CREATIVE MEDICAL

Infant SpO_2 Sensor with Disposable Wrap

Instructions for use

latex free

Last updated: November 1, 2024

3502-2290071 V1.7

Introduction

Product Name: Infant SpO_2 Sensor with Disposable wrap

Model Type: KS-YW02, KS-AYW02

Device Compatibility: Creative Oximeter ONLY

Components: It consists of 3 parts.

1. Y-style SpO_2 Sensor
2. Disposable Foot Wrap
3. Ankle Wrap

Recommended Patients: Infant (less than 12kg)

Instructions for use

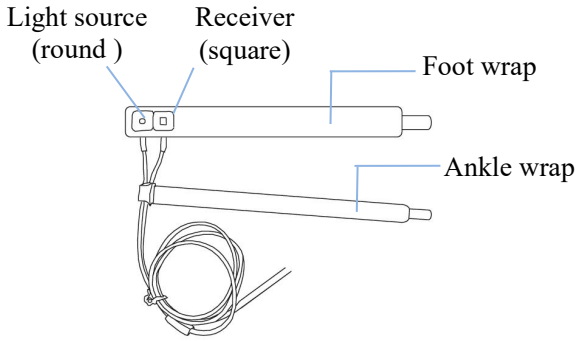
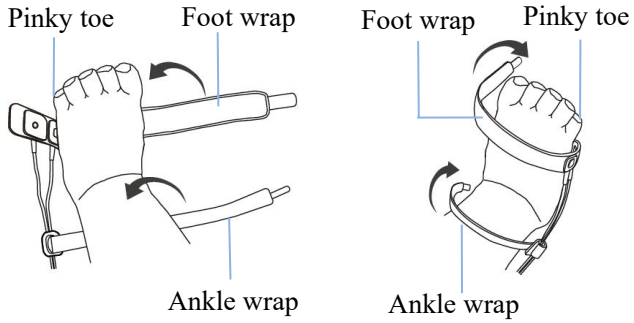


Figure A

1. For proper placement on either foot, place the sensors on the outside of the foot behind the pinky toe. Make sure the sensor touch the skin closely, then secure the foot wrap with Velcro (see Figure A and B). Do not over-tighten.



Left foot
(wrap goes under the foot)

Right foot
(wrap goes from top of the foot)

Figure B

Note: Improper sensor placement may result in difficulty acquiring signals or inaccurate results

2. Use the ankle wrap to secure the sensor cable on the ankle or leg (see Figure C). Do not over-tighten.

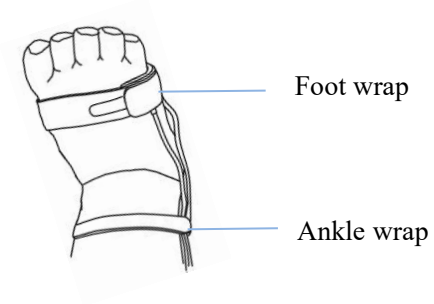


Figure C Right foot view

Note: the device display may show inaccurate reading or "Check Probe" due to motion artifact induced by the action of sensor placement. Power off and re-start the device after sensor placement to obtain accurate signal.

Change Disposable Wrap

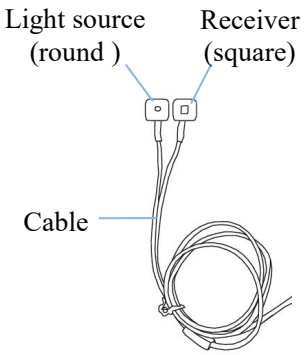
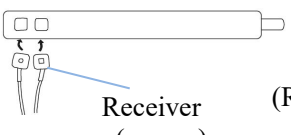


Figure D Y-style sensor

Figure E Foot wrap

Press the light source and receiver into the slots of the foot wrap respectively. Avoid pulling the silicon part of the sensor with force. Doing so may damage the sensor integrity and cause sensor malfunction. Please note that the light source, receiver and the Velcro should be facing the same side of the wrap (see Figure F).



Insert the sensors from the back of the wrap (Receiver closer to the Velcro)

Figure F

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Intended Use

This sensor is intended to be used with a compatible Creative brand pulse oximeter for measuring the functional oxygen saturation (SpO_2) and pulse rate of a specified patient type.

Attentions

- The operation of this sensor can only be performed by trained personnel.
- ALWAYS wrap and secure the sensor before switching on the Creative Oximeter device. (Wrapping with the device on may give inaccurate readings)
- If the sensor is wrapped too tightly, circulation may be blocked, which leads to discomfort and inaccurate readings.
- Make sure the light source and receiver of the Y-style sensor are placed near the edge of the instep, and wrapping is done with proper tightness.
- If the sensor does not provide reliable pulse signal, it may be incorrectly positioned. If such situation occurs, reposition the sensor on the foot until a reliable pulse signal can be detected.
- Strong surrounding light sources, such as fluorescent light, ruby lamp, infrared heating lamp, and direct sunlight, may cause inaccurate readings.
- Excessive patient movement and the extremely strong electromagnetic interference may cause unstable signals and inaccurate readings.

Warnings

- Do not alter or modify the sensor. Alterations and modifications may affect performance or accuracy.
- This sensor should be used together with the compatible oximetry device, otherwise the sensor may not work or the reading may be inaccurate.
- Although the biocompatibility evaluation has been performed on this sensor, some exceptional allergic patients may still cause anaphylaxis. Do not apply this sensor to those who has anaphylaxis.
- Change the measuring site every 2 or 3 hours. When the ambient temperature is over 35℃, change the measuring site every 2 hours. When the ambient temperature is over 37℃, STOP using this sensor immediately since long time measurement may cause serious scalding or burn injury.
- The measuring site must be examined more carefully for patients with special conditions. Do not place the sensor on the site with edema or fragile tissue.
- Misapplication of the sensor with excessive pressure for prolonged periods can induce pressure injury.

Specifications

SpO_2 measuring range: 35%~100%

SpO_2 measuring accuracy: Arms 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:

For KS-YW02 ： Red light: 663nm, Infrared light: 890nm

For KS-AYW02 :Red light: 660nm, Infrared light: 905nm

Notes: For the device designed with auto power on and/or off function, in the situation of ambient light illumination on the sensors, the readings may probably be lasting for a while after stopping the measurement, and in rare case, the device may automatically turn on. Please disconnect the sensor to avoid device misoperation after the measurement.

	Do not litter at will
	Refer to the accompanying documents
CE 0123	CE mark
	Manufacturer (including address)
	Date of manufacture
EC REP	Authorised representative in the European community
UK RP	UK Responsible Person

CE 0123

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