TORONTEK-B400 Pulse Oximeter

User Instructions

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, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

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

Regrettably, owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual.

This product is a medical device and can be used repeatedly.

WARNING:

- ⚠ **Discomfort or pain can occur if the device is used ceaselessly, especially for microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for longer than 2 hours.**
- ⚠ **For special patients, there should be a more prudent inspection of the placing process. The device should not be clipped on an edema or tender tissue.**
- ⚠ **The infrared light emitted from the device, though invisible, is harmful to the eyes. Avoid staring at it.**
- ⚠ **The patient cannot use nail enamel or other makeup.**
- ⚠ **The patient's fingernails must be clipped short.**
- ⚠ **Please refer to the related content about clinical restrictions and caution.**
- ⚠ **This device is not intended for treatment.**

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1 Safety

1.1 Instructions for Safe Operations

✧ Inspect the main unit and all accessories periodically to ensure that there is no visible damage that may affect the patient's safety, and monitor the performance of cables and transducers. It is recommended that the device should be inspected at least once a week. If there is obvious damage, stop using the device.

✧ Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to service the device by themselves.

✧ The Oximeter must not be used together with accessories not specified in the User Manual. Only accessories specified or recommended by the manufacturer can be used with this device.

✧ This product is calibrated before leaving the factory.

1.2 Warning

⚠ Explosive hazard—DO NOT use the oximeter in an environment with flammable gas, such as some ignitable anesthetic agents.

⚠ DO NOT use the Oximeter while the patient is measured by MRI and CT.

⚠ To avoid dropping the device, please do not break or cut the wrist strap. Users who are allergic to the wrist strap are not recommended to use it.

⚠ People who are allergic to rubber cannot use this device.

⚠ The disposal of this instrument and its accessories and packaging (including batteries, plastic bags, foams and paper boxes) should follow local laws and regulations.

⚠ Please check the packaging before use to make sure the device and accessories are in complete accordance with the packaging list or else the device may not work normally.

⚠ Use only accessories provided or approved by the manufacturer, using any other third party accessories will cause damage to the device.

⚠ Please only use the battery charger which is accompanies by the product and is in compliance with the requirements of IEC 60601-1. Using a different charges might damage the device.

⚠ DO NOT use the device while charging.

⚠ The device must only be used with a compatible probe.

1.3 Attention

🔔 Keep the Oximeter away from dust, vibrations, corrosive substances, explosive materials, high temperatures and moisture.

🔔 Stop operating the Oximeter if it gets wet.

🔔 DO NOT use the device immediately after moving it from a cold environment to a warm or humid environment.

🔔 DO NOT operate the keys on the front panel with sharp objects.

🔔 High temperature or high pressure steam disinfection of the Oximeter is not permitted. Refer to the User Manual in the relative chapter (7.1) for instructions on cleaning and disinfection.

🔔 DO NOT immerse the Oximeter in liquid. If it needs cleaning, wipe the surface with medical

alcohol using a soft material. Do not spray any liquid directly onto the device.

- When cleaning the device with water, ensure that the temperature of the water is lower than 60℃.
- Thin or cold fingers will affect the normal measure of the patient's SpO_2 and pulse rate. Be sure to clip a thick finger such as the thumb or middle finger deeply enough into the probe.
- The Pulse Oximeter can be used on adult or infants. Please select the appropriate probe depending on the patient.
- The update period of data is less than 5 seconds. This is changeable according to different individual pulse rates.
- The waveform is normalized. Please read the measured value when the waveform on-screen is uniform and steady-going. This measured value is the optimal value and this waveform is the standard one.
- If abnormal conditions appear on the screen during the test process, pull out the finger and reinsert it to restore normal use.
- The device has a lifespan of three years after the first electrified use.
- This device has an alarm function.
- Provided the alarm function is turned on, an alarm will automatically go off if the measured data goes beyond the highest or lowest limit.
- The alarm function can either be paused or turned off (default setting). The function can be turned back on through menu operation. Please refer to Chapter 6.1 for more information on the alarm function.
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.

2 Overview

The peripheral capillary oxygen saturation (SpO_2) is the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin (Hb) in the blood, or the oxygen concentration in the blood. It is an important bio-parameter for respiration. A number of diseases relating to the respiratory system may cause a decrease of SpO_2 in the blood. Furthermore, some other causes such as the malfunction of the body's self-adjustment, damage during surgery, and injuries caused by some medical examinations could also lead to a low oxygen supply in the human body. As a consequence, symptoms such as vertigo, impotence and vomiting would appear. Serious symptoms might endanger the patient's life. Therefore, prompt information of patients' SpO_2 is of great help for doctors to discover potential dangers and is of great importance in the clinical medical field.

