Instructions for Use—English

Model Number: Single-Patient Use, Non-sterile, Disposable Regional Oximetry Sensor with Attached Cable
Model 8204CA

Instructions for Use

This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

EQUANOX interrogates a small volume of tissue in areas such as the frontal cerebral cortex and is not necessarily reflective of simultaneous saturation values in other tissue areas.

The sensor is designed for external use over intact skin, outside of the sterile field.

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

• Remove from Packaging and Pre-check.
• Open the plastic pouch by tearing along the opening line. Insert the sensor(s) (one on left, one on right) firmly, place the sensor(s) on the desired site(s) (see examples at left). Ensure sensor and any components are firmly connected to the trunk cable and monitor.
• Select the site(s) on the patient's forehead lateral of the superior sagital sinus, on the forehead over the parietal area, or on the side of the patient's head.
• Inspect the sensor application site(s) at least every 2 to 4 hours to ensure correct sensor application and to identify any problems such as entanglement or strangulation.
• Inspect the sensor application site(s) prior to each use, ensuring the skin is not broken or cut. If there is any irritation or skin condition, discontinue use. Do not use the device in an MR environment, in an explosive atmosphere, or in the presence of cross-contamination.

Warnings:

• Do not use the device in an MR environment, in an explosive atmosphere, or in the presence of cross-contamination.
• This device is only defibrillation proof per IEC 60601-1 when used with the X-100SP signal processor or pod site(s) and cable pathways.
• Do not use a damaged sensor. If the sensor is damaged, discontinue use immediately.

• Inspect the sensor application site(s) at least every 2 to 4 hours to ensure correct sensor application and to identify any problems such as entanglement or strangulation.
• Inspect the sensor application site(s) prior to each use, ensuring the skin is not broken or cut. If there is any irritation or skin condition, discontinue use.
• This device is designed to determine regional hemoglobin oxygen saturation of blood through measurement of changes in the ratio of tissue oxygenated versus deoxygenated hemoglobin at 880 nanometers @ 4.5 mW maximum average power.
• This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.