

Instruction for Use



Product Name: SpO2 Sensor

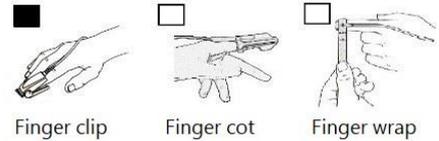
Model: CR001-5303A

Compatibility monitor: Nellcor™ Patient Monitor PM10N

Indicates this device is in compliance with MDR 2017/745
0123 is the Notified Body Number

Specifications

- Measurement Wavelengths and Output Power:
Red: 660nm±3nm @ 2 mw maximum average
Infrared: 905nm±10nm @ 2 mw maximum average
- Application site: Index or other finger
- Temperature Limitation: -10°C to +40°C (Operating / Storage / Transportation)
- Humidity: 0~80% non-condensing (Operating / Storage / Transportation)
- Atmospheric Pressure: 86kPa~106kPa (Operating / Storage / Transportation)



Clinical accuracy

- Oxygen Saturation Declared Accuracy Range (Arms): 70~100% SpO2, ±3 digits
- Pulse Rate Declared Accuracy Range (Arms): 20~250 bpm, ±3 digits

Essential Performance:

The accuracy of Oxygen Saturation in 70% ~100% is ±3 digits.

Lost or degraded essential performance can lead to incorrect responses by health care providers and an unacceptable risk (death) to the patient.

Indications/Contraindications

The SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40kg.

The SpO2 Sensors are contraindicated for use on active patients, conditions of motion, conditions of low perfusion or for prolonged use. It is not designed for long-term monitoring. It must be moved every 4 hours (or more often, if indicated by circulatory status and/or skin integrity) and reapplied to a different site. The device is suitable for professional healthcare facility environments, such as hospitals and clinics.

Intended User

This SpO2 sensor is intended used by qualified healthcare professionals who have been trained in the operation of pulse-oximetry monitoring equipment. Use by non-professionals (e.g., patients or lay caregivers) is prohibited unless under the direct, on-site supervision of trained medical personnel.

Instructions for Use

- 1) SpO2 sensors may be used on the same site for a maximum of 4 hours, and subjected to routine inspection of the site to ensure skin integrity and correct positioning. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients.
- 2) The specific monitor used with SpO2 Sensors has been validated and tested for compliance with EN ISO 80601-2-61:2019.
- 3) SpO2 Sensors belong to type BF applied parts.

To apply the SpO2 Sensor

- Select the most appropriate finger size for the sensor and ensure that the light source is directed from above onto the fingernail. Push the sensor over the fingertip in such a way that the fingertip touches but does not protrude from the end of the sensor.
- The cable should lie on the back of the hand. It may be held in place by wrist band.
- Refer to the instructions of the monitor to verify signal and data validity.

Caution: Please be advised that pulse oximeter readings may be influenced by skin pigmentation and perfusion status; these variables should be taken into account when interpreting results.

Cleaning

The sensor may be surface cleaned by wiping it with a solution such as 70% isopropyl alcohol. If low level disinfection is required, use a 1:10 bleach solution. DO not use undiluted bleach (5%-5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur.

To clean or care the sensor:

- 1) Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad
- 2) Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.
- 3) Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad.

Caution: Do not sterilize by irradiation or steam.

Warnings

- 1) SpO2 Sensors are designed for use with specific monitors, the operator is responsible for checking the compatibility of the monitor, sensor and cable before use, and incompatible components can result in degraded performance.
- 2) Using the sensor in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
- 3) SpO2 Sensors must be moved to a new site at least every 4 hours. As individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
- 4) Intravascular dyes may lead to inaccurate measurements.

- 5) The performance of the sensor is compromised by motion; Using of this sensor is contraindicated for active patients.
- 6) Do not apply tape to secure the sensor in place or to tape it shut; Venous pulsations may lead to inaccurate saturation measurements.
- 7) As with all medical equipment, be careful with route cables to reduce the possibility of patient entanglement or strangulation.
- 8) Do not use the sensor or other oximeter sensors during MRI scanning. Conducted current may cause burns. Also, the sensor may affect the MRI image, and the MRI may also affect the accuracy of oximeter measurements.
- 9) Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
- 10) The user and/or operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result.
- 11) Do not use if the wire or the shell of connector was broken.
- 12) Method of sterilization by ethylene oxide only.
- 13) The medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents of monitors.
- 14) The equipment is without a manual sensitivity adjustment. The minimum amplitude or value of patient physiological signal is 70% SpO2. Operation of the EQUIPMENT or SYSTEM below this amplitude or value may cause inaccurate results.
- 15) The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased EMISSION or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
- 16) The waste of SpO2 Sensors must not be disposed as unsorted municipal waste and must be collected separately, please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
- 17) Be aware that following removal of the sensor from the patient, it is possible that environmental light may cause the monitor to continue to display a waveform or data values, but these are not a basis for a clinical diagnosis.
- 18) Make sure the application site for the sensor is not deeply pigmented, or deeply colored. For example, nail polish, artificial nails, dye or pigmented cream may cause inaccurate measurements. In any of these cases reposition the sensor or choose an alternative sensor for use at a different site.
- 19) In case of any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Service Life

The product is valid for 1 year.

Statements

All materials used in this product have been tested for bio-compatibility.

The range of the peak wavelengths and maximum optical output power of the light emitted by the probe is very important, please see specifications

Warranty: To obtain information about a warranty, if any, for this product, contact your local representative.

Accuracy specifications

1) Functional tester cannot be used to assess the accuracy of SpO2 Sensors.

2) Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified saturation SpO2 range. Pulse oximeter SpO2 readings were compared to SaO2 values of drawn blood samples measured by hem-oximetry. All accuracies are expressed as \pm "X" digits. This variation equals \pm one standard deviation (\pm 1 SD), which encompasses 68% of the population.

Note: * All registered trademark and brand style mentioned in this information is always belonging to original made possessor.

EMC information

SpO2 sensor conforms to EMC requirements of IEC 60601-1-2:2014/A1 2020 and ISO 80601-2-61:2017 standards, and the user shall install and use this device according to EMC information provided in IFU.

Note:

- 1) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 2) The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- 3) Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 4) Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 5) Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1 Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A

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Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table 2 Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2Hz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2Hz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 2Hz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 2Hz

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 3 Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test	Band	Service	Modulation	IEC 60601-1-2	Compliance level
	Frequency (MHz)	(MHz)			Test Level (V/m)	(V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation 217 Hz	28	28
	1845					
	1970					

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			LTE Band 1, 3, 4, 25; UMTS			
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5 100 –	WLAN 802.11	Pulse modulation	9	9
	5500	5 800	a/n	217 Hz		
	5785					

Table 4 Guidance and manufacturer's declaration - electromagnetic Immunity

Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 MHz	Pulse modulation 50 kHz	7,5	7,5

See instructions before use	Caution	Non-sterile Packaging	Latex Free	Type BF applied part	Water Ingress Protection Class 2
					IPX2
Manufacturer	Authorized representative	Serial Number	Date of manufacture	Use-by date	Medical device
	EU REP	SN			MD
Temperature Limitation	Atmospheric pressure	Relative Humidity	Compliance with WEEE Standard		



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