Pulse Oximeter Probe User Manual

Product name: Pulse Oximeter Probe

Product model: ESB0059

Intended use:

The probe is used with Patient Monitor and Pulse Oximeter to measure SpO_2 of the adult weighing greater than 40 kg in professional healthcare facility environment.

Intended users:

The probe should be operated by trained medical staff or non-medical staff who have received instruction

Scope of application:

The probe is used with the blood oxygen measurement equipment manufactured by our company; it is the operator's responsibility to check the compatibility of the equipment, probe and cable before use, as incompatible accessories will cause performance degradation of the equipment.

Clinical benefits:

The probe is used with Patient Monitor and Pulse Oximeter to determine the SpO_2 value and reduced SpO_2 value quickly and easily. The possible symptoms for people with low oxygen saturation are tachypnea, tachycardia, decreased exercise ability, tension and sweating. So chronic and well-known desaturation need to be monitored by this device under medical supervision. Acute oxygen saturation, with or without accompanying symptoms, should be cleared immediately, as it may be a life-threatening situation.

Contraindication:

It is inapplicable for long-term monitoring or monitoring the motion state, the measuring position should be checked or changed per 4 hours.

Product performance:

1) The range of SpO_2 measurement: 0%～100%,

Accuracy: 70~100%:±2%,Below 70%: unspecified.

2) The range of pulse measurement: 30～250bpm,

Accuracy: ±2bpm or ±2%(select larger).

3) Optical Sensor:

Red light (wavelength is 650~670nm, 6.65mW)

Infrared (wavelength is 880~910nm, 6.75mW)

4)Working voltage: DC 3 V,Input current: 30mA.

Main configuration: Consisting of sensor,connector and cable.

Power supply requirement: The specific power is supplied by the Patient Monitor and Pulse Oximeter manufactured by our company, which meet the requirements of IEC60601-1.

Directions for use:

Note: This product is type CF applied part; The probe is the applied part.

Sketch map	Model explanation	Applied crowds	Placement
	Reusable adult Fingertip pulse oximeter probe	Weight>40Kg adult	Recommendatory placement:forefinger

Figure 1

1) As **Figure 1**, the pulse oximeter probe is applied to adult weighing greater than 40 kg .

2) Put the probe on recommendatory placement according to **Figure 1**.

3) Arrange the cable along the back of hand when place the pulse oximeter probe.

4) Connect pulse oximeter probe with oximeter or patient monitor and check if the operating procedure accords with the procedure introduced in user manual.

Notice items:

1) Pulse oximeter probe placement, the position without ductus arteriosus, BP cuff and vein input pipe is top-priority.

2) If the pulse oximeter probe can't monitor the state of pulsation, it shows that the position of probe is improper, or the position is too thick, too thin or having too deep pigment to reach a proper translucidus effect. If above things has happened, place the probe again or select probe of other type.

3) This pulse oximeter probe should be applied to the special medical equipment. Operator is responsible to check the compatibility Incompatible fittings or device will influence the measuring result.

4) The disposal of scrap instrument and its accessories and packing (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

Maintenance/cleaning/disinfection：

Maintenance：

1) Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patients safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.

2) Please clean and disinfect the device before/after using it according to the User Manual.

Cleaning:

1) Information on components to be cleaned: sensor, connector, and cable.

2) Cleaning method: The recommended cleaning agents are: soapy water solution(5%) and distilled water.

(1) When cleaning the pulse oximeter probe, please use a clean cotton cloth soaked in soapy water solution(5%), fully wring it dry, and then wipe the sensor, connector, and cable surfaces for 3 minutes each;

(2) Dip a clean cotton cloth in distilled water, thoroughly wring it dry, and then wipe the surfaces of the sensor, connector, and cable for 2 minutes each;

(3) Repeat the above steps 5 times until there are no obvious residues. During the cleaning process, it is necessary to prevent the entry of cleaning agents and water into the sensor and connector until the cleaning is completed. It is strictly prohibited to use alcohol or alcohol containing washing solutions.

Disinfection:

1)Information on components that need to be disinfected: sensor, connector, and cable.

2) Disinfection method: The recommended disinfectant is isopropyl alcohol(70%) and distilled water.

(1) Before disinfection, clean the cable components;

(2) Dip isopropyl alcohol(70%) with cotton ball or soft cloth, and wipe the sensor, connector and cable surface respectively for 3 minutes after fully screwing;

(3) Then dip a cotton ball or soft cloth in distilled water, thoroughly wring it dry, and wipe the surfaces of the sensor, connector, and cable for 2 minutes each;

(4) Place the cable components in a cool and shaded environment to dry.

Note: Don't immerse the product in the liquid, and don't expose it under the strong ultra-violet radiation

Service life: Two years.

