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Ver1.0

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Content

1. INTRODUCTION

1.1 Brief Introduction

Thank you for purchasing the VirtuOx Freedom GPRS Pulse Oximeter. The main functions of the device are to measure Hemoglobin Saturation (SpO_2) and Pulse Rate (PR) value of single patient and transmit data by GPRS. Please read the instruction manual carefully before using the device.

Note: The illustrations used in this manual may differ slightly from the actual product.

1.2 Safety Information

Warnings, Cautions and Notes

Warning, Cautions and Notes in this document are special information based on users operation.

★**Warning:**
   Indicates there may be a potential for injury to patient or medical professional.

★**Caution:**
   User takes full responsibility toward operating this device in a safe manner and assumes all liability for mis-use of device.

★**Note:**
   Serves as a critical notification for avoiding accidents during application of the device.

⚠ Warnings!

- Before use, please read the manual, directions, and all precautions and specifications carefully. VirtuOx will assume no warranty for using the device in an improper or unsafe manner.
- The user must check that the device is functioning safely and ensure that it is in proper working conditions before each use.

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- Do not use the VirtuOx Freedom in the presence of flammable anesthetics, vapors or liquids.
- Do not use the VirtuOx Freedom in an MRI or CT environment which is the source of some electric noise to influence the accuracy of the equipment and subsequent measurement.
- This equipment is intended only as an adjunct in patient assessment, and the measurement results only serve as a reference for any relevant treatment.
- 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 irritation, and discomfort.
- Connect the sensor correctly; please follow the directions for use of any accessories.
- The sensor is a sensitive device so please strictly follow the sensor application instructions.
- Use only the SpO_2 sensors supplied by VirtuOx. Use of sensors not intended for the device may cause erratic or unuseable data.
- The malfunction of sensor may cause inaccurate measurements and results.
- The disposable accessories should not be re-used.
- The device does not require periodic calibration and maintenance, except replacing batteries.
- When connecting this equipment to other peripherals, make sure that you are qualified to operate this device. Any peripherals must be certified according to the protocol of IEC 950 and IEC 60601-1-2. Any input/output device should be following the protocol of IEC 60601-1-2.

Cautions

- This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in the manual before using the device.
- The surface of the device can be wiped with alcohol gently. Do not use Acids or Strong Alkaline

products such as soaps or many sprays for cleaning.

- Unplug the sensor from the pulse oximeter before cleaning or disinfecting to prevent the sensor or pulse oximeter from being damaged, also protect the user.
- Clean the probe with an H_2O solution and a neutral detergent.
- Don't submerge the device or probe into any liquid. Do not use the device in autoclave (sterilizer).
- The materials that contact with human bodies are all non-toxic.
- If the specification or function of the device is abnormal during measuring, stop measuring immediately and consult us.
- Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Notes
- Application of this device in the background of electromagnetic areas may influence the measurement accuracy such as electro-surgery environment.
- SpO_2 measurement may be adversely affected in the presence of strong ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may adversely affect the accuracy of the SpO_2 measurement.
- Any condition that restricts blood flow, such as using a blood pressure cuff or extremes in systemic vascular resistance, may cause a failure to detect the accurate SpO_2 value and pulse rate.
- Remove fingernail polish or artificial fingernails before applying SpO_2 probes. Fingernail polish or artificial fingernails may lead to inaccurate SpO_2 readings.
- Optical cross talk can occur when two or more probes are located in adjoining area. 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 emission or receiving windows may cause a sensor failure. Make sure there are no obstructions and the sensor is clean.
- Hazards arising from software errors have been minimized. Hazard analysis conforms to meet ISO14971: 2000 and EN60601-1-4: 1996. Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methhemoglobin, will spawn an affection of the accuracy of the SpO$_2$ measurement.
- For routine equipment maintenance, please refer to the service procedures at the specific sections as indicated in the manual.
- 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.
- Dispose of the device or its accessories end of life in accordance with the local ordinances and regulations, otherwise, discarding them as you like may cause pollution to the environment.
- As to other attentions, please carefully look through the specific chapter in this instruction manual.

