

PROBE

REF		REF		REF	
GIMA 32903	ESA0005	GIMA 35105	LSA0019	GIMA 35153	ESA0061
GIMA 32907	ESA0016	GIMA 35106	ESA0015	GIMA 35215	ESA0063
GIMA 35049	ESA0089	GIMA 35107	ESC0029	GIMA 35216	ESC0064
GIMA 35054	ESA0091	GIMA 35118	ESA0014		
GIMA 35055	ESC0092	GIMA 35123	ESA0078		
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Pulse Oximeter Probe User Manual

Product name: Pulse Oximeter Probe

Intended purpose:

The Pulse Oximeter Probe can be used in measuring the pulse oxygen saturation and pulse rate.

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 SpO₂ value and reduced SpO₂ 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 SpO₂ 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)

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 finger-clip SpO2 probe	Weight>40Kg adult	Recommendatory placement:forefinger
	Reusable child finger-clip SpO2 probe	Weight 10~40kg child	Recommendatory placement:forefinger
	Reusable wrap SpO2 probe(type Y probe)	Weight 3-10kg neonate	Recommendatory placement:sole of foot

Figure 1

- 1) Put recommendatory placement according to **Figure 1**.
- 2) Arrange the cable along the back of hand when place the pulse oximeter probe.
- 3) 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) To avoid cross-infection, please clean and disinfect the probe in time when it is used by the other person.

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 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)Please read the User Manual carefully before using this device. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, device damage and human injury.
- 2)Do not operate it with wounded parts
- 3)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.
- 4) 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.
- 5) Improper usage can result in inaccurate measurement.
- 6) 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.
- 7) 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.
- 8) The dyestuff in blood vessel cab cause the inaccurate measurement.
- 9) The performance of pulse oximeter probe is influenced by movement easily, so it is not suitable for active patient to use it.
- 10) Don't fix the probe with belt or bundle it tightly, because the vein pulsation can cause inaccurate SpO₂ measurement.
- 11) Same as other medical equipment, the cable should be set properly to avoid enlacing or asphyxiate patient.
- 12) 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.
- 13) Don't change the product at will, otherwise the capability or accuracy of product will be influenced.
- 14) The probe is not intended for use during patient transport outside the healthcare facility.
- 15) DO NOT use the probe while the patient is being scanned by MRI or CT.
- 16) No modification of this equipment is allowed.
- 17) 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.
- 18) 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.
- 19) 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.
- 20) 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.

21) 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.

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

23) 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.

24) 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
	Follow instructions for use		Humidity limit
	Type CF applied part		Non-sterile
	Caution: read instructions (warnings) carefully		Product code
	Not made with natural rubber latex		Date of manufacture
	Serial number		Lot number
	WEEE disposal		Temperature limit
	Covering Protection rate		Material code
	Atmospheric pressure limit		Manufacturer
	European Representative		Medical device
	Unique Device Identifier		Medical Device compliant with Directive 93/42/EEC

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 an 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.						
Radiated RF IEC61000-4-3 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	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					
	870	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	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	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	2450					
	5240					
	5500	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	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: 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. $E = \frac{6}{d} \sqrt{P}$

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.

Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies