PULSE OXIMETER

USER MANUAL-TORONTEK-B400

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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 and/or equipment damage. No liability is accepted for injury, loss or damage incurred due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

ToronTek-B400 Pulse Oximeter comes with software. We highly recommend viewing our tutorial for this device on our website at: www.torontek.com

By using this device you agree to comply with term and conditions mentioned on manufacturers website available at: http://torontek.com/termsandconditions

1. Safety Information, Warnings, Cautions and Notes

- Check 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 Oximeter should be inspected at least once a week. When there is obvious damage stop using the device.
- Necessary maintenance and repair must be performed by qualified service engineers only.
- Federal law may restrict this device for sale by or on the order of a physician.
- DO NOT use the Oximeter while patient is undergoing MRI or CT.
- The sensor emits infrared light. Direct staring at the light should be avoided as it can be harmful to the eyes.
- The probe is latex free and made of plastic. Patients with allergy to plastic should avoid using the device.
- This Pulse Oximeter is battery-operated. Please be cautious in case of using pacemakers and other medical devices which could have interference with batteries.
- Please do not remove the wristband from the main unit.
- If experiencing allergy on wrist skin contacting the wristband, please refrain from using.
- In case of replacing the power adaptor, ensure compliance with the requirements of IEC 60601-1, or it may damage the device.
- To avoid damage to the product only use the accessories accompanying the Pulse Oximeter.
- DO NOT USE the device while charging.
- In case of discomfort due to continuous use, it is recommended to remove the device and use it on a different finger.
- Follow local laws and regulations for disposal of this instrument and its accessories
- Keep the Oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the Oximeter gets wet, stop using until it is fully dried.
- High temperature or high pressure disinfection process will damage the device. Refer to recommended method of disinfection in this manual.
- Do not immerge the Oximeter in liquid. For instruction on cleaning and disinfecting see 7.1.
- Do not use the device on infant or neonatal patients.
- The product is suitable for children above four years of age and adults weighing between 15kg to 110kg.
- This Pulse Oximeter may not work for all patients. Patients with Raynaud's disease or any low blood flow in hands will not get accurate reading. If you are unable to achieve stable reading, discontinue use.
- The data reading speed is 5 seconds on average. Individuals will experience different times for data update.
- The device has standard life of 5 years form the first date of use on battery.
- This device features alarm function which can be activated and deactivated from the menu. When activated, the alarm will sound if SPO2 or pulse rate goes beyond the minimum or maximum level set by user. For instruction on setting alarms see 6.1
- Keep away from children. Smaller accessories pose choking hazard.

This Pulse Oximeter is a health monitoring device and is not intended for treatment.

The readings of the device is not intended to be used to diagnose, treat, cure or prevent any medical condition nor should it be used as a substitute for your own health care provider's professional advice unless used by or under the direct supervision of a licensed health care provider. The manufacturer is not responsible for any injury, damage or loss caused by use or mis-use of this product.

2. Product Description

ToronTek-B400 measures oxygen saturation, pulse rate and pulse intensity. Oxygen saturation is the percentage of HbO2 in the total Hb in blood, also called the O2 concentration in blood. It is an important bio-parameter showing blood oxygen content. This Oximeter is calibrated and tested for accuracy before leaving factory.

ToronTek-B400's compact dimensions, low power consumption, convenient operation, comfortable wristband, recording capability, proprietary software, alarm feature and rechargeable battery makes it an ideal monitoring equipment.

2.1. Intended Use:

This Pulse Oximeter is a non-invasive device intended for spot-check, monitoring and recording of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate through the finger of adult patients. It is suitable for use at hospitals, clinics, ambulances, sports facilities as well as home use. This Oximeter is not intended for sport research or use during excessive movement, as the blood flow change affects readings. It can, however, be used before or after sports activities.

2.2. Quality of Service and Security

ToronTek-B400 assures timely, reliable, accurate, and secure data collection and recording. The recorded measurements can be transferred to computer via USB connection.

2.3. Classification

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

2.4. Environment Requirements

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

3. Measuring Principle

The formula of data process is calculated using Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in glow and near-infrared light zones. The operation of this device is based on Photoelectric Oxyhemoglobin Inspection Technology and Capacity Pulse Scanning & Recording Technology. Two light beams of different wavelengths are transmitted through human finger-tip into a photo sensor. The receiving sensor collects the data and sends them to microprocessors for analysis and transmission of values to digital screen.

