SpO_2 Probe

Directions for Use 3502-2290067 V1.6 **Latex Free**

Intended Use

It's applicable to be used with a compatible patient monitor or a pulse oximeter device. The probe is intended to be used for non-invasively monitoring the functional arterial oxygen saturation (SpO_2) and pulse rate (PR) for adult and pediatric patients.

Contraindications

This probe is contraindicated for use on active patients or for prolonged use.

Structure and Composition

It consists of light emitting diodes, photo-detector, plastic or rubber fixing mechanics, cable and connector. Please note that model KS-CM01 also contains the built-in electronic circuit for measurement.

Model and Configuration see the table below.

No.	Model	Probe Name	Built-in measuring module
1	KS-C01	Adult Finger Clip SpO_2 Probe	No
2	KS-CM01	Adult Finger Clip Smart SpO_2 Probe	Yes
3	KS-YW02	Universal Y-type with Rubber Wrap SpO_2 Probe	No
4	KS-R01	Adult Finger Rubber SpO_2 Probe	No
5	KS-R02	Pediatric Finger Rubber SpO_2 Probe	No

Note: Pediatric Finger Rubber SpO_2 Probe is for pediatric weighting between 15kg - 40kg (or finger thickness between 8mm - 16mm)

Instructions for Use

SpO_2 probe is a kind of very delicate part. Please follow the given steps and procedures while using it. Failure to operate correctly can cause damage to the SpO_2 probe.

1. Connect the SpO_2 probe to the panel connector marked with "SpO_2" label on the signal input of the patient monitor or oximeter. When unplugging the probe, be sure to hold the head of the connector and pull it out.
2. For Adult Finger Clip SpO_2 Probe, insert one finger (index finger is preferred, but middle or ring finger with proper nail length is possible as well) into the probe according to the mark on the probe clip, as shown in Figure 1.

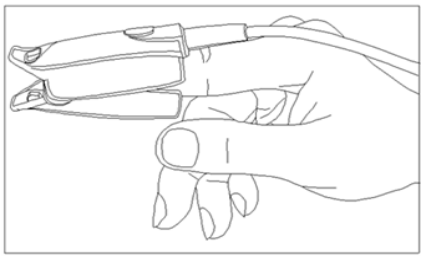

Figure 1 Finger Clip Probe

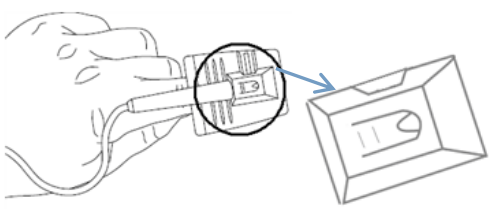

Figure 2 Finger Rubber Probe

3. For Adult Finger Rubber SpO_2 Probe, insert one finger (index finger is preferred, but middle or ring finger with proper nail length is possible as well) into the probe according to the mark on the probe cap, as shown in Figure 2. Note that the finger should be inserted deeply enough so that the light emitted from the opto-probe (at one side of Y-type probe) will transmit through the finger bone for light scattering before reaching to the receiving part of the Y-type probe.

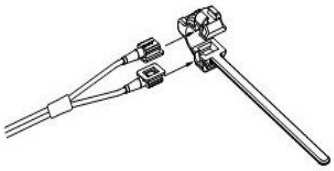

Figure 3 Universal Y-type Probe

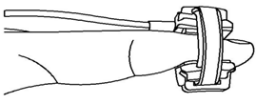

Figure 4(A/B) Y-type Probe on Finger/on Sole

4. For Universal Y-type with Rubber Wrap SpO_2 Probe, it can be wrapped onto finger or sole (especially for infant). This probe is shown in Figure 2 with open status, the rubber wrapper can be removed from the Y-type probe for cleaning, the wrapper fixation can be adjusted for probe alignment and proper tightness. Place the Y-type probe into its seating position within the wrapper and open the wrapper belt before wrapping onto finger or sole. When used on finger, put the finger inside the wrapper so as it is between the two sides of Y-type probe, then wrap the wrapper belt around the probe as illustrated in Figure 4(A). When used on sole, place the sole within the wrapper and wrap it up around the sole, then tighten the rubber belt with proper force as illustrated in Figure 4(B), it is strongly recommended to use self-adhesive gauze to fix the probe cable nearby the measuring site, so that the relative moving between the probe and the part to be measured could be avoided to increase signal quality.

Note:1) The probe placement is critical for the signal strength and quality especially for measurement on sole. Try to make the light aiming for the opto-emitting and receiving parts (Y-type probe) each other in the opposite side, so that the light beam is as vertically transmitted as possible and the light path is as short as possible.

2) Make sure there is arterial blood capillary (with artery pulse) and bone (for light scattering) within the light path between the opto-emitting and receiving parts, so that the measurement will be effective.

3) The rubber wrapper should be adjusted for adequate force with not too tight and not too loose. Too tight force (the skin color will become pale after a while) will be uncomfortable or even cause injury to the patient, too loose force will induce more motion artifact to degrade the signal quality.

Warnings and Attentions:

⚠ The SpO_2 probe should be used together with the compatible unit (such as a Patient Monitor and a Pulse Oximeter), otherwise, inaccurate measurement results will be caused.

