

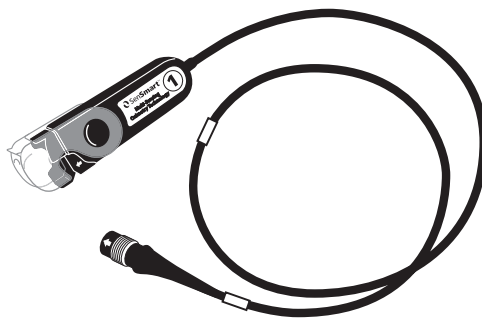


**Model 3500SP
OEM Multi-Sensing Oximeter**

Indications for Use

Nonin's signal processor is indicated for noninvasive spot-checking and/or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), carboxyhemoglobin (COHb), methemoglobin (MetHb), with pulse rate or cerebral or somatic hemoglobin oxygen saturation (rSO₂) of adult, pediatric, and neonate patients using the Nonin-branded (original) sensors.

Refer to the system manufacturer's instructions for a complete list of sensors, accessories, and use environments. Use environments may also be found in the sensor instructions for use.



Warnings:

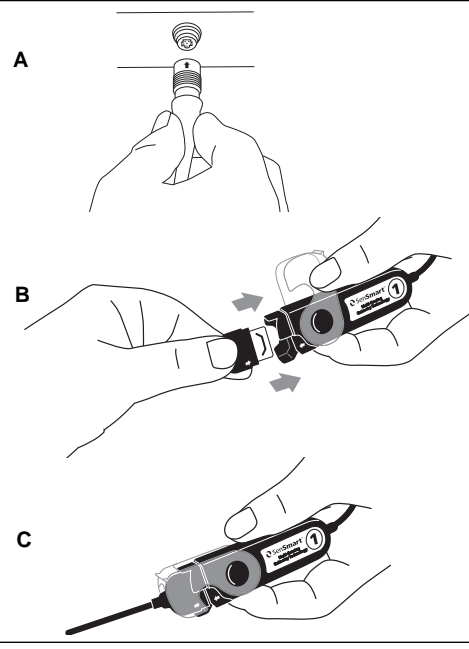
- Do not use this device in an MR environment.
- Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- Always inspect the device before use. Do not use a damaged device.
- To prevent improper performance and/or patient injury, verify compatibility of the monitor, sensor(s), and accessories before use.
- No modifications to this device are allowed as it may affect device performance.
- Protect from exposure to water or any other liquid, with or without AC power.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or tripping.
- The use of signal processors and sensors other than those specified may result in increased electromagnetic emission and/or decreased immunity of this device.
- This device is a precision electronic instrument and must be repaired by trained technical personnel. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results for SpO₂.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- See the sensor instructions for use for additional warnings.

⚠ Cautions:

- When using this device in an operating room, it must remain outside the sterile field.
- Do not place the device in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in these instructions.
- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your system manufacturer regarding take-back or recycling of the device.
- A functional tester cannot be used to assess the accuracy of the oximeter monitor or sensor.
- If this device fails to respond as described, discontinue use until the situation is corrected by your system manufacturer.
- Do not connect multiple extension cables between a monitor and a signal processor.
- See the sensor instructions for use for additional cautions.

Symbols:

Symbol	Definition	Symbol	Definition
	Follow Instructions for Use		Serial Number
	CAUTION!		Catalogue number
	Authorized Representative in the European Community.		Quantity
	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm in diameter, per IEC 60529.		Indicates separate collection for waste electrical and electronic equipment (WEEE)
	Defibrillation Proof Type BF Applied Part (patient isolation from electrical shock when connected to a 3500SP)		Storage /shipping temperature range
	Non-sterile		Manufacturer
	RoHS Compliant (China)		Country of manufacture/ date of manufacture
			Do not discard
			Do not pull on cable. Retract connector and remove.



Using the Signal Processor

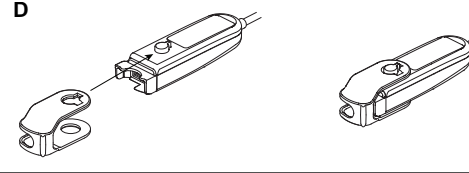
Connect/Disconnect Signal Processor to/from the System:

- To connect:
 - Align the arrow on the signal processor cable connector with the arrow on the system connector port (fig. A).
 - Push the signal processor cable connector straight into the port.
 - The signal processor cable connector will click when it locks into the system.
- To disconnect:
 - Grasp the retractable sleeve on the signal processor cable connector.
 - Retract the sleeve and pull the connector straight back. The signal processor will unlock and detach.

NOTE: When removing the signal processor from the monitor, do not pull on the signal processor cable.

Connect/Disconnect a Sensor to/from the Signal Processor:

- To connect:
 - Flip the clear lock on the signal processor back to expose the connection port.
 - Align the arrows on the sensor connector and the signal processor (fig. B). Insert the sensor connector into the signal processor connection port.
 - Flip the lock over the sensor connector and click it into place (fig. C).
- To disconnect:
 - Flip the clear lock on the signal processor back to disengage the lock from the connector.
 - Grasp the connector and remove it from the signal processor.



Replacing the Lock on the Signal Processor

NOTE: Replacement locks may be ordered if the lock is lost or damaged.

- Align the lock hinge with the connector end of the signal processor (fig. D).
- Gently spread the lock hinge so it fits over the end of the signal processor.
- Click the lock into place.

Cleaning Instructions

- Wipe the device with a soft cloth dampened with a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]). Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result.
- Dry with a soft cloth or allow to air dry.

Accessories

Refer to "Model 3500SP Accessories and Testing Summary" for a list of compatible, Nonin-branded accessories.

Specifications

Refer to the sensor instructions for use for accuracy specifications. Refer to "Model 3500SP Accessories and Testing Summary" for test methods and summaries.

- Temperature:**
 Operating: 0 to 40 °C (32 to 104 °F)
 Storage/Transportation: -40 to 70 °C (-40 to 158 °F)
- Humidity:**
 Operating: 15 to 93% non-condensing
 Storage/Transportation: Up to 93% non-condensing
- Operating Altitude:** 0 to 4,000 m (0 to 13,123 ft)

Compliance

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

Warranty

NONIN MEDICAL, INC. (Nonin) warrants to the purchaser (end user), for a period of 1 year from the date of purchase, each Model 3500SP signal processor. Any 3500SP signal processor, found to be defective in accordance with this warranty, shall be replaced or repaired free of charge, when Nonin has been notified by the purchaser by serial number that there is a defect, provided notification occurs within the applicable warranty period. If unable to repair, Nonin will replace with a 3500SP or comparable device. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Model 3500SP delivered to the purchaser which is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

This warranty excludes the cost of delivery to and from Nonin. Nonin reserves the right to charge a fee for a warranty repair request on any 3500SP that is found to be within specifications.

The Model 3500SP is a precision electronic instrument and must be repaired by trained Nonin personnel only. Any sign or evidence of opening the 3500SP, field service by non-Nonin personnel, tampering, or any kind of misuse of the 3500SP shall void the warranty. All non-warranty work shall be done at Nonin's standard rates and charges in effect at the time of delivery to Nonin.

Service

To obtain technical service or support, contact Nonin Technical Service.

Nonin reserves the right to make changes and improvements to these instructions and the product it describes at anytime, without notice or obligation.

