

Vigilance II Monitor

Venous Oxygen Saturation

Abbreviated Instructions for Use

To Perform *In Vitro* Calibration:

1. Connect catheter to optical module. Connect optical module to Vigilance monitor.
2. Select **SvO₂** using the navigation knob.
3. Select **IN VITRO CALIBRATION**.
4. Use the **CURSOR** key to select HGB (hemoglobin) OR Hct (hematocrit).
 - a. Use default value or enter lab value using navigation knob.
5. Press **CAL**.
6. Upon completion of a successful calibration, the monitor will display the following message: “*In Vitro* Calibration OK. Insert Catheter then press Start SvO₂”.
7. Remove catheter from tray.
8. Flush catheter.
 - a. Never flush lumens before *In Vitro* Calibration.
 - b. If using a Swan-Ganz catheter, check balloon.
9. Insert catheter into appropriate position as indicated on the product’s “Directions for Use” sheet.
10. Press **START SvO₂**.

To Perform *In Vivo* Calibration:

1. Select **SvO₂** using the navigation knob.
2. Confirm catheter position and SQI before performing – Press **IN VIVO CALIBRATION**.
3. Press **DRAW**, after checking for SQI of 1 or 2.
4. Slowly draw waste sample and discard. Slowly draw lab sample and send for analysis by co-oximeter.
5. Enter lab results using navigation knob.
6. Press **CAL**.

To Transport:

1. After reconnecting patient cable and optics module to the Vigilance monitor, **WAIT 20 SECONDS**, select **SvO₂** using the navigation knob.
2. Select **RECALL OM DATA**.
 - a. Calibration data must be less than 24 hours old.
 - b. Make sure time and date match if using different monitors.

SQI for Venous Saturation Monitoring

LEVEL	SIGNAL	DESCRIPTION
1	Normal	All aspects of the signal are optimal
2	Intermediate	Indicates a moderately compromised signal
3	Poor	Indicates poor signal quality
4	Unacceptable	Indicates severe problem with one or more aspects of signal quality

Signal quality may be compromised by:

- Pulsatility.
- Signal intensity (e.g., kinking of catheter, blood clot, hemodilution).
- Intermittent wall contact by the catheter.

Signal quality may be improved by:

- Try to aspirate distal lumen; if able to aspirate, flush lumen with extreme caution.
- Check catheter for kinking and recalibrate; replace catheter if required and recalibrate.
- Reposition catheter and if SQI > 2, recalibrate monitor by performing *in vivo* calibration.
- Attempt to distance electrocautery equipment and cables from the Vigilance monitor.
- Plug the power cords into separate AC circuits if possible.
- Update entered hemoglobin and hematocrit values when there is a physiologic change of 6% or greater in hematocrit or of 1.8 g/dL (1.1 mmol/L) or greater in hemoglobin.

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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