MedLinket

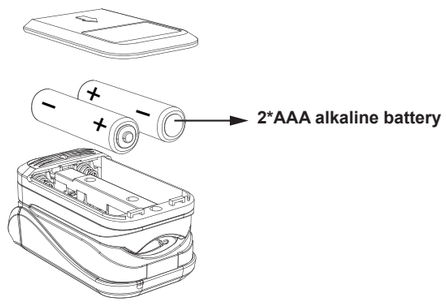
Pulse Oximeter BZ1321B REV:A.1

Welcome Guide

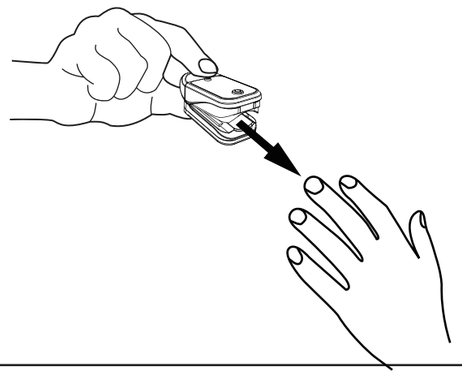
Model: AM801 (REF: AM-601)

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.

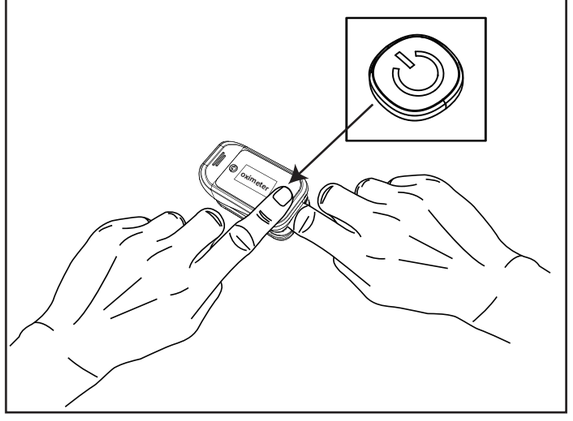


2.Open the clip of the pulse oximeter, insert a finger (The preferred application is middle finger and index finger), as shown below.

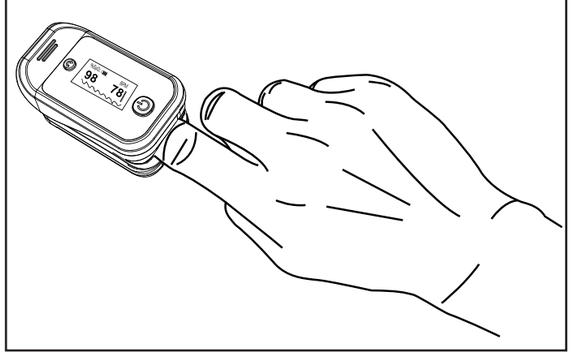


3. Make sure the sensor LED is above the fingernail as shown in the below.

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



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



Content

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 Monitor 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.

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.
- 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 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 and accessories are not made with natural rubber latex in any location that may result in patient contact.

Equipment Symbols

⚠	*Caution*	106kpa / 86kpa	*Atmospheric pressure limitation (Storage, Transportation and Operating)*
NON STERILE	*Non-sterile*		*Type BF applied part*
	Consult Instructions for Use	40℃ / -10℃	*Temperature Limit (Storage)*
	Reusable Do not throw away	80% / 0%	*Humidity limitation (Operating and Storage)*
IPX2	*Protected against vertically falling water drops when enclosure tilted up to 15°*	SN	*Serial number*
EC REP	*Authorized representative in the European Community*		*Date of manufacture*
	Waste electrical and electronic equipments must be disposed of in accordance with the local applicable regulations,not with domestic waste	CE 0123	*CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC. 0123 is Notified Body Number*

Technical Specifications

Pulse Oximeter	
SpO2 Range	70% to 100%
SpO2 Resolution	1%
SpO2 Accuracy	90% to 100% range: ±2%; 70% to 89% range: ±3% <70%: unspecified; complies with EN ISO80601-2-61
Alarms	Low voltage indicator,power auto-off after be-be sound.
Method	Dual wavelength LED
Pulae Rate Range	30 to 250 bpm
Pulse Rate Resolution	1 bpm
Pulse Accuracy	±3 bpm
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 Voltage Range	2.6V～3.6V
Pulse Oximeter	
Only SpO2 function works	±Less than 20mA
Display Parameters	SpO2, Pulse Rate, Pulse Waveform Display, Pulae Amplitude Indicator and Low Voltage Indicator

- Do not have the oximeter immerged 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℃.

Unpacking and Inspection

Remove the instrument 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 (instrument)	1 Piece
User Manual	1 Piece
Sling	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 does not input outer power. Install new batteries.
Install new batteries.

