NONIN 8100SS Soft Pulse Oximeter Sensors Instructions

Contents

1 NONIN 8100SS Soft Pulse Oximeter Sensors
2 Product Information
3 Product Usage Instructions
4 Safety Instruction
5 Symbols
6 Choosing the Appropriate Sensor Size
7 Attaching the Sensor
8 Cleaning the Reusable Sensor
9 Specifications
10 Measurement Wavelengths and Output Power
11 Warranty
12 Contact Information
13 Documents / Resources
13.1 References
14 Related Posts

NONIN 8100SS Soft Pulse Oximeter Sensors

Product Information

Specifications

- **Model:** 8100S(X)
- **Type:** Reusable, Soft Pulse Oximeter Sensor
- **Compatibility:** SenSmart oximetry system
- **Intended Use:** Non-invasive spot-checking and continuous monitoring of adult and pediatric patients
- **Conditions:** Well or poorly perfused, during both motion and non-motion conditions

Product Usage Instructions

Directions for Use

The Model 8100S(X) reusable soft sensor is indicated for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions. Please refer to the oximetry system's operator's manual for detailed instructions on use environments.

Warnings and Cautions

Warnings:

- Excessive ambient light
- Excessive motion
- Electrosurgical interference
- Moisture in the sensor
- Improperly applied sensor
- Carboxyhemoglobin
- Methemoglobin
- Blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)

- Incorrect sensor type
- Poor pulse quality
- Venous pulsations
- Anemia or low hemoglobin concentrations
- Cardiovascular dyes
- Dysfunctional hemoglobin
- Artificial nails or fingernail polish
- The residue (eg, dried blood, dirt, grease, oil) in the light path

Indications and Precautions

Directions:

- Cardiovascular dyes
- Excessive movement

Cautions:
Restriction of Blutflusses (durch arteriel Katheter, Blutdruckmanschetten, Infusionsleitungen usw.)

Frequently Asked Questions (FAQ)

Q: Can the Model 8100S(X) soft sensor be used on neonatal patients?
A: No, this sensor is indicated for adult and pediatric patients only. Please refer to the specific neonatal oximetry sensors for neonatal use.

SenSnart Model 8100S(X) Reusable, Soft Pulse Oximeter Sensor
For use only with the SenSmart oximetry system

Indications for Use
Nonin's Model 8100S(X) reusable soft sensor is indicated for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions.

Refer to the oximetry system's operator's manual for all use environments.

Safety Instruction

Warnings:

- Do not use the device in an MR environment or in an explosive atmosphere.
- This device is only defibrillation proof per IEC 60601-1 when used with the X-100SP signal processor.
- Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor may vary due to medical status or skin condition.
- Avoid excessive pressure on the sensor application site(s) as this may cause damage to the skin beneath the sensor.
- The use of sensor and oximeter combinations other than Non-in-branded products has not been tested for accuracy as a system and may affect the performance of the system.

- This sensor is only compatible with the SenSmart oximetry system. Refer to the Parts and Accessories List on the system operator's manual CD for a complete listing of Non-in-branded sensors, parts, and accessories. Patient injury can result from the use of non-compatible combinations.
- This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

Cautions:

