MedLinket CE 0123

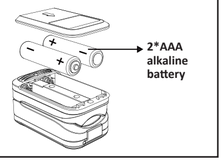
Quick Start Guide

Model: AM801R

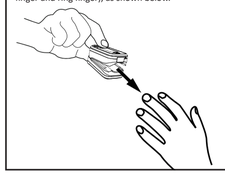
℞Only Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

How to begin?

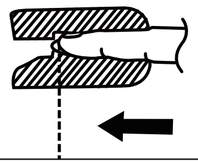
1. Open battery compartment cover and insert two new AAA alkaline batteries as indicated below to ensure the polarity (<+> and <->) of the batteries are correct and then close it.



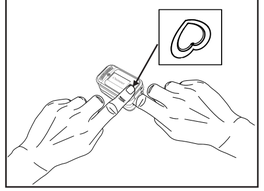
2. Open the clip of the pulse oximeter, insert a finger (The preferred application sites include index finger, middle finger and ring finger), as shown below.



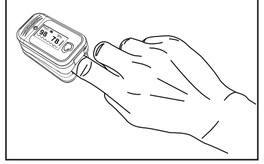
3. Make sure the sensor LED is above the fingernail as shown in the below.



4. Turn on the pulse oximeter by pressing the Power button.



5. Get the information of SpO2 directly from screen display.



Scan the QR Code to download the user manual or watch the instruction video, thanks!

User manual in PDF

English,Spanish

Instruction video

Scan the QR code to watch the instruction video on YouTube!

Instruction for Use

Model: AM801R

CONTENTS

Foreword

The Pulse Oximeter manual is intended to provide information for proper operation and maintenance. General knowledge of monitoring and understanding of the features and functions of the Pulse Oximeter are prerequisites for proper use. Please read these instructions carefully before using this equipment.
The manual describing the operating procedures should be followed strictly. Failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions.
The Pulse Oximeter is a medical device, and can be used repeatedly.

Contraindication

The device can not be used for patients with diseases or conditions including blood microcirculation disorder, excessive staining in the blood, disorders of important hemoglobin indicators and severe arrhythmia.

Warning ⚠

Warnings are identified by the WARNING symbol shown above.
- Explosion hazard. Do not use the PULSE OXIMETER in the presence of flammable anesthetics mixed with air, or with oxygen, or nitrous oxide.
- Do not spray, pour, or spill any liquid on the PULSE OXIMETER, its accessories, connectors, switches.
- Reusable sensors must be moved to a new site at least every 4 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
- At elevated ambient temperatures, patient skin could be severely burned after prolonged sensor application at sites that are not well perfused. To prevent this condition, be sure to check patient application sites frequently. All listed sensors operate without risk of exceeding 41℃ on the skin if the initial skin temperature does not exceed 35℃.
- Be aware that following removal of the sensor from the patient, it is possible that environmental light may cause the monitor device to continue to display a waveform or data values but these data should not be used as a basis for a clinical diagnosis.
- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
- The waste of PULSE OXIMETER must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
- Please refer to the correlative literature about the clinical restrictions and caution.
- This device is not intended for treatment.
- The LCD panel contains toxic chemicals. Do not ingest chemicals from a broken LCD panel.
- Do not modify this equipment without authorization of the manufacturer.

Latex Content Statement

The PULSE OXIMETER is not made with natural rubber latex in any location that may result in patient contact.

About This Manual

The PULSE OXIMETER is to be operated by qualified personnel only. Before servicing this product, read the operator's manual carefully and a thorough understanding of operation.

Section 1- Overview

Intended Use

Med-link Pulse Oximeter with model No. of AM801R is a reusable device intended for spot checking in measuring and displaying functional arterial oxygen saturation (SpO2), pulse rate and respiration rate of patients under non-motion conditions in hospitals, physician's office, clinical settings and home care environment. Application sites include fingers .For SpO2 and pulse rate, it's intended for adults and pediatrics who are well or poorly perfused.For respiration rate, it's intended for adults who are well perfused.

Essential Performance

The essential performance of this device is defined as SpO2 accuracy, pulse rate accuracy and respiration rate accuracy, or an indication of abnormal operation. result of exposure to electromagnetic disturbances that are outside of the environments listed in this Instruction For Use. If such a kind of situation appears, move the device away from the source of electromagnetic disturbances. When there's signal inadequacy, the symbol of "?" will be displayed on the screen, indicating the displayed SpO2 or pulse rate value is potentially incorrect.

About the Pulse Oximeter

The device contains a dual light source (red LED and infrared red LED) and a photo detector. Bone, tissue, pigmentation and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO_2). Because a measurement of SpO_2 is dependent on light from the device, excessive ambient light can interfere with this measurement.

Identification of Front Panel, Left Panel Buttons and Symbols

Refer to the PULSE OXIMETER Operator's manual for a complete description of all buttons, symbols, controls, displays and indicators.