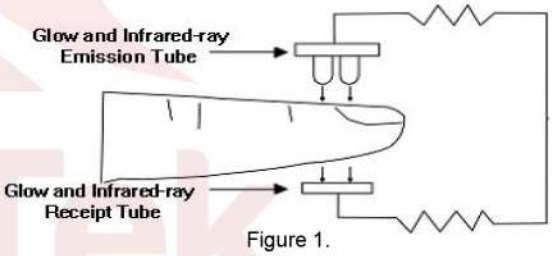

Figure 1.

4. Technical Specifications

4.1 Main features:

A. Pulse rate value display, bar graph display
B. Pulse waveform display
C. Low-battery indication: low-battery indicator appears signaling the need for connection to power charger.
D. Adjustable screen brightness and alarm sound
E. Pulse sound can be activated from the Menu.
F. Alarm can be set for lower and upper levels of SPO2 and pulse rate.
G. SPO2 and pulse rate readings can be recorded and transferred to computer for analysis by the proprietary software provided by manufacturer.
H. Wristband for ease of use
I. Built-in rechargeable lithium battery charged by USB port or power adaptor

4.2 Main Parameters

A. Measurement of SpO2

Measurement Range: 0% ~ 100%

Accuracy: 70 ~ 100%, ±2%; below 70% unspecified

B. Measurement of Pulse Rate

Measurement Range: 30 bpm ~ 250 bpm

Accuracy: ±2 bpm or ±2% (select the larger)

C. Resolution

SpO2 : 1%, Pulse rate: 1 bpm.

D. Resistance to Surrounding Light

The deviation between the value measured under artificial light or indoor natural light and that of a dark room is less than ±1%

E. Power Supply Requirement

DC 3.6 V - 4.2V.

F. Optical Sensor

Red light (wavelength is 660 nm, 6.65 mW)

Infrared (wavelength is 905 nm, 6.75 mW)

G. Adjustable Alarm Range

Adjustable range of SpO2 upper limit: 0% ~ 100%, cannot be defined less than the lower limit

Adjustable range of SpO2 lower limit: 0% ~ 100%

Adjustable range of PR upper limit: 0 bpm ~ 254 bpm, cannot be defined less than the lower limit

Adjustable range of PR lower limit: 0 bpm ~ 254 bpm

H. Default Alarm Settings

SpO2 upper limit: 99%

SpO2 lower limit: 85%

PR upper limit: 120 bpm

PR lower limit: 30 bpm

5. Installation

5.1 Front and rear panel view

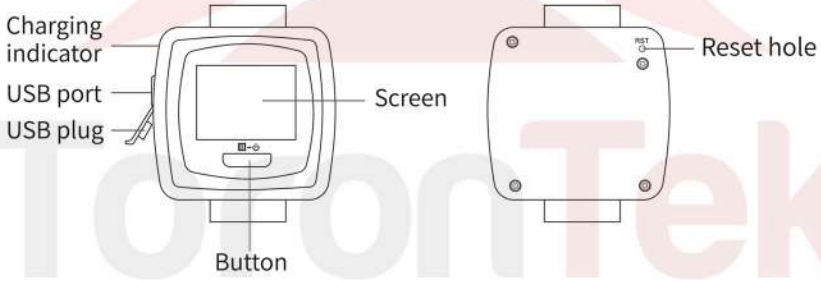

Figure 2. Front and rear view

-USB port: This port has multiple uses. The probe sensor is connected to the device through this port. When user needs to transfer the data to PC, this port will be the data transfer port. User needs to connect the accompanying data cable to USB port and the other end of the cable needs to be plugged into this port. User would need to remove the finger probe while managing data transfer. This unit can be charged through this port using a USB port or the accompanying power adaptor.

-Button: To power on, pause sound prompt, display clock, also to enter menu, to operate menu

-RESET hole: reset button is located inside. Insert a narrow object (not sharp and pointy) to hold and press down for 3 seconds to reset. (Cautions: all user settings will be reverted to factory setting and any recorded data will be lost)

- Charging indicator. When the Oximeter is charging via USB or power adaptor, the orange LED indicating light turns on. Once the device is fully charged the orange light changes to green. At this stage it is strongly recommended to unplug the device from the charging source. Overcharging the device can reduce battery lifetime. In case of power cut during charging process, unplug the device from charging source; wait for the power to return and only then plug in the Oximeter.

