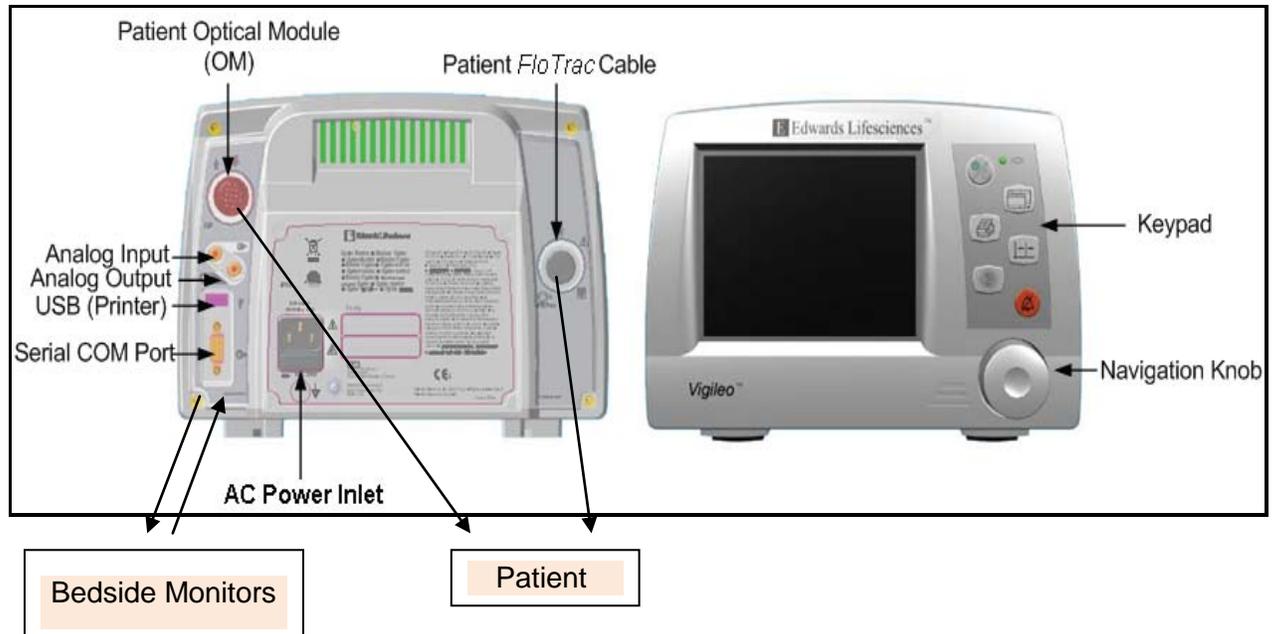


VIGILEO PERFORMANCE CHECK OUT

1.0 General:

The *Vigileo* Monitor Operational Environment Block Diagram is shown below:



As shown above the *Vigileo*[™] monitor operates in an environment that includes accessory cables, other patient monitors and the operator.

NOTE: *The performance check is not a substitution for the Operator's Manual, which is enclosed with the Vigileo monitor. The Operator's Manual should be followed at all times for the proper use of the monitor.*

2.0 Introduction:

This document provides a performance test of the operation of the *Vigileo* Cardiac Output/Oximetry Monitor. This procedure is designed to be followed in the order presented to assure the user that the computer is functioning properly. If the computer does not perform these tests as specified, please contact Technical Support at 800.822.9837.

3.0 Equipment Required

This procedure requires the following accessory items:

Item No.	Model Number	Description
1	APCO9	Patient Cardiac Output Cable
2	OM2, OM2E or OM2MH	Optical Module
3	MHD6... or MHD8...	FloTrac Sensor
4	X3820..., X3816..., XA3820..., XA3816..., XT245..., XT248..., XT358... or XT3515...	PreSep or PediaSat Catheter (Do not remove from package)

4.0 Power On Self Test (POST)

Perform the following steps for the Power On Self Test.

