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MOBERG DEVICE PROCEDURES

Brain Oxygen Optimization in Severe Traumatic Brain Injury - Phase 3 (BOOST 3)

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Supported by: The National Institute of Neurological Disorders and Stroke (NINDS)

Purpose of this Document

This document contains general instructions on how to operate the Moberg CNS Monitor and its accessories in the context of data collection for the Brain Oxygen Optimization in Severe Traumatic Brain Injury - Phase 3 (BOOST 3) trial. These instructions are not meant to replace complete familiarity with the User Manual prior to operating the Moberg CNS Monitor.

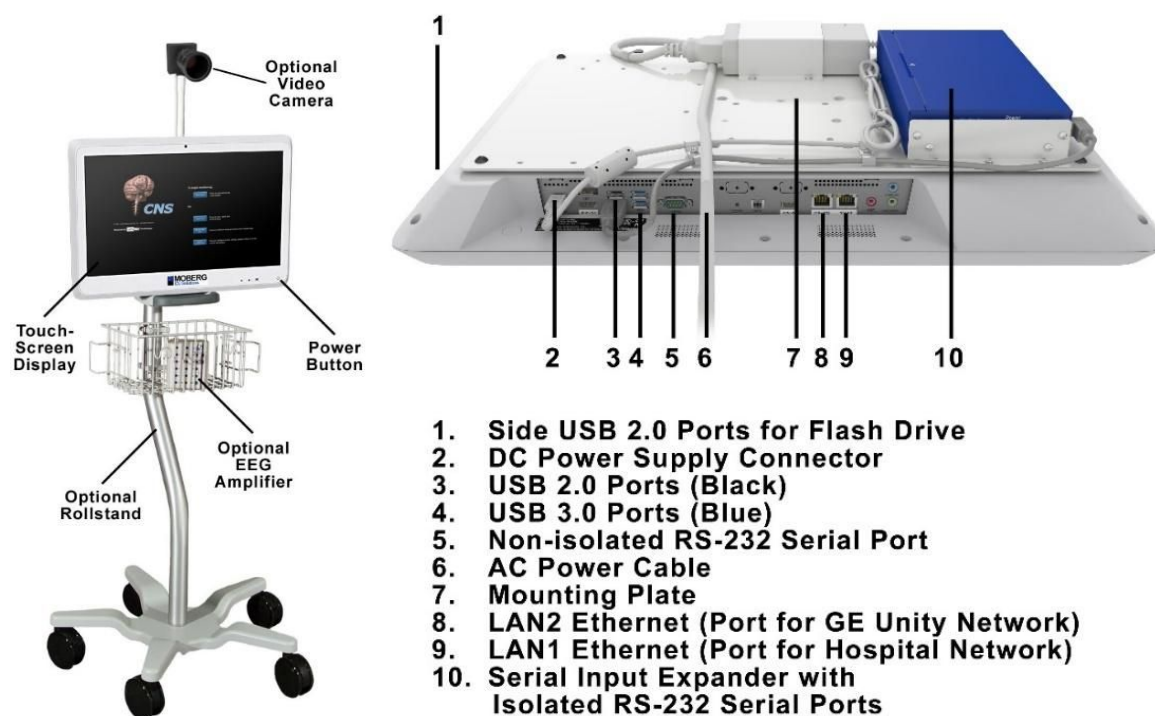
I. SET-UP FOR MONITORING A PATIENT

Position the Monitor and Connect Devices: Position the monitor to the side of the bed, near the head of the patient so the monitor can be viewed when setting up the patient and it is accessible for nursing staff to acknowledge episode and document interventions . Use the cables supplied by Moberg to connect interfaced external devices to the USB or Serial Port

connectors on the back or underside of the CNS Monitor. All device interface cables supplied by Moberg are labeled to indicate the appropriate compatible device.

Note: Digital port connectors should be plugged into any free USB port on the bottom of the CNS Monitor panel. If all four ports are taken, then the USB ports behind a small door on the right side of the monitor can be used. Serial device interface cables can be plugged into any free serial port labeled 1 through 4 on the back of the monitor. If these are unavailable, then the non-isolated serial port labeled COM on the bottom of the rear panel can be used.

