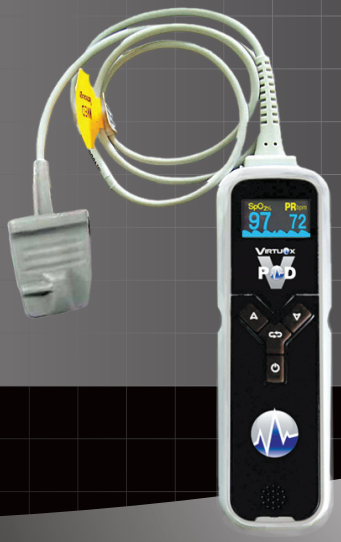
The VirtuOx Total Solution

No cost software + low cost oximeters =
The industry's most cost effective way to qualify oxygen patients!

VPOD-H Product Features:

- FDA Approved
- Data storage and transmission to VirtuOx Laboratory for Oxygen Qualification
- Data storage and transmission to VirtuOx O.E. Office Edition for Non Qualification
- USB interface for data transfer
- 72 hours of data storage
- High Resolution Pulse Oximetry (Records at 1 second intervals)
- Three display modes
- Special design for sleep monitoring
- LCD Displays SpO2, SpO2 waveform & Pulse Rate
- Low power consumption, uses 2 AAA battery
- Battery low indicator
- 3 year warranty



VIRTUOX

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Content

Chapter 1 Introduction

1.1 Brief Introduction

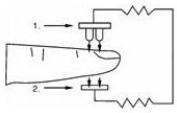
Thank you for purchasing the handheld pulse oximeter. The device is designed to measure SpO_2 and PR, delivering visual and audio alarm, sensor off alarm. Please read this manual carefully before using it.

Notice: The illustrations used in this manual may differ slightly from the appearance of the actual product.

Measurement principle

The principle of pulse oximetry is based on the red and infrared (IR) light absorption of oxygenated and deoxygenated hemoglobin present in the circulating blood. Oxygenated hemoglobin absorbs more IR and allows more red light to pass through. Deoxygenated hemoglobin conversely absorbs more red light and allows IR light to pass through. The detector probe is placed on the finger. The probe contains two light emitting diodes (LED's), one in the visible red spectrum. The beams of light from this probe pass through the tissues and some light is absorbed by the blood and soft tissues depending on hemoglobin concentration. The amount of light absorption at each light frequency is dependent on the degree of oxygenation of hemoglobin within the tissues.

The microprocessor can select out the absorbance of the pulsatile fraction of blood, i.e. that due to arterial blood, from constant absorbance due to non-pulsatile venous or capillary blood and other tissue pigments



Basis of Operation

1. Red and Infrared-ray Emitter Diode
2. Red and Infrared-ray Receptor Diode

1.2 Safety Information

Conception of Warning, Precaution and Notice

- **Warning - Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.**
- **Precaution - Reminds the user to pay close attention to device operation, failure of which may cause abnormal function of the instrument.**
- **Notice - Informs the user of other important information by suggestion, requirement and supplement.**

Warnings

- Please read this manual carefully before using this device. The user must check that the equipment functions safely and ensure that it is in proper working condition before being used.
- To avoid explosion hazard, do not use the oximeter in the presence of flammable anesthetics, vapors or liquids.
- Do not open the equipment housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.
- Do not use the pulse oximeter in an MRI or CT environment.
- The pulse oximeter is specified for use by medical professionals only.
- Prolonged use of the probe/sensor or the patient's condition may require changing the sensor site periodically. Change the sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours. Prolonged use may cause blisters, skin deterioration, and discomfort.
- Sensor malfunction may cause inaccurate data, possibly resulting in patient injury or death. Pay close attention to the sensor and inspect it often.

- When connecting this oximeter to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. The equipment connected to the pulse oximeter's data interface must be certified according to the respective IEC standards, i.e., IEC950 for data processing equipment or IEC 601-1 for medical electrical equipment. All combinations of equipment must be in compliance with IEC601-1-1 systems requirements.
- The physiological data and alarm messages displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.
- Worn-out data cables may also cause inaccurate data, so if the data is used as a reference to treat a patient, pay special attention to data cable and check it more frequently.
- When using the equipment with electrosurgical units (ESU), make sure the patient is safe.
- Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.
- Single-use accessories should never be reused.

