

Edwards PediaSat Oximetry Catheter

Edwards Oximetry Central Venous Catheter

Vigileo Monitor

Setup guide

Oximetry setup

1. Press the **Power on**  button on the panel.
2. When the system boot up process is complete, enter new patient data (patient ID, gender, age, height, and weight) or continue same patient.

Oximetry catheter

If catheter is already in place, skip to next section (Vigileo monitor calibration)

1. Connect the optical module (A) to the oximetry color-coded connection port (B) on the back of the Vigileo monitor. Allow several minutes for the optical module to warm up, or until *in vivo/in vitro* buttons are active.
2. Open side 1 of the oximetry catheter tray, exposing only the optics connection (C), and remove the optics connection, being careful not to contaminate tray contents in side 2.
3. Connect the oximetry catheter to the optical module, matching “TOP” (D) on both the optical module and the optics connection.



Optical module (A)



Vigileo monitor color-coded connection port (B)



Blue optics connection (C) in side 1 of the tray, and catheter and other contents in side 2



Optical module “TOP” (D)



Edwards

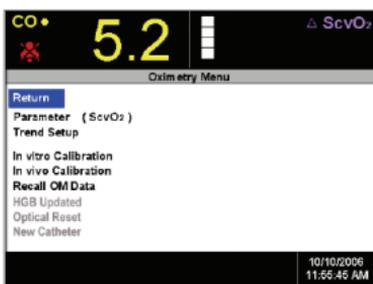
Vigileo monitor calibration

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 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.



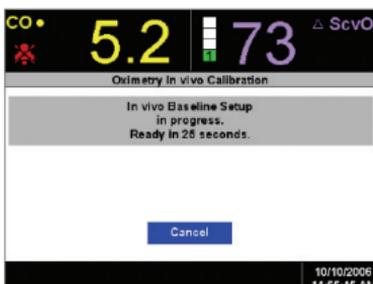
Navigation knob at lower right



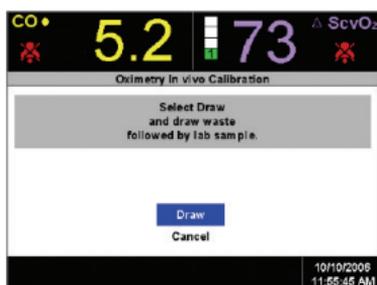
6. Select **Calibrate**. You will see the message: **In vitro calibration in progress. Ready in 20 seconds**. When the countdown reaches 0 seconds you will see the following message: **In vitro calibration OK**. Insert catheter then select **Start**.

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 here.
2. Select **Continue**. If the message **Wall Artifact, Wedge Detected** or **Unstable Signal** appears, troubleshoot the problem as instructed in "Chapter 12: Troubleshooting" of the user manual.



3. Press the navigation knob to select **Draw** 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 and send sample to lab for analysis.
6. Upon receipt of the lab values, use the navigation knob to enter the ScvO₂ or SvO₂ 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.



Vigileo monitor

How to move data during and after patient transfer

Patient data and system calibration information can be transferred with the patient via the optical module. With the PediaSat oximetry catheter or Edwards oximetry central venous catheter (CVC) 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**.
1. Press the knob.
2. Under the **Oximetry Frame**, select **Recall OM Data**.
3. The calibration data in the optical module will be displayed.

NOTE: If the optical module data is less than 24 hours old, confirmation instructions and a **Yes/No** button option are 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.

Keep the date and time of all Vigileo monitors current. If the date and/or time of the Vigileo monitor being transported "from" differ 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.

Edwards, Edwards Lifesciences, the stylized E logo, PediaSat, and Vigileo are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2016 Edwards Lifesciences Corporation.
All rights reserved. PP--US-1400 v1.0

Edwards Lifesciences • edwards.com
One Edwards Way, Irvine CA 92614 USA



Edwards