### Instructions for Use—English

**EQUANOX™ Technology**

Model 8004CB Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor

**Applications**

- This device is designed to determine regional hemoglobin oxygen saturation of blood.
- Refer to the system operator’s manual for additional warnings and cautions.
- A functional tester cannot be used to assess the accuracy of the 8004CB sensor.

**Contraindications:**

- EQUANOX™ Technology cannot be used to assess hemoglobin oxygen saturation in the brain. For blood in the brain, use a pulse oximeter.
- Do not sterilize, autoclave, or immerse in liquid of any kind.
- The Model 8004CB is designed for single-patient use and should not be reused.
- Reuse is not permitted.
- Do not use this device in an MR environment.
- Explosion hazard: Do not use in an explosive atmosphere, or in the presence of flammable anesthetics or gases.

**Applying the Regional Sensor(s)**

- Ensure all pulse oximeter sensors are kept a minimum of 6 cm (2.7 in.) away from all medical devices with active high-frequency output.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- Ensure all cable pathways are clear and unencumbered.
- Do not apply sensor over open wound, incision, compromised skin, or pre-existing skin dyes.
- The sensor is designed for external use only.
- Avoid excessive pressure to the sensor application site(s) as this may cause damage to the skin beneath the sensor.
- Inspect the sensor application site(s) 15 minutes after sensor application and at least every 2 to 4 hours to ensure correct sensor alignment and skin integrity.
- Patient injury can be caused by improperly applied sensor.
- An improperly placed sensor may result in inaccurate readings.
- The sensor should be applied at least a minimum of 6 cm away from pre-existing hardware.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.

**Measurement Wavelengths and Output Power**

- 810 nanometers @ 3.2 mW maximum average power
- 730 nanometers @ 3.0 mW maximum average power

**Storage/Transportation**

- Operating: 10 % to 90 % non-condensing
- Storage: 10 % to 95 % non-condensing

**Maintenance and Cleaning**

- Skin Preparation.
- Do Not Reuse
- Do Not Sterilize
- Do Not Autoclave
- Do Not Immers in Any Liquid

**Specifications**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute rSO2 Accuracy (Arms*)</td>
<td>±1</td>
</tr>
<tr>
<td>±2 digits (Arms*)</td>
<td>±2</td>
</tr>
<tr>
<td>±1 Arms encompasses 68% of the population.</td>
<td>±1</td>
</tr>
<tr>
<td>Inter/Intra Sensor Repeatability Accuracy</td>
<td>±2</td>
</tr>
<tr>
<td>±1 Arms encompasses 68% of the population.</td>
<td>±2</td>
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**Supported Pulse Oximeters**

- ELI™
- i-glove™
- i-sport™
- EQUINOX™

**Medical Prescription**

- EQUANOX™ Technology cannot be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other diagnostic modalities.
- Properly trained practitioners should interpret results.
- Do not use EQUANOX™ Technology without a complete listing of Nonin-branded sensors, parts, and accessories. Patient injury can be caused by the use without reference to a complete listing.

**Troubleshooting**

- If the system operator’s manual indicates that the displayed data correctly correlates with the sensor application site.
- Otherwise, consult the Troubleshooting section of the system operator’s manual.

**Symbols:**

- This information is especially useful for clinicians performing photodynamic therapy.
- Refer to the system operator’s manual for additional warnings and cautions.
- A functional tester cannot be used to assess the accuracy of the 8004CB sensor.

**Notes:**

- This product complies with ISO 10993-1.
- Sensor adhesive properties are guaranteed up to the Use By date.

**Contact Information**

- E-mail: info@nonin.com
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- Fax: +31 (0)13 - 79 99 043 (Europe)
- infointl@nonin.com (Europe)
- www.nonin.com

**Lot Number**

- Do Not Reuse
- Do Not Sterilize
- Do Not Autoclave
- Do Not Immers in Any Liquid

**Conformance to EC Directive**

- CE Marking indicating conformance to EC Directive

**Software Version:**

- 810 nanometers @ 3.2 mW maximum average power
- 730 nanometers @ 3.0 mW maximum average power

**Warranty:**

- 1 year

**GMP:**

- Good Manufacturing Practice

**Medical Devices Regulation:**

- No conformity to one of the applicable Directives of the Medical Devices Regulation

**Declaration of Conformity:**

- Manufacturer Address:
  - 13700 1st Avenue North
  - Seattle, WA 98133
  - USA
- Manufacturer Phone:
  - +1 206-317-9500
- Medical Devices Regulatory Affairs:
  - +1 206-317-9505
- Global Regulatory Affairs:
  - +1 206-317-9501
- European Regulatory Affairs:
  - +31 (0)13 - 79 99 042
- EU Representative:
  - 13700 1st Avenue North
  - Seattle, WA 98133
  - USA
- Manufacturer E-mail:
  - info@nonin.com
  - infointl@nonin.com (Europe)

**General Safety Information:**

- Electrical isolation from electrical power source.

**IP Rating:**

- IP32