SpO_2 Sensor

Directions for Use 3502-2290067 V1.3

Intended Use

It's applicable to used with a compatible patient monitor or a pulse oximeter device. The sensor 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 sensor 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	Sensor Name	Built-in measuring module
1	KS-C01	Adult Finger Clip SpO_2 Sensor	No
2	KS-CM01	Adult Finger Clip Smart SpO_2 Sensor	Yes
3	KS-YW02	Universal Y-type with Rubber Wrap SpO_2 Sensor	No
4	KS-R01	Adult Finger Rubber SpO_2 Sensor	No
5	KS-R02	Pediatric Finger Rubber SpO_2 Sensor	No

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

Instructions for Use

SpO_2 sensor 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 sensor.

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

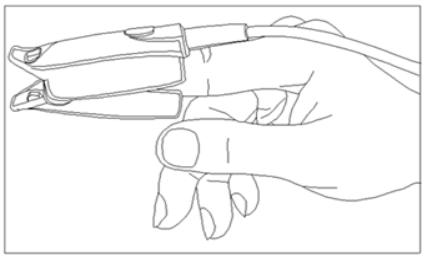

Figure 1 Finger Clip Sensor

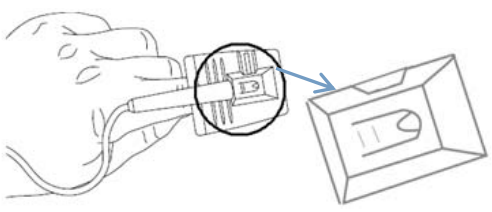

Figure 2 Finger Rubber Sensor

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

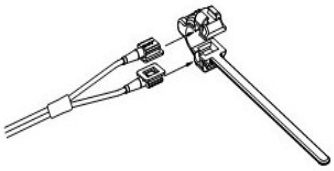

Figure 3 Universal Y-type Sensor

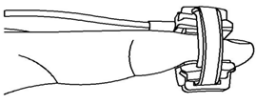

Figure 4(A/B) Y-type Sensor on Finger/on Sole

4. For Universal Y-type with Rubber Wrap SpO_2 Sensor, it can be wrapped onto finger or sole (especially for infant). This sensor is shown in Figure 2 with open status, the rubber wrapper can be removed from the Y-type sensor for cleaning, the wrapper fixation can be adjusted for sensor alignment and proper tightness. Place the Y-type sensor 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 sensor, then wrap the wrapper belt around the sensor 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 sensor cable nearby the measuring site, so that the relative moving between the sensor and the part to be measured could be avoided to increase signal quality.

Note:1) The sensor 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 sensor) 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 sensor 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 sensor 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 sensor.

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

⚠ 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 sensor.

2. The sensor should be situated in a place protected against direct sunlight, so as to prevent overheating inside it.
3. The sensor should be stored and used within specified temperature, humidity and atmospheric pressure range, or it may cause damage to the sensor 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 sensor flashes (do not stare at the light from the sensor), and check if the SpO_2 sensor 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 sensor, please pay attention to maintain it.
In case any indication of damage about the SpO_2 sensor 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 sensor 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 sensor 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.

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