ToronTek Pulse Oximeter

Model: L12 Pulse Oximeter

Date of Issue: August 2025, Version: V1.0

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

-This device may not cause harmful interference.

-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 may 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 intended 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 according to the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If the 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 using one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that of the receiver.
- Consult the dealer or an experienced radio/TV technician for assistance.

This equipment complies with FCC radiation exposure limits for an uncontrolled environment. It should be installed and operated with a minimum distance of 20 cm between the radiator and the user's body. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

Precautions

- Do not attempt to maintain the oximeter unless you are a qualified professional. Only personnel with proper maintenance training are authorized to perform internal maintenance when necessary.
- Periodically adjust the contact position between the oximeter probe and the finger before measurement. Ensure proper placement of the probe and check the integrity of the skin, blood circulation, and finger position.
- This device is not suitable for use on newborns.
- Seek medical attention promptly if measured values fall outside the normal range and you are confident the device is functioning correctly.
- Do not directly expose your eyes to the oximeter's light-emitting components, as this may cause eye injury.
- Keep the device away from lint, dust, direct sunlight, pets, pests, and children.
- This pulse oximeter is not intended to diagnose, treat, or monitor any medical condition or disease. Individuals requiring SpO_2 and pulse rate measurements for medical reasons should consult a physician before use.
- Do not self-diagnose or self-treat based on measurement results; always consult a doctor.
- For information on clinical limitations and contraindications, consult relevant medical literature.
- After storage at extreme temperatures, allow the device more than 30 minutes to reach a suitable operating temperature before use.
- Be aware that degraded sensors may reduce performance or cause other issues.
- The intended operator of this device is the patient. Lay operators or non-professional users should contact the manufacturer or the manufacturer's representative for assistance with:
- Setting up, using, or maintaining the equipment or system as needed.
- Reporting unexpected operation or events.
- The accuracy of measurements may be affected by the following factors:
- Use in environments with high-frequency devices, such as electrosurgical units or CT scanners.
- Placement of the oximeter probe on the same limb or body part as a blood pressure cuff, arterial line, or intravenous injection site.
- Conditions such as hypotension, severe vascular atrophy, severe anemia, or low oxygen levels.
- Sudden cardiac arrest or shock.
- Presence of nail polish or artificial nails on the measured finger.
- Degraded sensors that may reduce 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 barriers. It is recommended not to leave the sensor on the same finger for more than two hours.
- Individuals with a silicon rubber allergy should not use this device.

  Note: When used correctly, the device has no known side effects, and residual risks are considered acceptable.

Warnings

- WARNING: Do not use the oximeter in environments containing flammable gases, flammable anesthetics, or other combustible substances.
- WARNING: Do not attempt to charge standard dry batteries, as this may cause leakage, fire, or explosion. Dispose of used 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 wet from spills or condensation. Avoid moving the device directly from extremely cold environments to high-temperature, high-humidity conditions.
- WARNING: Do not modify this equipment, as unauthorized modifications may compromise safety.
- WARNING: Use only accessories and detachable parts specified or authorized by the manufacturer. Using other components may damage the device or create safety hazards for users or patients.
- WARNING: Keep the device 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 device or lanyard.
- WARNING: Do not dispose of batteries in fire, as this may cause an explosion.
- WARNING: Always close the battery cover while 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.
EC REP	Authorized European Representative
MD	Medical device
	Humidity
	Atmospheric Pressure

Overview

Oxygen saturation (SpO_2) represents the percentage of oxyhemoglobin (HbO_2) relative to the total hemoglobin capable of binding with oxygen (Hb). It is a critical physiological parameter involved in respiration and circulation. In a healthy individual, arterial blood oxygen saturation is typically around 98%. Generally, SpO_2 values should not fall below 94%; values lower than this may indicate insufficient oxygen supply.

Pulse rate refers to the number of heartbeat pulses per minute and generally corresponds to the heart rate. For most individuals, the normal pulse rate ranges from 60 to 90 beats per minute.

The Perfusion Index (PI) reflects the perfusion status of a patient's limb and indicates the detection precision of the oximeter. Measurements can still be performed accurately even under conditions of low or weak perfusion. In a healthy individual, the PI is typically 3% or higher.

Intended Use

The Fingertip Pulse Oximeter is a non-invasive device designed for spot-checking the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. This portable fingertip device is suitable for use in both home and hospital settings for adult and pediatric patients.

Intended Users: Professionals and laypersons.

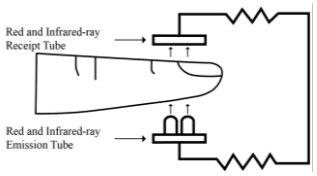
Scope of Application

The Fingertip Pulse Oximeter is suitable for use in a variety of settings, including homes, hospitals, oxygen bars, social healthcare institutions, and sports and wellness environments. It is intended for spot-check measurements before or after physical activity; continuous use during sports is not recommended. This device is not intended for continuous patient monitoring or critical care.

