Instructions for Use—English

℞ Only CE 0123

SenSmart Model 8330AA
Multi-Sensing Reusable Fingerclip Sensor

For use only with Nonin Multi-Sensing Oximetry

Indications for Use:

The 8330AA reusable fingerclip sensor when used together with Nonin Multi-Sensing Oximetry is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO2), carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb) and pulse rate in adult and pediatric patients (> 66 lbs/30 kg). The measurements may be spot-checks, multiple spot-checks to observe change, and/or monitoring during clinician assessment. It is intended for use in professional healthcare facilities, mobile, and emergency medical service (EMS) settings. 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.

⚠ 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 Nonin Multi-Sensing Signal Processor.
- Inspect the sensor application site periodically 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 Nonin-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 Nonin-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:

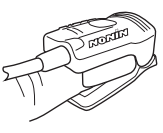
- Do not use a damaged sensor. If the sensor is damaged, discontinue use immediately.
- Ensure all oximetry sensors are kept a minimum of 6 cm (2.7 in.) away from all other sensors.
- Clean the sensor before applying it to a new patient.
- Disconnect the sensor from the signal processor before cleaning.
- 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
	Type BF Applied Part

Symbol	Definition
	Defibrillation Proof Type BF Applied Part (patient isolation from electrical shock when connected to a signal processor)
IP33	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529
	Manufacturer
℞ Only	Medical Prescription Required
	Indicates separate collection for waste electrical and electronic equipment (WEEE)
	Storage/shipping temperature range
	RoHS Compliant (China)
NON STERILE	Non-sterile

1



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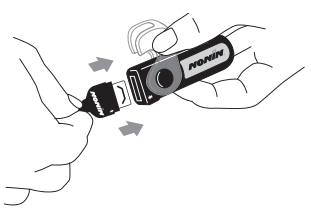

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Attaching the Sensor

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.

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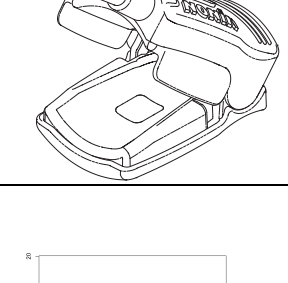


Cleaning the Reusable Sensor

- 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.

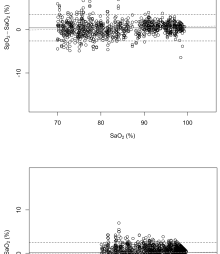
Specifications

Overall Accuracy:

Accuracy (A_{rms}) is expected to encompass approximately 68% of measured values and 95% Limits of Agreement are expected to ecompass approximately 95% of measured values.

Description	SaO_2 Range	MetHb or COHb Range	Accuracy (A_{rms})	Expected Accuracy/ 95% Limits of Agreement
$\%SpO_2$ accuracy with COHb	70 – 100%	0 – 3% COHb	± 2	(-2.6, 3.2)
$\%SpO_2$ accuracy with COHb	80 – 100%	0 – 15% COHb	± 2	(-2.3, 2.9)
$\%SpO_2$ accuracy with MetHb	70 – 100%	0 – 2% MetHb	± 2	(-2.3, 3.7)
$\%SpO_2$ accuracy with MetHb	80 – 100%	0 – 15% MetHb	± 2	(-3.0, 3.8)
%COHb accuracy	95 – 100%	0 – 15% COHb	± 3	(-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	± 1	(-1.5, 1.7)
%MetHb accuracy with elevated HHb	80 – 100%	0 – 15% MetHb	± 1	(-1.7, 2.1)

A



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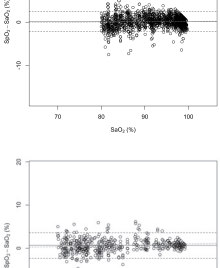

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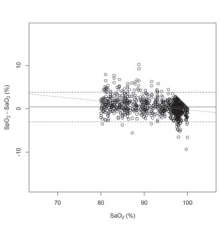

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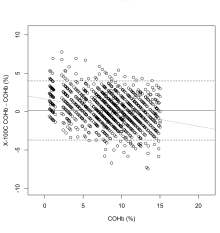

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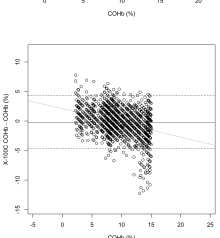

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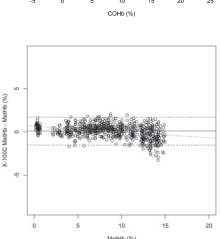

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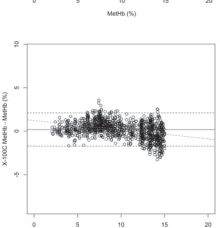

$\%SpO_2$ Clinical Accuracy (A_{rms}):

SaO_2 Range	COHb Range	Oxygen Saturation (Figure A)
70 – 100%	0 – 3%	± 2
70 – 80%		± 2
80 – 90%		± 3
90 – 100%		± 2

SaO_2 Range	COHb Range	Oxygen Saturation with COHb (Figure B)
80 – 100%	0 – 15%	± 2
80 – 90%		± 3
90 – 100%		± 2

SaO_2 Range	MetHb Range	Oxygen Saturation (Figure C)
70 – 100%	0 – 2%	± 2
70 – 80%		± 2
80 – 90%		± 2
90 – 100%		± 2

SaO_2 Range	MetHb Range	Oxygen Saturation with MetHb (Figure D)
80 – 100%	0 – 15%	± 2
80 – 90%		± 3
90 – 100%		± 2

%COHb Accuracy (A_{rms}):

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

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

%MetHb Accuracy (A_{rms}):

SaO_2 Range	MetHb Range	%MetHb Accuracy (Figure G)
97 – 100%	0 – 15%	± 1
	0 – 5%	± 1
	5 – 10%	± 1
	10 – 15%	± 1

SaO_2 Range	MetHb Range	%MetHb Accuracy with Elevated HHb (Figure H)
80 – 100%	0 – 15%	± 1
	0 – 5%	± 1
	5 – 10%	± 1
	10 – 15%	± 1

Pulse Rate Accuracy: 40 - 250 BPM ±3 digits (A_{rms})**:**

Temperature:
Operating: -10 to 40 °C (14 to 104 °F)
Transient Operating: -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 Operating: 15 to 90% non-condensing
Storage/Transportation: Up to 93% non-condensing

Operating Altitude: 0 to 4,000 m (0 to 13,123 ft)

Observed Clinical Study Accuracy

The tables below show A_{rms} values measured using the Model 8330AA in a clinical study of healthy volunteer subjects.

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.

Warranty

For warranty information refer to : http://www.nonin.com/warranty/