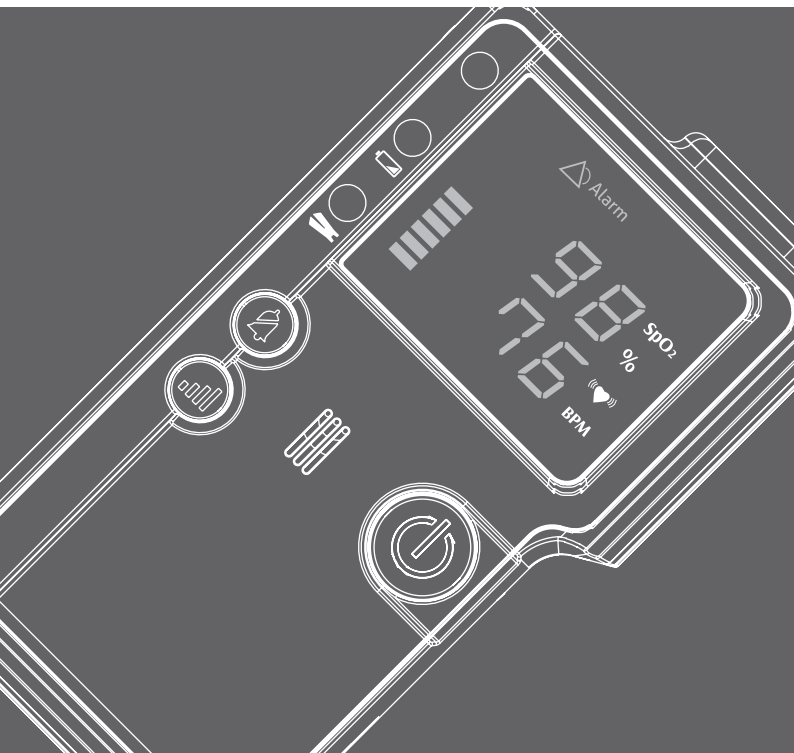
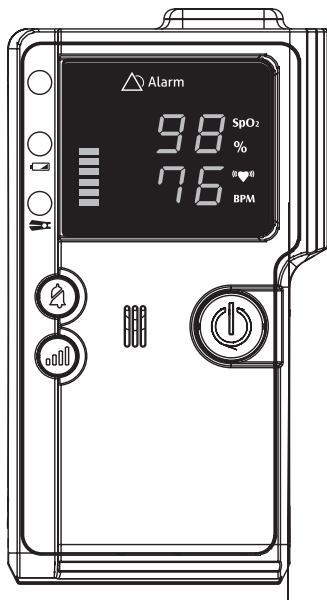


MTRUST Handheld Pulse Oximeter



Owner's Manual

MTRUST Handheld Pulse Oximeter



Owner's Manual

Ver 2.0 12, 2013
311-8201000-XXX

About the Manual

The precautions, warnings and notes throughout this manual are very important. Please read this entire manual carefully before using the V-TRUST Handheld Pulse Oximeter.

The information in the manual has been carefully checked and is believed to be accurate.

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SAFETY INFORMATION



Warning

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Do not use the oximeter in an MRI environment.
- The use of accessories, probes, and cables other than those listed in this manual may result in increased emission and/ or decreased immunity of the device.
- The oximeter is intended only as an adjunct in subject assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Explosion Hazard: Do not use the oximeter in an explosive atmosphere.
- If subjects' monitoring sites have trauma, disability or other medical status that make inaccurate results, operators should consult doctors before use.
- Use probe manufactured by manufacturer. Using other manufacturers' probes may cause improper oximeter performance. Also, do not use a damaged probe.
- When a system fault occurs, the subject will no longer be monitored.
- The oximeter has to measure the pulse properly to obtain accurate SpO₂ measurement. Blood flow restrictors (e.g., blood pressure cuffs) may hinder pulse measurements. Remove any objects that may hinder the performance of the oximeter.



