SpO2 Probe

Directions for use

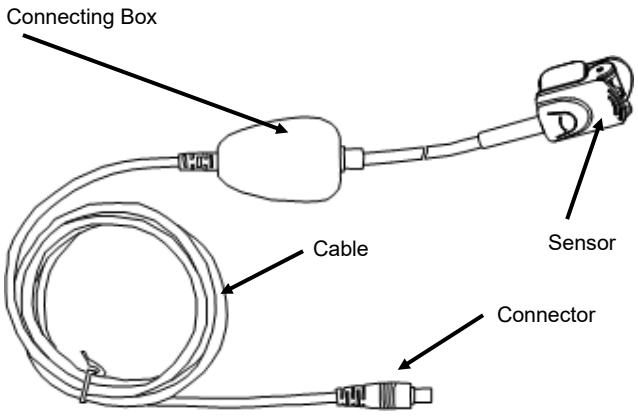
Introduction

Product Name: SpO2 Probe

Product Model: KS-CM02 (Part Number:15040063)

Conformation: It consists of sensor, cable and connector.

Applicable patients: Pediatric (weight 15kg~40Kg)

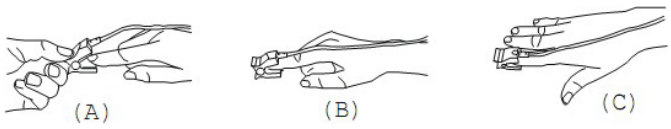


Instructions for use

(A). With the upper and lower jaws open, place a finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window.

(B). Spread open the rear tabs of the sensor to provide even force over the length of the pads.

(C). The sensor should be oriented in such a way that the cable is positioned along the top of the hand.



Specifications

SpO2 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: Red light: 663nm, Infrared light: 890nm

Perfusion index display range: 0.2%~20%.

Working environment: refer to the user manual of the compatible oximetry device.

Cleaning and Disinfection

Surface-clean the sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

Intended Use

This Pediatric Finger Clip SpO2 probe is intended to be used with a compatible pulse oximeter, spot-check monitor or patient monitor with oximetry function for measuring the functional oxygen saturation (SpO2) and pulse rate.

Attentions

🔔 Check the integrity of the sensor before use, discard and replace the sensor if any part of it is damaged.

🔔 The operation of this sensor can Only be performed by the trained personnel.

🔔 Make sure the measured finger 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.

Notes:

① This SpO2 sensor is compatible with patient monitors and oximeters produced by Shenzhen Creative Industry Co., Ltd.

② Other information about this sensor, please refer to the user manual of its compatible device (patient monitor or oximeter).

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Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies.

Symbols

	Follow instructions for use
REF	Product code
LOT	Lot number
	Date of manufacture
	Manufacturer
EC REP	Authorized representative in the European community
	WEEE disposal
CE	Medical Device complies with Directive 93/42/EEC
	Caution: read instructions (warnings) carefully
	Keep in a cool, dry place
	Keep away from sunlight
	Type BF applied part
NON STERILE	Non-sterile

REF 15040063 (GIMA 35164)

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3502-2290077 V1.2 Date: May 26, 2023