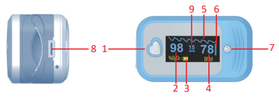


Figure 1: PULSE OXIMETER Front Panel and Left Panel

1—Menu button/Power button	5—PPG (photoplethysmograph)
2—%SpO_2 Display	6—Bar graph (The Pulse Amplitude Indicator)
3—Low Battery indicator	7—Screen turn switch
4—Pulse Rate Display (bpm)	8—Accessories Port Connector
9—Respiration rate（rpm）	

Equipment Symbols

	Type BF (Body Floating) Applied Part		Atmospheric Pressure limitation(Storage, Transportation and Operating)
	Non -sterile		Caution
	Refer to Instruction manual/booklet	-10°C 40°C	Storage & transportation temperature limit
0% 80%	Humidity limitation (Storage, Transportation and Operating)	5°C 40°C	Operation temperature limit
IPX2	Protected against vertically falling water drops when enclosure tilted up to 15°	10	Environment-friendly use period
	No SpO2 Alarm	LOT	Batch Code
	Compliance with WEEE Standard	CN	Date of Manufacture
MR	MR unsafe	#	Model number
MD	Medical device	UDI	Unique Device Identifier

Technical Specifications

Pulse Oximeter	
SpO_2 Range	70% to 100%
SpO_2 Resolution	1%
SpO_2 Accuracy (under good & low perfusion)	90% to 100% range: ±2%; 70% to 89% range: ±3% <70%: unspecified; complies with EN ISO80601-2-61
Low perfusion index	≤0.3%
Reminder	Battery-low indicator
Method	Dual wavelength LED
Pulse Rate Range	30 to 245 bpm
Pulse Rate Resolution	1 bpm
Pulse Accuracy (under good & low perfusion)	±3 bpm
Respiration rate range	4-70 RPM
Respiration rate resolution	1RPM
Respiration rate accuracy	±1 RPM (mean error); 2 RPM (ARMS)
LED Wavelengths	Red: approximately 660nm; Infrared: approximately 905nm
Optical output power	Less than 15mW
Power Supply Requirements Note: The Oximeter does not include batteries.	
Batteries	1.5V (AAA) alkaline batteryX2 (IEC Type LR03)
Adaptable Range	2.6V～3.6V
Operating Current	Less than 55mA
Display Parameters	SpO2, Pulse Rate, Pulse Waveform Display, Bar Graph and Battery Indicator and Respiration Rate
Data Update Period	8s
Reminder Response Time	<2s
SpO_2 plethysmogram, pulse sound	50Hz
Value of Pulse and SpO_2	1Hz
Environment	
Operating environment	Temperature 41°~104°(5℃~40℃), humidity ≤80%
Transportation and Storage environment	Temperature 14°~104°(-10℃~40℃), humidity ≤80%
Hyperbaric Pressure (Storage, Transportation and Operating)	86kPa～106kPa
Classification	
Medical device	Class Ⅱ a by EU Directive 93/42/EEC
Protection Against Liquids	IPX2
Dimension and Weighting	Weight: 31.5g (Not including batteries), Size: 61*34*30.5mm
Compliance	
Item	**Compliant with**
Equipment classification	Safety Standards: IEC 60601-1:2012, EMC: IEC 60601-1-2:2014
Type of protection	Internally powered equipment (on battery power)
Degree of protection	Type BF Applied part
Mode of operation	Continuous
Front panel and case labeling	ISO15223-1

Pulse oximeter	ISO 80601-2-61:2017
Compatibility	The surface material complies with ISO 10993-5:2009, ISO 10993-10:2010 and has no harm or toxicity for the person in contact.

Product parts

As shown in the figure below, the Pulse Oximeter is mainly composed of main unit, menu button, screen turn switch, display screen, applied part, battery cover and lanyard.

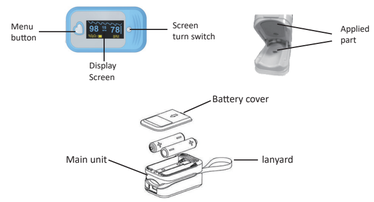


Figure 2: equipment

Principle of Measurement

The measurement of PULSE OXIMETER uses a multi-functional oxyhemoglobinometer to transmit some narrow spectrum light bands through blood samples, and to measure attenuation of spectrum with different wavelengths according to the characteristic that RHb, O2Hb, Met Hb and COHb absorb the light of different wavelength, thereby determining O2Hb saturation of different fractions. O2Hb saturation is called "fractional" O2Hb saturation.

$$\text{Fractional } O_2Hb \text{ saturation} = \frac{O_2Hb}{RHb+O_2Hb+MetHb+COHb} \times 100$$

Oppositely, pulse oxygen oximeter measure functional O_2Hb saturation:

$$\text{Functional } O_2Hb \text{ saturation} = \frac{O_2Hb}{RHb+O_2Hb} \times 100$$