Sites are encouraged, whenever possible, to keep all interface cables connected to the CNS Monitor even when it is not in use, to decrease set-up time and to reduce the likelihood of cable misplacement. The basket provided with the CNS Monitor will also be of help in storing cables between uses.



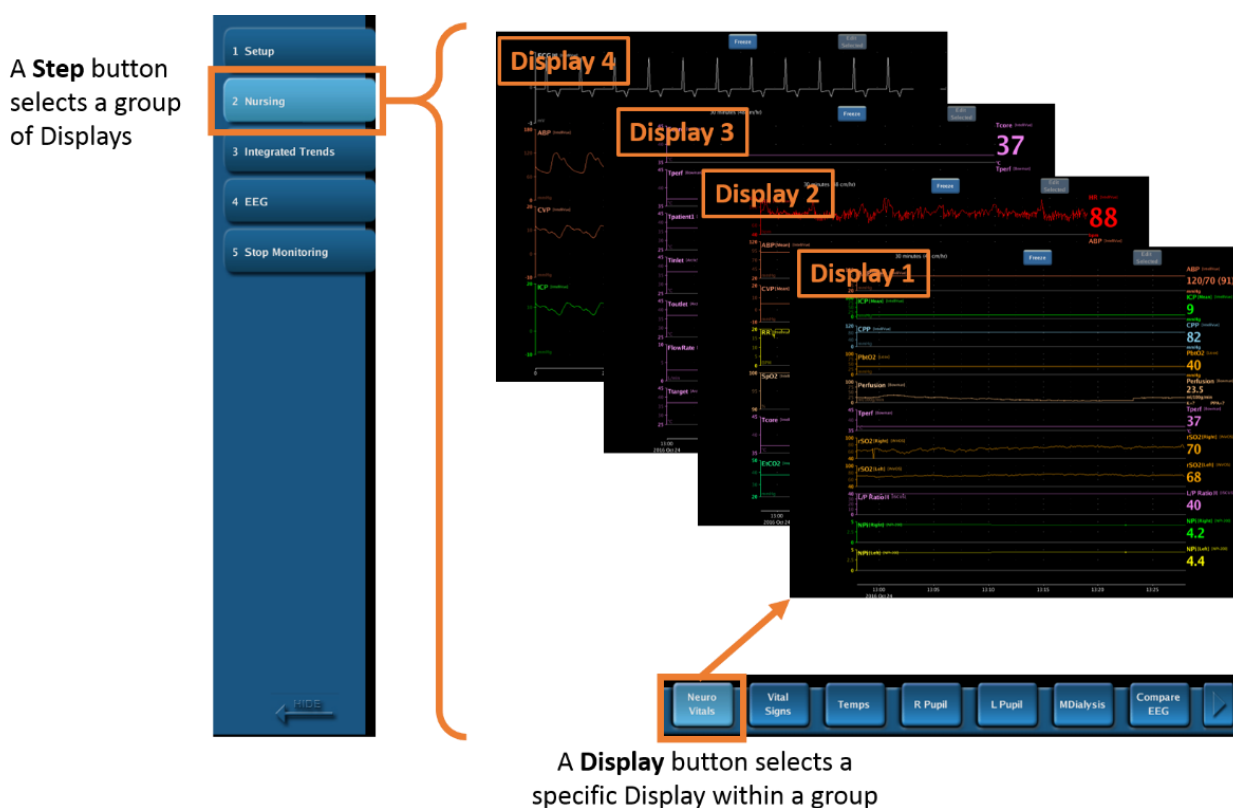
Power On: Plug the CNS Monitor power cord into the AC wall socket. Turn on power to the CNS Monitor using the power ON/OFF button located on the lower right corner of the display. The ON/OFF button will backlight with a soft green glow to show that the system is turning on. A power-up sequence will initiate.

Opening Screen: Following the power-up sequence, the opening/startup screen appears, offering a variety of options such as initiating a monitoring session or editing system configurations.

