

Rx only CE 0123 Model 8000R Reflectance Pulse Oximeter Sensor

Indications for Use

The Nonin Model 8000R Reflectance Sensor (Figure 3) is designed for use on peripheral skin surfaces of patients weighing greater than 30 kilograms. The application site will usually be the forehead.

The Model 8000R Reflectance Sensor Holder (Figure 1) and the double-back tape (Figure 2) provide the precise pressure against the skin needed for this sensor.

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.

Warnings:

- Do not use the device in an MRI environment.
- Do not use the adhesive tape while applying the sensor. This may cause inaccurate readings of skin blisters.
- Factors that may degrade pulse oximeter performance include the following:
 - excessive ambient light
 - excessive motion
 - electromagnetic interference
 - arterial catheters, blood pressure cuffs, ultrasound dopplers
 - moisture in the sensor
 - improperly applied sensor
 - carboxyhemoglobin
 - methemoglobin
 - incorrect sensor type

Cautions:

- To prevent improper performance and/or patient injury, verify sensor and pulse counter compatibility before use.
- Do not use a damaged sensor. If the sensor is damaged in any way, do not use, or discontinue use immediately.
- Reflectance sensors are not recommended for pediatric or neonatal use. Sensor accuracy has not been established for pediatric or neonatal use.
- Do not sterilize, autoclave, or immerse in liquid of any kind. Do not spray any antiseptic on the sensor. Do not sterilize with EO.
- Do not use caustic or abrasive cleaning agents on the sensors. Do not use ultrasonic cleaning.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the sensor and any components.
- Always use the sensor in the manner specified in the accuracy of a pulse oximeter monitor or probe.

Refer to the pulse oximeter operator's manual for additional warnings and cautions.

Discouraged use: If the patient exhibits allergic reactions to the adhesive material. Do not stretch the adhesive tape while applying the sensor. This may cause inaccurate readings of skin blisters.

Factors that may degrade pulse oximeter performance include the following:

- excessive ambient light
- excessive motion
- electromagnetic interference
- arterial catheters, blood pressure cuffs, ultrasound dopplers
- moisture in the sensor
- improperly applied sensor
- carboxyhemoglobin
- methemoglobin
- incorrect sensor type

Symbols:

Symbol	Definition	Symbol	Definition
	Follow Instructions for Use		Indicates separate collection for waste electrical and electronic equipment (WEEE)
	CAUTION		Storage/keeping
	CE Marking indicating conformity to EC Directive No. 93/42		Authorized representative in the European Community
	Country of manufacture		Manufacturer
	Protected against vertically falling water (equivalent to IPX2)		Country of origin
	Protected against liquids (up to 15 degrees of inclination)		Manufacturer
	Protected against liquids (up to 30 degrees of inclination)		Manufacturer
	Protected against liquids (up to 60 degrees of inclination)		Manufacturer
	Protected against liquids (up to 90 degrees of inclination)		Manufacturer
	Protected against liquids (up to 120 degrees of inclination)		Manufacturer
	Protected against liquids (up to 150 degrees of inclination)		Manufacturer
	Protected against liquids (up to 180 degrees of inclination)		Manufacturer
	Protected against liquids (up to 210 degrees of inclination)		Manufacturer
	Protected against liquids (up to 240 degrees of inclination)		Manufacturer
	Protected against liquids (up to 270 degrees of inclination)		Manufacturer
	Protected against liquids (up to 300 degrees of inclination)		Manufacturer
	Protected against liquids (up to 330 degrees of inclination)		Manufacturer
	Protected against liquids (up to 360 degrees of inclination)		Manufacturer
	Protected against liquids (up to 390 degrees of inclination)		Manufacturer
	Protected against liquids (up to 420 degrees of inclination)		Manufacturer
	Protected against liquids (up to 450 degrees of inclination)		Manufacturer
	Protected against liquids (up to 480 degrees of inclination)		Manufacturer
	Protected against liquids (up to 510 degrees of inclination)		Manufacturer
	Protected against liquids (up to 540 degrees of inclination)		Manufacturer
	Protected against liquids (up to 570 degrees of inclination)		Manufacturer
	Protected against liquids (up to 600 degrees of inclination)		Manufacturer
	Protected against liquids (up to 630 degrees of inclination)		Manufacturer
	Protected against liquids (up to 660 degrees of inclination)		Manufacturer
	Protected against liquids (up to 690 degrees of inclination)		Manufacturer
	Protected against liquids (up to 720 degrees of inclination)		Manufacturer
	Protected against liquids (up to 750 degrees of inclination)		Manufacturer
	Protected against liquids (up to 780 degrees of inclination)		Manufacturer
	Protected against liquids (up to 810 degrees of inclination)		Manufacturer
	Protected against liquids (up to 840 degrees of inclination)		Manufacturer
	Protected against liquids (up to 870 degrees of inclination)		Manufacturer
	Protected against liquids (up to 900 degrees of inclination)		Manufacturer
	Protected against liquids (up to 930 degrees of inclination)		Manufacturer
	Protected against liquids (up to 960 degrees of inclination)		Manufacturer
	Protected against liquids (up to 990 degrees of inclination)		Manufacturer
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	Protected against liquids (up to 1050 degrees of inclination)		Manufacturer
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	Protected against liquids (up to 1890 degrees of inclination)		Manufacturer
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	Protected against liquids (up to 2160 degrees of inclination)		Manufacturer
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