ToronTek Pulse Oximeter

Model: G64+ Pulse Oximeter

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

Precautions

- Do not attempt to service or repair the Oximeter unless you are a qualified professional. Only trained personnel with proper maintenance certification may perform internal maintenance if required.
- Periodically change the contact position between the Oximeter probe and the finger during measurement. Before measurement, adjust the probe position and check skin integrity, blood circulation, and proper finger placement.
- This product is not intended for use with newborns.
- If measured values are outside the normal range and you are certain the device is functioning properly, seek medical attention promptly.
- Do not look directly into 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, treat, cure, or prevent any medical condition or disease. Individuals who require SpO_2 and pulse rate monitoring due to a medical condition should consult their physician.
- Do not self-diagnose or self-treat based on measurement results; always consult a doctor.
- For details on clinical limitations and contraindications, consult relevant medical literature.
- After storage at minimum or maximum temperature limits, allow the device to stabilize for at least 30 minutes before use.
- Be aware that degraded or damaged sensors may reduce performance or cause inaccurate readings.
- The patient is considered an intended operator.
- For lay operators or organizations responsible for use, please contact the manufacturer or representative for:
- Assistance with setup, operation, or maintenance of the equipment if needed.
- Reporting of unexpected operations or events.

  Factors that may affect accuracy include:
- Use in environments with high-frequency equipment, such as electrosurgical devices or CT scanners.
- Placement of the Oximeter probe on the same limb as a blood pressure cuff, arterial line, or IV line.
- Patient conditions such as hypotension, severe vascular atrophy, severe anemia, or hypoxemia.
- Patients experiencing cardiac arrest or shock.
- The presence of nail polish or artificial nails, which may cause incorrect SpO_2 readings.
- Degraded sensors that affect performance.
- Do not mix old and new batteries, or batteries of different brands.
- Continuous use of the device may cause discomfort, especially in patients with poor circulation. The sensor should not be applied to the same finger for more than 2 hours.
- This device must not be used by individuals who are allergic to silicone rubber.
- Note: The device has no side effects when used correctly, and any residual risk is 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 depleted batteries according to environmental protection regulations.
- WARNING: Do not use the Oximeter in an MRI or CT environment.
- WARNING: Do not operate the Oximeter if it is damp due to overflow or condensation. Avoid moving the device directly from an extremely cold environment to a warm, humid environment.
- WARNING: Do not modify this equipment under any circumstances, as this may compromise safety.
- WARNING: Do not use accessories or detachable parts that are not specified or authorized by the manufacturer. Doing so may cause device damage or pose risks to the user or patient.
- WARNING: Keep the unit and lanyard out of reach of children. The lanyard may present a choking or entanglement hazard. Adult supervision is required; never leave children unattended with the unit or lanyard.
- WARNING: Do not throw batteries 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
EC REP	Authorized European Representative
MD	Medical device
	Humidity
	Atmospheric Pressure

Overview

Oxygen Saturation (SpO_2):

Oxygen saturation is the percentage of oxyhemoglobin (HbO_2) bound to oxygen compared to all available hemoglobin (Hb). It is a key physiological parameter in both respiration and circulation.

- In healthy individuals, arterial blood oxygen saturation is typically around 98%.
- Normal values should not fall below 94%.
- If the measured value is below 94%, it may indicate an insufficient oxygen supply.
- Pulse Rate (PR):

  The pulse rate is the number of pulse beats per minute. Under normal conditions, it corresponds to the heart rate. In adults, the typical range is 60 to 90 beats per minute.
- Perfusion Index (PI):

  The PI reflects the blood perfusion status of the measured limb and also indicates the

detection sensitivity of the instrument. Reliable measurements can still be obtained under low or weak perfusion conditions.

- A normal PI value is 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 both adult and pediatric patients in home or hospital settings.

Intended Users: Professional or layperson.

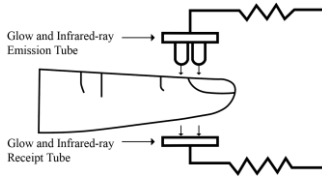
Scope of Application

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.