5.2 Display screen

Once measuring the SPO2 and pulse rate display will as illustrated below.

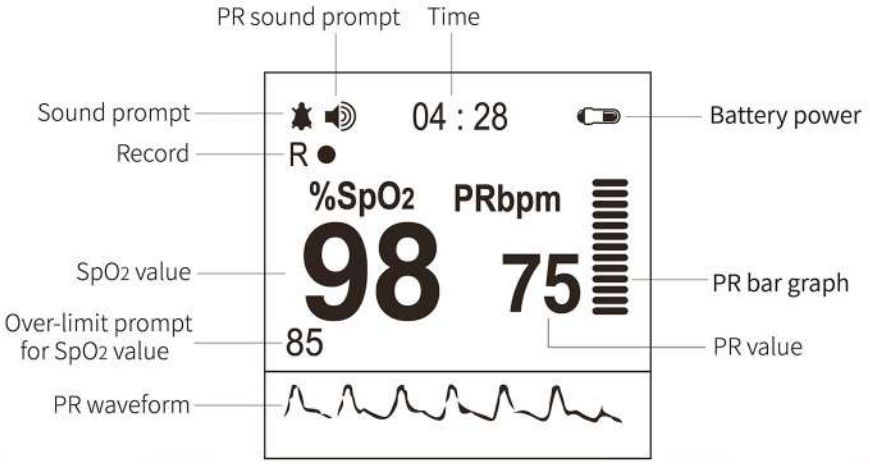

Figure 3. Measuring screen interface

5.3 Accessories

A. Finger probe
B. Power adaptor
C. Data cable
D. An adult Oximeter probe
E. User Manual

6. Operating Guide

6.1 Operating the Device

a) Connect the probe to the main unit by Opening the USB plug of the device, then inserting the SpO2 probe interface into the USB port of the device.

b) Insert the index or middle finger deep inside the probe. Correct placement of the finger (i.e. fingernail facing upward) is important. The cable connecting the probe to the main unit should pass over the back of your hand and not the palm. Make sure your finger is clean, free of any moisturizer, make-up or moist.

c) Keep the body still with the arm stretched out and relaxed over a surface. Make sure there is nothing to restrict the normal blood flow. Keep the wrist straight and the fingers stretched.

d) Turn on the device by pressing and holding the power button on the front panel.

e) Wait till the screen shows readings.

⚠ ***Note the finger placement indication on the probe tip.***

⚠ ***If the alarm function is "ON", the device will provide medium-priority alarm signal when finger is out. To stop the alarm you can insert the finger or go to main menu and deactivate the alarm.***

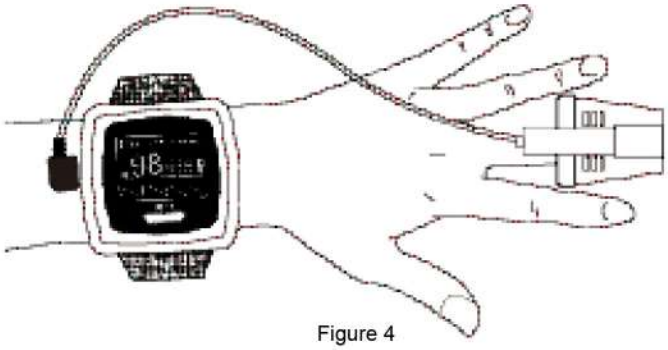

Figure 4

(Note: due to ongoing development and enhancement, actual probe might be different from the image.)

Operating the Menu:

Note the following definitions while reading through the manual:

PRESS = short press and immediate release of the power button **PRESS AND HOLD** = prolonged pressing (1 sec) of the power button **BUTTON**= the power button on the front panel

⚠ **As a rule, press once to scroll down a menu, press and hold for 1 second to select a setting.**

A. Entering and Exiting the Clock Interface

When in measurement mode (i.e. the screen showing readings) press the button in order to enter the clock interface, which shows the date and time. If there is no activity, the device automatically switches back to the measurement display interface in 30 seconds. To go back to the measurement interface faster simply press the button again.

B. Pausing the Alarm

a) The alarm can be turned on by user from the menu and will be triggered when the SPO2 and pulse rate reading go beyond or fall below the limits set by user.
b) If the alarm function is triggered while on measuring interface, it can be paused by pressing the button. If within 60 seconds the readings are back within the limits set by user, the alarm will stop, otherwise it will be triggered again.
c) User can switch off the alarm feature from the Main Menu.

