NONIN 8330AA Multi-Sensing Reusable Fingerclip Sensor Instruction Manual

Contents

NONIN 8330AA Multi-Sensing Reusable Fingerclip Sensor

Product Information

Product Name: SenSmart Model 8330AA Product Type: Multi-Sensing Reusable Fingerclip Sensor Compatible with: Nonin Multi-Sensing Oximetry Indications for Use: This product is used for measuring oxygen levels non-invasively in patients.

Warnings:

- Excessive ambient light may interfere with accurate readings.
- Anemia or low hemoglobin levels may affect the accuracy of the readings.
- Excessive motion during usage may result in inaccurate measurements.
- Electrosurgical interference, cardiovascular dyes, and moisture in the sensor may affect the performance of the sensor.
- Improperly applied sensor, artificial nails or fingernail polish, blood flow restrictors, and residue in the light path may affect the accuracy of the readings.
- Use the correct sensor type for accurate measurements.
- Poor pulse quality and venous pulsations may affect the accuracy of the readings.

Usage Instructions

1. Ensure that the SenSmart Model 8330AA Fingerclip Sensor is compatible with your Nonin Multi-Sensing Oximetry device.
2. Clean and dry the patient's finger before applying the sensor.
3. Gently place the finger into the fingerclip sensor, ensuring a snug fit.
4. Securely attach the sensor to the patient's finger.
5. Follow the instructions provided with your Nonin Multi-Sensing Oximetry device to start the measurement process.
6. Ensure that the patient remains still during the measurement to avoid motion artifacts.
7. After the measurement is complete, remove the fingerclip sensor from the patient's finger.
8. Clean and disinfect the sensor according to the manufacturer's instructions before reuse.
   Please note that it is important to read and follow all instructions provided in the user manual for proper and safe usage of the SenSmart Model 8330AA Fingerclip Sensor.

SenSmart Model 8330AA
Multi-Sensing Reusable Fingerclip Sensor

For use only with Nonin Multi-Sensing Oximetry

Indications for Use

The Model 8330AA reusable finger clip sensor is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO2), carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and pulse rate of adult and pediatric patients (> 66 lbs / 30 kg). The measurements may be multiple spot checks to observe change and/or continuous monitoring. It is intended for use in Emergency Medical Service (EMS), professional healthcare facilities, and mobile environments.
This device is not meant for sole use in clinical decision-making; it must be used in conjunction with additional methods of assessing clinical signs and symptoms.

Clinical Benefits

Nonin pulse oximeters allow for the management of patients' medical conditions by providing fast, accurate, real-time, noninvasive oxygen measurement in order to meet patients' medical needs.

Warnings:

- This device should not be used to diagnose or make treatment decisions related to suspected carbon monoxide poisoning.
- 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 Nonin Multi-Sensing Signal Processor.
- Inspect the sensor application site at least every 4 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 to the sensor application site as this may cause damage to the skin beneath the sensor.
- The use of sensor and oximeter combinations other than Non-in-branded products have not been tested for accuracy as a system and may affect performance of the system.
- This sensor is only compatible with Nonin Multi-Sensing Oximetry. Refer to the system operator's manual for a complete listing of Non-in-branded 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 oximetry 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 any cleaning solution other than those recommended here, as permanent damage could result.
- The sensor is designed for external use, over intact skin, outside of the sterile field.
- Follow local governing ordinances and recycling instructions regarding 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 oximeter performance include the following:
    - excessive ambient light
    - excessive motion

- electrosurgical interference
- moisture in the sensor
- improperly applied sensor
- 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:

