NuvōMed™
HEALTHY LIVING MADE SIMPLE.

TOS-6/0925
Blood Oxygen
Audible Fingertip Pulse Oximeter

Instruction Manual

Please read all instructions carefully and retain for future use

Table of Contents

Introduction

Know your Device

Indications for Use

The 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 minimize 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.

Important Safety Information and Precautions

- Do not attempt to service the 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 to the testing accuracy of the pulse oximeter.
- High-frequency electrosurgical equipment.
- Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or intravascular line
- The patient has hypotension severe vasoconstriction severe anemia or hypothermia.
- The patient is in cardiac arrest or is in shock.
- Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

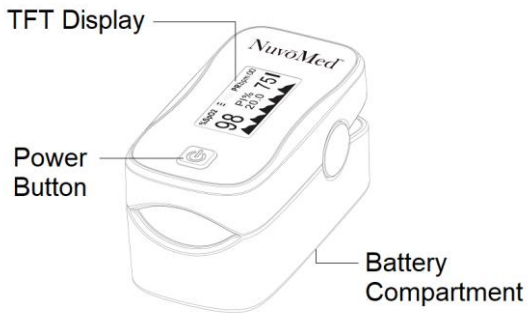
⚠ WARNING

- Do not use this device over a wound, as this can cause further injury.
- This device possible cause improper result due to external interference, such as acceleration during transport or transport in general.
- Do not attempt to modify this device in any way.
- Do not immerse this device in water or clean with cleaning products, alcohol, or solvents. Carefully follow cleaning instructions provided.
- Remove batteries if this device will not be used for three or more months.
- Ensure that the device is used in the environment specified in the EMC declaration in this IM, otherwise, may result in improper operation.
- Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation.
- This electrical medical equipment requires specific precautions regarding electromagnetic compatibility. It must be installed and used according to the electromagnetic information.
- Do not use this device where flammable gases or liquids are present.
- Never drop the device.
- Store this device in a cool, dry place. Do not subject this device to extreme temperatures, humidity, or sunlight. This device might not meet performance specifications if stored or used outside the ranges specified in the "Specifications" section. Keep away from rain.

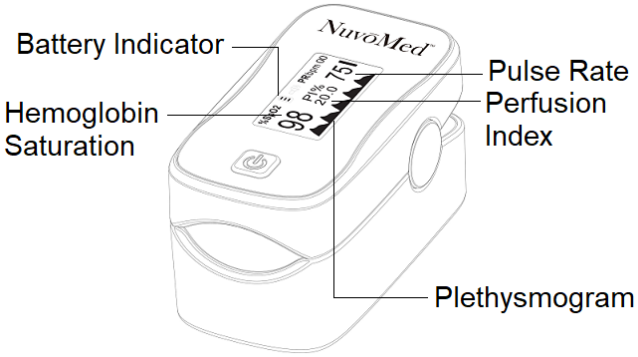
Technical description is contained in the instruction manual.

Preparation

Table 3.1.1 Parts Definition and Description



Name	Description
Power Button	Turn on the machine
TFT Display	Display the SP02 / PR data & Plethysmogram



Note:

- When battery power is at lowest level, the battery capacity indicates symbol of remind users of replacement of battery.
- The plethysmograph can be regarded as correct if the wave is fluctuated regularly.

BATTERY WARNING:

- Do not mix alkaline, stand (carbon-zinc) and rechargeable batteries (nickel hydride).
- Do not mix old and new batteries.
- Non-rechargeable batteries are not to be recharged.
- Rechargeable batteries are to be removed from the unit being charged (if removable).
- Rechargeable batteries are only to be charged under adult supervision (if removable).
- Exhausted batteries are to be removed.
- The supply terminals are not to be short-circuited.
- Only batteries of the same or equivalent type as recommended are to be used.
- Batteries are to be inserted with the correct polarity (see diagram).