II. MONITORING A NEW PATIENT

Begin Monitoring: To begin monitoring a new patient using a previously selected protocol, press the green *Begin Monitoring* icon. To view details about the protocol or to select a different protocol, press *View/Select Protocol*.

Note: A Monitoring Protocol is the set of devices, measurements, displays, etc. used for a monitoring session.



Note: The CNS Monitor software offers a default 'BOOST-3' protocol that will show the basic study variables. Users are encouraged to customize the protocol to include any additional measurements collected from the devices connected to the CNS Monitor. In order to customize the CNS Monitor protocol while no patient is admitted, press the *System Configuration* button in the opening screen, select *Protocols*, and then select *Edit Protocol*.

For further instructions, refer to the User Manual or contact Moberg ICU Solutions at support@moberg.com.

Once the desired protocol is selected, press *Confirm* to return to the previous screen and *Begin Monitoring*.

When prompted, select the participant's group ('ICP Only' or 'ICP plus PbtO2'). If the 'ICP plus PbtO2' group is select, the Study Coordinator Password will be required.

Study Measurements: Subsequently, check and adjust or confirm the labels/sources for the study measurements, namely Primary ICP, Primary PbtO2, Primary BP, and Primary Temp. Note that this is a crucial step in order to receive the correct notifications at the beginning of each episode and it is of particular importance when multiple ICPs are recorded. Press *Accept*.

III. SETUP STEPS

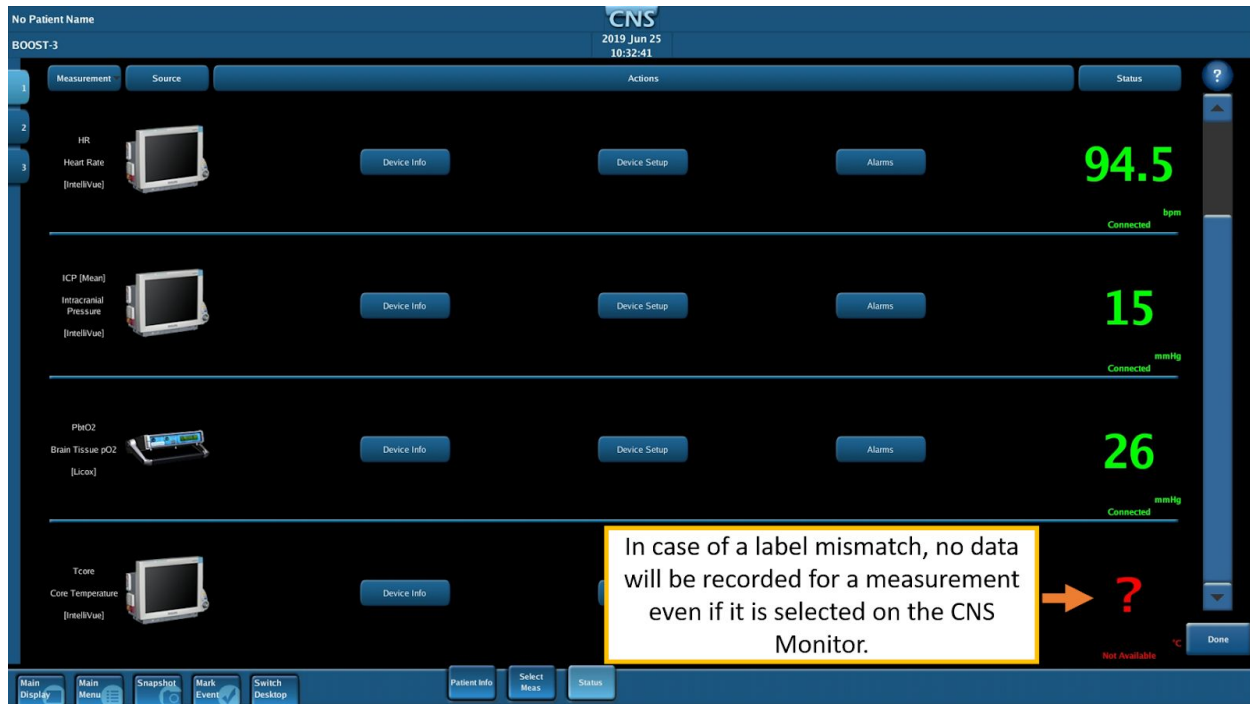
Begin at Step 1, *Setup*, on the Protocol Step Bar (on the left hand side). The sequence of display buttons at the bottom right of the screen (left to right) will guide you through setup and data quality checks.

