

SpO₂ Sensor

Directions for Use

3502-1290298 V1.3 2025-11

Latex Free

Intended Use

It's applicable to be 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 (SpO₂) 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.

Model and Configuration see the table below.

Model	Sensor Name	Built-in measuring module
KS-AC01	Adult Finger Clip SpO ₂ Sensor	No
KS-AC02	Pediatric Finger Clip SpO ₂ Sensor	No
KS-AE01	Adult Ear Clip SpO ₂ Sensor	No
KS-AR01	Large-sized Rubber Wrap SpO ₂ Sensor	No
KS-AR02	Pediatric Finger Rubber SpO ₂ Sensor	No
KS-ALW02	L-type with Rubber Wrap SpO ₂ Sensor	No
KS-ALW02S	Disposable L-type with Rubber Wrap SpO ₂ Sensor	No

Note: Pediatric Finger Rubber SpO₂ Sensor is for pediatric weighting between 15kg~40kg (or finger thickness between 8mm~16mm)

Instructions for Use

- SpO₂ 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 SpO₂ sensor.
1. Connect the SpO₂ sensor to the panel connector marked with “SpO₂” 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 SpO₂ 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.

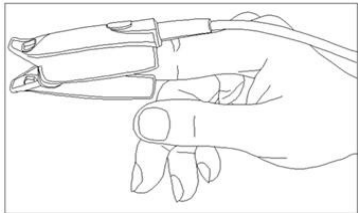


Figure 1 Finger Clip Sensor

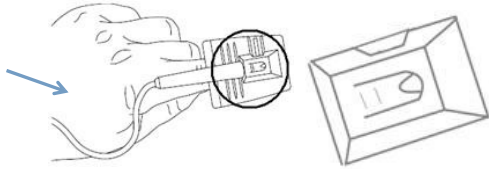


Figure 2 Finger Rubber Sensor

3. For Adult Finger Rubber SpO₂ 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.

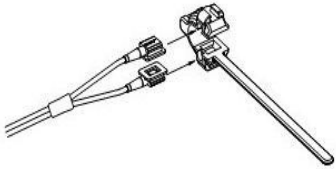


Figure 3 Universal Y-type Sensor

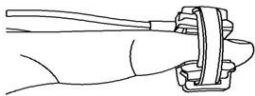


Figure 4(A/B) Y-type Sensor on Finger/on Sole

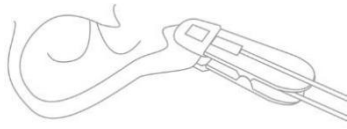


Figure 5 Ear Clip SpO₂ Sensor

4. For Universal Y-type with Rubber Wrap SpO₂ 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.
5. For Ear Clip SpO₂ Sensor, clip the sensor on the patient's earlobe, as shown in Figure 5.

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 SpO₂ 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 SpO₂ sensor.

- ⚠ A functional tester cannot be used to assess the accuracy of the SpO₂ 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 SpO₂ module, the device conforms to IEC 60601-1.

The electric safety classification: Type BF applied parts.

Accuracy Specifications

- SpO₂:** 1. Transducer: dual-wavelength LED Wavelength: Red light: 663 nm, Infrared light: 890 nm Maximal optical output power: less than 2mW maximum average
2. SpO₂ measuring range: 35%~100% 3. SpO₂ measuring accuracy: Arms value (defined in ISO 80601-2-61) is not greater than 3% for SpO₂ 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 SpO₂ module.

Symbols Description

Symbol	Description	Symbol	Description	Symbol	Description	Symbol	Description
	To identify a type BF applied part complying with IEC 60601-1		Medical device		CE mark		Authorised representative in the European community
	Unique device identifier		Batch code		Manufacturer (including address)		CN: Manufacturing country YYY-MM-DD: Manufacturing date
IPX2	Protected against vertically falling water drops when the enclosure is tilted up to 15°		Serial number		Refer to instruction manual (Background: blue; Symbol: white)		General warning sign (Background: yellow; Symbol and line: black)
	Follow WEEE regulations for disposal		UK responsible person				

Troubleshooting

If no measurement readings, please check if the light emitting component within the SpO₂ sensor flashes (do not stare at the light from the sensor), and check if the SpO₂ 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 SpO₂ sensor, please pay attention to maintain it.
In case any indication of damage about the SpO₂ 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 SpO₂ sensor together with the main unit can be thoroughly inspected by qualified personnel, including performance and safety examinations.

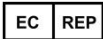
- ⚠ If the hospital fails to carry out a satisfactory maintenance program about the main unit (oximeter or patient monitor), it may damage the SpO₂ sensor and harm the patient's safety and health.
- ⚠ If there is any indication of cable and transducer damage or they deteriorate, they are prohibited from any further use.
- 🔔 The SpO₂ simulator can not be used to verify the SpO₂ 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 SpO₂ simulator for routine verification of precision.
- 🔔 Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO₂ simulator, e.g. for Index 2 series SpO₂ simulator from Fluke Biomedical Corporation, please set "Make" to "DownloadMake: KRK", then the user can use this particular R-curve to test the SpO₂ function. If the SpO₂ simulator does not contain "KRK" R-curve, please ask the manufacturer for helping to download the given R-curve into the SpO₂ simulator.



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