Cautions

- The oximeter is not an apnea monitor.
- The oximeter determines the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- Cardiogreen and intravascular dyes, depending on the concentration, may affect the accuracy of SpO₂ measurements.
- The performance of the oximeter might be affected by the presence of a defibrillator.
- The oximeter may not work on all subjects. If you are unable to achieve stable readings, discontinue use.
- The oximeter has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the oximeter may still interpret motion as good pulse quality. Minimize subject motion as much as possible.
- Verify that all visible indicators illuminate during the startup (initialization) sequence, if any indicator is not lit do not use the oximeter. Please contact your agent for help.
- Do not immerse the oximeter or probes in liquid to clean, and also do not expose them to excessive moisture or liquids.
- Do not use caustic or abrasive cleaning agents on the oximeter or probes.
- Do not mix new and old batteries at the same time. It may cause the batteries to leak. Dispose of batteries properly.
- Batteries might leak chemicals if unused for a long period of time. Remove the batteries if the oximeter is going to be stored for more than one month.
- Batteries may leak or explode if used or disposed of improperly.
- The oximeter is a precision electronic instrument and must be repaired by trained personnel only.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.

INTRODUCTION

► Intended for Use

The V-TRUST Handheld Pulse Oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for patients during no-motion condition. The oximeter is suitable for use in hospital and clinical sites.

This device is indicated for non-invasive spot checking or continuous monitoring.

► General Description

The oximeter is a digital handheld that displays numerical values for blood oxygen saturation. It provides visual alarm for medium priority conditions. The range of the peak wavelengths and maximum optical output power of the light emitted by the oximeter probe and the reading result can be especially useful to clinicians.

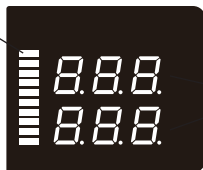
The oximeter with reusable SpO_2 probe accessories operates on battery power for up to 40 hours. The oximeter requires no routine calibration or maintenance other than replacement of alkaline batteries. When the batteries are low, the indicator will blink to warn users to replace the batteries.

► Principle of Measurement

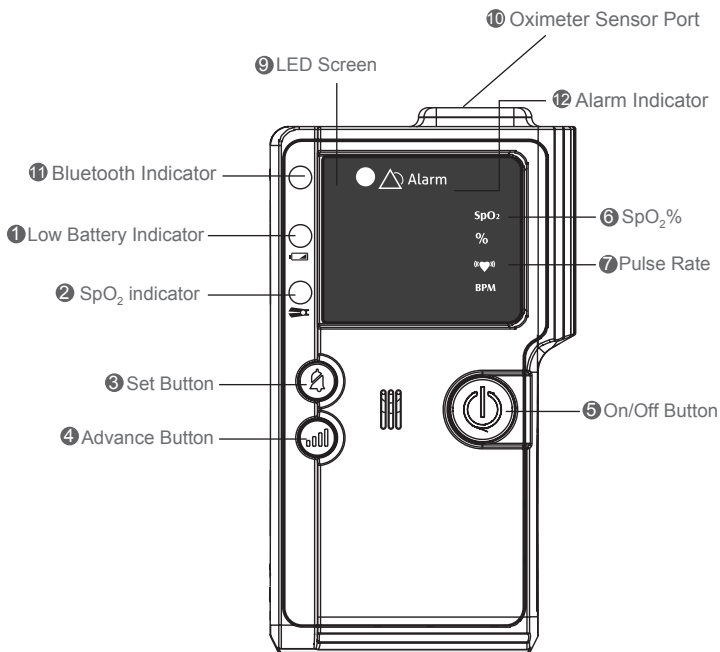
The V-TRUST Handheld Pulse Oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.

► Meter Appearance and Key Function

⑧ Pulse Amplitude



Reading Value Display Area



1. Low Battery Indicator

Red light appears when power is insufficient to the oximeter.

2. SpO₂ Indicator

Red light appears when probe disconnects from oximeter. Green light appears when finger insert probe sensor from oximeter.

3. Set Button

Is used to set up settings.

4. Advance Button (Bluetooth Key)

Is used to review status. For Bluetooth transmission, press and hold the Advance Button (Bluetooth key) for 3 seconds to enter pairing mode.

5. On/Off Button

Is used to turn on or turn off the oximeter by pressing On/Off button.

6. SpO₂ %

The measurement result of oxygen saturation in percentage.

7. (♥) Pulse Rate

The measurement result of pulse rate.

8. Pulse Amplitude

The strength of the signal is detected by the oximeter.

9. LED Screen

Display measurement results.

10. Oximeter Sensor Port

Connect the probe and the oximeter.

11. Bluetooth Indicator (for TD-8201B only)

Blue light appears when turn on bluetooth.