⚠ Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.

⚠ All the parts of the probe should NOT be replaced at will. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused.

⚠ Local laws and regulations must be followed when disposing of the SpO_2 probe.

⚠ A functional tester cannot be used to assess the accuracy of the SpO_2 probe.

⚠ Please do not use nail polisher or other cosmetic product on the nail.

⚠ Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

Refer to the Monitor's/Oximeter's User Manual for additional warnings and attentions.

Operating Environment

1. Ambient temperature range: 5°C - 40°C; Relative humidity: 15% - 95%; Atmospheric pressure: 70kPa - 106.0kPa; Operate method: the compatible unit supplies power for the probe.
2. The probe should be situated in a place protected against direct sunlight, so as to prevent overheating inside it.
3. The probe should be stored and used within specified temperature, humidity and atmospheric pressure range, or it may cause damage to the probe or inaccurate measurement result.

Compliance

When used with the compatible Oximeters or Patient Monitors with compatible SpO_2 module, the device conforms to

IEC 60601-1. The electric safety classification: Type BF applied parts.

Accuracy Specifications

SpO_2: 1. Transducer: dual-wavelength LED

Wavelength: Red light: 663 nm, Infrared light: 890 nm

Maximal optical output power: less than 2mW maximum average

2. SpO_2 measuring range: 35%~100%

3. SpO_2 measuring accuracy: Arms value (defined in ISO 9919) is not greater than 3% for SpO_2 range from 70% to 100%.

Pulse Rate: 1. Measuring range: 30bpm - 240bpm

2. Accuracy: ±2bpm or ±2%, whichever is greater.

Classification

The type of protection against electric shock: Evaluate with the compatible main unit;

The degree of protection against electric shock: At least with Type BF applied parts when used with the main unit.

All specifications validated with the series product of Creative Pulse Oximeter (such as PC-68 series) and Patient Monitor (such as UP-8000, UP-6000 etc.) with Creative SpO_2 module.

Troubleshooting

1. If no measurement readings, please check if the light emitting component within the SpO_2 probe flashes (do not stare at the light from the probe), and check if the SpO_2 probe cable is properly connected to the right connector on the signal input panel of the oximeter. If the problem still exists, please contact the manufacturer.

Maintenance

To make sure the normal working and prolong the using life of the SpO_2 probe, please pay attention to maintain it.
In case any indication of damage about the SpO_2 probe is detected and proven, it is not allowed to use any more. Please contact the local dealer or the manufacturer for help.

- **Routine Maintenance**

At each routinely maintenance or the yearly maintenance, the SpO_2 probe together with the main unit can be thoroughly inspected by qualified personnel, including performance and safety examinations.

- **If the hospital fails to carry out a satisfactory maintenance program about the main unit (oximeter or patient monitor), it may damage the SpO_2 probe and harm the patient's safety and health.**
- **If there is any indication of cable and transducer damage or they deteriorate, they are prohibited from any further use.**
- The SpO_2 simulator can not be used to verify the SpO_2 measuring accuracy, which should be supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark-skinned subjects in an independent research laboratory. However it is necessary for the user to use SpO_2 simulator for routine verification of precision.
- Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO_2 simulator, e.g. for Index 2 series SpO_2 simulator from Fluke Biomecidal Corporation, please set "Make" to "DownLoadMake: KRK", then the user can use this particular R-curve to test the SpO_2 function. If the SpO_2 simulator does not contain "KRK" R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO_2 simulator.

Cleaning and Disinfection of the Probe

It is recommended to clean the measuring accessories (including probe/probe, wrapper and cable) with 75% Alcohol or 70% Isopropanol (Isopropyl) before use.

- **Do not use damaged accessories.**
- **Do not immerse in fluid of any kind.**
- **Do not attempt any other type of disinfection other than that indicated.**

Storage

For maximum probe life and optimum performance, store the probe at room in a dry, dust-free, non-corrosive gas environment. Storage environment:

Ambient temperature: -20 - 60°C， Relative humidity: 10% - 95%， Atmospheric pressure: 53kPa - 106kPa

Transportation

The probe can be transported via road rail or air in accordance with the manufactures guidelines. Do not drop or throw the probe in its packaging.

Symbols and Descriptions

Symbol	Description	Symbol	Description	Symbol	Description
	Attention-refer to the manual		Manufacturer		Manufacturing date
EC REP	Authorized representative in the European Community	SN	Serial Number		Follow WEEE regulations for disposal
CE 0123	This mark means that this device is fully in conformance with the Council Directive Concerning Medical Devices 93/42/EEC.	UK RP	UK responsible person		BF type applied part

CE 0123

Manufacturer: Shenzhen Creative Industry Co., Ltd.

Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park,
Songbai Road, Xili Street, Nanshan District, 518110
Shenzhen, P. R. China
Tel: +86-755-2643 3514
Fax: +86-755-2643 2832
E-mail: market@creative-sz.com

EC REP **EC-Representative:**

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

UK RP **Etheria Medical Ltd**

The Old Brush Factory Unit 2d Whickham Industrial Estate,

Swalwell, Newcastle Upon Tyne, United Kingdom, NE16 3DA

Tel: +44-191-4889922 Fax: +44-191-4889922