C. Menu Operations

While in measurement interface, press and hold the power button in order to enter the menu interface as shown in figure 5. Several functions are controlled through the Main Menu, such as System, Alarm, Clock, Record, and Power off. The specific operation methods are as follows:

Figure 5. Main Menu Interface

(Note: due to continuous enhancements and developments menu options might be added and removed by manufacturer.)

c.1) Display Brightness Setting

On the Main Menu interface, by each pressing the selector moves down one item. Press the button until “System” is highlighted. Press and hold the power button. In the sub menu press the button to move the selector to “Brightness” . Hold the button to adjusts brightness between 4 different levels. When happy with a level of brightness simply release the button.

c.2) Setting the Alarm

On the main menu interface, press the button to move selector to “Sound”. Press and hold the power button to enter the alarm setting interface.

a. Adjusting the High and Low Limits of Alarm Trigger Parameters

Press and hold the button to choose “up” or “down” when selector is on “Direction”. (This will determine whether the value of the limits increases or decreases by each press of the button.)

To raise the SpO2 and pulse rate limit, choose “up” as “Direction”, then press the button to highlight the parameter to be adjusted: SpO2 high limit (SpO2 ALM HI), SpO2 low limit (SpO2 ALM LO), Pulse rate high limit (PR ALM HI), Pulse rate low limit (PR ALM LO). Press and hold the button to adjust the selected limit to the desired higher value and release the button once the higher limit has been reached.

To lower the SpO2 and pulse rate limit, choose “down” as “Direction”, then Press the button to choose the parameter to be adjusted. Press and hold the button to adjust the selected limit to the desired lower value and release the button once the lower limit has been reached.

⚠ ***After setting the parameters make sure the alarm is turned on. If the alarm is on, the device will provide medium-priority alarm signal when the value of SpO2 or pulse rate is beyond the limit.***

Medium priority indicates that prompt operator response is required: intermittent alarm will occur and the measurement will be shown in yellow.

b. Turning the Alarm ON or OFF:

Press the button until “Alarm” is highlighted, then press and hold the button to choose “on” or “off”.

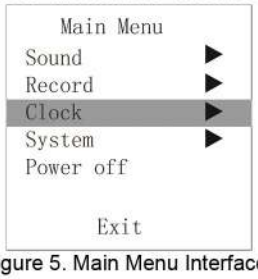

Figure 5. Main Menu Interface

c.3) Pulse Sound Indication Setting

Press the button until "Pulse Sound" is highlighted. Then press and hold the button to choose to have the Pulse Sound (heart beat) alarm "on" or "off". When the sound is "on", the Oximeter beeps with each pulse beat.

c.4) Exiting the Alarm Settings

Move the selector on "Exit" by pressing the button. Then press and hold the button to exit the Alarm Settings Menu.

d) Sound volume adjustment:

On the Main Menu interface, by each pressing the selector moves down one item. Press the button until "System" is highlighted. Press and hold the power button. Press the button to select "Sound Volume" press and hold the button to adjust the sound level from 1 to 3 with 3 being the loudest.

e) Clock Setting

On the main menu interface press the button until "Clock" is highlighted, and then enter the clock setting interface by pressing and holding the button.

Figure 8. Clock Setting Menu

a. When entering the clock setting menu, "set time" state would be "no" by default, reason being the avoidance of time change by mistake or unintentional pressing of the button. To change the time first you need to change the "set time" status to "yes" by pressing and holding the button.

b. Press the button to highlight the parameter that you want to change and then adjust the data by pressing and holding the button.

c. Press the button until "Exit" is highlighted. Then exit the clock setting menu by pressing and holding the button. If you have reset the time or date, when exiting the clock setting menu, first the renewed time and date will be displayed on the screen, then it will return to the main menu; if you didn't reset the time and date, when exiting the clock setting menu, the device will return to the main menu directly.

f) Recording the Data

ToronTek-B400 has two recording modes "Manual" and "Auto"

"Manual" mode: user will need to turn on/off recording from the operation menu. In this mode up to 24 hours of data is saved

"Auto" mode: the device will automatically start recording when stable data is read from the user. By removing finger form the probe the recording would stop and the data recorded will be saved as group 1 of data. By inserting the finger to the probe again the recording starts automatically as a part of group 2 of data. (99 groups of data a most is supported). In this mode the total duration of recorded data will be maximum 72 hours.

