MedLinket CE 0123

Temp-pulse oximeter

Model AM801 (REF: AM-806)

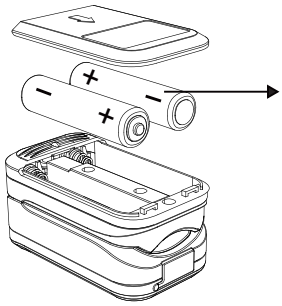
20220826 B.0

Contents

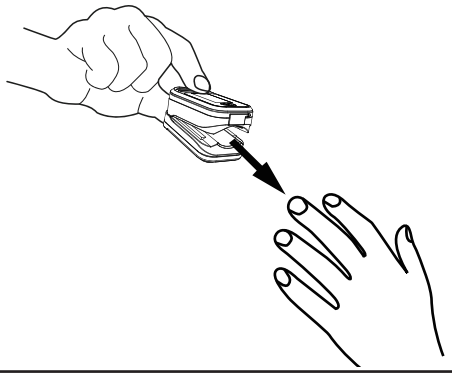
Quick Start Guide

How to begin?

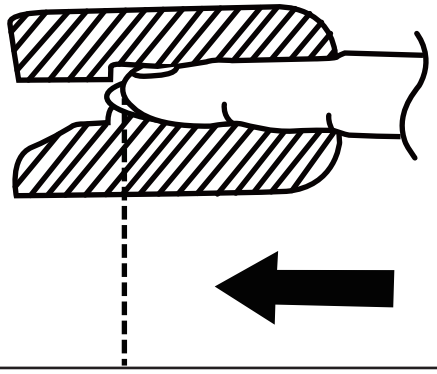
1. Open battery compartment cover and insert two new AAA alkaline batteries as indicated below to ensure the polarity (<+> and <->) of the batteries are correct and then close it.



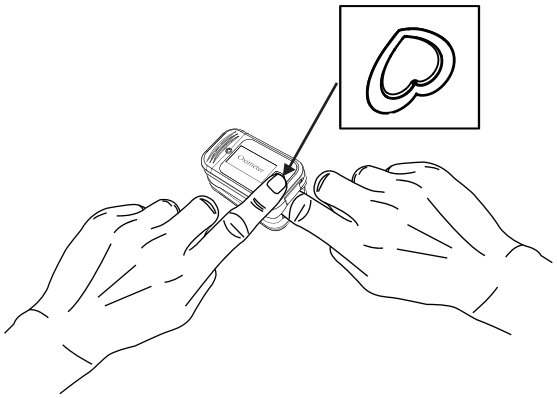
2. Open the clip of the pulse oximeter, insert a finger (The preferred application is middle finger and index finger), as shown below.



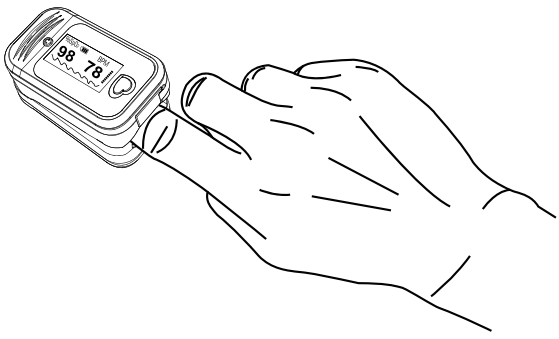
3. Make sure the sensor LED is above the fingernail as shown below.



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



5. Get the information of SpO_2 directly from screen display.



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

User manual in PDF

English, Français, Español, Deutsch, Nederlands, Italiano

Instruction video

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

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.

⚠ 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 and its accessories.
● 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 , be sure to check patient application sites frequently. The temperature of the sensor contacting with skin won't exceed 41℃ if the initial skin temperature doesn't exceed 35℃.
● Be aware that following removal of the sensor from the patient, it is possible that environmental light may cause the oximeter 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 disposal of your equipment.
● 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.
● Don't reuse disposable temperature probe or it may cause cross-infection among patients.

Latex Content Statement

The PULSE OXIMETER and accessories are 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 to get a thorough understanding of operation.

Section 1- Overview

Intended Use

The Pulse Oximeter is intended for spot checking in measuring and displaying functional arterial oxygen saturation (SpO2), pulse rate and temperature of patients in hospitals, physician's office, clinical settings and home care environment.
Target population: Adult, adolescent and child.

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, 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.

