Pulse Oximeter
⬚#⬚ SP62B

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EC | REP

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Importer

Distributor

INSTRUCTION MANUAL
Please read this instruction manual carefully
Before using the device

Content

INTENDEDE USE

SP62B is intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches ~0.9 inches) and for patients during no-motion condition.
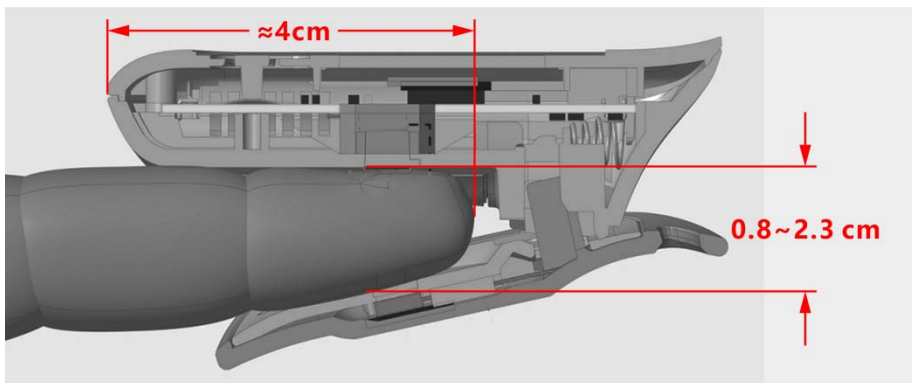
Contraindications:

1. Presence of an ongoing need for measurement of pH, PaCO2, total hemoglobin, and abnormal hemoglobins may be a relative contraindication to pulse oximetry

2. A pulse oximeter cannot distinguish the differences and the reading will show the total saturation level of oxygen and carbon monoxide. Carbon monoxide molecules, even in a small amount, can attach to the patient's hemoglobin replacing oxygen molecules.

3. Irregular heartbeats or by patient's movements can post irregular signal.

4. A high level of methaemoglobin would cause a pulse oximeter to have a reading of around 85% regardless of the actual oxygen saturation level. The higher percentage of methaemoglobin can be genetic or caused by exposure to certain chemicals and medications.

PRINCIPLE OF OPERATION

Physiological Principle
SP62B determines SpO_2 by measuring the absorption of red & infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine SpO_2 reading and pulse rate.

Date Update and Signal Processing
SP62B in the algorithms automatically extends the amount of data required for measuring SpO_2

and pulse rate depending on the measuring conditions. During normal measurement conditions, the averaging time is three to six heart beats. **SP62B** automatically adjusts the signal processing during degraded conditions, such as finger motion, ambient light, electromagnetic interference, and patient motion, which results in an increase in the dynamic averaging beyond 10 heart beats or may reach 40 heart beats.

Pulse Indicator

The Pulse Indicator displays a loading bar when detect a pulse. When the pulse rate is detected, the bar will continue to show to indicate the connection of reading, but it does not mean it is the signal strength, nor will it affect the strength of signal.

Pulse Waveform Display

The display provides the pulse waveform to detect the real-time sensor signal. The relative pulsation rate of the input signal can be observed.

CONTENT OF PACKAGE

SP62B includes the following items:

A.   Fingertip Pulse Oximeter, 1 unit
B.   User Manual, 1 sheet
C.   AAA-Size Alkaline Battery, 1 piece

Please make sure all items are packed. All items are non-sterile. If any item is missing or damaged, contact your distributor.

WARNINGS (general)
- Do not use the oximeter in an explosive atmosphere to avoid explosion hazard.
- Do not use the oximeter when applied part temperature is over 41°C (105.8°F).
- The oximeter has to measure the pulse properly to obtain accurate SpO2 reading. Blood flow restrictors (e.g., blood pressure cuffs) may hinder pulse measurements. Remove any objects that may hinder the performance of the oximeter.
- **SP62B** is a no SpO_2 alarm device. Please do not use **SP62B** under alarm-required situation.
- Exposure to strong external light while taking measurement may result in inaccurate readings. Shield the sensors from bright lights. Strong electro-magnetic fields may also affect readings.

- Nail polish and pressed-on nails may interfere with readings.

- Intravenous dyes (such as methylene blue, indigo carmine, and indocyanine green) can cause inaccurate readings.

- **Seek professional advice** if measured irregular reading. SP62B is designed to monitor user health condition, not diagnosis or interpretation of health condition.

WARNINGS (for health professionals)
- Do not use the oximeter in an MRI or CT environment.
- The oximeter is intended as an adjunct in subject assessment. It must be used in conjunction with other methods to assess clinical signals and symptoms.
- When replace a battery of the device, a user shall not to touch the battery contact or battery and the patient simultaneously.