1. Open and remove the battery cover.See Figure 3.
2. Insert two "AAA" size batteries, making sure the battery's positive and negative poles are correctly oriented in the battery compartment,
3. Install the battery cover.

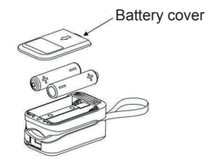


Figure 3: Installing Batteries

⚠ **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.

Environmental	
Operating Temperature Limit	5 to 40℃ (41 to 104℉)
Storage Tempeerature Limit	-10 to 40℃ (14 to 104℉)
Atmospheric Pressure limitation (Storage, Transportation and Operating)	86KPa~106KPa
Classification	
Medical device:	Class Ⅱ Equipment （Ⅱa 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: EN 60601-1,EN60601-1-2
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	EN ISO80601-2-61

Product parts and accessories

The Pulse Oximeter is consists display screen,power button, applied part, battery cover and sling. Detail of the instrument see Figure2.

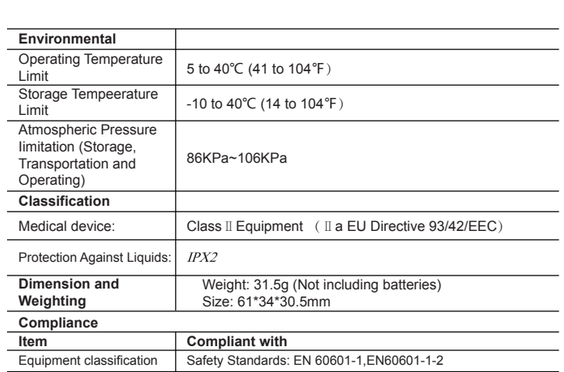


Figure 2 Instrument

- **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.

General Operation

- **Preparative for operating**
  1) Open the battery cover carefully and then install two "AAA" Alkaline batteries according to the (+/-) electrodes.
  2) Press the power button for 1 second to activate the device.
- **SpO2 measure**
  1) Open the clip of PULSE OXIMETER, See figure 4. ①.
  2) Place a finger (The preferred application is middle finger and index finger) on the silicone (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 SpO2 directly from screen display.

Figure 4: measurement

Note: When put finger into the silicone cushions of the clip, make sure nail is upturned.

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

The Pulse Oximeter is intended for continuous use or spot checking in measuring and displaying functional arterial oxygen saturation (SpO2)and pulse rate of patients in hospitals, physician's office, clinical settings and home care environment.

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 (SpO2). Because a measurement of SpO2 is dependent on light from the device, excessive ambient light can interfere with this measurement.

Identification of Front Panel and Symbols

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

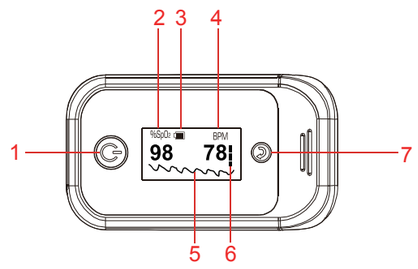


Figure 1: PULSE OXIMETER Front Panel

1— Menu button/Power button	5— Waveform Display
2— %SpO2 Display	6— Bar graph (The Pulse Amplitude Indicator)
3— Low Battery indicator	7— Screen turn switch
4— Pulse Rate Display (bpm)	

Principle of Measurement

The measurement of PULSE OXIMETER is 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.

$$\text{Fractional O2Hb saturation} = \frac{O_2Hb}{RHb+O2Hb+Met\ Hb+COHb} \times 100$$

Oppositely,pulse oxygen oximeter measure functional O2Hb saturation:

$$\text{Fractional O2Hb saturation} = \frac{O2Hb}{RHb+O2Hb} \times 100$$

Present Pulse 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. Pulse 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%.

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/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 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 methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (MetHb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO2 determination by this monitor may be inaccurate.
3) The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO2 measure.
4) The SpO2 value serves only as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO2 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.

Safety

1) Safety

Instructions for safe operations

- Check the Pulse Oximeter 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 monitor when there is obvious damage.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- 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 instrument to stop measure then the Pulse Oximeter will power off automatically within 8 seconds if the instrument must be closed for the urgent status.

2) Warnings ⚠

- Explosive hazard—DO NOT use the Pulse 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 sling. Please do not break the sling during usage to avoid device damage. Please don't use sling if allergic to it.
- Please don't use this product if you allergic to silicone cushion and ABS plastic.
- Please dispose the device, batteries and package materials (including plastic bag, foam and carton) according to local law.

3) The attention of Operation

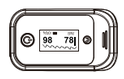
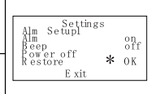
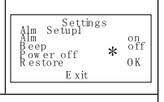
- The equipment should be fully tested to see if it can be used normally before using.
- The finger should be placed properly (see figure 4 of this manual), otherwise it may cause inaccurate measurement.
- The SpO2 sensor and photoelectric receiving tube should be arranged in a way with the testee's arteriole in a position in between.
- The SpO2 sensor 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.

