

Operator's Manual



C € 0123

Section 1 Safety

1.1 Instructions for the Safe Operation and Use of the Fingertip Pulse Oximeter

· Do not attempt to service the Finger tip Pulse Oximeter. Only qualified service personnel should attempt any needed internal servicing.

· Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status and correct alignment at least every 2 hours

 SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.

- · The following reason will cause interference and defibrillators
- High-frequency electrosurgical.
- · Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or
- The patient has hypotension severe hypothermia.

- The patient is in cardiac arrest or is
- · Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

1.2 Warnings

WARNING: EXPLOSION HAZARD - Do not use the Pulse Oximeter in a flammable atmosphere where concentrations of flammable mesthetics or other materials may

WARNING: Do not throw batteries in fire as this may causes them to explode.

WARNING: Do not attempt to recharge normal dry-cell batteries, they may leak, And may cause a fire or even

WARNING: Do not use the pulse oximeter in an MRI or CT environment. WARNING: Do not modify this equipment without authorization of the

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment nmediately after moving it from a cold environment to a warm, humid

CAUTION: Never use sharp or pointed objects to operate the front-panel witches

CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a long time. CAUTION: The device shall only be

used if the battery cover is closed. CAUTION: The battery must be proper disposed according to local regulation after their use

CAUTION: The device should keep away from the children, pets and pests to avoid swallowing

98 65 199 86

Type 4

SpO2% @ PR bpm

Type 6

္လီထင္စီႏုိင္ငံ

- Time

3 O. E. .. F.

Type 8

Ø 18 \ \

1.3 Defi	nitions and Symbols	
Symbol	Description	
∱	Type BF Equipment	
LOT	Batch code *	
M 2000 00	Date of manufacture *	
SN	Serial NO*	
ш	Information of manufactur including name and address	
X	Temperature limitation	
X	When the end-user wishes t discard this product, it must be sent to separate collection facilities for recovery and recycling	
(3)	Follow instruction for use	
IP22	Anti-dust& Anti-water class	
	The information you should	

* Batch code, Date of manufacturer and Serial No are printed on the label on the battery cover.

Section 2 Introduction

2.1 General

This chapter provides a general description of the Fingertip Pulse Oximeter including.

- · Brief device description
- Product features

2.2 Brief Device Description

Fingertip Pulse Oximeter, based on all digital technology, is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2). Advanced DSP algorithm can minish the influence of motion artifact and improve measurement accuracy of low perfusion.

The Oximeter can be used to measure human Hemoglobin Saturation and heart rate through finger. The product is suitable for family, hospital (including clinical use in internist /surgery, Anesthesia, pediatrics, intensive care and etc.) Oxygen Bar, social medical organizations, physical care in sports and etc.

2.3 Product Features

· Lightweight for carrying and Easy-To-

· Manually adjust the direction of interface

- · Color OLED display, simultaneous display for testing value and plethysmogram.
- Low Perfusion down to 0.2%. Visual alarm function. Real-time spot-
- checks.
- · Low Battery voltage indicator Automatically switch off.
- Standard two AAA 1.5V Alkaline Battery support more than 20 hours

CAUTION: The device can not be used to measure the child below 1 years as the test result is not guarantee to

CAUTION: The fingertip pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of ssessing clinical signs and symptoms.

CAUTION: A function tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

(usually resulting from fluctuations in the amount of Clinical testing is used to establish the blood or air it contains). SpO2 accuracy. The measured arterial PI (Perfusion Index): is the ratio of the pulsatile hemoglobin saturation value (SpO2) of

blood flow to the non-pulsatile static blood flow in a patient's peripheral tissue, such as finger tip, toe, or ear lobe. Perfusion index is an indication of the pulse strength at the sensor site.