f.1) When the device is recording a red dot with recording sign "R●" will be visible on device measurement interface.

f.2) While recording, to save battery the screen switches to standby mode and the beep tone stops after 30 seconds of inactivity. If you press the button, the screen will read "recording" and if you press and hold the button, the screen returns to measurement mode.

f.3) The Oximeter does not power off while recording. Recording has to be turned off before powering off.

f.4) To stop recording select "record" on the main menu. Stop recording from this menu

f.5) Before connecting the Oximeter to PC for data transference make sure recording has been stopped.

f.6) on Manual mode when turning the "Record" on, the device will prompt that by activating record the last data stored will be lost as the system will over-write the data recorded last time. To avoid losing the data, it is recommended to transfer the data to PC prior to starting a new recording session.

f.7) While recording is ON user cannot switch the mode from auto to manual or vice versa. Recording would need to be stopped before switching the mode.

f.8) under Auto mode menu selection "Delete All" will enable the user to delete all the recorded data groups at once.

f.9) Once the memory is full while device is recording a prompt is shown as "Memory is full". The device will be entering standby mode after several seconds. By pressing the button the device will show the "memory is full prompt" again. To go to measurement interface press the button once more when this prompt is shown.

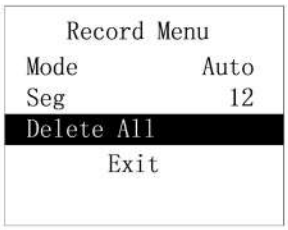

Figure 9 Record menu interface (Auto mode)

g) Uploading the Saved Data to PC through the Software:

Only this PC-installed SpO2 Assistant proprietary Software can communicate with the Pulse Oximeter. Before transferring recorded data to PC you would need to download it from the manufacturer's website at www.TORONTEK.com

The software is integrated with the function of USB cable data transmission. First install the software on your PC. The software icon is shown in Figure 10 below. Open the software on your PC. Remove the probe from the main unit and connect the device with USB cable to your PC USB port. Make sure the device is switched ON. It is very important to use the cable which is accompanying the device. Third party data cables are not compatible with this device even though they might have similar sockets. For detailed instruction on transferring data to PC, please visit: www.torontek.com. and download the SOFTWARE MANUAL.

⚠ ***The computer used to download the data from Oximeter should be compatible with the standard of IEC60950 and the operating system which is on the PC should be in compliance with the requirements of IEC60601-1-1.***

Figure 10 SpO2 Assistant Software

h) Device ID

The user can modify the device ID through the SPO2 Assistant software.

i) Power Off

On the Main Menu interface, press the button until "Power off" is highlighted, then press and hold the button to shut down the Oximeter.

j) Exiting the Main Menu

On the Main Menu interface, press the button until "Exit" is highlighted. Then press and hold the button to exit the Main Menu.

6.2. Charging the Battery

The Oximeter can be charged using one of the two following methods:

a) Connect the device to a computer through the USB port with the accompanying data cable. The battery indicator will show charging symbol.

b) Connect the device to power supply using the Data cable and the power adaptor accompanying the device. The battery indicator will show charging symbol. The orange battery charging LED indicator on the unit will remain illuminated while the battery is charging. When the device is fully charged the color turns green.

⚠ ***If the alarm function is on, the device will provide high-priority alarm signal when the battery is in low power status.***
High priority alarm indicates that immediate operator response is required: Intermittent alarm occurs and the battery indicator turns red and starts flashing.

6.3 Attention for Operation

- The finger should be inserted properly as illustrated in figure 5. Failing to follow this will affect the readings.
- The patient's fingernail should not be too long. The finger needs to be completely clean and dry without any moisturizer, cream, makeup and medication.
- The SpO2 sensor should not be used on a hand tied with arterial block cord or blood pressure cuff.
- When it is carried from cold environment to warm or humid environment, please wait until the device temperature reaches the environment temperature.
- DO NOT operate keys on front panel with sharp objects.
- For accurate reading the finger should not be too cold or hot. Start using the device when fingers are at room temperature.
- Readings will be inaccurate if patient is intoxicated with carbon monoxide; this device is not recommended for use under this circumstance.
- If dots or abnormal values appear during test process, pull out the finger and reinsert to get accurate reading.
- Excessive ambient light may affect the measuring result. This includes fluorescent lamps, infrared heaters and direct sunlight.
- Please clean and disinfect the device after operating according to the User Manual.