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, andcan 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.	

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

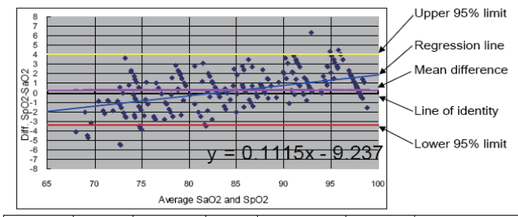
Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user ofthe Pulse Oximeter should assure thatitis used in such an environment.		
Emissions test	compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Pulse Oximeter uses 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 CISPR11	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.

● Guidance & Declaration - Electromagnetic Immunity

Table4—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 kV contact ± 2 kV, ±4kV, ±8 kV, ±15 kV air	± 8 kV contact ± 2 kV, ±4kV, ±8 kV, ±15kV 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 IEC 61000-4-3	10 V/m 80MHz to 2.7GHz 80% AM at 1kHz	10 V/m	

b) Bland-Altman Plot Comparing the SpO2 Difference between the PULSE OXIMETER and the Reference CO-Oximeter During Non-Motion Conditions



Points analyzed	Sres (%)	Standard deviation.	Bias	95% limits of agreement	# of Mean±2SD	# beyond the 95% limits of agreement
241	1.93	1.90	0.30	-3.44, 4.05	10	12

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 it lightly the surfaces of the oximeter.

⚠ 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.

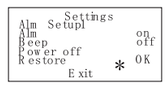
Calibrating

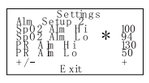
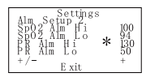
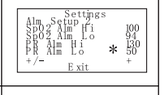
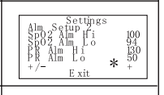
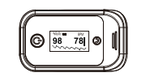
1) Please use the SpO2 simulator of Fluke Biomedical index 2 to calibrate PULSE OXIMETER for the function of SpO2 measure. The calibration must be operated to by qualified personnel only.

2) The SpO2 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 becomplied with standard of EN ISO80601-2-61.

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.



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 "SpO_2 Alm Hi", long press the button to adjust the parameter of SpO_2 in the scope of 50% to 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 "SpO_2 Alm Lo", long press the button to adjust the parameter of SpO_2 in the scope of 50% to 100%.	
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 5-250bpm.	
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 5-250bpm.	
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.

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 Pulse oximeter 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% SaO2 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

ARMS Results:

The final analysis was performed on 249 data points collected across 11 subjects. The SpO2 accuracy performance of each pulse oximeter and sensor combination is identified below.

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

Where:

ARMS is the accuracy root mean square.

SpO2 is the test pulse oximeter readings during sample i.

RefSaO2 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.

- The best storage environment of the device is -10℃ to 40℃ ambient temperature and not higher than 80% relative humidity.
- Please maintain properly for ensuring the device can be used normally.
- 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 environment-friendly and appropriate disposal. Take local 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

Section 3- Troubleshooting

This section explains how to troubleshoot the PULSE OXIMETER. The 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: Troubleshooting Guide

Phenomenons	Possible Causes	Solutions
Unnormal booth of Pulse Oximeter (display screen and transmitting tube of LCD presenting lights off)	The power button did not press 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	Check and re-install battery
	Partial damage of Metal dome (which is directly connected to the 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, pulse amplitude has no display on screen, while the transmitting tube of LCD presenting lights on, and the finger insert in place)	If the pulse amplitude has no display on screen please: 1) Adjust the finger position; 2) Use your middle or index finger in preference; 3) 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

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/CN 60601-1-2 .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 monitor may not seem to operate correctly.

Table 6—overall Average Root Mean Square (ARMS) for PULSE OXIMETER in the SpO2 range of 70%-100%.

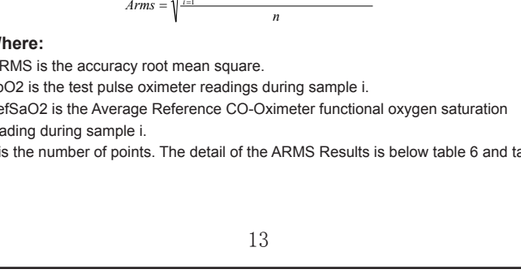
Compared to Avg. Reference CO-Oximeter, Functional SaO_2 Apr 6-8, 2012	Functional SaO_2 70-100% A_{RMS}	# of Points	Specification 70-100% A_{RMS}
Pulse Oximeter	1.92	241	Pass A_{RMS} of 3

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% A_{RMS}	SaO_2 ranges of 80-90% A_{RMS}	SaO_2 ranges of 90-100% A_{RMS}
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
A_{RMS}	1.92	1.66	1.87	2.20
Max diff	6.30			
Min diff	-5.50			

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