WARNINGS (for patients)
- If the monitoring sites have trauma, disability or other medical conditions, users should consult doctors before use.
- Please do not leave the device to a child and always keep the battery cover in attach to avoid swallowing by a child.

DEVICE FEATURES

Two color OLED display
Press the ⟳ key to rotate the screen
Lanyard Hole
Battery Cover

SYMBOLS AND TERMINOLOGY

1	SpO2% – The symbol shows the oxygen saturation in percentage.
2	▤ PR bpm The pulse rate symbol shows pulse rate in beats per minute
3	◣ ◣ Pulse Indicator – It shows the signal being detected by the oximeter.
4	▥ - Battery condition symbol. When ▭ is shown, battery is at low voltage.
5	📶 The bluetooth icon indicates that SP62B is under broadcast condition

⚠ **CAUTION**

- This oximeter is not an apnea monitor.
- Significant levels of dysfunctional hemoglobin such as carbonxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- Cardio green and intravascular dyes may affect the accuracy of **SP62B**.
- The performance of the oximeter might be affected by the presence of a defibrillator.
- The oximeter may not work on all subjects. If you are unable to achieve stable readings, please discontinue use.
- The oximeter has motion tolerant algorism to minimize the possible motion artifact. However, the oximeter may be still interpreted by motion. Please minimize subject motion as much as possible.
- All the materials of the oximeter in contact with a patient or a user have passed ISO 10993 Biological Evaluation of Medical Devices accordingly. It shall be no toxicity harm to children, pregnant or nursing women.

BEFORE USE

➢ **First Time Use**

For the first time use, a protective plastic membrane is attached to the front panel of the oximeter. Please remove the plastic membrane to allow the OLED display to show its best performance.

The oximeter is calibrated in the factory before deliveried, there is no need to calibrate it during its life cycle.

➢ **Battery Replacement**

Before start any measurement, please make sure the battery power is sufficient and the setting is correct. If not, please refer to the following procedures. Make sure the oximeter is off when replacing the battery. The device is powered by one AAA-size alkaline battery. Please press the ⯈ mark on the battery cover to open it up and installing a new battery

⚠ **CAUTION**

- Please use alkaline battery to ensure the best performance of device.
- Please dispose the battery according the proper procedure.

⚠ **CAUTION**

- **SP62B** can be operated by either a patient or trained personnel. Consult healthcare professionals before use.
- The oximeter might not work on cold extremities due to poor circulation. Please warm or rub the finger, or reposition the device to improve it.
- Check the applied site of a patient frequently to evaluate body circulation and skin sensitivity. The recommended maximum applied time at a single spot is 30 minutes. Misapplication of the oximeter on applied site with excessive pressure for prolonged periods can introduce pressure injury.

OPERATION

STEP1. Open up the oximeter and put one of your fingers into the opening. Please make sure that your finger face up and touch the bottom (Inner Base) of the opening before releasing the clamp.
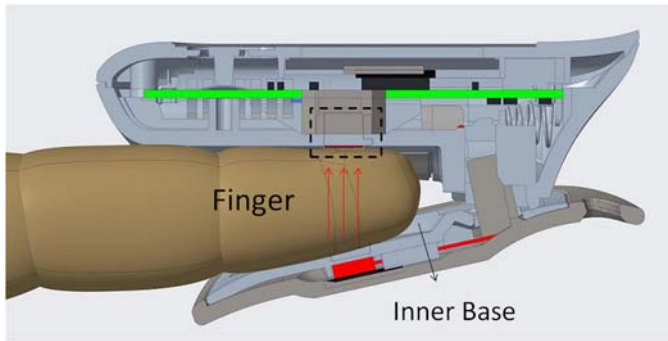
STEP2.   The device will turn on automatically after finger is inserted.

STEP3.   Reference to Data Transferring, for Bluetooth setup.

STEP4.   After detecting the pulse signal, the oximeter shows SpO_2 and pulse rate on the display. The readings will be updated based on the signal received with each pulse.

STEP5.   During the operation, if you press the ⟳ key, the screen will rotate in different direction to allow users in desired view angle.

STEP6.   If the finger is not detected or removed, the oximeter will show "Finger Out". As the finger keeps being undetectable, the device will turn off automatically in about **8** seconds.

STEP7.   After finish use, follow the cleaning instruction to clean the device thoroughly.

Data Transferring

This product is a Pulse Oximeter. Design without entering personal information. If the device has a transmission function, the transmission measurement data is designed to be encrypted and transmitted, and will not be tampered with or retrieve user-related information during the transmission process. The firmware and software of the product have been programmed in the production process, and the programming interface is different from the data transmission interface. When programming to the microcontroller, use an encrypted programmer, so there is no need to worry about the software being tampered with during transmission.