Instruction For Use

Set Up Your Device

Battery Installation

1. Press the tab on the battery cover at the back of this device, so as to lift it up and remove.
2. Insert 2 AAA (Included) alkaline batteries according to the +/– markings.
3. Snap the battery cover on, ensuring it clicks into place. Make sure that the battery cover is securely in positon.

NOTE: When the low battery symbol appears on screen, turn off this device and follow the instructions above to replace batteries.

⚠CAUTION

Never leave any low battery in the battery compartment as it may leak and cause damage to this device.

Measurement

Press power button to 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: The oximeter will be automatically powered off when no finger in the device for longer than 16 seconds.

Setting of Parameter

When the device is under measuring interface, press the power button for 1 second in order to entering into Menu Setup (Figure 1).

Menu Setup

Under the Menu Setup, user can short press the power button each time moving the "*" symbol to the back of the SYSTEM SETTINGS, ALM SETTING, SPO2 SETTING or PR SETTING for adjustment.

- SYSTEM SETTINGS (Figure 2)
  Move the "*" symbol to the back of SYSTEM SETTINGS, press the power button for 1 second going to set the MODE, DEMO, BRIGHTNESS & RESTORE. Short press the power button to select the item between MODE, DEMO, BRIGHTNESS & RESTORE.

  MODE - Move the "*" symbol to the back of MODE, long press the power button to select CONTINUOUS or SINGLE measurement (**REMARK:** only SINGLE measurement will give audible read out of the readings for the user after 30 seconds.)

  DEMO - Move the "*" symbol to the back of DEMO, long press the power button to turn it ON/OFF.

  BRIGHTNESS - When the "*" symbol shows behind "BRIGHTNESS", long press the power button each time can change the brightness value from 1 to 5.

  RESTORE - When the "*" symbol shows behind "RESTORE", long press the power button can change to "OK", which causes the device to restore factory data setting.

- ALM SETTING (Figure 3)
  Move the "*" symbol to the back of ALM SETTING, press the power button for 1 second going to set the ALM & BEEP. Short press the power button to select the item between ALM & BEEP.

ALM - Move the “*” symbol to the back of ALM, long press the power button to turn it ON/OFF.
(Note: If the measured value exceeds the maximum or minimum value of SPO2 or PR, there will give off sound when ALM is turned on.)

BEEP - Move the “*” symbol to the back of BEEP, long press the power button to turn it ON/OFF.
(Note: When Beep is turned ON, the sound emitted during the test indicates the pulse rate sound.)

- SPO2 SETTING (Figure 4)
  Move the “*” symbol to the back of SPO2 SETTING, press the power button for 1 second going to set the SPO2 ALM HI, SPO2 ALM LO & +/-. Short press the power button to select the item between SPO2 ALM HI, SPO2 ALM LO & +/-.

  When the * symbol show behind the “+/-”, press direction button for 1 second to change the “+” to “-” or change the “-” to “+”.

  SPO2 ALM HI - Move the “*” symbol to the back of SPO2 ALM HI. With “+” shows on the right side of +/-, long press the power button each time can increase the value to a higher value (until it reaches to the highest).

  SPO2 ALM LO - Move the “*” symbol to the back of SPO2 ALM LO. With “-” shows on the right side of +/-, long press the power button each time can reduce the value to a lower value (until it reaches to the lowest).

- PR SETTING (Figure 5)
  Move the “*” symbol to the back of PR SETTING, press the power button for 1 second going to set the PR ALM HI, PR ALM LO & +/-. Short press the power button to select the item between PR ALM HI, PR ALM LO & +/-.

  When the * symbol show behind the “+/-”, press direction button for 1 second to change the “+” to “-” or change the “-” to “+”.

  PR ALM HI - Move the “*” symbol to the back of PR ALM HI. With “+” shows on the right side of +/-, long press the power button each time can increase the value to a higher value (until it reaches to the highest).

  PR ALM LO - Move the “*” symbol to the back of PR ALM LO. With “-” shows on the right side of +/-, long press the power button each time can reduce the value to a lower value (until it reaches to the lowest).

