PROFESSIONAL MEDICAL PRODUCTS

PROBE

REF

LSA0019 (GIMA 35105)
ESA0015 (GIMA 35106)
ESC0029 (GIMA 35107)
ESA0004 (GIMA 35149)
ESA0014 (GIMA 35118)
ESA0005 (GIMA 32903)
ESA0061 (GIMA 35153)
ESC0064 (GIMA 35216)

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CE 0123

LATEX MD

IPX1 106kPa 86kPa 80% 0% 40°C -10°C

M35105-EN-Rev. 1 - 07/24

Pulse Oximeter Probe user manual

Product name: Pulse Oximeter Probe

Product model: ESA0015 (GIMA 35106), ESC0029 (GIMA 35107), ESA0004 (GIMA 35149), ESA0014 (GIMA 35118), ESA0005 (GIMA 32903), LSA0019 (GIMA 35105), ESA0061 (GIMA 35153), ESC0064 (GIMA 35216)

Scope of application:

This product is used to match CONTEC Patient Monitor 、Pulse Oximeter and Electronic sphygmomanometer, collect and transmit the SpO_2 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 SpO_2 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 、Pulse Oximeter and Electronic sphygmomanometer which are applicable to the requirements of IEC60601-1.

Directions for use:

Note: This product is type BF applied part;

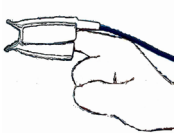
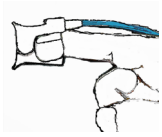
Sketch map	Model explanation	Applied crowds	placement
	Reusable adult finger-clip SpO2 probe (LSA0019, ESA0004, ESA0005, ESA0014, ESA0061)	Weight>40Kg adult	Recommendatory placement: forefinger
	Reusable child finger-clip SpO2 probe (ESA0015, ESA0016)	Weight10～40kg child	Recommendatory placement: forefinger
	Reusable wrap SpO2 probe (type Y probe) (ESC0029, ESC0064)	Weight3-10kg neonate	Recommendatory placement: sole of foot

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 Pulse oximeter, Patient Monitor or Electronic sphygmomanometer and check if the operating procedure accords with the procedure introduced in user manual.

5) Pulse Oximeter probe ESC0029 needs the help of the FST0001 Pulse Oximeter probe extension cable to be connected in to the jack of the Pulse Oximeter CMS60D, CMS70A or Patient Monitor CMS8000(old model),Pulse Oximeter probe ESC0029 needs the help of the FST0004 Pulse Oximeter probe extension cable to be connected in to the jack of the Electronic Sphygmomanometer CONTEC08A,Pulse Oximeter probe ESC0029 needs the help of the FST0002 Pulse Oximeter probe extension cable to be connected in to the jack of the Patient Monitor PM50. Pulse Oximeter probe ESC0029 needs the help of the FST0014 Pulse Oximeter probe extension cable to be connected in to the jack of the Patient Monitor CMS8000(new model)

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℃～+40℃
2) Humidity: less than 80%
3) Pressure: 86kPa～106kPa

Operating

1) Temperature: 10℃～+40℃
2) Humidity: 30% ~ 75%
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.

Explanation about graphs and symbols used on the product:

	Follow instructions for use		Date of manufacture		Disposable device, do not re-use		Keep in a cool, dry place
	Keep away from sunlight		Type BF Applied Part		WEEE disposal	IPX1	Covering Protection rate
LOT	Lot number	SpO2	The pulse oximeter saturation (%)	BPM	Pulse rate (bpm)	REF	Product code
	Manufacturer	EC REP	Authorized representative in the community European		CE 0123	Medical Device complies with Directive 93/42/EEC	
	Temperature limit		Atmospheric pressure limit			Humidity limit	
MD	Medical Device	UDI	Unique device identifier			Not made with natural rubber latex	

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 of the user of the pulse oximeter probe should assure that it is used in such and 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.
RF emission CISPR 11	Class B	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.
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			
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**
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	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. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
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.			

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.

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