Present SpO2 oximeter transmits light of two wavelengths only, red light and infrared, to differentiate HbO2 from HbR. One side of the sensor contains two LEDs, and the other side contains a photoelectric detector. SpO2 oximeter measures HbO2 saturation in the blood by the light plethysmograph when the pulse beats. The result is quite precise when HbO2 saturatiion is between 70% to 100%. For respiration rate, it is provided through the same mechanism of action as SpO2 measurement. It is provided by first applying a SpO2 sensor which is embedded in

the pulse oximeter to the application site (e.g. finger). The SpO2 sensor then detects the physiological variations which result in the variation in the absorption of the wavelength that are signals used to display the pleth. The detected physiological signals are then processed to identify the cyclic variations associated with the expression of the respiration rate upon the pleth. And those cyclic variations are further processed to estimate the respiration rate which is then displayed.

Clinical Restrictions

1) As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of the testee is required. For a testee with weak pulse due to shock, low ambient, major bleeding, or use of vascular contracting drug, the SpO_2 waveform will decrease. In this case, the measurement will be more sensitive to interference.
2) For those with a substantial amount of staining dilution drug such as monoxide hemoglobin (COHb), or methionine (MetHb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO2 determination by this device may be inaccurate.
3) The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measure.
4) The SpO_2 value serves only as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop using.
- When it is carried from cold environment to warm and humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User's Manual for instructions of cleaning and disinfection.
- Do not have the oximeter immersed in liquid. When it needs cleaning, please wipe its surface with disinfect solution by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be less than 60℃.
- Measurements are recommended to be carried out in sitting, standing or supine position instead of prone or lateral position that may affect measurement accuracy.

Unpacking and Inspection

Remove the equipment of PULSE OXIMETER from the shipping carton and examine for signs of shipping damage. Please check all materials against the packing list. Save the invoice, bill of lading and all packing materials. These may be required if it is necessary to process a claim with the carrier.
If anything is missing or damaged, please contact the Technical Service Department.

You can contact by:
- Phone: +86 755 61120085
- Fax: +86 755 61120055
- Email: user07@med-linket.com

Included in the package

Description	Qty
PULSE OXIMETER (equipment)	1 Piece
PULSE OXIMETER Operator's Manual	1 Piece
lanyard	1 Piece

Section 2- Operation

Installation and Verification

- **Battery installation**

Caution: The Pulse Oximeter does not operate with dead batteries and can not be powered by external power source. Install new batteries.

1. Unplug all accessories from the Pulse Oximeter, and press the menu button to access the Setting Interface, turn the PULSE OXIMETER off. See table 1.
2. Remove the battery cover out from the bottom of the PULSE OXIMETER. See Figure 3.
3. Insert two "AAA" size batteries, making sure the battery's positive and negative poles are correctly oriented in the compartment as shown in Figure 3.
4. Closing the battery rear cover.

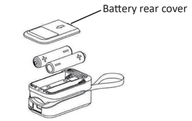


Figure 3: Installing Batteries

⚠ **WARNING:** Explosion hazard. Do not use the PULSE OXIMETER in the presence of flammable anesthetics mixed with air, with oxygen, or nitrous oxide.

WARNING: To ensure accurate performance and prevent device failure, do not expose the PULSE OXIMETER to extreme moisture such as rain.

- **Performance Verification**

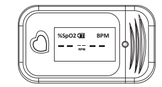
1. Performance Tests
The power-up performance test verifies that the PULSE OXIMETER is ready for patient monitoring.
2. Power-On Self-Test
Before using the PULSE OXIMETER, you must verify that the PULSE OXIMETER is working properly and is safe to use. Proper working conditions are verified each time when the PULSE OXIMETER is turned on as described in the following procedure. The verification procedure (POST) takes 2 to 3 seconds to complete.

Caution: If any indicator or display element does not light when the PULSE OXIMETER is turned on, do not use the PULSE OXIMETER. Instead, contact qualified service personnel, your local MED-LINKET representative, or MED-LINKET's Technical Services Department.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the PULSE OXIMETER's ability to detect and show measurements, including dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

Note: The Pulse Oximeter automatically starts the Power-On Self-Test (POST) to ensure that its internal circuits are functioning properly.

Procedure
1) Turn on the PULSE OXIMETER by pressing the Menu button.
2) After the device completes the Power-On Self-Test (POST), it will directly switch to measure interface.



3) Long press the button to switch device interface of PULSE OXIMETER, adjustment parameters. See table-1.

Low perfusion test

SpO2 simulator is used to simulate SpO2 and pulse rate values to verify oximeter's performance under low perfusion condition. First, the oximeter is clamped onto the optical signal generator of the SpO2 simulator, then the simulator is turned on to set specific SpO2 and pulse rate values. In addition, different perfusion levels like 0.1% can also be set on the simulator. The values of SpO2 and pulse rate displayed on the oximeter are then compared to those preset on the SpO2 simulator to verify whether accuracy requirements can be met.