1.3 Intended Use

This pulse oximeter is a portable, non-invasive device intended for continuous monitoring and transmitting functional arterial oxygen saturation (SpO$_2$) and pulse rate of single adult and pediatric (greater than 3 years of age) patients in hospital and home care. The device is reusable. The normal application site is the finger.

1.4 Electromagnetism Interference

This pulse 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 Explanation of Symbols

Symbol	Meaning
⚠	Attention, consult the accompanying documents.
🚶	Type BF applied part
☔	Protect from rain
🌡 RH≤80% non-condensing	Storage temperature and relative humidity
IPX1	Protected against dripping water
SN	Serial number
〰	Date of Manufacture
SpO$_2$	Haemoglobin Saturation

PR	Pulse Rate
⬜	Battery power indication
G	GPRS data transmission

1.6 Product Features

- ✧ Simple to use and easy to operate.
- ✧ Portable and compact in design.
- ✧ Long-distance data transmission by GPRS or Cellular.
- ✧ OLED display screen.
- ✧ Power off automatically after 30s if no operation and measure are carried out.
- ✧ Low power consumption: the backlight will turn off automatically when there is no operation in 20s.
- ✧ Immediate information on low battery.

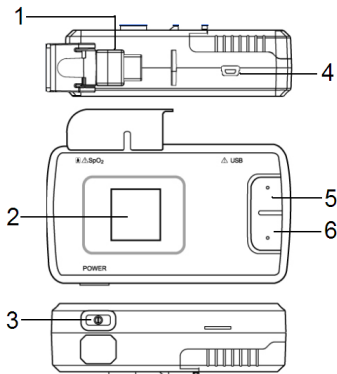# 2. GENERAL DESCRIPTION

2.1 Appearance

Fig.2-1

Description of Fig.2-1

(1) SpO$_2$ Socket: used for connecting SpO$_2$ probe;

(2) Display Screen;

(3) Power Button: Press and hold this button for about 3 seconds to power the device on, and for about 4 seconds to turn the device off.

   When there is no measurement or no press on keys for 30 seconds, "Auto Power Down" displays

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on the screen. And then it will power off automatically.

(4)   USB Interface: used for power charging

(5)   Menu Button: You can enter the menu interface by press this button in the measuring screen, press this button to enter the selected menu item and conform your setting;

(6)   Adjust Button: press this button to select different menu item and adjust its corresponding value;

2.2 Power Supply

The device can be powered by Lithium-ion rechargeable battery. The standard Lithium-ion rechargeable battery (1250mAh) can support the device operation for up to 30 hours of data transmission.

Battery Installation:

(1) Use your thumb to slide the battery cover in the direction of the mark, and lift the end of the cover upwards.

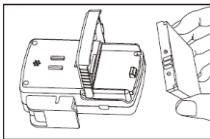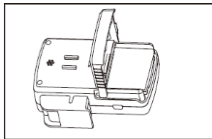Fig.2-2   Fig.2-3   Fig.2-4
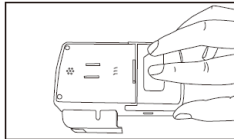
(2) Put the battery into the battery compartment Text facing up .

(3) Carefully re-position the battery cover. Do not force the cover into other place; it fits well only when positioned properly.

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Notes:

- Keep away from source of fire and/or heat;
- Do not disassemble battery and/or battery pack;
- Do not connect the positive and negative pole directly using conductive metal; avoid short circuit;
- Do not put the battery into water or dampness;
- Do not cut the battery;
- Do not strike or poke the battery;
- Charge the battery using specified chargers;
- Do not solder the battery directly;
- Do not use the battery in un-specified application;

Battery Charging:

Power low notification: When the battery indicator becomes a frame with display of "Power low" information, the unit will power off a short time later. You should charge the battery before this occurs.

You can charge the battery by connecting the device to AC power source through the power adapter or to a computer through a USB cable, or a secondary battery charger approved by VirtuOx for the purpose.

3. TAKING A MEASUREMENT

3.1 Sensor Installation

Before use, please connect the sensor/probe to the pulse oximeter as shown in the following figure.
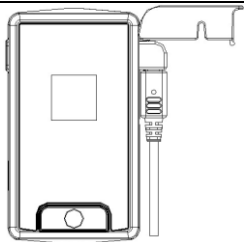
Fig.3-1

3.2 Taking a Measurement

(1) First plug the sensor into the interface of the pulse oximeter.