12. Alarm Indicator

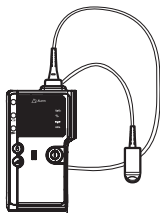
Red light appears when oxygen saturation value upper or below the setting ranges.

► Content of the System

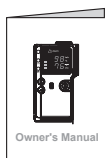
The V-TRUST Handheld Pulse Oximeter includes the following items:

- A. Handheld Pulse Oximeter with Probe
- B. Owner's Manual x 1
- C. AA Alkaline Batteries x 4
- D. Warranty Card

A



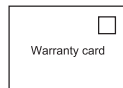
B



C



D



Confirm that the items listed are packed with the V-TRUST Handheld Pulse Oximeter. If any item on this list is missing or damaged, contact your distributor.

All of the system with accessories is provided non-sterile.

BEFORE USE

Low battery capacity is indicated with a flashing red light. We recommend that you replace the new batteries if the low battery indicator turns red.

► Battery Replacement

Make sure the oximeter is switched off when replacing the batteries.

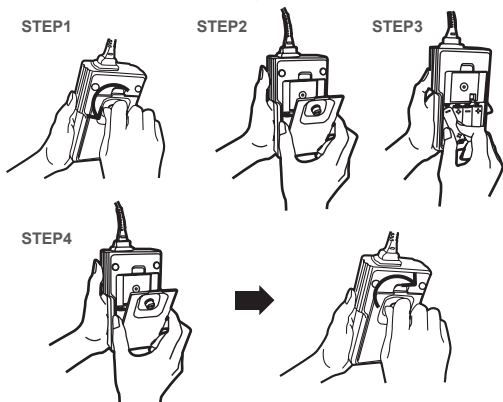
The oximeter is powered by 4 AA alkaline batteries. Replace new batteries by the following steps.

STEP1. Loosen the screw at the back of the oximeter and remove the battery cover.

STEP2. Remove the old batteries from battery compartment.

STEP3. Insert four new AA alkaline batteries. Correctly align the polarities (+ and -) with battery indication marks on the oximeter.

STEP4. Replace the battery cover and tighten the screw.

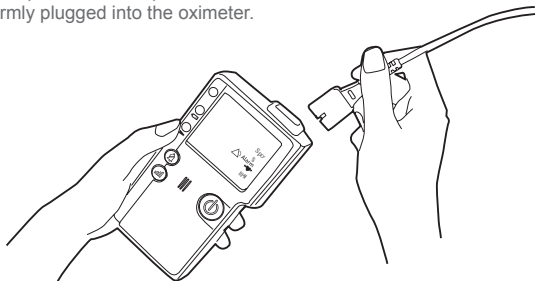


CAUTION!

1. Use only 1.5 AA new batteries with this device. Replace the batteries as soon as possible after a low battery indicator appears.
2. If the oximeter does not work after installed the batteries. Reinstall the batteries.

► Connecting the Probe



Connect the probe to the top of the oximeter as shown below. Make sure that the probe is firmly plugged into the oximeter.

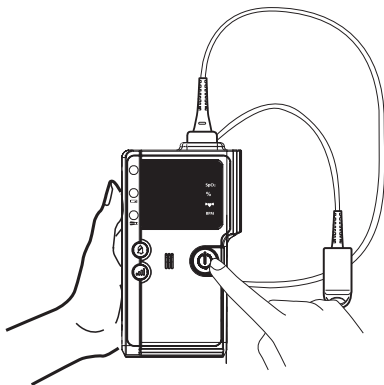


NOTE

Please make sure to connect the probe properly. If not, the SpO₂ indicator will light up with reminding voice while the probe fell off.

► Power On/Off



- Turn on the oximeter by pressing and releasing the  button.
- Turn off the oximeter by pressing and holding the  button for about 3 seconds.

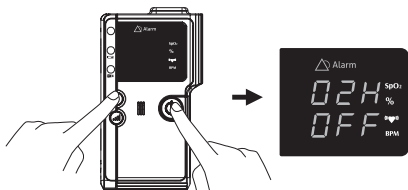


► Set up the Oximeter

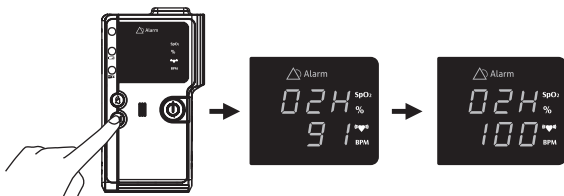
Your oximeter comes with the alarm function including the upper/lower limit of SpO₂ and heart rate, and the brightness of LED backlight preset. If you need to set these parameters, please follow below steps.