General Operation

The PULSE OXIMETER can be measure functional oxygen saturation in the blood, pulse rate and respiration rate by itself. See table-1.

- **Preparative for operating**

1) Open up battery compartment cover carefully and then install two "AAA" Alkaline batteries according to the (+/-) polarity.
2) Press the "power switch" key for 1 second to activate the device.

- **SpO_2 ,pulse rate and respiration rate**

1) Open the clip of PULSE OXIMETER, See figure 4.①.
2) Place a finger on the silicone pad. The recommended application sites include index finger, middle finger and ring finger. Appropriate fingers for accurate measurements are within a size range of 8.5-24.3mm thick.
Ensure the finger position is correct that the LED (irradiancy) window against finger prominence and the accepting window against finger lunula), see figure 4.②, and then clip the finger, see figure 4.③.
3) Turn on the PULSE OXIMETER by pressing the Power button "⏻"
4) Get the information of SpO_2 ,pulse rate and respiration rate directly from screen display.

① ② ③

Figure 4: measurement

Note:
1. The detail of setting see table - 1.
2. When put finger into the silicone cushions of the clip, make sure nail is upturned.

- **Switch Screen turn switch**

1) Press the Screen turn switch, See figure 5.

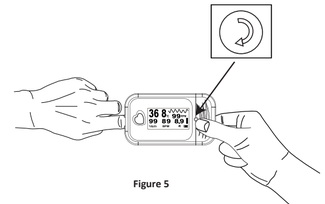


Figure 5

2) There are eight display modes for your choice, See Figure 6. Figure 6.①-Figure 6.⑨ display SpO_2 and pulse rate.

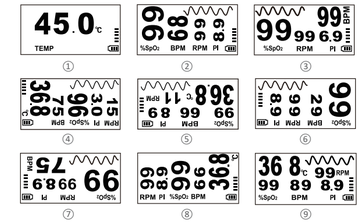


Figure 6

Safety

1) Safety

Instructions for safe operations
- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected once a week at least. Please stop using the device when there is obvious damage.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User's Manual. Please use the device recommended by Manufacturer.
- At elevated ambient temperatures, patient skin could be severely burned after prolonged sensor application at sites that are not well perfused. To prevent this condition, be sure to check patient application sites frequently. All listed sensors operate without risk of exceeding 41℃ on the skin if the initial skin temperature does not exceed 35℃.

- Please remove the finger from the equipment to stop measure and pull the accessories from the equipment, then the PULSE OXIMETER will power off automatically within 8 seconds if the equipment must be closed for the urgent status.

2) Warnings ⚠

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the testee is under measurement of MRI and CT.
- Be cautious of the hanging rope. Please do not break the hanging rope during usage to avoid device damage. Please don't use hanging rope if allergic to hanging rope.
- Please don't use this product if you are allergic to silica gel and ABS plastic.
- Please dispose the device, accessory and packing (including plastic bag, foam and carton) according to local law.
- It's not an apnea monitor and should not be used for arrhythmia analysis.
- The device should not be used on patients with severe arrhythmia (defined as three or more events of irregularity observed within 30 seconds) because the presence of these irregular cardiac rhythms may cause inaccurate values or the loss of displayed information. Safety and effectiveness of SpO2, pulse rate and respiration rate in patients with significantly irregular cardiac rhythms (such as but not limited to supraventricular tachycardias, ventricular ectopy) have not been established. Use an alternate means of monitoring ventilatory status for patients with significant cardiac dysrhythmia.

3) The attention of Operation

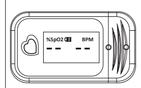
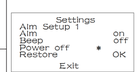
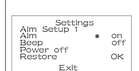
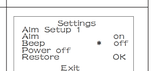
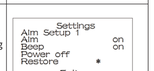
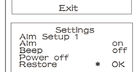
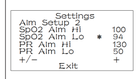
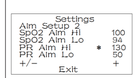
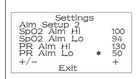
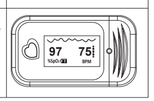
- The equipment should be fully tested to see if it can be used normally before using.
- The finger should be placed properly (see figure 4 of this manual), or else it may cause inaccurate measurement.
- The SpO2 sensor and photoelectric receiving tube should be arranged in a way with the testee's arteriole in a position in between.
- The device should not be used at a location or limb tied with arterial canal or blood pressure cuff of receiving intravenous injection.
- Make sure the optical path is free from any optical obstacles like rubberized fabric; otherwise it may result in venous pulsation and inaccurate measure of SpO2.
- 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 testee or extreme electrosurgical interference may also affect the accuracy.
- Testee cannot use enamel or other makeup.
- Please clean and disinfect the device after operating according to the user manual.
- The calculation of respiration rate may be affected by factors such as exercise, environmental interference and low perfusion level, which may result in a large deviation of calculation results.