- 4.1 Place the *Vigileo* on a table.
- 4.2 Check for loose hardware by tilting the unit to the left side, to the right side, to the back and to the front.
- 4.3 Thoroughly examine the monitor exterior for general physical condition. Make sure the housing is not cracked, broken or dented, that everything is present. Make sure there is no sign of spilled liquids or signs of abuse. Check for bent or missing pins.
- 4.4 Attach the appropriate end of the power cord securely to the *Vigileo* monitor. Connect the other end to an AC power outlet. The AC indicator will illuminate.
- 4.5 Turn the *Vigileo* monitor ON by pressing the ON/OFF. If s/w is <3.02, as seen on start up screen, please call technical support at 800.822.9837.

Keypad ON/Off button located on the top right-hand corner of the front panel.





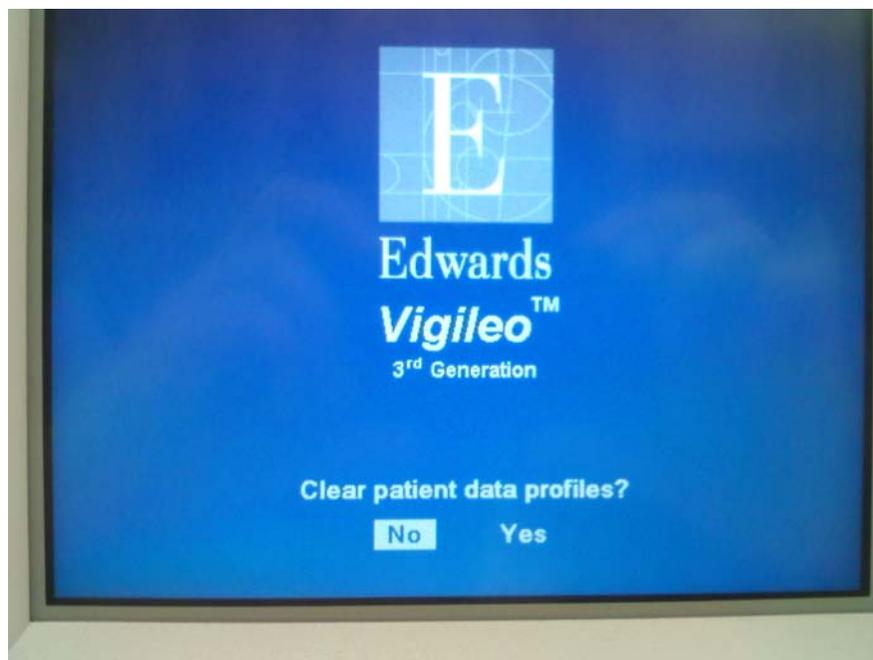
NOTE:

If an error message is received during POST, carefully record the exact message and call Technical Support at 800.822.9837.

When the POST has completed and no malfunction has been detected, the *Vigileo* monitor displays either the patient information and body surface area (BSA) entry screen or asks “Clear patient data profiles?” if any patient data exists that is less than 8 hours old, as shown below.



OR



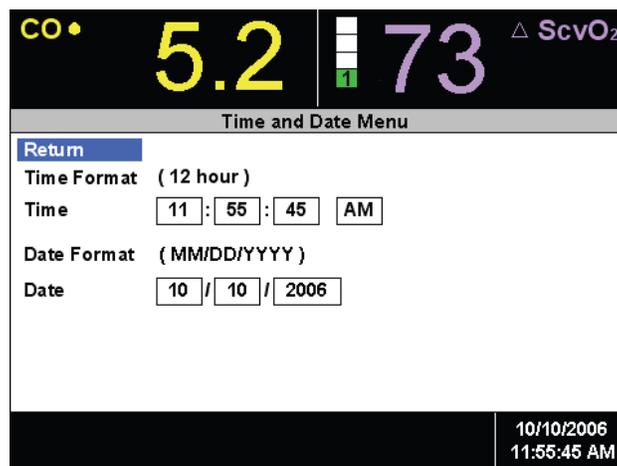
What happens if NO is selected:	What happens if YES is selected:
<ul style="list-style-type: none"> • Activates previous record for continuation • Keeps Alarms settings and enable/disable alarms status • Displays screen configuration as last used for that patient 	<ul style="list-style-type: none"> • Clears patient data from memory • Reset alarms limits to defaults • Enables all alarms • Starts a new patient record • Displays the patient information screen

