

#### **Intended Use**

Spo2 sensor as a part of pulse and blood oxygen terminal, used for continuous non-invasive monitoring on patient's arterial oxygen saturation and pulse rate.

Adult finger clip and soft tip spo2 sensors >50Kg

Pediatric finger clip and soft tip spo2 sensors 15-50Kg or Slim Finger

## Type: Adult Finger Clip Spo2 Sensor, Adult Soft Tip Spo2 Sensor, Pediatric Finger Clip Spo2 Sensor, Pediatric Soft Tip Spo2 Sensor, Wrap Spo2 Sensor **Contraindications**

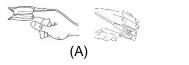
This product is only used as a part of pulse and blood oxygen terminal for auxiliary diagnostic tool in patients. It must be used in combination with clinical manifestations and symptoms.

This product can be not used during nuclear magnetic resonance (MRI) examination.

Uses who is allergic to rubbers, can not use this product.

#### **Directions for Use**

- 1. Before use, choose proper size Spo2 sensor and check if it is compatible with patient monitor.
- 2. Open finger clip of sensor, put index finger on clip pad, fingertip reach bottom of sensor (or put index finger directly to soft tip bottom), as picture (A). If can't use with index finger, can use other fingers except thumb.
- 3. The sensor cable should put along patient's hand back and be parallel with hand back, as picture (B).
- 4. Connect the sensor with patient monitor. if need Spo2 extension cable, connect the sensor with extension cable, as picture (C).







#### **Cleaning and Disinfection**

- 1. The sensor appearance and cable can be cleaned with a soft cloth moistened with mild detergent.
- 2. Disinfection with isopropyl-alcohol 70% or other disinfectant suggested in device user manual.

# Caution: Don't disinfect with ray irradiation, steam or ethylene oxide.

## Warnings

- 1. Patient with much movement, nail polish, overlarge finger or improper placement of sensor, etc. will affect accuracy of measurement.
  - 2. Strong light will affect accuracy of measurement, please shade with opaque material.
  - 3. Do not use Spo2 sensor during MRI scanning, this may cause burns.
- 4. Do not reuse the sensor on a different patient until it has been disinfected, but the sensor can be reused on the same patient for the patient's entire stay in hospital.
- 5. At elevated ambient temperatures, patient skin could be severely burned after prolonged sensor application at sites that are not well perfused, so be sure to check patient application sites frequently.
- 6. Should change the sensor application site every 4 hours, or change more often if circulation or skin integrity is compromised.
- 7. Choose a sensor site on limb without arterial catheter, blood pressure cuff or intravenous tube.
  - 8. Don't use the damaged Spo2 sensor.

#### **Performance**

Measure	Oxygen saturation (SpO2)		70%~100%	
range	Pulse		20bpm~250bpm	
Accuracy	Blood Oxygen saturation (SpO2) (Used with N-560 pulse oximeter of NELLCOR)		±2% (when SpO2 value is 90%~100%); ±4% (when SpO2 value is 70%~100%)	
	Pulse		±3bpm	
Resolution	Oxygen saturation (SpO2)		1%	
	Pulse		1bpm	
Light emitting diode	Infrared light wavelength: 890nm			
	Red light wavelength: 663nm			
	The max. average output power: ≤1.5mw			
Operation environment	Temperature	0℃~	~40℃	
	Humidity	15% $\sim$ 85%RH, Non condensing		
	Air pressure	86KPa∼106 KPa		
Storage and	Temperature	-40℃	0℃~70℃	
transport	Humidity	15%	$\%{\sim}85\%$ RH, Non condensing	
environment	Air pressure	86KF	86KPa∼106 KPa	
Device information	Classification of electric shock type: internal power supply equipment			
	Type of application part: BF type			
	Protection against liquid: IPX0			

## **Disposing the Sensor**

According to local laws and regulations regarding the disposal of hospital waste.

## **Symbols instruction**

<b>†</b>	BF type application part	LOT	Lot number
X	Recycling according to local regulations	~~ <u>~</u>	Date of manufacture
$\bigcap$ i	See the Instruction		Manufacturer
IPX0	IP degree	EC REP	European union representative
DATEX	Latex free		

## **Contact Information:**

Manufacturer: Xuzhou Maicuff Technology Co., Ltd

Address: 8#-2-1106 Jinxiujiayuan, Jianguo West Road, 221006 Xuzhou City, Jiangsu Province,

PEOPLE'S REPUBLIC OF CHINA

Tel: 0086-516-85908810 Fax: 0086-516-85908830 Http://www.maicuff.com E-mail:info@maicuff.com



MedNet EC-Rep GmbH

Borkstrasse 10, 48163 Münster, Germany