Patient Info: Enter the *Subject ID* and *Site ID* provided by the study, so that they will be included in the stored data. Press *Done* to advance to the next screen.

Select Meas: Verify that each measurement of interest is being recorded. This list is pre-selected based on the monitoring protocol.

Status: View the status of each measurement being recorded. Use the *Actions* buttons to view device information, instructions for connecting devices, instructions for patient setup, and also to configure settings and alarms. The right-hand column of the Status Bar indicates if the CNS Monitor is receiving data from the intended device. Once setup is complete and signal connection is verified, press *Done* to begin data collection.

Note: In order for a measurement to be recorded by the CNS Monitor, the measurement needs to be identified using the same label that appears on the external monitoring device. For example, if the temperature measurement on the vital signs monitor is labeled 'Temp' but the temperature measurement selected on the CNS Monitor is 'Tcore', no temperature information will be recorded and a red question mark will appear next to the measurement in the *Status* tab, as seen in the screenshot below.



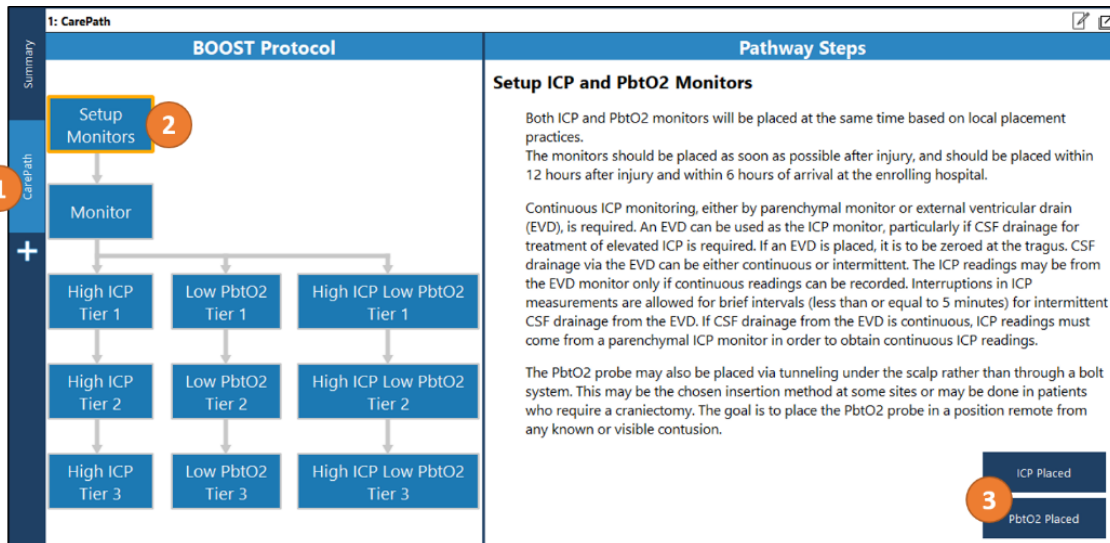
IV. START CAREPATH

Open Monitoring Session: Press the *Switch Desktop* button at the bottom of the screen to switch to the Application PC Windows desktop.

If CNS Reader is running, close it. Then relaunch it by double-clicking on the *CNS Reader Admitted* shortcut on the desktop: this will launch the CNS Reader application and open the monitoring session of the currently admitted patient.

Start CarePath: In the menu bar, go to *Layouts* and confirm that the layout with the CarePath protocol for BOOST-3 is currently selected (as identified by a checkmark).