- 4.6 Press “Yes” to clear patient data screen. (Based upon situation this may be different for the end user in a clinical setting)
- 4.7 Enter patient data. Gender-M, Age-65, Height-67”, Weight-183 lbs. Then select continue.
- 4.8 Verify navigation knob turns freely and depresses (you will hear an audible click) when selections are made.

5.0 System Setup

5.1 Setting Time and Date:

- 5.1.1 The Time/Date frame menu is used to set the time and date, and to select the display format of how the time and date will appear on the screen. Access the menu by highlighting the Time/Date frame located at the right bottom of the screen using the navigation knob. Press the knob to select the Time/Date frame menu for display. The menu is illustrated below.



- 5.1.2 Enter the correct date and time and the format using the navigation knob.
- 5.1.3 Press “Return” to go back to the main screen.

Always use a straight in or out motion to connect or disconnect the cables.

6.0 Oximetry Verification

6.1 Check OM2 cable for bent or missing pins and signs of damage.

6.2 Connect the OM2 to the Vigileo SvO₂ color coded burgundy connector located on the back of the *Vigileo* monitor.

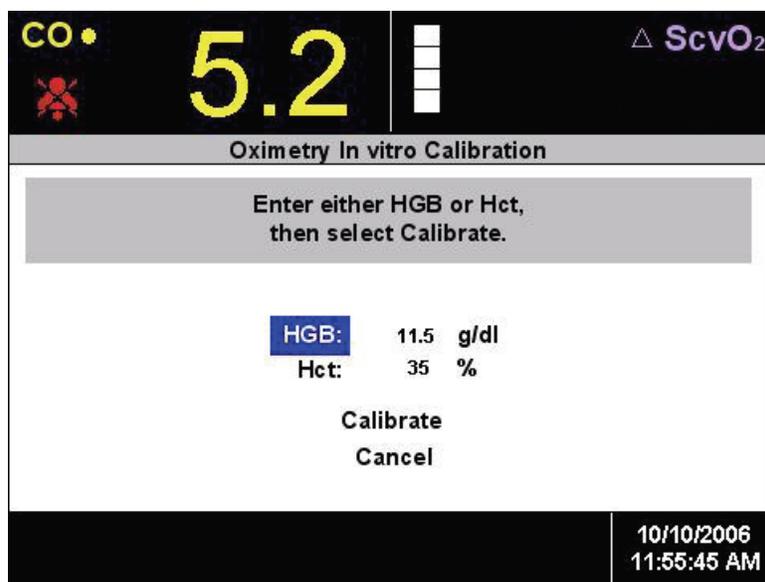


6.3 The message “**OM Connected, Please Wait**” will appear on the bottom portion of the display screen. Please wait until the message clears.

6.4 Connect the catheter’s flat blue optical connector to the OM2. Do not remove catheter from tray.

6.5 Using the navigation knob rotate to highlight the SvO₂ or ScvO₂ Large parameter frame (upper right screen) then press knob to display the menu.

6.6 Using the navigation knob highlight “In-Vitro calibration” then press knob to select. The following menu will be displayed in the secondary frame:



Large Parameter Frame Menu for Oximetry Parameter

- 6.7 Ensure the Hct is set to 35% (default values), if not change the Hct value to 35% using the navigation knob. Using the navigation knob select “Calibrate”. The following message will be displayed.

