PULSE OXIMETER

USER MANUAL-TORONTEK-H50

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INSTRUCTIONS TO USER

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.
The Manual describes the Pulse Oximeter's features, main structure, functions, specifications and recommended methods for handling, usage, operation, repair, maintenance and storage. It also details the procedures related to the user and the device safety.

Please read the User Manual carefully before using this product. The safety procedures and operating recommendations in this manual should be followed strictly. Failure to follow may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

DISCLAIMERS:

- This device is not interned for continuous monitoring of patients in emergency or intensive care units.
- The readings are not accurate when patient is intoxicated with carbon monoxide, the device is not recommended to be used under this circumstance.
- This device 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. If you think you may be suffering from any medical conditions you should seek immediate medical attention.
- No part of this document may be photocopied, reproduced or translated to another language without prior written consent of the manufacturer.
- No liability is accepted for injury, loss or damage incurred by use or mis-use of this product

WARNING:

- Tingling or temporary fingertip numbness may occur in case the device is clipped on a finger for a prolonged period. If you experience this, please remove the device or put it on a different finger.
- The sensor has infrared light emitted which is harmful to the eyes, staring at the infrared light should be avoided by user and any person handling the device.
- Users' finger-tip should be completely cleaned off any moisturizer, cream or makeup.
- Users' fingernail should not be too long preventing proper placement of sensor on the fingertip. This can affect the device readings.
- Users' fingernails should be cleaned off any nail polish. Nail polishes may distort the emitted light affecting the device accuracy.

1. Safety

1.1 Instructions for operation safety

- Inspect the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- Necessary maintenance and repair must be performed by qualified service engineers only.
- Only accessories recommendatory by manufacture can be used with this device.
- This product is calibrated before leaving factory.

1.2 Warnings

- Explosive hazard—DO NOT use the oximeter in environment with inflammable.
- DO NOT use the oximeter while patient is undergoing MRI and CT.
- The singer tip pad is made of plastic. Patients with allergy to plastic should avoid using the device.
- For disposal of instrument and its accessories and packing (including battery, plastic bags, foams and paper boxes) local laws and regulations should be followed.
- This device operates with batteries. Please be cautious in case of using pacemaker and other medical devices which could have interference with batteries.
- The battery lid and the neck-strap could be dangerous in hand of children. Please keep away from children.

1.3 Attentions

- For accurate reading the finger should not be too cold or hot. Start using the device when fingers are at the same temperature as the room temperature.
- For accurate reading insert the index finger deep inside the device. Keep your body and arm still with your arm stretched out on a support surface like arm chair handle bar or table. Keep your wrist straight to make the blood flow easily in your fingers.
- For accurate reading do not expose the device to excessive ambient light. This includes fluorescent lamp, dual ruby light, infrared heater and direct sunlight.
- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the unit gets wet, stop using until is fully dried.
- When it is carried from cold environment to warm or humid environment, please wait till the device temperature matched the environment temperature.
- DO NOT operate front panel keys with sharp materials.
- High temperature or high pressure disinfection process will damage the device. Refer to recommended method of disinfection in this manual.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol and cotton swab. Do not spray any liquid on the device directly.
- Do not use the device on infant or neonatal patients.
- The product is suitable for children above four years old and adults (weighing between 15kg to 110kg).
- The device may not work for all patients. Patients with Raynaud's disease or any low blood flow in hands will not get accurate reading.
- The data reading speed is average 5 seconds. Individuals will experience different times for data readings.
- If dots or abnormal values are shows during test process, pull out the finger and reinsert to get accurate reading.
- The device has standard life of 3 years form the first date of use on battery.
- The neck-strap accompanying the product is made from non-allergy material, in case of any allergy shown like rashes and itching while contacting skin please refrains from using the strap.
- Change the battery when the battery is low in voltage. Use standard batteries which are compatible with the device.
- Batteries must be removed if the device is going to be stored for more than one month, or else batteries may leak damaging the device.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

2. Overview

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter showing the blood oxygen content. Simultaneously this device will measure and display the pulse rate.
ToronTek-H50 features are: compact size, low power consumption, convenient operation and light weight. The device is powered with 2xAAA batteries and will show the SPO2 saturation and pulse rate values on digital screen by inserting the finger in the device.