Precautions

- Autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.
- The operator must be thoroughly familiar with the information in this manual before using the device.
- Unplug the sensor from the oximeter before cleaning or disinfecting it.
- If liquid is accidentally spilled on the unit, clean and dry thoroughly before reuse.
- Do not try to use the SpO_2 and NIBP measurement on the same arm at the same time. This could potentially affect measurement accuracy.

Notices

- Operation of this device in an electromagnetic field may influence its accuracy.
- SpO_2 measurements may be influenced by high ambient light, especially sunlight. Shield the sensor area if necessary.
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may influence the accuracy of the SpO_2 reading.
- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause a failure to determine accurate pulse rate and SpO_2 readings.
- Remove fingernail polish or artificial fingernails before applying SpO_2 sensors. Fingernail polish or artificial fingernails may cause inaccurate SpO_2 readings.
- Optical cross-talk can occur when two or more sensors are located in adjoining areas. It can be eliminated by covering each site with opaque material. Optical cross-talk may adversely affect the accuracy of the SpO_2 readings.
- Obstructions or dirt on the sensor's red light or detector may cause a sensor failure. Make sure there are no obstructions and the sensor is clean.
- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.
- As to the other concerns for attention, please carefully look through the specific chapter in this instruction.

1.3 Equipment symbol

Symbols	Definition
	Attention ! Refer to the relevant the prompt. Read the operator's manual carefully before using the oximeter.
	Type BF applied part
	Date of Manufacture

	Manufacturer's information.
	Low power indicator
IPX1	Protected against dripping water

1.4 Electromagnetism interference

This oximeter is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the electronic medical device - IEC 60601-1-2. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (e.g. cellular phones, mobile two-way radios, electrical appliances) it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

This apparatus complies with the IEC 60601-1-2 international standard. The requirements of this international standard are: CISPR11, GROP1, and CLASS B.

1.5 Equipment classification

Classification according to IEC-60601	
According to the type of protection against Electrical shock:	Internal electrical power source equipment
According to the degree of protection against Electrical shock:	Type B equipment
According to the degree of protection against harmful ingress of water:	Ordinary equipment(enclosed equipment without protection against ingress of water)
According to the methods of sterilization or disinfection	Non-sterilizable: Use of Liquid surface disinfectants only.
According to the mode of operation:	Continuous operation
Equipment not suitable for use in the presence of a flammable anesthetic mixture air or with oxygen or nitrous oxide.	

1.6 Intended Use

The purpose and function of the handheld pulse oximeter is to indicate measure and display the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adults and pediatric patients in hospital, ambulatory, home, and EMS (emergency medical service) environments. The pulse oximeter is intended for spot-checking these levels and not indicated for continuous monitoring. It can assist the clinician diagnostically by quickly displaying the patient's SpO_2% and pulse rate and can additionally store 72 hours of data.

1.7 Product features

- ✧ Compact, lightweight design and simple operation
- ✧ Color OLED with adjustable backlight displays SpO_2, pulse rate and pulse bar
- ✧ Up to 10 patient ID and 72-hour record storage, visual & audio alarm, low battery alarm
- ✧ Data transfer to PC for storage or printing
- ✧ Convenient 2 AA size alkaline batteries
- ✧ Suitable for adult and pediatric patient

1.8 Accessory

Standard accessories:

Operator's manual
VPROBE V_SOFT Finger sensor: compatible with The VPOD
Two AA-Size Alkaline batteries
Subscription to Virtuox

Optional accessories:

1. Finger sensor for adult
2. SpO_2 sensor for pediatric and infant
3. Software license
4. Data cable for transmission to Virtuox
5. 2 year extended warranty

Confirm that the items listed are packed with the pulse oximeter. If any item on this list is missing or damaged, contact your distributor. Contact the carrier immediately if the shipping carton is damaged.

