

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.

Type: Disposable Spo2 Sensor

Contraindications

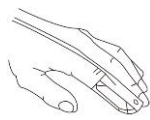
This product is only used as a part of pulse and blood oxygen terminal for auxiliary diagnostic tool in patients. It must be used in combination with clinical manifestations and symptoms.

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. Choose proper size sensor and check if it is compatible to patient monitor.
2. Peel the protective film off the sensor, revealing two optical windows with LED and photo detector, attaching the cable side to patient limb and adhere it on fingertip, and make sure LED and photo detector align with each other.
3. Put the cable along hand back or foot plantar, as picture (A) (B) (C) (D).
4. Connect the sensor with extension cable, as picture (E).



(A)



(B)



(C)



(D)



(E)

Warnings

1. Don't use on patient who is allergic to adhesive tape.
2. This product is used with single-patient only, as long as the tape is sticky, it can use with the same patient continually.
3. Make sure the application site for the sensor is not deeply pigmented or deeply colored, or, it may cause inaccurate measurements.
4. Strong light will affect accuracy of measurement, please shade with opaque material.
5. Don't use Spo2 sensor during MRI scanning, this may cause burns.
6. 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.
7. **Should change the sensor application site every 2~4 hours. or change more often if circulation or skin integrity is compromised.**
8. Choose a sensor site on limb without arterial catheter, blood pressure cuff or intravenous tube.
9. Don't use the damaged Spo2 sensor.

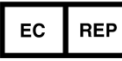
Performance

Measure range	Oxygen saturation (SpO2)	70%~100%
	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%～85%RH, Non condensing
	Air pressure	86KPa～106 KPa
Storage and transport environment	Temperature	-40℃～70℃
	Humidity	15%～85%RH, Non condensing
	Air pressure	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

	BF type application part		Lot number
	Recycling according to local regulations		Date of manufacture
	See the Instruction		Manufacturer
IPX0	IP degree		European union representative
	Latex free		Single Use

Contact Information:

Manufacturer: Xuzhou Maicuff Technology Co., Ltd

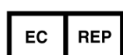
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