2.1 Classification:

Class II b(MDD93/42/EEC IX Rule 10)

2.2 Features

- User friendly and easy to operate.
- Super light in weight (total weight is about 50g including batteries) making it convenient to carry around.
- Low-battery indicator.
- Power consumption of the product is low and 2 AAA batteries can power the device continuously for 24 hours
- The device will automatically be powered off when no signal is in the product within 5 seconds to save battery.

2.3 Major applications and scope of application

This pulse oximeter can be used to measure human Hemoglobin Saturation and pulse rate through finger and shows the digital values. The pulse intensity is also displayed in a form of a bar graph. The product is suitable for use at hospitals, clinics, ambulance, sport facilities as well as home use.

2.4 Environment requirements

Storage Environment
a) Temperature :-40℃~+60℃
b) Relative humidity :≤95%
c) Atmospheric pressure :500hPa~1060hPa
Operating Environment
a) Temperature: :10℃~40℃
b) Relative Humidity :≤75%
c) Atmospheric pressure:700hPa~1060hPa

3. Principles of operation

3.1 Principle of measurements

Principle of the Oximeter is as followed: The formula for calculation of the Oxygen saturation is calculated upon Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones. This device operation is based on Photoelectric Oxyhemoglobin Inspection Technology and Capacity Pulse Scanning & Recording Technology. Two beams of different wavelength of lights are transmitted through human finger-tip through emission sensor. The receiving sensor will collect the data and sent to microprocessors for analysis and transmitted in valued to digital screen.

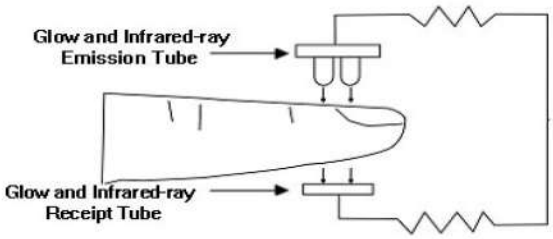

Figure 1. Operating Principle

3.2 Caution

1. The finger should be inserted properly with finger nails to be on the same side as the display screen.As illustrated in figure 5. Failing to follow this would affect the readings.
2. The SpO2 sensor should not be used on a hand while tied with arterial block cord or blood pressure cuff.
3. Make sure the optical path is free from any external particles or materials blocking sensors.
4. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater and direct sunlight.

3.3 Clinical restrictions

1. The devices measurement is based on of arteriole pulse and normal pulsating blood flow of user is required. For patients with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 waveform (PLETH) will show lower that the accurate level.
2. For patients with substantial amount of blood thinning medications (such as Methylene blue, Indigo green and Acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or Thiosalicylic hemoglobin, and patient with icterus problem, the SpO2 reading of the device may be inaccurate.
3. Use of drugs like Dopamine, Procaine, Prilocaine, Lidocaine and Butacaine may also lead to inaccurate SpO2 measurement.

4. Technical

4.1 **Display Format:** Digital tube display;
SpO2 Measuring Range: 0% - 100%;
Pulse Rate Measuring Range: 30 bpm - 250 bpm;
Pulse Intensity Display: columniation display

4.2 **Power Requirements:** 2 ×1.5V AAA alkaline battery (or using the rechargeable battery instead),
Adaptable range: 2.6V~3.6V.

4.3 **Power Consumption**: Smaller than 25 mA.

4.4 **Resolution:** 1% for SpO2 and 1 bpm for Pulse Rate.

4.5 **Measurement Accuracy:** ±2% in stage of 70%-100% SpO2, and invalid when stage being smaller than 70%. ±2 bpm or±2% (select larger) for Pulse Rate.

4.6 **Resistance to surrounding light:** The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

4.7 **Auto Shut-off function** .The Oximeter will powered off in case no finger is the Oximeter for 5 seconds.