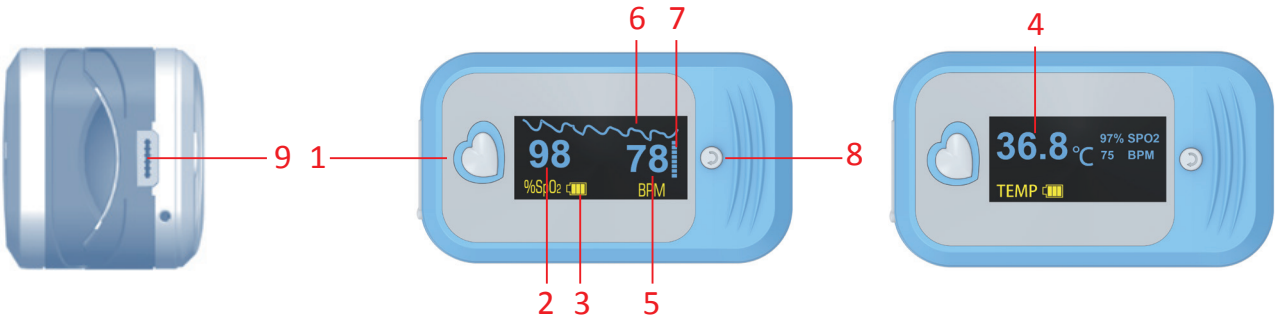


Figure 1: PULSE OXIMETER Front Panel and Left Panel

1—Menu button/Power button	6—PPG (photoplethysmograph)
2—%SpO2 Display	7—Bar graph (The Pulse Amplitude Indicator)
3—Low Battery indicator	8—Display mode switch
4—Temperature Display	9—Accessories Port Connector
5—Pulse Rate Display (bpm)	

Equipment Symbols

	Caution	106kPa 86kPa	Atmospheric Pressure limitation
NON STERILE	Non sterile Packaging		Type BF (Body Floating) Applied Part
	Refer to Instruction manual/booklet	40°C -10°C	Temperature limit
	Compliance with WEEE Standard	10	Environment-friendly use period
80% % 0%	Humidity limitation	LOT	Batch Code
IPX2	Protected against vertically falling water drops when enclosure tilted up to 15°		No SpO2 Alarm
MR	MR unsafe		Do not re-use
#	Model number	CN	Date of manufacture
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;
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
LED Wavelengths	Red: approximately 660nm; Infrared: approximately 905nm
Optical output power	Less than 15mW
Temperature Note:The function of temperature measurement works by the accessory of temperature probe.	
Shortest measurement time recommended	5min
Measuring site	skin surface
Reference body site	Oral cavity and axilla
Range, Accuracy	77°to 113°F (25℃ to 45℃): ±0.1℃
Display Resolution	±0.1℃
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
Only SpO_2 function works	Less than 55mA
Only Temp function works	Less than 40mA
SpO_2 and Temp function work together	Less than 60mA
Display Parameters	SpO_2, Pulse Rate, Pulse Waveform Display, Bar Graph and Low Battery Indicator
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 Ⅱa 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**
Type of protection	Internally powered equipment (on battery power)
Degree of protection	Type BF Applied part
Mode of operation	Continuous
Compatibility	The surface material has no harm or toxicity for the person in contact.

Product parts and accessories

The Pulse Oximeter is composed of instrument and accessories. The accessories include adapter cable and temperature probe . Detail of the instrument and accessories see figure 2 and figure 3.

