Introduction

Product Name: Y-style SpO$_2$ Sensor with wrap

Model Number: 15040072

Device Compatibility: CMI Health Oximeters ONLY

Components: It consists of 2 parts.

      1. Y-style SpO2 Sensor

      2. Disposable Velcro wrap

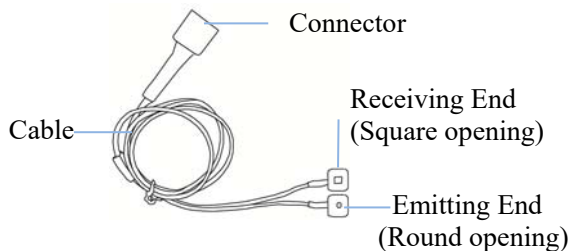**Recommended Patients:** Infants and toddlers under 25 lbs.

Instructions for use

Figure A Y-style sensor

Connector
Cable
Receiving End (Square opening)
Emitting End (Round opening)

Velcro — Slots

Figure B Foot wrap

Velcro — Threading slit

Figure C Ankle wrap

1. Press the emitting end and receiving end into the slots of the foot wrap respectively. Please note that the emitting end, receiving end and the Velcro are on the same wrapper surface. (see figure D and E)

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

Figure D

2. Insert the side with Velcro of the Ankle wrap into the threading slit at other side, and pull the Ankle wrap until it is secure on the sensor cable (see figure E).
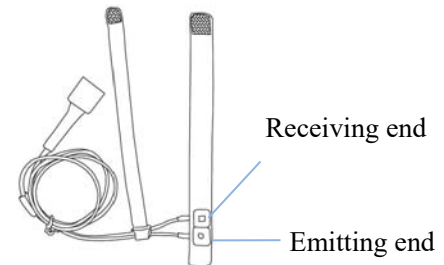

Receiving end
Emitting end

Figure E

3. The preferred site is on patient's foot. Place the receiving end and emitting end on the edge of instep right next to the little toe, wrap the sensor firmly, but not too tightly around the foot, then secure the wrap with the Velcro. After wrapped, make sure the receiving end and emitting end touch the skin closely (see figure F).

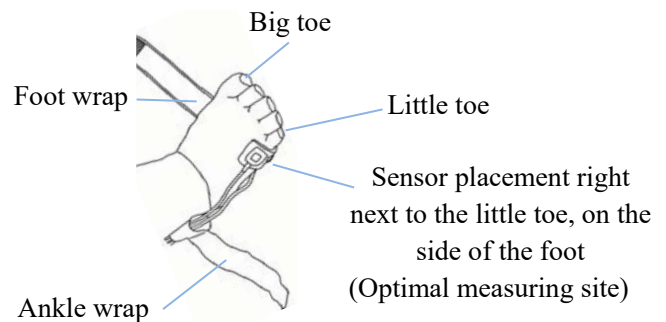Note: the optimal measuring site is on the edge of instep near the little toe.

Big toe
Foot wrap
Little toe
Sensor placement right next to the little toe, on the side of the foot (Optimal measuring site)
Ankle wrap

Figure F

4. The Ankle wrap is recommended to use for wrapping on the ankle or leg to secure the sensor cable when necessary (see figure G).
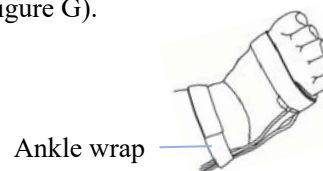

Ankle wrap

Figure G

5. Plug the Y-style sensor into the compatible device and verify proper operation.

Intended Use

This sensor is intended to be used with a compatible CMI Health brand pulse oximeter for measuring the functional oxygen saturation (SpO₂) and pulse rate of a recommended patient.

Attentions

- The operation of this sensor can only be performed by trained personnel.
- ALWAYS wrap and secure the sensor before switching on the CMI Health 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 emitting and receiving end 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 interference from electro-surgical unit 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.
- Check the integrity of the sensor before use, discard and replace the sensor if it is damaged.

Note: This sensor is compatible only with devices sold by CMI Health or the CMI Store. Other information about this sensor, please refer to the user manual of its compatible device.

Specifications

SpO₂ measuring range: 35%~100%

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

Do not litter at will

Refer to the accompanying documents