Function Setting Introduction

Press the Pulse Oximeter Menu button to power on and access to the testing interface, or press the Menu button repeatedly during normal operation sequentially switch parameter-setting interfaces to set up the parameters and then return to the POST display. Settable parameters include high and low SpO2 limit, high and low bpm limits, high and pulse beep volume.
The device will power off automatically within 8 seconds when there is no any signals input, and users can also use the menu button under parameter-setting interfaces to turn the PULSE OXIMETER off.

Menu Setting

Table 1：Instruction for Menu setting

Function	Instruction for operation	Figures
Power “on” and “off”	● **Power on** Turn on the PULSE OXIMETER by pressing the Menu/Power button “ ”. ● **Power off setting** Short press the button, move the cursor to select the item of “power off”, and then long press the button to turn the power off. **Note:** The device will power off automatically within 8 seconds when there is no any signal input.	
Setting enter and exit	**Setting enter** Long press the button to enter the interface of settings. The setting interface of PULSE OXIMETER includes “Alm Setup 1”, “Alm Setup 2” and “Sounds Setup”. **Exit PULSE OXIMETER setting interface** ● Short press the button, move the cursor to select the item of “Exit”, long press the button return to the POST display.	
“Alm” on or off setting	**“Alm” on or off setting** ● Short time presses the menu button to enter the interface of settings of “Alm Setup 1”. Move the cursor select the item of “Alm”, and then long press the button turn the functions on or off. ● Short press the button, move the cursor to select the item of “Exit”, and then long press the button return to the POST display.	
“Beep” on or off setting	**“Beep” on or off setting** Short press the button, move the cursor to select the item of “Beep”, and then long press the button to turn the functions on or off.	
Default setting	**Default setting** Short press the button, move the cursor to select the item of “Restore”, then long press the button to returns the PULSE OXIMETER to factory default setting. After completing the setting, the interface will indicate “OK”. Move the cursor to select the item of “Exit” by short press the button, and then long press the button to return to the POST display.	 
SpO_2 High Limit setting	**SpO_2 High Limit setting** Long press the button to enter the interface of settings of “Alm Setup 2”. Short press the button, move the cursor to select the item of “SpO2 Alm Hi”, long press the button to adjust the parameter of SpO2 in the scope of 52% to 100%. The default upper limit is 100%.	
SpO_2 Low Limit setting	**SpO_2 Low Limit setting** Short press the button in the interface of “Alm Setup 2”, move the cursor to select the item of “SpO2 Alm Lo”, long press the button to adjust the parameter of SpO2 in the scope of 50% to 98%. The default lower limit is 94%.	
Pulse Rate (PR) High Limit setting	Short press the button in the interface of “Alm Setup 2”, move the cursor to select the item of “PR Alm Hi”, long press the button to adjust the parameter of BPM in the scope of 32-245bpm. The default upper limit is 130 bpm.	
Pulse Rate (PR) Low Limit setting	Short press the button in the interface of “Alm Setup 2”, move the cursor to select the item of “PR Alm Lo”, long press the button to adjust the parameter of BPM in the scope of 30-243bpm. The default lower limit is 50bpm.	
Return to the POST display	After completed above setting, press the button switch to any interface of setting, move the cursor to select the item of “Exit” to return to the POST display.	

Warning

- Uncomfortable or painful feeling may appear if use the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 4 hours.
- For the special patients, there should be a more prudent inspecting in the placing process. The device cannot be clipped on the edema and tender tissue.
- The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.
- Testee cannot use enamel or other makeup.
- Testee’s fingernail cannot be too long.
- Please refer to the correlative literature about the clinical restrictions and caution.
- This device is not intended for treatment.

- The user is not allowed to repair the equipment. Changes or modification not expressly approved by Shenzhen Med-link may void the warranty.
- Removing the batteries to avoid battery leakage and device damage if long time no use.

Note: The device has No Alarm System, just only warning signal is provided.

- The symbol of “?” will be displayed on the screen when there’s signal inadequacy, indicating the displayed SpO2 or pulse rate value is potentially incorrect.

Section 3- Troubleshooting

This section explains how to troubleshoot the PULSE OXIMETER. Tables list possible PULSE OXIMETER difficulties, along with probable causes, and recommended actions to correct the difficulties. Detailed see table 2 as below.

Table 2：Instruction for Menu setting

Phenomena	Possible Causes	Solutions
Abnormal booth of Pulse-Oximeter (display screen and transmitting tube of LCD presenting lights off）	The power button is not pressed in place	Re-press the power button in place, and keep 1-2 seconds
	Not Install battery	Install battery
	Battery use-out	Replace battery
	Install battery improperly Partial damage of Metal dome (which is directly connected to the battery).	Check and re-install battery Contact authorized distributors
	Damage in Connection between mainboard and battery holder (i.e. Damage in flexible printed circuit board (FPCB) or break in soldering spot).	Contact authorized distributors
No display on screen, but the transmitting tube of LED lights on.	With damage in display screen or break in the connection spot of display screen	Contact authorized distributors
No reading display on Pulse-Oximeter	Poor perfusion problem (generally, oscillator intensity has no display on screen, while the transmitting tube of LCD presenting lights on, and the finger insert in place)	If the oscillator intensity has no display on screen. Please, Adjust the finger position; Use your middle or index finger in preference; Warm your fingers;
	The transmitting tube of LED lights off	Contact authorized distributors
Fail auto-off	Damage in collection tube or other device parts.	Contact authorized distributors

- **Guidance & Declaration - Electromagnetic Immunity**

Section 4- Electromagnetic Environment

Electromagnetic Interference Caution

This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2 and MDD 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), 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 Fingertip pulse oximeter is not designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the device may not seem to operate correctly.

Electromagnetic Environment

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

Warning:

PULSE OXIMETER should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, PULSE OXIMETER should be observed to verify normal operation in the configuration in which it will be used.

Table 3—Declaration electromagnetic emissions

PULSE OXIMETER is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter probe should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The PULSE OXIMETER uses RF energy 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 is suitable for use in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Table 4—Guidance & Declaration — electromagnetic immunity

The PULSE OXIMETER is intended for use in the 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) IEC 61000-4-2	±8 kVcontact ±2 kV,±4kV, ±8 kV, ±15 kV air	±8kVcontact ±2 kV,±4kV±8 kV ±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 %.
Radiated RF Electromagnetic Fields IEC61000-4-3	10 V/m 80MHz to2.7GHz 80% AM at 1kHz	10 V/m	
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Section 5- Measurement Validation

The SpO2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-Oximeter. In a controlled desaturation study, healthy adult volunteers with saturation levels between 70% and 100% SaO_2 were studied.

Subject Demographics

The population characteristics for those studies as follow table 5

Table 5—PULSE OXIMETER Clinical study Subject Demographics Record.

Subject #	Gender	Age	Height (cm)	Weight (kg)	Skin Tone	Remark
1#	M	31	160	70	Light	Asian (Chinese)
2#	M	24	165	55	Light	Asian (Chinese)
3#	F	22	160	45	Light	Asian (Chinese)
4#	M	29	175	60	Medium Dark	Asian (Chinese)
5#	F	22	160	49	Light	Asian (Chinese)
6#	F	19	160	45	Light	Asian (Chinese)
7#	F	21	162	54	Light（White）	Caucasian
8#	M	34	192	102	Light（White）	Caucasian
9#	F	27	178	58	Light（White）	Caucasian
10#	M	23	178	78	Dark dark	African
11#	F	24	174	80	Dark dark	African
12#	M	26	169	65	Dark dark	African

Points analyzed	Sres (%)	Standard deviation	Bias	95% limits of agreement	# of Mean±2SD	# beyond the 95% limits of agreement	within-subject variance(σ^2)	within-subject variance(σ_w^2)
241	1.93	1.90	0.30	-3.44, 4.05	10	12	2.47	1.12

Furthermore, the Respiration Rate accuracy performance of the Med-link oximeter has been evaluated during non-motion conditions as compared to the respiration rate of the ETCO2 monitoring. The final analysis was performed on 218 data points collected across 33 adult subjects, with subjects in sitting or supine position. The results showed the Shenzhen Med-link Pulse Oximeter to have a mean error of -0.19 and an Arms of 1.05 during steady state conditions over the range of 4-45BPM.

Subject Demographics:

The population characteristics for the studies are shown in Table 8 below.

