Fingertip Pulse Oximeter

Model : 456 **USER MANUAL**

CE 0120

Introduction

Thank you for purchasing a Prestige Medical® Pulse Oximeter. This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice. The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details. Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults. Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual.

General Overview

Oxygen saturation is a percentage of oxyhemoglobin (HbO_2) capacity, compounded with oxygen, by all combinative hemoglobin (Hb) capacity in blood. In other words, the consistency of oxyhemoglobin in blood. This is an important parameter of the Respiratory Circulation System as many respiratory diseases can result in low oxygen saturation of the blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. These conditions might result in light-headedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that problems can be assessed in a timely manner.

Included Accessories

- Two AAA batteries
- One Nylon Lanyard
- One Protective Silicone Case
- One User Manual

Features

- Simple and convenient operation.
- Small and light weight (total weight is about 50g including batteries).
- Low power consumption with automatic power off (when no signal is detected for 5 seconds).
- Low-battery flash indicator.

Scope of Application

This device is suitable for use with family, hospital (ordinary sickroom), oxygen bar, and other medical organizations.

⚠ This device is not suitable for use in continuous supervision for patients.

⚠ This device is not recommended to be used if the user is suffering from toxicosis (caused by carbon monoxide) as an overrating may occur.

Storage Requirements

- Temperature :-40°C~+60°C
- Relative humidity :≤95%
- Atmospheric pressure :500hPa~1060hPa

Operating Requirements

- Temperature: :10°C~40°C
- Relative Humidity :≤75%
- Atmospheric pressure:700hPa~1060hPa

Safety Information

Indication for Use

The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist / surgery, anesthesia, intensive care, etc.). This device is not intended for continuous monitoring.

Guidelines for Safe Operation

- Check the main unit and accessories periodically to make sure that there is no visible damage that may affect the users safety. It is recommended that this device be inspected at least once a week. When there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by a qualified service engineer only. DO NOT attempt to repair this device youself.
- This device cannot be used together with other devices not specified in this manual. Only use accessories that are recommended in this manual with this device.
- This device is calibrated before leaving factory.

NOTE: Federal law (USA) restricts this unit to sale by or on the order of a licensed practitioner.

Warnings

- DO NOT use this device in environments with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use this device if the user is being measured by MRI or CT.
- DO NOT use this device if you are allergic to rubber.
- The disposal of materials such as batteries, plastic bags, foam and paper boxes should follow local laws and regulations for waste removal.
- Please check the packaging to ensure this device and accessories are totally in accordance with the packing list.
- DO NOT use this device with function test paper.
- Uncomfort or pain may occur if this device is used with users with a microcirculation barrier.
- DO NOT use the same finger with this device for over 2 hours.
- For certain users, a more careful inspection in the placing process is needed. DO NOT use this device on edema and tender tissue.
- The light (the infrared is invisible) emitted from the device is harmful to the eyes. DO NOT stare directly at the light.
- DO NOT use this device if the user has enamel or other makeup.
- DO NOT use this device if the user has a long fingernail.
- Please refer to the literature about the clinical restrictions and caution.
- This device is NOT intended for treatment.