CHAPTER 2 BASIC OPERATION

2.1 Outer View

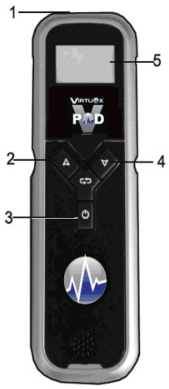


Fig.1

Description of Fig.1：

1— Double-functional socket：for oximeter probe and data transfer cable.
— Oximeter probe socket: Connect the probe with the oximeter before taking a measurement.
— Data cable socket: Connect the oximeter with PC by a data cable for transferring data recorded to Virtuox software.

2— The **function** button: short press the button to change the display mode on the measurement screen; And on the normal screen, extended press the button for about 4 seconds to change the setting items.

3— The **POWER** on/off button

Note：If no press on any button for 30 seconds, the oximiter will power off automatically.

4— The **Setting** button: Press this button repeatedly to increase the parameter under adjustment by one decrement.

5— Display screen, displays date and time, SpO_2 data, PR data, error information etc.

2.2 Rear Panel

Fig.2

Install the batteries

The oximeter can be powered by 2 AA-Size alkaline batteries (which will typically provide 50 hours of continuous operation), or by the optional rechargeable battery pack.

When battery power is lower than 2.7±0.1V, the sign will flicker in its display area. Replace the battery (or rechargeable batteries) as soon as possible. The installation steps are shown as Fig. 2.3.

Be sure to insert the batteries in the correct polarity, as indicated by polarity marking (+ and -)

inside the battery compartment.

Fig. 3

Cautions!

- ✧ Be sure to install batteries with correct polarities.
- ✧ Only use the approved batteries.
- ✧ Do not use batteries not specified for this unit.
- ✧ Do not dispose of batteries in fire.
- ✧ If battery fluid gets on your skin or clothing, rinse with plenty of clean water immediately.
- ✧ Remove the batteries from this unit when you are not going to use it for a long period of time (approximately one month).
- ✧ Do not use batteries of a different type together.
- ✧ Do not use new and used batteries together.
- ✧ Dispose of batteries in accordance with the local ordinances and regulations.

2.3 Connect the sensor

Connect the oximeter sensor to the top of the oximeter as shown in Fig. 4. Ensure that the sensor is firmly plugged in.

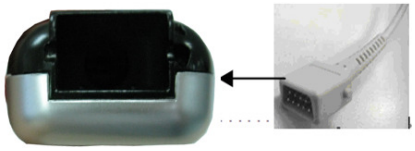


Fig. 4

Notice:
The connector is also applied to upload data to Virtuox software for managing data.

CHAPTER 3 Setup before Operation

3.1 Power on the oximeter

Short press the Power button to power the oximeter on.
Notice: To maintain the highest degree of accuracy, it is recommended that the finger and the oximeter sensor/probe should be kept as still as possible.

3.2 Enter “Setting mode”

Press the function button for about 4 second (extended press), the oximeter will enter into “Setting mode” and you will find a parameter item which include its title and value on the top right corner of the display (refer to Fig.5).
After entering the setting mode from the normal screen, continually press Function button, the current parameter item will be changed sequentially in the following order:
Br(brightness) -->ID(patient’s ID) -->Y(year) -->M(month) -->D(date) -->H(hour) -->m(minute) -->S(second) --Br(brightness)-->...

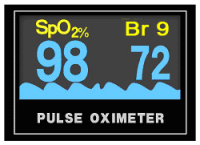


Fig.5

Notice: When setting date and time, please don’t insert finger.

b) Save and exit from “Setting mode”
①Under the “Setting mode”, press “function key (left key)” to select the desired parameter item.
②Then press “Setting key (right key)” to adjust the value.
Each time when you press the “Setting key (right key)”, current parameter value will be added by 1 unit sequentially.
Double press the “Setting key (right key)” and the current parameter setting will be added by 10 units sequentially. All use circular logic.
③Press “function key (left key)” to select the next desired parameter item. Then redo step ② to adjust the value. You can continually redo step ① to ② until no parameter’s setting need to be changed.
④To finish setup, **fleetly press both left and right keys together to confirm**. Then the modifications

under the “Setting mode” will be saved, at the same time, the system will exit from “Setting mode”.