Subject #	Gender	Age	Height(cm)	Weight(kg)	Skin Tone	Remark
01	Male	49	158	64	Yellow / Asia	hospitalized volunteer
02	Female	55	149	50	Dark / Asia	hospitalized volunteer
03	Female	44	160	39	Light / Asia	hospitalized volunteer
04	Female	56	wheelchair[2]	wheelchair[2]	Yellow / Asia	hospitalized volunteer
05	Male	50	166	64	Yellow / Asia	hospitalized volunteer
06	Female	58	flat car[1]	flat car[1]	Yellow / Asia	hospitalized volunteer
07	Male	24	165	65	Yellow / Asia	healthy volunteer
08	Female	26	150	42.5	Yellow / Asia	healthy volunteer
09	Female	24	166	53	Light / Asia	healthy volunteer
10	Male	24	167	55	Yellow / Asia	healthy volunteer
11[1]	Male	58	162	49	Yellow / Asia	hospitalized volunteer
12	Male	29	170	67	Yellow / Asia	healthy volunteer
13	Female	40	156	65	Yellow / Asia	hospitalized volunteer
14	Female	25	155	50	Yellow / Asia	healthy volunteer
15	Male	25	175	80	Yellow / Asia	healthy volunteer
16	Female	24	162	56	Dark dark/ Africa	healthy volunteer
17	Female	30	161	50	Dark dark/ Africa	healthy volunteer
18	Male	22	170	80	Yellow / Asia	hospitalized volunteer
19	Male	54	160	48	Yellow / Asia	hospitalized volunteer
20	Male	49	170	38	Dark / Asia	hospitalized volunteer
21	Male	55	162	55	Yellow / Asia	hospitalized volunteer
22	Male	54	166	67	Yellow / Asia	hospitalized volunteer
23	Male	28	168	58	Yellow / Asia	healthy volunteer
24	Male	28	168	52	Yellow / Asia	healthy volunteer
25	Female	55	160	68	Yellow / Asia	hospitalized volunteer
26	Female	51	165	82	Yellow / Asia	hospitalized volunteer
27	Female	43	165	80	Yellow / Asia	hospitalized volunteer
28	Male	57	168	52	Yellow / Asia	hospitalized volunteer
29	Female	37	153	47.5	Yellow / Asia	hospitalized volunteer
30	Female	47	154	60	Yellow / Asia	hospitalized volunteer
31	Male	51	171	72	Yellow / Asia	hospitalized volunteer
32	Male	43	170	54	Yellow / Asia	hospitalized volunteer
33	Female	29	flat car[1]	flat car[1]	Yellow / Asia	hospitalized volunteer
34	Male	53	170	60	Yellow / Asia	hospitalized volunteer

ARMS Results:

The final analysis was performed on 218 data points collected across 33 subjects. The respiration rate accuracy performance of each pulse oximeter combination is identified below.

$$Arms = \sqrt{\frac{\sum_{i=1}^{n}(DUT_i - \mathrm{Re}\,f_i)^2}{n}}$$

Itrm	4--45	4--<10	10--<20	20--<30	30--<40	40--45
#pts	218.00	34	61	59	44	20
Bias	-0.19	0.53	-0.08	-0.20	-0.57	-0.85
Arms	1.05	0.91	0.80	1.13	1.08	1.53
Max diff	2.00					
Min diff	-3.00					

b) Bland-Altman Plot Comparing the respiratory rate Difference of the Pulse Oximeter to the Reference EtCO2 monitor During Non-Motion Conditions

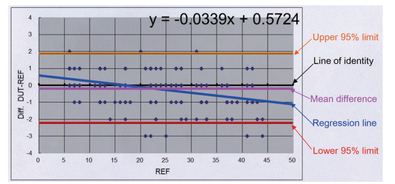


Figure 9—Brand-Altman difference chart analysis compares the consistency of DUT and REF respiration rate values

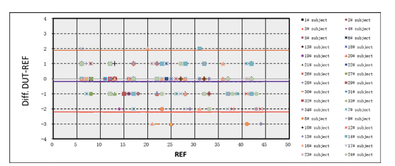


Figure 10—Brand-Altman difference chart analysis and compaison of DUT and REF respiration rate values (using the scattered points of different signs to represent the corresponding subjects)

Points analyzed	Sres	Standard deviation	Bias	95% limits of agreement	# of Mean ±2SD	# beyond the 95% limits of agreement	# of exceeding ±2	within-subject variance (σ2)	between-subject variance (σy2)
218	1.06	1.04	-0.19	-2.22,1.87	10	10	6	1.066	0.004

Graphs

a) Scater Plot of the respiratory rate data of AM-801 Temp-Pulse Oximeter to the Reference EtCO2 monitor During Non-Motion Conditons.

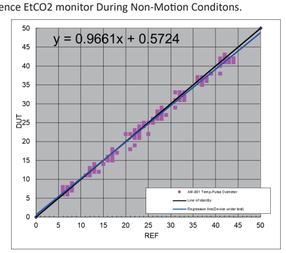


Figure 7—Scatter plot analysis to compare the difference between DUT and REF respiration rate values During Non-Motion Conditions

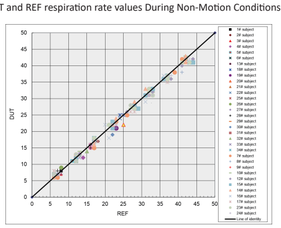


Figure 8—Scatter plot of analysis to compare the difference between DUT and REF respiration rate values During Non-Motion Conditions (using the scattered points of different signs to represent the corresponding subjects)

Where:
ARMS is the accuracy root mean square.
DUT is the respiratory rate value measured by the device under test readings during sample i.
Ref is the respiratory rate value measured by the EtCO2 monitor reading during sample i.
n is the number of points.