Ensure that the sensor is plugged in correctly and firmly.

(2) Secondly place the sensor on your finger correctly as shown in Fig.3-2. Be sure to make the finger touches the bottom of the probe and the nail surface is facing upwards as shown.
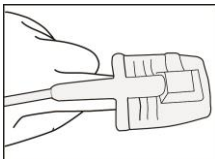
Fig.3-2

(3) After several seconds the following should will appear on the display.
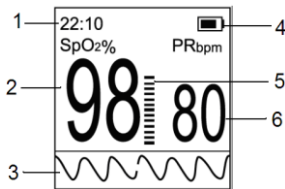
Fig.3-3

Description of Fig.3-3

(1) Current time;

(2) SpO$_2$ value measured;

(3) Blood Oxygen plethysmogram;

(4) Battery charge indicator;

(5) Pulse Bar;

(6) Pulse rate wave graph;

3.3 Factors That May Affect The Measurement

Proper sensor placement is critical for good performance. The following factors may degrade the performance of the pulse oximeter.

Inaccurate measurements may be caused by:

1.Incorrect sensor application, position or use;

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2.Excessive patient movement;

3.Significant levels of dysfunctional hemoglobins (e.g.,carboxyhemoglobin or methemoglobin);

4.Exposure to excessive light such as xenon light sources, bilirubin lamps or direct sunlight (should this occur, cover the sensor and application site with opaque material);

5.Intravascular dyes such as indocyanine green or methylene blue.

Loss of pulse signal may be caused by:

1. Patient is in cardiac arrest or shock;

2. Applying the sensor too tightly or on to large a finger;

3. Inflating a blood pressure cuff on the extremity where the sensor is attached;

4. Patient who has hypotension, severe vasoconstriction, severe anemia or hypothermia;

5. An arterial occlusion proximal to the sensor;

6. Excessive illumination.

Potential adverse events:

The following potential risks may be associated with the use of pulse oximetry sensors. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Swelling or reddening of skin;

2. Burns;

3. Blisters;

4. Pressure sores;

5. Skin removal.

3.4 Applying The Band

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The Band is applied to secure the oximeter around the user's wrist.

Please use the following steps to apply the band securely and comfortably around the user's wrist:

(1). Thread one terminal of the band through one hole of the bracket, make sure the even side faces the oximeter and hook-and-loop fastener back to it.

(2). One the already-threaded terminal of the band, press the hook side onto the loop side to secure them, refer to Fig.3-4.

(3) Thread the other terminal of band through the other hole of the bracket, refer to Fig.3-5.

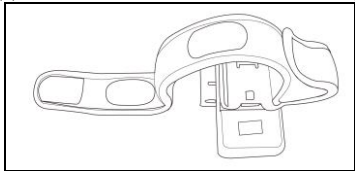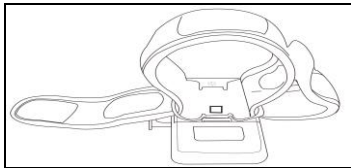Fig.3-4   Fig.3-5

4. SETTINGS

Press and hold this button for about 3 seconds to power the device on, and then press the Menu button to enter the menu interface similar to the one shown in the following Figure (4-1).

Fig.4-1

4.1 Date and Time Setting

The date and time by the Wireless provider, and cannot be set manually.

4.2 Brightness Setting

In the menu interface as shown in Fig.4-1 press the Adjust button to select the brightness icon ☼, and then press the Menu button to enter the brightness set interface, you can change the brightness level by pressing the Adjust button. The setting range is 1~7.

4.3 Battery Setting

In the menu interface as shown in Fig.4-1 press the Adjust button to select the battery icon, and then press the Menu button to enter the battery set interface, you can set the Power Save mode on or off.

Power Save Mode: The screen will darken if no key is pressed for 20 seconds; The light of backlight will be restored whenever there is a key-press.

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4.4 Reading ID Set Mode

In the menu interface as shown in Fig.4-1 press the Adjust button to select the G icon ![G icon], and then press the Menu button to enter the Reading ID setting mode, you can set Reading ID for your patient in this menu.

