

Instructions for Use



REF RES7100

Disposable SpO2 Sensor Neonatal/Adult

Similar to Nellcor MAXN

1. Product Description

Disposable pulse oximetry sensor, calibrated to display functional oximetry, to be used in conjunction with oximetry equipment and suitable for continuous non-invasive monitoring of patients' oximetry and pulse rate. This guide includes the instructions for use and technical specifications. The product is intended to be used by medical staff with medical nursing knowledge.

Product name: Disposable SpO2 sensor

Components: Sensor, cable and machine end connector

Type: Strip wrap

Intended population: Adult, Neonate (<3kg / <6.6 lbs)

Compatible monitor: Nellcor

Intended measuring position: Adult finger or neonate foot

2. Intended Use

For use with corresponding monitor or oximeter to collect and transmit the blood oxygen saturation and pulse rate signal of patients. The sensor has been tested and verified for YY0784-2010 use with the approved pulse oximetry monitor.

Applicable status: Static

3. Performance Specifications

- SpO2 test range: 70%~ 100%, accuracy: $\leq \pm 3\%$
- Pulse rate range: 30bpm~250bpm , Accuracy: $\leq \pm 2\text{BPM}$.
- Type BF
- Continuous operation

Note: Using the sensor in strong light may result in measurement errors. If sensor must be used in strong light, cover sensor with an opaque material.

- Luminescent tube red light $660 \pm 5\text{nm}$, infrared light $905 \pm 5\text{nm}$
- Maximum output power of the transmitter tube: RED: 110mw; Infrared IRED: 160mw.

4. Operating Environment

Temperature: $+5^\circ\text{C} \sim +40^\circ\text{C}$

Humidity: $\leq 80\%$

Atmospheric pressure: 86KPa~106KPa

Power supply: DC3-5V

5. Storage and Packaging

Sensors are individually packaged.

A sensor must be stored in its original packaging and in accordance with the storage conditions to maximize the storage life of the sensor.

Required storage conditions:

- **Ambient temperature:** $-20^\circ\text{C} \sim +55^\circ\text{C}$
- **Relative humidity:** $\leq 93\%$
- **Atmospheric pressure:** 86KPa~106KPa

6. Instructions for Use

- If package is damaged, do not use. Discard and replace the sensor.
- Before use, check the compatibility of the SpO₂ sensor by connecting the cable to the device. Ensure the sensor works properly according to the prompts.
- For best results, use adult patient's index finger or foot of neonate patients for measurement. If the index finger cannot be positioned correctly on the sensor, use another finger.
- Ensure the measurement site is well-perfused, clean and completely dry before application.
- Align the sensor so the dotted line on the adhesive tape is in the center of the adult patient's finger or the neonate patient's foot.
- Unpeel the backing and wrap the adhesive tape around the patient fingertip or foot, with the cable free. The cable should run along the top of the finger and back of the hand, or along the bottom of the neonate foot. Ensure cables are properly positioned to avoid entangling or suffocating the patient.
- Plug the sensor into a blood oxygen saturation tester and verify that it is functioning and installed correctly.
- Patient should remain as still as possible during measurement.
- The disposable SpO₂ sensor is for one-time use by single patient. To discard the sensor, please follow the relevant local regulations or the waste disposal system of the hospital director.

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Prioritize limb sites without ductus arteriosus, blood pressure cuffs and intravenous tubes when choosing a sensor site.

If the sensor doesn't accurately detect the pulse, it may be improperly positioned or applied to a measurement site that does not permit sufficient light. If this occurs, reposition the sensor.

The sensor is for use with specialized medical equipment. It is the operator's responsibility to check for compatibility, as incompatible parts or equipment could affect the test results.

Data and waveforms may still appear on the monitor or oximeter after the sensor has been removed from the patient, due to interference from external light. This does not indicate sensor malfunction. These displayed values are invalid and must not be used for diagnosis.

Use only on intact skin. Do not apply to skin with wounds or allergic conditions.