The Pulse Oximeter features a small size, low power consumption, convenient operation and portability. The patient only needs to put one of their fingers into a probe for diagnosis and a display screen will show the measured value of pulse oxygen saturation with high accuracy.

2.1 Features

A. Operation of the device is simple and convenient.
B. The device is small in size, light in weight and convenient to carry.
C. The device has low power consumption.

2.2 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure the pulse oxygen saturation and pulse rate through a finger. The product is suitable for use in the home, hospitals, oxygen bar, community health care, and physical care in sports (it can be used before or after doing sports and is not recommended to be used during sporting activities).

⚠The problem of overrating will emerge if the patient is suffering from toxicosis caused by carbon monoxide. The device is not recommended to be used under these circumstances.

2.3 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 Principle

Principle of the Oximeter: for the calculation of blood oxygen level the device uses a formula to process the data according to Lambert Beer Law and Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in glow & near-infrared zones.

Operation principle of the Oximeter: Photoelectric Oxyhemoglobin Inspection Technology is applied together with Capacity Pulse Scanning & Recording Technology so that two beams of light of different wavelengths can be focused onto a human nail tip through a perspective clamp finger sensor. A measured signal is obtained by a photosensitive element and acquired information will be shown on-screen through treatment in electronic circuits and microprocessors.

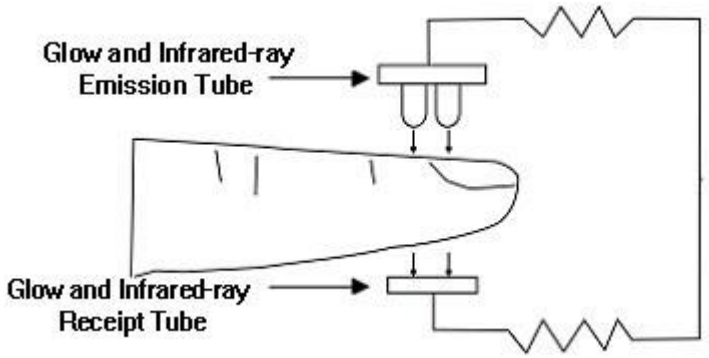

Figure 1.

4 Technical Specifications

4.1 Main Performance

A. SpO_2 value display.
B. Pulse rate value display, bar graph display.
C. Pulse waveform display.
D. Low battery indication: low battery indicator appears when battery is drained. Device may work abnormally if battery is low.
E. The display mode can be changed.
F. Screen brightness can be changed.
G. A pulse rate sound indication.
H. Alarm function.
I. SpO_2 value and pulse rate value data can be uploaded to a computer.
J. Device can be connected to an external Oximeter probe.
K. Clock function

4.2 Main Parameters

A. Measurement of SpO_2
Measuring range: 0%~100%
Accuracy:
When the SpO_2 measuring range is 70% ~ 100%, the permission of absolute error is ±2%;
Below 70% unspecified

B. Measurement of pulse rate
Measuring range:30bpm~250bpm
Accuracy: ±2 bpm or ±2% (select larger)

C. Resolution
SpO_2 : 1%, Pulse rate : 1bpm.

D. Measurement Performance in Weak Filling Condition
SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).

E. Resistance to surrounding light
The deviation between the value measured in the condition of man-made light or indoor natural light and that of a dark room is less than ±1%.

F. Power supply requirement: 3.6 V DC ~ 4.2V DC.

G. Optical Sensor

Red light (wavelength is 660nm,6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