Notices:

1. To confirm the modification, the act of pressing both buttons simultaneously must be fleet. Do not press them for long time.

2. When setting date and time, please don’t insert finger.

Cancel and exit from “Setting mode”

Under the Setting mode, double-press the Function button, the modification under “Setting mode” will be cancelled and simultaneously, the system will exit from “Setting mode”.

If there is no operation under Setting mode” for more than 30 seconds, the system will exit from “Setting mode” automatically.

CHAPTER 4 Take a measurement

4.1 Monitoring

SpO_2 measuring is a non-invasive technique used to measure the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light emitted by a red and infrared light-emitting diodes passes through the tissue and is converted into electrical signals by a photodiode.

After finishing the settings contained in chapter 3, plug your finger into the sensor shown as the following picture:

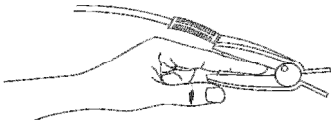


Fig 6 placement of the sensor

- Select the suitable sensor in terms of type and dimension.
- Clip the sensor to the rational position of the patient finger. And ensure that the patient’s nail surface is facing upward.
- Plug sensor into SpO_2 port on top panel of pulse oximeter.

Notice: To maintain the highest degree of accuracy, it is recommended that the finger and the oximeter sensor/probe are kept as still as possible.

4.2 Mode switch

After turning on the oximeter, each time the function button is pressed, the oximeter will switch to another display mode, shown as Fig.7.

4.3 Factors that may affect the measurement

During operation, the accuracy of oximeter readings can be affected by the following factors:

4.3.1 Instrument performance depends on the pulsatile character of the artery. The measurement would not be considered reliable and accurate if the following conditions are present during measurement:

- Shock or cardiac arrest
- Temperature of the digit
- After the administration of a cardiovascular drug
- Anemia
- Evidence of ventilation-perfusion mismatch

4.3.2 Instrument performance depends on the wavelength absorption for oxyhemoglobin and deoxyhemoglobin. If there are substances absorbing the same wavelength, this would induce false or low SpO_2 values. The following may affect these values:

- carboxyhemoglobin
- methemoglobin
- methylene blue
- Indigo carmine

4.3.3 Extremely high illumination could affect the SpO_2 measurement. Use a semi-translucent or opaque cover to shield the sensor.

4.3.4 Other factors

a) High-frequency electrosurgical interference from external devices, including defibrillators.
b) Placement of a sensor on an extremity that currently has installed a blood pressure cuff, arterial catheter, or intravascular line;
c) The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
d) An arterial occlusion proximal to the sensor.

⚠Warnings

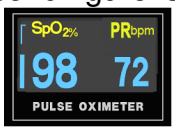
- Use only SpO_2 sensors provided by manufacturer. Other SpO_2 sensors may cause improper performance.
- Do not use an SpO_2 sensor with exposed optical components.
- Excessive patient movement may cause inaccurate measurements.
- Tissue damage can be caused by incorrect operation or misusing sensor; for example, by

wrapping the sensor too tight. Inspect the sensor site to ensure the skin's integrity and the adhesion position of the sensor is correct. More frequent inspection should be taken if necessary.

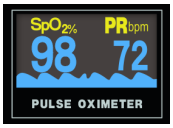
- Loss of pulse signal can occur in any of the following situations:
  a) The sensor is too tight;
  b) There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight;
  c) A blood pressure cuff is inflated on the same extremity as the one to which an SpO_2 sensor is attached.

4.4 Display mode

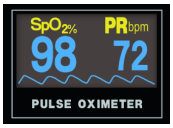
The handheld pulse oximeter uses an OLED display for a readout. It can display the SpO_2 and pulse rate (PR) value, as well as a pulse column and SpO_2 waveform.
There are three display modes shown in Fig 7. The first figure is pulse column display mode. The second figure is the waveform mode. The third figure is line waveform mode indicating SpO_2% trend.