Start with the oximeter is off.

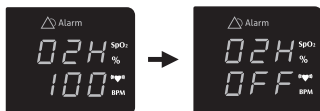
- STEP 1.** Press  Button and  button at the same time to enter setting mode.
The first screen shows SpO₂ upper limit settings. The factory default is off.




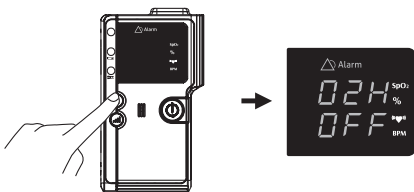
- STEP 2.** Press  button to change settings. You can press  button to increase the number from 91% to 100%.





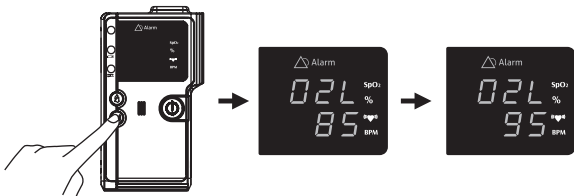
When the setting value goes to the upper limit, press  button again and the screen will turn back "OFF" setting.




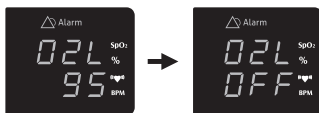
STEP 3. When the desired setting is displayed on the screen, press  button to enter SpO₂ lower limit setting. The factory default is off.




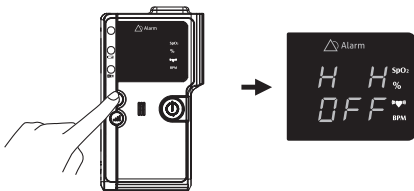
STEP 4. Press  button to change settings. You can press  button to increase the number from 85% to 95%.



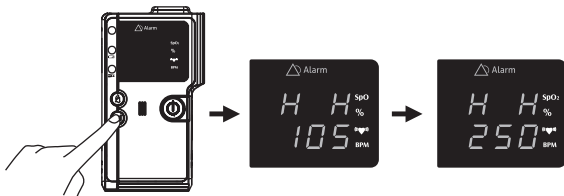
When the setting value goes to the upper limit, press  button again and the screen will turn back "OFF" setting.




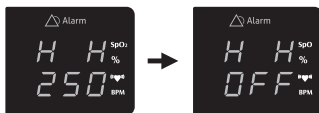
STEP 5. When the desired setting is displayed on the screen, press  button to enter heart rate upper limit setting. The factory default is off.




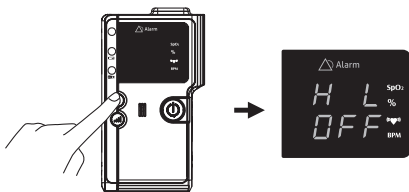
STEP 6. Press  button to change settings. You can press  button to increase the number from **105 BPM to 250 BPM**.



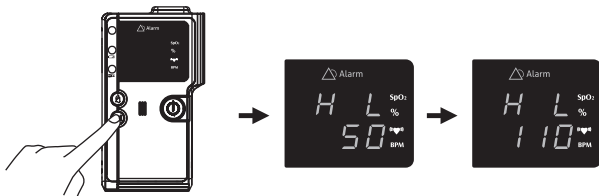
When the setting value goes to the upper limit, press  button again and the screen will turn back "OFF" setting.




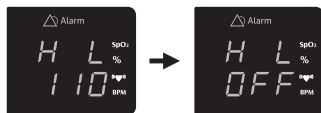
STEP 7. When the desired setting is displayed on the screen, press  button to enter heart rate lower limit setting. The factory default is off.




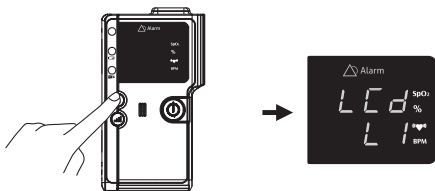
STEP 8. Press  button to change settings. You can press  button to increase the number from 50 BPM to 110 BPM.





