

INSTRUCTIONS FOR USE AND TECHNICAL SPECIFICATIONS OF DISPOSABLE SpO2 SENSORS



Product name: Disposable SpO2 sensors.

Model: refer to product label.

Manufacturer: Medical Cables S.L.

Intended use:

Series A Sensors

Medical Cables A series disposable sensors are indicated for use when continuous short-term noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing more than 40 Kg. These series sensors are contraindicated for use on patients weighing less than 40 Kg or on active patients.

Series AN Sensors

Medical Cables AN series disposable sensors are indicated for use when continuous short-term noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing more than 40 Kg and less than 3 Kg. The AN series sensor is contraindicated in another case.

Series P Sensors

Medical Cables P series disposable sensors are indicated for use when continuous short-term noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 10-50 Kg. The sensor is contraindicated in patients whose body weight is outside this range.

Series I Sensors

Medical Cables I series disposable sensors are indicated for use when continuous short-term noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing between 3-20 Kg. The sensor is contraindicated in patients whose body weight is outside this range.

Clinical application and limitations

1. Remove the plastic backing from the SpO2 sensor and place the transparent windows located on the adhesive side on the extremity. Transparent windows are covering optical components (LEDs) (A). You can see the marks and dashed line between the marks on non-adhesive side (B).



2. You can use the mentioned marks to know where to place the SpO2 sensor. Place the SpO2 sensor so the dashed line is on the lateral edge of the site.

- The preferred site for neonates is a foot. Alternatively, use a hand.

The window next to the cable goes on the sole of foot (as shown).

- The preferred site for adults is an index finger. Alternatively, use another finger. The window next to the cable goes on the nail side.

Do not place the window on a joint.

The cable must be positioned on the top of the hand.

When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.

3. Wrap the SpO2 sensor firmly but not too tightly around the foot or finger. Windows must be in opposite positions.

4. Plug the SpO2 sensor into the monitor and verify the proper operation, as described in the monitor operator's manual.

If the sensor does not track the pulse reliably, it may be incorrectly positioned, or the sensor site may be too thick, thin, or deeply pigmented or, otherwise, deeply coloured (for example, nail polish, dye, etc) to permit appropriate light transmission. If any of these situations occurs, reposition the sensor or choose an alternate SpO2 sensor for use on a different site.

Visually monitor the sensor site to ensure the integrity of the skin.

Precautions:

For further instructions, warnings and precautions refer to the operating instructions provided with your oximeter or multiparameter monitor. Do not autoclave or immerse the sensor in liquid.

CAUTION: in the event of damage to the packaging, do NOT use. Follow local governing ordinances and recycling instructions regarding disposal or recycling of sensors.

Clinical benefits of Medical Cables SpO2 sensors

1. Continuous oxygenation monitoring: facilitates continuous monitoring of the patient's blood oxygen saturation, allowing a constant evaluation of their oxygenation status through the monitoring equipment to which it is connected.

2. Early detection of hypoxemia: contributes to the early detection of low blood oxygen levels by transmitting precise signals to the monitoring equipment, alerting healthcare personnel to potential respiratory or cardiovascular problems.

3. Therapy optimization: enables more precise therapy by providing real-time signals to the monitor, helping to adjust the delivery of supplemental oxygen or other therapeutic interventions as needed.

4. Treatment response monitoring: facilitates monitoring of the patient's response to treatment by transmitting continuous signals to the monitoring equipment, allowing the effectiveness of therapeutic interventions to be evaluated over time.

5. Monitoring during medical procedures: helps lung function monitoring during medical procedures, such as mechanical ventilation, by sending precise signals to the monitoring equipment, helping to optimize therapy and prevent respiratory complications.

Warnings:

- Match the sensor model with your brand of oximeter. A mismatch may cause patient injury, inaccurate measurements, or equipment damage.

- Check the sensor periodically and reposition or remove it every 2-4 hours or more frequently if the circulatory status and/or skin integrity so recommend and reposition at a different site. Otherwise, this may cause burn or harm to the patient's finger. The sensor must not be fixed at the site of tissue damage.

- Do not reuse the sensor on different patients. Otherwise, this may cause infections or red and swollen and/or inflammation.

- Do not use the sensor after the indicated period or do not use the sensor many times in the same patient. Otherwise, it cannot be well placed on patient's finger, and it cannot work properly.

- Avoid application of the sensors to edematous or fragile tissue. Otherwise, this may cause red and swollen and/or inflammation.

- Avoid application of the sensors to excessive patient motion, excessive ambient light, electromagnetic interference, dysfunctional hemoglobin, low perfusion, intra vascular dyes, fingernail polish and long or artificial fingernails, what may affect the sensor performance and the accuracy of the measurement.

- Do not use the sensor if it is damaged. Use of a damaged sensor could cause patient injury or equipment failure.

Note: the materials used in the manufacture of the sensor contain no natural latex protein. The materials have undergone extensive biocompatibility testing. No modification of this probe is allowed.

Operating environment:

- Operating temperature range: 10°C~32°C

- Relative humidity: <80%.

- Storage and transportation temperature range: -20°C~55°C

SpO2 and pulse rate accuracy:

- Adults: 70-100% ±3 digits; <69% unspecified

- Neonates: 70-100% ±3 digits; <69% unspecified

- Pulse rate: 20-250 BPM, ±2BPM.

Warranty

Products come with our manufacturer's warranty.

Medical Cables SpO2 sensors are warranted against defects in material and/or workmanship for a period of 3 years from the date of shipment. During this warranty period, Medical Cables will replace, free of charge, any product found to be defective.

This warranty will not be valid in the event of misuse, improper use of the product, improper handling of the product by an unauthorized person, deterioration of the product due to external agents such as water or other harmful chemical or corrosive products, inadequate maintenance or lack of cleaning, or any fault that is the result of normal wear and tear. Alterations or modifications to the product void this warranty. The conformity of the products is guaranteed according to the use for which they are intended.

Return policy

The term for changes or returns of purchased products is 12 months from the date of shipment of the order.

It is required to notify your sales representative by email mentioning the reason for the change or return. The commercial will assess your request and will contact you to arrange the collection of the material.

Waste

Do not throw garbage. Check local laws and regulations for information on how to dispose of SpO2 sensors.

WARNING

Any serious incident related to the product must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient are established.



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