H. Adjustable alarm range

SpO_2 : 0%~100%

Pulse Rate: 0bpm~254bpm

5 Installation

5.1 View of Front Panel

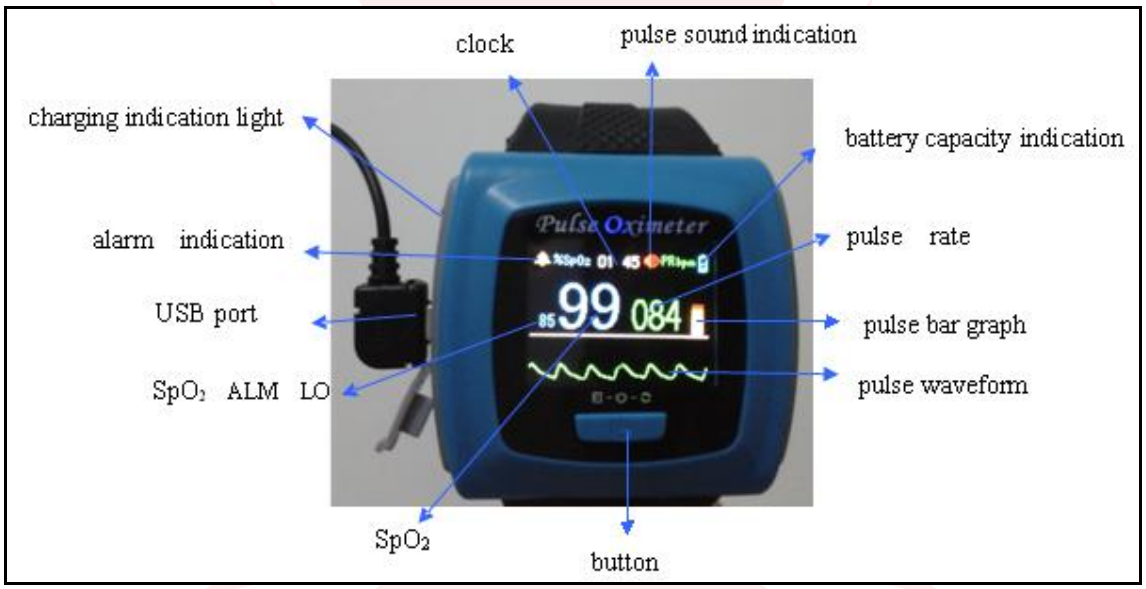

Figure 2. Front view

(Actual probe may be differ from the probe in Figure 4)

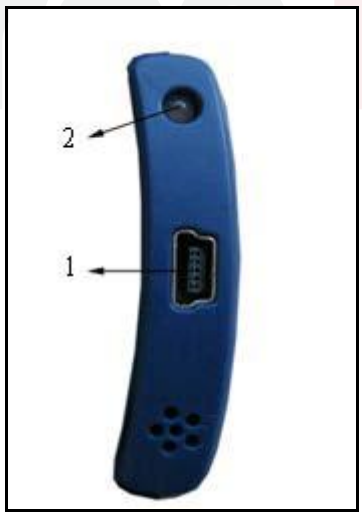

Figure 3. Left side view

1. USB port used to connect a personal computer to export the trend data, and charge the lithium battery via a data line. It is also used to connect the SpO_2 sensor to measure the oxygen saturation and pulse rate.
2. Charging indication light. When the device is charging, the light turns orange. When the battery status is full, the light turns green.

5.2 Probe Connection

A. Insert the USB plug of the probe into the USB port of the device.

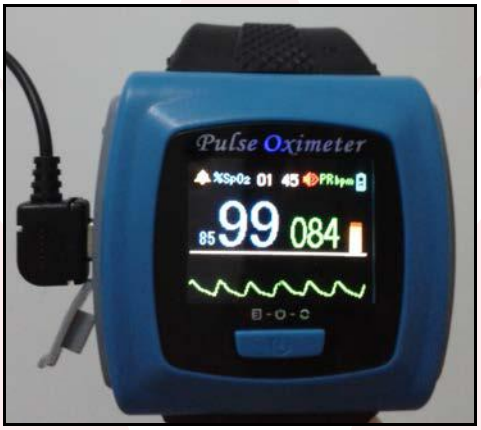

Figure 4. Display after installation.

5.3 Accessories

A. 1 User Manual.
B. 1 Power adapter.
C. 1 Data line.
D. 1 Disk (PC software)
E. 1 Adult Oximeter probe.
(An infant-oximeter probe can be purchased separately.)

6 Operating Guide

6.1 Application Method

A. Install the probe according to the instructions in Chapter 5.2.

a) Put the suitable probe into the jack on the right side of the Oximeter. (Use the probe provided by the manufacturer. Do not use similar ones provided by other manufacturers).

b) Put the finger into the probe.
c) Press the Power Button on the front panel to turn the device on.
d) Do not shake the finger. Keep the patient still and at ease during the process.
e) The data can be read directly from the screen on the measuring interface.

⚠ **Fingernails and the luminescent tube should be on the same side.**

⚠ **If the alarm function is on, the device will produce a medium-priority alarm signal when**

the finger is removed. An intermittent alarm will go off and the user interface will display "FINGER OUT".

Figure 5.
(Medium priority indicating that prompt operator response is required.)

Attention:

CLICK = Short push of power button. **PRESS** = Prolonged push of power button.

B. Change display direction

On the measuring interface, while you click the button once and the screen display rotates 180 degrees and you click once more and it rotates again to the initial display direction.