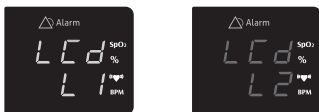
When the setting value goes to the upper limit, press  button again and the screen will turn back "OFF" setting.



STEP 9. When the desired setting is displayed on the screen, press  button to enter LED backlight setting mode.



STEP 10. Press  button to change settings. **L1 setting is brighter than L2 setting.** Press  button to turn off the oximeter.



(For TD-8201B)

STEP 11. Press  to change settings. Press  button to turn on Bluetooth.





Setting Table

Item	Default	Adjustment Options	Increments
SpO ₂ High	Off	Off, 91-100	1%
SpO ₂ Low	Off	Off, 85-95	1%
Pulse Rate High	Off	Off, 105-250	5 BPM
Pulse Rate Low	Off	Off, 50-110	5 BPM
Brightness	L1	L1 and L2	N/A
Bluetooth	F-b_1	F-b_1 and F-b_2	N/A

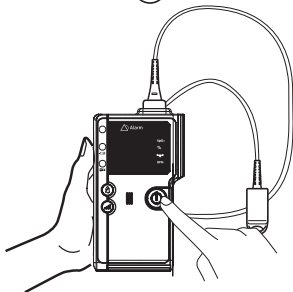
► Power On Self-Test

When the oximeter is turned on for normal operation, the unit will check if the oximeter is ready for use. If probe does not connect to oximeter, the SpO₂ indicator will appear red light. If probe does not touch the subject's measurement site or the signal is unstable, the SpO₂ indicator will turn orange light.

OPERATION

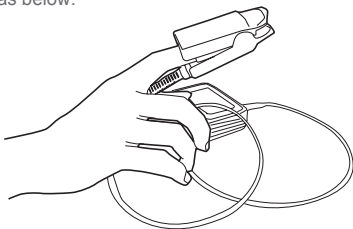
All functions of the oximeter are controlled by  and  buttons found on the front of the unit.

STEP 1. Turn on the oximeter by press  Button.



The LED Screen shows as above to indicate the oximeter is ready to use.

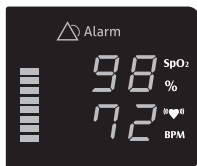
STEP 2. Clip subject's finger as below:



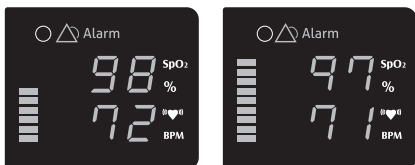
CAUTION!

1. Consult health professional before you start to use the oximeter.
2. The oximeter probe might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the probe.
3. Check the probe application site frequently to determine circulation, positioning and skin sensitivity. The recommended maximum application time at a single site is 4 hours.

STEP 3. After detecting the pulse signal, the oximeter shows the readings of SpO₂ and pulse rate on LED.



STEP 4. The alarm indicator will light up if the readings out of the limit setting.



► **SpO₂ Symbol (%SpO₂)**

The SpO₂ symbol shows the current oxygen saturation in percentage .

► **Pulse Rate Symbol ("♥")**

The pulse rate symbol shows pulse rate in beats per minute.

► **Pulse Amplitude**

The strength of signal is detected by the oximeter.

(For TD-8201B)

STEP 5. Two modes can be selected for Bluetooth communication.

- (a) F-b 1 : With the meter turned off, start Bluetooth communication via control of host device to upload SpO₂ readings. The transmission frequency is fixed to one reading per minute. You can upload those readings within one hour prior to the meter turned off.
- (b) F-b 2 : With the meter turned on, the meter will initiate Bluetooth transmission during measurement to upload the instant readings via control of host device. The host device can control the time tempo for transmission in a maximum of one reading per minute.

► Visual Alarm

The alarm turns off unless the alarm function is cancelled or the status is normal. To turn off alarm, please refer to "Set up the Oximeter" section for details.

Adjusting alarm settings is only possible when the oximeter is in setting mode. For every power on in which alarm settings have not been recalled or adjusted in Setup mode, the default alarm settings remain in effect.

Refer to the table below for detailed information about alarm conditions, activation criteria.