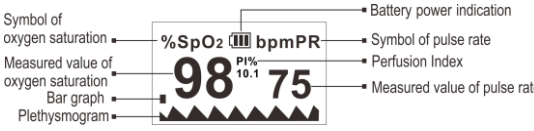
Working Principles

The pulse oximeter 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.

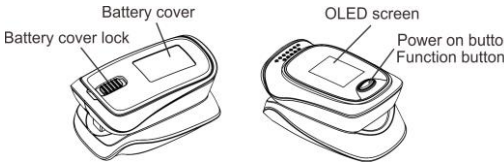


Screen Display



Device Overview

The figure below shows the information displayed on the OLED screen of the Oximeter during normal measurement.



Power-On Button/Functional Button Operations

After powering on the Oximeter, hold the power/functional button for about one second to display the parameter setting interface. Use press or hold actions on the button to perform the corresponding operations or switch the display mode:

- Hold the button to set an item.
- A press lasts no more than 0.5 seconds, while a hold lasts more than 0.5 seconds.

Alert Sound Setting

Hold the power/functional button while the Oximeter is powered on. Parameter Setting Interface 1 will be displayed, as shown in the figure below.

- Move the "*" symbol to the desired option and hold the button to adjust settings:
- Alert: Set to ON or OFF.
- When ON, the Oximeter emits an alert sound if SpO_2 or pulse rate exceeds the upper or lower limit.
- When OFF, no alert sound is given, even if values go beyond the limits.
- Beep: Set to ON or OFF.
- When ON, a tick sound is heard with each pulse during measurement.
- When OFF, no sound is emitted during pulse measurement.
- To restore factory settings, move the "*" symbol to the Restore option and hold the functional button.

Brightness Setting

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

Alert Range Setting

On Parameter Interface 2, press the functional button to switch between options. In this interface, you can set the upper and lower limits for SpO_2 and PR.

- When the "*" symbol is on the +/- option, hold the functional button to toggle between + and – modes.
- In + mode, select the desired option and hold the button to increase the upper or lower limit.
- In – mode, hold the button to decrease the upper or lower limit.
- Move the "*" symbol to the Exit option and hold the functional button to return to the monitoring interface.

Alert setup	*
Alert	on
Beep	off
Demo	off
Restore	ok
Brightness	4
Exit	

Interface 1

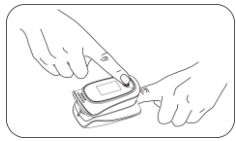
Limit Setup	*
SpO2 Hi	100
SpO2 Lo	94
PR Hi	130
PR Lo	50
+/-	+
Exit	

Interface 2

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.

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

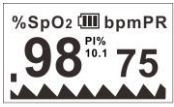


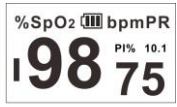
⚠ Do not move or vibrate your finger during measurement, and keep your body still. Once the readings stabilize, read the measured values of oxygen saturation (SpO_2) and pulse rate (PR) on the display.

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

Screen Display

Continuously press the **functional 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.

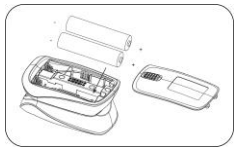




Replace the batteries

Replace the batteries when the battery level is low and the battery symbol ( ) **flickers** on the screen.

Insert **two AAA dry batteries** into the battery compartment according to the polarity markings, then secure the battery cover.



Cleaning

Power off the device and remove the batteries before cleaning.

Ensure the device's exterior is clean, dust-free, and free of dirt.

Clean the outer surface, including the OLED screen, using 75% medical alcohol and a soft, dry cloth.

Cautions:

- Avoid letting any liquid flow into the device during cleaning.
- Do not immerse any part of the device 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.

Technical Specifications

1. Dimensions: 62.0 mm (Width) × 37.0 mm (Depth) × 33.1 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
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.

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

8.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%.

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.

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

Appendix: Electromagnetism Compatibility

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	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m

IEC 61000-4-3	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