1. Instrument

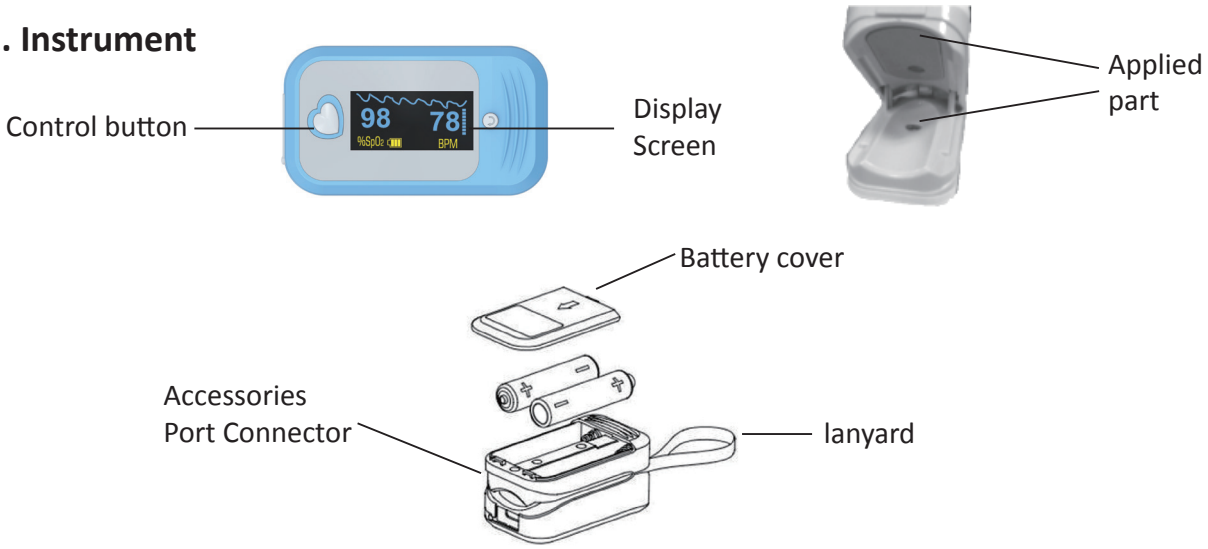


Figure 2: instrument

2. Accessories (Separate Purchase)

2.1 multi-functional adapter

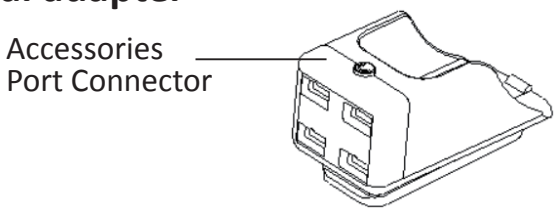


Figure 3-1: multi-functional adapter

2.2 Probes

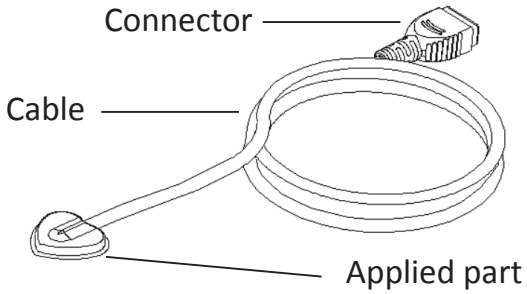


Figure 3-2: Temperature probe

2.3 Adapter Cable

Figure 3-3: Adapter Cable

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%.

Regarding temperature measurement, it's based on the principle that resistance of thermistor based on the metal conductor increases with temperature decrease, and changes linearly with the temperature measurement characteristics.

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.

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 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℃.
● Temperature probe that is compatible with pulse oximeter mentioned in this IFU include W0024E.
● The operator is responsible for checking the compatibility of the equipment connected,probe cable extender and probe before use.
● Incompatible components can result in degraded performance.

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
PULSE OXIMETER Operator's Manual	1 Piece
lanyard	1 Piece
Temperature probe: Disposable Skin-surface Temperature Probe, 0.9m.	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.
1. Unplug all accessories from the Pulse Oximeter, and press the menu bar to access the Setting Interface, turn the PULSE OXIMETER off. See table 1.
2. Remove the battery rear cover towards the direction indicated on the cover.
3. Insert two “AAA” size batteries, making sure the battery’s positive and negative poles are correctly oriented in the battery compartment as shown in Figure 4.
4. Close the battery rear cover.