Condition	Alarm Activation Criteria
SpO ₂ High	Activates when displayed SpO ₂ is equal to or greater than the SpO ₂ upper limit setting.
SpO ₂ Low	Activates when displayed SpO ₂ is equal to or less than the SpO ₂ lower limit setting.
Pulse Rate High	Activates when the displayed pulse rate is equal to or greater than the pulse rate upper limit setting.
Pulse Rate Low	Activates when the displayed pulse rate is equal to or less than the pulse rate lower limit setting.

Response for the operator after the most Alarm is Triggered

Medium priority alarm

The operator may not be interrupted, but the operator is able to describe the cause of the alarm status as early as possible after the urgent task is done.

Alarm Message List

	Alarm	Priority	Description
Pulse Rate	visual alarm	Medium	The pulse rate value is lower/higher than the value set in the menu.
SpO ₂	visual alarm	Medium	The SpO ₂ value is lower/higher than the value set in the menu.

Information Signal List

	Information signal	Description
SpO ₂ Probe OFF	Warning Tone	The connection of probe is not connected well.
Low Battery	Warning Tone	The batteries are low.
Improper Insertion of Patient's Finger	Warning Tone	The patient's finger is not inserted well.

DATA TRANSMISSION VIA BLUETOOTH

You can transmit your SpO₂ and pulse rate data from the meter to your device (e.g. smart phone, tablet, PC...) via Bluetooth. Please contact your local customer service or place of purchase for assistance.

Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

1. With the meter off, press and hold the Advance Button (Bluetooth key) for 3 seconds. The meter enters pairing mode.
2. Turn on the Bluetooth function of your device so that it can begin searching for the meter. When the name of the meter appears on the pairing list, select and add it to the list.
3. On your device, the meter will be shown as a paired device, suggesting successful pairing.

* For Android system, it's suggested to turn off the meter while the meter is in pairing mode. And then turn it on again to accelerate the speed for connection.

Bluetooth indicator on the blood glucose monitor:

BLUETOOTH INDICATOR	STATUS
Flash Fast	The meter is pairing and connecting.
Lit Solid	The connection is established. The meter is transmitting data now.

NOTE

(a)F-b 1 : With the meter turned off, start Bluetooth communication via control of host device to upload SpO₂ readings. The transmission frequency is fixed to one reading per minute. You can upload those readings within one hour prior to the meter turned off.

(b)F-b 2 : With the meter turned on, the meter will initiate Bluetooth transmission during measurement to upload the instant readings via control of host device. The host device can control the time tempo for transmission in a maximum of one reading per minute.

MOBILE PHONE COMPATIBILITY ISSUES

The Bluetooth functionality is implemented in different ways by the various mobile phone manufacturers.

Unfortunately, in some mobile phone models, even with Bluetooth functionality, they may be compatible only with certain types of devices. If a problem occurs in the connection between your mobile phone and the blood glucose monitor, or if you are uncertain regarding your mobile phone's Bluetooth capabilities, please consult your mobile phone manual or contact your local customer service for assistance.

WARNING:

- While the meter is in transmission mode, it will be unable to perform a test.
- Make sure your device has the Bluetooth function turned on and the meter is within the receiving range before transmitting the data.


CLEANING THE OXIMETER

Cleaning oximeter is just as important as proper use. For surface-cleaning and disinfecting the oximeter and reusable SpO₂ probes we recommend the following procedures:

- ▶ Turn off the oximeter before cleaning.
- ▶ Wipe exposed surfaces with a soft or a pad moistened with a mild detergent solution or medical alcohol (70% isopropyl alcohol solution).
- ▶ Clean your oximeter whenever you see any type of soil, dirt or obstruction in it.
- ▶ Ensure that no dirt or blood is on the optical components.
- ▶ SpO₂ probes can be cleaned and disinfected with same solutions. Let the probe dry before using it again. The rubber inside of the SpO₂ probe belongs to medical rubber, which has no toxin and no harmful to the skin of human being.
- ▶ Replace the batteries timely when battery indication is low. Please follow the law of the local government to deal with used batteries.
- ▶ Remove the batteries inside the battery cassette if the oximeter will not be operating for a long time.
- ▶ It is recommended that the oximeter should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the oximeter.
- ▶ **Caution:** Do not spray, pour, or spill any liquid on the oximeters, their accessories, switches or openings.









