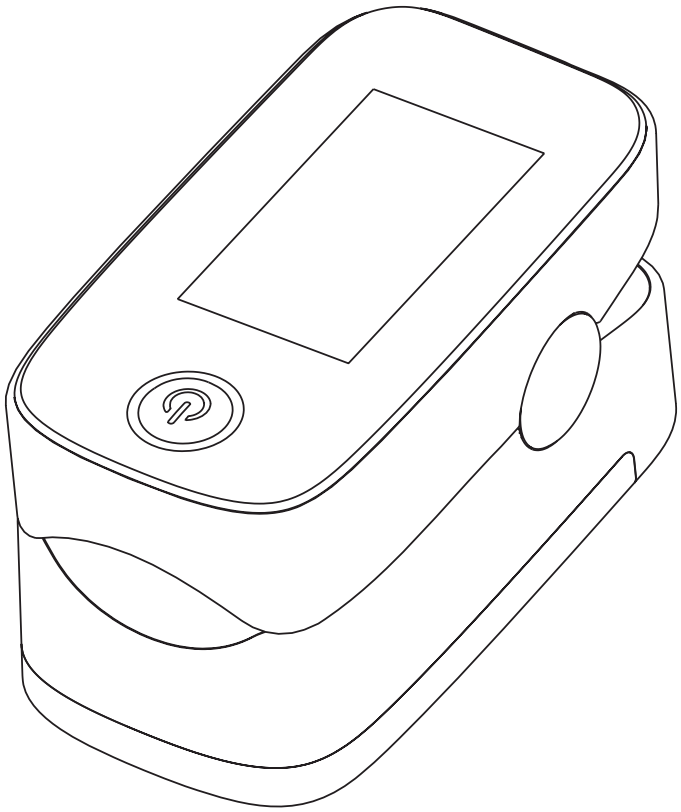
SUNSET
HEALTHCARE SOLUTIONS

Instruction Manual

Pulse Oximeter

RES5102



Manufactured for
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Chicago IL 60604

MADE IN CHINA

IFU-00054 REV 1.03
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1. Product Introduction and Operation Guide

1.1 Front View

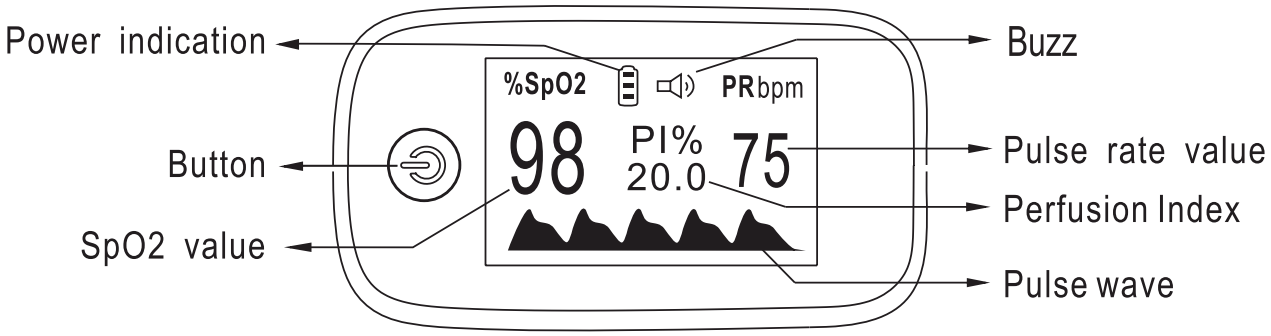


Figure 1 Front View of RES5102

1.2 Battery Installation

A. Put the two AAA batteries into battery compartment in correct polarities (Figure2).

B. Push the battery cover horizontally in the direction of the arrow

WARNINGS:

- Battery polarities should be correctly installed, otherwise, damage may be caused to the equipment.
- Please remove the batteries if the equipment will not be used for a long time.