Bluetooth function requirement:
- An Android device with Android version 4.3 or above and hardware support for Bluetooth 4.2.
- An iOS device with iOS version 5 or above and hardware support for Bluetooth 4.2.

How to activate the Bluetooth function:
Please refer to the instruction manual of your mobile phone or computer for how to activate the Bluetooth function.

Set Up Process
(1) Please check if your mobile phone or computer has BLE4.2.
(2) Turn on the SP62B (put your finger into the pulse oximeter), when the Bluetooth icon shows on the device, it means SP62B is under broadcast condition.
(3) Enable Bluetooth function from your mobile phone or computer. Check for available Bluetooth connection, the device name should be "SP62B".
(4) It require manual Bluetooth connection for every time, once the connection is connected the measure reading will automatically transfer to your mobile phone or computer.

TROUBLE SHOOTING

Problem	Possible Causes	Solutions
The oximeter won't turn on.	The battery is dead.	Replace with a new battery.
	The battery is installed incorrectly.	Verify correct battery orientations.
	Finger might be trembling or place incorrectly.	Keep the finger steady or align the finger inward at vertical-middle of the device.
Display lockup or blank. If the device is on a finger, changes do not	The measuring function is malfunction.	The reading might not be reliable; discontinue using the device.
	Electromagnetic interference	Remove the surrounding electronic devices

appear at wave form or pulse indicator.	(EMI).	away. eg. MRI, CT at hospital, or microwave at home environment.
	Finger might be trembling or place incorrectly.	Keep the finger steady or align the finger inward at vertical-middle of the device.
No reading of SpO_2 or pulse rate and shows dash-line.	Low finger pulse quality.	Please try the following. 1. Reposition the finger 2. Warm the finger by rubbing. 3. Select another finger.
SpO_2 or pulse rate warning/indicator appears	A patient's condition is abnormal.	Provide immediately medical attention to this patient.
Low battery "▭" appears on display.	The battery power is low.	Replace with a new battery.

If you have followed the actions recommended above but the problem keeps unresolved, please call your agent for assistance.

FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/ TV technician for help.

CAUTION:

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

RF exposure warning

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.

The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.

MAINTENANCE AND STORAGE

- Remove the batteries inside the battery compartment if the oximeter will not be operated for more than one month.
- It is best to preserve the product in a place where ambient temperature range is from -30°C ~ 70 °C (-22 °F ~ 158 °F), humidity range from 10% to 90%, and atmospheric pressure range from 700hPa to 1060 hPa.
- The commercially available bench top functional testers and patient simulators may only be suitable to validate the pulse rate, but may not be able to verify the proper oximetry of this pulse oximeter. Please consultant with your distributor or the manufacturer proper model and the usage of functional testers and patients simulator for this oximeter.
- Furthermore, after a long term operation, the light sensor within the device may degrade with time. The testers and simulators may be useful for verifying that the pulse oximeter are working normally A functional tester cannot be used to assess the accuracy of pulse oximeter device.
- During the warranty period, if the evident shows that the device is misused or the device has been opened or tampered with the components within the casing by non-authorized service personnel, the warranty will be invalidated and a charge for repair will be assessed.

  ⚠ **CAUTION**

  - Do not spray, pour, or spill any liquid on the oximeter, accessories, switches or openings.
  - Do not use caustic or abrasive cleaning agents on the oximeter.
  - This is a precision medical instrument and must be repaired by qualified personnel from manufacturer only.
  - Please follow local governing ordinances and recycling instructions regards disposal or recycling of the device and components.

Clean and Disinfection

- For home use device disinfection, use 75% alcohol (available in the pharmacy) with damp cloth for cleaning and disinfection, the device can be clean up to 1000 times. Clean it thoroughly the body and the finger groove.
- Never use abrasive cleaning agents, thinners or benzene for cleaning. Do not scratch the surface of the lens or the display. Do not expose the oximeter to extreme temperatures, humidity, direct sunlight, or shock.
- Do not immerse the pulse oximeter into water, as the liquid can penetrate and damage the device nor ever place any heavy objects on the device.