Respiratory rate or breathing rate: is the number of breaths a person takes in one minute while at rest. The act of breathing is controlled by the brain, which tells the body to breath based on oxygen and carbon dioxide levels in the blood, and certain factors, such as exercise, drugs, and alcohol, can affect a person's breathing rate. An abnormally high or low respiratory rate may indicate certain medical conditions such as bradypnea, apnea, or

Section 3 Installation, Setup, and Operation

3.1. Description of the Front Panel (as figure 3.1.1)



Figure 3.1.1 Parts of front&back panel

10°C to 50°C

non-condensing

bottom limit:50

Item Name Description Turn on/off the machine Direction change& Direction Parameter setting button in menu OLED Display the SPO2/PR data&Plethysmogram Panel

Table 3.1.1 Part Definition and Description

3.2 Display After switch on, the OLED display of Fingertip Pulse Oximeter is as follows:

Battery

partment

Com-



Figure 3.2.1 OLED display

3.3 Parameter setting

Press the direction button ("M") for one second (for 1s), the oximeter will enter into parameter setting. There are two submenu for choice:

When the * signal shown on the Alarm Setup, press "M" for 1s and enter into the Sound Setting menu (figure 3.3.1), press "M" for 1s to turn on/off for the alarm and

When the * signal shown on the Sounds Setup, press "M" for 1s and enter into the Alarm Setting menu(figure 3.3.2), you can press "M" in turn to select the item. And press "M" for 1s to change the data you

On the Sounds Setup menu (figure 3.3.1) when the * signal shown on front of the "+/-", sign "+" on the right side can be changed to "-", by pressing "M" for 1s. When "+" shows on the right side, press "M" for 1s can increase the SPO2 and PR's highest and lowest alarm value. When "-" shows on the right side, press "M" for 1s can reduce the SPO2 and PR's highest and lowest alarm

On the Alarm Setup menu (figure 3.3.2). When the * signal shown on "Restore", press "M" for 1s, the right side can be changed to "OK", which cause the device to restore factory setting data.

On the Alarm Setting menu, you can set the device in demo mode, which shows how the device display. Change eight different display modes by short pressing direction button, and turn off the demo mode by long pressing direction button. Note: In demo mode, device can not perform the detecting

On the Alarm Setup menu, when the ignal shown on "Brightness", the brightness takes a float form 1 to 5 by long prssing direction button



Operation

3.4.1 Install battery Installing two AAA batteries into battery cassette in correct polarities and cover it.



Change Brightness



Figure 3.3.1 Figure 3.3.2

Press power button for 2 seconds to turn the Pulse Oximeter on. 3.4.3. Read correspondent data from

display screen.

3.4.4 Display Description of OLED The display interface of "OLED" can rotate four directions with eight different display modes after pressing the direction

Type 1

button. It is shown as below:

SpO₂% © PR bpm 98 PI% 65 98 10.0 65 SpO₂% (TII PR born 144444

WARNING: Do not attempt to recharge normal alkaline batteries, they may leak and may cause a fire or

3.4.2 Turn the Pulse Oximeter on

Put one of fingers into rubber hole of the Oximeter (it is best to put the finger thoroughly) with nail surface upward. then releasing the clamp.





Note: when battery power is at lowest level, the battery capacity indicates symbol of " in OLED, remind users of replacement of battery.

Section 4 Cleaning and Disinfection

4.1 Cleaning

Type 3

SpO₂% C PR bpm

Type 5

Switch off the power and take out the batteries before cleaning. Keep the exterior surface of the device clean and

free of dust and dirt. Cleaning exterior surface (OLED display screen included) of the unit with a dry and soft cloth. Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid alcohol permeates into the device

know to protect patients and medical staff from possible

equipment from possible

The important information

know to protect the

damage

The information you should

CAUTION: Don't use strong solvent. For example, acetone

CAUTION: Never use an abrasive such as steel wool or metal polish

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquids on the device while cleaning. CAUTION: Don't remain any cleaning solution on the surface of the device.

Section 5

Troubleshooting and Maintenance 5.1 Maintenance

Replace the batteries timely when battery indication is low.Clean surface of 5.2 Troubleshooting

oblems	Reason	Resolutions
emoglobin art rate can e shown ally	1.Finger is not plugged correctly. 2.Patient's perfusion is too low to be measured.	1.Retry by plugging the finger 2.Try some more times, If you can make sure about no problem existing in the product, Please go to a hospital timely for exact

the Pulse Oximeter before it is used in diagnosis for patients.

- Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.
- It is better to preserve the product in a place where ambient temperature is -10-40°C and humidity is 10%-80%. · Regular inspection to make sure that
- safety and performance of device. · No flammable substance, overtop or
- in operation conditions.

oblems	Possible Reason	Resolutions
emoglobin urt rate can e shown ally	1.Finger is not plugged correctly. 2.Patient's perfusion is too low to be	1.Retry by plugging the finger 2.Try some more times, If you can make sure about no problem existing in the product, Please on to a

Possible Reason Resolutions Problems 1. Finger might 1.Retry by not be plugged deep enough plugging the

status

might be

inadequat or not

2.Batteries

he there

1. Power of

finger 2.Try not to

Please replace

2.Please reinstall

3.Please contact

customer service

the batteries

with local

of heart rate is trembling or move, patient's body is Let the patient

no obvious damage existed to affect the lower temperature and humidity existed

Table 5.2.1

troubleshooting		might be installed	center	
ossible eason	Resolutions		incorrectly 3.The Oximeter might be	
1.Retry by	1.Retry by plugging		damaged	
nger is not ged ectly. tient's usion is ow to be sured.	the finger 2. Try some more times, If you can make sure about no problem existing in the product, Please go to a hospital timely for exact	The screen are suddenly off	1 The product is automatically powered off when no signal is detected longer than 8 seconds 2.Power quantity of the batteries	1. Norr 2. Repl batterie

The Oximeter

can not be

powered on

Specification

Fingertip Pulse Oximeter Specifications: Physical Characteristics

Machine: Dimensions -74 mm (L) x 37mm (W) x 38mm (D) Weight

the sensor is compared to arterial

hemoglobin oxygen(SaO2) value,

determined from blood samples with a

laboratory CO-oximeter. The accuracy

of the sensors in comparison to the CO-

oximeter samples measured over the SpO2 range of 70 -100%. Accuracy data

is calculated using the root-mean-

square(Arms value) for all subjects. Only

about two-thirds of PULSE OXIMETER

EOUIPMENT measurements can be

Pulse simulator shall be used to assess

pulse rate accuracy. The measured pulse

rate is compared to the preset pulse rate

*DSP algorithm: Digital signal processor algorithm.

*Low Perfusion: In physiology, perfusion is the

process of a body delivering blood to a capillary

low perfusion, the measurement of non-invasive

saturation of pulse-blood oxygen is low-accurate.

*Plethysmograph: is an instrument for measuring

changes in volume within an organ or whole body

bed in its biological tissue. Under the condition of

value in simulator. Accuracy data is

caculated using the root-mean-square

(Arms value) for all subjects.

value measured by a CO-Oximeter.

expected to fall within ±Arms of the

approx: 55 g (including 2 xAAA battery) Outer box:

-87mm(L)x69mm(w)x40mm(D) Gross Weight: 85g

Outer carton: Dimensions -490mm (L) X370mm (W) X240mm (H) Gross Weight: 9.7 kg

Anti-electric Shock Type: Internally powered equipmen Anti-electric Shock Degree: Type BF

Classification

EMC: Type B Mode of operation: Continuous Operation Enclosure Degree of ingress protection:IPX4*

Power

2xAAA 1.5v a Internal lkaline battery Power Smaller than Consumption 30mA (Normal) Environmental Operating 5°C to 40°C

Temperature Storage Temperature 15% to 80%

Relative Humidity Alarm default value

> Parameter Value Hemoglobin Upper limit: 100/ bottom limit:90 saturation Upper limit: 130 / Pulse rate

> > **Flectronics Parameters**

Parameter	Value 35-100%	
Hemoglobin saturation display		
Pulse rate Display	30-250 BPM	

Hemoglobin 1% Saturation 1 RPM Pulse rate Hemoglobin ±3% (70%-100%) Saturation unspecified(<70%) Accuracy Pulse rate ± 1 BPM For any query contact: dr@drtrustusa.com