- Do not use a damaged sensor. If the sensor is damaged, discontinue use immediately.
- Ensure all pulse oximeter sensors are kept a minimum of 6 cm (2.7 in.) away from all other sensors.
- Clean the sensor before applying it to a new patient.
- Disconnect the sensor from the signal processor before cleaning.
- Do not sterilize, autoclave, or immerse the sensor in liquid of any kind. Do not pour or spray any liquids onto the sensor.
- Do not use caustic or abrasive cleaning agents on the sensor. Do not use cleaning agents containing ammonium chloride. The use of these chemicals may shorten the life of the product.
- The sensor is designed for external use, over intact skin, outside of the sterile field.
- Follow local governing ordinances and recycling instructions regarding the disposal or recycling of the sensor and any components.
- A functional tester cannot be used to assess the accuracy of an oximeter monitor or sensor.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- Refer to the system operator's manual for additional warnings and cautions.
- Refer to the system's operator's manual for ingress protection (IP) rating.
- Factors that may degrade pulse oximeter performance include the following:
    - excessive ambient light
    - excessive motion
    - electrosurgical interference
    - moisture in the sensor
    - improperly applied sensor
    - carboxyhemoglobin
    - methemoglobin
    - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
    - incorrect sensor type
    - poor pulse quality
    - venous pulsations
    - anemia or low hemoglobin concentrations
    - cardiovascular dyes
    - dysfunctional hemoglobin
    - artificial nails or fingernail polish
    - residue (e.g., dried blood, dirt, grease, oil) in the light path

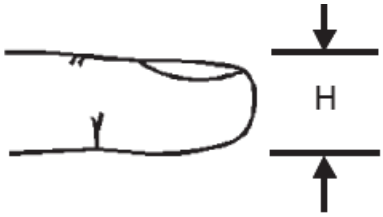
Symbols

Symbol	Definition of Symbol
	Follow Instructions for Use
	CAUTION!
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
	Do Not Reuse
LOT	Lot Number
	Type BF Applied Part
	Defibrillation Proof Type BF Applied Part (patient isolation from electrical shock when connected to a signal processor)
	RoHS Compliant (China)
	Importer
	Distributor
MD	Medical Device
UDI	Unique Device Identifier

Symbol	Definition of Symbol
EC REP	Authorized Representative in the European Community.
CH REP	Authorized Representative in Switzerland
SN	Serial number
REF	Catalogue number
QTY	Quantity
	Indicates separate collection for waste electrical and electronic equipment (WEEE)
	Storage/shipping temperature range
Rx Only	Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.
	Manufacturer
	Date of Manufacturing
	Country of Manufacturing
	Non-sterile
	Handle With Care
	Keep Dry
	Humidity Limitation
	Use By

Choosing the Appropriate Sensor Size

- Use the measurements provided below to determine which sensor should be used.
- Sensor recommendations are based on digit height (thickness), as indicated on the left.
  - Model 8100SL (large): 12.5 – 25.5 mm (0.5 – 1.0 in.)
  - Model 8100SM (medium): 10 – 19 mm (0.4 – 0.75 in.)
  - Model 8100SS (small): 7.5 – 12.5 mm (0.3 – 0.5 in.)

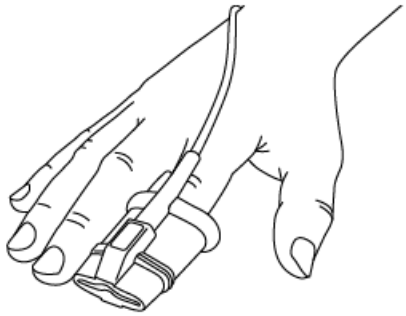


Attaching the Sensor

NOTE:
Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in SpO2 inaccuracies.

1. Carefully remove the sensor from the plastic pouch and uncoil the sensor cable. Check the sensor for any sign of damage in transport. If signs of damage are found, replace the sensor.
2. Insert the selected digit (refer to the sizing recommendations above) into the sensor as illustrated in Figures 1 and 2. The patient's digit must reach the end of the sensor.
3. Direct the cable along the patient's digit, parallel to the arm or leg.
4. Secure the sensor cable with medical tape so the cable does not become caught on nearby equipment. Ensure that the tape securing the cable does not restrict blood flow or pull the sensor out of position.
5. Align the arrows on the sensor connector and the signal processor. Insert the sensor connector into the signal processor connection port.
6. Flip the sensor lock over the sensor connector and click it into place.
7. Verify proper operation as described in the system operator's manual. Verify the sensors are connected as needed for the desired system configuration and that the displayed data correctly correlates with the sensor application site.

