This device is intended only as an adjunct device in patient assessment. It should not be used to diagnose the condition of the patient. If the patient becomes symptomatic, consult a physician. This device is not intended for continuous monitoring for diagnostic purposes or with hemodynamic monitoring units. Do not use this device on patients under 4 months of age.

**Measurement Wavelengths and Output Power**

- **730 nanometers @ 3.0 mW maximum average power**

**Signal Processor or Pod Site(s) and Cable Pathways.**

- Select an appropriate site to locate the signal processor or oximetry pod. The ideal site avoids the midline, superior to the eyebrow and inferior to the hairline (see example in image). Ensure sensor surface adheres to the skin to prevent light from traveling between emitting or receiving elements or ambient light from entering.

- Ensure all pulse oximeter sensors are kept a minimum of 6 cm (2.7 in.) away from all tissue areas.

- Do not apply sensor over open wound, incision, compromised skin, or pre-existing skin sensitivity to the sensor may vary due to medical status or skin condition.

- The sensor is designed for external use only.

- The 8004CB sensor is only compatible with systems using EQUANOX technology.

- Inspect the sensor application site(s) 15 minutes after sensor application and at least every 2 hours thereafter.

- Do not use a damaged sensor. If the sensor is damaged, discontinue use immediately.

- Do not clean the sensor. Cleaning the sensor will damage it.

- Do not reuse.

- Do Not Reuse

- Instructions for Use—English

- Symbol Definition of Symbol
- Symbol Definition of Symbol

- Skin Preparation.

- Somatic Site(s).

- 4.

- **This information is especially useful for clinicians performing photodynamic therapy.**

- Measurement Wavelengths and Output Power

- Absolute rSO2 Accuracy (Arms*):

  - 95% confidence limits: 730 nanometers ± 18 ppb (0.02)

- Error percentages:

  - ± 15 percent

  - ± 3 percent

- Measurement accuracy is order of a licensed practitioner.

- **WARNING:** Federal law (USA) restricts this device to sale by or for licensed practitioners.

- Do not use in an MR environment.

- Do not use in an explosive atmosphere, or in the presence of flammable anesthetics and other flammable substances.

- Do not use this device in an MR environment.

- Do not use this device in an operating room, it must remain outside the sterile field.

- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the sensor and any components.

- In order to avoid erroneous readings, ensure all cable connections are correct and secure.

- Avoid adjacent placement of non-Nonin branded NIRS sensors to prevent interference.

- The value of data from the system has not been demonstrated in specific disease states.

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