When entering the RID (Reading ID) be sure to note and record the response from the system sent in BLUE numbers this number should be the selected Patient ID.

4.5 Version Information

In the menu interface as shown in Fig.4-1 press the Adjust button to select the version icon ![version icon], and then press the Menu button to enter the version information interface, you can check the information on version of software.

4.6 Return

You can return to the measurement screen by performing this item.

Note: The system returns to the measurement screen as shown in Fig.3-3 in case keys are pressed for 10 seconds.

5. MAINTENANCE AND CLEANING

Warning!

The advanced circuit inside the oximeter does not require periodic calibration and maintenance, beyond the replacing of batteries. Don't open the cover of oximeter or repair electronic circuits. Its open will cause the damage of the device and void the warranty.

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5.1 Equipment Maintenance

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse any part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

Caution: If you spill liquid on the equipment or accessories, contact us or your service personnel.

Note: To clean or disinfect reusable accessories, refer to the instructions delivered with the accessories.

5.2 Battery Maintenance

Warning!

Dispose of all used batteries in a proper waste disposal according to local applicable regulations.

For detailed information about battery maintenance please refer to chapter *2.2 Power Supply.*

5.3 Preventive Maintenance

The following simple preventive maintenance tasks should be performed monthly to ensure continued performance of the device at maximum capacity, and to reduce the possibility of a failure.

Mechanical Inspection

Check for splits, cracks or imperfections in the case. If you have any questions or doubts, call your VirtuOx.

Do not make any repairs by yourself

Do not attempt to open or disassemble your oximeter, if so you may run the risk of electric shock and void the limited warranty. No user-serviceable parts are inside. Only authorized service personnel may repair the product.

5.4 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your organizations regulations for cleaning the equipment.

Recommended cleaning agents are:

- Mild soap (diluted)
- Ammonia (diluted)
- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

1. Shut down the pulse oximeter and take the batteries out of the battery compartment.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated, cool place.

Cautions:
- Do not allow any liquid to enter the case, and avoid pouring water or other liquid on the device while cleaning.
- Never use abrasives such as wire wool or metal polish.
- During cleaning, make sure you do not expose the device to temperature excess of 40°C.
- Please take out batteries before cleaning the oximeter.

Warnings!

To reduce the chance of shock or injury, do not use your oximeter in or near water or wet locations.
- Keep your oximeter away from sources of liquids, such as drinks, wash basins, bathtubs, shower stalls, and so on.
- Protect your oximeter from direct sunlight and rain or other moisture.
- Take care not to spill any food or liquid on oximeter. If you do, unplug oximeter before cleaning up the spill.
- Depending on what you spilled and how much of it got into your equipment, you may have to send your equipment to VirtuOx for service.

Environment

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- Keep away from extreme heat. Do not leave it on the dashboard of a car or near a heater. Do not leave it in any place that is extremely damp or dusty.
- As this product is not waterproof, do not use it or store it where fluids such as water can splash onto it. Raindrops, water spray, juice, coffee, steam, perspiration, etc. may also cause a malfunction.
- Keep accessories that might be swallowed away from children.

6. TROUBLESHOOTING

Trouble 1: When the probe is not inserted or the probe is defective, the system may prompt user with the information "Probe Off".
Solution 1: Remove and reinsert the sensor or change to a new available sensor.

Trouble 2: When the finger is not inserted into the probe or the probe will not detect any signal, the system may prompt user by the information "Finger Off".
Solution 2: Pull your finger out and reinsert it to make your finger fully contact the inner detector of probe or rub your hands to warm them if your hands are too cool.

When encountering other troubles, please contact our service department.

7. WARRANTY AND REPAIR

7.1 Service Method

a）VirtuOx RMA hours of operation are: 9:00am～8:00pm, Monday to Friday Eastern Standard time.
b）Service support: VirtuOx Offers user telephone and e-mail support and parts change.
Parts change: our company will change parts   when necessary, free of charge during the

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warranty period.

User should send all defective parts back to VirtuOx if not instructed otherwise.

c）Certain Firmware updates will be free of charge.