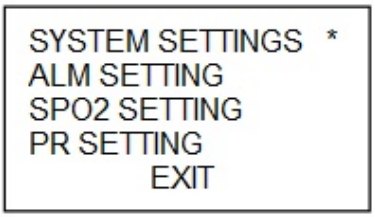


Figure 1

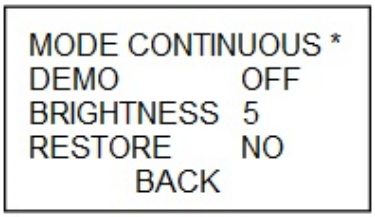


Figure 2

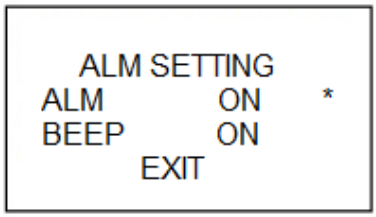


Figure 3

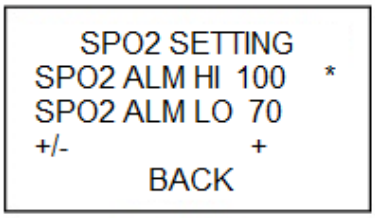


Figure 4

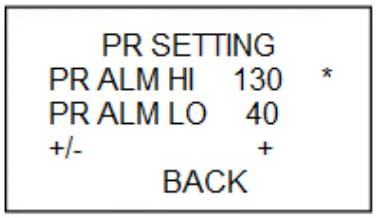


Figure 5

Note:

1. ALM = 1 second delay after the incorrect result being detected.
2. The customer can preset the limit value to the 98 or 99 to check whether it is normal for ALM setting.

Care and Maintenance

- For regular maintenance, this device only needs to be wiped gently with a soft, dry cloth.
- Never immerse this device or any components in water.
- Do not carry out repairs of any kind yourself. If a defect occurs, please contact your local authorized distributor. Use only authorized parts and accessories.

Troubleshooting

Oxyhemoglobin or heart rate not shown normally

Reason: Finger is not plugged correctly OR patient's perfusion is too low to be measured.

Solution: Retry by plugging the finger OR try few times, if you can make sure about no problem existing in the product.

Oxyhemoglobin or heart rate is shown unstably

Reason: Finger might not be plugged deep enough OR finger is trembling or patient's body is in movement status.

Solution: Retry by plugging the finger OR try to let patient keep calm.

Oxyhemoglobin or heart rate is abnormal and causes ALM

Reason: Finger is not plugged correctly OR patient's SPO2 & PR is abnormal.

Solution: Retry by plugging the finger OR go to the hospital for further examination.

The Oximeter cannot be powered on

Reason: Power of batteries might be inadequate / batteries may not be detached fine / batteries might be installed not properly / oximeter might be damaged

Solution: Replace batteries OR re-install batteries

Screen shut down suddenly

This device is automatically powered off when no signal longer than 16 seconds.

Note: Please go to a hospital timely for exact diagnosis.

Specifications

Model		TOS-6/0925
Dimensions		56mm (L) x 30mm (W) x 30mm (D)
Anti-electric Shock Type		Internally Powered Equipment
Anti-electric Shock Degree		Type BF Equipment
EMC		Type B
Mode of Operation		Continuous Operation
Enclosure Degree of ingress protection: IP22		
**IP22 means the outer body of the product can withstand the water dropping to the surface when the body deviate 15 degree from horizontal surface.*		
Power		2 AAA (Included)
Power Consumption		25- 50mA (Normal)
Environmental		
Operating Temperature		About +50~+104°F / +10~ +40°C
Storage Temperature		About .-4~+140°F / -20~+60°C
Relative Humidity		15% - 95% non-condensing
Air Pressure		About 70Kpa to 106Kpa
ALM Limit Default Value		
Parameter		**Value**
Hemoglobin Saturation		Limit: 100 (Upper) 94 (Bottom)
Pulse Rate		Limit: 130 (Upper) 50 (Bottom)
Electronics Parameters		
Parameter		**Value**
Hemoglobin Saturation Display		0-99%
Pulse Rate Display		30-250BPM
Resolution	Hemoglobin Saturation	1%
	Pulse Rate	1 BPM
Measure Accuracy:	Hemoglobin Saturation	± 2% (70% -100%) Unspecified (<70%)
	Pulse Rate	± 3 BPM
PI	Display	0-20%
	Resolution	0.1%
	Measure Accuracy	0-1%: 0.1%
Probe TFT Specification	**Wave Length**	**Radiant Power**
Red	660±2 nm	1.8 mW
Infra RED	905±2 nm	2.0 mW