C. Enter and exit the clock interface

a) On the measuring interface, click the power button in order to enter the clock interface. The device will automatically return to the measuring interface if there are no more operations within 30 seconds.

b) On the measuring interface, press the button for 10 seconds to enter the clock interface. Press the button for another 10 seconds to return to the measuring interface.

D. Pause alarm

a) There are several alarms devised on the device including the alarm of measure data's going beyond the limits, the alarm of low-voltage, the alarm of probe or finger's out of position.

b) You can pause the alarm when it goes off by clicking the power button while on the measuring interface. The alarm will restart in 60 seconds.

c) Use the menu operations to turn the alarm off permanently.

E. Menu operations

When the device is on the measuring interface, press and hold the button to enter the menu interface (as shown in Figure 6). Through the main menu, users can adjust settings such as Backlight, Alarm, Clock, Data Transmission (with the data line) and Data Storage, as well as power the device off.

Figure 6. Main Menu

The specific operation methods are listed below:

a) Backlight adjustment

On the main menu, select "Brightness." Press and hold the power button to adjust the backlight brightness.

b) Alarm settings

On the main menu, select "Alarm." Press the power button (1 sec) to enter the alarm settings interface as shown in Figure 7:

a. Adjusting the high and low limits of alarms

Select "Direction", then press the button to choose Up or Down (this will be the direction the value of the high-low limits of SpO_2 and pulse rate will be adjusted.)

To raise the SpO_2 and pulse rate limit, select "Up", then click the button to select the parameter to be adjusted: SpO_2 high limit (SpO_2 ALM HI), SpO_2 low limit (SpO_2 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 it once the desired higher limit has been reached.

To lower the SpO_2 and pulse rate limit, select “Down", then click the button to select the parameter to be adjusted. Press and hold the button to adjust the selected limit to the desired lower value and release it once the desired lower limit has been reached.

⚠ **If the alarm function is on, the device will produce a medium-priority alarm signal when the data of SpO_2 or pulse rate is beyond the set limit. An intermittent alarm will go off and the measurement will be displayed in yellow.**

⚠ **Medium-priority alarm indicates immediate operator response is required.**

b. Setting the alarm

On the main menu, select "Alarm", then select “On” or “Off.”

Figure 7. Alarm Settings

c. Pulse sound indication setting

Select "Pulse Sound", choose to have the Pulse Sound (heart beat) alarm either "On" or "Off."

d. Exiting the Alarm settings

Select "EXIT" to exit the Alarm Settings Menu.

c) Clock settings

On the main menu, select "Clock " to enter the clock settings.

Figure 8. Clock Setting Menu

a. When entering the clock settings menu, the menu choice bar would be on the item of "set time", and the default status will be always set to "NO" ensuring that by mistake you will not change the time or date on this menu. If you want to modify the time and date you would need to change the “Set time” status to “ YES” by holding down the menu button.

b. Select the parameter that you wish to change, then adjust the data by pressing the button.

c. Select "Exit" to exit the clock setting menu. If you have reset the date or time, the new time and date will be displayed on the screen before returning to the main menu.

d) Uploading Saved Data

Connect the device to a computer using a data line then open the PC software. Please refer to <SpO_2 Assistant user manual> for detailed operation method for uploading data.

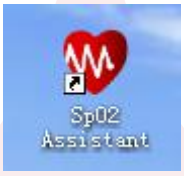

Figure 9 Software Symbol

⚠ The computer which you connect the device device should be in accordance with the standard of IEC60950, and the system which is the operating system of the computer connected to the device should be in accordance with the requirements of IEC60601-1-1.

e) Device ID

The user can modify the device ID by the software "SpO_2 Assistant". Please refer to <SpO_2 Assistant user manual> for detailed operation method.

f) Power off

On the main menu, select "Power off." Press the button to shut down the device.

g) Exit the main menu

On the main menu, select "Exit." Press the button to exit the main menu.

F. Charging

There are two charging methods:

a) Connect the device to a computer via data line. The device will begin charging.

b) Connect the device to a power supply via a power adapter. The device will begin charging.

When the device is charging, the indication light is orange. When the battery is full, the light turns green.

⚠ **If the alarm function is on, the device will produce a high-priority alarm signal when the battery is low. An intermittent alarm will go off and the battery icon will flash red.**

⚠ **High-priority alarm indicates that immediate operator response is required.**

6.2 Attention for Operation

A. Please check the device before use to ensure that it is working normally.

B. The finger should be placed in the proper position or else it may result in inaccurate measurement (see the illustration in Figure 4).

C. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff, or receiving intravenous injection.

D. Do not fix the SpO_2 sensor with adhesive or else it may result in venous pulsation and inaccurate measure of the SpO_2 and pulse rate.