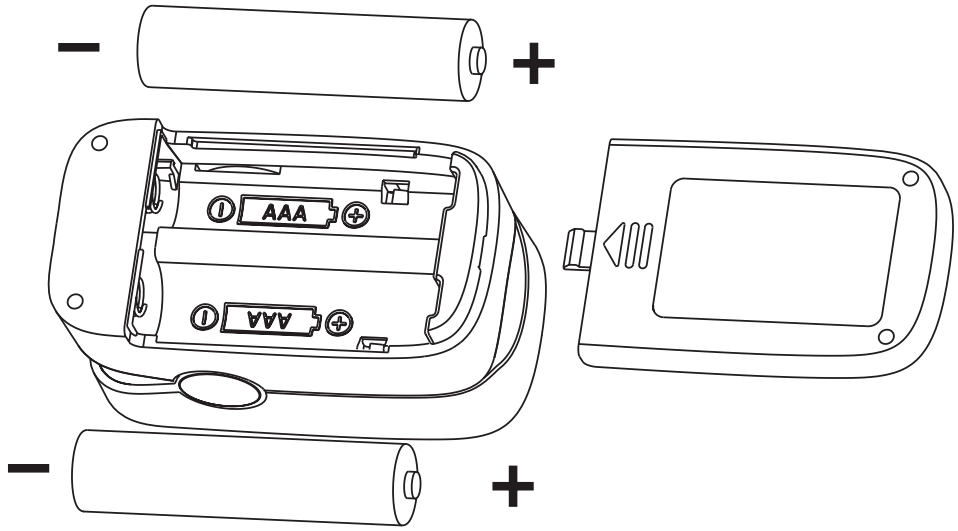


Figure 2 Battery Installation

1.3 Lanyard installation

A. Pass the thinner end of the lanyard through the hanging hole.

B. Loop the thicker end of the lanyard through the thinner end and tighten the lanyard (Figure 3).

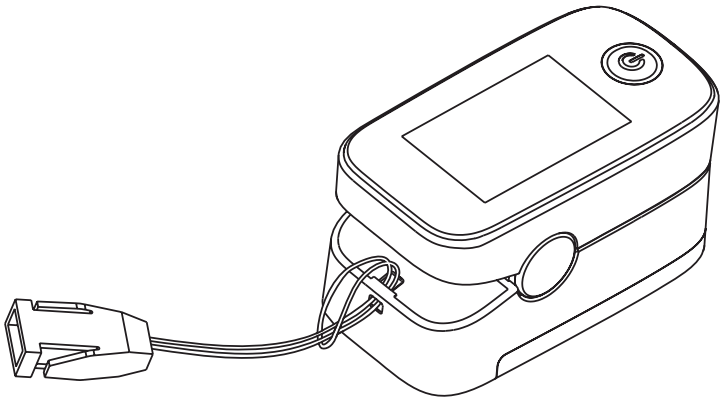


Figure 3 Lanyard Installation

1.4 Before Operating

A. Before use check and confirm that the user's finger size is appropriate

B. Before use check and confirm that the environment contains only non-combustible material, and avoid high or low temperature and humidity. Pay attention to the following:

   a) Avoid glare and exposure to direct sunlight.

   b) Avoid infrared radiation or ultraviolet radiation.

   c) Avoid contact with the organic solvent, mist, dust, corrosive gas.

C. The equipment should not be used on the hand of an arm tied with an arterial canal, when using a blood pressure cuff or when receiving an intravenous injection.

D. The equipment may not work normally on microcirculation barrier patients. Warming or rubbing the finger, or re-positioning the equipment could improve the measurement.

E. The patient should not use enamel or other makeup.

F. Avoid inserting a wet finger into the probe.

Notes:

A. The user should fully insert the finger into the probe.

B. It is recommended to let the LED light shine directly on the nail (Figure 4).

C. Don't shake finger. Try to keep still during the measurement.

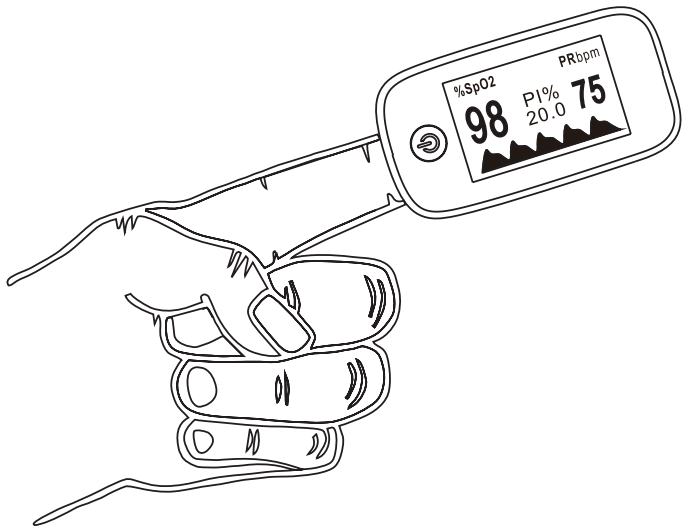


Figure 4 Finger Placement Diagram

1.5 Operation

A. Press the bottom of the equipment to open the probe, then insert one finger into the probe.

B. Turn on the oximeter by pressing and holding the power button for about 2 seconds.

C. After about 8 seconds, the measurement result can be read directly from the display screen.

D. Before reading the parameters, make sure that the pulse oximeter numbers have remained stable for more than 4 second.

E. The equipment will turn off automatically in 8 seconds after the finger leaves the probe.

1.6 Function and menu operation

To set the menu, turn on the oximeter. When it displays the parameter setting interface set it by pressing the power button. A long press will set the button hold time for 1-2s, a short-press will set the button hold time for less than 0.5s.