(1)



(2)



(3)

Fig.7 Three display modes

- **SpO_2:** Percent oxygen saturation value displayed above is 98%
- **PR:** Pulse rate value displayed is 72 bpm
- Fig.7(1) **Pulse column:** This is used for signal identification and quality indication during motion and low signal to noise situations. The bar rises and falls with the pulse, its height indicating signal quality. When the bar is very low, the SpO_2 and pulse rate values may be suspect.
- Fig.7(2) **Filling-up SpO_2 plethysmogram wave:** SpO_2 plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If , for example, 98% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 98%. The SpO_2 numeric on the Oximeter will read 98%, refer to Fig.7.(2). The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2 plethysmogram measurement can also provide a plethysmogram wave. During this mode, the PR tone is dumb.
- Fig.7(3) **SpO_2 plethysmogram wave**
- **PR tone modulation**: Beeps in sync with the patient's pulse, even under most challenging patient motion conditions.

CHAPTER 5 Other information

5.1 Alarm

Alarm: Technical alarm and physiological alarm.
Technical alarm: finger out, probe off, power low and error code.
In the situation that the finger is not inserted correctly or the connection state of the probe is not good results in failure of measurement, "Finger out" or "Sensor off" may be displayed on the normal screen.

When battery power is lower than 2.7±0.1V, the sign will flicker in its display area. Replace the batteries as soon as possible.

In the failure state, the oximeter will display error codes, and will automatically power off if the error code display lasts for more than 8 seconds. For the details and definitions on error, please refer to chapter 4.2.

Physiological alarm: SpO_2 and PR
If the measured SpO_2 and/or PR value is beyond the default limit, alarm will be activated, and the corresponding value will flash with audio alarm "didi—didi…." .
By default:
SpO_2: The upper limit: 100%
The lower limit: 90%
PR: The upper limit: 100bpm
The lower limit: 60bpm

Note: during the alarm is issued, long press the functional button, you can silence the alarm for 30 seconds.

5.2 About the button

1) Definition of button
There are three buttons in the oximeter: Power button, Function button and Setting button.
Power button: This acts as a Power On switch when the unit is in an Off condition.
Function Button: When the unit is On, it acts as a Function button.
Setting button: Located at the right of the oximeter, it has no function when the power is off. When the unit is On, it acts as a Setting button.
2) Definition of Button Press
There are three ways to press the button:
Short Press: press the button quickly, the duration time should no more than 1 second.
Double press: Two-time continuous press, the time between the two press actions should be no more than 0.5 second.

Extended press: Press the button for more than 1.5 seconds.
Long press: Press the button for more than 2 seconds.

5.3 Data replay and transmission

The oximeter can record SpO_2 and PR value for more than 72 hours, but the oximeter itself has no data replay function. You can transmit the history data to a PC using "Virtuox" software and a special data cable. As for detailed setup and operation, please refer to the "Virtuox" website. www.virtuox.net

Note: Virtuox can be obtained at no charge with the purchase of this device. Please contact Virtuox customer service to set up an account. 877-337-7111

5.4 Maintenance

It is very important for user to perform daily maintenance of oximeter and parts in order to maintain its function and appearance. Disinfection procedures may be performed with the use of the below mentioned cleaner/disinfectants. Failure to perform these procedures may result in invalidating the warranty. Local disinfection protocols will apply.
Please take out battery before cleaning the oximeter.
The external surface of the oximeter can be cleaned by wiping with a damp cloth. Do not submerge the oximeter in any solution at any time. To do so will void the warranty
Use the following permitted solutions:

- Ammonia (diluted)
- Glutaraldehyde
- 10% Bleach solution
- Mild soapy water (diluted)
- Do not use the following cleaners:
  - Any kind of scrubbing or scouring solution
  - Acetone
  - Alcohol-based cleaners

Probe cleaning and disinfecting

1. Clean or disinfect the sensor before each use.
2. Unplug the sensor from the oximeter before cleaning and/or disinfecting.
3. Clean the external sensor surfaces and patient contact surfaces with a soft cloth moistened with water or a mild detergent solution.
4. To disinfect the sensor, wipe the surfaces with a disinfecting solution. Isopropyl alcohol is recommended
5. Do not immerse the sensor in any solution. To do so will void the warranty.
6. Do not sterilize the sensor by irradiation, steam autoclaving or ethylene oxide

Battery maintenance

- Remove the batteries if you will not be using the oximeter for a long time.
- Charge the batteries (Ni-MH) fully prior to storage.
- Please charge over 14 hours at first time, or will reduce the battery life.

