Multi-Compatible Reusable SpO2 Sensors

Instruction for Use

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.*

Instruction for Use for Finger Sensors (S100A, S200A , S300A, S400A, S100P, S200P, S300P, S400P)

1. With the upper and lower jaws open, place an index finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window (Fig.1). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
2. Spread open the rear tabs of the sensor to provide even force over the length of the pads (Fig. 2).
3. The sensor should be oriented in such a way that the cable is positioned along the top of the hand (Fig. 3).
4. Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.
5. Inspect the sensor site every 2 hours for skin integrity.

Fig. 1

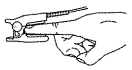

Fig. 2

Fig.3

Instruction for Use for Soft-Finger Sensors

(T100A, T200A, T300A, T400A, T100P, T200P, T300P, T400P)

1. Hold the sensor with its opening towards the patient's index finger (Fig. 4). The sensor should be oriented in such a way that the sensor side with a finger tip sign is positioned on the top.
2. Insert the patient's index finger into the sensor until the fingernail tip against the edge at the end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor. Direct the cable along the top of the patient's hand (Fig. 5).
3. Apply the blue wrist band to secure the cable (Fig. 6). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
4. Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.
5. Inspect the sensor site every 2 hours for skin integrity.

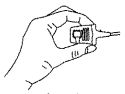

Fig. 4

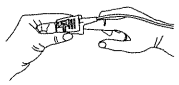

Fig. 5

Fig. 6

Instruction for Use for Y-Type Sensors (Y100, Y200, Y300, Y400)

1. Insert the two sensor tips into the slots on the rubber wrap (Fig. 7), (Fig. 8).
2. Place the sensor on the neonate's foot, wrap the rubber belt around the foot and tighten accordingly (Fig. 9).
3. Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.
4. Inspect the sensor site every 2 hours for skin integrity.

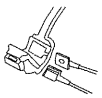

Fig. 7

Fig. 8

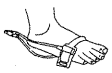

Fig. 9

Instruction for Use for Wrap Sensors (W100A/N, W200A/N, W300A/N, W400A/N)

1. Place the sensor on the adult's index finger (Fig. 10), or the neonate's foot (Fig. 11). Wrap the rubber belt around the foot and tighten belt.
2. Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.
3. Inspect the sensor site every 2 hours for skin integrity.

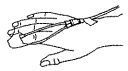

Fig. 10

Fig. 11

Instruction for Use for Y- Type Ear Sensors (Y100E, Y200E, Y300E, Y400E)

1. Slide the sensor pads along the ear clip (large or small clip) slots until they are fully engaged in the clip, as shown (Fig. 12).
2. Slide the sensor cable through the ear hanger in the direction as shown (Fig. 13).
3. Place the ear hanger on the patient's ear. Clip the sensor on the patient's ear lobe as shown (Fig.14), with the sensor cable running down the side of the patient's face and body.
4. Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.
5. Inspect the sensor site every 2 hours for skin integrity.

Fig. 12

Fig. 13

Fig. 14

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Multi-Compatible Reusable SpO2 Sensors

SCE-0010-01-01-N(Rev. 2.4)

Instruction for Use

Intended Use

Patient Type	Neonatal	Infant	Pediatric	Adult
Patient Weight	1- 4 kg	3 – 15 kg	10 – 40 kg	> 40 kg
Sensor Type	W / Y type	W / Y type	S / T /Y-Ear type	S/T/W/Y/Y-Ear type

When used with a compatible patient monitor or a pulse oximeter device, the *Solaris* sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO2) and pulse rate monitoring of patients. The sensors must be used by trained clinical professionals.

The sensor consists of three parts: plug, cable and probe. Applied part of the sensor is probe.

Caution

1. *This sensor is for use only with compatible patient monitors or pulse oximeter devices, incompatible components can result in degraded performance.*
2. *This sensor satisfies the compatibility between the materials used with which the patient or any other person can come into contact and biological tissues.*

Contraindications

The Solaris 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

Nellcor, BCI, GE, Goldway, Invivo, HP, Siemens, Spacelabs, Mindray, Datex, CSI, Datascope, Nihon Kohden, Novametrix, Ohmeda, etc.

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 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.

Transport and Storage Environment

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

Operating Environment

1) Temperature: 5℃~40℃ 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.

Warranty

Solaris offers a 12-month warranty against manufacturing defects in materials and workmanship from the original date of purchase.

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

CE 0123 The probes comply with the requirements of the Council Directive 93/42/EEC. concerning medical devices with identification No. 0123

Rx ONLY Federal Law (USA) restricts this device to sale by or on the order of a physician.

EC REP Authorized Representative in the European Community

Manufacturing date

Humidity

Temperature Limitation

Caution

IPX1 Protection against moisture

LATEX Contains no latex

Manufacturer

REF Catalog or model number

LOT Batch or lot number

P/N Part Number

SN Serial Number

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