PULSE OXIMETER

USER MANUAL-TORONTEK-E400

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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-E400 Pulse Oximeter comes with software on minidisc. 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 manufacturer's 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.
- This Pulse Oximeter is battery-operated. Please be cautious in case of using pacemakers and other medical devices which could have interference with batteries.
- 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.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.
- 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 6.1.4
- The probe is made of plastic. Patients with allergy to plastic should avoid using the device.
- The accompanying neck-strap could be dangerous in the hands of children. Keep away from children. Also smaller accessories may 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 misuse of this product.

2. Product Description

ToronTek-E400 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-E400'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. Classification

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

2.2. 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.

2.3. Quality of Service and Security

ToronTek-E400 assures timely, reliable, accurate, and secure data collection and recording. The recorded measurements can be transferred to computer via USB connection.

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.

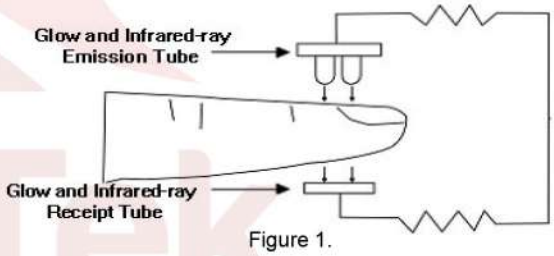


Figure 1.

4. Technical Specifications

4.1 Main features:

A. Pulse rate value display, bar graph display
B. Pulse waveform display
C. The product enters standby mode within 5 seconds when there is no signal input.
D. Low-battery indication: low-battery indicator appears signaling the need for connection to power charger.
E. Screen brightness can be adjusted to 4 different levels.
F. Pulse sound can be activated from the Menu. Alarm level is adjustable.
G. Alarm can be set for lower and upper levels of SPO2 and pulse rate.
H. SPO2 and pulse rate readings can be recorded and transferred to computer for analysis by the software coming with the device.
I. Built-in rechargeable lithium battery charged by USB port or power adaptor
J. SpO2 value display

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. Measurement interface view

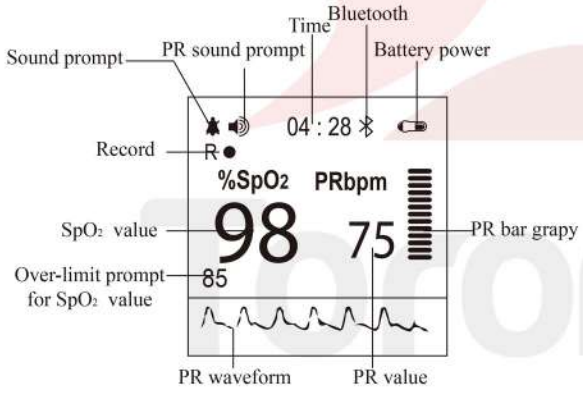


Figure 2. Measurement interface view

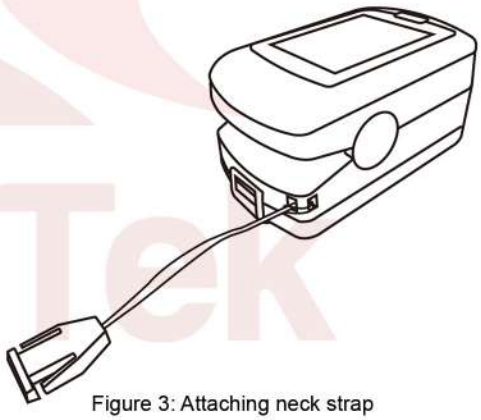


Figure 3: Attaching neck strap

5.2. Attaching the Neck Strap

Step 1. Thread the small end of the strap through the strap eyelet on the device.

Step 2. Pass the other end of the strap through the loop and pull. (Figure 3)

5.3. Accessories

A. Neck Strap

B. User Manual

C. Power Adapter

D. Data transferring cable

6. Operating Guide

6.1 Operating the Device

A . Squeeze the clamp, put a finger into the rubber hole, then release clamp. Correct placement of the finger (i.e. fingernail facing upward) is important. (Figure 4.)

B . 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.

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

D . Wait till the screen shows readings

⚠ ***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. Medium priority alarm indicates that prompt operator response is required.***

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.**

6.1.3 Display Mode Change:

This device is equipped with smart auto-rotation technology. When the device is held in different directions, the display rotates automatically to provide an easy reading experience for user.

6.1.4 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. The alarm will also signal a "finger out" situation.