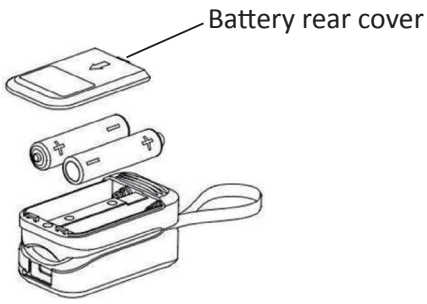


Figure 4: Installing Batteries

- **Performance Verification**

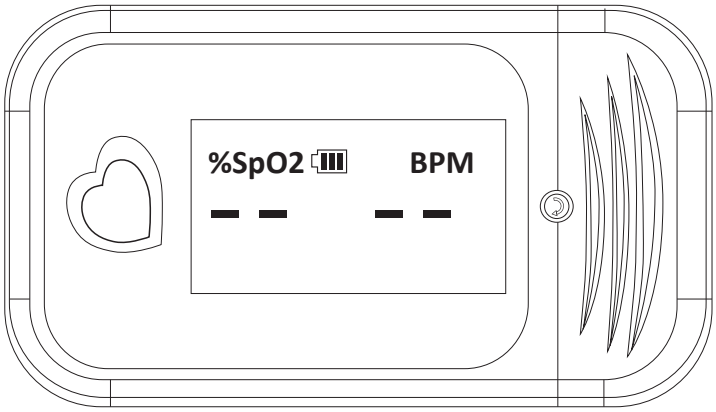
1. Performance Tests
Power up the device to get the oximeter ready for measurement.
2. Power-On Self-Test
Before using the PULSE OXIMETER, you must verify that the PULSE OXIMETER is working properly and is safe to use. Proper working conditions are verified each time when the PULSE OXIMETER is turned 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 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 measurement interface.



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

3. 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 by itself or plug an accessory of MED-LINKET SpO2 probe into the instrument. To measure the body temperature by apply a temperature probe of MED-LINK. See table-1.

● **Preparative for operating**

1) Insert batteries according to the installation procedure above.
2) Press the "power " key for 1 second to activate the device.

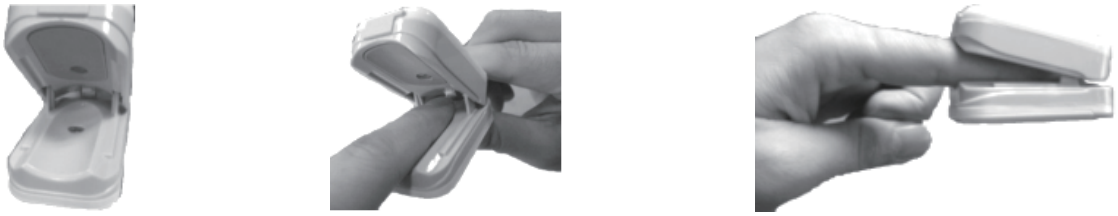
● SpO2 measurement

1) Open the clip of PULSE OXIMETER, See figure 5.①.

2) Place a finger (The preferred application is middle finger and index finger) on the silicone and ensure the finger position is correct , see figure 5.②, and then clamp the finger, see figure 5.③.

3) Turn on the PULSE OXIMETER by pressing the Power button “ ”

4) Get the information of SpO2 directly from screen display.



① ② ③

Figure 5: 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.

● Temperature measurement

1) Plug the temperature probe connector side into the instrument’s USB female connector , and then place another side of the temperature probe to patient’s surface or Esophageal/Rectal for collecting the temperature signal.

2) Get the information of Temperature directly from screen display.

● Switch screen display mode

1) Press the Display mode switch, See figure 6.

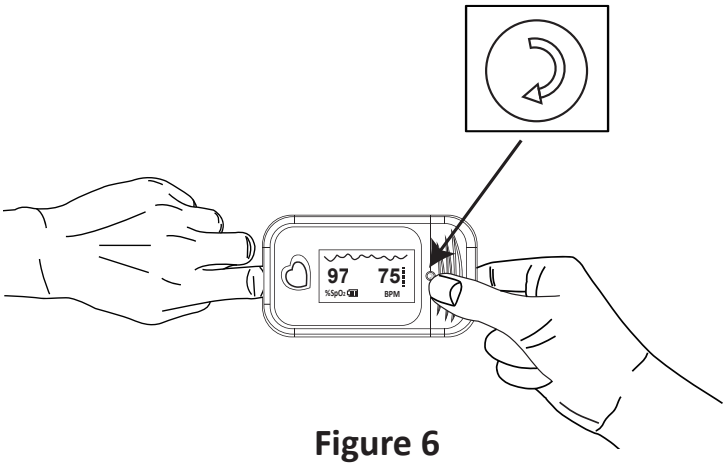


Figure 6

2) There are nine display modes for your choice, See Figure 7. Figure 7.①-Figure 7.⑧ display SpO2 and pulse rate, Figure 7. ⑨ display SpO2, pulse rate and temperature.