E. Excessive ambient light may affect the measuring result. This includes fluorescent lamps, dual ruby lights, infrared heaters, direct sunlight etc.

F. Strenuous action of the patient or extreme electrosurgical interference may also affect accuracy.

G. The patient cannot use nail enamel or other makeup.

H. Please clean and disinfect the device after operating it according to the User Manual (7.1).

6.3 Clinical Restrictions

A. As the measurement is taken on the basis of arteriole pulse, substantial pulsating blood flow of the patient is required. For a patient with a weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drugs, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

B. For patients with a substantial amount of staining dilution drugs (such as methylene blue, indigo green and acid indigo blue), carboxyhemoglobin (COHb), methionine (Me+Hb) or thiosalicylic hemoglobin, and some with an icterus problem, the SpO_2 determination by this monitor may be inaccurate.

C. Drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious errors of SpO_2 measurements.

D. As the SpO_2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

7-Maintenance, Transportation and Storage

7.1 Cleaning and Disinfection

Use medical alcohol to disinfect the device and leave to air dry. Otherwise, clean it with a soft cloth.

7.2 Maintenance

A. Please clean and disinfect the device before use according to the User Manual (7.1).

B. Please recharge the battery when the  icon is displayed.

C. Recharge the battery soon after discharge. The device should be recharged every six months if it is not regularly used. This will extend the battery life.

D. Users are advised to calibrate the device termly (or according to the calibration program of the hospital). It also can be performed at the state-appointed agent or you can contact us for calibration.

7.3 Transportation and Storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. DO NOT transport the device with toxic or corrosive materials.

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

8 Troubleshooting

Problem	Possible Reason	Solution
The SpO_2 and Pulse Rate are not displayed normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure there is nothing wrong with the device.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deeply enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm and still.
The device cannot be turned on	1. The battery is drained or almost drained. 2. Malfunction of the device.	1. Recharge the battery. 2. Please contact the local service center.
The display turns off suddenly	1. The battery is drained or almost drained. 2. Malfunction of the device.	1. Recharge the battery. 2. Please contact the local service center.
The device cannot be used for full time after charge	1. The battery is not fully charged. 2. The battery is broken.	1. Recharge the battery. 2. Please contact the local service center.
The battery is not fully charged even after 10 hours charging time.	The battery is broken .	Please contact the local service center.

9 Key of Symbols

Symbol	Description
⚠	Warning – See User Manual
%SpO_2	Pulse oxygen saturation (%)
PRbpm	Pulse rate (bpm)
	Battery fully charged
	Low battery

	Close the alarm sound indication
	Pause the alarm sound indication
	Open the alarm sound indication
	Turn off the pulse sound indication
	Turn on the pulse sound indication
	Menu button/Power button/Function button
	Type BF
SN	Serial number
	1. No finger inserted 2. Probe error 3. Signal inadequacy indicator
IP22	International Protection
	WEEE (2002/96/EC)

10 Function Specification

Information	Display Mode
The Pulse Oxygen Saturation (SpO_2)	2-digit digital OLED display
Pulse Rate(PR)	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO_2 Parameter Specification	
Measuring range	0% ~ 100%, (the resolution is 1%).
Accuracy	70% ~ 100%:±2% ,Below 70% unspecified.
Average value	Calculate the Average value in every 4 measure value. The deviation between average value and true value does not exceed 1%.

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Pulse Parameter Specification	
Measuring range	30bpm ~ 250bpm, (the resolution is 1bpm)
Accuracy	±2bpm or±2% (select larger)
Average pulse rate	Calculate the Average pulse rate every 4 cardio-beats cycle. The deviation between average value and true value does not exceed 1%
Safety Type	Interior Battery, B F Type
Pulse Intensity	
Range	Continuous bar-graph display. Higher display indicates stronger pulse.
Battery Requirement	
Voltage 3.7 rechargeable lithium battery × 1	
Battery working life	
Charge and discharge no less than 500 times.	
Power Adapter	
Input Voltage	100 to 240 VAC, 50/60 Hz
Output voltage	5 VDC
Output current	1000mA
Oximeter Probe	
Wavelength:660nm 880nm	
Dimensions and Weight	
Dimensions	61(L) × 56(W) × 24 (H) mm
Weight	About 60g (with the lithium battery*1)

Appendix 1

State	Alarm condition delay	Alarm signal generation delay
Low battery alarm	0.6s	20ms
SpO_2 alarm	400ms	20ms
Pulse rate alarm	400ms	20ms
Probe error alarm	400ms	20ms