Edwards PediaSat Oximetry Catheter Edwards Oximetry Central Venous Catheter HemoSphere Advanced Monitor

Setup guide

## Oximetry setup

- 1. Connect the HemoSphere oximetry cable to the left side of the HemoSphere advanced monitor (A).
- 2. Press the power button  $\bigcirc$  to turn on the HemoSphere advanced monitor. All functions are accessed through the touch screen.
- 3. Select Continue Same Patient or New Patient and enter new patient data (patient ID, gender, age, height, and weight).
- 4. Open side 1 of the oximetry catheter tray, exposing only the optical connector (B). Be careful not to contaminate tray contents in side 2.
- 5. Insert the optical connector of the catheter "TOP" side up into the oximetry cable and snap the enclosure shut (C).
- 6. The HemoSphere oximetry cable must be calibrated before each monitoring session.



HemoSphere advanced monitor (A)



Optical connector (B)



Oximetry cable enclosure (C)



Edwards

## HemoSphere advanced monitor

How to move data during and after patient transfer

*In vitro* **Calibration** (*if catheter has not been inserted yet*)

- Touch the clinical actions icon 
  Oximetry Calibration icon.
- Select Oximetry Type: ScvO<sub>2</sub> or SvO<sub>2</sub>.
- 3. Touch In vitro Calibration button.
- Enter either the patient's hemoglobin (HGB) or hematocrit (Hct) value. A default value may be used until the patient's HGB or Hct is available.
- 5. Touch Calibrate button.
- 6. When the calibration successfully completes, the following message appears: *In vitro* Calibration OK, insert catheter.
- 7. Insert the catheter as described in the catheter instructions for use.
- 8. Touch **Start** button.
- If ScvO<sub>2</sub>/SvO<sub>2</sub> are not current key parameters, touch the displayed parameter label located outside of any parameter globe to select ScvO<sub>2</sub>/SvO<sub>2</sub> as a key parameter from the parameter popup.
- 10. Touch within the ScvO<sub>2</sub>/SvO<sub>2</sub> parameter globe to adjust Alarms/Targets.

*In vivo* Calibration (performed after catheter has been inserted)

- 1. Touch the clinical actions icon <a>></a> Oximetry Calibration icon.
- Select Oximetry Type: ScvO<sub>2</sub> or SvO<sub>2</sub>.
- 3. Touch *In vivo* Calibration button. If setup is unsuccessful, see Chapter 10: Help and Troubleshooting in the HemoSphere Advanced Monitor Operator's Manual.
- 4. When baseline calibration is successful, touch **Draw** button and then draw the blood sample.
- 5. Draw the blood sample slowly and send the blood sample to the lab for measured analysis by co-oximeter.
- 6. Enter **HGB** or **Hct** and **ScvO<sub>2</sub>/SvO<sub>2</sub>** when lab values are received.
- 7. Touch Calibrate button.
- If ScvO<sub>2</sub>/SvO<sub>2</sub> are not current key parameters, touch the displayed parameter label located outside of any parameter globe to select ScvO<sub>2</sub>/SvO<sub>2</sub> as a key parameter from the parameter popup.
- 9. Touch within the ScvO<sub>2</sub>/SvO<sub>2</sub> parameter globe to adjust Alarms/Targets.

## HemoSphere advanced monitor How to move data during and after patient transfer

**Recall Oximetry Cable Data** can be used to recall data from the oximetry cable after a patient has been transported away from the HemoSphere advanced monitor. This allows the patient's last calibration to be recalled along with the patient's demographic data for immediate oximetry monitoring. Calibration data within the oximetry cable must be less than 24 hours old to use this function.

- With the catheter connected to the HemoSphere oximetry cable, unplug the cable from the HemoSphere advanced monitor and transport it with the patient. The catheter should not be disconnected from the oximetry cable.
- 2. If the oximetry cable is being connected to another HemoSphere advanced monitor, make sure that previous patient data is cleared.
- 3. Once the patient has been transferred, reconnect the oximetry cable to the HemoSphere advanced monitor and turn it on.
- Touch the clinical actions icon 
   Oximetry Calibration icon.

- 5. Touch Recall Oximetry Cable Data button.
- If the oximetry cable data is less than 24 hours old, touch Yes button to start oximetry monitoring using the recalled calibration information. OR Touch No button and perform an *in vivo* calibration.
- 7. From the oximetry calibration menu, touch *In vivo* **Calibration** button to recalibrate the cable. To review patient data that was transported with the oximetry cable, touch the settings icon.
- 8. Touch Patient Data button.

**CAUTION** Do not disconnect the oximetry cable while calibration or data recall are in process. **CAUTION** If the oximetry cable is being transferred from a HemoSphere advanced monitor to another HemoSphere advanced monitor, check that the patient height, weight, and BSA are correct prior to beginning monitoring. Re-enter patient data, if necessary. NOTE: Keep the time and date of all HemoSphere advanced monitors current. If the date and/or time of the HemoSphere advanced monitor being transported "from" differs from the HemoSphere advanced monitor being transported "to" the following message may appear:

"Patient data in oximetry cable more than 24 hours old – Recalibrate."

If the system needs to be recalibrated, a 10 minute warm up period for the oximetry cable may be required.

For professional use. CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device directive 93/42/EEC bear the CE marking of conformity.

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