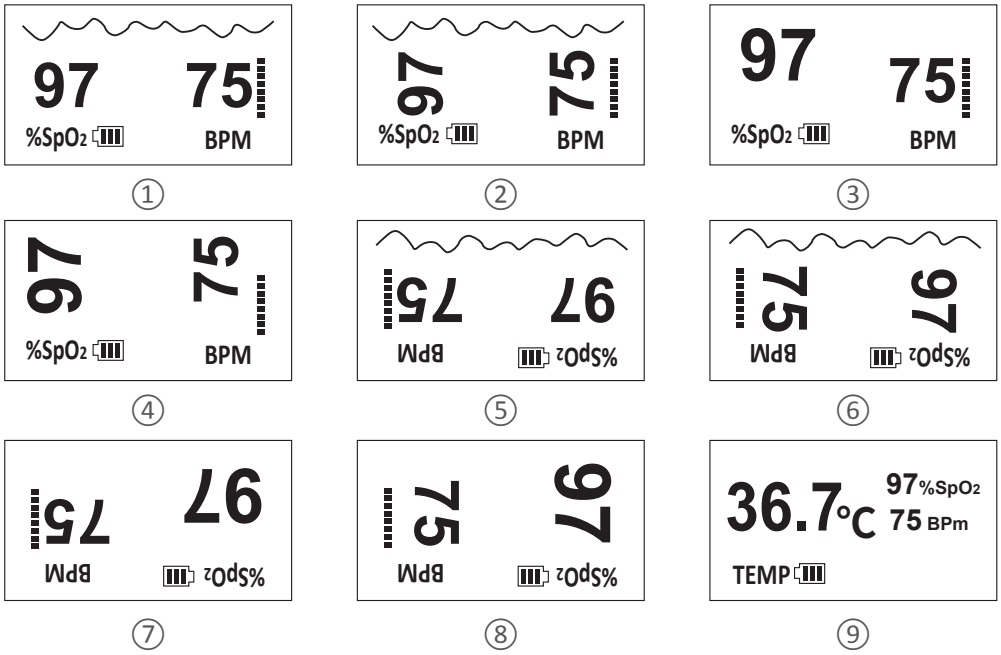


Figure 7

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.

● Please remove the finger from the instrument to stop measure and pull the accessories from the instrument, 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 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 cable. Please do not break the cable during usage to avoid device damage. Please don't use cable if allergic to cable.

● Please don't use this product if you are allergic to silicone pad and ABS plastic.

● Please dispose the device, accessory and packing (including plastic bag, foam and carton) according to local law.

3) The attention of Operation

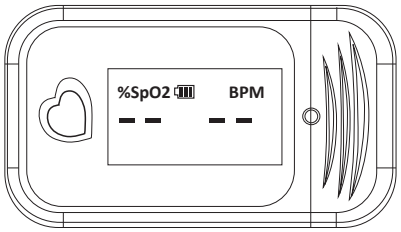
● The equipment should be fully tested to see if it can be used normally before using.
● The finger should be placed properly (see figure 5 of this manual), or else it may cause inaccurate measurement.
● The SpO2 sensor and photoelectric receiving tube should be arranged in a way with the testee's arteriole in a position in between.
● The SpO2 sensor should not be used at a location or limb tied with arterial catheter 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 device is not intended for use under motion conditions.

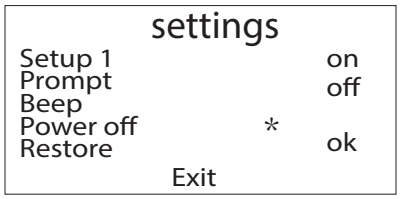
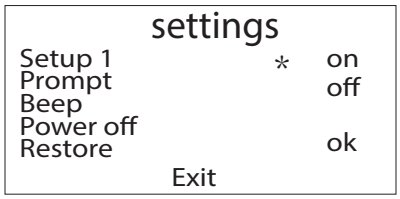
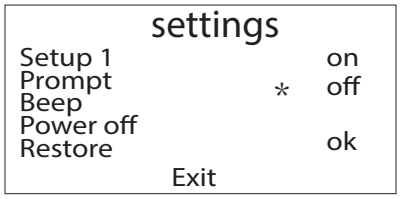
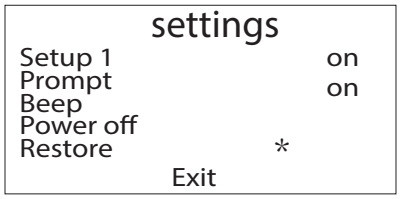
Function Setting Introduction

