H 4R7 - Tel: +1 800 301 3040 –Email:- customer-service@torontek.com - Website: www.torontek.com

EMC Information-Guidance and Manufacturer's Declaration

- WARNING Equipment Proximity:** Use of this equipment adjacent to or stacked with other devices should be avoided, as it may result in improper operation. If such use is necessary, both this equipment and the other devices should be monitored to ensure normal operation.
- WARNINR Accessories and Cables:** Use only accessories, transducers, and cables specified or provided by the manufacturer. Using other items may increase electromagnetic emissions or reduce the device's electromagnetic immunity, potentially causing improper operation.
- WARNING RF Communications Equipment:** Portable RF communication devices (including peripherals such as antenna cables and external antennas) should be kept at least 30 cm (12 inches) away from any part of the medical electrical equipment, including manufacturer-specified cables. Failure to maintain this distance may degrade device performance

Table 1

declaration - electromagnetic emission	
Emissions 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 immunity		
Immunity test	IEC 60601 test 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 equipment					
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	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation : 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m

	2450 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation : 217Hz	0.2 W	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.				

DISCLAIMER: This unit is NOT intended to be used to diagnose, treat, cure or prevent any medical condition unless used by or under the direct supervision of a licensed health provider. Using this device is not a substitute for your own healthcare provider's professional advice. You should never delay seeking medical advice, disregard medical advice or discontinue medical treatment because of using this product. By using this device, you agree to comply with the terms and conditions specified at www.torontek.com/termsandconditions.

Manufacturer: GloCommerce Inc- 22-140 McGovern Dr, Cambridge, ON- N3H 4R7