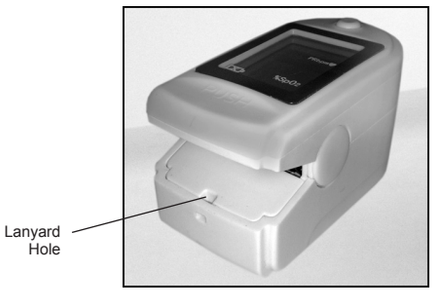
Precautions

- DO NOT expose this device to dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- DO NOT use this device if it gets wet.
- DO NOT use this device immediately if it is transferred from a cold environment to warm or humid environment.
- DO NOT allow sharp materials to come into contact with the front panel.
- DO NOT use high temperature or high pressure steam disinfection of this device. Refer to this manual for instructions of cleaning and disinfection.
- Do NOT emerge this device in liquid. When cleaning, wipe its surface with medical alcohol by soft material. DO NOT spray on this device directly.
- If cleaning this device with water, the temperature should be lower than 60°C.
- Users with fingers which are too thin or too cold may affect the measurement of SpO_2 and pulse rate. In these cases, use of the thumb or middle finger may produce better results.
- DO NOT use this device on infant or neonatal patients.
- This device is suitable for ages four and up (Weight should be between 15kg to 110kg).
- This device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- The update period of data is less than 5 seconds, which may change according to different users pulse rates.
- If abnormal readings appear on the screen during the test process, take the finger out and reinsert to restore normal use.
- The lifecycle of this device under normal use is three years from its first use.
- The lanyard included is made from a non-allergy material, if a user is sensitive to the lanyard, stop use.
- Use of the lanyard around the neck may cause harm.
- This device does not have a low-voltage alarm function, it only shows the low-voltage. Change the batteries when needed.
- This device does not have an alarm function.
- DO NOT use this device in situations where alarms are required.
- Batteries must be removed if the device is going to be stored for more than one month.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

Installation Instructions

Attaching the Lanyard

1. Thread the thin end of the lanyard through the lanyard hole on the unit.
2. Next, thread the thick end of the lanyard through the thin end and pull it tightly.



Notes:
Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.

Do not hang the lanyard from the unit's electrical wire.

Installing the Batteries

1. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
2. Slide the battery door cover horizontally to close.

Notes:
Install the batteries with the correct polarity. Incorrect placement may cause damage to the bracket.

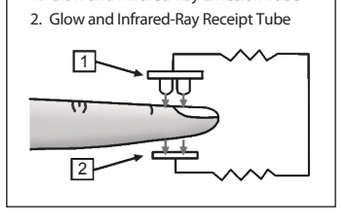
Remove the batteries if the oximeter will not be used for long periods of time.

Functionality and Restrictions

Principle of Measurement

A mathematical formula is established making use of the Beer-Lambert Law according to spectrum absorption characteristics of reductive hemoglobin (RHb) and oxyhemoglobin (HbO_2) in glow and near-infrared zones. Operation functionality: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelengths of light (660nm glow and 940nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measurement is obtained by a photosensitive element and its data is displayed on the front LED panel by use of the unit's internal circuits and microprocessor.

1. Glow and Infrared-Ray Emission Tube
2. Glow and Infrared-Ray Receipt Tube



Clinical Restrictions

- As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a user with weak pulse due to shock, low ambient / body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
- For users with a substantial amount of carbon monoxide hemoglobin (COHb), methionine (Me+Hb) or thiosalicylic hemoglobin, users with icterus problems and users on staining dilution drugs (such as methylene blue, indigo green and acid indigo blue), the SpO_2 readings may be inaccurate.
- Drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may cause reading errors of SpO_2 measurement.
- As the SpO_2 percentage serves as a reference value for the judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also recieve good SpO_2 measurement.

Operating Instructions

1. Open the clamp by pushing down on the end of the unit. (indicated by "PUSH").
2. Insert fingertip fully (facing up) into the opening before releasing the clamp.
3. Press the power button once on the front panel.
4. Keep your finger and body still during measurement.
5. Read corresponding data from display screen.

• The finger should be placed properly (see image), or else it may cause inaccurate measurement.

• The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.

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

• Make sure the optical path is free from any optical obstacles like rubberized fabric.

• Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.

• Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

• Enamel or makeup will cause inaccurate readings.

Maintenance and Storage

- Replace the batteries in a timely manner when the low voltage indicator is lit.
- Clean the surface of this unit before it is used in diagnosis for patients.
- Remove the batteries if the oximeter is not being used for long periods of time.
- It is best to store this unit in temperatures ranging from -40°C to +60°C and in ≤95% humidity.
- Keep the unit in a dry place. Extreme moisture may cause damage to the unit.
- Dispose of the batteries properly. Follow any applicable local battery disposal laws.

Cleaning the Fingertip Pulse Oximeter

- Use a soft cloth dampened with 70% isopropyl alcohol to clean the inside silicone surface of the unit.
- Do not pour or spray liquids onto the unit.
- Do not allow any liquid to enter any openings of the unit.
- Allow the unit to dry thoroughly before use.