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. To switch off the alarm. Go to menu and select alarm. Press and hold the menu button to change the status to OFF.

6.1.5 Menu Operations:

While in measurement interface, press and hold the power button in order to enter the menu interface as shown in figure 5. IMPORTANT NOTICE: When the display direction is vertical pressing and holding the button will not take you to menu options. In order to enter the menu, first the display has to rotate to landscape mode.

From the main menu the following items can be set and managed:

Display Brightness, Alarm setting, ID setting, data storage (Record), and turning on/off Data upload. The specific operation methods are as follows:

Please note in the Settings Menu:

Figure 5 Main Menu Interface

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

A) Display Brightness Setting

On the Main Menu interface, by each pressing the selector moves down one item. Press the button until "Brightness" is highlighted. Press and hold the power button. This adjusts brightness between 4 different levels. When happy with a level of brightness simply release the button.

B) Setting the Alarm

On the main menu interface, press the button to move selector to "alarm". Press and hold the power button to enter the alarm setting interface. (Figure 6)

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".

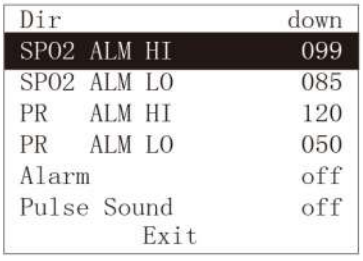


Figure 6 Alarm Setting Menu

c. 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.

d. 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.

e. Alarm 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.

C) Recording data

This device 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.

- C.1) When the device is recording a red dot with recording sign "R●" will be visible on device measurement interface.
- C.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.
- C.3) The Oximeter does not power off while recording. Recording has to be turned off before powering off.
- C.4) To stop recording select "record" on the main menu. Stop recording from this menu
- C.5) Before connecting the Oximeter to PC for data transference make sure recording has been stopped.
- C.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.
- C.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.
- C.8) under Auto mode menu selection "Delete All" will enable the user to delete all the recorded data groups at once.
- C.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.

D) Uploading the Data

The wireless model, ToronTek-E400W, uses Bluetooth connection to transfer data and does not require USB cable data transmission. ToronTek-E400 will need to be connected to PC with USB cable provided to transfer data. 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. For detailed instruction on how to move the data from device to PC using the software, download the SPO2 Assistant manual from www.torontek.com

E Enabling Bluetooth function (On TornTek-E400W model)

Under main menu, press the button to select "Bluetooth", then press and hold the button to enter its selection interface as shown in Figure 7 and Figure 8. When the Bluetooth is "ON',if no data is transmitted for several minutes, then the Bluetooth will be turned off automatically to save device battery.

⚠ **Under transmitting data by Bluetooth, the Bluetooth can not be turned off.**

Figure 7 Bluetooth "ON" interface

Figure 8 Bluetooth "OFF" interface

F) Adjusting the clock

a. For the automatic time setting we recommend synchronizing the device time with your PC. Connect the oximeter to PC by following the instruction in "SPO2 Assistant User Manual"(found on www.torontek.com)- when the device is connected in real-time mode from the software menu bar select OPTIONS-->"Synchronize device time"

b. Set device time manually

Under main menu, press the button to select "Clock", press and hold the button to enter its sub-menu as shown in Figure 9.

Figure 9- Clock setting

Press the button to select the option to be adjusted, press and hold the button to change the value.

"Set Time": set the time, Press and hold to change status to "yes": to allow, time adjustment.

"Set Year": set the year

"Set Month": set the month

"Set Day": set the day

"Set Hour": set the hour

"Set Minute": set the minute

After setting, press the button to select "Exit", then press and hold the button to exit time setting interface and return to main menu.

6.1.6 PC Software Operation

Please refer to "SpO2 Assistant User Manual" at www.torontek.com for detailed explanation.

6.1.7 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 blue battery charging LED indicator on the unit will remain illuminated while the battery is charging. When the device is fully charged the LED turns off.

⚠ 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.

6.2. Attention for Operation

- The finger should be inserted properly as illustrated in figure 4.. 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.
- Make sure the optical path is free from any external particles or materials blocking sensors.
- 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. (7.1)

6.2 Manual reset

Squeeze the clamp as shown in Figure 10, then use a pointy but not sharp object (for example, a paper clip) to press the reset button inside of the reset pinhole, to reset the device.

WARNING: Resetting will erase the time setting and remove the recorded data.

