



Reusable SpO2 Sensor

Revision date: 19/01/2022
Revision number: 00/ Jan 2022

Instructions For Use

Intended use

Oximetry sensors are indicated for use in continuous noninvasive monitoring of arterial oxygen saturation and pulse rate. They are fully compatible replacement sensors intended for use with major brands of pulse oximeter.

The SpO2 sensor is designed to match the specifications of the original equipment manufacturer, therefore ensure the appropriate sensor model number is selected for a particular pulse oximeter technology.

Patients' category:

Category	Recommended weight (kg)
Adult	>40
Pediatric	15-40
Infant	3-15
Neonate	2-4

Direction For Use

Follow the instructions below for correct installation and utilization of the sensor and its connecting cable.

Patient

- 1- Place the SpO2 sensor on the patient at the appropriate measurement site.

Application

- 1- The sensor and its cable must be cleaned before each patient.
- 2- Place the sensor on the index finger ensuring the finger is fully inserted and the tip of the finger rests against the finger stop inside the sensor.
- 3- Possible alternate sites are small-sized thumb, middle and ring fingers as well as the little finger or the big toe.
- 4- Ensure the fingernail is located under the finger stop on the SpO2 sensor clamp.
- 5- The sensor must not be located on the same arm as the blood pressure cuff, arterial catheter, or intravascular line.
- 6- Remove all nail polish as this can affect accuracy.
- 7- Do not use the sensor inside or near an MRI.
- 8- Avoid having intense light sources near the sensor.
- 9- For long-term use, the measurement site must be changed every 4 hours to guarantee the integrity of the patients' skin.
- 10- In restless patient (excessive motion), use the soft tip, wrap or multi-site sensor to help secure the sensor to the patient.

Equipment

- 1- Connect the sensor cable to the appropriate equipment (pulse oximeter).
- 2- Turn equipment on and check correct operation by consulting the monitors operation instructions.
- 3- To ensure proper operations of the monitor, connect and disconnecting the sensor cable from the monitor cable. The correct, safe use of the sensor and its connecting cable requires systematic checks to be carried out at least once or more per month depending on the frequency of use, and of the disinfections of the cable.
- 4- Visual check (appearance of insulators, connector contact pins, etc.).
- 5- Verify the mechanical integrity of the connectors.
- 6- Do not use and discard any sensor that appears to have any mechanical or electrical flaws.
- 7- The operating conditions for the SpO₂ sensor and its cable are as follows:
 - I. Ambient temperature: 41° – 113° F (+5° to +45° C)
 - II. Relative humidity: 30 to 75%
 - III. Atmospheric pressure: 700 to 1060 HPa

To use the SpO₂ sensor and its connecting cable in departments where sterility levels are to be observed. Recommended the use of the following methods of cleaning, disinfections or sterilization:

Cleaning the equipment

- 1- Clean the sensor and its connecting cable with warm soapy water.
- 2- The probe and the cable must be cleaned using a soft cloth moistened with soapy water or 70% isopropyl alcohol. Carefully avoid damaging the surface of the visual indicator and the detector. Allow the probe and the cable to dry thoroughly before use. Do not use any abrasive agents or chemical product except 70% isopropyl alcohol
- 3- Do not irradiate, autoclave, soak or immerse the probe in any kind of solution. Keep the probe clean and dry.
- 4- The average life expectancy of a SpO₂ sensor is more than a year under the conditions of use advocated in these operating instructions.

Warning

- 1- Sensors are designed for use with specific monitors.
- 2- The operator is responsible for checking the compatibility of the monitor, probe and cable before use
- 3- Incompatible components can result in degraded accuracy and performance.
- 4- Do not assess the sensor's accuracy by using a functional tester or oximetry simulator.
- 5- Consult the operation instructions for the equipment concerned and the related accessories before operating equipment to ensure their compatibility.
- 6- Portable and mobile RF communications equipment can be affected equipment.
- 7- Disposal of the sensor shall comply with local regulation.
- 8- Cannot contact impairment skin (scald and trauma).

Performance/Reliability/Safety/Compatibility/ Mechanical Integrity

A. Performance/Reliability:

1. The SpO2 finger sensor with its compatible pulse oximeter has been validated and tested for compliance with ISO 080601-2-61:2011.
2. Comparative value measurement in % saturation:
 - I. SpO2 Range (70%-100%) ---Accuracy ± 3 Arms
 - II. SpO2 range (<69%) ---no specified
 - III. Pulse rate range: 20-250bpm----Accuracy ± 3 digits

B. Safety:

1. Degree of protection from electric shocks: Type BF
2. Classification is in accordance with MDD 93/42/EEC: Class IIb

C. Compatibility:

In order to ensure compatibility and claimed accuracy of the devices, InnoQ SpO2 sensors are only to be used with the specified equipment for which they have been designed and labeled use for.

D. Mechanical Integrity:

InnoQ sensors are designed to be extremely durable with high quality materials to ensure the sensors stand up to the rough hospital environment. The solid connectors are fitted with flexible sleeves, minimizing the risk of the cable parting and have no accessible metallic parts.

Storage/Packaging

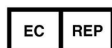
- 1- The sensors are individually packaged.
- 2- A sensor must be stored in its original packaging and within the storage conditions to maximize the storage life of the sensor.
- 3- Storage conditions are as follows:
 - Ambient temperature: 13° F to 131° F (-25 to +55°C)
 - Relative humidity: 10 to 85%

Symbol explanation:

Caution	Catalogue number	Manufacturer	BF type	Degree of protection against water	Non-sterile
				IPX2	
EU representative	See the instructions	Waste electrical and electronic equipment	Use-by date	Lot number	Date of manufacturing
					
CE mark	Medical device				
					



Shenzhen Caremed Medical Technology Co., Ltd
 East side, 3/F, C buliding, Kelunte Low-carbon industries Park, Gaofeng community, Dalang offices,
 Longhua district 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
 Tel:+8675536560977 Fax:+8675527186486 cm001@szcaremed.com
 www.szcaremed.com



SUNGO Europe B.V.
 Olympisch Stadion 24, 1076DE Amsterdam, Netherlands