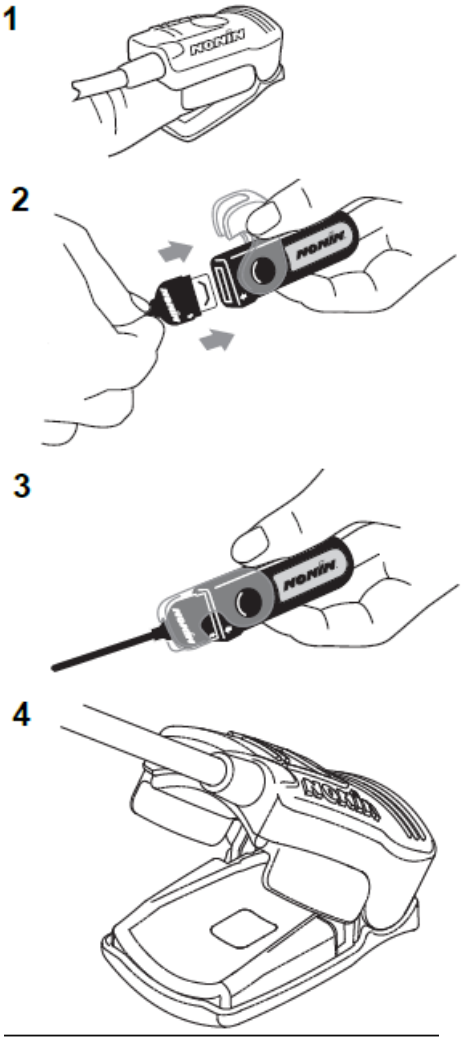
Symbol	Definition
	Follow Instructions for Use
	CAUTION!
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
EC REP	Authorized Representative in the European Community.
LOT	Lot number
REF	Catalogue number
QTY	Quantity
	Importer
	Distributor
MD	Medical Device
UDI	Unique Device Identifier
	Handle With Care
	Keep Dry

Symbol	Definition
	Type BF Applied Part
	Defibrillation Proof Type BF Applied Part (patient isolation from electrical shock when connected to a signal processor)
	Manufacturer
	Indicates separate collection for waste electrical and electronic equipment (WEEE)
	Storage/shipping temperature range
	RoHS Compliant (China)
	Non-sterile
Rx Only	Prescription Required
	Country of Manufacture
	Date of Manufacture
	Humidity Limitation
	Use By
	Do Not Reuse

Attaching the Sensor

The sensor is for use on an index, middle, or ring finger that has a thickness of 7.6 – 25.4 mm (0.3 – 1.0 in.). This finger thickness correlates to patients weighing greater than 30 kg (66 lb).

NOTE: Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in measurement 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 a finger (index, middle, or ring finger) into the sensor until the end of the finger reaches the finger stop. Keep the fingernail facing the sensor top (figure 1). Ensure that long fingernails do not interfere with proper finger position.
3. Direct the cable along the patient's digit, parallel to the arm.
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 (figure 2). Insert the sensor connector into the signal processor connection port.
6. Flip the clear lock over the sensor connector and click it into place (figure 3).
7. Verify proper operation as described in the system operator's manual.

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 any cleaning solution other than those recommended here, as permanent damage could result.
    1. To clean the sensor, wipe all patient contact surfaces (figure 4) 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: Do not open the sensor's case more than 40°, or the case may be damaged.

Figure 4 shows the appropriate opening of the case for cleaning.

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

Specifications

Overall Accuracy:

Description	SaO2 Range	MetHb or COHb Range	Clinical Accuracy	Expected Accuracy/ 95% Limits of Agreement
%SpO2 accuracy with COHb	70 – 100%	0 – 3% COHb	± 2	(-2.6, 3.2)
%SpO2 accuracy with COHb	80 – 100%	0 – 15% COHb	± 2	(-2.3, 2.9)
%SpO2 accuracy with MetHb	70 – 100%	0 – 2% MetHb	± 2	(-2.3, 3.7)
%SpO2 accuracy with MetHb	80 – 100%	0 – 15% MetHb	± 2	(-3.0, 3.8)
%COHb accuracy	95 – 100%	0 – 15% COHb	± 2	(-5.2, 4.3)
%COHb accuracy with elevated HHb	80 – 100%	0 – 15% COHb	± 3	(-5.5, 4.5)
%MetHb accuracy	97 – 100%	0 – 15% MetHb	± 0.8	(-1.5, 1.7)
%MetHb accuracy with elevated HHb	80 – 100%	0 – 15% MetHb	± 1.0	(-1.7, 2.1)

Accuracy by Decade
The tables below show Arms values measured using the Model 8330AA in a clinical study.

