

Instructions for Use—English

Model 8000SX, 8000SX-WO, 8000SX-WO2
Reusable Soft Pulse Oximeter Sensors

Indications for Use
Nonin's Model 8000SX-Series Reusable Soft Sensors are indicated for non-invasive pulse oximetry monitoring and continuous monitoring of adult and pediatric patients who are well or poorly perfused. It is intended for use in environments including operating rooms, emergency departments, intensive care units, emergency room, long-term care, home use, and mobile environments.

Box CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

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.

Contraindications:

- Do not use the device in an MR environment or in an explosive atmosphere.
- The device is not deformation proof per IEC 60601-1.

Warnings:

- The use of sensor and connector combinations other than Nonin-branded products have not been tested for accuracy as a system and may affect performance of the system. Refer to Nonin pulse oximeter user instructions, reportозвызувайтесь с нами о любых неизвестных проблемах с вашим устройством.
- Inspect the sensor application site at least every 8 to 10 hours to ensure the skin is intact and there is no redness or irritation. The sensitivity to patients' capillaries 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.

Cautions:

- Do not use a damaged sensor. If the sensor is damaged, discontinue use immediately.
- Do not sterilize, autoclave or immerse in liquid if any kind.
- Do not use the device in an MR environment or in an explosive atmosphere.
- Follow local government ordinances and recycling instructions regarding disposal of the device.
- A functional test is not used to verify the accuracy of a pulse oximeter monitor or sensor.
- After cleaning, carefully remove patient cables and connectors to reduce the possibility of entanglement or strangulation.
- For patients with certain types of implants, carefully route patient cables and connectors to reduce the possibility of entanglement or strangulation.
- For patients that may degrade pulse oximeter performance include the following:
 - extensive ambient light
 - poor pulse quality
 - electrocautery interference
 - improperly applied sensors
 - cardioversion
 - carboxyhemoglobin
 - blood low resistance (arterial cuff, infusion lines, etc.)
 - incorrect sensor type

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
LOT	Lot Number
IP32	Protected against vertically falling water drops when enclosed is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm in diameter per IEC 60329.
	Storage/shipping temperature range (if applicable)
	Storage/shipping humidity range (if applicable)
Rx Only	Medical prescription required
Qty	Quantity
Manufacture	Manufacturer
Date of Manufacture	Date of manufacture
Country of Manufacturer	Country of manufacturer
EC REP	Authorized Representative in the European Community
CH REP	Authorized Representative in Switzerland
Importer	Importer
Distributor	Distributor
MD	Medical Device
UDI	Unique Device Identifier
Handle With Care	Handle with care
Keep Dry	Keep dry
Use By	Use by
Do Not Use	Do not use

Choosing the Appropriate Sensor

Use the measurements provided below to determine which sensor should be used. Sensor recommendations are based on digit height (thickness), as indicated at left.

• For heights between 0.5 and 1.0 mm, utilize the model 8000SL (pett).

• For heights between 0.4 and 0.75 inches (10 – 19 mm), use the Model 8000SM (Medium).

• For heights between 0.3 and 0.5 inches (7.5 – 12.5 mm), use the Model 8000SS (Small).

• For heights between 12.5 and 25.5 mm, utilize the model 8000XL (Large).

• For heights between 10 and 19 mm, utilize the model 8000SM (Medium).

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