Environment requirements:

Transport and storage

1) Temperature: -20℃～+55℃
2) Humidity: ≤ 95%
3) Pressure:500hPa～1060hPa

Operating

1) Temperature: +5℃～+40℃
2) Humidity: ≤ 90%
3) Pressure: 700hPa～1060hPa

Statement:

1) Pulse oximeter probe needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in User Manual and test report.
2) Portable and mobile RF communications equipment can affect pulse oximeter probe.

Warning:

1) The use of cables other than those specified, with the exception of cables sold by CONTEC as replacement parts for internal components, may result in increased emissions or decreased immunity of pulse oximeter probe.

2) Pulse oximeter probe should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the pulse oximeter probe should be observed to verify normal operation in the configuration in which it will be used.

3) Improper usage can result in inaccurate measurement.

4) Using it under too strong light will cause inaccurate measurement, in case of that, please set a opaque stuff around the probe to cut light off.

5) You should move the probe to other position per 4 hours at least. Because the state of local skin can influence the ability of skin to enduring probe, it is necessary to replace the position of probe according to the state of patient. Please do that when skin integrity changes.

6) The dyestuff in blood vessel cab cause the inaccurate measurement.

7) The performance of pulse oximeter probe is influenced by movement easily, so it is not suitable for active patient to use it.

8) Don't fix the probe with belt or bundle it tightly, because the vein pulsation can cause inaccurate SpO_2 measurement.

9) Same as other medical equipment, the cable should be set properly to avoid enlacing or asphyxiate patient.

10) Don't use it in the process of MRI scan, because the conductor current may burn the skin of patient, moreover, the probe will influence MRI image and MRI set will also influence the accuracy of SpO_2 measurement.

11) Don't change the product at will, otherwise the capability or accuracy of product will be influenced.

12) The probe is not intended for use during patient transport outside the healthcare facility.

13) DO NOT use the probe while the patient is being scanned by MRI or CT.

14) No modification of this equipment is allowed.

15) 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.

16) 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.

17) 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.

18) 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 equipment, including cables specified by the manufacturer.Otherwise, degradation of the performance of this equipment could result.

19）Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

20) Misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.

21) For PULSE OXIMETER PROBES, the PULSE OXIMETER MONITOR(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER PROBES have been VALIDATED and tested for compliance with this document. The list may be made available by electronic means.

22) FUNCTIONAL TESTER cannot be used to assess the ACCURACY of a PULSE OXIMETER PROBE or a PULSE OXIMETER MONITOR.

Key of Symbols:

Symbols	Meaning	Symbols	Meaning
	Caution, consult accompanying documents		Use-by date
	Type CF applied part		Humidity limitation

	Attention! Refer to the accompanying file	NON STERILE	Non-sterile
LATEX	No latex	REF	Catalogue namber
SN	Serial number		Manufacture Date
	Recycling garbage WEEE (2012/19/EU)	LOT	Batch No
IPX2	Preventing from water		Temperature limitation
	Atmospheric pressure limitation	P/N	Material code
EC REP	European Representative		Manufacturer
UDI	Unique Device Identifier	MD	Medical device
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.		

Note：Your device may not contain all the following symbols.

EMC

Table 1:

Guidance and manufacturer's declaration – electromagnetic emissions	
The pulse oximeter probe is intended for use in the electromagnetic environment specified below. The customer of the user of the pulse oximeter probe should assure that it is used in such and environment.	
Emission test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A

Table 2:

Guidance and manufacture's declaration – electromagnetic immunity		
The pulse oximeter probe is intended for use in the electromagnetic environment specified below. The customer or the user of pulse oximeter probe should assure that it is used in such an environment.		
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
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz

Table 3:

Guidance and manufacturer's declaration – electromagnetic immunity		
The pulse oximeter probe is intended for use in the electromagnetic environment specified below. The customer or the user of pulse oximeter probe should assure that it is used in such an environment.		
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2Hz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2Hz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 2Hz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 2Hz

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] 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 pulse oximeter probe is used exceeds the applicable RF compliance level above, the pulse oximeter probe should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pulse oximeter probe.

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

Table 4:

Guidance and manufacturer's declaration - electromagnetic Immunity						
The pulse oximeter probe is intended for use in the electromagnetic environment specified below. The customer or the user of pulse oximeter probe should assure that it is used in such an environment.						
	Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance level (V/m)**
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100 –	WLAN	Pulse	9	9
	5500	5800	802.11 a/n	modulation 217 Hz		
	5785					

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

Table 5

Guidance and manufacturer's declaration - electromagnetic Immunity				
The pulse oximeter probe is intended for use in the electromagnetic environment specified below. The customer or the user of pulse oximeter probe should assure that it is used in such an environment.				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Test Frequency**	**Modulation**	**IEC60601-1-2 Test Level** (A/m)	**Compliance level** (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 MHz	Pulse modulation 50 kHz	7,5	7,5

Note：The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

CONTEC CE 0123

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