SOP: NIRS device and sensor handling during SafeBoosC

Version	Author(s)	Date	Changes	Approved by
1.0	Simon Hyttel-Sørensen	29.05.12	Initial Version	Gorm Greisen
1.1	Simon Hyttel-Sørensen	04.06.12	Sequence during repositioning changed	Gorm Greisen
1.2	Simon Hyttel-Sørensen	24.09.12	Information about data storage changed	Gorm Greisen
1.3	Berit Grevstad	10.12.12	Minor	Simon Hyttel-Sørensen

CONTENT

1.0 Introduction

The SafeBoosC software application should be installed and a properly working connection between laptop and NIRS device should be insured before inclusion of the first patient. Please refer to the 'SafeBoosC Software Manuel' for further instructions. Technical assistance may be needed.

Before a procedure is initiated please carefully read the instructions for every step of the procedure.

2.0 How to begin patient NIRS monitoring in SafeBoosC

NIRS monitoring has to be started within the first 3 hours of life. If this is not accomplished the infant cannot participate in SafeBoosC. If the patient is in the blinded group it is necessary to conceal the NIRS device before placing the sensor on the infant.

Procedure

1. Make sure the patient has been included in the SafeBoosC trial and all relevant forms have been signed.
2. Verify the group allocation - open/blinded.
3. Turn on the NIRS device and make sure the correct sensor is connected (Adult SomaSensor for INVOS 5100 C; Probe Holder S type with NIRO 200 NX)
4. Enter new patient, identification is not important.
5. Silence or turn off the internal alarm system of the device
6. 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.
7. Make sure the device and the trial laptop are connected.
8. Lock away the NIRS device in the box
9. Open the application 'SafeBoosC' on the laptop
10. Choose the appropriate 'Study set'
11. Enter the patients 'Patient No', i.e., the next available number in the site-specific 'Patient Inclusion List' of possible Study-IDs
12. IMPORTANT - CHECK THE CHECK BOX `BLIND` IF THE PATIENT IS RANDOMISED TO THE BLINDED GROUP.
13. Position the sensor on the infants head as described below
14. Press 'START'

3.0 How to position the NIRS sensor on the infant’s head

If using INVOS apply the adhesive side of the SomaSensor 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 may 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.

4.0 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

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, if any, please fill in the relevant information in the adverse events form in the eCRF after the sensor has been repositioned.
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 INTEGRETY OF THE SKIN SHOULD BE FOLLOWED.

5.0 Saving and transfer of data

All data will be stored in as a zip file at c:\values identified by the Study ID, e.g. DK1201.SBC. When the NIRS monitorering period is over this folder should be transfered by ftp to CTU Copenhagen. Please go to the 'SOP: Data transferring with FTP' for futher directions.