5.5 Troubleshooting

a) Error Definitions
Err 1: program memory damaged.
Err 2: data memory damaged.
Err 3: sensor Red Emission Diode damaged.
Err 4: sensor Infrared-ray Emission Diode damaged.
Err 5: sensor Infrared-ray Receipt Diode damaged.
Err 6: exterior crystal oscillator damaged.
Err 7: sensor emission diode or receipt diode damaged.
Err 9: real time clock damaged.
Err 10: EEPROM chip damaged.

b) Possible problem and corresponding resolution

Problems	Possible reason	Solution
SpO_2 or PR cannot be displayed normally	1. Finger is not plugged correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1. Retry by plugging the finger 2. Attempt several time to obtain a reading, If are sure that no problem exists, obtain further clinical examination
SpO_2 or PR display is unsta	1. Finger might not be plugged deep enough 2. Finger is	1. Retry by plugging the finger 2. Urge the patient to

ble	trembling or patient is moving continually	remain still
The Oximeter can not be powered on	1. Battery power may be inadequate or not installed 2. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Contact local customer Technical Service
"Error 3" or "Error 4" Displayed on screen	1. Receiving diode may be shielded or damaged together with broken connector. 2. Mechanical Misplace for receive-emission diode 3. Amp circuit malfunction.	1. Contact local customer Technical Service 2. Contact local customer Technical Service 3. Contact local customer Technical Service
"Error 7" displayed on screen	1. Emission diode damaged. 2. Current control circuit malfunction.	1 Contact local customer Technical Service 2 Contact local customer Technical Service
"Probe off" displayed on screen	1. The sensor is not connected 2 The connection between the Probe and Oximeter is loose	1. Connect the sensor 2. Please check if the probe was connected with oximeter correctly

5.5.1 Service Method

a）Service hours: 9:00am～5:30pm, Monday - Friday

b）Service support: Telephone and e-mail support.

Parts Replacement: Virtuox will replace parts if necessary free of charge during the warranty period.

5.5.2 Exemptions and limitations:

a) Not responsible for damage caused by force majeure. For example: fire, lightning, flood, cyclone, hail and earthquake.

b) Warranty expiration. The corresponding cost of insurance, disassembling, refurbishing, repackaging and shipping the oximeter or its components

c) Damage caused by a third party

d) Damage and caused by user or its representative not in compliance with the operator's manual.

e) The oximeter is installed or connected with such external device without our company permission as printer, computer, netline and lead to oximeter failure. Our company will charge for the maintenance.

d) Warranty Limitation -

Warranty is void if parts made from other manufacturers are used in the servicing of the device.

5.5.3 User Guarantee

a) User must read user manual carefully before operation.
b) User must operate and perform daily maintenance under manual specifications.
c) Power supply and environment must be maintained under manual specifications.

5.5.4 Circumstances that may void the warranty

- The device does not remain in original condition.
- The shell of the device is breached or cracked.
- Evidence of water damage.
- Accessories adulterated or appearance of physical abuse.
- Evidence of crushing damage to the probe.
- Original Packaging during transportation is not used.
- Non authorized service is performed on oximeter.
- Damage to a product as a result of not conforming to manual specifications.

5.5.5 User's Special Request for Extended Warranty

Our warranty is consistent with industry standards. The device and accessories come standard with a 1 year warranty. An extended warranty can be purchased from Virtuox at the user's request.

Return Policy:

Warranty and non warranty returns should be handled in the following manner:
Contact the Technical Support Department and obtain a RMA (Return Materials Authorization) number.
The RMA number must appear on the outside of the shipping container.
Return shipments will not be accepted if the RMA number is not clearly visible.
Please provide the model number, serial number (SN), and a brief description of the reason for return.

Freight policy:

1. Within Warranty: The customer is responsible for freight & insurance charges when the equipment is shipped to Virtuox for service. Virtuox is responsible for the freight & insurance charges from us to the customer.
2. After Warranty: The customer is responsible for any freight & insurance charges for returned product.

