

Pulse Oximeter Probe user manual

Product name: Pulse Oximeter Probe

Product model: GSE0002(2.3.10.0009), GSE0003(2.3.10.0006), GSE0004(2.3.10.0007), GSE0005(2.3.10.0008)

Scope of application:

This product is used to match CONTEC Patient Monitor CMS8000, collect and transmit the SpO₂ signal from patient with continuance and no trauma. It is inapplicable to monitor the weak perfusion moving state and monitor for long, so check the measuring position or change for another position per 4 hours.

Taboo disease:

Don't fix the product on the position with tissue injury. It is inapplicable for the patient or users allergic to PVC、TPU、TPE、ABS plastic.

Product performance:

1) The range of SpO₂ measurement: 70%~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)

Main configuration: Consisting of plug, cable and probe.

Power supply requirement: The special power is supplied by from the equipments of CONTEC Patient Monitor CMS8000.which are applicable to the requirements of IEC60601-1.

Directions for use:

Note: This product is type BF applied part;

Sketch map	Model explanation	Applied crowds	Placement
	GSE0003 Adult disposable sensor	Weight>30Kg adult	Recommendatory placement: forefinger
	GSE0004 Pediatric disposable sensor	Weight10~50kg Pediatric	Recommendatory placement: forefinger
	GSE0005 Infant disposable sensor	Weight3~20kg Infant	Recommendatory placement: big toe
	GSE0002 Neonatal disposable sensor	Weight<3 kg neonate /weight>40kg adult	Recommendatory placement: neonate's foot, adult's forefinger

Figure 1

1) As **Figure 1**, the pulse oximeter probe of different types is applied to different crowds.

2) Select proper probe and put 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.

5) Pulse Oximeter Probe needs the help of the FSP0001 blood Oximeter extension cable to be connected into the SpO₂ socket of CMS8000 patient monitor's SpO₂ module for normal use. The FSP0001 has a DB9F interface and is compatible with CMS8000 Patient Monitor. Connect a FSP0001 blood oximeter extension cable to the SpO₂ Sensor Port of the SpO₂ module (on the side board of CMS8000), then connect pulse oximeter probe to the other end of the FSP0001 blood oximeter extension cable. Plug the sensor connector firmly into the FSP0001 blood oximeter extension cable.

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:

- 1) Check if the product is undamaged and clean before using.
- 2) This product is not allow to use disinfection liquid for disinfection, this probe belong to one-off products.

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

Service life: Suggest this product use only once, don't use again.

Environment requirements:

Transport and storage

- 1) Temperature: -10°C ~ +40°C
- 2) Humidity: less than 80%
- 3) Pressure: 86kPa ~ 106kPa

Operating

- 1) Temperature: 10°C ~ +40°C
- 2) Humidity: 30% ~ 75%
- 3) Pressure: 700hPa ~ 1060Pa




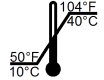
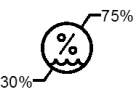
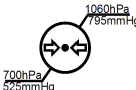



Statement:

- 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 SpO₂ 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 SpO₂ 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.

Explanation about graphs and symbols used on the product:

	Refer to instruction manual/booklet		Non-sterile		DO NOT REUSE		Temperature limitation
	Humidity limitation		Atmospheric pressure limitation		WEEE (2002/96/EC)	IPX1	International Protection
LOT	Batch code	SpO₂	The pulse oximeter saturation (%)	BPM	Pulse rate (bpm)	EC REP	EUROPEAN REPRESENTATIVE
REF	Catalogue number	CE ₀₁₂₃	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.				
	DO NOT USE IF PACKAGE IS DAMAGED		TYPE BF APPLIED PART				


Guidance and manufacturer’s declaration – electromagnetic emissions-for pulse oximeter probe

Guidance and manufacturer’s declaration – electromagnetic emission		
The pulse oximeter probe is intended for use in the electromagnetic environment specified below. The customer or the user of the pulse oximeter probe should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The pulse oximeter probe 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. The pulse oximeter probe 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.
RF emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacture’s declaration – electromagnetic immunity – for pulse oximeter probe

Guidance and manufacture’s declaration – electromagnetic immunity			
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields Should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer’s declaration – electromagnetic immunity –for pulse oximeter probe that are not LIFE-SUPPORTING

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 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the pulse oximeter probe, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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.			
<p>^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.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended separation distances between portable and mobile
RF communications equipment and pulse oximeter probe–
for pulse oximeter probe that are not LIFE-SUPPORTING**

Recommended separation distances between portable and mobile RF communications equipment and the pulse oximeter probe			
The pulse oximeter probe is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the pulse oximeter probe can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pulse oximeter probe 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			

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