In the *CarePath* page of the layout, select the *Setup Monitors* block and proceed to acknowledge the placement of the ICP and PbtO2 probes by pressing on the respective buttons on the right hand side. Once this step is complete, the protocol will automatically transition to the *Monitor* step.



Note: The CarePath protocol is not monitoring the data for episodes until the *Monitor* step is initiated.

Note: The CNS Monitor will alert the user if the CarePath *Monitor* step is not initiated timely and it will prompt the user to switch to the Application PC desktop and proceed through the CarePath steps.

V. UNBLINDING ('ICP Only' Group)

The unblinding operation is limited to Study Coordinators and it is password protected.

Unblinding on the CNS Monitor: Press on the blinded PbtO2 trend and press *Edit Selected*. Press on *Blinding*, enter the Study Coordinator password and press OK. Then select *Disabled* and press OK.

Unblinding on CNS Reader/CarePath: Right-click on the blinded PbtO2 trend, enter the Study Coordinator password and click on the check mark to *Accept* (✓).

Note: This unblinding operations are only temporary and meant for use in cases such as FiO2 challenges.

Note: If the wrong Study Group was selected when data collection was started, the Study Group can be changed without interrupting data collection. In order to do so, go to the *Setup* step

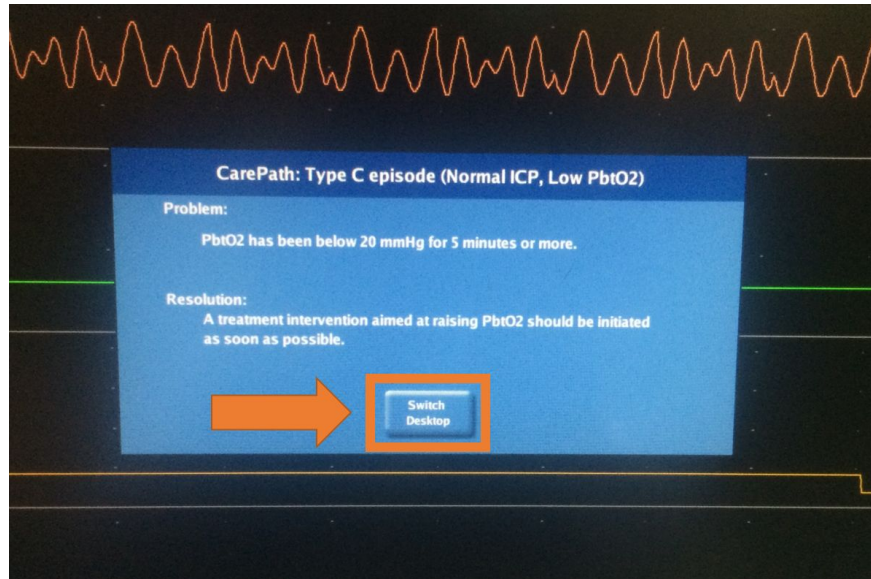
on the Protocol Step Bar on the CNS Monitor. Press on the *Study Group* field in the Patient Information dialog and enter the Study Coordinator password if requested. Select the new group and press *Done*.



VI. EPISODES AND NOTIFICATIONS

If the CarePath application identifies an episode (abnormally high ICP and/or abnormally low PbtO2 for longer than 5 minutes), an audible alarm will be played.