The sensor is for single-patient use. Do not use the sensor if it is damaged or does not adhere properly.


1. Do not use if the sensor or cable are damaged, contaminated, deteriorated or if the packaging has been damaged.
2. Do not use the product on skin with tissue damage.
3. Do not use with patients or users allergic to PVC or non-woven fabric.
4. When the patient is monitored continuously for an extended period of time, the application site should be checked and changed at least every 2 hours. Some patients may need more frequent site rotations, such as those with perfusion disorders or skin sensitivities. Prolonged monitoring may increase the risk of unexpected skin changes, such as irritation, redness, blistering or compression necrosis.
5. This product can only be used with designated equipment. It is the user's responsibility to read the instruction manual of the equipment or consult the manufacturer before use to confirm the compatibility of the product with the extension cable and equipment as detailed in the "P Series Product Compatible Oxygen Equipment List". Misuse may cause injury to the patient.
6. It is not recommended to place sensor on a limb with an arterial catheter, a sphygmomanometer cuff or an IV line.
7. To minimize the influence of the electrosurgical device on measurement, do not place the cable near the power cable of the electrosurgical device.
8. Do not use sensor during a magnetic resonance imaging (MRI) scan as the induced current may cause burns.
9. Do not immerse the sensor in any solvent.
10. Binding the sensor too tightly on the patient can lead to venous pulsation, blocked cycle of blood sequencing, compression traces, compression necrosis, spurious error or inaccurate measurement. If too loose, it will lose optical alignment or fall off.
11. If the perfusion at the measurement site is too low, the pulse oxygen saturation measurement may be inaccurate.
12. If sensor is used during whole-body radiation therapy, place the sensor outside the radiation area. If the sensor is exposed to the radiation area, the reading may be inaccurate or non-functional during the effective radiation period.
13. Using the sensor in strong light may result in measurement errors. To use in strong light, cover the sensor with an opaque material.
14. The accuracy of the SpO₂ sensors should not be evaluated by a functional tester such as a blood oxygen simulator.
15. Use beyond the validity period may lead to inaccurate measurement.


7. Maintenance

- Keep the SpO2 sensor protected from moisture during long-term storage.













8. Service Life

- **Production date:** see label.
- **Expiration date:** 2 years.

 **CAUTION:** Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

 **CAUTION:** In order to ensure compatibility and accuracy of the devices, SpO2 sensors are only to be used with the specified equipment for which they have been designed.

9. Symbol Glossary

 Consult Instructions for Use	 LOT Number	 Single use only
 Expiration Date	 Warning / Caution	 Not made with natural rubber latex
 Catalog number	 Manufacture Date	 Non-sterile
 Atmospheric pressure limitation	 Humidity Limitation	 Temperature Limitation

IEC 60601-1-2:2014/AMD1:2020 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product

The information below covers the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

The ME EQUIPMENT or ME SYSTEM is suitable for healthcare professionals and environments only.

Warning: Do not use 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.

Warning: 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.

Warning: 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.

Warning: 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 Disposable SpO2 sensor (RES7100), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

Technical Specifications

Tables below include all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life and Guidance and Manufacturer's Declaration - Electromagnetic Emissions and Immunity.

SpO2 sensors do not contain magnetically sensitive electronic components and circuitry.

Table 1:

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance

Table 2:**Guidance and Manufacturer's Declaration - Electromagnetic Emissions and Immunity (cont'd)**

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	Power supply lines: ±2 kV 100 kHz repetition frequency	Power supply lines: ±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s): ± 1 kV.	line(s) to line(s): ± 1 kV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (ISM bands between) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (ISM bands between) 80% Am at 1kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	Not applicable

Table 3:**Guidance and Manufacturer's Declaration - Electromagnetic Emissions and Immunity (cont'd)**

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test level (V/m)	Compliance level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
745							
780							
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 - 2 570	Bluetooth, WLAN, 802. 11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240	5 100 -5 800	WLAN 802. 11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9
5500							
5785							