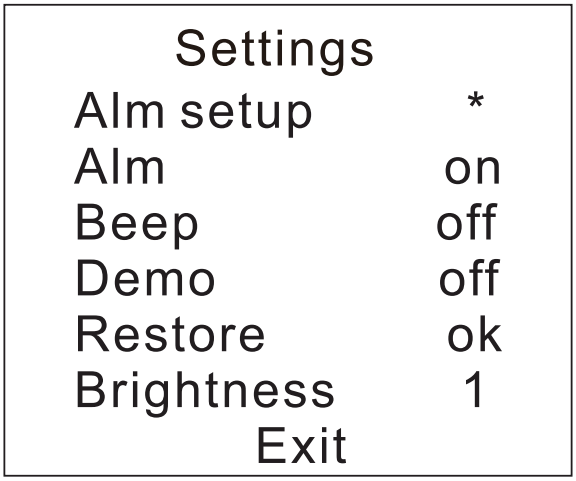
On parameter interface 1

- Move"*" to the corresponding option, and hold the button to set alarm or beep to on or off.
- When alarm is set to on and the measured SpO2 or PR Values go beyond the upper limit or lower limit, the oximeter gives off an alert sound.
- When alarm is set to off and the measured values go beyond the limit, the Oximeter will not give any alert sound.
- When beep is set to on, a ticking sound synchronized with the pulse is emitted during the measurement, and when beep is set to off, no sound will play.
- While the "*" symbol stays on the restore option, hold the button to restore factory settings.
- Press the button to select a brightness level ranging from 1 to 5. The greater the value, the brighter the screen.

On parameter interface 2

- Press the power button again to switch between options. On this interface, you can set the upper limit and lower limit of SpO2 alarm and PR alarm.
- While the "*" symbol stays on the +/- option, hold the button to set the option to + or -. In + mode, select the corresponding option and hold the button to increment the upper or lower limit. in - mode, hold the button to decrement the upper or lower limit.
- Move "*" to the exit option, and hold the button to return to the monitoring interface.

Interface 1



Interface 2

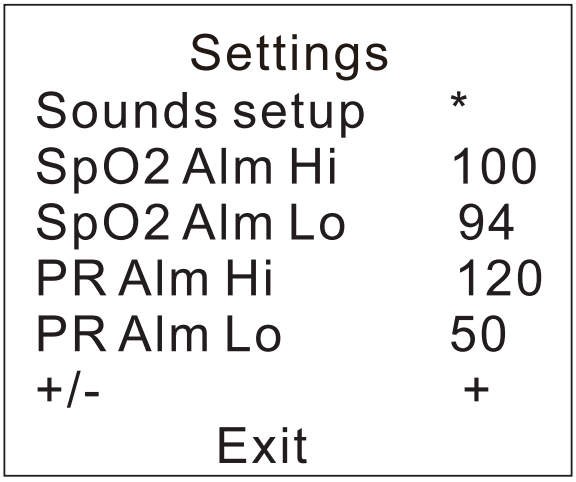


Figure 5 The setting interfaces of the oximeter

2. Specification

2.1 Classification

Type of protection against electric shock: II (Internally powered equipment)

Degree of protection against electric shock: Type BF-Applied part

Operating mode : Spot checking

Application: Sport use only

Degree of protection against hazards of explosion: IP22

2.2 Power Requirements

Specification of alkaline batteries: Two AAA (LR03)

Operating current: 25-50mA

2.3 Physical Specifications

Width*Height*Depth: 57×30×31 mm

Weight: 28g (Bare machine)

2.4 Measurement Specifications

SpO2 declared accuracy: 70%~100%: ±2 digits

0% ~ 69%: unspecified

SpO2 Display Range: 30%~99%

SpO2 Resolution: 1%

PR declared accuracy: 25-250bpm: ±3 digits

PR Resolution: 1bpm

2.5 Environmental Specifications Temperature

Temperature

Operating: +50~+104°F / +10~ +40°C
Storage/Transportation: -4~+140°F / -20~+60°C

Humidity

Operating: 15~95%, noncondensing
Storage/Transportation: 10~95%, noncondensing

Atmosphere Pressure

Operating: 70~106kpa
Storage/Transportation: 50~107.4kpa

2.6 Display

Display Color: 1.3",Blue
Display content: SpO2%, Pulse Rate, PI%, Bar Graph Battery Indicator, Pulse Wave

Notes:

1. The claim for oxygen saturation accuracy should be supported by clinical studies covering the entire claimed range. The fraction of inspired oxygen (FiO2) delivered to test subjects is varied to achieve a series of targeted steady-state saturation periods over the specified SpO2 accuracy range (e.g. 70 % to 100 %),then the SpO2 accuracy is calculated by comparing SpO2 readings of the pulse oximeter to the values of SpO2 determined with a Co-Oximeter.
2. The clinical trial included 11 subjects, including 6 males and 5 females, with an age range of 18 to 46 years and with varied skin color.