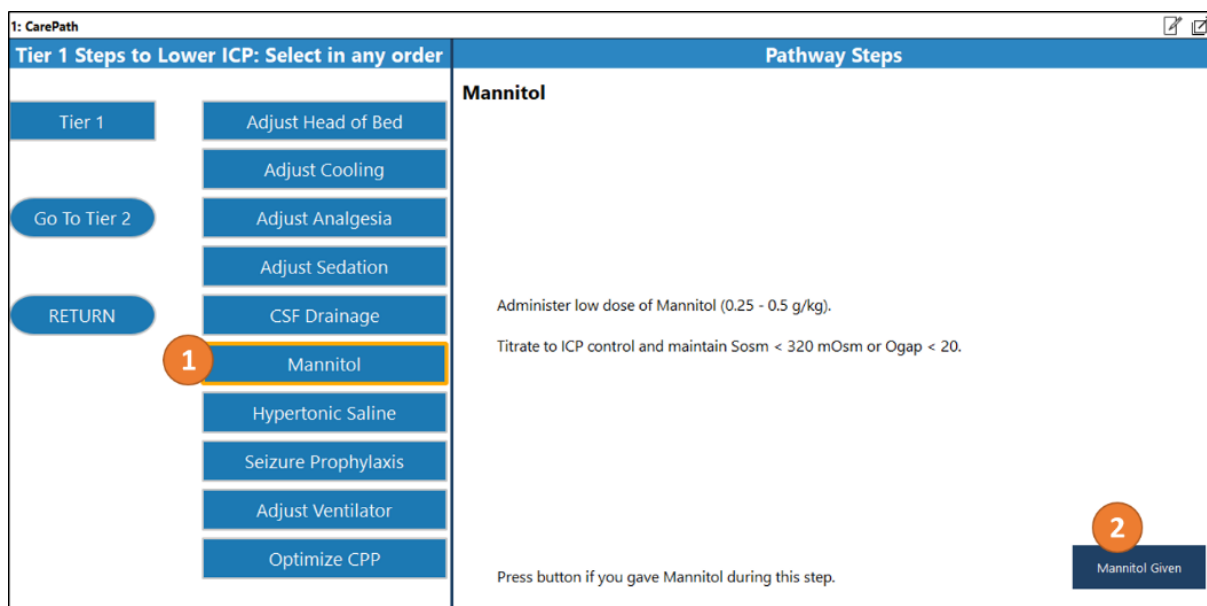
On the CNS Monitor: A pop-up message will appear on screen prompting the user to *Switch Desktop* in order to acknowledge the beginning of an episode and initiate intervention. Press *Switch Desktop* in order to switch to CNS Reader/CarePath where the episode start will then need to be acknowledged. (See below for details).



Note: Simply switching to CNS Reader/CarePath will not acknowledge the beginning of the episode nor end the audible alarm.

On CNS Reader/CarePath: Details about the type of episode and its current duration will be presented to the user. In order to proceed to the appropriate list of tiered interventions and silence the audible alarm, press the button *Intervention Required, Press to Acknowledge*. Performing this operation will also document the time the episode was acknowledged.

Automatically, the appropriate list of tiered interventions will be presented, accompanied by instructions. Press on the intervention of interest and, if performed, press on the button on the right hand side of the display to document that.



VII. END A MONITORING SESSION

Stop Monitoring: When ready to end the monitoring session, close CNS Reader/CarePath, then *Switch Desktop* to the CNS Monitor. On the Protocol Step Bar of the CNS Monitor, press *Stop Monitoring*. To end monitoring and discharge the patient, press *Discharge Patient*. A dialog will prompt the user to confirm the intent to discharge the patient. Once confirmed, the monitor will address any changes made to the monitoring protocol (including changes to display screens, etc.). If changes were made, a dialog box will ask how to handle those changes.

Archiving Patient Data: Upon discharging the patient, the CNS Monitor offers options for managing the collected patient data. To create a permanent record of patient data on external media, press *Archive Now*. To keep the session on the monitor until you are ready to archive, press *Archive Later*.

- Archive Now: Pressing *Archive Now* gives the user the option to archive collected data to an external USB drive. The user will be instructed to insert the USB drive. Once the USB drive has been verified, archiving will begin and a moving status bar will indicate the progress of archiving. A dialog box will appear once archiving is complete.
- Archive Later: Pressing *Archive Later* saves the patient file on the CNS Monitor for review or archiving at a later time. Saved files can be found by pressing *Manage Data Files* on the CNS opening/start-up screen. Selecting the desired patient provides information about the file and allows the user to *Review*, *Archive*, or *Erase* data.

Note: It is recommended to password protect the *Erase* option to avoid accidental deletion by non-study personnel. Password protection settings can be changed when in the opening/start-up screen by pressing *System Configuration* and then selecting *System Administration*. Enter the administrator password (default: *moberg*) and press *Password Setup* to select the desired level of protection.