5.5.6 Repackaging for returns

- Place all accessories in a watertight Ziploc bag
- Use original package and packing material if possible. User will be responsible for damage caused by improper packaging during transportation.
- Ensure the RMA number is clearly printed on the Box.
- Include an insert describing the reason for the return.

APPENDIX A Specifications

Notices:

- **Specifications may be changed without prior notice.**
- **The circuit diagrams, the list of components, the illustration of diagrams, and the detailed rules of calibration, are provided exclusively to professional personnel authorized by our company.**

SpO_2
Display Range: 0-100%
Measurement Range: 70%-100%
Resolution: 1%
Accuracy: 80%-100%: ±2%
70%-79%: ±3%
0%-69%: unspecified

Heart (Pulse) Rate
Display Range: 0-254 bpm
Measurement Range: 30-235 bpm
Resolution: 1bpm
Accuracy: ±2bpm or ±2% (the larger is applied)

Alarm
Alarm: Technical alarm and physiological alarm
Modes: Visual and audible
SpO_2: The upper limit: 100%
The lower limit: 60%
PR: The upper limit: 100bpm
The lower limit: 60bpm

Display
Type: OLED, double color
Parameters: SpO_2, PR, SpO_2 plethysmogram waveform, PR bar
Mode: 3 display modes.

Record
Patient ID 1-10
Data record Up to 72 hours

Data transmission
Transmission method: Cable Transmission
Data Cable Interface: DB9 (Connected to Pulse Oximeter)
USB (Connected to PC)

Operation Environment
Operating temperature: 5℃～40 ℃
Relative humidity: ≤80%, no condensation
Atmosphere pressure: 86 kPa～106 kPa
Power supply: Two AA alkaline batteries
Operation time About 50 hours of typical operation

Transport and Storage Environment
Storage Temperature: -20□～55□
Relative humidity: ≤93%, no condensation
Atmosphere pressure: 50 kPa～106 kPa

Classification according to IEC60601-1
Type of protection: Internally powered equipment
Degree of protection: Type B-Applied Part
Mode of Operation: Continuous
Safety: IEC Standard 60601-1
Dimensions: 139mmX44mmX24mm (LXWXH)
Weight: 110g (with alkaline batteries)

APPENDIX B

Guidance and manufacturer's declaration - electromagnetic immunity

Guidance and manufacture's declaration - electromagnetic immunity			
The Handheld Pulse Oximeter is intended for use in an electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance Level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC610004-2	6kV contact 8kV air	6kV contact 8kV air	Floors should be wood, concrete or ceramic tile. If floor are converted with Synthetic material, the relative humidity should be at least 30%

Guidance and manufacturer's declaration - Electromagnetic Immunity for Equipment and Systems that are not Life-Supporting

61000-4-6 Radiated RF IEC 61000-4-3	3V/m 80Hz to 2.5 GHz	d= $\frac{3.5}{V_1}\sqrt{P}$ 80MHz to 800MHz d= $\frac{3.5}{E_1}\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Inter terence may occur in the vicinity of equipment marked with the following symbol.
NOTE1 At 80MHz and 800MHz, the higher frequency range applies. NOTE2 These guideline 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		

situation 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 considered. If the measured field strength in the location in which the Handheld Pulse Oximeter is used exceeds the applicable RF compliance level above, the Handheld Pulse Oximeter should be observed.

Recommended separation distances between portable and mobile RF communications equipment and the Handheld Pulse Oximeter

The Handheld Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Handheld Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Handheld 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)		
	150KHz to 80 MHz $d=\frac{3.5}{V_1}\sqrt{P}$	80MHz to 800 MHz $d=\frac{3.5}{E_1}\sqrt{P}$	800MHz to 2.5 GHz $d=\frac{7}{E_1}\sqrt{P}$
0.01	0.1167	0.1167	0.2334
0.1	0.3689	0.3689	0.7378
1	1.1667	1.1667	2.3334
10	3.6893	3.6893	7.7386
100	11.6667	11.6667	23.3334

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (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.

NOTE1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic interference is affected by absorption and reflection from structures, objects and people.