Working Principles

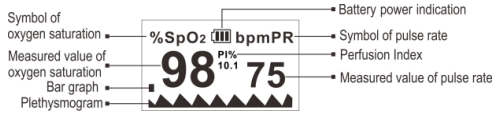
The pulse oximeter operates by placing a sensor on a pulsating arteriolar vascular bed. The sensor contains a dual light source and a photodetector. One wavelength of the light source is 660 nm (red light), and the other is 905 nm (infrared light). Skin, bone, tissue, and venous blood normally absorb a relatively constant amount of light over time. The photodetector in the finger sensor collects the transmitted light and converts it into an electronic signal proportional to light intensity.

During systole and diastole, the arteriolar bed pulsates, causing variable absorption of light as blood volume increases and decreases. The oximeter uses these variations to calculate oxygen saturation and pulse rate.



Screen Display

The following figure shows the information display on the LED screen of the Oximeter in normal detection state:



Note: The battery power indicator and the Bluetooth symbol will be displayed alternately

Power-On Button/Functional Button Operations

Press and release the button to turn on the device. Hold the button for about one second to display the parameter setting interface. Use press or hold actions to perform the corresponding operations: hold to set an item, or press to switch an option or change the display mode. A "press" means less than 0.5 seconds, while a "hold" means more than 0.5 seconds.

Alert Sound Setting

Hold the function button while the Oximeter is powered on. Parameter Setting Interface 1 will be displayed, as shown in the figure below. Press and release the button to move the "*" symbol to the desired option. Hold the function button to set Alert to ON or Beep to OFF.

- When Alert is ON and the measured blood oxygen saturation or pulse rate exceeds the upper or lower limit, the Oximeter will emit an alert sound.
- When Alert is OFF, no alert sound will be given, even if the measured values go beyond the limits.
- When Beep is ON, a tick sound will be heard in sync with each pulse during measurement.
- When Beep is OFF, no sound will be heard during pulse measurement.

When the "*" symbol is on the Restore option, hold the function button to restore the factory settings.

Brightness Setting

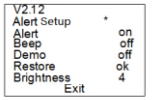
On Parameter Interface 1, press the function button to select the *Brightness* option. Then hold the function button to set the brightness to a value from 1 to 5. The higher the value, the brighter the screen.

Alert Range Setting

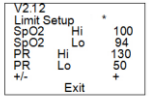
On Parameter Interface 2, press the function button to switch between options. In this interface, you can set the upper and lower limits for the SpO_2 Alert and PR Alert. When the "*" symbol is on the +/- option, hold the function button to toggle between + and – modes.

- In + mode, select the desired option and hold the function button to increase the upper or lower limit.
- In – mode, hold the function button to decrease the upper or lower limit.

Move the "*" symbol to the Exit option and hold the function button to return to the monitoring interface.



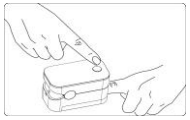
Interface 1



Interface 2

Operation Guide

⚠ Ensure that your finger is fully inserted into the chamber.



Incomplete insertion may result in inaccurate measurements.

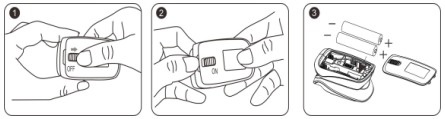
⚠ Do not move or vibrate your finger during measurement, and keep your body still. Once the readings stabilize, read the measured values of oxygen saturation (SpO_2) and pulse rate (PR) on the display. **Note:** The oximeter will automatically power off approximately 10 seconds after your finger is removed.

Screen display

Continuously press the function button during monitoring. The monitored data and display mode will cycle on the OLED screen in two formats (large fonts and plethysmogram) and four orientations, as shown in the figure below.

Replace Battery

⚠ Replace the batteries in low power when the icon （ ） flickers on screen. Open the battery cover with your fingers and replace the batteries, ensuring correct polarity.



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.

⚠ Do not disinfect the instrument using high-temperature/high- pressure or gas Sterilizations methods.

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

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

Technical Specifications

1. Dimensions: 62.0 mm (Width) × 37.0 mm (Depth) × 32.0 mm (Height)
   Weight: 42.5 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) .

7. 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
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	times	About 685 measurements with new 1200mAh battery.
	Service life	More than 20 hours of continuous use

9.Technical statement

- The device does not provide physiological alarms for SpO_2 or pulse rate conditions.
- If the signal detected by the pulse oximeter is inadequate or weak, the SpO_2 and pulse rate readings will display as "--" and "---", respectively.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or the oximeter monitor.
- The pulse oximeter operates with a specific calibration curve that is accurate only when used with its corresponding probe. Errors measured by a functional tester originate from the main oximeter unit; the device's accuracy can be verified by replicating this calibration curve.
- The manufacturer will provide, upon request, circuit diagrams, component part lists, descriptions, calibration instructions, and other information necessary to assist authorized service personnel in maintenance or repair.
- The pulse rate waveform is normalized. When the waveform is smooth and stable, the measurement is considered optimal. Data update occurs in less than 30 seconds, with averaging performed over every 8 data points.

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

Note 2: According to a controlled desaturation study guided by ISO 80601-2-61, Annex EE, which provides guidelines for evaluating and documenting SpO_2 accuracy in human subjects, the accuracy distribution was observed within the range of 70%–100%.

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 Manufacture's Declaration

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	
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 in 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