Technical Specification

Dimension & Weight	L68mm (2.68'') x W37.8mm (1.49'') x H30.2mm (1.19''); without battery: approx. 26g (0,92 ounces)
Display	Two color OLED
Auto on/off	Whenever user inserts a finger, the device will turn on automatically. Vise versa, the device will turn off automatically when the finger is removed from it.
Input key	◎ key for screen rotate
Measurement Method	Dual wavelength LED (660 nanometers @ 3.2mW and 905 nanometers @ 2.4mW; both as max average
SpO$_2$ Range & Resolution	Range: 0% to 100%; resolution: 1%
SpO$_2$ Accuracy	Range 70% to 100% range ± 2%, less than 70% are unspecified
Pulse Rate Range & Resolution	Range: 30 to 250 bpm; resolution: 1 bpm
Pulse Rate Accuracy	±2 bpm or ±2%, whichever is greater
Water-resistance	Against water splash (IP22 Approved)
Battery Type	1 AAA-size Alkaline battery
Usage Life	> 18 hrs typical operation under default setting
Ambient Temperature	Operation: 5 °C - 40 °C (41 °F - 104 °F); Storage: -30°C ~ 70 °C (-22 °F ~ 158 °F)
Atmospheric Pressure	Operation & storage are both 700 hPa - 1060 hPa
Humidity	Operation & storage are both 10% - 90%, non-condensing
Degree of Electrical Protection	Type BF
Bluetooth Frequency	2402~2480GHz
Bluetooth Output Power Range	<=4dBm

This device has been tested under compliance with IEC 60601-1, IEC 60601-1-2, ISO 80601-2-61, and ISO 10993 requirements.

EMC Tables

The oximeter is intended for use in the electromagnetic environment specified as below. The customer or the user should assure that it is used under such an environment.

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment			
Fingertip Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Fingertip Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Fingertip Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	80 MHz to 800 MHz $d=1.17\sqrt{P}$	800 MHz to 2.5 GHz $d=2.33\ \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

Declaration - electromagnetic emissions		
Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Fingertip Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Fingertip Pulse Oximeter 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.
RF emissions CISPR 11	Class B	Fingertip Pulse Oximeter 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.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	N/A	

Fingertip Pulse Oximeter declaration – electromagnetic immunity			
Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below.			
The customer or the user of Fingertip Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms ; 6 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m ; 10V/m 80 MHz – 2.7 GHz 80%	10 V/m 80 MHz – 2.7 GHz 80%	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m	385 MHz	27 V/m	385 MHz	
	28 V/m	450 MHz	28 V/m	450 MHz	
	9 V/m	710 MHz	9 V/m	710 MHz	
		745 MHz		745 MHz	
		780 MHz		780 MHz	
	28 V/m	810 MHz	28 V/m	810 MHz	
		870 MHz		870 MHz	
		930 MHz		930 MHz	
	28 V/m	1720 MHz	28 V/m	1720 MHz	
		1845 MHz		1845 MHz	
		1970 MHz		1970 MHz	
	28 V/m	2450 MHz	28 V/m	2450 MHz	
	9 V/m	5240 MHz	9 V/m	5240 MHz	
		5500 MHz		5500 MHz	
		5785 MHz		5785 MHz	

Declaration – electromagnetic immunity			
Fingertip Pulse Oximeter is intended for use in the electromagnetic environment specified below.			
The customer or the user of Fingertip 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 , ±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 %.
Electrical fast transient/burst	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or

IEC 61000-4-4			hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T ; 0 , 5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0°	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

ESSENTIAL PERFORMANCE

The essential performance of **SP62B** Fingertip Pulse Oximeter is defined as Spo2 accuracy and pulse rate accuracy. The specification of **SP62B** Fingertip Pulse Oximeter in non-motion conditions is ±2 which is in compliance with the specified oxygen saturation, Arms of 2. The essential performance will not be affected under the electromagnetic environment specified as above.

Explanation of Symbols

Symbol	Definition
CE XXXX	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of European Medical Device Directive 93/42/EEC
MD	Medical Device
(Manufacturer symbol)	Manufacturer
EC REP	Authorized representative in the European Community
LOT	Batch code LOT WWWXXXXX LOT: Lot Number; WWW: working sheet; XXXXX: serial no.
SN	Serial number SN YYMWWWXXXXX YY: year; M:month; WWW: working sheet; XXXXX: serial no.
(Umbrella symbol)	Keep dry
(Thermometer symbol)	Temperature limit
(%)	Humidity limitation
(Pressure symbol)	Atmospheric pressure limitation
⚠	Caution
(Consult symbol)	Consult the instruction for use
(Waste bin symbol)	Disposal information: Should you wish to dispose of the article, do so in accordance with current regulations. Details are available from your local authority. WEEE 2012/19/EU Directives
RoHS	This product fulfilling the requirements of the RoHS Directive 2011/65/EU.
REACH	This product fulfilling the requirements of the REACH Directive EC 1907/2006 and its amendments, do not contain Substances of Very High Concern in concentration above the limit of 0.1 %. No substance(s) is/are present in the parts of the product above the concentration of 0.1 % weight by weight.

	Device classification type BF
IP 22	This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm Ø and greater and against vertically falling water drops when enclosure tiled up to 15°)
	The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.
	Importer
	Distributor
	Model Number
	Country of Manufacturer
UDI	Unique Device Identifier
	Keep away from sunlight
	No alarm

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2022.12.08