TROUBLESHOOTING

Problem	Possible Cause	Possible Solution
The oximeter won't turn on.	The batteries are out.	Replace all batteries.
	The batteries are installed incorrectly.	Verify correct battery orientations.
A dash appears in the LED.	A probe fault exists. The probe may have become dislodged from the oximeter or from the subjects.	Verify that the probe is correctly connected to the oximeter and the subject. Try a new probe if the condition persists.
The displayed pulse rate does not correlate to the pulse rate displayed on the ECG monitor connects to patient.	Excessive motion at the probe site may be prohibiting the oximeter from acquiring a consistent pulse signal.	Eliminate or reduce the cause of the motion artifact or reposition the probe to a new probe site where motion is not present.
	The subject may have an arrhythmia resulting in some heart beats that do not yield a pulse amplitude signal at the probe site.	Examine the subject: the condition may persist even though both monitors are functioning properly if the subject's arrhythmia persists.
	A non-oximeter probe is being used.	Replace the probe with a oximeter probe.
	The ECG monitor may not be functioning properly.	Examine the subject: replace the ECG monitor or refer to the operator's manual for the ECG monitor.

Problem	Possible Cause	Possible Solution
Segments of the SpO ₂ or pulse rate displays are missing.	Defective LED displays.	Displayed values may not be reliable; discontinue use of the oximeter.
Disruption in the oximeter performance.	Electromagnetic interference (EMI).	Remove the oximeter from the EMI environment.
Red light battery indicators appears accompanying the message displayed on LED as shown below: 	The batteries are low.	Replace the batteries.
The message display shown "E01"	Probe fail	Replace the Probe

If you have followed the actions recommended above but the problem keeps unsolved, please contact your local dealer for assistance.

SYMBOL INFORMATION

	Type BF applied part Part- not defibrillator proof
IPX2	Resistant to liquid ingress
	Caution, consult accompanying documents
	Manufacturer
	Authorised representative in the European Community
	Indicates separate collection for electrical and electronic equipment (WEEE).
	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical device
	Consult instructions for use
	Serial number (located under the battery cover)

SPECIFICATION

Pulse Oximetry	
Range:	35% to 100%
Resolution:	1%
Accuracy:	70% to 79% \pm 3%, 80% to 100% \pm 2%, others are undefined
Method:	Dual wavelength LED (660nm/905nm)
Neonate mode	Not Available
Heart (pulse) Rate	
Range:	30 to 250bpm
Resolution:	1bpm
Accuracy:	\pm 1bpm or \pm 1%, whichever is greater
Displays	
Type:	7-Segment LED
Parameters:	SpO ₂ ; pulse rate; pulse bar (can also indicate low perfusion)
Status:	Indicate a stable reading is taken; Probe fall-off detection indication; Battery status indication
Data	
Memory	Store SpO ₂ & Heart Rate readings every minute
Uploading	Instant uploading or to upload after switching off
Keys	
On/Off key	One button
Functional key	Two buttons
Warning	
Medium Priority Alarm	SpO ₂ value is higher/lower than predefined setting, or pulse too high/low
Information Signal	Low battery , improper insertion of patient's finger, or probe fall off
Setting	
SpO ₂ high/low value	Alarm level setting
Pulse high/low value	Alarm level setting

Mechanical	
Weight:	With batteries: 240g
Size:	Reference dimension 14cm (H) x 7cm (W) x 3.2cm (D);
Water-resistance	Against water splash
Impact-resistance	Against repeat impact from 1 meter height
Transmission	Bluetooth(TD-8201B)
Battery	
Type:	4 AA alkaline battery
Usage life:	40 hrs typical operation
Environmental	
Operating Temperature:	10°C to 40°C (50°F to 104°F)
Storage Temperature:	-20°C to 60°C (-4°F to 140°F)
Operating Humidity:	Below 95%, non-condensing
Classification	
Degree of Protection:	Type BF applied part
Mode of operation:	Continuous
Safety:	IEC60601-1
EMC:	IEC60601-1-2
Harmonized standard:	ISO 80601-2-61
Water-resistance:	IPX2
Bluetooth:	EN300 328, EN301 489

FEDERAL COMMUNICATIONS COMMISSION (FCC) STATEMENT

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

Federal Communications Commission (FCC) Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) This device may not cause harmful interference and
- 2) This device must accept any interference received, including interference that may cause undesired operation of the device.


FCC RF Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

End users must follow the specific operating instructions for satisfying RF exposure compliance.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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