User's Manual

CE 0123

1-Product Description

- Product name: Reusable spo2 sensors
- Components: Plug, LED, PD, cable and fitting parts.
- This instruction manual includes the instruction manual and the technical instruction manual.
- Model: Table 1

Table 1 Model table of Spo2 sensors

Model(REF)	Type	Intended population	Compatible monitor	Intended measuring position
P9119	Finger clip	Adult （>40 kg）	Nellcor	Finger or toes
P9318E	Finger clip	Adult （>40 kg）	Nellcor	Finger or toes
P9318H	Finger clip	Adult （>40 kg）	Nellcor	Finger or toes
P9325A	Finger clip	Adult （>40 kg）	Nellcor	Finger or toes
P9119A	Finger clip	Adult （>40 kg）	Nellcor	Finger or toes
P8325A	Finger soft tip	Adult （>40 kg）	Nellcor	Finger or toes
P8318H	Finger soft tip	Adult （>40 kg）	Nellcor	Finger or toes
P8119A	Finger soft tip	Adult （>40 kg）	Nellcor	Finger or toes
P8119	Finger soft tip	Adult （>40 kg）	Nellcor	Finger or toes
P7119	Finger clip	Pediatric （10-50kg）	Nellcor	Finger or toes
P7119A	Finger clip	Pediatric （10-50kg）	Nellcor	Finger or toes
P6119	Finger soft tip	Pediatric （10-50kg）	Nellcor	Finger or toes
P6119A	Finger soft tip	Pediatric （10-50kg）	Nellcor	Finger or toes
P5119	Soft wrap	Pediatric （10-50kg）	Nellcor	Finger or toes
P5318E	Soft wrap	Pediatric （10-50kg）	Nellcor	Finger or toes
P4119	Soft Multi-Y	Pediatric （10-50kg）	Nellcor	Finger,toes or palm

2-Intended Use

Use with the corresponding pulse oximetry device, suitable for continuous nontraumatic monitoring of pulse oxygen saturation and pulse rate in patients.

3-Scope of application

- It is mainly matched with the corresponding monitor or oximeter to collect and transmit the blood oxygen saturation and pulse rate signal of patients.
- Applicable status: static.

4-Basic performance

- Oxygen saturation error.
- Pulse rate error.

5-Product performance:

- Emission wavelength: 660±3nm, absorption wavelength: 905±5nm, maximum optical output power: 2mw.
- Output power of the transmitter tube: RED: 110mw; Infrared IRED: 160mw.
- SpO2 test range: 70%~ 100%, accuracy: ≤± 3%
- Note: Using the sensor in strong light may result in measurement errors. To use in strong light, cover the sensor with an opaque material.
- Pulse rate range:： 30bpm~250bpm ， Accuracy: ≤ ±2BPM.
- A. 1 Main safety features of Spo2 sensors.

  A. 1. 1 Electric shock protection type: It depends on the host.

  A. 1.2 Degree of protection from electric shocks: type BF

A. 1.3 Classification according to the degree of protection against liquid intake: Not applicable.

A. 1.4 Classification by degree of safety when used in the presence of flammable anaesthetic gases mixed with air or flammable anaesthetic gases mixed with oxygen or nitrous oxide: Not applicable.

A. 1.5 Classification by Running Mode: Continuous Running.

A. 1.6 Rated voltage and frequency: Not applicable.

A. 1.7 Input Power: Not applicable.

A. 1.8 Does the device have application of protection against defibrillation discharge effect: Not applicable.

A. 1.9 Does the Device have A signal output or input part? Not applicable.

A. 1. 10 Permanently installed devices or not permanently installed devices: Not applicable.

A. 1. 11 Electrical insulation diagram: not applicable, determined by the supporting host.

6-Operation environment

- Temperature: +5 ° C~+40°C
- Humidity: ≤80%
- Atmospheric pressure: 86KPa~106KPa
- Power supply: DC3-5V

7-Storage/Packaging

- The sensors are individually packaged.
- A sensor must be stored in its original packaging and within the storage conditions to maximize the storage life of the sensor.
- Storage conditions are as follows:
- Ambient temperature: -20 ° C ~ +55 ° C
- Relative humidity:≤93%
- Atmospheric pressure: 86KPa~106KPa

8-Installation / Use:

- Before opening the package for the first time, check whether the package is complete: 1PCS of products; One copy of product instruction manual.
- According to the device's instruction manual, check the compatibility of the Spo2 sensors, connect the probe to the tyn cable, and connect it to the device, and check whether the probe can work properly according to the prompts.
- The best measurement is the index finger. If the index finger cannot be positioned correctly on the index finger or the index finger cannot be used, another finger can be used as the measuring site.
- Place your index finger on the measuring opening of the probe, with the tip of your finger level and touching the tip of the clip.
- Tape the cable in place along the back of your hand.
- Do not use if the package is damaged, replace the probe with a new one.

