

Edwards Vigileo Monitor Setup

Setup and Calibration of Edwards PreSep Catheter

Edwards PreSep Oximetry Catheter Setup

1. Connect the optical module to the oximetry color-coded connector on the back of the Vigileo monitor. Allow 20 minutes for the optical module to warm up.



2. Open the PreSep catheter lid exposing only the optics connection or entire tray, depending on technique, remove optics connection being careful not to contaminate tray contents.



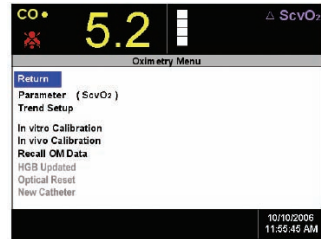
3. Connect PreSep catheter to the optical module matching "TOP" on both optical module and optics connection.



Vigileo Oximetry Monitor

In vitro Calibration

1. Rotate the navigation knob to highlight the Oximetry Frame and press to display the Oximetry Menu.
2. Rotate the knob to select Parameter and then press the knob.
3. Rotate the knob and highlight the parameter you will be using for oximetry (ScvO₂ or SvO₂) and then press the knob.
4. Rotate the navigation knob to select **In vitro Calibration**.
5. Rotate the navigation knob to select **HGB (hemoglobin) or Hct (Hematocrit)**, then enter the lab value if available or otherwise use the default values.
6. Select **Calibrate**. You will see the message: **In vitro calibration in progress. Ready in 20 seconds.** When the countdown reaches 0 seconds you will see the following message: **In vitro calibration OK. Insert catheter then select Start.**



Vigileo Oximetry Monitor

In vivo Calibration

1. *In vivo* calibration is performed after the catheter has been inserted into the patient.
2. Rotate the navigation knob to highlight **In vivo Calibration**. The monitor begins the calibration process as shown in the following figure.
3. Select **Continue** unless a **Wall Artifact or Wedge Detected**, or **Unstable Signal** message appears, attempt to troubleshoot the problem as instructed in Chapter 12: Troubleshooting, in the user's manual.

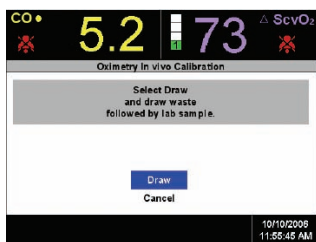


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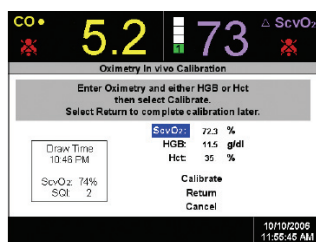
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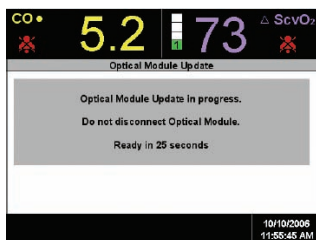
4. Press the navigation knob and then draw the blood sample. The display changes to show the draw time and the value of parameters ScvO₂/SvO₂ and HGB at the draw time, as shown in the following figure.



5. Draw the waste blood (clearing volume) sample slowly from the distal lumen.
6. Draw the laboratory blood sample slowly (2 ml [cc] over 30 seconds).
7. Send the blood sample for measured analysis by co-oximeter.
8. Upon receipt of the lab values from the drawn sample, use the navigation knob to enter the oximetry value and either the HGB or Hct.



9. After the values are entered, rotate the navigation knob to select **Calibrate**. This action initiates the calibration of the optical module.
10. At the end of the 25 second countdown, the **Calibration Menu** is removed from the screen and the **Oximetry Menu** is displayed.



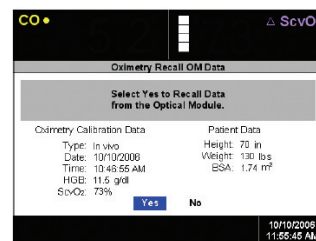
Vigileo Oximetry Monitor Recall Optical Module Data

1. In the event that a patient needs to be transported while oximetry is being monitored, patient data (e.g., height, weight, and BSA) and system calibration information can be transferred with the patient via the optical module, eliminating the need to recalibrate the monitor.
2. With the catheter connected to the optical module, unplug the optical module cable from the Vigileo monitor and transport it with the patient. The catheter should not be disconnected from the optical module.
3. If the optical module is being connected to another Vigileo monitor, make sure that previous patient data is cleared from the monitor.
4. Once the patient has been transferred, reconnect the optical module cable to the Vigileo monitor.
5. Rotate the navigation knob to highlight the **Oximetry Frame**.
6. Press the knob.
7. Under the **Oximetry Frame**, select **Recall OM Data**.
8. The calibration data in the optical module will be displayed

If the optical module data is less than 24 hours old, confirmation instructions and a **Yes/No** confirmation is displayed. Select **Yes** to start oximetry monitoring using the recalled calibration information OR select **No** and perform an *in vivo* calibration. If the optical module data is more than 24 hours old, the optical module data cannot be recalled and a new calibration must be performed.

NOTE

Keep the date and time of all Vigileo monitors current. If the date and/or time of the Vigileo monitor being transported "from" differs from the Vigileo monitor being transported "to," then the 24 hour test may not work properly.



Rx only. See instructions for use for full prescribing information.

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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