Compared to Reference respiratory rate value measured by the EtCO2 monitor	respiratory rate 4-45BPM ARMS	# of Points	Specification 4-45BPM ARMS
AM-801 Temp-Pulse Oximeter	1.05	218	Pass ARMS of 2

ARMS Results:

The final analysis was performed on 241 data points collected across 12 subjects. The SpO_2 accuracy performance of each pulse oximeter and sensor combination is identified below.

$$Arms = \sqrt{\frac{\sum_{i=1}^{n}(SpO2_i - SaO2_i)^2}{n}}$$

Where:
ARMS is the accuracy root mean square.
SpO2 is the test pulse oximeter readings during sample i.
SaO2 is the Average Reference CO-Oximeter functional oxygen saturation reading during sample i.
n is the number of points. The detail of the ARMS Results is below table 6 and table 7.

Table 6—Overall Average Root Mean Square (ARMS) for PULSE OXIMETER in the SpO_2 range of 70%-100%.

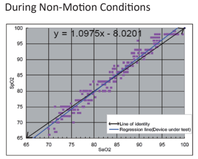
Compared to Avg. Reference CO-Oximeter, Functional SaO_2 Apr 6-8, 2012	Functional SaO_2 70-100% ARMS	# of Points	Specification 70-100% ARMS
PULSE OXIMETER	1.92	241	Pass ARMS of 3

Table 7—ARMS values measured by using PULSE OXIMETER in a clinical study.

Compared to Avg. Reference CO-Oximeter, Functional SaO_2 Apr 6-8, 2012	SaO_2 ranges of 70-80% ARMS	SaO_2 ranges of 80-90% ARMS	SaO_2 ranges of 90-100% ARMS
PULSE OXIMETER	2.20	1.87	1.66

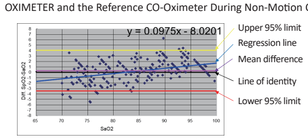
Graphs

a) Scatter plot of the data of PULSE OXIMETER to the Reference CO-Oximeter During Non-Motion Conditions



Item	70-100	90-100	80-<90	70-<80
# pts	241	80	82	79
Bias	0.30	1.09	0.61	-0.80
ARMS	1.92	1.66	1.87	2.20
Max diff	6.30			
Min diff	-5.50			

b) Bland-Altman Plot Comparing the SpO_2 Difference between the PULSE OXIMETER and the Reference CO-Oximeter During Non-Motion Conditions



Section 6- Service and Maintenance

Cleaning and Disinfecting

1. Clean the surface of the oxmeter by using a soft cloth dampened with either a commercial, non-abrasive cleaner or a solution of 70% isopropyl alcohol in water, and wiping the surfaces of the oximeter lightly.

⚠ Please switch off pulse oximeter before cleaning. Clean the LED and photo-sensor with moist cloth or cotton ball and alcohol gently.

2. The aforementioned general cleaning process is not for infection prevention. Please contact the specialist for process of contagious infection.

Calibrating

1) Please use the SpO_2 simulator of Fluke Biomedical index 2 to calibrate PULSE OXIMETER for the function of SpO_2 measure. The calibration must be operated to by qualified personnel only.

2) The SpO_2 accuracy can be validated in human studies against arterial blood sample reference measured with a CO-oximeter. All of the process of the clinical study must be complied with standard of EN ISO80601-2-61:2011.

Repairing and Maintenance

1. Please change the batteries when the low-voltage indicator lightens.
2. Please clean the surface of the device before using. Wipe the device with alcohol first, and then let it dry in air or clean it by dry clean fabric.
3. Please take out the batteries if the oximeter is not in use for a long time.
4. The best storage environment of the device is -10℃ to 40℃ ambient temperature and not higher than 80% relative humidity.
5. Please maintain properly for ensuring the device can be used normally.
6. The device needs to be calibrated once a year (or according to the calibrating program of hospital). It can also be performed at state-appointed agent or just contact us for calibration.

Warnings

- High-pressure sterilization cannot be used on the device.
- Do not immerse the device in liquid.
- It is recommended that the device should be kept in a dry environment. Humidity may reduce the using life , or even damage the device.

Disposal

1) Used batteries should not be disposed of in the household rubbish. Used Batteries should be deposited at a collection point.
2) At the end of its life, the appliance should not be disposed of in household rubbish. Enquire about the options for regulations into account.

Warranty

Our company warrants pulse oximeter at the time of its original purchase and for the subsequence time period of one year.
The warranty does not cover the followings:

- The device series number label is torn off or cannot be recognized.
- Damage to the device resulting from misconnection with other devices.
- Damage to the device resulting from accidents.
- Changes performed by users without the prior written authorization of the company.

Qualified certificate

(QUALIFIED CERTIFICATE)	
PRODUCT NAME	**See product labels**
PRODUCT MODEL	**See product labels**
DATE	
INSPECTOR	**QC001**

Shenzhen Med-link Electronics Tech Co., Ltd.
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