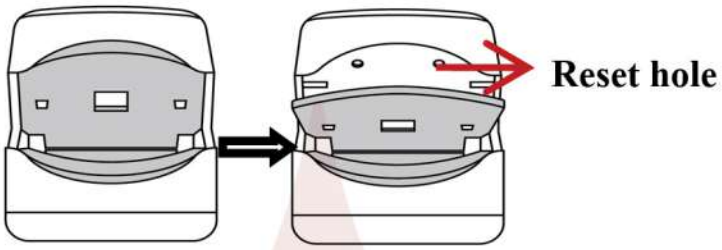


Figure 10 Reset pinhole

6.3. 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 problem, 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

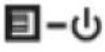
A. The packed device should be stored in room with no corrosive gases and with good ventilation. Temperature: -40 °C ~ 60 °C; Relative Humidity: ≤ 95%

8. Troubleshooting

Problem	Possible Reason	Solution
The SpO2 and Pulse Rate 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. Place the finger properly and try again. 2. Try again; contact medical professionals 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 device cannot be turned on	1. The battery is drained or almost drained. 2. The device's malfunction	1. Please recharge the battery. 2. Please contact the local service center.
The display suddenly turns off.	1. The product turns off within 5 seconds when there is no signal input. 2. The device is malfunctioning while the finger is in. 3. The battery is drained away or almost drained away.	1. Normal 2. Please contact the local service center. 3. Please recharge the battery
The battery cannot be fully charged even after 10 hours of charging.	The battery is failing	Please contact the local service center.

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

9. Symbol Definition

Symbol	Definition	Symbol	Definition
$\%SpO_2$	Pulse oxygen saturation (%)		Signal inadequacy indicator: 1. Finger clip has come off (no finger inserted) 2. Sensor error
PR bpm	Pulse rate (beats per second)	IP22	International Protection
	Battery fully charged		WEEE (2002/96/EC)
	Low battery		Date of manufacture
	Alarm deactivated		Storage and Transport Temperature limitation
	Alarm paused		Storage and Transport Humidity limitation
	Alarm activated		Storage and Transport Atmospheric pressure limitation
	Pulse sound deactivated		This side up
	Pulse sound activated		Fragile, handle with care.
	Menu button / Power button		Keep dry.
	USB		Recyclable

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%).
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)
Accuracy	±2bpm or±2%
Average Pulse Rate	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	
Power Adapter	
Input Voltage	100 to 240 VAC, 50/60 Hz
Output Voltage	5 VDC
Output Current	1000mA
Output Power	5W
Oximeter Probe	
Wavelength: 660nm-905nm	
Dimensions and Weight	
Dimensions	57(L) × 32(W) × 32 (H) mm
Weight	About 50g (with lithium battery ×1)

Appendix 1

State	Alarm condition delay	Alarm signal generation delay
Low battery alarm	60 s	5ms
SpO2 alarm	1s	5ms
Pulse rate alarm	1s	5ms
Probe error alarm	16ms	5ms

Appendix 2

Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
ToronTek-E400 and E400W Pulse Oximeters are intended for use in the electromagnetic environment specified below.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	ToronTek-E400-E400W Oximeters use RF energy only for the internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	ToronTek-E400-E400W Pulse Oximeters are suitable for use in all establishments with different power supplies, including residential establishments directly connected to the public low-voltage power supply network.

Guidance and manufacture's declaration – electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
ToronTek-E400-E400W are intended for use in the electromagnetic environment specified below. It is user's responsibility to comply with the conditions provided underneath			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. the manufacturer may recommend the ESD precautionary procedures to user.
Power frequency (50Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should have the specifications of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration – electromagnetic immunity for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
ToronTek-E400-E400W pulse oximeters are intended for use in the electromagnetic environment specified below. It is user's responsibility to comply with the conditions provided underneath			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3V(0.15MHz–80MHz),6V(in ISM bands between 0.15MHz and 80MHz)	3V(0.15MHz–80MHz),6V(in ISM bands between 0.15MHz and 80MHz)	Portable and mobile RF communications equipment should not be used in closer distance than recommended separation proximity (as specified underneath) to ToronTek-E400-E400W and their accessories including cables. The equation applicable to the frequency of the transmitter. Recommended proximity distance $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended proximity distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7GH	10 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be conducted. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device is considered to be in capable of normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile

RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *CMS50E Pulse Oximeter.*

ToronTek-E400-E400W pulse oximeters are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pulse oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter(m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.058	0.035	0.07
0.1	0.18	0.11	0.22
1	0.58	0.35	0.7
10	1.83	1.10	2.21
100	5.8	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended proximity distance (d) in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, animals and human.

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