9-WARNING ⚠

- Measurements are best when the probe is at the same level as the heart.
- Limb sites without ductus arteriosus, blood pressure cuffs, and intravenous tubes should be given priority when choosing a sensor site.
- If the sensor doesn't accurately detect the pulse, it's in the wrong place or the area it's placed in is too thick, thin, or dark to give the right amount of light. If this happens, reposition the sensor or select another type of sensor.
- The sensor is used in specialized medical equipment, where it is the operator's responsibility to check for compatibility, as incompatible parts or equipment could affect the test results.
- Data and waveforms may still appear on the monitor or oximeter even after the probe is removed from the human body, due to interference from external light. This doesn't mean the probe is faulty, but the values displayed at this point can't be used as a clinical diagnosis.
- When using this product, the skin in contact with the probe should be intact, and do not touch the skin with wounds or allergies.

10-Contraindications, warnings and suggestive statements:

- Contraindications: Do not fix the product in the site of tissue damage; Not applicable to patients and users allergic to PVC, TPU, TPE, ABS plastics.
- Warning: ⚠

1. If the probe and cable are found to be damaged, contaminated, or material deterioration, or the package is found to be damaged, please do not use it for patient monitoring.

2. If you want to discard it, please follow the relevant local regulations or the waste disposal system of the hospital director. Do not discard it at will.

3. Try to place the probe on a limb that does not have an arterial catheter, a sphygonometer cuff, or an IV line.

4. To minimize the influence of the electrosurgical device on the measurement, do not place the cable near the power cable of the electrosurgical device.

5. The measurement site should avoid frequent movement, and the patient should be kept quiet as far as possible to reduce movement. Try to select the part that is well perfused and can completely cover the sensor. Clean the measuring part before placing the probe, and place the probe after the measuring part is completely dry.

6. When the patient is monitored continuously for a long time, the measurement site should be checked and changed at least every 2 hours. Some patients may need more frequent testing, such as those with perfusion disorders or skin sensitivities. Prolonged monitoring may increase unexpected skin changes, such as irritation, redness, blistering, or compression necrosis.

7. This product can only be used with designated equipment. It is the user's responsibility to read the instruction manual of the equipment or contact the company for consultation before use to confirm the compatibility of the product with the use of the extension cable and the equipment.

8. The measurement site must be checked every 2 hours.

9. Cables should be properly positioned to avoid entangling or suffocating the patient.

10. Do not use a probe during a magnetic resonance imaging (MRI) scan because the induced current may cause burns.

11. Do not immerse the probe in any solvent.

12. Too tight binding of the probe will lead to venous pulsation, blocked cycle of blood sequencing, compression traces, compression necrosis, spurious error, and inaccurate measurement. If it is too loose, it will lose the optical alignment and even fall off.

13. If the perfusion at the measurement site is too low, the pulse oxygen saturation measurement may be inaccurate.

14. If a probe is used during whole-body radiation therapy, place the probe outside the radiation area. If the probe is exposed to the radiation area or, the reading may be inaccurate or zero during the effective radiation period.

15. Using the probe when light is strong may lead to measurement errors. If you want to use a light - tight material to cover the probe when the light is strong.

16. Before using the probe and cable, the operator must check the compatibility of the probe with the device. Misuse may cause injury to the patient.

17. The accuracy of the Spo2 sensors should not be evaluated by a functional tester such as a blood oxygen simulator.

18. If the probe and cable are found to be damaged, contaminated or material deteriorated, or if the package is found to be damaged, please do not use it for patient monitoring.

19. If you want to discard, please follow the relevant local regulations or the waste disposal system of the hospital director. Do not discard at will.

20. Try to place the probe on a limb that does not have an arterial catheter, a sphygonometer cuff, or an IV line.

21. To minimize the impact of the electrosurgical device on the measurement, do not place the cable close to the power line of the electrosurgical device.

22. The probe has been confirmed and tested for YY0784-2010 conformance together with the pulse oximetry monitor. And can be given electronically.

23. Use beyond the validity period may lead to inaccurate measurement.

24. The product cannot be repaired. Please replace it.

25.Some scenarios may affect the function and accuracy of the pulse oximeter, such as weak perfusion and diseased hemoglobin

26. The probe fixation site should have a normal and continuous arterial beating. Pigment interference at the fixed site of the probe can affect the results.

