SleepSense®

# Reusable SpO2 Sensor User Manual

***Intended Use***

| *Patient Type* | *Pediatric* | *Adult* |
|---|---|---|
| *Patient Weight* | *10 – 40 kg* | *> 40 kg* |
| *Sensor Type* | *T type (Pediatric)* | *T type (Adult)* |

*When used with a compatible monitor or pulse oximeter device, the SleepSense SpO2 sensor is intended to provide continuous, non-invasive, functional arterial oxygen saturation (SpO2) and pulse rate monitoring of patients.*
*The sensor must be used by trained clinical professionals.*
*The sensor consists of three parts: plug, cable and probe. The part of the sensor which is applied to the patient is the probe.*

## *Instruction for Use for Soft-Tip Finger Sensors*

1. Hold the sensor probe with its opening towards the patient's index finger (Fig. 1). The sensor should be oriented with the fingertip symbol facing upwards.
2. Insert the patient's index finger into the sensor until the fingernail reaches its edge, at the back end of the sensor. Adjust the finger so it is placed evenly in the middle base of the probe. Place the cable along the top of the patient's hand (Fig. 2).
3. Apply a medical grade adhesive band to secure the cable (Fig. 3). If an index finger cannot be positioned correctly, or is not available, other fingers can be used as well.
4. Plug the sensor into the oximeter and verify proper operation as described in the oximeter's user manual.
5. Inspect the sensor's site every 2 hours for skin integrity.

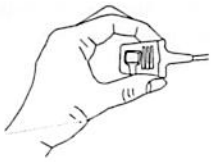

Fig. 1

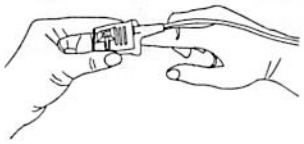

Fig. 2

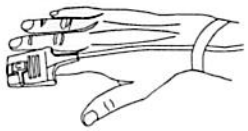

Fig. 3

N8110-EN-E Rev 1.0

***Caution***

*1. This sensor is for use only with compatible patient monitors or pulse oximeter devices. Incompatible components can lower the device's performance.*

***Contraindications***

The SleepSense sensor is contraindicated for use on active patients or for prolonged use.

***Specifications***

**1)** SpO2 Accuracy @90%-100% : ±2%; @70%-89%: ±3%
**2)** Pulse Rate Accuracy @30-245bpm: ±3 bmp
**3)** Peak Wavelength Red: 660-668nm, Infrared: 880-950nm
**4)** Maximum Power Dissipation: 90mW

***Compatible Devices***

Nonin® pulse-oximeter modules

***Note:*** *The sensors and compatible devices should comply with IEC 60601-1, ISO80601-2-61.*

***Cleaning & Disinfection***

Unplug the sensor before cleaning or disinfecting.
**1)** Dip clean the sensor part (not the connector) in a mild detergent solution, or a 70% isopropyl alcohol solution. If low-level disinfection is required, use a 1:10 bleach solution.
**2)** Rinse the sensor/probe part (not the connector) in water, wipe it with a dry cloth and leave to dry completely.

***Caution***

Do not sterilize by irradiation steam, or ethylene oxide.

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***Transport and Storage Environment***

1) Temperature: -20°C~+55°C 2) Relative humidity: ≦95% 3) Atmospheric pressure: 500hPa~1060hPa

***Operating Environment***

1) Temperature: 5°C~40°C 2) Relative Humidity: ≦90% 3) Atmospheric pressure: 700hPa~1060hPa

***Warnings: Patient Safety***

- This sensor is for use only with compatible patient monitors or pulse oximeter devices.
- Check the site every 2 hours (more frequently if perfusion is poor).
- Routinely check to ensure adequate distal circulation to the sensor site.
- Carefully route cables to reduce any possibility of patient entanglement or strangulation.
- Patient conditions (such as reddening, blistering, skin discoloration, ischemic skin necrosis, and skin erosion) may warrant changing the site frequently or using a different style of sensor.
- Do not use the sensor if the sensor or the sensor cable appears damaged.
- This device is not intended for use in a magnetic resonance imaging (MRI) environment.

***Warnings: Data Validity***

- Conditions that may cause inaccurate reading and impact alarms include interfering substances, excessive ambient light, electrical interference, excessive motion, low perfusion, low signal strength, incorrect sensor placement, poor sensor fit, and movement of the sensor on the patient.
- Do not use a blood pressure cuff or arterial blood pressure measurement device on the same limb as the sensor site.
- It is possible for any device to malfunction; therefore, always verify unusual data by performing a formal patient assessment.

***Limited Warranty***

This product is covered by an 18-month limited warranty against manufacturing defects in materials and workmanship from the original date of purchase. The sole liability of SLP and our distributor(s) is limited to replacement or repair of the product at the option of SLP with no charge for parts or labor if any part is proven to be defective in workmanship, performance, or materials during the warranty period. Under no circumstances shall SLP or our Distributor(s) be liable for any loss of revenues or damage, direct, consequential, or incidental, including loss of profit, property damage, or personal injury arising from the use of, or the inability to use this product. This Warranty is intended only for the original buyer and is in lieu of all other warranties or previous agreements, expressed or implied. This warranty is rendered void if the product is used for other than its intended purpose or is subject to abuse, misuse, tampering, neglect, or unauthorized modifications. Use of this product constitutes acceptance of this warranty in total.

***Compliance***

- EMC Compliance: IEC60601-1-2，Group I，Class B.
- Equipment Classification：Class IIb, MDD 93/42/EEC.
- Degree of Protection：Type BF-Applied Part.
- IPX1 Approved

***Definitions of Product Symbols***

| | | | |
|---|---|---|---|
| | Consult instruction for Use | IPX1 | Protection against moisture |
| | Caution | LATEX | Latex free |
| Rx ONLY | Federal Law (USA) restricts this device to sale by or on the order of a physician. | | Manufacturer |
| | Manufacturing date | REF | Catalog or model number |
| | Humidity | LOT | Batch or lot number |
| | Temperature | SN | Serial Number |
| CE 0123 | Complies with Council Directive 93/42/EEC devices with identification No. 0123 | EC REP | Authorized Representative in the European Community |
| | To be taken to separate collection at the end of product life. Do not dispose of the product as unsorted municipal waste. | | Type BF applied part |

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

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