1



2

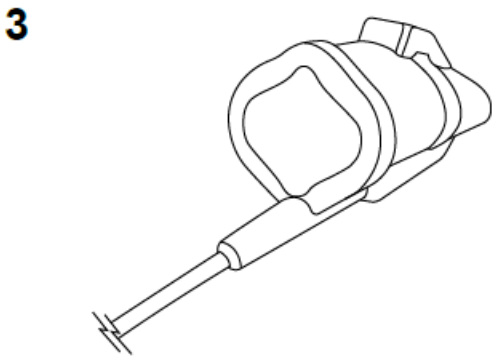
Cleaning the Reusable Sensor

Cautions:

- Clean the sensor before applying it to a new patient.
- Disconnect the sensor from the signal processor before cleaning.
- Do not sterilize, autoclave, or immerse the sensor in liquid of any kind. Do not pour or spray any liquids onto the sensor.
- Do not use caustic or abrasive cleaning agents on the sensor. Do not use cleaning agents containing ammonium chloride. The use of these chemicals may shorten the life of the product.

1. To clean the sensor, wipe all patient contact surfaces (see figure 3) with a soft cloth dampened with a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]).
2. Allow the sensor to dry thoroughly before reusing.

NOTE:
To minimize cable deterioration when cleaning the cable, gently wipe away from the plug end towards the sensor end.



Specifications

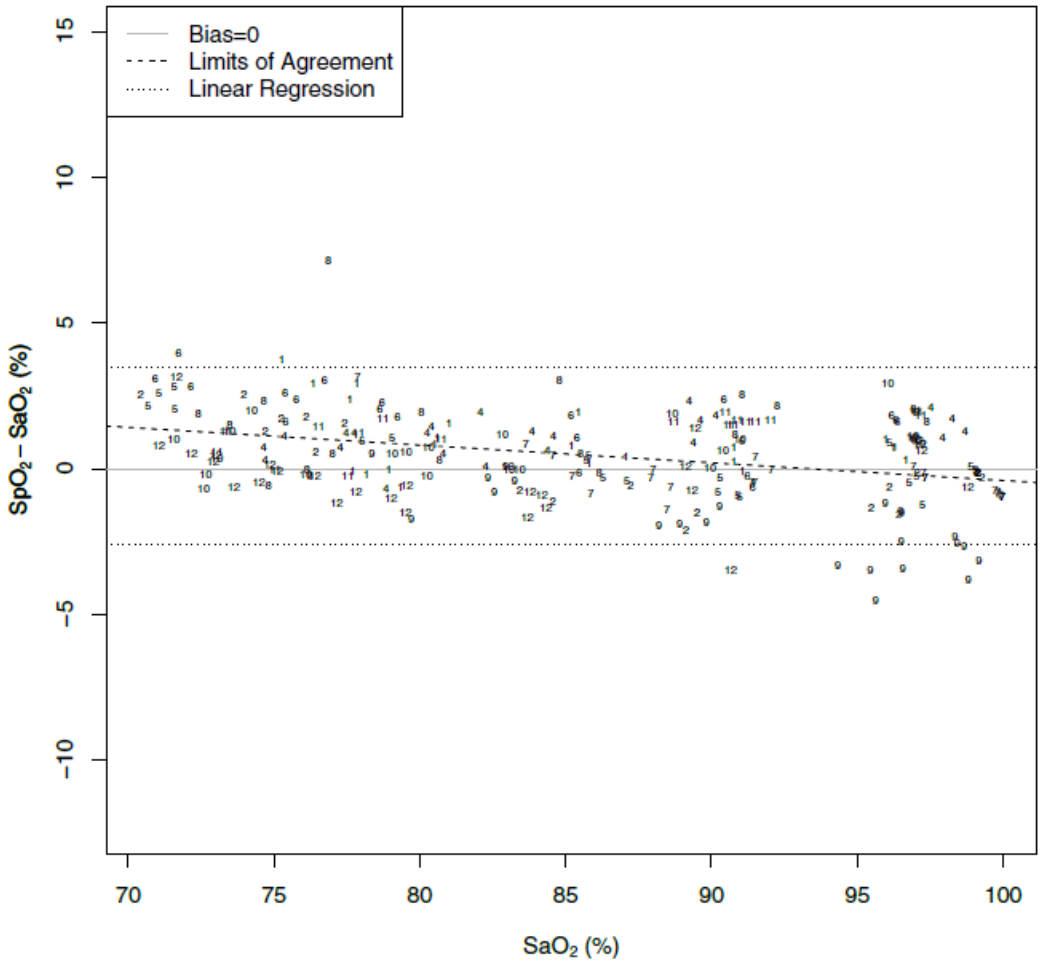
SpO2 Accuracy*:
The table below shows Arm values measured using the Model 8100S(X) in a clinical study.

