

PediaSat Oximetry Catheter Vigileo Monitor Setup Guide

Vigileo Monitor Recall Optical Module Data

Patient data and system calibration information can be transferred with the patient via the optical module. 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. If the optical module is being connected to another Vigileo monitor, make sure that previous patient data is cleared from the monitor. Reconnect the optical module cable to the Vigileo monitor.

1. Rotate the navigation knob to highlight the **Oximetry Frame**.
2. Press the knob.
3. Under the **Oximetry Frame**, select **Recall OM Data**.
4. 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.

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



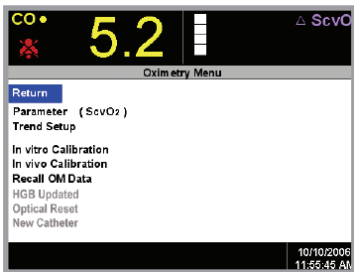
Note: Immediate oximetry monitoring may be accomplished through an *In vitro* calibration followed by insertion of the PediaSat catheter. However, the PediaSat catheter can be inserted followed by connection to optical module and *In vivo* calibration if desired.

3. Connect PediaSat catheter to the optical module matching “TOP” on both optical module and optics connection.



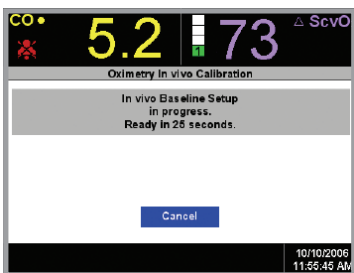
In vitro Calibration (if catheter has not been inserted yet)

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) 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**.



In vivo Calibration (performed after catheter has been inserted)

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



3. Press the navigation knob and then draw the blood sample.
4. Draw the waste blood (clearing volume) sample slowly from the distal lumen.
5. Draw the laboratory blood sample slowly (2 ml [cc] over 30 seconds), and send sample to lab for analysis.
6. Upon receipt of the lab values, use the navigation knob to enter the ScvO₂ value and either the **HGB** or **Hct**.
7. After the values are entered, rotate the navigation knob to select **Calibrate**. This action initiates the calibration of the optical module.
8. At the end of the 25 second countdown, the **Calibration Menu** is removed from the screen and the **Oximetry Menu** is displayed.

