

Multiple-Use SpO₂ Sensor

Directions for use

Introduction

Product Name: SpO₂ Sensor with L-type Wrapper

Product Model: KS-LW02

Conformation: It consists of light emitting diode, photo-detector, silicone rubber, non-woven cloth strip, cable and connector.

Applicable Patients:

Neonate (weights less than 3 kg, age less than 6 months)

Infant (weights 3 kg to 15 kg, age from 6 months to 3 years)

Pediatric (weights 15 kg to 40 kg, age greater than 3 years)

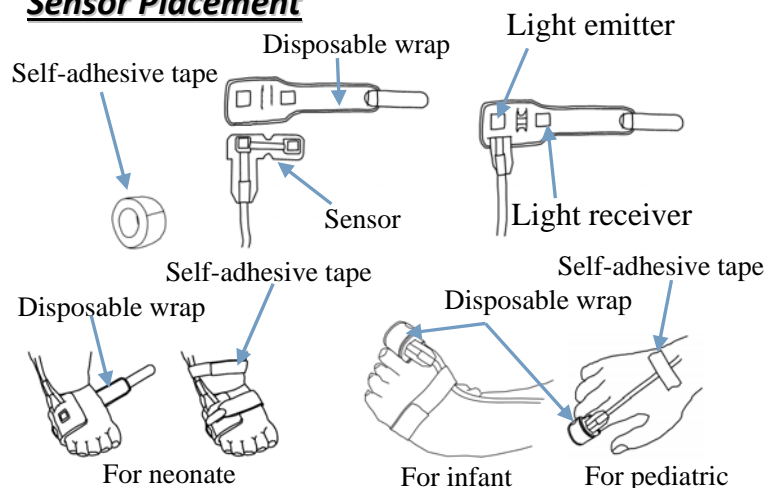
Attentions

- ⚠ The operation of this sensor can Only be performed by the trained personnel. Different measuring position should be chosen for different patient type, forefinger is preferred for pediatric, big toe is for infant, and sole is for neonate respectively.
- ⚠ When applying this sensor on infant and neonate, the self-adhesive tape is recommended to be used for wrapping on the sole or ankle to fix the sensor cable.
- ⚠ Make sure the light emitting and receiving end are aimed each other, and wrapping is done with proper tightness
- ⚠ Make sure the measured finger or toe nail has not any cosmetic painting (e.g. nail polisher), otherwise the measurement might be inaccurate or no readings.
- ⚠ High emission of surrounding light sources, such as fluorescent light, ruby lamp, infrared heating lamp, and direct sunlight, can affect the measuring results.
- ⚠ Excessive patient movement and the interference from electro-surgical unit can also affect the measuring accuracy.

Warnings

- ⚠ This sensor should be used together with the compatible oximetry device, otherwise the sensor may not work or the measurement will be inaccurate.
- ⚠ Although the biocompatibility evaluation has been performed on this sensor, some exceptional allergic patients may still have anaphylaxis. Do Not apply this sensor to those who has anaphylaxis.
- ⚠ Change measuring site every 2 or 3 hours. When the ambient temperature is over 35°C, change the measuring site every 2 hours. When the ambient temperature is over 37°C, STOP using this sensor on the patient, since long term of measurement can cause serious scalding or burn injury.
- ⚠ The measuring site must be examined more carefully for some special patient. Do not place the SpO₂ sensor on the site with edema or fragile issue.
- ⚠ Misapplication of the sensor with excessive pressure for prolonged periods can induce pressure injury.
- ⚠ Check the integrity of the sensor before use, discard and replace the sensor if any part of it is damaged.

Sensor Placement



The typical sensor placing method is: Place the emitting end of the sensor on the fingernail near to the nail root (or on the instep near to little toe), and wrap the sensor strap with receiving end around the finger (or foot).

Tips: 1) For finger or toe, pay attention to place the emitting end on the middle of the fingernail, and near to the nail root. Do not place the emitting end near the tip of nail nor the joint near the nail root. After wrapped, if the receiving end aims at the emitting end within the arch of $\pm 15^\circ$ (see figure A for front view and figure B for side view), it indicates the placement is appropriate. If not, it means the finger (or toe) is too thin (or too thick) to fit this sensor, you should find another measuring site or change other type of sensor.

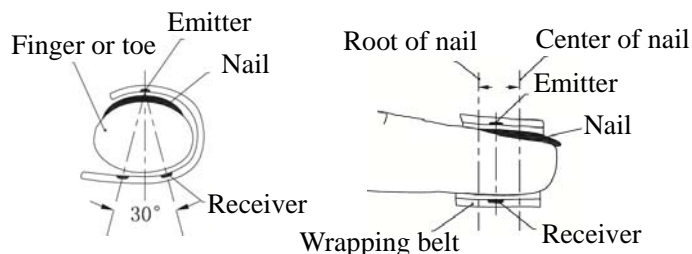


Figure A Front view (for finger or toe)

Figure B Side View (for finger)

2) For foot, pay attention to place the emitting end on the edge of instep, so as to make the receiving end aiming at the emitting end within the arch of $0^\circ \sim 30^\circ$ (see figure C). If not, it indicates the foot is too thick to fit this sensor.

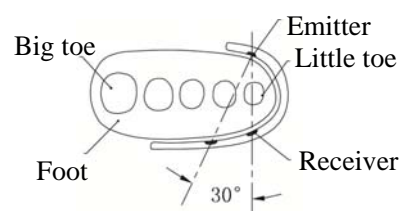


Figure C Front view---for foot

Note: for measuring on different site we provide two disposable wraps with different length, and the Velcro may located on different site (see figure D and figure E).

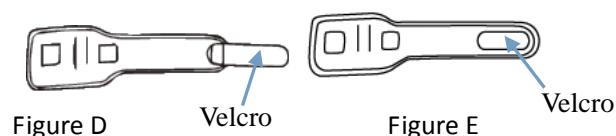


Figure D

Velcro

Figure E

Velcro

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Intended Use

It is intended to be used with a compatible pulse oximeter or patient monitor with oximetry function for measuring the functional oxygen saturation (SpO₂) and pulse rate.

Specifications

SpO₂ measuring accuracy: A_{rms} value (defined in ISO 9919/ISO 80601-2-61) is not greater than 3% in the range of 70%~100%.

Pulse Rate measuring range: 30bpm~250bpm


Pulse Rate measuring accuracy: ±2bpm or ±2%, whichever is greater.


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

Notes: ①For the device designed with auto power on function, in the situation of ambient light illumination on the sensors, the readings may probably be lasting for a while after stopping the measurement. In rare case, the device automatically turns on. Please disconnect the sensor or wrap it up to avoid ambient light after measurement.

②This SpO₂ sensor is compatible with patient monitors and oximeters produced by Shenzhen Creative Industry Co., Ltd. Other information about this sensor, please refer to the user manual of its compatible device (patient monitor or of oximeter).

SN: Serial number;

 0123: CE mark;

 Do not litter at will;

 Refer to the accompanying documents

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