

Reprocessed by



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Instructions for Use Hygia Pediatric Cerebral-Somatic Oximetry Sensor IFU

Reprocessed Device for Single Use.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

NON-STERILE NOT MADE WITH NATURAL RUBBER LATEX

Cerebral-Somatic Oximetry Sensor Description

The Reprocessed pediatric sensors are used to noninvasively monitor site-specific adequacy of perfusion in the brain or body tissue directly beneath its sensors. This allows for real-time data generation on regional oxygen saturation (rSO₂).

Indications for Use

The Hygia Health Services Reprocessed Pediatric Cerebral-Somatic Oximetry Sensors (SPFB-USA) are indicated for use when continuous noninvasive oxygen saturation is required for pediatric patients weighing < 40 kg. The reprocessed sensor has been validated with the OEM's INVOS 5100C System and is intended to be used with the OEM INVOS 5100C System only.

The noninvasive INVOS System is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states. The prospective clinical value of data from the INVOS System has not been demonstrated in disease states. The OEM suggests the INVOS System should not be used as the sole basis for diagnosis or therapy.

Warnings

- The sensor is designed for single use only and may not be reused. Reuse may cause inaccurate or erratic readings, or no readings at all. Also, reuse may cause an increased risk of cross-contamination among patients.
- Do not autoclave or gas sterilize the sensors.
- The sensor is designed for external use only as described in the instructions. Do not use the sensors internally for any reason.
- Do not immerse the sensor in any liquids as they may cause electric shock hazard or damage the device.
- Do not use the sensor in the presence of flammable anesthetics or in other flammable environments.

Precautions

- Do not use the INVOS System as the sole basis for making decisions regarding diagnosis or therapy because the INVOS rSO₂ index values may not represent absolute venous oxygen saturation.
- INVOS readings represent a small volume of tissue beneath the sensor and may not reflect oxygenation disturbances that occur elsewhere.
- Ensure all connectors are fully engaged and free of moisture. Moisture intrusion may cause inaccurate or erratic readings, or no readings at all.
- Different INVOS System sensors (adult, pediatric, and infant/neonatal) cannot be used simultaneously on the same monitor. Cerebral sensors can be used with somatic sensors on the same monitor.
- Use of the INVOS System with any other sensor will compromise accuracy.
- Be careful when applying or removing sensor. Do not position on broken or undeveloped skin.
- If present, the following may cause inaccurate readings: "Cardiogreen," "Indigo Carmine," "Methylene Blue" or other intravascular dyes, Carboxyhemoglobin or other dyshemoglobins, Hemoglobinopathies, Conjugated hyperbilirubinemia (direct), Myoglobin (Mb) in muscle tissues.
- Do not position sensor on regions with severe tissue edema to reduce possibility of skin lesions.

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- Use of an electrosurgical/electrocautery instrument in the vicinity of the INVOS System may interfere with the signal and result in no readings.
- Environments with excessive ambient light such as bright sunlight or strong operating room lighting may require loosely covering the area of the sensor with an opaque drape.
- To avoid pressure sores do not apply pressure (e.g. headbands, wraps, tape) to sensor.
- Sensors do not need to be removed for X-ray or CT Scan, but will appear on image. Sensors must be removed for MRI.

Instructions for Use

1. Remove sensor from package and look for obvious signs of visual damage. If sensor is damaged, replace with a new undamaged sensor.
2. Somatic Site Positioning: Choose appropriate tissue site to place somatic sensor. Avoid positioning sensor over fatty deposits, hair, and bony protuberances. Do not position sensor over nevi, broken skin or hematomas, each of which may cause no readings or readings that are not representative of the tissue. If two somatic site sensors are positioned, they must be connected to the same preamplifier. The location of the sensor site is at the clinician's discretion provided it follows the criteria given in these Instructions For Use. Positions may include: Upper Leg, Calf, Abdomen, Chest, Forearm, Upper Arm, and Posterior Flank (T10-L2, right or left of midline). Cerebral Site Positioning: Choose appropriate tissue site on the right or left side of forehead. Placement of sensor in other cerebral locations, or over hair, may cause inaccurate or erratic readings, or no readings at all. Do not place sensor over nevi, sinus cavities, the superior sagittal sinus, subdural or epidural hematomas or other anomalies such as arteriovenous malformations, each of which may cause no readings or readings that are not representative of the tissue.
3. For optimum adhesion, the patient's skin must be clean. Dry skin with a gauze pad.
4. Holding the cable, peel away white liner at the point where cable meets sensor pad. Apply to skin. Continue applying sensor by smoothing it to the skin from center outward. Seal sensor edges.
5. Plug sensor cable into preamplifier connector. Secure sensor cable to a fixed object to avoid tension on the sensor/skin interface using tension-relief clips. Ensure cable is properly inserted into preamplifier. Calibration is automatic and begins in seconds. Status messages on the INVOS System monitor will appear if monitoring conditions are impaired. Check skin integrity periodically following your institution's patient care protocol(s). If sensors are removed or peeled away to achieve this, ensure sensor is properly re-sealed to skin to prevent light from entering. **For extended monitoring, it is recommended replacing sensors every 24 hours or if adhesive fails to seal the sensor to the skin.**

Specifications:

Range: Saturation: 15-95% Temperature: Operational: 16°C-32°C (60°F-90°F)
Humidity: 20% - 80%, non-condensing Temperature: Storage: -20°C-45°C (-4°F-110°F)

Patient contact materials have been demonstrated to be biocompatible for patient use.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

This product and its packaging have been exposed to ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, proposition 65, a State of California voter initiative, requires the following notice:

Warning: this product and its packaging have been exposed to ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.