135 pirkimo dalis. Smegenų oksigenacijos elektrodai

COVIDIEN

Disposable Adult SomaSensor®
Model SAFB-SM

For use with INVOS® 5100/5100B/5100C Systems ONLY. The SomaSensor® disposable sensor Model SAFB-SM has been designed for cerebral – somatic monitoring of site-specific regional oxygen saturation (rSO_2) in adult patients weighing > 40 kilograms. For additional information regarding setup and use of the INVOS® System, consult the Operations Manual.

INDICATIONS FOR USE: The noninvasive INVOS 5100C is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in individuals greater than 2.5 kg at risk for reduced-flow or no-flow ischemic states. It is also 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 in any individual.

CONTRAINDICATIONS: None

WARNINGS:

- The sensor is designed for single patient use only and may not be used on multiple patients due to 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 INVOS System or sensor in any liquids as they may cause electric shock hazard or damage the device.
- Do not use the INVOS System in the presence of flammable anesthetics or in other flammable environments.
- The prospective clinical value of data from the INVOS System has not been demonstrated in disease states. The INVOS System should not be used as the sole basis for diagnosis or therapy.

PRECAUTIONS:

- INVOS readings represent a small volume of tissue beneath the sensor and may not reflect oxygenation disturbances that occur elsewhere.
- Make sure all connectors are fully engaged and free from moisture. Moisture intrusion may cause inaccurate readings, erratic readings or no readings at all.
- Different INVOS System sensors (adult, pediatric and infant/neonatal) cannot be used simultaneously on the same monitor.
- Use only Covidien recommended or provided accessories. Use of the INVOS System with any other sensor will compromise accuracy.
- Use care when placing or removing sensor. Do not place 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 place the sensor on regions with severe tissue edema to reduce the possibility of skin lesions.
- 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. However, sensors will appear on image. Sensors must be removed for MRI.

INSTRUCTIONS FOR USE

Pre-use Check: Remove the sensor from the package and examine for visual signs of damage. If any signs of damage are observed, select another sensor.

Cerebral Site Selection: Select sensor site on the right and left side of forehead. Placement of the sensor in other cerebral locations, or over hair, may cause inaccurate readings, erratic readings, or no readings at all. Do not place the sensor over nevi, sinus cavities, the superior sagittal sinus, subdural or epidural hematomas or other anomalies such as arteriovenous malformations, as this may cause readings that are not reflective of brain tissue or no readings at all.

Somatic Site Selection: Select sensor site over tissue area of interest (site selection will determine which body region is monitored). Avoid placing the sensor over thick fatty deposits, hair or bony protuberances. Do not place the sensor over nevi, hematomas or broken skin, as this may cause readings that are not reflective of tissue or no readings at all. When two somatic site sensors are placed, they must be connected into the same preamplifier. Sensor location is at the clinician's discretion, provided it adheres to the criteria noted on this Instruction For Use. Placements may include:

- Over the spine (upper and lower)
- On the lateral or posterior calf
- The upper arm or leg
- On the forearm
- On the chest

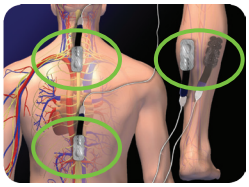
Patient Prep: Remove any moisture or perspiration from the patient's skin with a dry gauze pad. Then, degrease the skin. Ensure patient's skin is completely dry and remove degreaser residue, if any, with a dry gauze pad.

Sensor Placement: Remove the protective backing label from the adhesive side of the sensor and apply to the skin. Continue applying the sensor by smoothing it to the skin from the center outward. Ensure edges of the sensor are sealed to prevent light from entering.

Monitoring: Plug the sensor into the cable connector. Secure the sensor cable to a fixed object to avoid strain on the sensor-to-skin interface using strain-relief clips. Ensure the reusable cable is properly inserted into the preamplifier. Calibration is automatic and monitoring will begin in seconds.

Status messages on the INVOS System display will appear if monitoring conditions are compromised. Check the sensor periodically to assess skin integrity and the security of sensor placement. Always ensure sensor is properly sealed to skin to avoid light entering. **For extended monitoring, Covidien recommends using a new sensor every 24 hours or if adhesive is inadequate to seal the sensor to the skin.**





LATEX FREE PVC FREE **Rx ONLY**

Reordering Information: Reorder SomaSensor number SAFB-SM from Covidien at 800-635-5267, in the U.S. or Covidien's website at www.covidien.com

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