# Instructions for Use—English

## Reflectance Pulse Oximeter Sensor

### Indications for Use

The Nonin Model 8000R Reflectance Pulse Oximeter Sensor (hereafter referred to as "Sensor") is intended for use in conjunction with Nonin's Model 8000H Reflectance Sensor Holder to provide high-performance noninvasive measurement of oxygen saturation and pulse rate. It is intended for use on the arms of adults weighing greater than 30 kilograms. It is not intended for use on children or non-well-vascularized skin surfaces of patients weighing less than 30 kilograms.

### Contraindications

- The sensor is contraindicated in patients who have had trauma to the sensor area within 30 days.
- The sensor is contraindicated in patients who have had surgery to the sensor area within 30 days.

### Warnings

- Do not use the sensor on patients who have had trauma to the sensor area within 30 days.
- Do not use the sensor on patients who have had surgery to the sensor area within 30 days.

### Symbols

#### Symbol Definition

- **Caution:** Use with Nonin pulse oximeters only.
- **Warning:** Do not use on patients who have had trauma to the sensor area within 30 days.

### Temperature

- The sensor's expected service life is 90 days.
- This product complies with ISO 10993.
- Red: 660 nanometers @ 3 mW nominal
- Green: 530 nanometers @ 1 mW nominal
- Blue: 470 nanometers @ 0.5 mW nominal

### Humidity

- Operating: 10% to 95% non-condensing
- Storage/Transportation: -40 °C to 70 °C (-40 °F to 158 °F)
- Range of 70 % to 100 %.

### Pulse Rate Accuracy

- 4, 5
- Pulse Rate Accuracy: 40 to 240 BPM ±3 digits (Arms*)

### SpO2 Accuracy

- 1, 2, 3
- SpO2 Accuracy: 70 – 100% ±2
- 70 – 80% ±3

### SpO2 Low Perfusion Accuracy

- SpO2 Low Perfusion Accuracy: 40 – 70% ±6

### Pulse Rate Low Perfusion Accuracy

- Pulse Rate Low Perfusion Accuracy: 40 – 70% ±5

### Cautions

- Do not stretch the adhesive tape while applying the sensor. This may cause inaccurate readings or skin blisters.
- Do not use the sensor on patients who have had trauma to the sensor area within 30 days.
- Do not use the sensor on patients who have had surgery to the sensor area within 30 days.

### Instructions for Use

#### Attaching the Reflectance Sensor

1. Clean the patient's skin with an alcohol wipe before applying the sensor.
2. Remove the backing from the adhesive tape and press it onto the patient's skin.
3. Remove the backing from the other side of the tape.
4. Press the adhesive tape to secure the sensor and cable to the patient to avoid pulling or tipping out (Figure 5).
5. Attach the sensor and sensor holder to the patient. Use additional medical tape (Figure 2) to secure the sensor and cable to the patient to avoid pulling or tipping out (Figure 5).

#### Reflectance Pulse Oximeter Sensor

- The sensor's expected service life is 90 days.
- This product complies with ISO 10993.
- Red: 660 nanometers @ 3 mW nominal
- Green: 530 nanometers @ 1 mW nominal
- Blue: 470 nanometers @ 0.5 mW nominal

#### Monitoring the Reflectance Sensor

- Do not stretch the adhesive tape while applying the sensor. This may cause inaccurate readings or skin blisters.
- Do not use the sensor on patients who have had trauma to the sensor area within 30 days.
- Do not use the sensor on patients who have had surgery to the sensor area within 30 days.

### Instructions for Cleaning

- To clean the sensor, wipe all patient contact surfaces with a soft cloth.
- Do not use caustic or abrasive cleaning agents on the sensors. Do not use cleaning agents containing ammonium chloride.
- Do not sterilize, autoclave or immerse the sensors in liquid of any kind. Do not spray any liquids into the sensor. Do not sterilize with EtO.
- Do not use a damaged sensor. If the sensor is damaged in any way, do not use, reprocess, or repair it.
- Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
- Use only with Nonin pulse oximeters. These pulse oximeters are manufactured to meet the accuracy specifications for Nonin sensors. Using other pulse oximeters may cause improper sensor performance. Refer to Nonin pulse oximeter operator's manuals for a complete listing of compatible oximeters, oximeters may cause improper sensor performance. Refer to Nonin pulse oximeter operator's manuals for a complete listing of compatible oximeters,

### Warnings

- Do not stretch the adhesive tape while applying the sensor. This may cause inaccurate readings or skin blisters.
- Do not use the sensor on patients who have had trauma to the sensor area within 30 days.
- Do not use the sensor on patients who have had surgery to the sensor area within 30 days.

### Symbols

#### Symbol Definition

- **Caution:** Use with Nonin pulse oximeters only.
- **Warning:** Do not use on patients who have had trauma to the sensor area within 30 days.

### Instructions for Cleaning

- To clean the sensor, wipe all patient contact surfaces with a soft cloth.
- Do not use caustic or abrasive cleaning agents on the sensors. Do not use cleaning agents containing ammonium chloride.
- Do not sterilize, autoclave or immerse the sensors in liquid of any kind. Do not spray any liquids into the sensor. Do not sterilize with EtO.
- Do not use a damaged sensor. If the sensor is damaged in any way, do not use, reprocess, or repair it.
- Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
- Use only with Nonin pulse oximeters. These pulse oximeters are manufactured to meet the accuracy specifications for Nonin sensors. Using other pulse oximeters may cause improper sensor performance. Refer to Nonin pulse oximeter operator's manuals for a complete listing of compatible oximeters,

### Warnings

- Do not stretch the adhesive tape while applying the sensor. This may cause inaccurate readings or skin blisters.
- Do not use the sensor on patients who have had trauma to the sensor area within 30 days.
- Do not use the sensor on patients who have had surgery to the sensor area within 30 days.

### Symbols

#### Symbol Definition

- **Caution:** Use with Nonin pulse oximeters only.
- **Warning:** Do not use on patients who have had trauma to the sensor area within 30 days.