7.2 Warranty Limitations

a) Our company is not responsible for such damage caused by force majeure. For example: fire, thunder flash, flood, cyclone, hail, earthquake, house collapse, commotion, plane crash and traffic accident, deliberate damage, lack of fuel or water, labor and capital bother, strike and stop-working etc.

b) No-service offer

The corresponding charge and insurance charge of disassembling, refurbishing, repackaging and moving the oximeter or the part of it.

The damage caused by the third party not authorized by our company to adjust, install, replace the parts of the oximeter.

The damage and failure caused by the user or its representative non-compliance with the operator's manual.

c) The oximeter is installed or connected with an external device (eg. printer, computer) without our company's permission and this leads to oximeter failure. In such case our company will charge for the maintenance.

d）Responsibility limitation

During the period of maintenance contract validity, if user changes any parts manufactured by other manufacturers without the permission of our company, our company is entitled to stop the contract.

7.3 User Guarantee

a) Please read the manual carefully before operation

b) The advanced circuit inside the oximeter does not require periodic calibration and maintenance, beyond replacing the batteries.

7.4 No-Warranty Principle

The annulment of the warranty will be caused by following instances:

- There is physical damage to the oximeter and/or its accessories.
- There are liquid leftovers and this has led to short circuit and plugboard failure.
- The probe and accessories are considered consumable and will not be replaced free.
- Damage of probe caused by mechanical force will not be replaced free.
- Oximeter Maintenance seal has been removed.
- Bad packaging leads to oximeter damage during the transportation.
- Oximeter operation by non-professional or without reading the manual first leads to oximeter failure.

7.5 Warranty Period

Our warranty for oximeter complies with electronic product after-sale service standard regulated by national laws. The warranty period of mainboard is one year, and for all the accessories the period is three months.

7.6 Repackaging

- Take all the accessories and put them into plastic bag.
- Try to use original package and packing materials. User will be responsible for such damage caused by bad package during transportation.

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● Please describe failure in detail

7.7 Storage and Transportation

Storage: Storage Temperature -20°C～55°C, Relative Humidity≤93%.
Transportation: Transport by air, train or vessel after packing according to request.

APPENDIX SPECIFICATIONS

Note: The specifications are subject to change without prior notice.

Display

Display Type:	OLED
Display Parameter:	SpO_2, pulse rate, pulse bar, SpO_2 plethysmogram, date and time, power quality indicator and other prompt information.
Data Update Time:	one second interval

SpO_2

Display Range:	0%-100%
Measuring Range:	70%-100%
Measuring Accurate:	70%-100%±3%, ＜70% unspecified
Resolution:	1%

PR

Display Range:	0～255bpm
Measuring Range:	30～235bpm
Measuring Accurate:	±2bpm or 2% (the greater)

Resolution: 1bpm

Operating Conditions

Operating temperature: 5℃～40℃

Relative humidity: ≤80% (non-condensation)

Atmosphere pressure: 86kPa～106kPa

Package & Storage Conditions

Storage temperature: -20℃～55℃

Relative humidity: ≤93% (non-condensation)

Atmosphere pressure: 50kPa～106kPa

Power Supplied

A rechargeable Li-battery with the voltage of 4.2V and battery capacity 1250mAh.

Continuous working time: up to 30 hours of transmitted data.

Power Adapter

Input Voltage: AC 100-240V

Input Frequency: 50~60Hz

Output Voltage and Current: DC 5V/500mA

Model: CN-01C5-1000

Equipment Classification

According to the type of protection against Electrical shock:

        Internal electrical power source equipment;

According to the degree of protection against Electrical shock:

Type BF equipment;

According to the degree of protection against harmful ingress of water:

IPX1;

According to the mode of operation:

Continuous operation;

Dimensions & Weight

Dimensions: 133mmX63mmX33mm (length×width×height)

Weight: 200g (including batteries)

Standard Accessories

- One SpO$_2$ Sensor (model: M-50G)
- One power adapter (5V/500mA) for U.S. standard
- One lithium ion rechargeable battery (1250mAh)
- One USB cable
- One Operator's manual

Optional Accessories

- One auxilliary power adapter (5V/500mA) for U.S standard
- One Spare lithium ion rechargeable battery (1250mAh)
- One piece of wrist band
- One piece Wrist band retainer

Manufactured for: VirtuOx Inc.
5850 Coral Ridge Dr. Ste 304
Coral Springs, Florida 33076