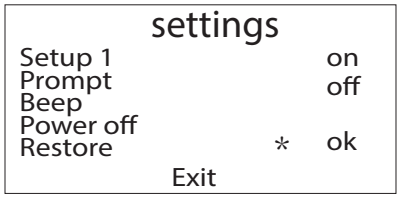
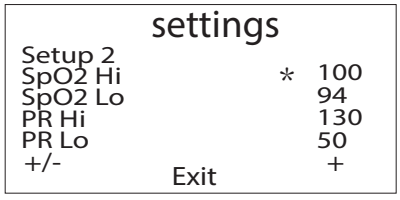
Press the Pulse Oximeter Menu button to power on and access to the testing interface, or press the Menu button repeatedly during normal operation to switch to parameter-setting interfaces to set up the parameters and then return to the POST display. Settable parameters include high and low SpO2 limit, 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, which can also be turned off by using the menu button under parameter-setting interfaces.

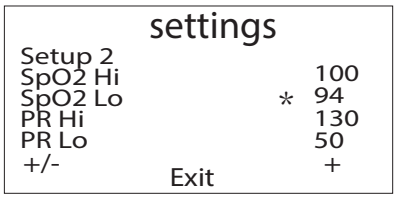
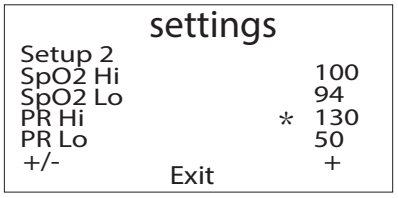
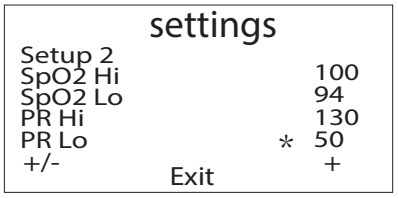
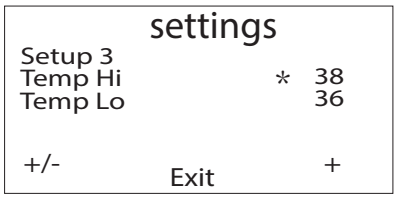
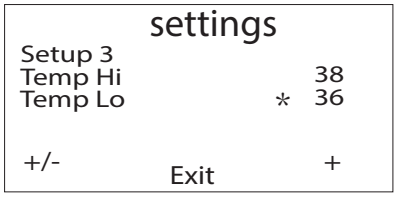
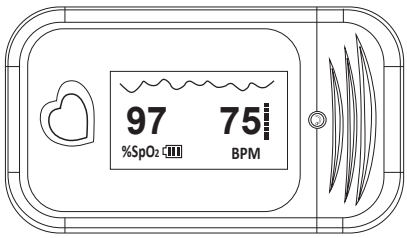
Menu Setting

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.	

<table>
<tr>
<td rowspan="2">Setting enter and exit</td>
<td>Setting enter
Long press the button to enter the interface of settings.
The setting interface of PULSE OXIMETER includes “ Setup 1”, “ Setup 2” and “Sounds Setup”.</td>
<td rowspan="2"> 
</td>
</tr>
<tr>
<td>Exit PULSE OXIMETER setting interface
● Short press the button, move the cursor to select the item of “Exit”, long press the button to return to the POST display.</td>
</tr>
<tr>
<td>“prompt” on or off setting</td>
<td>“prompt” on or off setting
● Short press the menu button to enter the interface of settings of “Setup 1”. Move the cursor to select the item of “prompt”, and then long press the button to 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 to return to the POST display.</td>
<td> 
</td>
</tr>
<tr>
<td>“Beep” on or off setting</td>
<td>“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.</td>
<td> 
</td>
</tr>
<tr>
<td>Default setting</td>
<td>Default setting
Short press the button, move the cursor to select the item of “Restore”, then long press the button to return 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.</td>
<td> 


</td>
</tr>
<tr>
<td>SpO2 High Limit setting</td>
<td>SpO2 High Limit setting
Long press the button to enter the interface of settings of “Setup 2”. Short press the button, move the cursor to select the item of “SpO2 Hi”, long press the button to adjust the parameter of SpO2 in the scope of 52% to 100%.
The default upper limit is 100%.</td>
<td> 
</td>
</tr>
</table>