“In-Vitro Calibration in progress”
Ready in xx seconds

The “xx” value starts at 20 and counts down by 1sec. Upon completion of a successful calibration, the monitor will display the following message.

“In-Vitro Calibration OK.
Insert catheter then select Start”

- 6.8 Using the navigation knob select “Start” and Press to start. The following message will be displayed:

Optical Module Update in progress
Do not disconnect Optical Module.
Ready in xx seconds.

- 6.6 At the end of the update, verify the large parameter frame displays an SvO₂/ScvO₂ value of 81 +/- 3 %.

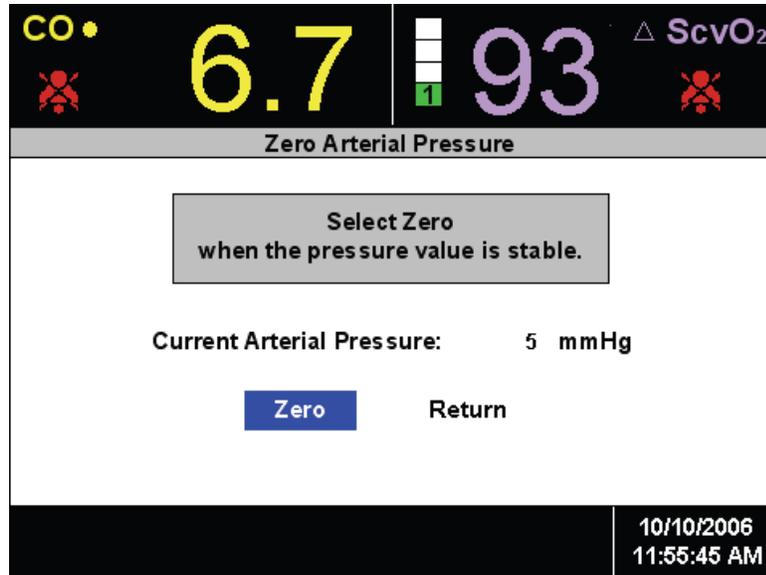
7.0 CO Cable Verification Test

- 7.1 Check APCO9 cable for bent or missing pins and signs of damage.
- 7.2 Prepare the *FloTrac* sensor. Tighten all connections and flush per the instructions for use.
- 7.3 Attach the patient APCO9 CO color coded green cable to the connector on the back of the *Vigileo*.



- 7.3 Connect cable to the FloTrac sensor.

- 7.4 Using the navigation knob rotate to highlight the CO Large parameter frame (upper left screen) then press knob to display the menu.
- 7.5 Select Zero Arterial Pressure to zero the sensor to atmospheric air. (The below values are used as an example.)



- 7.6 Once the pressure value stabilizes, press the knob to select Zero. A tone will sound and you will see the message:

**Arterial pressure setting zeroed.
Select "Exit" to begin CO with new setting.**

Then after selecting "Exit" this message may appear (this is normal):

Fault CO/SV: Check Arterial Waveform

- 7.7 No CO values will be generated during testing. Verify the monitor does not display any errors. If an error message is received carefully record the exact message and call Technical Support at 800.822.9837.
- 7.8 Upon completion of the oximetry and CO verification test, disconnect the APCO9 and OM2.

8.0 Keypad Verification



Refer to the above picture to complete the following steps.

- 8.1 Push button 1 to ensure screen switches between three Multipurpose Frame Screens. Return to home screen.
- 8.2 Button 2 is used when a printer is connected to unit. (currently unavailable).
- 8.3 Push button 3 to ensure screen toggles to trend scroll mode. A white box with arrows on each side will appear at top of graph. Return to home screen.
- 8.4 Push button 4 to display help screens. Return to home screen.
- 8.5 Push button 5 to silence alarms. A double beep will sound during this test.

If these buttons do not perform as indicated please call technical support at 800.822.9837.

THIS CONCLUDES THE VIGILEO PERFORMANCE CHECK