Specifications

Classification

Class II b (MDD93/42/EEC IX Rule 10)
Class II (U.S.FDA)

- Display Format: Digital tube Display;
- SpO2 Measuring Range: 0% - 100%;
- Pulse Rate Measuring Range: 30 bpm - 250 bpm;
- Pulse Intensity Display: columniation display
- Power Requirements: 2 ×1.5V AAA alkaline battery, adaptable range: 2.6V~3.6V.
- Power Consumption: Smaller than 25 mA.
- Resolution: 1% for SpO_2 and 1 bpm for Pulse Rate.
- Measurement Accuracy: ±2% in stage of 70%-100% SpO_2, and meaningless when stage is smaller than 70%. ±2 bpm or ±2% (select larger) for Pulse Rate.
- Measurement Performance in Weak Filling Condition: SpO_2 and pulse rate will be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).
- Resistance to surrounding light: The deviation between the value measured in the condition of man-made light or indoor natural light and that of a darkroom is less than ±1%.
- Equipped with a function switch. The Oximeter will power off if no finger is detected in the device for 5 seconds.
- Optical Sensor
  Red light (wavelength is 660nm, 6.65mW)
  Infrared (wavelength is 880nm, 6.75mW)

Declaration

Appendix: Electromagnetism Compatibility

Guidance and Manufacturer's declaration – electromagnetic emissions-
For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic emission		
The 456 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of 456 Pulse Oximeter should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic Environment – guidance**
RF emissions CISPR 11	Group 1	The 456 Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The pulse Oximeter (456) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's declaration – electromagnetic immunity-
For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic immunity			
The 456 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the 456 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) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's declaration – electromagnetic immunity-
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's declaration - electromagnetic immunity			
The 456 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the 456 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment – guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter (456), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection structures, objects and people.			
a Field strengths from fixed transmitters, such as base station 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 Pulse Oximeter (456) should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Pulse Oximeter (456). b Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS - For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and *Pulse Oximeter (456)*		
The Pulse Oximeter (456) is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (456) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (456) 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)**	
	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334
For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Troubleshooting

Problem	Possible reason	Solution
SpO_2% or PR is not displaying correctly	1. Finger is not inserted correctly 2. Patient's Oxyhemoglobin value is too low to be measured.	1. Retry by inserting the finger. 2. Try a few more times. Provided there is not a problem with the unit, consult a physician for a more detailed diagnosis.
SpO_2% or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Finger is trembling or the patient's body is moving.	1. Retry by inserting the finger. 2. Try not to move.
The unit will not power on	1. Battery power is low or batteries are missing. 2. Batteries might be installed incorrectly. 3. The oximeter might be damaged.	1. Replace the batteries. 2. Please reinstall the batteries. 3. Contact local customer
Indication lamps suddenly turn off	1. The product is automatically powered off when no signal is detected longer than 5 seconds. 2. Power level of the batteries is low.	1. This is normal. 2. Change the batteries.

Function Specifications

Display Information	Display Mode
The Pulse Oxygen Saturation(SpO_2)	Digital
Pulse Rate(BPM)	Digital
Pulse Intensity (bar-graph)	Digital bar-graph display

SpO_2 Parameter Specification

Measuring range	0%~100%, (the resolution is 1%).
Accuracy	70%~100%:±2% ,Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 880nm)

Pulse Parameter Specification

Measuring range	30bpm~250bpm (the resolution is 1 bpm)
Accuracy	±2bpm or ±2% select larger

Pulse Intensity

Range	Continuous bar-graph display, the higher display indicate the stronger pulse.

Battery Requirement

Two 1.5V (AAA size) alkaline batteries or rechargeable batteries

Battery Life

Two batteries can work continually for 24 hours

Dimensions and Weight

Dimensions : 57(L) × 31(W) × 32(H) mm

Weight : About 50g (with the batteries)

Symbol Definitions

	Type BF applied part.		Attention, consult accompanying documents.
	Attention / Warning		1. No finger inserted 2. An indicator of signal inadequacy
IPX1	Protected against dripping water.		Battery positive electrode
SpO_2%	Oxygen saturation		Battery cathode
PRbpm	Pulse rate (BPM)		WEEE (2002/96/EC)
	Low power indication		Manufacturer's information
	No SpO_2 Alarm		Date of Manufacture
	Power switch	CE 0120	European union approval
SN	Serial No.	EC REP	Authorized representative in the European community
	Storage temperature and relative humidity		

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

Manufactured for

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