Range	Oxygen Saturation (Arms**)	Motion Oxygen Saturation (Arms**)	Low Perfusion Oxygen Saturation (Arms**)
70 – 100%	± 2	± 3	± 2
70 – 80%	± 2	± 3	± 2
80 – 90%	± 2	± 3	± 2
90 – 100%	± 2	± 2	± 2

Range	95% Limits of Agreement (SpO2)
70 – 100%	(-2.6, 3.5)

Pulse Rate Accuracy*:

- Non-motion: 18 – 300 BPM ±3 digits (Arms**)
- Motion: 40 – 240 BPM ±5 digits (Arms**)
- Low perfusion: 40 – 240 BPM ±3 digits (Arms**)
- **Temperature:**
  - **Operating:** 0 °C to 40 °C (32 °F to 104 °F)
  - **Storage/Transportation:** -30 °C to 70 °C (-22 °F to 158 °F)
- **Humidity:**
  - **Operating:** 15 – 93% non-condensing
  - **Storage/Transportation:** Up to 93% non-condensing
- **Operating Altitude:** 0 to 4,000 m (0 to 13,123 ft)
  - * Additional accuracy and performance information can be found in the system operator’s manual.
  - ** ±1 Arms encompasses 68% of the population.



Measurement Wavelengths and Output Power

- **Red:** 660 nanometers @ 0.8 mW nominal
- **Infrared:** 910 nanometers @ 1.2 mW nominal

This information is especially useful for clinicians performing photodynamic therapy.

Compliance

- This product complies with ISO 10993-1.
- Not made with natural rubber latex.

Warranty

- 2 years from the date of delivery.

Users and/or patients should report adverse events involving their Nonin device to Nonin Medical, Inc. and the competent authority of the EU Member State in which the user and/or patient is established, if applicable.

Contact Information

Nonin Medical, Inc.

- 13700 1st Avenue North Plymouth, MN 55441, USA
- www.nonin.com
- **E-mail:** info@nonin.com
- +1 763-553-9968
- 800-356-8874 (US and Canada)

Nonin Medical B.V.

- Doctor Paul Janssenweg 150 5026 RH Tilburg, Netherlands
- **Email:** infointl@nonin.com (Europe)
- +31 (0)13 – 45 87 130 (Europe)

EC/REP
MPS, Medical Product Service GmbH Bomgasse 20 D-35619 Braunfels, Gemany.

CH/REP
MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug Switzerland.

8655-000-06 01/2024

Documents / Resources

	NONIN 8100SS Soft Pulse Oximeter Sensors [pdf] Instructions 8100S X, 8100SS, 8100SM, 8100SL, 8100SS Soft Pulse Oximeter Sensors, 8100SS, Soft Pulse Oximeter Sensors, Pulse Oximeter Sensors, Oximeter Sensors, Sensors

References

- Pulse and Regional Oximeters, Capnographs, Sensors | Nonin
- User Manual