SpO_2 Low Limit setting	**SpO_2 Low Limit setting** Short press the button in the interface of “Setup 2”, move the cursor to select the item of “SpO_2 Lo”, long press the button to adjust the parameter of SpO_2 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 “Setup 2”, move the cursor to select the item of “PR Hi”, long press the button to adjust the parameter of BPM in the scope of 32-245bpm. The default upper limit is 130bpm.	
Pulse Rate (PR) Low Limit setting	Short press the button in the interface of “Setup 2”, move the cursor to select the item of “PR Lo”, long press the button to adjust the parameter of BPM in the scope of 30-243bpm. The default lower limit is 50bpm.	
Temp High Limit setting	Short press the button in the interface of “Sounds Setup”, move the cursor to select the item of “Temp Hi”, long press the button to adjust the parameter of temperature in the scope of 10-45℃.	
Temp low Limit setting	Short press the button in the interface of “Sounds Setup”, move the cursor to select the item of “Temp Lo”, long press the button to adjust the parameter of temperature in the scope of 10-45℃.	
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 clamped 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.
● 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.
●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.

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

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 starting-up of Pulse-Oximeter (display screen and transmitting tube of LCD presenting lights off）	The power button was 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 welding 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, there's no display on pulse amplitude indicator but the light of LED transmitting tube is on and the finger is inserted in place)	If there's no pulse amplitude displayed on the 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	External Temp-probe is still working	Pull out the external temp-probe
	Damage in collection tube or other device parts.	Contact authorized distributors
Inaccurate Temp Measurement	The surface Temp-Probe did not firmly stick on the skin surface.	Stick the Temp-Probe on the proper measuring position by medical proof fabric
	Wrong position of Temp-Probe	Place the Temp-Probe in proper position according to the specification
	No enough measuring time	Keep the correct measuring method by 10 mins, and then get the result.

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 monitor 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.

- **Guidance & Declaration - Electromagnetic Immunity**

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) lEC 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 mag-netic 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 241 data points collected across 12 subjects. The SpO2 accuracy performance of each pulse oximeter and sensor combination is identified below

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

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.

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

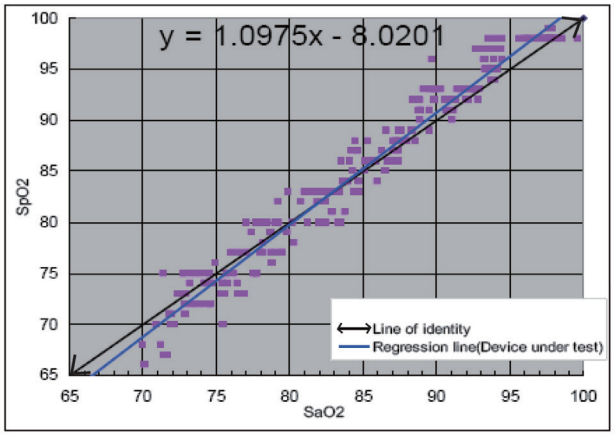
Compared to Avg. Reference CO-Oximeter, Functional SaO_2 Apr 6-8, 2012	Functional SaO_2 70-100% ARMS	# of Points	Specification 70-100% ARMS
PULSE OXIMETER	1.92	241	Pass ARMS of 3

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

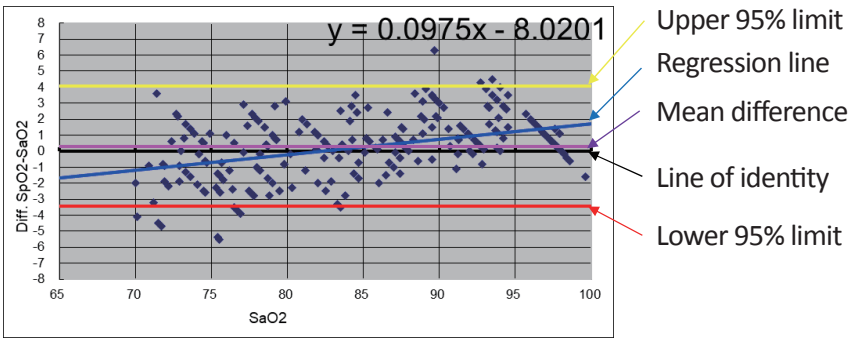
Graphs

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



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 measurement. The calibration must be operated to by qualified personnel only.
2) Please use the Temperature simulator of BC Biomedical MULTI-PARAMETER PATIENT SIMULATOR to calibrate PULSE OXIMETER for the function of temperature measurement. This calibration must be operated by qualified personnel only.
3) 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 be complied 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.
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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