27. Intravascular dye or externally applied colored substances may cause inaccurate measurement of the sensor.

- Read the instructions before you use them. This instruction manual includes the instruction manual and the technical

instruction manual. Can be provided to the user in the form of electronic documents to obtain paper documents, please contact our company.

- The product is BF application part or CF application part at the host's discretion.

11-Maintenance:

- Keep the Spo2 sensors protected from moisture during long-term storage.
- Clean or sterilize the probe as follows before using.

12-Cleaning/disinfection:

- Do not immerse the probe in water or disinfectant.
- Do not wet the pins of the cable assembly.
- Sterilizing the probe too often can damage it. It is recommended that the probe be sterilized only when necessary, according to hospital regulations.
- Use only the cleaners and disinfectants specified in this manual.
- Scrub the probe with a cotton ball or soft cloth dipped in clean water.
- After cleaning, dry the probe with a cloth first.
- Place the probe in a cool environment to dry.
- Recommended disinfectants include a solution of 75% ethanol, 70% isopropanol, and 2% glutaraldehyde.

13-Service life:

- Production date: see the label.
- Expiration date: 2 years.

14-CAUTION:

- Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
- In order to ensure compatibility and claimed accuracy of the devices Shenzhen MedKe Technology Co., Ltd.. SpO2 sensors are only to be used with the specified equipment for which they have been designed and labeled use for.
- Any serious adverse event related to the device should be reported to the manufacturer and the competent authority of the user member.

15-After service

- Please contact your local customer center for warranty information about this product.

16-Warranty/Liability

Shenzhen MedKe Technology Co., Ltd. offers a six month warranty against defects in material and /or workmanship from the date of purchase. Medke does not cover the damage or breakage due to the abusive use or negligent care of the sensor. Shenzhen MedKe Technology Co., Ltd. guarantees that the equipment conforms to the specifications of the safety and performance standards currently in force and applicable to it.

17- CLASSIFICATION RULE

As the device can be used for continuous surveillance of vital physiological parameters in anesthesia, intensive care or emergency care, it falls under the classification of IIb in accordance with the 1st paragraph and 3rd indent exceptional case of Rule 10 in Chapter III of Annex VIII of Regulation (EU) 2017/745. Additionally, this classification is supported by Note 3 mentioned on page 43 of MDCG 2021-24. Therefore, the device should be classified as a Class IIb medical device.

18- Intended clinical benefits

Offer SpO2 for user to detect hypoxemia.

19-Symbol explanation

	The operation guide must be read		Series number	**IPX2**	When the probe is tilted from vertical to 15 degrees, dripping water will not cause damage to the equipment
	Use-by date		See instructions before use		Latex Free
	Compliance with WEEE Standard		Date of manufacture		NON-sterile

REF	Catalogue number	EC REP	Authorized representative in the European Community		Type BF Applied Parts
CE 0123	European conformity	MD	Medical device		Atmospheric pressure limitation
	Humidity limitation		Temperature limitation		Manufacturer
UDI	UDI	/	/	/	/

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When necessary, the company shall provide the product connection diagram, circuit components list and other information. This manual can be provided to users with electronic documents or paper documents. If necessary, please contact the email address: info@medke.com.

IEC 60601-1-2:2014/AMD1:2020 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for Professional healthcare facility environment and so on.

Warning：Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning： Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning：Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SpO2 sensors (P9119, P9318E, P9318H, P9325A, P9119A, P8325A, P8318H, P8119A, P7119, P7119A, P6119, P6119A, P5119, P5318E, P4 119), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any：a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any：the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

Technical description

1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. SpO2 sensors do not contains magnetically sensitive electronic components and circuitry.

3. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2** **Test level**	**Compliance level**
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
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV 100 kHz repetition frequency	Power supply lines：±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s)：± 1 kV.	line(s) to line(s)：± 1 kV.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4- 11	0% 0.5 cycle At 0º , 45 º , 90 º , 135 º , 180 º , 225 º , 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0º , 45 º , 90 º , 135 º , 180 º , 225 º , 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle

Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz： 3Vrms 6Vrms (ISM bands between) 80% Am at 1kHz	150KHz to 80MHz： 3Vrms 6Vrms (ISM bands between) 80% Am at 1kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	Not application
NOTE UT is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Maximum Power**(W)	**Distance** (m)	**IEC 60601-1-2 Test level** (V/m)	**Compliance level** (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
	450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
	745							
	780							
	810	800 –	GSM 800/900,	Pulse modulatio	2	0.3	28	28
	870							

	930	960	TETRA 800, iDEN 820, CDMA 850,	n 18 Hz				

			LTE Band 5					
	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	2450	2 400 – 2 570	Bluetooth, WLAN, 802. 11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240 5500 5785	5 100 – 5 800	WLAN 802. 11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9