4.8 **Optical Sensor**
Red light (wavelength is 660nm, 6.65mW)
Infrared (wavelength is 880nm, 6.75mW)

5. Accessories

- **One neck-strap**
- **Two batteries (optional);**
- **One User Manual.**

6. Direction for use

6.1 View of the front panel

Figure 2. Front View

6.2 Battery

Step 1. Remove the battery cap by sliding the cap to disengage.

Step 2. Insert 2xAAA batteries. Note the direction of batteries as indicated in the battery compartment

Step 3. Place back the battery cover

⚠ ***Please note as the improper batteries insertion may damage the device.***

Figure 3. Batteries Installation

6.3 Attaching the Neck-strap

Step 1. Put the threaded-end of the strap through the devised hole on the device.

Step 2. Put another end of the strap through the loop and pull it to tighten it up.

Figure 4. Attaching the neck-strap

7. Operating Instruction

7.1 Open the battery lid. Pay close attention to the battery direction imprinted at the battery compartment. Insert two AAA batteries and close the cover.

7.2 Open the clip by pushing the two end of the device as indicated with "PUSH".

Figure 5. Insert finger properly inside the clip-on probe

7.3 Insert the finger into the rubber cushions of the clip (make sure the finger is in the right position with finger nail facing you), and then release the device so the device clips on the finger.

7.4 Press the switch button once on front panel.

7.5 Avoid body and hand movements. Leave your arm relaxed on a surface with fingers extended out.

7.6 Read the data shown on the display.

7.7 If you need to reset for any reason press the power button while the device is on your finger.

⚠ ***While inserting finger, fingernails and the digital screen should be on the same side.***

8 Repairing and Maintenance

- Change the batteries when the low-voltage displayed on the screen.
- Clean the surface of the device before using. Wipe the device with medical alcohol first, and then let it dry in air or clean it by dry clean fabric.
- Using the medical alcohol to disinfect the product after use, prevent from cross-contamination for next time use.
- Take out the batteries if the oximeter is not in use for a long time. (more than a month)
- The best storage environment of the device is - 40ºC to 60ºC ambient temperature and not higher than 95% relative humidity.

⚠ ***High-pressure sterilization cannot be used on the device.***

⚠ ***Do not immerse the device in liquid.***

⚠ ***It is recommended that the device should be kept in a dry environment. Humidity may reduce the useful life of the device, or even damage it.***

9. Troubleshooting

Trouble	Possible Reason	Solution
The SpO2 and Pulse Rate cannot be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; If still reading is too low and you are sure the device is reading correctly, contact your family doctor.
The SpO2 and Pulse Rate are not displayed stably	1. The finger is not inserted deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Try again while user is still.
The device cannot be turned on	1. The batteries are not inserted properly 2. The batteries are drained or almost drained. 3. The malfunction of the device.	1. Open the battery compartment. Pay close attention to battery direction instruction imprinted in the compart-ment.re-insert batteries 2. Change batteries. 3. Please contact the local service center.
The display is off suddenly	1. The device will power off automatically when it gets no signal within 5 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

10. Key of Symbols

Symbol	Description
	Type BF
	Warning – See User Manual
SpO_2%	The pulse oxygen saturation(%)
PRbpm 	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)
	1. no finger inserted 2. An indicator of signal inadequacy
	battery positive electrode
	battery cathode
	Power switch
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
IP22	Ingress of liquids rank

11. Function Specification

Display Information	Display Mode
The Pulse Oxygen Saturation(SpO2)	Digital
Pulse Rate(BPM)	Digital
Pulse Intensity (bar-graph)	Digital bar-graph display
SpO2 Parameter Specification	
Measuring Range	0%~100%, (resolution is 1%).
Accuracy	70%~100%:±2% , Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 880nm)
Pulse Parameter Specification	
Measuring Range	30bpm~250bpm, (resolution is 1bpm)
Accuracy	±2bpm or±2% select larger
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
Battery Useful Life	
Two batteries can work continually for 24 hours	
Dimensions and Weight	
Dimensions	57(L) × 31(W) × 32 (H) mm
Weight	About 50g (with the batteries)

NOTE: If you find this manual text too small to read, Please find the magnified version in manufacturer portal: www.TORONTEK.com