

# **SOP: NIRS device and sensor handling in SafeBoosC III**

| Version | Author(s)                             | Date     | Changes         | Approved by  |
|---------|---------------------------------------|----------|-----------------|--------------|
| 1.0     | Mathias Lühr Hansne<br>Marie Rødkilde | 16.01.19 | Initial version | Gorm Greisen |

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## **1.0 Introduction**

This Standard Operation Procedure is meant as a general guidance when beginning NIRS monitoring for a patient in the experimental arm of SafeBoosC III. For further instructions, we recommend to go through the individual devices' instruction manuals. It is recommended to use adjust this SOP for local circumstances (e.g. different devices), thereby creating a local procedure description for NIRS monitoring.

## **2.0 How to begin patient NIRS monitoring in SafeBoosC III**

NIRS monitoring has to be started within the first 6 hours of life. If this is not accomplished, the infant cannot participate in SafeBoosC III.

### **Procedure**

1. Make sure the patient has been included in the SafeBoosC III trial and all relevant forms have been signed
2. Verify the group allocation – experimental/control group.
3. Turn on the NIRS device and make sure the sensor is connected (all CE-marked devices where the appropriate intervention threshold, corresponding to a rStO<sub>2</sub> value of 55% using the INVOS adult SomaSensor have been defined, can be used in this trial)
4. Enter new patient, identification is not important.
5. Place probe on your own forearm. The device should give readings between 50% and 90%. If not  
1. Check correct placement of sensor, 2. Change sensor.
6. Position the sensor on the infant's head as described below
7. Press 'START'

## **2.0 How to position the NIRS sensor on the infant's head**

If using INVOS, or other devices with adhesive sensors, apply the adhesive side of the sensor on a clean surface, e.g. the inside of the packaging repeatedly, until the adhesive strength wears off.

### **Procedure**

1. To ensure good contact, clean/degrease the skin using water. Ensure patient's skin is completely dry with a gauze pad.
2. Check that the sensor is not defect. If it is, discard it immediately and take a new.
3. Select sensor site on the head. Aim for a site with as little hair as possible, as this can introduce inaccurate readings. Do not place the sensor over sinus cavities, the superior sagittal sinus, subdural or epidural haematomas or other anomalies such as arterio-venous malformations, as this may cause readings that are not reflective of brain tissue or no readings at all.

4. Ensure intact skin surface.
5. Apply sensor to the head so that the light source is facing towards the skin. The sensor should be fixed with a self-adhesive single use bandage.
6. Secure the cable to a fixed object to avoid strain on the sensor to skin interface.

CAUTION: TO AVOID PRESSURE SORES, KEEP THE EXTERNAL PRESSURE ON SENSOR TO A MINIMUM WHILE MAINTAINING SUFFICIENT SENSOR-SKIN CONTACT.

CAUTION: THE SENSOR IS NOT MRI COMPATIBLE.

### **3.0 How to change the position of the NIRS sensor**

For extended monitoring, the sensor should be repositioned at a different location. For infants with scalp oedema, or poor perfusion this may be as often as every 4 hours to avoid damage from heat and/or pressure. If possible, do it as part of the routine handling of the infant to disturb the infant as little as possible.

#### **Procedure**

The following procedure is

1. Press 'NIRS resiting' on the lower right of the screen
2. Gently remove the sensor from the skin
3. Carefully inspect the skin for any sensor related marks.
4. Apply the sensor on a different site according to the instructions above.
5. Press 'NIRS resiting' on the lower right of the screen again.

CAUTION: IF THE SENSOR IS DIFFICULT TO REMOVE, THE LOCAL PROTOCOL FOR PROTECTION OF THE INTEGRITY OF THE SKIN SHOULD BE FOLLOWED.