EMC Declaration

Manufacturer's Declaration of the EMC
Guidance and manufacturer´s declaration – electromagnetic emission –for all EQUIPMENT AND SYSTEMS

Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The user of this device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	This device 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
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the pubic low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Immunity Test	IEC 60601 Test level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV for differential mode ± 2kV common mode	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0° 0 % UT; 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity
– for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

This device is intended for use in the electromagnetic environment specified below. The user of this device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of theA310 Fingertip Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation
Radiated RF IEC 61000-4-3	6Vrms in ISM band between 150 kHz to 80 MHz		Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$
	80 MHz to 2.7 GHz	10 V/m	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz 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 metres (m).b 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 is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations 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 A310 Fingertip Pulse Oximeter is used exceeds the applicable RF compliance level above, the A310 Fingertip Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the A310 Fingertip Pulse Oximeter.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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

Recommended separation distances between portable and mobile RF communications equipment and this device.

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter	Separation distance according to frequency of transmitter		
W	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d 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.

Warranty Information

WARRANTY DURATION: All materials and workmanship are warranted to the original consumer purchaser for a period of ninety (90) days from the original purchase date.

WARRANTY COVERAGE: This product is warranted against defective materials or workmanship. This warranty is void if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, commercial use, repairs by unauthorized personnel or other causes not arising out of defects in materials or workmanship. This warranty does not cover the following which may be supplied with product, including but not limited to; LCD Screens, glass parts, lenses, bulbs etc. This warranty is effective only if the product is purchased and operated in USA, and does not extend to any units which have been used in violation of written instructions furnished by manufacturer or to units which have been altered or modified or, to damaged products or parts thereof which have had the serial number removed, altered, defaced or rendered illegible.

WARRANTY PERFORMANCE: During the above 90 day warranty period, a product with a defect will be either repaired or replaced with a reconditioned comparable model (at manufacturer's option). The repaired or replacement product will be in warranty for the balance of the 90 day warranty period and an additional one-month period. No charge will be applicable for such repair or replacement. SERVICE AND REPAIR: If service is required for this product, you should first contact Nuvomed Inc. Customer Service at info@nuvomed.us or by calling Toll-Free Number 1 (877) 612 5619, Monday to Friday 10am to 6pm EST.

NOTE: Manufacturer cannot assume responsibility for loss or damage during incoming shipment. As a precautionary measure, carefully package the product for shipment, and insure it with the carrier. Be sure to enclose the following details with the product: your full name, return address and daytime phone number, a note describing the problem you experienced, a copy of your sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.
This manufacturer's product warranty extends to the original consumer purchaser of the product. Neither the retailer nor any other company involved in the sale or promotion of this product is a co-warrantor of this manufacturer warranty.

WARRANTY DISCLAIMERS: This warranty is in lieu of all warranties expressed or implied and no representative or person is authorized to assume for manufacturer any other liability in connection with the sale of our products. There shall be no claims for defects or failure under any theory of tort, contractor commercial law including but not limited to, negligence, gross negligence, strict liability, breach of warranty and breach of contract. Under no circumstances will Manufacturer’s / Distributor’s maximum liability exceed the retail value of the product.