%SpO2 Accuracy (Arms) 1, 2:

<table>
<tr><th>SaO2 Range</th><th>COHb Range</th><th>Oxygen Saturation (Figure A)</th></tr>
<tr><td>70 – 100%</td><td rowspan="4">0 – 3%</td><td>± 2</td></tr>
<tr><td>70 – 80%</td><td>± 2</td></tr>
<tr><td>80 – 90%</td><td>± 3</td></tr>
<tr><td>90 – 100%</td><td>± 2
<table>
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<tr><td>90 – 100%</td><td>± 2</td></tr>
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SaO2 Range	COHb Range	Oxygen Saturation with COHb (Figure B)
80 – 100%	0 – 15%	± 2
80 – 90%		± 3
90 – 100%		± 2

SaO2 Range	MetHb Range	Oxygen Saturation (Figure C)
70 – 100%	0 – 2%	± 2
70 – 80%		± 2
80 – 90%		± 2
90 – 100%		± 2

SaO2 Range	MetHb Range	Oxygen Saturation with MetHb (Figure D)
80 – 100%	0 – 15%	± 2
80 – 90%		± 3
90 – 100%		± 2

%COHb Accuracy (Arms)1, 2:

SaO_2 Range	COHb Range	%COHb Accuracy (Figure E)
95 – 100%	0 – 15%	± 2
	0 – 5%	± 3
	5 – 10%	± 2
	10 – 15%	± 2

SaO_2 Range	COHb Range	%COHb Accuracy with Elevated HHb (Figure F)
80 – 100%	0 – 15%	± 3
	0 – 5%	± 3
	5 – 10%	± 2
	10 – 15%	± 3

%MetHb Accuracy (Arms)1, 2:

SaO_2 Range	MetHb Range	%MetHb Accuracy (Figure G)
97 – 100%	0 – 15%	± 0.8
	0 – 5%	± 0.7
	5 – 10%	± 0.8
	10 – 15%	± 1.0

SaO_2 Range	MetHb Range	%MetHb Accuracy with Elevated HHb (Figure H)
80 – 100%	0 – 15%	± 1.0
	0 – 5%	± 0.7
	5 – 10%	± 1.1
	10 – 15%	± 1.1

Pulse Rate Accuracy1: 40 – 250 BPM ±3 digits (Arms) 2:

Temperature:

- Operating: -10 to 40 °C (14 to 104 °F)
- Transient Operating3: -20 to 50 °C (-4 to 122 °F)
- Storage/Transportation: -40 to 70 °C (-40 to 158 °F)

Humidity:

- Operating: 15 to 93% non-condensing
- Transient Operating3: 15 to 90% non-condensing
- Storage/Transportation: Up to 93% non-condensing
- Operating Altitude: 0 to 4,000 m (0 to 13,123 ft)

1 Additional accuracy and performance information can be found in the system operator's manual (expected accuracy). 2 ±1 Arms encompasses 68% of the population at zero bias (tested accuracy).

3 The system will operate for a minimum of 20 minutes when exposed to the extreme environmental operating conditions.

Measurement Wavelengths and Output Power

Wavelength range: 600 to 910 nanometers
Output range: 1.5 to 18 mW

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

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.

Warranty

1 year from the date of delivery. The device's expected service life is 1 year.
Nonin reserves the right to make changes and improvements to these instructions and the product it describes at any time, without notice or obligation

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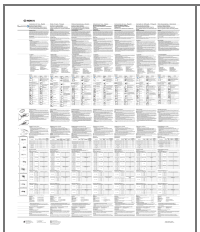
Documents / Resources

	NONIN 8330AA Multi-Sensing Reusable Fingerclip Sensor [pdf] Instruction Manual 8006CA, 8330AA, 8330AA Multi-Sensing Reusable Fingerclip Sensor, Multi-Sensing Reusable Fingerclip Sensor, Reusable Fingerclip Sensor, Fingerclip Sensor, Sensor

References

- Pulse and Regional Oximeters, Capnographs, Sensors | Nonin