6.4 Clinical Restrictions

- The device's measurement is on the basis 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 drugs, the SpO2 waveform (PLETH) will show lower than accurate level.
- 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 patients with icterus, the SpO2 reading of the device may be inaccurate.
- Use of drugs like Dopamine, Procaine, Prilocaine, Lidocaine and Butacaine may also lead to inaccurate SpO2 measurements.

7. Maintenance, Transportation and Storage

7.1. Cleaning and Disinfecting

Use medical alcohol and cotton swab to wipe the device. Let it dry by air or wipe with soft cloth. Do not spray any liquid directly on the Oximeter.

7.2. Maintenance:

A. Recharge when the screen indicates low battery.

B. When the device is fully charged unplug it to prevent battery damage. In case of power cut during charging period, unplug from the electricity outlet to avoid possible damage by power surge.

7.3. Storage and Handling

A. The packed device should be stored in a room with no corrosive gases and with good ventilation. Temperature: -40 °C ~ 60 °C; Relative Humidity: ≤ 95%-

When the device is not used for a prolonged period of time it is recommended the battery is charged every 6 month in order to extend the battery life time.

8. Troubleshooting

Problem	Possible Reason	Solution
The SpO2 and Pulse Rate readings are not displayed within the normal range.	1. The finger is not properly positioned. 2. The patient's SpO2 is too low to be detected.	1. Insert the finger properly and try again. 2. Try again; contact medical professional for a diagnosis if you are sure the device works all right.
The SpO2 and Pulse Rate displayed are not steady.	1. The finger is not placed inside 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 display suddenly turns off.	1. The device is malfunctioning. 2. The battery is drained away or almost drained away.	1. Please contact the local service center. 2. Please recharge the battery
The battery cannot be fully charged even after 10 hours of charging.	The battery is broken.	Please contact the local service center.

For further troubleshooting and tutorial please visit our website at www.TORONTEK.com

9. Symbol Definition

Symbols	Meaning	Symbols	Meaning
	Refer to instruction manual/booklet	PRbpm	Pulse rate (bpm)
	Type BF applied part	%SpO_2	Pulse oxygen saturation (%)
	No alarm	RST	RESET hole
	Manufacturer		Use-by date
SN	Serial number		USB
+	Battery anode		Battery cathode
IP22	International Protection		Fully charged
	Temperature limitation		Humidity limitation
	Atmospheric pressure limitation		This way up
	Fragile, handle with care		Keep away from rain
	Low battery		Close the sound prompt
	Pause the sound prompt		Open the sound prompt
	Menu/ Power button		Close the PR sound
	Recyclable		Open the PR sound
R•	Recording	Sensor Fault	Probe failure
Sensor Off	The probe is disconnected.	Finger Out	The finger is not inserted.
	WEEE (2002/96/EC)		Date of manufacture

10. Function Specification

Information	Display Mode
The Pulse Oxygen Saturation (SpO2)	2 digits LED display
Pulse Rate (PR)	3 digits LED display
Pulse Intensity	bar-graph LED display
SpO2 Parameter Specification	
Measuring Range	0%~100%, (resolution is 1%).
Pulse Accuracy	70%~100%:±2% , Below 70% unspecified.
Average Value	Mean value is calculated using 4 measured values.The deviation between average value and true value does not exceed 1%.
Pulse Parameter Specification	
Measuring Range	30bpm~250bpm, (resolution is 1bpm)
Pulse Accuracy	±2bpm or±2%
Average Value	The Average pulse rate is calculated for 4 cardiac cycles. The deviation between average value and true value does not exceed 1%
Safety Type	Interior Battery, BF Type
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates stronger pulse.
Battery Requirement	
Voltage 3.7 Rechargeable Lithium Battery × 1 – Useful battery life of 500 times full charge.	
Power Adapter	
Input Voltage	100 to 240 VAC, 50/60 Hz
Output Voltage	5 VDC
Output Current	1000mA
Oximeter Probe	
Wavelength: 660nm-905nm	
Dimensions and Weight	
Dimensions	61(L) × 56(W) × 24 (H) mm
Weight	About 50g (with lithium battery ×1)

Appendix 1

State	Alarm condition delay	Alarm signal generation delay
Low battery alarm	0.6s	20ms
SpO2 alarm	400ms	20ms
Pulse rate alarm	400ms	20ms
Probe error alarm	400ms	20ms

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