3. Maintenance, Cleaning, Disinfection

3.1 Maintenance

The equipment's design life expectancy is about 2 years. Keep equipment and accessories free of dust and dirt, and observe the following rules:

A. Please clean the equipment before use according to chapter 6.2. Remove the batteries inside the battery cassette if the equipment will not be operated for a long time.

B. Replace the batteries when the battery voltage indicates lamps are empty.

C. It is recommended that the equipment be kept in a dry environment with no corrosive gases and good ventilation at all times. Moisture and high-light environments will affect equipment lifetime and may damage equipment.

D. It is best to keep the product in a place where the temperature is between -20 to 60°C and the relative humidity is less than 95%.

E. The packed equipment can be transported by ordinary conveyance. The equipment should not be transported mixed with toxic, harmful, corrosive materials.

WARNINGS:

- No modification of this equipment is allowed.

3.2 Cleaning

Equipment should be cleaned on a regular basis. If there is heavy pollution, dust or sand in its storage environment, it should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations. Recommended cleaning agents are:

A. Mild soap (diluted).

B. Ethanol (70%).

To clean your equipment, follow these rules:

A. Shut down the pulse oximeter.

B. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.

C. Clean the exterior surface of the equipment and probe using a soft cloth dampened with the cleaner.

D. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.

E. Dry your equipment in a ventilated, cool place. To avoid damage to the equipment, follow these rules:

CAUTIONS:

- Always dilute according to the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment in the liquid.
- Do not pour liquid onto the equipment or accessories.
- Never use abrasive materials (such as steel wool or silver polish), or

erosive cleaners (such as acetone or acetone-based cleaners).

- If you spill liquid onto the equipment, contact your service personnel.

3.3 Disinfection

Clean the pulse oximeter before disinfecting it. The recommend disinfectant is ethanol 70%. Disinfection steps are the same as cleaning.

CAUTION

- Never use ETO or formaldehyde for disinfection.

3.4 Disposal

Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations.

4. Accessories

One lanyard.

Two AAA batteries (Optional).

One user manual.

5. Troubleshooting

Trouble	Possible Reason	Solution
The equipment can't be turned on.	The battery is depleted or almost depleted.	Please replace batteries.
	The battery installation is incorrect.	Install the battery over again.
	The device is damaged.	Please contact product distributor.
The Spo2 and PR are not displayed normally	The finger size is too big or small.	Select the suitable size finger to measure.
	Excessive ambient light.	Aviod excessive ambient light irradiation.
	User's blood perfusion is very low.	Warm the finger and try again.
The display shuts off suddenly.	The equipment automatically shuts down in 8 seconds when there are no correct physiological signals.	Normal.
	The battery is depleted.	Replace batteries.

Trouble	Possible Reason	Solution
The Spo2 and Pulse Rate are unstable.	The finger is not inserted deep enough.	Replace the finger and try again.
	The finger is shaking or the body is moving.	Try to keep still.
	Device is not being used in environment required by this manual.	Please use in normal working environment.
	The device is damaged.	Please contact the product distributor.

6. Appendix A EMC

The equipment complies with the requirement of standard EN 60601-1-2:2014"Electromagnetic Compatibility – Medical Electrical Equipment".

1	**Guidance and manufacturer´s declaration – electromagnetic emission**
2	The model RES5102 is intended for use in the electromagnetic environment specified below. The customer or the user of the model RES5102 should assure that it is used in such an environment.

3	**Emissions test**	**Compliance**	**Electromagnetic environment – guidance**
4	RF emissions CISPR 11	Group 1	The Model RES5102 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	The Model RES5102 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	Not applicable	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Model RES5102 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model RES5102 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, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±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%.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/ output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0% UT (100% dip in UT) for 1 cycle at 0° 70% UT (30% dip in UT) for 25/30 cycles at 0° 0% UT (100% dip in UT) for 250/300 cycle at 0°	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	**IEC 60601 test level**	**Com-pliance level**	**Electromagnetic environ-ment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Model RES5102, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	**Recommended separation distance** $d\left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d\left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz

			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A. The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

B. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

C. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the YM201is used exceeds the applicable RF compliance level above, the YM201should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the YM201/YM301.

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